JMIR Pediatrics and Parenting

Impact Factor (2023): 2.1
Volume 8 (2025) ISSN 2561-6722 Editor in Chief: Sherif Badawy, MS, MD, MBA

Contents

Original Papers

Association Between the Parenting Competence and Quality of Life of Family Caregivers of Children Aged 0-3 Years: Cross-Sectional Study (e67872)
Wei He, Le-shan Zhou, Long-yi Hu. . . . 11

Examination of Chronic Sorrow Among Parents of Children With Disabilities: Cross-Sectional Study (e65754)
Samaa Al Anazi, Naseem Alhujaili, Dina Sinqali, Ftoon Al Heej, Lojain Al Somali, Samaher Khayat, Talah Ramboo. . . . 19

Practicality of the My Baby Now App for Fathers by Fathers: Qualitative Case Study (e64171)
Mathew Gaynor, Kylie Hesketh, Kidane Gebremariam, Karen Wynter, Rachel Laws. . . . 31

The Added Value of Parents Practicing in Virtual Reality to Illustrate the Use of Innovative Methods in Parent-Child Interaction Therapy: Single-Case Experimental Design (e60752)
Iza Scherpbier, Mariëlle Abrahamse, Samantha Bouwmeester, Robert Belleman, Arne Popma, Ramón Lindauer. . . . 43

Immediate Kangaroo Mother Care for Sick Newborns: Quality Improvement Implementation and Feasibility Study (e78207)
Belén Fernández-Monteaguado, Ana Peña-Moreno, Inés Ramírez-de Andrés, Patricia Barbero-Casado, Eduardo Zarzuela-NÚñez, Beatriz Bellón-Vaquerizo, Cristina Martin Arriscado-Arroba, María Moral-Pumarega, Salvador Piris-Borregas, Carmen Pallás-Alonso. . . . 65

The Practice of Shaking in Disciplining Young Children in Lower-Income Communities of Bangladesh: Cross-Sectional Exploratory Study (e64474)
Fahmida Tofail. . . . 71

The Maternal Support Framework Studying Mothers' Perceived Understanding and Support During Excessive Infant Crying: Exploratory Qualitative Study (e75669)
Oona Janssens, Anna Galle, Ineke De Kruijff, Katrijn Brenning. . . . 79

Analysis of Cough Factors and Quality of Life Score Among Children With Protracted Bacterial Bronchitis: Cross-Sectional Study (e82887)
Haonan Ning, Wenyu Zheng, Jinghui Zhang, Fuhai Li, Nana Qiao. . . . 92

Evaluation of the Use of a Novel Intelligent Diagnosis and Cost Control System on Pediatric Bronchopneumonia Outcomes: Retrospective Cohort Study (e74964)
Yanjun Wu, Kaijie Liu, Xinli Mao, Danjie Wu, Feng Zhu. . . . 107

Hospitalization and Mortality in Brazilian Children and Adolescents Due to COVID-19: Retrospective Study (e67546)
Ana Pereira de Godoy, Reinaldo Bulgarelli Bestetti. . . . 116

XSL•FO
RenderX

Exploring Stress and Stress-Reduction With Caregivers and Clinicians in the Neonatal Intensive Care Unit to Inform Intervention Development: Qualitative Interview Study (e66401)
Kristin Ginsberg, Jane Alsweiler, Jenny Rogers, Phoebe Ross, Anna Serlachius. 124

Implementing Diabetes Distress Screening in a Pediatric Endocrinology Clinic Using a Digital Health Platform: Quantitative Secondary Data Analysis (e65107)
Nicole Kahhan, Larry Fox, Matthew Benson, Susana Patton. 137

Enhancing Effect of eHealth Use on the Associations Between Social Supports and Well-Being in Japanese Employed Women Providing Childcare or Care: Bayesian Structural Equation Modeling Study (e68119)
Noyuri Yamaji, Daisuke Yoneoka, Daichi Suzuki, Kiriko Sasayama, Erika Ota, Etsuko Nishimura, Hisateru Tachimori, Eiko Saito. 146

Impact of Digitalization on Pediatric Practice and Childhood Health Care in Spain: Nationwide Survey Study (e75310)
Alicia Santamaría-Orleans, Luis Ortiz-González, Maite Pérez-Hernández, Cristóbal Coronel-Rodríguez. 159

Using WhatsApp for Nutrition Surveillance Among Children Under 5 Years in West Java, Indonesia: Cross-Sectional Survey and Feasibility Study (e58752)
Dewi Aisyah, Chyntia Mayadewi, Astri Utami, Fauziah Rahman, Nathasya Adriani, Erlangga Al Farozi, Meldi Sayoko, Aulia Chairunisa, Liza Restiana, Logan Manikam, Zisis Kozlakidis. 174

Parent-Child Mutual Influences on Sugar-Sweetened Beverage Consumption Behaviors: Actor-Partner Analysis (e76943)
May Lwin, Allison Seet, Seraphina Leo, Peter Schulz. 193

Monetary Valuation of Congenital Heart Disease in Indonesia: Economic Modeling Study (e80696)
Muhammad Iqhrammullah, Derren Rampengan, Ikhwan Amri, Surna Lastri, Starry Rampengan, Radityo Prakoso, Muhammad Habiburrahman.
2 0 5

Preliminary Effectiveness of a Postnatal mHealth and Virtual Social Support Intervention on Newborn and Infant Health and Feeding Practices in Punjab, India: Quasi-Experimental Pre-Post Pilot Study (e65581)
Garima Verma, Lakshmi Gopalakrishnan, Alison Ayadi, Nadia Diamond-Smith, Rashmi Bagga, Shashi Dhir, Pushpendra Singh, Navneet Gill, Vaibhav Miglani, Naveen Mutyala, Ankita Kankaria, Jasmeet Kaur, Alka Ahuja, Vijay Kumar, Mona Duggal. 225

Impact of a 6-Week Postpartum Text Messaging Program (Essential Coaching for Every Mother) at 6 Months: Follow-Up Study to a Randomized Controlled Trial (e62841)
Justine Dol, Marsha Campbell-Yeo, Megan Aston, Douglas McMillan, Amy Grant. 239

Fetal Birth Weight Prediction in the Third Trimester: Retrospective Cohort Study and Development of an Ensemble Model (e59377)
Jing Gao, Xu Jie, Yujun Yao, Jingdong Xue, Lei Chen, Ruiyao Chen, Jiayuan Chen, Weiwei Cheng. 249

An Online Family Literacy and Wellness Program for Latino Dual Language Learners: Pilot Randomized Waitlist Controlled Trial (e60764)
Kevin Guerrero, Lucia Lakata, Daniel Lima, Caroline Mendoza, Nila Uthirasamy, Lesley Morrow, Silvia Perez-Cortes, Maria Pellerano, Alicja Bator, Pamela Ohman Strickland, Benjamin Crabtree, Manuel Jimenez. 264

Parental Use of Social Media and the Internet in the Context of Their Child's Genetic Neurodevelopmental Disorder: Mixed Methods Study Nested in the GenROC Cohort Study (e76526)
Karen Low, Georgia Treneman-Evans, Sarah Wynn, Jenny Ingram, John Powell. 292

A Low-Cost, Social Media–Supported Intervention for Caregivers to Enhance Toddlers' Language Learning: Mixed Methods Feasibility and Acceptability Study (e66175)
Mollie Romano, Diana Abarca, Frances Baehman. 304

XSL•FO
RenderX

A Noninvasive Approach to Assess the Prevalence of and Factors Associated With Anemia Risk in Malaysian Children Under Three Years of Age: Cross-Sectional Study (e58586)
Muhammad Jalaludin, Ho Kiau, Suriati Hasim, Wai Lee, Angie Low, Nik Kazim, Jia Hoi, Sri Taher. . . . 320

Preoperative Anxiety Management Practices in Pediatric Anesthesia: Comparative Analysis of an Online Survey Presented to Experts and Social Media Users (e64561)
Armin Sablewski, Christine Eimer, Marcus Nemeth, Clemens Miller. . . . 334

Social and Environmental Determinants of Childhood Stunting in Indonesia: National Cross-Sectional Study (e68918)
Yuni Arief, Fildzah Yunita, Ferry Efendi, Fadhaa Murti, Rifky Pradipta, Lisa McKenna. . . . 346

Comparing Sociodemographic, Health Status and Resources, Macroeconomic Status, and Environmental Factors on Infant Mortality Rates in Bahrain, Kuwait, and Oman: Longitudinal Time-Series Study (e73203)
Mallak Al-Saqry, Rawaa Eltayib, Al-Hasan Al-Busaidi, Moon Chan. . . . 357

Parental Experiences of Administering Pediatric Tuina for Sleep and Appetite in Early School-Aged Children With Attention-Deficit/Hyperactivity Disorder: Qualitative Study in Hong Kong (e65471)
Shu-Cheng Chen, Kwai-Ching Lo, Han Li, Pong-Ming Wong, Lok-Yi Pang, Jing Qin, Wing-Fai Yeung. . . . 366

Evaluating the Reach, Usage, Human Support Needs, and Clinical Outcomes of Digital Parent Training for Child Oppositional Defiant Disorder Before and During Wartime: Longitudinal Study (e80420)
Amit Baumel, Or Brandes, Chen Saar. . . . 378

Enhancing Adherence and Mental Well-Being in Pediatric Growth Hormone Therapy: Feasibility Prospective Observational Study of a Family-Centered Digital Companion (e67102)
Antonio de Arriba Muñoz, Amalia García-Durán, Patricia Sanz-Aznar, Silvia Quer-Palomas, Ioannis Bilionis, Alba Xifra-Porxas, Joia Nuñez, Ricardo Berrios, Luis Fernández-Luque. . . . 392

Exploring the Acceptance and Opportunities of Using a Specific Generative AI Chatbot to Assist Parents in Managing Pediatric Rheumatological Chronic Health Conditions: Mixed Methods Study (e70409)
Cheryl Lau, Klaudia Kupiec, Polly Livermore. . . . 403

Evaluating the Impact of Pediatric Digital Mental Health Care on Caregiver Burnout and Absenteeism: Longitudinal Observational Study (e67149)
Darian Lawrence-Sidebottom, Kelsey McAlister, Aislinn Beam, Rachael Guerra, Amit Parikh, Monika Roots, Donna McCutchen, Landry Goodgame Huffman, Jennifer Huberty. . . . 416

Exploring Service Users' Experiences of a Community-Based Intervention to Improve Follow-Up at Bharatpur Eye Hospital in Nepal: Qualitative Study (e65023)
Manisha Shrestha, Gopal Bhandari, Sadhan Bhandari, Gudlavalleti Murthy, Ruchi Priya, Binod Pandey, Daya Chaudhary, Puspa Giri, Sureshkumar Kamalakannan, Operational Research Capacity Building Study Group. . . . 432

Perspectives of Adolescents and Young Adults With Inflammatory Bowel Disease on a Biopsychosocial Transition Intervention: Qualitative Interview Study (e64618)
Brooke Allemang, Ashleigh Miatello, Mira Browne, Melanie Barwick, Pranshu Maini, Joshua Eszczuk, Chetan Pandit, Tandeep Sadhra, Laura Forhan, Natasha Bollegala, Nancy Fu, Kate Lee, Emily Dekker, Irina Nistor, Sara Ahola Kohut, Laurie Keefer, Anne Griffiths, Thomas Walters, Samantha Micsinszki, David Mack, Sally Lawrence, Karen Kroeker, Jacqueline de Guzman, Aalia Tausif, Claudia Tersigni, Samantha Anthony, Eric Benchimol. . . . 440

Perspectives on Swedish Regulations for Online Record Access Among Adolescents With Serious Health Issues and Their Parents: Mixed Methods Study (e63270)
Josefin Hagström, Charlotte Blease, Arja Harila, Päivi Lähteenmäki, Isabella Scandurra, Maria Hägglund. . . . 455

XSL•FO
RenderX

Digital Health Program to Support Family Caregivers of Children Undergoing Growth Hormone Therapy: Qualitative Feasibility Study (e55023)
Alba Jiménez-Díaz, Maitena Pierantonelli, Patricia Morte Coscolín, Amaia Salinas-Uhalte, Silvia Quer-Palomas, Octavio Rivera-Romero, Rocío Herrero, Luis Fernández-Luque, Rosa Baños, Ricardo Berrios, Antonio de Arriba. 474

Community Caregivers' Perspectives on Health IT Use for Children With Medical Complexity: Qualitative Interview Study (e67289)
Farah Elkourdi, Onur Asan. 488

Content Development for a Multilevel Intervention to Operationalize Behavior Change Theory and Improve Parenting Behaviors for Physical Activity: Descriptive Study (e73510)
Breanne Wilhite, Erin Hennessy, Christina Economos, Jennifer Sacheck, Rachel Zive, Christine Odalen, Stephanie Herrick, Daniel Hatfield. . 5 0 0

Moderators of a mHealth Intervention for Adolescent Physical Activity: Intervention Refinement Study (e59334)
Christopher Cushing, Adrian Ortega, David Fedele, Calissa Leslie-Miller, Jordan Carlson, Ann Davis, Joshua Smyth. 514

Using a Consumer Wearable Activity Monitoring Device to Study Physical Activity and Sleep Among Adolescents in Project Viva: Cohort Study (e59159)
Yutong Zhang, Nicole Bornkamp, Marie-France Hivert, Emily Oken, Peter James. 523

Parental Perceptions of Priorities and Features for a Mobile App to Promote Healthy Lifestyle Behaviors in Preschool Children: Mixed Methods Evaluation (e65451)
Jessica Thompson, Summer Weber, Shelagh Mulvaney, Susanna Goggans, Madeline Brown, Anthony Faiola, Lynn Maamari, Pamela Hull. . . 5 3 4

The Role of Early Engagement in a Self-Directed, Digital Mental Health Intervention for Adolescent Anxiety: Moderated Regression Analysis (e60523)
Emma-Leigh Senyard, Arlen Rowe, Govind Krishnamoorthy, Susan Spence, Caroline Donovan, Sonja March. 550

Sex Differences in the Joint Trajectories of Depressive Symptoms and Body Mass Index From Adolescence to Early Adulthood: Longitudinal Observational Study (e72722)
Jing Chen, Rui Shan, Wen Yuan, Qiong Wu, Yang Yang, Yi-Hang Yang, Jing-Yao Liu, Wu-Cai Xiao, Shanghang Zhang, Li-Ming Wen, Xiao-Rui Zhang, Zheng Liu, Yi Song. 564

Adapting Cognitive Behavioral Therapy for Adolescents in Iraq via Mobile Apps: Qualitative Study of Usability and Outcomes (e67137)
Radhwan Ibrahim, Marghoob Yaas, Mariwan Hamarash, Salwa Al-Mukhtar, Mohammed Abdulghani, Osama Al Mushhadany. 575

The Impact of Parental Support on Adherence to Therapist-Assisted Internet-Delivered Acceptance and Commitment Therapy in Primary Care for Adolescents With Anxiety: Naturalistic 12-Month Follow-Up Study (e59489)
Anna Larsson, Sandra Weineland, Linnea Nissling, Josefine Lilja. 587

Changes in Internet Activities and Influencing Factors for Problematic Internet Use During the COVID-19 Pandemic in Korean Adolescents: Repeated Cross-Sectional Study (e66448)
Sol Kim, Jae-Chan Jin, Seo-Koo Yoo, Doug Han. 603

Effects of Web-Based Single-Session Growth Mindset Interventions for Reducing Adolescent Anxiety: Four-Armed Randomized Controlled Trial (e63500)
Shimin Zhu, Yuxi Hu, Di Qi, Samson Tse, Ko Chan, Jessica Sun, Paul Lee. 617

XSL•FO
RenderX

Developing Digital Mental Health Tools With Culturally Diverse Parents and Young People: Qualitative User-Centered Design Study (e65163)
Isobel Butorac, Roisin McNaney, Joshua Seguin, Patrick Olivier, Jaimie Northam, Lucy Tully, Talia Carl, Adrian Carter. . . . 636

Real-World Symptom Trajectories in Adolescents With and Without Suicide Risk Receiving Care from Rula Health: Retrospective Study (e81444)
Lara Baez, Kelsey McAlister, Douglas Newton, Sam Seiniger, Allie Woodhouse, Jennifer Huberty. . . . 658

Empowering Caregiver Well-Being With the Adhera Caring Digital Program for Family Caregivers of Children Living With Type 1 Diabetes: Mixed Methods Feasibility Study (e66914)
Antonio de Arriba Muñoz, Elisa Civitani Monzon, Maria Ferrer, Marta Ferrer-Lozano, Silvia Quer-Palomas, Joia Nuñez, Alba Xifra-Porxas, Francesca Aimée Mees Mlatiati, Ioannis Bilionis, Ricardo Berrios, Luis Fernández-Luque. . . . 673

Effects of the Jump Step Kids Program on Functional Movement and Self-Report Outcomes in Children Aged 7 to 12 Years With Chronic Ankle Instability: Randomized Controlled Trial (e81860)
Kitiyawadee Srisim, Supannikar Yingyongsaksri, Janya Chuadthong. . . . 682

Feasibility, Barriers, and Facilitators of Long-Term Physical Activity Tracking During Treatment: Interview Study Among Childhood Cancer Patients (e75322)
Emma den Hartog, Wim Tissing, Sebastian Bon, Patrick van der Torre, Emma Verwaaijen. . . . 694

Children's and Their Parents' Experiences With Home-Based Guided Hypnotherapy: Qualitative Study (e58301)
Ilse Ganzevoort, Adriëlla van der Veen, Manna Alma, Marjolein Berger, Gea Holtman. . . . 734

eHealth Literacy and Adolescent Health in Japanese Female High School Students in Sendai: Cross-Sectional Study (e73237)
Takashi Takeda, Kana Yoshimi, Sayaka Kai, Fumi Inoue. . . . 747

Advice for Improving the Experience of Web-Based Patient Portals: Qualitative Interviews With Caregiver-Adolescent Dyads (e72134)
Rachel Granberg, Jessica Goldberg, Alison Antes, Christine Bereitschaft, Fabienne Bourgeois, James DuBois, Bryan Sisk. . . . 761

Increasing Vaccination Awareness for Italian Primary Care Pediatricians: Game Design and Usability Study (e70049)
Federico Marchetti, Martino Barretta, Antonio Di Mauro, Marco Bona, Chiara Amerighi, Antonio D'Avino. . . . 775

A Companion Robot for Children With Asthma: Descriptive Development and Feasibility Pilot Study (e68943)
Jinnaphat Sangngam, Somsiri Rungamornrat, Rungnapa Santipipat, Kunchira Ponthanee. . . . 802

Guided Inhalation via Electronic Monitoring in Children With Uncontrolled Asthma (the IMAGINE Study): Randomized Controlled Trial (e78526)
Esther Sportel, Kris Movig, Bernard Thio, Mattienne Van der Kamp, Job Van der Palen, Marjolein Brusse-Keizer. . . . 810

Exploring the Impact of Perceived Parental Oversight on Problematic Smartphone Use Among Adolescents in the Digital Age: Database Analysis (e75837)
Mary Ho, Peter Schulz, Angela Chang. . . . 824

Novel Profiles of Family Media Use: Latent Profile Analysis (e59215)
Nicole Hamp, Jenny Radesky, Heidi Weeks, Alison Miller, Niko Kaciroti. . . . 843

Parental Perspectives on the Use of Smartwatch Activity Trackers by Young Children: Qualitative Study (e79851)
Raymond Davey, Amity Campbell, Amber Beynon, Charlotte Rasmussen, Danica Hendry, Sarah Stearne, Courtenay Harris, Leon Straker, Juliana Zabatiero. . . . 856

XSL•FO
RenderX

Challenges and Opportunities in Recruiting a Very Large Sample of Pregnant Individuals: Secondary Analysis of an Online Nationwide Randomized Controlled Trial (e72580)
Breanne Laird, Sara Moyer, Jennifer Huberty, Susan Bodnar-Deren, Patricia Kinser. 869

Impact of COVID-19 on Dutch General Practitioner Prenatal Primary Care: Retrospective, Observational Cohort Study Using an Interrupted Time-Series Approach (e64831)
Wikje Berends-Hoekstra, Maarten Homburg, Anke Oenema, Matthijs Berends, Lilian Peters. 880

COVID-19 Vaccine Uptake, Sources of Information and Side Effects Reported by Pregnant Women in Western Australia: Cross-Sectional Cohort Survey (e66645)
Nicole Catalano, Shailender Mehta. 895

Usability and Acceptability of a Pregnancy App for Substance Use Screening and Education: A Mixed Methods Exploratory Pilot Study (e60038)
Haley Fitzgerald, Madison Frank, Katelyn Kasula, Elizabeth Krans, Tamar Krishnamurti. 901

Simulation of Contraceptive Access for Adolescents and Young Adults Using a Pharmacist-Staffed e-Platform: Development, Usability, and Pilot Testing Study (e60315)
Kayla Knowles, Susan Lee, Sophia Yapalater, Maria Taylor, Aletha Akers, Sarah Wood, Nadia Dowshen. 915

Quality of First Prenatal Consultations in Malemba Nkulu, Democratic Republic of Congo: Challenges and Opportunities in a Cross-Sectional Study (e78511)
Fiston Ilunga Mbayo, Pascal Geri Madragule, Pacifique Kanku wa Ilunga, Ignace Bwana Kangulu, Dalau Nkamba Mukadi. 927

Augmented Reality Playgrounds to Promote Physical Activity in Young Children: Feasibility Study Using a Repeated Measures Laboratory Design (e75302)
Sarah Stearne, Amber Beynon, Charlotte Lund Rasmussen, Juliana Zabatiero, Louise Paatsch, Daniel Johnson, Leon Straker, Amity Campbell.
9 3 9

Development and Implementation of a Birth Forecasting Tool to Optimize Resources in Obstetrical Care During the COVID-19 Pandemic: Mixed-Methods Study (e68284)
Huibert-Jan Joosse, Karin Jongsma, Marcel Moes, Kitty Bloemenkamp, Wouter Tiel Groenestege, Wouter van Solinge, Saskia Haitjema, Maarten Kok. 955

The Neo-MILK Web App as a Health Technology to Support Mothers of Preterm and Sick Neonates During Lactation: Usability Study (e69079)
Isabella Schwab, Tim Ohnhaeuser, Roxane Rothe, Till Dresbach, Katharina Schmitz, Natalie Tutzer, Nicola Dymek, Juliane Köberlein-Neu, Nadine Scholten, Neo-Milk. 964

Developing an Evidence- and Theory-Informed Mother-Daughter mHealth Intervention Prototype Targeting Physical Activity in Preteen Girls of Low Socioeconomic Position: Multiphase Co-Design Study (e62795)
Carol Brennan, Grainne ODonoghue, Alison Keogh, Ryan Rhodes, James Matthews. 974

Augmenting Parenting Programs With the Pause Mobile App: Mixed Methods Evaluation (e68807)
Nathan Hodson, Peter Woods, Stephanie Donohoe, Juan Solano, James Gardner, Manuel Giardino, Michael Sobolev, Domenico Giacco. . .
1 0 0 7

Understanding the Implications of mHealth Technology in Collaborative Care Programs and Its Role in Supporting Postpartum Care: Qualitative Interview Study of the Baby2Home Intervention Using the Parallel Journeys Framework (e70936)
Chryselle Rego, Joshua Santiago, Emily Miller, Craig Garfield, Jacqueline Gollan, Kathleen O'Sullivan, Dinah Williams, Enid Montague, Young Lee. 1019

XSL•FO
RenderX

Exploring Parental Intentions to Use Digital Tools to Enhance Parent-Child Sexual Communication in Europe: Cross-Sectional Questionnaire Study (e75489)
Talia Hubble, Luca Carbone, Laura Vandenbosch, Jaan Toelen, David De Coninck. . . . 1046

Development of Chatbot-Based Oral Health Care for Young Children and Evaluation of its Effectiveness, Usability, and Acceptability: Mixed Methods Study (e62738)
Kittiwara Pupong, Jaranya Hunsrisakhun, Samerchit Pithpornchaiyakul, Supawadee Naorungroj. . . . 1065

Internet-Based Cognitive Behavioral Therapy for Children and Adolescents With Dental or Injection Phobia: 1-year Follow-Up Assessment (e80376)
Robert Schibbye, Erik Hedman-Lagerlöf, Viktor Kaldo, Göran Dahllöf, Shervin Shahnavaz. . . . 1081

Promoting Family Engagement With Early Childhood Developmental Screening via the Baby Steps Text Messaging and Web Portal System: Longitudinal Randomized Controlled Trial (e73443)
Hyewon Suh, Julie Kientz. . . . 1097

Usability Testing of an Internet-Based Responsive Parenting Program for Caregivers of Young Survivors of Childhood Cancer Living in Rural and Appalachian Communities: Mixed Methods Study (e70055)
Emily Moscato, Eva Darow, Jessica Quach, Adrien M Winning, Matthew Schmidt, Shari Wade, Cynthia Gerhardt, Emre Sezgin. . . . 1110

Evaluating a Digital Intervention to Reduce Aggression and Pro-Firearm Violence Attitudes Among Young Black Males: Pretest-Posttest Feasibility Study (e70048)
Chuka Emezue, Jessica Bishop-Royse, Andrew Froilan, Tara Wilkes, Niranjan Karnik, Wrenetha Julion. . . . 1126

Effects of Cold and Vibration on Venipuncture Pain Management in Children Aged 2-7 Years Old: Randomized Controlled Trial (e67918)
Zi-yun Zhou, Long-yi Hu, Ming-li Wang, Si-qi Li, Le-shan Zhou. . . . 1143

Supervised and Unsupervised Screen Time and Its Association With Physical, Mental, and Social Health of School-Going Children in Dhaka, Bangladesh: Cross-Sectional Study (e62943)
Shahria Kakon, Tanjir Soron, Mohammad Hossain, Rashidul Haque, Fahmida Tofail. . . . 1175

Effectiveness of Virtual Reality–Based Cognitive Control Training Game for Children With Attention-Deficit/Hyperactivity Disorder Symptoms: Preliminary Effectiveness Study (e66617)
Hyunjoo Song, Yunhye Oh, JongIn Choi, Seong-Yong Ohm. . . . 1187

Evaluating Telepsychiatric Assessment Satisfaction in Children and Adolescents With Autism Spectrum Disorder and Attention-Deficit/Hyperactivity Disorder and Their Caregivers: Randomized Controlled Trial (e69791)
Shunya Kurokawa, Yuko Kawade, Kensuke Nomura, Nana Hosogane, Takashi Nagasawa, Yu Matsumoto, Shuichi Morinaga, Yuriko Kaise, Ayana Higuchi, Akiko Goto, Naoko Inada, Masaki Kodaira, Taishiro Kishimoto. . . . 1199

Development of an eHealth Intervention in Pediatric Home Infusion Therapy: Interview Study of Needs and Preferences of Parents and Health Care Professionals (e63260)
Helena Hansson, Charlotte Castor, Hanne Larsen, Martha Topperzer, Mette Olesen. . . . 1208

Assessing the Impact of a Telemedicine Program on Caregivers of Children With Complex Chronic Conditions: Pre-Post Intervention Study (e62953)
Aurora Madrid-Rodríguez, María Peláez-Cantero, Alfonso Lendínez-Jurado, Ana Suárez-Carrasco, Elena Godoy-Molina, Antonia Gámez-Ruiz, Ana Corripio-Mancera, Yolanda Ramón-Telo, Ana García-Ruiz, Isabel Leiva-Gea. . . . 1221

Multilevel Factors and Indicators of Atypical Neurodevelopment During Early Infancy in Japan: Prospective, Longitudinal, Observational Study (e58337)
Daigo Kato, Akiko Okuno, Tetsuo Ishikawa, Shoji Itakura, Shinji Oguchi, Yoshiyuki Kasahara, Kenji Kanenishi, Yuzo Kitadai, Yoshitaka Kimura, Naoki Shimojo, Kazushige Nakahara, Akiko Hanai, Hiromichi Hamada, Haruta Mogami, Seiichi Morokuma, Kazuhiro Sakurada, Yukuo Konishi, Eiryo Kawakami. . . . 1231

XSL•FO
RenderX

Co-Design and Development of the SmilesUp Text Messaging Intervention Using Behavioral Theory to Support Parents of Children With Early Childhood Caries: Mixed Methods Study (e72107)
Rebecca Chen, Michelle Irving, Carrie Tsai, Bradley Christian, Harleen Kumar, Angela Masoe, Neeta Prabhu, Woosung Sohn, Heiko Spallek, Clara Chow. 1244

Enhancing Access to Mental Health Services for Antepartum and Postpartum Women Through Telemental Health Services at Wellbeing Centers in Selected Health Facilities in Bangladesh: Implementation Research (e65912)
Aniqa Hossain, Md Rahman, Ridwana Manna, Ema Akter, SM Islam, Md Hossain, Tasnu Ara, Nasimul Usmani, Pradip Chandra, Maruf Khan, SM Rahman, Helal Ahmed, Muhammad Mozumder, Jesmin Juthi, Fatema Shahrin, Sadia Shams, Fahmida Afroze, Mukta Banu, Shafiqul Ameen, Sabrina Jabeen, Anisuddin Ahmed, Mohammad Amin, Shams Arifeen, Mohammad Shomik, Ahmed Rahman. 1255

Understanding Pediatric Patient Experiences with Urotherapy Tools: Qualitative Focus Group Study (e79142)
Lola Bladt, Anka Nieuwhof-Leppink, Rose-Farah Blomme, Jiri Vermeulen, Alexandra Vermandel, Gunter De Win, Lukas Van Campenhout. . .
1 2 9 9

Likelihood of Leveraging Augmented Reality Technology to Promote HIV Prevention and Treatment Among Adolescent Girls and Young Women in Cameroon: Cross-Sectional Survey (e69471)
Zhao Ni, Intan Batubara, Jackson Ndenkeh, Georges Bediang, Habakkuk Yumo, Xuehong Zhang, Sunyong Oh, Yuchen Zhao, LaRon Nelson.
1 3 1 3

A Mobile Phone App to Support Self-Management and Transition to Adult Health Services in Young People With a Chronic Illness: Single-Arm Pilot Intervention Study (e67061)
Shehani Samarasinghe, Riham Al Na'abi, Hoi Cheng, Jeffrey Yeung, Katharine Steinbeck. 1322

Benefits and Barriers of Caregiver App Engagement for Supporting Diverse Children With Asthma: Mixed Methods Study (e69755)
Kandia Lewis, Cynthia Zettler-Greeley, Amy Milkes, Kathryn Blake. 1338

Validation and Acceptability of the Mobile App Version of the Control of Allergic Rhinitis and Asthma Test for Children (CARATKids): Cross-Sectional Study (e73531)
Dulce Abreu da Mata, Inês Pais-Cunha, Sandra Ferraz, Daniela da Rocha Couto, Catarina Ferraz, Sónia Silva, José Valente, Pedro Vieira-Marques, João A Fonseca, Inês Azevedo, Cristina Jácome. 1354

An Information App (e-TOP) to Support Parents' Information Needs During the First Year at Home After Preterm Birth: Development and Usability Study (e75569)
Monique Flierman, Eline Möller, Vincent Vijn, Raoul Engelbert, Martine Jeukens-Visser, Anton van Kaam, Daniel Bossen. 1364

Integrating Infant Safe Sleep and Breastfeeding Education Into an App in a Novel Approach to Reaching High-Risk Populations: Prospective Observational Study (e65247)
Tamar Krishnamurti, Rachel Moon, Rudolph Richichi, Rachel Berger. 1381

Evaluating the Characteristics and Outcomes of Acute Pharmaceutical Exposure in Children: 5-Year Retrospective Study (e66951)
Zhu Duan, Yan Qu, Rui Tang, Jun Liu, Hui Wang, Meng Sheng, Liang Wang, Shuang Liu, Jiao Li, Lin Guo, Si Zheng. 1390

Exploring the Association Between Behavioral Determinants and Intention to Use a Chatbot-Led Parenting Intervention by Caregivers of Adolescent Girls in South Africa: Cross-Sectional Study (e76992)
Maria Ambrosio, Seema Vyas, Juliet Stromin, Shallen Lusinga, Paula Zinzer, Kanyisile Brukwe, Zamakhanya Makhanya, Hlengiwe Gwebu, Anne Schley, Laurie Markle, David Stern, Chiara Facciolà, G Melendez-Torres, Frances Gardner, Jamie Lachman. 1405

XSL•FO
RenderX

Efficacy, Feasibility, and Acceptability of an Emotional Competence Tele-Intervention for Mandarin-Speaking Children Aged 5 to 7 Years With Developmental Language Disorder: Pilot Study With an Interrupted Time-Series Design (e60333)
Hsin-Hui Lu, Shih-Yuan Liang, Yi-Chia Huang. . . . 1421

Evaluating the Preliminary Efficacy of the TRUST Intervention on Alone-Time and Communication During Well-Adolescent Visits: Quasi-Experimental Study (e71433)
Jyu-Lin Chen, Marissa Raymond-Flesch, Thomas Hoffmann, Chen-Xi Lin, Ling Xu, Kimberly Koester. . . . 1440

Body Fat and Obesity Rates, Cardiovascular Fitness, and the Feasibility of a Low-Intensity Non–Weight-Centric Educational Intervention Among Late Adolescents: Quasi-Experimental Study (e67213)
Areeg Zuair, Fahad Alhowaymel, Rola Jalloun, Naif Alzahrani, Khalid Almasoud, Majdi Alharbi, Rayan Alnawwar, Mohammed Alluhaibi, Rawan Alharbi, Fatima Aljohan, Bandar Alhumaidi, Mohammad Alahmadi. . . . 1454

Effects of Exergames on Motor Skills, Psychological Well-Being, and Cognitive Abilities in Schoolchildren and Adolescents: Scoping Review (e71416)
Eleonora Rosi, Valentina Bianchi, Ilaria Baù, Rebecca Nuzzo, Stefania Valsecchi, Massimo Molteni, Paola Colombo. . . . 1484

Reviews

Effect of Digital Safety Interventions on Parental Practices in Safeguarding Children's Digital Activities: Systematic Review and Meta-Analysis (e70745)
Maggie Zgambo, Edah Anyango, Diana Arabiat, Irene Ngune, Evalotte Mörelius, Min Zhang, Lisa Whitehead. . . . 275

Digital Interventions for Patients With Juvenile Idiopathic Arthritis: Systematic Review and Meta-Analysis (e65826)
Zihan Ren, Yawen Chen, Yufeng Li, Panyu Fan, Zhao Liu, Biyu Shen. . . . 711

Evidence of Interventions for the Prevention of Unintentional Injuries: Scoping Review (e67877)
Sheela Shetty, Baby Nayak, Anice George, Avinash Shetty, Vasudeva Guddattu. . . . 787

Extended Reality (XR) in Pediatric Acute and Chronic Pain: Systematic Review and Evidence Gap Map (e63854)
Courtney Hess, Brittany Rosenbloom, Giulia Mesaroli, Cristal Lopez, Nhat Ngo, Estreya Cohen, Carley Ouellette, Jeffrey Gold, Deirdre Logan, Laura Simons, Jennifer Stinson. . . . 1155

Early Digital Engagement Among Younger Children and the Transformation of Parenting in the Digital Age From an mHealth Perspective: Scoping Review (e60355)
Nafisa Anjum, Md Hasan, Nursat Jahan, Sheikh Ahamed, Allison Garefino, Nazmus Sakib. . . . 1504

Assessing and Enhancing Nutrition and Physical Activity Environments in Early Childhood Education and Care Centers: Scoping Review of eHealth Tools (e68372)
Joyce Hayek, Kelsi Dickson, Lynne Lafave. . . . 1519

Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review (e64814)
Neda Barbazi, Ji Shin, Gurumurthy Hiremath, Carlye Lauff. . . . 1545

Letter to the Editor

Pediatric Hearts and Minds: Reimagining Health Education Through Play and Narrative (e72675)
Alina Yang. . . . 1276

XSL•FO
RenderX

Viewpoints

A Holistic Digital Health Framework to Support Health Prevention Strategies in the First 1000 Days (e55235)
Silvia Gabrielli, Oscar Mayora Ibarra, Stefano Forti. 1278

Preventing Urgent Pediatric Readmissions: The Need for and Promise of Real-Time Monitoring (e60802)
Isha Thapa, Brian Han, David Rosenthal, Stephen Roth, Andrew Shin, Nicholas Bambos, David Scheinker. 1286

Leveraging AI to Investigate Child Maltreatment Text Narratives: Promising Benefits and Addressable Risks (e73579)
Wilson Lukmanjaya, Tony Butler, Sarah Cox, Oscar Perez-Concha, Leah Bromfield, George Karystianis. 1290

Corrigenda and Addendas

Correction: Digital Health Program to Support Family Caregivers of Children Undergoing Growth Hormone Therapy: Qualitative Feasibility Study (e76508)
Alba Jiménez-Díaz, Maitena Pierantonelli, Patricia Morte Coscolín, Amaia Salinas-Uhalte, Silvia Quer-Palomas, Octavio Rivera-Romero, Rocío Herrero, Luis Fernández-Luque, Rosa Baños, Ricardo Berrios, Antonio de Arriba Muñoz. 1466

Correction: Sex Differences in the Joint Trajectories of Depressive Symptoms and Body Mass Index From Adolescence to Early Adulthood: Longitudinal Observational Study (e84632)
Jing Chen, Rui Shan, Wen Yuan, Qiong Wu, Yang Yang, Yi-Hang Yang, Jing-Yao Liu, Wu-Cai Xiao, Shanghang Zhang, Li-Ming Wen, Xiao-Rui Zhang, Zheng Liu, Yi Song. 1468

Research Letters

The Effect of COVID-19 on Health Care Utilization Among Children with Medical Complexity: Retrospective Chart Review Study (e65751)
Onur Asan, Ilse Super, Stephen Percy, Katharine Clouser. 1470

A Primary Care Group Resilience Intervention Promotes Child and Caregiver Behavioral Health (e67638)
Joan Jeung, Andrew Nguyen, Jennifer Martinez, Li Zhang. 1476

Importance of Engaging Partners in Digital Postpartum Depression Prevention: Qualitative Study (e71764)
Adam Lewkowitz, Liana Lum, Katrina Ursino, Melissa Guillen, Gabriela Garcia, Sarai Sales, Saloni Taneja, Crystal Ware, William Grobman, Caron Zlotnick, Kate Guthrie, Emily Miller. 1480

XSL•FO
RenderX

Association Between the Parenting Competence and Quality of Life of Family Caregivers of Children Aged 0-3 Years: Cross-Sectional Study

Wei He[1], BMed; Le-shan Zhou[2], PhD, MM, BMed; Long-yi Hu[2], BMed

[1]Department of Nursing, The Third Xiangya Hospital of Central South University, Changsha, China

[2]Department of Clinical Nursing, Xiangya School of Nursing, Central South University, 172 Tong Zi Po Rd., Yuelu District, Changsha, China

Corresponding Author:
Long-yi Hu, BMed
Department of Clinical Nursing, Xiangya School of Nursing, Central South University, 172 Tong Zi Po Rd., Yuelu District, Changsha, China

Abstract

Background: The quality of life (QoL) for family caregivers significantly influences not only their own well-being but also the well-being of children aged 0 - 3 years. Competence stands out as a crucial subjective factor that impacts this QoL.

Objective: This study aimed to examine the factors affecting the QoL of caregivers of children aged 0 - 3 years and its correlation with parenting competency.

Methods: Caregivers of children aged 0 - 3 years from the child health department of a tertiary hospital in Changsha, Hunan Province, were chosen as the study sample through convenience sampling. The study investigated the relationship between parenting competency and the caregivers' QoL, utilizing general information, the parenting competency scale, and the family caregiver quality of life scale.

Results: In this study, 291 family caregivers, including 13 fathers and 278 mothers of children aged 0 - 3 years, were evaluated. The mean (SD) parenting competence score was 68.70 (9.816) and the mean (SD) QoL score was 56.81 (8.922). It was found that higher caregiver QoL scores were significantly associated with greater parenting competence (R=0.665, P<.001). Furthermore, each dimension of parenting competence demonstrated a significant positive correlation with each dimension of the QoL (P<.001).

Conclusions: The data suggest a notable association between parenting competence and QoL among family caregivers of children aged 0 - 3 years. This association has implications for improving fertility rates, as enhancing parenting competence may reduce childcare-related stress and thereby enhance the overall QoL.

(JMIR Pediatr Parent 2025;8:e67872) doi:10.2196/67872

KEYWORDS

child; toddler; pediatric; infant; quality of life; QoL; family caregiver; caregiver; well-being; competence; quality of life factors; parenting competency; correlation; child health department; tertiary hospital; convenience sampling; parenting competency scale; family caregiver quality of life scale

Introduction

Quality of life (QoL) constitutes a subjective evaluation of one's place in life in the context of one's personal goals and value systems [1], spanning physical, social, spiritual, and psychological domains. The QoL of family caregivers for children aged 0 - 3 years not only mirrors the caregivers' own life quality, correlating with superior physical health and reduced incidence of anxiety or depression [2], but also influences the quality of care provided to the children [3]. Importantly, caregivers with a higher QoL tend to deliver improved care, which in turn enhances the life quality of children aged 0 - 3 years [4]. Consequently, evaluating the QoL is a crucial aspect in the study of family caregiving for this age group.

The QoL is profoundly influenced by a myriad of factors. Among these, for family caregivers, the challenges posed by childcare significantly impact their well-being. Parenting stress is associated with reduced life satisfaction, deteriorated mental health, and a diminished overall QoL [5]. The QoL is inherently subjective, and thus, subjective factors often provide more reliable indicators than objective ones [6]. A critical subjective factor is the sense of competence in parenting, which encompasses an individual's comprehensive assessment of their effectiveness within the parenting role, particularly in terms of parenting efficacy and satisfaction [7]. Parents with high parenting competence typically display greater confidence and motivation when addressing and resolving challenges that arise in the course of childrearing [8]. For children between the ages of 0 - 3 years—a crucial phase in developmental terms—the

XSL•FO
RenderX

pressures of parenting are acute. The research hypothesizes a correlation between the QoL and parenting ability, suggesting that enhancing parenting competence can alleviate parental stress and improve the QoL.

Recent studies on the QoL of child caregivers focused on parents caring for children with special needs or intergenerational caregivers [9]. However, they overlooked the experiences of typical parental caregivers. The purpose of this study was to explore the connection between parent competence and the QoL among caregivers of children aged 0 - 3 years. It also aimed to offer insights and guidance for the development of effective parenting strategies and interventions for families with children in this age group.

Methods

Design

The convenience sampling method was employed to select eligible family caregivers of children aged 0 - 3 years from the Child Health Department at a tertiary hospital in Changsha, for a questionnaire survey conducted from January to April 2024.

Participants

According to the widely recognized method for estimating sample size, it is recommended to have a sample size that is 5 to 10 times the number of variables under study [10]. This research encompasses 8 demographic and disease-related variables and 6 additional dimensions from the scale, resulting in a total of 14 variables. Consequently, an initial sample size of 70 to 140 participants is suggested. To accommodate a potential 10% loss of samples and the presence of invalid questionnaires, the minimum sample size should be adjusted to range from 77 to 154 participants. In this study, a total of 300 questionnaires were disseminated; 9 of them were excluded due to incomplete questionnaires.

The inclusion criteria were as follows: (1) guardians of children aged 0 - 3 years acting as primary caregivers; (2) possessing adequate cognitive communication skills; (3) consenting to participate in the study; and (4) capable of independently completing the survey. Conversely, exclusion criteria encompassed: (1) individuals with psychiatric disorders or those averse to collaboration; (2) family members of sick children; and (3) participants withdrawing for various reasons (for example, not having time to complete all the questionnaires, or unwilling to continue participating midway).

To guarantee the integrity of the data collection process, the investigator remained present to assist participants with any queries and to verify that the questionnaires were filled out completely.

Ethical Considerations

The study was approved by the Ethics Committee (No. E2023121). The data are anonymized. The participants were informed of the purpose and procedures of the study prior to participation, and we obtained informed consent from the parents. The participants did not receive any remuneration.

Data Collection and Measurements

General Information

This information encompassed the relationship with the child, marital status of the child's parents, family structure, child's age, identity of the primary family caregiver, physical health of both the child and the caregiver, method of the child's conception, and feeding practices employed.

Parenting Competence Scale

The Parenting Competence Scale was developed by Gibaud-Wallston and Wandersman [11] in 1978 and translated by Yang et al [12]. The scale comprises 17 items, bifurcated into two principal dimensions: efficacy and satisfaction. The efficacy component encompasses eight items that gauge parents' self-perceptions of their parenting skills, whereas the satisfaction component comprises nine items that assess parents' contentment with their role as caregivers. The scale ranged from "1: Totally Disagree" to "6: Totally Agree." The scores fluctuate between 17 and 102, with elevated scores mirroring enhanced parenting competence. The reliability of the scale is substantiated by a Cronbach α coefficient of 0.80.

Family Caregiver Specific QoL Scale

The Family Caregiver Specific QoL scale, developed by Nauser et al [13] and transcribed by Hyland Qian [14], was employed to assess the QoL in family caregivers. It comprised 16 items that span four dimensions: physical, social, spiritual, and psychological well-being. Four entries for each dimension. All domains carry equal importance. Employing a 5-point Likert scale, it allows respondents to answer with options ranging from "1: Strongly Disagree to "5: Strongly Agree." Items that were negatively expressed were reverse-scored. The scale scores spanned from 16 to 80, with higher scores suggesting an enhanced QoL for the caregiver. The Cronbach α for the Chinese version of the scale was 0.84, further confirming its reliability and validity. This scale has been applied in family caregivers for children with heart disease, premature infants, and newborns [15,16].

Statistical Analyses

Statistical analysis was conducted using SPSS software (version 24.0; IBM Corp). The general information was analyzed descriptively using frequency counts (component ratios). The QoL and parenting competence scores of family caregivers were characterized using means and standard deviations, provided they adhered to a normal distribution. One-way analyses were carried out to identify factors influencing QoL using *t* tests or ANOVA. The association between the QoL and parenting competence of family caregivers was assessed using the Pearson correlation analyses.

Results

General Information

A total of 300 parents participated in the survey, of which 291 responses were valid, yielding a questionnaire recovery rate of 97%. The participants comprised 13 fathers and 278 mothers, as detailed in Table 1.

XSL•FO
RenderX

Table . General information (N=291).

Items	n (%)
Relationship	
Father	13 (4.47)
Mother	278 (95.53)
Family structure	
Nuclear family	170 (58.42)
Stem family	118 (40.55)
Single-parent family	3 (1.03)
Marital status	
Married	289 (99.31)
Divorcee	2 (0.69)
Child's age	
0 - 6 months	233 (80.07)
~1 year old	30 (10.31)
~2 years old	16 (5.50)
~3 years old	12 (4.12)
Caregivers' physical health	
Good	247 (84.88)
Not well	44 (15.12)
Child's physical condition	
Good	275 (94.50)
Not well	16 (5.50)
Pregnancy method	
Planned	264 (90.72)
Assisted reproduction	22 (7.56)
Unplanned	5 (1.72)
Feeding style	
Exclusive breastfeeding	124 (42.61)
Artificial feeding	28 (9.62)
Mixed feeding	139 (47.77)

Scores of Parenting Competence and QoL

In this study, we evaluated the parenting competence of family caregivers for children aged 0 - 3 years, finding an average (SD) score of 68.70 (9.816), while the average (SD) QoL score stood at 56.81 (8.922). Detailed scores for each dimension are depicted in Table 2.

XSL•FO
RenderX

Table . Score of parenting competence and quality of life (N=291).

Items	Range	Median (P_{25} ,P_{75})	Mean (SD)
Parenting competence	34, 101	68 (62,75)	68.70 (9.816)
Efficacy	17, 47	33 (29,39)	32.98 (5.604)
Satisfaction	17, 54	35 (32,29)	35.72 (4.975)
Quality of life	20, 80	57 (50, 63)	56.81 (8.922)
Physical well-being	6, 20	14 (12,16)	14.23 (2.568)
Spiritual well-being	4, 20	16 (13,16)	15.10 (2.987)
Social well-being	4, 20	14 (12,16)	13.90 (2.981)
Psychological well-being	4, 20	13 (12,16)	13.59 (3.391)

Association Between Caregiver Parenting Competence and QoL

Notably, there was a significant positive correlation between the caregivers' QoL score and parenting competence (r=0.665, P<.001).Positive correlations were consistently observed across all dimensions of parenting competence and the corresponding dimensions of QoL (P<.001), as detailed in Table 3.

Table . Correlation analysis of parenting competence and quality of life (N=291).

	Parenting competence	Quality of life	Efficacy	Satisfaction	Physical well-being	Spiritual well-being	Social well-being	Psychological well-being
Parenting competence	1	N/A[a]	N/A	N/A	N/A	N/A	N/A	N/A
Quality of life	.665[b]	1	N/A	N/A	N/A	N/A	N/A	N/A
Efficacy	.936[b]	.634[b]	1	N/A	N/A	N/A	N/A	N/A
Satisfaction	.919[b]	.598[b]	.721	1	N/A	N/A	N/A	N/A
Physical well-being	.481[b]	.815[b]	.461[b]	.430[b]	1	N/A	N/A	N/A
Spiritual well-being	.583[b]	.711[b]	.502[b]	.584[b]	.424[b]	1	N/A	N/A
Social well-being	.373[b]	.748[b]	.369[b]	.319[b]	.536[b]	.437[b]	1	N/A
Psychological well-being	.545[b]	.731[b]	.553[b]	.452[b]	.542[b]	.284[b]	.298[b]	1

[a]not available

[b]P<.001

Discussion

Main Findings

The parenting competence scores of family caregivers for children aged 0 - 3 years exhibited a positive correlation with the caregivers' QoL (R=0.665, P<.001). Additionally, scores across all domains of parenting competence demonstrated positive correlations with scores across all dimensions of QoL (P<.001).

General Information on Family Caregivers

Composition of Family Caregivers

In this study, out of 291 participants, 278 were mothers (95.53%); therefore, mothers emerged as the predominant family caregivers. Consequently, efforts to enhance the QoL for family caregivers should prioritize understanding and addressing the experiences and sentiments of maternal caregivers. Out of 291 families, there are 170 nuclear families (58.4%) and 118 stem families (40.6%). Stem families refer to families where grandparents, parents, and children live together. This type of family is common. Although the mother is the primary caregiver, in China, grandparents are usually more involved in parenting. There may be differences in parenting concepts between parents and grandparents. Future research could explore the impact of grandparents' involvement in parenting on family dynamics.

Level of Caregiver Parenting Competence and QoL

Parenting Competence of Family Caregivers

The mean (SD) parenting competence score among family caregivers of children aged 0 - 3 years was 68.70 (9.816). This study is pioneering in investigating the parenting competence for this age group, as the majority of existing research has primarily concentrated on children age 1 years, particularly the

XSL•FO
RenderX

initial 42 days postdelivery, thereby limiting comparative analysis [17]. The present study revealed a medium level of parenting competence. The efficacy and satisfaction dimensions had different numbers of entries and were not comparable.

QoL of Family Caregivers

In this study, the mean (SD) caregiver QoL score was found to be 56.81 (8.922). Given the plethora of scales designed to measure caregiver QoL, particularly those catered to children with special needs, direct comparisons with other studies are challenging [18]. Among the four dimensions assessed, family caregivers exhibited the highest scores in psychological well-being. Parent-child interactions appear to bolster parent-infant attachment, especially during early development stages (0 - 3 y). Therefore, promoting these interactions within families could be an effective strategy for future interventions [19]. The social and psychological dimensions of QoL were notably deficient, so strengthening social support for caregivers of children aged 0 to 3 years and addressing their related psychological issues is a way to improve the QoL for caregivers [20].

Association Between Caregiver Parenting Competence and QoL

Impact of Parenting Efficacy on QoL

Research has consistently demonstrated a positive correlation between parenting efficacy and the QoL of caregivers [21-23]. Enhanced parenting efficacy not only bolsters cognitive and behavioral functioning but also catalyzes improvements in physical and mental health. Alam et al [24] found that caregivers are susceptible to physiological issues such as sleep disorders, weight loss, and fatigue due to their caregiving responsibilities. According to Bandura's theory [25], parents with a heightened sense of efficacy are more adept at self-regulation and self-management when confronted with challenging parenting scenarios, such as a decline in the child's health, thereby enjoying a higher physiological QoL. In terms of mental aspects, the task of caregivers is to manage the daily needs of children aged 0 to 3 years, take care of family members, and participate in decision-making, which may lead to mental health challenges. The research implies that individuals possessing a stronger sense of efficacy may exhibit an enhanced ability to mitigate the detriments of negative mental health [26]. Confronted with obstacles in parenting, such as disputes concerning educational philosophies, they are inclined towards adopting positive coping tactics to regulate their emotional state and promote superior mental health quality. From a social perspective, an unwavering focus on infants and toddlers might curtail a carer's independence, consequently posing adverse effects on their psychosocial development. Numerous investigations establish a linkage between social support and QoL [27-29]. Such findings indicate that the QoL could potentially intermediate the relationship between a collective sense of efficacy and parenting proficiency. In other words, caregivers possessing a stronger sense of efficacy are likely to be more assertive in pursuing social support, are more equipped to furnish social support, and possess a better overall social QoL. The psychological state of a caregiver is heavily influenced in their interaction with children aged 0 - 3 years [30]. Factors such as concern for the child's health, challenges in transitioning to caregiving roles, and understanding the child's expressions may catalyze anxiety and depression among caregivers. Loh et al [31] proposed that caregivers who are capable of effectively managing, adjusting to, and surmounting difficulties experience lesser burden and exhibit fewer symptoms of anxiety and depression. Furthermore, these caregivers tend to have a better social QoL due to their increased sense of efficacy.

Impact of Childcare Satisfaction on QoL

The positive correlation between childcare satisfaction and caregiver QoL has been well-documented. Numerous studies have examined the correlation between satisfaction and the QoL, typically comparing the two as indicators for assessing outcomes [32,33]. However, Sansó et al [34] postulated a direct correlation between life satisfaction and the QoL. Parenting satisfaction represents an individual's comprehensive evaluation of their parenting role. Physiologically, parents experiencing high levels of satisfaction are less inclined to engage in self-reproach, exhibit reduced susceptibility to fatigue and burnout while attending to children aged 0 - 3 years, and provide superior care, thereby enhancing their physiological QoL. Psychologically, these parents demonstrate a decreased likelihood of experiencing frustration and negative emotions when confronted with childcare challenges. Moreover, the subjective experience of well-being is recognized as a fundamental element for maintaining high mental health and satisfaction [35]. Consequently, parents who report satisfaction tend to exhibit a lower threshold for experiencing pleasure, reduced vulnerability to mental or psychological issues, and an elevated mental and psychological QoL. Socially, in line with societal expectations in many cultures, Chinese parents who fall short in their parenting duties are held accountable by various segments of society. Parents with high parenting satisfaction are more likely to cultivate higher-quality social connections, receive enhanced social support for their childcare responsibilities, and enjoy a superior quality of social life.

Limitations

This study employed a convenience sampling method from a single hospital, limiting its representativeness. Future research should consider stratified sampling across various countries, hospitals, and communities. Additionally, investigating the mediating factors between parenting competence and QoL may offer valuable insights for further studies.

Conclusion

The study found that family caregivers of children aged 0 - 3 years exhibit a correlation between parenting competence and QoL, with all dimensions showing significant correlations. Health care professionals have the potential to enhance QoL by fostering parenting competence.

XSL•FO
RenderX

Acknowledgments

This work was supported by Hunan Women's Studies Association (22ZDB07).

Conflicts of Interest

None declared.

References

1. Wright JD. International Encyclopedia of the Social & Behavioral Sciences 2015. URL: https://www.sciencedirect.com/referencework/9780080970875/international-encyclopedia-of-the-social-and-behavioral-sciences [accessed 2025-06-09]
2. Borstelmann NA, Gray TF, Gelber S, et al. Psychosocial issues and quality of life of parenting partners of young women with breast cancer. Support Care Cancer 2022 May;30(5):4265-4274. [doi: 10.1007/s00520-022-06852-7] [Medline: 35091846]
3. Witt S, Kolb B, Bloemeke J, Mohnike K, Bullinger M, Quitmann J. Quality of life of children with achondroplasia and their parents - a German cross-sectional study. Orphanet J Rare Dis 2019 Aug 9;14(1):194. [doi: 10.1186/s13023-019-1171-9] [Medline: 31399110]
4. Sun Y, Ji M, Leng M, Li X, Zhang X, Wang Z. Comparative efficacy of 11 non-pharmacological interventions on depression, anxiety, quality of life, and caregiver burden for informal caregivers of people with dementia: A systematic review and network meta-analysis. Int J Nurs Stud 2022 May;129:104204. [doi: 10.1016/j.ijnurstu.2022.104204] [Medline: 35247788]
5. Suonpera E, Lanceley A, Ni Y, Marlow N. Parenting stress and health-related quality of life among parents of extremely preterm born early adolescents in England: a cross-sectional study. Arch Dis Child Fetal Neonatal Ed 2024 Apr 18;109(3):253-260. [doi: 10.1136/archdischild-2023-325429] [Medline: 37879883]
6. Boettcher J, Boettcher M, Wiegand-Grefe S, Zapf H. Being the pillar for children with rare diseases-a systematic review on parental quality of life. Int J Environ Res Public Health 2021 May 8;18(9):4993. [doi: 10.3390/ijerph18094993] [Medline: 34066738]
7. Johnston C, Mash EJ. A measure of parenting satisfaction and efficacy. J Clin Child Psychol 1989 Jun;18(2):167-175. [doi: 10.1207/s15374424jccp1802_8]
8. Holley CE, Haycraft E. Mothers' perceptions of self-efficacy and satisfaction with parenting are related to their use of controlling and positive food parenting practices. Matern Child Nutr 2022 Jan;18(1):e13272. [doi: 10.1111/mcn.13272] [Medline: 34528391]
9. Feng Y, Zhou X, Qin X, et al. Parental self-efficacy and family quality of life in parents of children with autism spectrum disorder in China: the possible mediating role of social support. J Pediatr Nurs 2022;63:159-167. [doi: 10.1016/j.pedn.2021.10.014] [Medline: 34782156]
10. Ni P, Chen JL, Liu N. The sample size estimation hi quantitative nursing research. Chinese Journal of Nursing 2010;45(4):378-380. [doi: 10.3761/j.issn.0254-1769.2010.04.037]
11. Gibaud-Wallston J, Wandersman LP. Development and utility of the parenting sense of competence scale. : The American Psychological Association in American Psychological Association; 1978 Presented at: Proceedings of the American Psychological Association in American Psychological Association.
12. Yang X, Gao LL, Zhang Z, Wu D, Zhang Y. The reliability and validity of the Chinese version of parenting sense of competence scale. Chinese Journal of Nursing 2014;49(7):881-885.
13. Nauser JA, Bakas T, Welch JL. A new instrument to measure quality of life of heart failure family caregivers. J Cardiovasc Nurs 2011;26(1):53-64. [doi: 10.1097/JCN.0b013e3181e4a313] [Medline: 21127427]
14. Qian HL, Wang JQ, Shen WQ, Mu AF, Yu YM. The Chinese version of family caregiver-specific quality of life scale: validation among community family caregivers of chronic heart failure patients. Journal of Nursing Science 2012;27(21):85-87.
15. Shen L, Zhang L, Tao Y, Tang YJ, Bao MJ, Lu HZ. Study on correlation between care burden and quality of life of family caregivers of children with tuberculosis. Chinese Journal of Antituberculosis 2018;40(10):1118-1124.
16. Xu HJ, Zhang D, Du ZY, Gao YY, Yao WX. Mediating effects of coping styles and social support on parental care burden and quality of life. Chinese Journal of Birth Health And Heredity 2024;32(1):200-204. [doi: 10.13404/j.cnki.cjbhh.2024.01.037]
17. Li Y, Zhang QY, Zhang CH. Influencing factors of maternal parenting sense of competence in China: a meta-analysis. Journal of International Obstetrics and Gynecology 2023;50(6):711-717.
18. Suen MW, Ningrum V, et al. The association between parenting stress, positive reappraisal coping, and quality of life in parents with autism spectrum disorder (ASD) children: a systematic review. Healthcare (Basel) 2021 Dec 28;10(1):52. [doi: 10.3390/healthcare10010052] [Medline: 35052216]
19. Nordahl D, Rognmo K, Bohne A, et al. Adult attachment style and maternal-infant bonding: the indirect path of parenting stress. BMC Psychol 2020 Jun 8;8(1):58. [doi: 10.1186/s40359-020-00424-2] [Medline: 32513300]

XSL•FO
RenderX

20. Wang Z, Wang L, Chang S, Wang H. The mediating effect of parenting stress on the relationship between social support and quality of life in parents of children with autistic spectrum disorder: a meta-analytic structural equation modeling. Front Psychiatry 2022;13(713620):713620. [doi: 10.3389/fpsyt.2022.713620] [Medline: 35250654]
21. Nelligan RK, Hinman RS, Kasza J, Crofts SJC, Bennell KL. Effects of a self-directed web-based strengthening exercise and physical activity program supported by automated text messages for people with knee osteoarthritis: a randomized clinical trial. JAMA Intern Med 2021 Jun 1;181(6):776-785. [doi: 10.1001/jamainternmed.2021.0991] [Medline: 33843948]
22. Huang Z, Liu T, Chair SY. Effectiveness of nurse-led self-care interventions on self-care behaviors, self-efficacy, depression and illness perceptions in people with heart failure: A systematic review and meta-analysis. Int J Nurs Stud 2022 Aug;132(104255):104255. [doi: 10.1016/j.ijnurstu.2022.104255] [Medline: 35623153]
23. Melgarejo González-Conde V, Pérez-Fernández V, Ruiz-Esteban C, Valverde-Molina J. Impact of Self-efficacy on the quality of life of children with asthma and their caregivers. In: Bronconeumol A, editor. Arch Bronconeumol (Engl Ed) 2019 Apr;55(4):189-194. [doi: 10.1016/j.arbres.2018.07.008] [Medline: 30119934]
24. Alam S, Hannon B, Zimmermann C. Palliative care for family caregivers. J Clin Oncol 2020 Mar 20;38(9):926-936. [doi: 10.1200/JCO.19.00018] [Medline: 32023152]
25. Bandura A. Self-efficacy: toward a unifying theory of behavioral change. Psychol Rev 1977 Mar;84(2):191-215. [doi: 10.1037//0033-295x.84.2.191] [Medline: 847061]
26. Mo PKH, Fong VWI, Song B, Di J, Wang Q, Wang L. Association of Perceived threat, negative emotions, and self-efficacy with mental health and personal protective behavior among chinese pregnant women during the COVID-19 pandemic: cross-sectional survey study. J Med Internet Res 2021 Apr 12;23(4):e24053. [doi: 10.2196/24053] [Medline: 33729983]
27. Jafari A, Naddafi F, Gholian-Aval M, Tehrani H. Relationship between diabetes health literacy, distress, burnout, social support, complications, self-care behaviors, and quality of life among patients with type 2 diabetes: a path analysis study. Diabetol Metab Syndr 2024 Jul 5;16(1):150. [doi: 10.1186/s13098-024-01391-z] [Medline: 38970113]
28. Davidson Arad B, McLeigh JD, Katz C. Perceived collective efficacy and parenting competence: the roles of quality of life and hope. Fam Process 2020 Mar;59(1):273-287. [doi: 10.1111/famp.12405] [Medline: 30403404]
29. Cahuas A, Marenus MW, Kumaravel V, et al. Perceived social support and COVID-19 impact on quality of life in college students: an observational study. Ann Med 2023 Dec;55(1):136-145. [doi: 10.1080/07853890.2022.2154943] [Medline: 36519501]
30. Bolbocean C, Andújar FN, McCormack M, Suter B, Holder JL Jr. Health-related quality of life in pediatric patients with syndromic autism and their caregivers. J Autism Dev Disord 2022 Mar;52(3):1334-1345. [doi: 10.1007/s10803-021-05030-8] [Medline: 33937973]
31. Loh KP, Mohamed MR, Kadambi S, et al. Caregiver-oncologist prognostic concordance, caregiver mastery, and caregiver psychological health and quality of life. Oncologist 2021 Apr;26(4):310-317. [doi: 10.1002/onco.13699] [Medline: 33523583]
32. Shin E, Kim M, Kim S, Sok S. Effects of reminiscence therapy on quality of life and life satisfaction of the elderly in the community: a systematic review. BMC Geriatr 2023 Jul 10;23(1):420. [doi: 10.1186/s12877-023-04001-1] [Medline: 37430198]
33. Bogart K, Hemmesch A, Barnes E, et al. Healthcare access, satisfaction, and health-related quality of life among children and adults with rare diseases. Orphanet J Rare Dis 2022 May 12;17(1):196. [doi: 10.1186/s13023-022-02343-4] [Medline: 35549731]
34. Sansó N, Galiana L, Oliver A, Tomás-Salvá M, Vidal-Blanco G. Predicting professional quality of life and life satisfaction in Spanish nurses: a cross-sectional study. Int J Environ Res Public Health 2020 Jun 18;17(12):4366. [doi: 10.3390/ijerph17124366] [Medline: 32570795]
35. Tokay Argan M, Mersin S. Life satisfaction, life quality, and leisure satisfaction in health professionals. Perspect Psychiatr Care 2021 Apr;57(2):660-666. [doi: 10.1111/ppc.12592] [Medline: 33216397]

Abbreviations

QoL: quality of life

Edited by S Badawy; submitted 24.10.24; peer-reviewed by A Yamazaki, T Kawahara; revised version received 12.02.25; accepted 14.04.25; published 16.06.25.

Please cite as:
He W, Zhou LS, Hu LY
Association Between the Parenting Competence and Quality of Life of Family Caregivers of Children Aged 0-3 Years: Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e67872
URL: https://pediatrics.jmir.org/2025/1/e67872
doi:10.2196/67872

XSL•FO
RenderX

© Wei He, Le-shan Zhou, Long-yi Hu. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 16.6.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Examination of Chronic Sorrow Among Parents of Children With Disabilities: Cross-Sectional Study

Samaa Al Anazi[1,2], RN, FNP, PhD; Naseem Alhujaili[3], MBBS, SB-Psych, AB-Psych; Dina Sinqali[1,2], RN; Ftoon Al Heej[1,2], RN; Lojain Al Somali[1,2], RN; Samaher Khayat[1,2], RN; Talah Ramboo[1,2], RN

[1]King Abdullah International Medical Research Center, Jeddah, Saudi Arabia

[2]College of Nursing - Jeddah, KSAU, KAMC, National Guard Health Affairs, PO Box 9515, Jeddah, Saudi Arabia

[3]Department of Medicine, Division of Psychiatry, Faculty of Medicine in Rabigh, King Abdulaziz University, Jeddah, Saudi Arabia

Corresponding Author:
Samaa Al Anazi, RN, FNP, PhD
King Abdullah International Medical Research Center, Jeddah, Saudi Arabia

Abstract

Background: Parents of children with disabilities face many challenges when providing care, along with persistent worry and fear about the child's health outcomes and the impact of the disability on their lives. These parents experience stressful situations and face many emotions, one of which is chronic sorrow (CS). Therefore, the theory of CS was introduced to examine and measure feelings of CS among parents. Little research has been conducted with Saudi parents with a child with disabilities and the utilization of CS theory in this population is limited.

Objective: This study aims to examine the application of CS theory on parents of children with disabilities in Saudi Arabia.

Methods: A cross-sectional design was used to obtain data from 89 participants who are parents of children with disabilities. A web-based questionnaire was distributed to measure CS.

Results: The study examined the concepts within CS theory. The concept of loss experience yielded a moderately high score (mean 3.3, SD 1.10); of all the variables measuring loss experience, parents scored high in feeling sad when thinking about their child's disability (mean 3.9, SD 1.24). Parents also reported a moderately high score (mean 3.3, SD 1.06) for the concept of disparity, specifically when their child does not meet the same developmental milestones as their peers (mean 3.8, SD 1.30). Feelings of CS also displayed a moderately high score (mean 3, SD 0.87), with the periodic nature of CS scoring the highest within the concept of CS (mean 3.6, SD 1.16). In addition, internal and external management methods that parents believe are effective were examined. Internal management of CS was believed to be of high importance (mean 4.6, SD 0.33), specifically the belief of fatalism (mean 4.8, SD 0.50). Parents also viewed external management as important in navigating their emotions (mean 4.5, SD 0.42), specifically social support from family and the community (mean 4.7, SD 0.55). This study identified strong positive relationships between sorrow and loss experience and disparity (both r=0.765 and P<.001). Lastly, the study found no relationship between CS and time elapsed since parents received their child's diagnosis (r=−0.009; P=.94).

Conclusions: This study applied the theory of CS to the parents of children with disabilities and they reported feelings of loss, disparity, and CS. Therefore, this population should be screened and provided with parental emotional care. Interventions to enhance parental mental health and well-being and support CS management should be developed and used by health care workers. Parental acceptance of their child's disability does not mean the absence of CS, as it is part of the normal grieving process. Anticipating CS triggers and applying internal and external management are essential to improving parental mental health and child health outcomes.

(JMIR Pediatr Parent 2025;8:e65754) doi:10.2196/65754

KEYWORDS

chronic sorrow; sadness; parent; disability; pediatric; infant; neonatal; children; youth; adolescence; Saudi Arabia

Introduction

Background

In 2017, the Saudi General Authority of Statistics issued a detailed report of people with disabilities who reside in Saudi Arabia, noting that a total of 1,445,723 people with varying degrees of disability (mild, moderate, or severe) reside in the country, of which 52.2% were males and 47.7% were females [1]. This illustrates that people with disabilities represent a substantial portion of the Saudi community and more attention should be directed to them and their families.

Parents of children with disabilities face numerous difficulties in their daily life when caring for their child, along with feelings of worry and stress about their child's long-term survival and

XSL•FO
RenderX

well-being [2]. The difficulties that the parents face may include their ability to deal with day-to-day challenges, transformation of their social interactions with relatives and friends, and modification of their daily activities [2]. Parents of children with disabilities worry about their child's acceptance in society, as well as the opportunities and resources that might not be available to them when caring for their child. As the child grows and their condition persists, parents become concerned about where and with whom their child will live when they are adults [3]. In addition, parents of children with disabilities experience emotions that are overwhelming and do not follow a predictable sequence. Their emotions can include sadness, anger, and frustration and be periodic in nature [4]. Multiple studies have aimed to measure chronic sorrow among parents of children with different health conditions. These include but are not limited to chronic illness and disabilities [4], autism [5,6], cancer [7], sickle cell disease [8], neurodevelopmental disorders [9], type 1 diabetes [10], and Down syndrome [11].

As a result, the concept of chronic sorrow emerged to explore the daily experiences of these parents. Roos [12] defined chronic sorrow as "a set of pervasive, profound, continuing, and recurring grief responses resulting from a significant loss or absence of crucial aspect of oneself (self – loss) or another living person (other – loss) to whom there is a deep attachment. The way in which the loss is perceived determines the existence of chronic sorrow. The essence of chronic sorrow is a painful discrepancy between what is perceived as reality and what continues to be dreamed of. The loss is ongoing since the source of the loss continues to be present. The loss is a living loss."

The Theoretical Framework of Chronic Sorrow

Chronic sorrow was initially proposed by psychiatrist Olshansky [13]. In his work with mentally challenged children, their parents, and family members, Olshansky observed that parents of children with disabilities display a widespread psychological response to the experience of having a child with disabilities [13]. The parents often had long-lasting, chronic sorrow because the loss they experienced lacked a clear end. It was also uncertain how long the loss would persist [14]. Parents who care for children with disabilities have described having profound emotional experiences. These emotions may be felt occasionally but they may not always be present. These intense emotions may include shock, disbelief, rage, irritation, a feeling of isolation, and a profound sense of sadness and loss. As a result, it is hypothesized that parents of children with disabilities are more likely to report experiencing persistent sadness [15].

Eakes et al [16] defined the variables of the theory of chronic sorrow as the following:

- Chronic sorrow: "ongoing disparity resulting from loss characterized by pervasiveness and permanence. Symptoms of grief recur periodically, and these symptoms are potentially progressive."
- Loss: occurs because of the discrepancy between the "ideal" or "imagined" situation versus the lived experience and occurs in the early stages of the child's diagnosis.
- Disparity: disparity follows the loss experience and can be classified as a trigger for chronic sorrow. The loss experience occurs in the early stages of the child's diagnosis, whereas disparity reemerges as time passes, when the child does not meet his or her developmental milestones like his or her peers, such as attending school graduations and birthday parties.
- Management methods: strategies used by parents or individuals to minimize the impact of sorrow. These methods can be internal (personal and individualized methods) or external (support from health care workers or institutions).

Studies that have addressed chronic sorrow among parents of children with disabilities are very scarce, especially in Arabic. The Kendall Chronic Sorrow Instrument was found to be useful in measuring the chronic sorrow of mothers of a child with disabilities [17]. Fernandes et al [18] analyzed the theory of chronic sorrow and found that the theory is well-defined and its concepts captured the phenomena under study. When measuring its concepts, they found that the theory had high reliability.

It is worth noting that parents experiencing chronic sorrow are usually overlooked and remain unexamined by society. Parents of children with disabilities must navigate their emotions of sorrow and an unending sense of commitment while maintaining their level of functionality [19]. The objectives of this study are important because parents of children with disabilities report multiple negative outcomes such as psychological distress, a sense of isolation, a lack of financial support, and the absence of tools to help them manage their child's condition [20].

Lastly, the theory of chronic sorrow can be used by nurses caring for parents of children with disabilities to help the parents identify and use management and coping strategies.

This descriptive study aims to explore chronic sorrow among parents of children with different types of disabilities in the Kingdom of Saudi Arabia. The objective of this study is to answer the following questions: With the use of chronic sorrow as a theoretical framework, what are the parental experiences of chronic sorrow in the context of caring for a child with a disability? Is there a relationship between the concepts of the theory of chronic sorrow, specifically between loss and disparity with chronic sorrow? Lastly, is there a relationship between the time elapsed since the child's diagnosis and parental feelings of chronic sorrow?

Methods

Design

A quantitative, descriptive cross-sectional study design will be used to conduct this study exploring chronic sorrow among parents of children with disabilities. We will also identify the strength of the relationships between the triggers (loss experience and disparity) of chronic sorrow. Lastly, we will investigate the impact of time since the child's diagnosis on parental feelings of chronic sorrow.

Instrument

Data were collected for this study through a web-based questionnaire. The questionnaire and consent form were sent

XSL•FO
RenderX

to the participants after obtaining institutional review board approval from King Abdullah International Medical Center.

The questionnaire was distributed electronically to participants via WhatsApp. The questionnaire consisted of parental demographic data (8 items), loss experience (5 items), disparity (3 items), chronic sorrow (9 items), and management of chronic sorrow (9 items). The chronic sorrow measurement was originally created by Kendall (Kendall Chronic Sorrow Instrument) [21], then the Arabic version of the same instrument was created by Baker et al [22], who confirmed that the internal consistency of the correlation coefficient of the scale was greater than 0.7, with a high degree of validity in the Loach method for all statements, with a score of 0.62. In addition, the Cronbach α was 0.8. All of the above parameters have met the psychometric properties of a valid and reliable instrument [22]. As a result, the Arabic version of the instrument was used for this study due to the proximity of the populations in both studies, both of which speak Arabic and have shared cultural characteristics and religious backgrounds.

For the measurement of chronic sorrow, every item in the scale had a total of 5 responses (5-point Likert scale), ranging from strongly disagree (score of 1 point), disagree (2 points), neutral (3 points), agree (4 points), to strongly agree (5 points). Scoring criteria were as follows: 1 - 2 indicated a low score of chronic sorrow, 2 - 3 indicated a moderately low score, 3 - 4 indicated a moderately high score, and 4 - 5 indicated a high score of chronic sorrow.

Sample, Setting, and Data Collection

Recruitment of study participants was done using nonprobability convenience sampling. The tool targeted parents with a child with disabilities currently residing in Saudi Arabia. The participants who were eligible for this study fulfilled the following criteria: the mother, father, or primary caregiver of a child with a disability, the child had a confirmed medical diagnosis, the parent could speak and read Arabic, and parental age was above 18 years.

For this descriptive study, the significance level of α was set at 0.05 with a power of 0.8 to calculate the sample size and estimate power analysis. The sample size was estimated by G*Power software. This study will be the first to examine the use of chronic sorrow as a theoretical framework among Saudi parents who have a child with a disability. As a result, no previously reported effect size was available for use in the power analysis. Cohen [23] stated that in cases like our study where effect size has not been previously reported in the literature, the estimation of effect size should be based on logic and judgment. Therefore, a medium effect size of 0.30, a power of 0.80, and α significance level of 0.05 were used to guide our statistical analysis, with a sample size of 64.

Potential participants were recruited via invitation through WhatsApp, Facebook, and X (formerly known as Twitter). Upon filling out the questionnaire, the researcher identified parents who met the inclusion criteria and enrolled them in the study. If the participant agreed to fill out the questionnaire after reading the consent form, they were directed to the questionnaire page. Consent was obtained from participants electronically; if the participant agreed to fill in the questionnaire, he or she was directed to an electronic informed consent form. After reading the consent form, the participant was required to sign the form electronically by clicking the “I agree to participate” box, after which the questionnaire would appear.

We used Microsoft Forms for its easy accessibility and user-friendliness for the general population to promote data collection and reduce missing data.

Data Analysis

Once data collection was complete, we entered the data into an Excel database for analysis. SPSS (version 30; IBM Corp) was used to analyze the data on a password-protected computer. Different types of analysis were proposed for this study. Descriptive statistics were calculated on all variables of interest, including means, standard deviations, frequencies, and percentages. Pearson correlation coefficients were used to examine the relationships among continuous variables. Statistical significance was based on the standard α level of .05.

Frequencies and percentages were used for analyzing descriptive data to evaluate the variables of chronic sorrow. Pearson correlations were used to analyze numerical data and assess the relationship between the triggers and the concept of chronic sorrow.

Ethical Considerations

This study received ethics approval from the institutional review board of the King Abdullah International Medical Research Center (SP23J/144/09) on October 16, 2023, and the data collection lasted for 6 months.

Various measures were undertaken to maintain the privacy and confidentiality of participants. Although there was minimal risk involved, all measures to protect participants’ information were taken. Participants’ responses to each survey item were not shared with other participants or individuals not associated with the research project. By accessing and completing the survey, participants gave their consent to take part in the study. Participation in the study was voluntary. Participants could withdraw from the study at any time. No compensation was provided to the participants.

Results

Participant Characteristics

As Table 1 shows, a total of 89 participants completed the survey. Of these participants, 78% (n=69) were mothers of a child with disabilities. Most of the participants (n=42, 48%) were aged 40-49 years. Many of the participants were caring for a child with a permanent disability (n=79, 89%) and most participants had a university level of education (n=54, 61%). Most of the children had been diagnosed for less than 1 year (n=45, 51%) and Down syndrome was the most reported disability (n=39, 44%).

XSL•FO
RenderX

Table . The sample demographic characteristics (N=89).

Demographic variable	Participants, n (%)
People completing the survey	
Mother	69 (78)
Father	5 (6)
Nonparent	15 (17)
Age group (years)[a]	
20 - 29	5 (6)
30 - 39	20 (23)
40 - 49	42 (48)
50 - 59	16 (18)
60 - 65	4 (5)
Permanence of the child's disability	
Temporary disability	10 (11)
Permanent disability	79 (89)
Educational level	
Primary school	4 (4)
Intermediate school	5 (6)
High school	26 (29)
University	54 (61)
Time since the child was diagnosed with a disability (years)	
Less than 1	45 (51)
2 - 3	11 (12)
4 - 9	25 (28)
More than 10	8 (9)
Nature of the child's disability	
Down syndrome	39 (44)
Autism and attention-deficit/hyperactivity disorder	15 (17)
Mental retardation	8 (9)
Physical disability	21 (24)
Undisclosed disability	6 (7)

[a]There were 87 responses for this question (ie, 2 participants did not respond).

Descriptive Statistics of the Theory of Chronic Sorrow

The data in the following 5 sections illustrate the descriptive statistics of the participants toward the concepts of the theory of chronic sorrow, which is used to measure the following aspects: the triggers of loss experience and disparity, chronic sorrow, internal management, and external management.

Descriptive Statistics for Loss Experience

As shown in Table 2, the reported score of the loss experience that parents of children with disabilities face was a mean of 3.3 (SD 1.10). Of all the variables measuring loss experience, feeling sad when thinking about the child's disability was the highest (mean 3.9, SD 1.24) and a sense of overwhelming sorrow scored the lowest (mean 2.8, SD 1.40). The results showed that parents with children with disabilities reported moderately high loss experience.

XSL•FO
RenderX

Table . Descriptive statistics of loss experience (N=89).

Loss experience	Score, mean (SD)
It feels like the disability happened to me	3.5 (1.18)
Sorrow feelings when I think about my child's disability	3.9 (1.24)
The sorrow feeling remains the same as the day of the diagnosis	3.3 (1.43)
Urge to cry when I remember the disability	3.3 (1.42)
Overwhelming sorrow	2.8 (1.40)
Total score of loss experience	3.3 (1.10)

Descriptive Statistics for Disparity

As shown in Table 3, the total score of the concept of disparity reported by parents of children with disabilities had a mean of 3.3 (SD 1.06). The highest score among the disparity variables was the feeling of sorrow and sadness parents face when their child cannot meet developmental milestones, often associated with significant events or dates including birthdays, with a mean score of 3.8 (SD 1.30). On the other hand, the lowest score reported was the feeling of sorrow when thinking about their child without the disability (mean 2.7, SD 1.28). According to this study, the feeling of disparity experienced by parents of children with disabilities is moderately high, which is aligned with the experiences of loss.

Table . Descriptive statistics of disparity (N=89).

Disparity	Score, mean (SD)
Sorrow emerges when I remember my child's disability	3.3 (1.29)
I feel sorrow about things that do not matter for parents with healthy children (such as birthdays and entering school)	3.8 (1.30)
I feel sorrow when I picture my life without my child's disability	2.7 (1.28)
Total score of disparity	3.3 (1.06)

Descriptive Statistics for Chronic Sorrow

As shown in Table 4, the total score of the chronic sorrow reported by parents of children with disabilities had a mean of 3 (SD 0.87). Of the variables measuring chronic sorrow, the variable of sorrow and its nature of coming and going (ie, its periodic nature) had the highest score (mean 3.6, SD 1.16), along with reported energy to handle sorrow (mean 3.6, SD 1.11). On the other hand, the least reported variable within the chronic sorrow concept was parents reporting that their life is not what they imagined due to their child's disability (mean 2.6, SD 1.33), followed by feeling that parental desires and goals do not match what life has given them (mean 2.7, SD 1.32). Overall, parents reported moderately high levels of chronic sorrow, indicating that these feelings of sorrow are manageable and can be reduced or that its cyclic nature can be spaced out.

Table . Descriptive statistics of chronic sorrow (N=89).

Chronic sorrow	Score, mean (SD)
Sorrow regarding my child's disability comes and goes	3.6 (1.16)
I feel like my child's disability makes me give up some aspects of my life	3.4 (1.40)
I feel like I do not have control over my life	2.9 (1.36)
I feel like my life is not like I imagined due to my child's disability	2.6 (1.33)
The feelings of sorrow can transform into feelings of loneliness	2.8 (1.38)
I feel like I have energy to handle life's stressors	3.6 (1.11)
Sudden changes in my child's disability have led to exhaustion	3.0 (1.26)
I think that what I desired does not align with what life has given me	2.7 (1.32)
I feel older due to my child's disability	2.9 (1.34)
Total score of chronic sorrow	3.0 (0.87)

XSL•FO
RenderX

Descriptive Statistics of Internal Management of Chronic Sorrow

Table 5 presents the descriptive statistics of how parents of children with disabilities view the effectiveness of internally managing their child's disability as a means to overcome chronic sorrow. The total score of internal management had a mean of 4.6 (SD 0.33), which is a high score, highlighting the important role of internal management of chronic sorrow. Of all the variables measuring the internal management of chronic sorrow, accepting the child's disability as destined by God (also known in the Islamic religion as fatalism) demonstrated the highest score with a mean of 4.8 (SD 0.50), followed by the availability of resources that parents need to manage their child's disability (mean 4.7, SD 0.47). These were followed by feeling better when parents are more aware and can make independent decisions about the child's disability (mean 4.4, SD 0.62). The results of this study showed that internal management of a child's disability is crucial for reducing chronic sorrow and empowering the parents of children with disabilities to minimize their episodes of chronic sorrow, allowing them to provide the best care for their child.

Table . Descriptive statistics of internal management of chronic sorrow by parents of children with disabilities.

Internal management of chronic sorrow	Score, mean (SD)
I feel better when I am more aware of my child's disability	4.4 (0.62)
Making independent decisions about my child's disability is empowering for me	4.4 (0.62)
Accepting my child's disability as destined by God makes me feel better	4.8 (0.50)
The availability of resources (eg, financial and therapeutic) for my child induces a sense of relief	4.7 (0.47)
Total score of internal management	4.6 (0.33)

Descriptive Statistics of External Management of Chronic Sorrow

Table 6 shows results related to parents' external management of chronic sorrow, with the overall utilization of external management displaying great importance (mean 4.5, SD 0.42). Of all the variables measuring external management of chronic sorrow, feeling better when social support is provided displayed the highest score (mean 4.7, SD 0.55), followed by feeling better when the community is kinder and more considerate (mean 4.5, SD 0.56). The results of this study showed that both external and internal management of chronic sorrow are important tools that parents need to use and navigate to manage the periodic and unpredictable nature of chronic sorrow.

Table . External management of chronic sorrow by parents of children with disabilities.

External management of chronic sorrow	Score, mean (SD)
I feel better when doctors and nurses provide more information about my child's condition	4.4 (0.64)
I feel better when support is provided by family and the community	4.7 (0.55)
I feel better when I am allowed to express my emotions freely and without judgment	4.3 (0.71)
I feel better when I believe that we as a family have created a coping strategy that is specific to us	4.4 (0.62)
I feel better when more people in the community are considerate and kind to me and my child	4.5 (0.56)
Total score of external management of chronic sorrow	4.5 (0.42)

Association Between Chronic Sorrow and Parental Loss Experience and Disparity

Table 7 shows the Pearson correlation between chronic sorrow and the sense of loss experience and disparity. The study results showed a strong correlation between chronic sorrow and the concepts of disparity and loss.

As shown in Table 7, chronic sorrow is strongly and positively correlated with loss experience (r=0.765; P<.001). In addition, the same strong correlation emerged between chronic sorrow and disparity (r=0.765; P<.001). Lastly, another positive and strong correlation emerged between the concept of loss experience and disparity (r=0.791; P<.001).

XSL•FO
RenderX

Table . Pearson correlation between chronic sorrow and loss experience and disparity.

Variable	Chronic sorrow	Loss experience	Disparity
Chronic sorrow			
r	1	0.765	0.765
P value	—[a]	<.001	<.001
Loss experience			
r	0.765	1	0.791
P value	<.001	—	<.001
Disparity			
r	.765	0.791	1
P value	<.001	<.001	—

[a]Not applicable.

Association Between Chronic Sorrow and Time Since Diagnosis of the Child's Disability

Table 8 illustrates the results of the Pearson correlation between chronic sorrow and the amount of time elapsed since parents received their child's diagnosis. The correlation was negative and very weak (r=–0.009; P<.93), indicating that, as time passes, the feelings of chronic sorrow among parents do not subside. This study showed an inverse yet very weak relationship between time since diagnosis and the chronic sorrow score, indicating that time passing does not play a role or have an impact on the recurrent nature of chronic sorrow. It is also worth mentioning that an increase in chronic sorrow as time passes was not indicated. Therefore, health care workers need to assess parents for chronic sorrow whether the diagnosis was received recently or a long time ago, highlighting the importance of multiple interventions to manage and coexist with chronic sorrow.

Table . Pearson correlation between the concept of chronic sorrow and time since diagnosis.

Variable	Chronic sorrow	Time since child's diagnosis
Chronic sorrow		
r	1	–0.009
P value	—[a]	.94
Time since child's diagnosis		
r	–0.009	1
P value	.94	—

[a]Not applicable.

Discussion

Principal Findings

Literature examining chronic sorrow among parents with a child with a disability was scarce in the international and Saudi literature alike. Therefore, this study was designed to examine the application of the theory of chronic sorrow by Olshansky [13] to Saudi parents with a child with a disability. The study examined the major variables in the theory including loss experience, disparity, chronic sorrow, and internal and external management. In addition, we attempted to examine the relationships between these variables and whether time since diagnosis decreased the sense of chronic sorrow. The results of the study showed that parents reported a moderately high level of loss experience, disparity, and chronic sorrow. On the other hand, management methods (internal or external) played a crucial role for these parents in adapting to and managing their child's disability. In addition, the reported concepts of loss experience and disparity had a moderately strong relationship with the feelings of chronic sorrow that the parents were experiencing. Lastly, time elapsed since the child's diagnosis did not have an inverse relationship with the feeling of chronic sorrow, indicting that time passing does not play a role in the feeling of chronic sorrow.

Parents of children with disabilities have experienced loss, which is different for every parent; in addition, different parents have different abilities to navigate emotions. Loss experience can be interpreted as the loss of the ideal child [24]. This study found a moderately high level of loss experience and that its consequences can trigger the feeling of chronic sorrow. Loss experience among parents of children with disabilities has been reported in previous studies, reflecting the results of our study despite cultural and religious differences between the study populations. A study by Phillips [25] examined loss among parents of children with disabilities, viewing loss as a consequence that they are not familiar with, and its ability to impact the family's well-being. Studies by Fernandez et al [18] and Fernández-Alcántara et al [24] examined loss and grief (eg,

XSL•FO
RenderX

related to loss of the ideal child, a traumatic experience, and shock) in the same population, and the concept of the theory of chronic sorrow emerged there as well. Loss experience among parents is a crucial step that parents undergo to explore their chronic sorrow, eventually leading to acceptance and hope for their child's future.

Disparity is one of the major concepts of the theory of chronic sorrow. It follows the feelings of loss experience and is triggered by certain developmental milestones that parents of children with disabilities observe in healthy children [8]. Multiple studies have illustrated the presence of disparity within parents; those results were congruent with the results of this study. A study by Nikfarid et al [26] examined chronic sorrow in parents of children who were diagnosed with cancer, while a study by Olwit et al [8] investigated chronic sorrow in parents with children diagnosed with sickle cell disease. In both of these studies, parents mentioned the presence of disparity and its role in triggering chronic sorrow, contributing to its ongoing nature. Lastly, a study by Masterson [27] explored parental chronic sorrow and disparity when a child with cerebral palsy becomes an adult. The study showed that mothers still experienced disparity, which triggered a loss of hope as the child aged without meeting milestones.

Chronic sorrow among parents with a child with a disability is different from the normal grieving process or sadness because it is characterized by its cyclic nature, and it can be triggered by feeling of loss and disparity [13]. Results from studies examining chronic sorrow among parents with children with disabilities have been similar to and consistent with the results of this study. The theory of chronic sorrow explains the realistic feelings and emotions encountered by these parents and that these feelings do not manifest the same way as grief or a single loss because they can appear after parental acceptance of the disability [26-29]. Studies by Olwit et al [8] and Hobdell [30] found that chronic sorrow among parents needs to be assessed by health care workers as it has the potential to affect parental health and parental management of their child's disability. In parents, chronic sorrow may present as reduced social interaction, psychological distress, anger, and even guilt [20,31,32].

Internal management of chronic sorrow that is effective and used by parents plays a crucial role in minimizing the recurrence of chronic sorrow episodes, particularly if it is used correctly [18]. This study illustrates that fatalism (accepting God's destiny regarding the child's disability) represents the most effective internal management strategy for chronic sorrow. Multiple studies have displayed similar results in spite of different religious or spiritual beliefs among the study participants. Studies by Mikołajczuk and Zielińska-Król [33] and Pillay et al [34] reported that parents of children with disabilities found that religion and accepting God's destiny were effective coping mechanisms that improved parental resiliency, acceptance, and management of daily challenges. The participants of this study were predominantly from the Islamic religion, and the concept of fatalism as a means to internally manage chronic sorrow was most reported in this population. Fatalism in the Islamic religion is the belief that the future of man is already determined by God and cannot be swayed or changed whether the destiny is good or bad, and man should accept god's destiny and surrender to his will. Khan et al [35] and Othman et al [36] studied Muslim parents of children with disabilities and their results—in which parents found comfort, hope, and resiliency when integrating religion and spirituality when caring for their children—are congruent with this study.

Its important to note that this study is the first to use the theory of chronic sorrow among Saudi parents of children with disabilities, and it is crucial to incorporate religion and the concept of fatalism into this framework to fully capture the phenomena of chronic sorrow as the role of religion in navigating emotions is important in this population. The role of religion and belief in this context was previously reported in the literature by Alqunaibet [37] and Çaksen [38], who illustrated that religion and spirituality play an important role in helping parents and caregivers manage sorrow and stress.

Our questions regarding the external management of chronic sorrow aimed to capture the most efficient method used by parents. The results of the study identified social support (from family and the community in particular) to be key to externally managing chronic sorrow. The results of the study correspond with those of Ha et al [39] and Felizardo et al [40], who investigated the role of social support from family and the community, which yielded similar results to this study. Mantri‐Langeveldt et al [41] conducted a scoping review to illustrate the important role of family support for parents with children with disabilities, reaffirming the importance of social support measurement by health care professionals.

This study identified a strong positive relationship between chronic sorrow and loss. The loss expressed by parents of children with disabilities is known as ambiguous loss as it is not definitive and not clearly visible as the child is alive, though not experiencing normal development. In addition, the loss associated with chronic sorrow in this population does not provide closure; the loss of the ideal child cannot be mourned because that child never existed [42]. Brown [43] conducted a study to capture the importance of sorrow and grieving in the healing process for mothers of children with intellectual disabilities. The results are similar to this study, as mothers experienced loss specifically after diagnosis and felt loss for their child and for their role as mothers. Senenac et al [44] described the parental experience of having a child with disabilities and the results identified that the themes of sorrow and loss are associated, along with other emerging concepts such as stigma and guilt.

This study identified a strong and positive relationship between chronic sorrow and disparity. Disparity, unlike loss, reemerges as time passes and the parents tangibly observe the inability of their child to meet developmental milestones like their peers, which triggers feelings of chronic sorrow [17]. Claassens et al [4] examined parental chronic sorrow among parents with children with disabilities. The results of the review yielded multiple findings, one of which was the strong relationship between chronic sorrow and disparity. The review identified events that parents undergo that trigger the resurgence of chronic sorrow and their role in reminding parents about the disparity and gap between the "idealized and hoped-for child" and "the

XSL•FO
RenderX

ill or disabled child" [4]. Multiple studies have found that the same phenomenon is seen with disparity and its role in triggering chronic sorrow in parents caring for children with different types of disabilities or diseases that require caregiving, such as autism spectrum disorder [45], sickle cell disease [8], and cerebral palsy [46].

This study examined the relationship between time elapsed since the child received their diagnosis and chronic sorrow among parents. The results of this study have shown that there is no relationship between time passing and chronic sorrow, indicating that time does not play a role in reducing or increasing feelings of chronic sorrow. The results of this study correspond with the literature. A study by Fernandez et al [18] found that loss and sorrow persist over time and therefore emotional interventions are crucial for the parents of children with disabilities. Fernández‐Ávalos et al [47] rationalized this phenomenon by explaining that parents are faced with daily challenges and worries when caring for their child. As a result, these challenges influence their perception of managing chronic sorrow and their quality of life. Therefore, delivering early interventions and realistic expectations of the child's development and disease prognosis are crucial, along with providing emotional care for parents. These interventions will play a role in managing chronic sorrow over time and eventually lead to acceptance, resilience, and enhanced mental health [48-50].

Limitations

This study collected data from parents primarily residing in Jeddah, Saudi Arabia. Therefore, the results of the study might not be generalizable to other countries or cultures. Another limitation was the type of disability that the children were diagnosed with, as much of the data were collected from parents with children with Down syndrome (44%), which limits generalizability to other types of disabilities that can be more severe or require less caregiving.

This study used nonprobability convenience sampling to recruit the parents of children with disabilities. This type of sampling has the potential to limit generalizability and therefore lacks external validity. It is worth noting that the study was conducted in Jeddah City, Saudi Arabia, and the majority of the participants reside in the western region of the country; we did not examine chronic sorrow in more rural areas of Saudi Arabia or other Middle Eastern countries that share multiple cultural aspects, which limits the generalizability of the study findings.

Another limitation was the study's cross-sectional design. Cross-sectional study designs create ambiguity about the direction of the causal relationship between study variables. Lastly, to overcome time and financial constraints that the researchers were faced with, data were self-reported via a web-based questionnaire. Therefore, the conditions in which parents filled out the survey were not controlled nor objectively measured.

Conclusion and Recommendation

The aim of this study was to examine the experience of parents of children with disabilities with chronic sorrow in Saudi Arabia using the theory of chronic sorrow. We found moderately high levels of loss experience, disparity, and feelings of chronic sorrow among study participants. Therefore, the results of this study highlight the importance of chronic sorrow management and the creation of interventions to enhance parental mental health and well-being. In addition, internal management of chronic sorrow played a crucial role. In particular, we demonstrated the importance of the concept of fatalism and religious and spiritual beliefs among Arab Muslim parents of children with disabilities. With regard to external management, parents reported that family and community support were pivotal for the management of chronic sorrow, highlighting the social responsibility of all members of the community to provide support to both parents and children. This study also identified a strong and positive relationship between the concepts of the theory of chronic sorrow, specifically between the identified triggers of loss and disparity and chronic sorrow. Lastly, the study results found no relationship between feelings of chronic sorrow and time elapsed since the parents received their child's diagnosis. Given the results of this study, parents of children with disabilities need to be periodically screened for chronic sorrow as these feelings and coping strategies need to be addressed. Parental acceptance of their child's disability does not signify the absence of chronic sorrow, as it is part of the normal grieving process, but rather the anticipation of the triggers of chronic sorrow. The use of management methods, both internal and external, is essential for promoting parental mental health and child health outcomes.

This study has the potential to provide the foundation for future studies navigating and investigating chronic sorrow among parents with a children with a disability. Future studies could include an investigation of chronic sorrow based on the severity of the disability among parents caring for adult children with a disability and could be expanded to extended family members and caregivers.

Conflicts of Interest

None declared.

References

1. Disability survey. Saudi General Authority of Statistics. 2017. URL: https://www.stats.gov.sa/search?q= [accessed 2023-02-15]
2. Kearney PM, Griffin T. Between joy and sorrow: being a parent of a child with developmental disability. J Adv Nurs 2001 Jun;34(5):582-592. [doi: 10.1046/j.1365-2648.2001.01787.x] [Medline: 11380726]

XSL•FO
RenderX

3. Batchelor LL, Duke G. Chronic sorrow in parents with chronically ill children. Pediatr Nurs 2019 Jul 1;45(4):163-173,183 [FREE Full text]
4. Claassens H, Delespaul P, Feringa D. Chronic sorrow: lived experiences of family caregivers of people with severe mental illness. Illness, Crisis & Loss 2025 Apr;33(2):474-489. [doi: 10.1177/10541373241256247]
5. Oropeza NR. Chronic sorrow in parents and caretakers of children and adult children with autism [Dissertation]. : Palo Alto University URL: https://www.proquest.com/openview/457afed516002cfe43320b9311473020/1?pq-origsite=gscholar&cbl=18750&diss=y [accessed 2025-06-19]
6. Bravo-Benítez J, Pérez-Marfil MN, Román-Alegre B, Cruz-Quintana F. Grief experiences in family caregivers of children with autism spectrum disorder (ASD). Int J Environ Res Public Health 2019 Nov 30;16(23):4821. [doi: 10.3390/ijerph16234821] [Medline: 31801231]
7. Heydari F, Nikfarid L, Oujian P, Nasiri M, Motefakker S. Predictors of perceived family sense of coherence in parents of children with cancer. Indian J Palliat Care 2022;28(1):28-36. [doi: 10.25259/IJPC_107_21] [Medline: 35673383]
8. Olwit C, Mugaba M, Osingada CP, Nabirye RC. Existence, triggers, and coping with chronic sorrow: a qualitative study of caretakers of children with sickle cell disease in a National Referral Hospital in Kampala, Uganda. BMC Psychol 2018 Oct 20;6(1):50. [doi: 10.1186/s40359-018-0263-y] [Medline: 30342559]
9. Brennan E, Clarke M, Guerin S. Healthcare professionals' discussion of loss and grief with parents of children with life-limiting severe neurological impairment: findings from a scoping review. Pall Supp Care 2025;23. [doi: 10.1017/S1478951524001743]
10. Lowes L, Lyne P. Chronic sorrow in parents of children with newly diagnosed diabetes: a review of the literature and discussion of the implications for nursing practice. J Adv Nurs 2000 Jul;32(1):41-48. [doi: 10.1046/j.1365-2648.2000.01418.x] [Medline: 10886433]
11. Damrosch SP, Perry LA. Self-reported adjustment, chronic sorrow, and coping of parents of children with Down syndrome. Nurs Res 1989;38(1):25-30. [Medline: 2521384]
12. Roos S. Chronic Sorrow: A Living Loss: Routledge; 2014. [doi: 10.4324/9781315800578]
13. Olshansky S. Chronic sorrow: a response to having a mentally defective child. Soc Casework 1962 Apr;43(4):190-193. [doi: 10.1177/104438946204300404]
14. Wikler L, Wasow M, Hatfield E. Chronic sorrow revisited: parent vs. professional depiction of the adjustment of parents of mentally retarded children. Am J Orthopsychiatry 1981 Jan;51(1):63-70. [doi: 10.1111/j.1939-0025.1981.tb01348.x] [Medline: 7212030]
15. Fernández-Ávalos MI, Pérez-Marfil MN, Ferrer-Cascales R, Cruz-Quintana F, Fernández-Alcántara M. Feeling of grief and loss in parental caregivers of adults diagnosed with intellectual disability. J Appl Res Intellect Disabil 2021 May;34(3):712-723. [doi: 10.1111/jar.12842] [Medline: 33244855]
16. Eakes GG, Burke ML, Hainsworth MA. Middle‐range theory of chronic sorrow. Image – The Journal of Nursing Scholarship 1998 Jun;30(2):179-184. [doi: 10.1111/j.1547-5069.1998.tb01276.x]
17. Bordonada TM. Examining chronic sorrow among parents of a child with autism spectrum disorder (ASD) [Dissertion]. : University of South Carolina URL: https://www.proquest.com/openview/a00f5e17cc4f9bd97c445ad40e575ab5/1?pq-origsite=gscholar&cbl=18750 [accessed 2025-06-19]
18. Fernandes MA, Nóbrega MML, Zaccara AAL, Freire MEM, Andrade FF, Costa SFG. Fawcett analysis and evaluation model applied to the theory of chronic sorrow. Texto contexto - enferm 2021;30. [doi: 10.1590/1980-265x-tce-2020-0010]
19. Raap E, Weille KL, Dedding C. 'It is up to me because I gave him this life' How the awareness of being permanently and unconditionally responsible shapes the experience of chronic sorrow in parents of disabled children. Psychol Health 2024 Aug 11:1-21. [doi: 10.1080/08870446.2024.2378736] [Medline: 39129195]
20. Buthelezi S, Mawila D. There is always sorrow: risk factors faced by parents of children presenting with severe intellectual disabilities. J Intellect Disabl Diagn Treat 2024 May 17;12(1):12-21. [doi: 10.6000/2292-2598.2024.12.01.2]
21. Kendall LC. The experience of living with ongoing loss: testing the Kendall Chronic Sorrow Instrument [Dissertation]. : Virginia Commonwealth University; 2005 URL: https://www.proquest.com/openview/6fb78c89c33e149371c5f15d5e43f27a/1?pq-origsite=gscholar&cbl=18750&diss=y
22. Baker HI, Shanad S, Albdulhazfiz LA. The scale of chronic sorrow among mothers with mentally disabled children (Arabic adaptation). Sci J Fac Educ New Valley Univ 2021;13:36-48. [doi: 10.21608/sjsw.2021.233080]
23. Cohen J. Statistical Power Analysis for the Behavioral Sciences: Academic Press; 2013. [doi: 10.4324/9780203771587]
24. Fernández-Alcántara M, García-Caro MP, Laynez-Rubio C, et al. Feelings of loss in parents of children with infantile cerebral palsy. Disabil Health J 2015 Jan;8(1):93-101. [doi: 10.1016/j.dhjo.2014.06.003] [Medline: 25096631]
25. Phillips BE. Experience of parents caring for a child with an acquired disability [Dissertation]. : West Virginia University; 2022. [doi: 10.33915/etd.11307]
26. Nikfarid L, Rassouli M, Borimnejad L, Alavimajd H. Chronic sorrow in mothers of children with cancer. J Pediatr Oncol Nurs 2015;32(5):314-319. [doi: 10.1177/1043454214563407] [Medline: 25576316]
27. Masterson MK. Chronic sorrow in mothers of adult children with cerebral palsy: an exploratory study [Dissertation]. : Kansas State University; 2010 URL: http://krex.k-state.edu/dspace/bitstream/handle/2097/3906/MarilynMasterson2010.pdf? sequence=1 [accessed 2025-06-20]

XSL•FO
RenderX

28. Whittingham K, Wee D, Sanders MR, Boyd R. Sorrow, coping and resiliency: parents of children with cerebral palsy share their experiences. Disabil Rehabil 2013 Aug;35(17):1447-1452. [doi: 10.3109/09638288.2012.737081] [Medline: 23167453]
29. Jenkins KS. Parents of children with disabilities: chronic sorrow and parenting stress [Dissertion]. : University of Southampton; 2005 URL: http://eprints.soton.ac.uk/id/eprint/467117 [accessed 2025-06-20]
30. Hobdell E. Chronic sorrow and depression in parents of children with neural tube defects. J Neurosci Nurs 2004 Apr;36(2):82-88. [doi: 10.1097/01376517-200404000-00005] [Medline: 15115362]
31. Disasa B. Families of children with disabilities: challenges and coping strategies in some selected towns of Arsi zone. Journal of Disability & Religion 2023 Jul 3;27(3):383-399. [doi: 10.1080/23312521.2022.2078759]
32. Bowes S, Lowes L, Warner J, Gregory JW. Chronic sorrow in parents of children with type 1 diabetes. J Adv Nurs 2009 May;65(5):992-1000. [doi: 10.1111/j.1365-2648.2009.04963.x] [Medline: 19399973]
33. Mikołajczuk K, Zielińska-Król K. The role of religion in the family life of people with disabilities: a legal and social study. Religions (Basel) 2023 Oct 31;14(11):1371. [doi: 10.3390/rel14111371]
34. Pillay D, Girdler S, Collins M, Leonard H. 'It's not what you were expecting, but it's still a beautiful journey': the experience of mothers of children with Down syndrome. Disabil Rehabil 2012;34(18):1501-1510. [doi: 10.3109/09638288.2011.650313] [Medline: 22324752]
35. Khan BA, Zargar WA, Najar SA. Exploring support system for parents of children with disability: role of religion. Insight Islamicus 2016;16 [FREE Full text]
36. Othman EH, Ong LZ, Omar IA, Bekhet AK, Najeeb J. Experiences of Muslim mothers of children with disabilities: a qualitative study. Journal of Disability & Religion 2022 Jan 2;26(1):1-25. [doi: 10.1080/23312521.2021.1911734]
37. Alqunaibet T. Ethnographic study of the religious coping forms of mothers' experiences of bringing up a child with ASD in Saudi Arabia [Dissertation]. : UCL (University College London); 2021 URL: https://discovery.ucl.ac.uk/id/eprint/10127280 [accessed 2025-06-20]
38. Çaksen H. Religious coping in parents of children with Down syndrome: a systematic review of the literature. J Relig Health 2025 Feb;64(1):462-518. [doi: 10.1007/s10943-024-02207-0] [Medline: 39847214]
39. Ha JH, Greenberg JS, Seltzer MM. Parenting a child with a disability: the role of social support for African American parents. Fam Soc 2011;92(4):405-411. [doi: 10.1606/1044-3894.4150] [Medline: 22661878]
40. Felizardo S, Ribeiro E, Amante MJ. Parental adjustment to disability, stress indicators and the influence of social support. Procedia - Social and Behavioral Sciences 2016 Feb;217:830-837. [doi: 10.1016/j.sbspro.2016.02.157]
41. Mantri-Langeveldt A, Dada S, Boshoff K. Measures for social support in raising a child with a disability: a scoping review. Child Care Health Dev 2019 Mar;45(2):159-174. [doi: 10.1111/cch.12646] [Medline: 30690765]
42. Boss P, Roos S, Harris DL. Grief in the midst of ambiguity and uncertainty: an exploration of ambiguous loss and chronic sorrow. In: Grief and Bereavement in Contemporary Society 2021 Sep 8: Routledge:163-175. [doi: 10.4324/9781003199762-16]
43. Brown JM. Recurrent grief in mothering a child with an intellectual disability to adulthood: grieving is the healing. Child Fam Soc Work 2016 Feb;21(1):113-122. [doi: 10.1111/cfs.12116]
44. Sentenac M, Rapp M, Ehlinger V, Colver A, Thyen U, Arnaud C. Disparity of child/parent‐reported quality of life in cerebral palsy persists into adolescence. Develop Med Child Neuro 2021 Jan;63(1):68-74. [doi: 10.1111/dmcn.14638]
45. Wayment HA, Brookshire KA. Mothers' reactions to their child's ASD diagnosis: predictors that discriminate grief from distress. J Autism Dev Disord 2018 Apr;48(4):1147-1158. [doi: 10.1007/s10803-017-3266-2] [Medline: 28856474]
46. Krstić T, Mihić L, Mihić I. Stress and resolution in mothers of children with cerebral palsy. Res Dev Disabil 2015 Dec;47:135-143. [doi: 10.1016/j.ridd.2015.09.009] [Medline: 26421350]
47. Fernández-Ávalos MI, Pérez-Marfil MN, Ferrer-Cascales R, Cruz-Quintana F, Clement-Carbonell V, Fernández-Alcántara M. Quality of life and concerns in parent caregivers of adult children diagnosed with intellectual disability: a qualitative study. Int J Environ Res Public Health 2020 Nov 23;17(22):8690. [doi: 10.3390/ijerph17228690] [Medline: 33238511]
48. Da Paz NS, Siegel B, Coccia MA, Epel ES. Acceptance or despair? Maternal adjustment to having a child diagnosed with autism. J Autism Dev Disord 2018 Jun;48(6):1971-1981. [doi: 10.1007/s10803-017-3450-4] [Medline: 29307036]
49. Sheehan P, Guerin S. Exploring the range of emotional response experienced when parenting a child with an intellectual disability: the role of dual process. Brit J Learn Disabil 2018 Jun;46(2):109-117. [doi: 10.1111/bld.12221]
50. Kandel I, Merrick J. The child with a disability: parental acceptance, management and coping. ScientificWorldJournal 2007 Nov 12;7(1):1799-1809. [doi: 10.1100/tsw.2007.265] [Medline: 18040541]

Abbreviations

CS: chronic sorrow

XSL•FO
RenderX

Edited by S Badawy; submitted 25.08.24; peer-reviewed by A Garoot, D Poddighe, J Fallatah; revised version received 16.05.25; accepted 20.05.25; published 02.07.25.

Please cite as:
Al Anazi S, Alhujaili N, Sinqali D, Al Heej F, Al Somali L, Khayat S, Ramboo T
Examination of Chronic Sorrow Among Parents of Children With Disabilities: Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e65754
URL: https://pediatrics.jmir.org/2025/1/e65754
doi:10.2196/65754

© Samaa Al Anazi, Naseem Alhujaili, Dina Sinqali, Ftoon Al Heej, Lojain Al Somali, Samaher Khayat, Talah Ramboo. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 2.7.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Practicality of the My Baby Now App for Fathers by Fathers: Qualitative Case Study

Mathew Gaynor[1], MPP; Kylie Hesketh[1,2], PhD; Kidane Gebremariam[1], PhD; Karen Wynter[3,4], PhD; Rachel Laws[1,2], PhD

[1]Institute for Physical Activity and Nutrition, School of Exercise and Nutrition Science, Deakin University, Geelong, Australia

[2]Centre of Research Excellence in the Early Prevention of Obesity in Childhood, National Health and Medical Research Council, Melbourne, Australia

[3]Centre for Women's and Children's Mental Health, Department of Psychiatry, Monash University, Melbourne, Australia

[4]School of Nursing and Midwifery, Deakin University, Melbourne, Australia

Corresponding Author:
Mathew Gaynor, MPP
Institute for Physical Activity and Nutrition, School of Exercise and Nutrition Science
Deakin University
75 Pigdons Road
Geelong, 3216
Australia
Phone: 61 3 9244 6613
Email: mgaynor@deakin.edu.au

Abstract

Background: Evolving societal trends are resulting in fathers having an increasing influence on the health-related behaviors that children develop. Research shows that most fathers are committed to their role and when equipped with knowledge, can have a positive impact on their child's health. However, parenting resources typically target mothers, with fathers being excluded. While evolving mobile phone technology provides an efficient means for delivering parenting resources, many fathers find that mobile health (mHealth) technology does not provide material they can engage with.

Objective: This study aimed to explore how to make parenting apps more engaging and useful for fathers using an existing parenting mHealth resource, the My Baby Now app, as a case study.

Methods: A total of 14 purposefully selected, Australian fathers of 7 months to 5-year-old children took part in a qualitative study, comprising either focus groups or interviews. Recorded focus groups and interviews were transcribed verbatim, then coded using a combination of deductive and inductive methods. Reflexive thematic analysis was undertaken to identify patterns and themes.

Results: Current parenting apps provide parenting information that can be unappealing for fathers. To improve paternal engagement with mHealth resources, fathers highlighted the need for father specific information, with an increase in positive imagery and positive descriptions of fathers in their parenting role. There should be father-exclusive domains such as forums, and also push notifications to provide positive reinforcement and encouragement for fathers.

Conclusions: mHealth has the capacity to deliver information to fathers when needed. This reduces the risk of paternal frustration and disengagement from parenting. Further benefit will be gained by research to understand possible differences in mHealth app usage by fathers of differing socioeconomic position, cultural backgrounds, and family status, such as single fathers and same-sex couples.

(JMIR Pediatr Parent 2025;8:e64171) doi:10.2196/64171

KEYWORDS

fathers; parenting resources; health promotion; My Baby Now; MBN; app; mobile phone

Introduction

Parents have a central role in shaping children's long-term health behavior by the behaviors they promote and role model [1-5]. Changing societal trends of increasing rates of maternal participation in the workforce have resulted in child rearing activities in the home environment becoming increasingly shared with fathers [6,7]. Fathers are, thereby having an increasing

XSL•FO
RenderX

influence on the health-related behaviors that children develop [8]. Emerging research shows that when fathers are equipped with skills and knowledge, they can have a positive influence on the dietary and physical activity behaviors of their children [9,10]. However, many fathers lack knowledge and confidence about how to do engage with their children [10]. Multiple barriers that exist to gain skills and knowledge, including a lack of father-focused support, resources, and services are exacerbating this problem for fathers [3,11,12], lack of trained staff specifically to work with fathers [13], differing cultural beliefs toward fathers' roles [8], and a lack of father-specific, best practice guidelines [9,14]. In addition, paternal involvement in traditional parenting education programs has been low owing to fathers' full-time employment and not being available for parenting programs during traditional office hours [15], perceived attitudes of stoicism and self-reliance in fathers [16], and programs failing to engage fathers [17,18].

The proliferation of mobile phone usage may present an avenue to conveniently deliver relevant parenting resources and information to fathers [13]. Mobile phone ownership is pervasive in high income countries at over 90% [19] and increasing rapidly in low- and middle-income nations [20-22]. Through their personal mobile devices, parents now have at their disposal, a multitude of resources and information that can be accessed, including websites, social media and apps [23]. International trends for mobile devices being used to seek parenting information are increasingly becoming apparent, where for instance, recent Canadian research shows that 81% of parents rated their smart phone as a more important parenting resource than books (56%) [24].

International parenting research has shown positive results in providing perinatal health information to mothers through their mobile phone, whereby mothers found that they learned information in the perinatal period they otherwise would not have known without the use of texts to their personal phone [25]. Also, recent evidence in Australia and Africa has demonstrated increases in both maternal and paternal knowledge and confidence to breastfeed through the provision of a parenting app during the perinatal period [26,27]. Despite the convenience of parenting apps however, fathers have invariably experienced frustration in their use as a parenting resource, with information being predominantly mother-centric, and some even trivializing the roles of the fathers [28]. However, of the limited evidence of apps specifically targeting and providing information for fathers, positive experiences have been noted by fathers of being provided with convenient and nonjudgemental support [29,30]. Similarly, the Australian Milk Man app used such strategies as push notifications and social connectivity with other fathers to engage fathers with breastfeeding information [31]. This provided the impetus for increased conversations with partners about the benefits and facilitation of breastfeeding.

At present, despite research indicating that mobile health (mHealth) resources and apps are an effective tool for parents, there is a paucity of evidence examining the acceptability, usefulness, and effectiveness of such resources for fathers [32]. Evaluations of the limited number of apps for fathers (ie, Milk Man and mDad) have provided some evidence of the benefits of using these resources for support and guidance of fathers in limited areas of parenting, such as breastfeeding. However, there is a need to consult directly with fathers to gain greater understanding of their specific needs and preferences for mHealth resources promoting positive dietary and physical activity behaviors in young children. This will inform understanding of how mHealth parenting resources can be made more engaging for fathers to use. To our knowledge, no app exists exclusively for fathers to promote positive dietary and active play/physical activity behaviors in children aged 5 years or younger. Therefore, the aim of this study is to explore how to make parenting apps more engaging and useful for fathers using an existing app (My Baby Now) as a case study.

Methods

Study Context- Use of the My Baby Now App

This study used the My Baby Now (MBN) app as an example of an existing parenting app for fathers to provide feedback on. This app was chosen as it is currently being made available to parents as part of the roll out of the established Infant Feeding and Active Play and Nutrition (INFANT) program, which is a broader evidence-based group program that focuses on providing anticipatory guidance on feeding and play from birth to 18 months of age across Victoria, Australia [33]. The MBN app provides evidence-based information and support on infant feeding and active play from pregnancy to 18 months of age, in line with Australian Infant Feeding Guidelines and 24-hour Movement Guidelines for Early Years [34,35]. Presented as a parenting app with family imagery and language throughout, the MBN app has a strong focus on developing parenting confidence and skills. The app includes topics on feeding (breast, formula, mixed feeding and introduction to solids, and recipes) sleep and feed patterns, play, parental well-being, and dental care. Users receive 3 push notifications per week tailored to their child's stage of development and feeding mode (breast, formula, or mixed feeding). A facilitated forum to share experiences with other users is provided along with activities such as goal setting and quizzes to provide tailored feedback in areas such as feeding practices [26]. The app is informed by extensive formative research with mothers [36] and practitioners [37] and a feasibility study of an earlier version of the app, "Growing healthy" [38]. The app has been found to be acceptable and useful to mothers; however, it is less well used by fathers with the vast majority of participants being mothers [26].

Study Design

This study used qualitative inquiry in focus groups and one-on-one interviews to gain an understanding of fathers' views and experiences in using mHealth resources and to obtain fathers feedback on the MBN app. The overall methodology of this study was guided by a pragmatic research paradigm, which provides the flexibility to apply research methods best suited to answering a research problem [39]. In our study, qualitative enquiry [40] with thematic analysis [41], was deemed most suitable. In allowing for different worldviews of researchers and participants to be represented [42], the authors recognize that the data will be socially constructed.

XSL•FO
RenderX

Recruitment

All participants in this study were recruited from a larger, nationwide Australian study [9], that surveyed fathers about their perceived role, self-efficacy and support needs in promoting positive dietary and physical activity behaviors in early childhood. The survey was open to fathers or expectant fathers (aged 18 years or older) with children aged 5 years or younger residing in Australia, with sufficient fluency in English to complete the survey. At the completion of the survey, participants were asked if they would be interested in participating in further research. Email invitations were sent to those who had expressed interest in further research to invite them to participate in the focus groups and interviews. If participants did not respond to the initial email, 2 further reminder emails, at 1-week interval were sent. Once the participants replied to the original or a reminder email, confirmatory emails were sent with details of the zoom meeting and instructions on how to download the MBN app.

Depending on their availability or preference, participants were offered the choice of being in a focus group or having a one-on-one interview. Focus groups and interviews occurred 1-2 weeks after the confirmatory email was sent.

Data Collection

As part of the larger survey study [9], sociodemographic characteristics of participants were collected including, fathers' age, level of education, employment status, marital status, location, country of birth, languages spoken at home, number of children and children's age. Informed by the end user version of the mobile rating scale (uMars), which provides a reliable method to assess the quality of mHealth apps [43], a broad, semistructured focus groups and interview guide was used for this study (Multimedia Appendix 1). The guide was developed to explore fathers' perceptions of the appeal and usefulness of the solids, feeding, and play sections of the MBN app. After using the MBN app in the 1-2 weeks before the focus groups and interview, fathers provided feedback on their experiences seeking information in MBN, the functionality and aesthetics of MBN, their engagement with MBN, and their opinions of the information within the MBN app. The guide was reviewed by 2 researchers (MG and RL), and minor amendments were subsequently made to the wording of some questions to avoid using leading questions and to improve clarity.

In the confirmation email which participants received before their focus group, they were asked to download the MBN app to their phone before the meeting and were encouraged to explore the features of the app. Participants were advised that during their focus groups and interview, the solids and play sections of the app would be discussed in detail. All clients reported that they were able to download the app before their focus groups and interview as directed. During the focus groups and interviewss, participants used Menti (poll maker) to vote on the usefulness of a sample of 5 MBN app push notifications by selecting one of 5 options, very helpful, helpful, neutral, unhelpful, and very unhelpful. The Menti app enables multiple users to share knowledge and real-time feedback in meetings [44]. Participants voting provided impetus for further discussion on their subjective opinions on the positive or negative aspects of the notification and how it may be improved. The format for rating the push notifications was the same for both focus groups and interviews.

The lead author (MG) conducted the focus groups and interviews between April and May 2023, and these were recorded with the permission of the participants and transcribed verbatim. Each focus group had a primary facilitator, and an observer (KG), who completed reflexive notes.

Data Analysis

All focus groups and interviews were transcribed by an online platform (zoom) and then manually checked for accuracy by the interviewer. To minimize participatory burden on fathers, transcripts were not returned to participants for review. The interviewer (MG) and observer (KG) took notes throughout the interview and these notes were reviewed with the interview transcripts.

Reflexive thematic analysis was used to identify patterns and themes. Phases of analysis were based on Braun and Clarke's [41] 6-step method and were conducted by the first author. Initially, the data were coded deductively using uMars as a framework, and then inductive coding was used for data that did not align with uMars domains [45]. After initial coding by the first author, the coding framework was discussed with the research team with a sample of 2 transcripts, resulting in minor refinements. NVivo 11 (Lumivero) was used for coding and retrieval of data [46].

Researcher Reflexivity and Credibility

Qualitative research relies on nuanced judgements that require researcher reflexivity, to account for how subjectivity shapes their inquiry [47]. MG is a PhD candidate and a registered psychologist and is also a father of a young child and is motivated in role modelling positive health behaviors. However, MG has very little experience with using either general parental, or father specific parenting apps. MG did not have any involvement in the development of MBN app or any similar app, and this was made clear to the participants at the beginning of the focus groups and interviews. MG was conscious that some fathers will not share his knowledge and attitude toward the development of healthy behaviors and was careful not to judge participants in interviews [48].

Ethical Considerations

This study was approved by the Deakin University Human Research Ethics Committee (HEAG-H 30_2022). All participants were provided with an Aus $25 (US $15.6) supermarket or home hardware shopping voucher for their time. Written informed consent was obtained from all fathers before participation.

Results

Participants

Of the 200 surveys completed in the larger study, 58 participants expressed an interest in participating in this study and were invited to take part in the focus groups and interviews. Of these, 18 indicated interest in either the initial, or one of 2 reminders

XSL•FO
RenderX

to participate. After organizing time slots for focus groups and interviews, 4 of the participants cancelled their scheduled participation and did not reschedule an alternate time and were omitted from the study. A total of 5 participants chose to have an interview and 9 took part in one of 3 focus groups, which ranged from 2-5 participants. Interviews took an average of 51 (range 39-64) minutes, while focus groups lasted for an average of 58 (range 51-73) minutes.

The 14 participating fathers were on average around 40 years of age, had 1 or more children aged 5 years or younger with an average age of 2.4 years (Table 1). The majority of the fathers identified as Australian born (12/14) and all spoke English at home and were married. The majority of fathers were university educated (10/14) and were employed full-time (12/14). Participants in this study were broadly similar of survey participants; however, in contrast to participants in the survey who were 61.5% metropolitan based, the majority of fathers in the qualitative study (64.3%) were region or rural based (9/14).

Five key themes (and 19 codes) from the focus groups/ interviews relate to the previous parenting information seeking of the fathers, the functionality of the MBN app, fathers' engagement with the MBN app, the aesthetics of the MBN app, and fathers' perceptions of the information in the MBN app (Table 2).

Table 1. Characteristics of fathers participating in focus groups and interviews.

Characteristics	Fathers and children (N=14)
Father's age (years) mean (SD), range	40.2 (5.4), 51.1-31.5
Child's age (years) mean (SD), range	2.4 (1.9), 0.7-5.8
Father status	
1 or more children aged 5 years or younger	14 (100)
Age of children	
Infant (birth to 1 year)	5 (35.7)
Toddler (2-3 years)	4 (28.5)
Preschool (4-5 years)	5 (35.7)
Level of education	
High school	1 (7.1)
Trade certificate/ TAFE[a]	3 (21.4)
University	10 (71.4)
Employment	
Full-time	12 (85.7)
Home duties	1 (7.1)
Other (share trader)	1 (7.1)
Marital status	
Married/De facto	14 (100)
Location	
Metropolitan	5 (35.7)
Regional/rural	9 (64.3)
Country of birth	
Australian born	12 (85.7)
Other	2 (14.3)
Language spoken at home	
English	14 (100)

[a]Technical and further education.

XSL•FO
RenderX

Table 2. My Baby Now (MBN) app focus groups/ interview themes, codes, and illustrative quotes.

Themes and codes	Example quotes
Previous information seeking	
Traditional	• We've got a local library, so we try and go there for information about development and stuff. (F1) • They [parenting groups] tend to fall back into that stereotype that moms are the primary carers. (F6)
App technology	• I do have an app that at a certain time every day is going to send me a message and you get used to it. (F10) • I've used one [an app], it did tell you what stage your baby's at, like okay, you're at week five, so you may notice this behaviour. (F2)
Social media	• They're absolutely great, there's a dad's one on Facebook. I like to know what other dads find challenging or have questions about. (F9) • There's a Facebook page - Advice for Dads. It became pointless, as every experience was different and just not that relevant to me. (F3)
Websites/YouTube	• It can be stressful, just going onto a parenting website and you get bombarded with pop-up windows and ads. (F1) • I want it to be accessible, so if I was cooking, you don't have to go into the app, you can just access it immediately on youTube (F14)
Functionality of the MBN app	
Ease of navigation	• That's good to be able to jump around, because you'll read something and then you'll get further down, and the reference is further away (MBN app). (F7) • I understand when you're in, it went to 3 to 4 months, it just takes you to that section within a really long sheet. I started scrolling around and then I realized I wasn't looking at 3 to 4 months (MBN app). (F10)
Useful tools	• So it's good that it tells you foolproof. It tells you how to safely set it up [play equipment] and what you'll need. I think those kinds of things are fantastic. (F14) • You look at it (MBN quiz), and go, bang, bang. You go tick, tick and then it's done…and you get the follow-up information straight away. (F12)
Fathers engagement with the MBN app	
Tools to bond	• I went to the video library, had a look at the video for chicken Bolognese. Easy to follow, the video was perfect. I was like, oh, that's easy. It's their favourite. (F6) • Having lots of different activities [in MBN] is fantastic, to be able to come up with new games and experiment with them and play with them (children) to help them create their own. (F4)
Customization videos	• Having some presented by a male would be advantageous. You're not feeling like you're being lectured to by mums. (F11) • In the recipe sections, the videos, it's all veggies and fruit. You could chuck meat on there because for dads, it's going to resonate with him. (F2)
Dads' sanctuary	• To engage a dad, you need other dads already there, so they feel more comfortable, and this is actually a space for dads. (F6) • Moms are always really keen if they think you're this bumbling idiot dad, and they can give you all the answers, but as soon as you have an opinion, the moms don't want you in their forum anymore. (F12)
Interactivity (push notifications)	• That American one (different app to MBN), you can imagine it was over the top, trying to pump you up. But it was good to get those kind of positive messages (reassuring/motivational messages for dads). (F4) • Age-based, just some prompts using the age, whether it was those age bands that you had earlier each month in the first 12 months and then probably less frequent after that depending how far out it goes. (F11)
Aesthetics of the MBN app	
Layout (clutter)	• Subheadings or something just to, because there's a lot there, it's quite comprehensive, but just to make it more intuitive to navigate. (F3) • if you've got a few minutes to have a look at this, but then you've got to go away for something, just to be able to go back to where you were and go on with what you were doing would be great. (F7)
Graphics	• The information's there plus the visual video too. So, there's a structured approach, that's tailored to how you learn, so you can go bang. (F9) • I like the pictures and stuff. That's how I've always picked up stuff [retained information]. (F2)

XSL•FO
RenderX

Themes and codes	Example quotes
Visual appeal	• I know it's probably going to be very hard, but so when you do look through a lot of pictures, there aren't really any men in any of the photo's. (F1) • I mean, that bottom photo with the pregnancy where the mom's in the pool laying on her back. I mean, she could be being held by her husband in the pool. Why not? (F13)
Fathers perceptions of information in the MBN app	
Specificity	• It breaks the recipe up and says, at this point you take the baby's portion out and then you'll add, spices chili or whatever else, which is quite handy when you are cooking for your family. (F9) • Quite a variety of topics [active play], I like that. Some apps, it just gives you a tiny bit of information and topics, but here [MBN], it puts it down for the different ages, what they should be doing. (F7)
Comprehensiveness	• We've had issues, if a bloke takes a child into a parent's room, there's a "what are you doing in here" attitude". You feel rejected. it'd be good to have advice there, how dads can manage that sort of thing. (F12) • Just prioritizing the topics based on the app. I think, although genders is one thing and roles. So, it could be, it's not just dad, mom, it's also - are you the primary care or secondary or what's your role? (F2)
Availability of info - breast-feeding	• The breastfeeding thing, even if it's not as relevant for dads. It would be great if there was a section that's like how to support your partner during breastfeeding. (F2) • Because in the early stages it's hard. The baby's not latching and you're just standing there useless as a dad. (F3)
Credibility of source	• Yeah, she obviously knows what she's on about [cooking video], but I can follow it ok. She's explaining it ok. (F3) • But, it's like, is this all kosher? Is it what the professionals recommend [play activities]. (F10)

Theme 1: Previous Information Seeking

This theme included the experiences of fathers so far in searching for information in their fatherhood journey. Although all fathers were proficient using modern technology, such as smart phones, most of the fathers also made use of traditional methods, such as hard copy books when searching for information. It was apparent that most fathers did not necessarily have a preferred source of information, they did however, want information to be credible. Many fathers had also involved themselves in parenting groups but highlighted negative experiences in these groups where invariably they felt they did not belong (subtheme 1.1). The majority of fathers had made use of apps on their smart devices and had found the experiences, such as getting age specific information through reminder texts, to be positive (subtheme 1.2). The majority of fathers used social media in some form for information seeking and many highlighted the reassurance they felt in learning of the experiences of other fathers. However, other fathers reported frustration in navigating the quantity and range in quality of information on social media (subtheme 1.3). Similarly, many fathers found the convenience and accessibility of the internet in seeking information on the internet to be positive, however they could feel overwhelmed by the amount and variable credibility of information they must process (subtheme 1.4). Across all sources of traditional or modern sources of information, fathers highlighted frustration that it was targeted more to mothers than fathers.

Theme 2: Functionality of the My Baby Now App

In this theme, fathers' spoke about what was important to them in regard to how the MBN app should function. Most fathers made comments about the importance of being able to navigate around the MBN app easily. However, some fathers highlighted some frustration with needing to scroll or swipe excessively, which resulted in them losing their place (subtheme 2.1). When able to locate and engage with the sections of the MBN app as desired, fathers spoke positively about the reassurance they felt from the information provided (subtheme 2.2).

Theme 3: Engagement With the My Baby Now App

In this theme, fathers spoke about the reasons why they may engage with the MBN app. Many fathers spoke positively about the combination of written and video information available, which provided ideas and strategies about how to engage with their children in areas such as pleasurable games and providing enjoyable food (subtheme 3.1). A consistent theme from fathers was for them to engage with the MBN app, it needs male imagery that could also include males presenting information in videos (subtheme 3.2). Fathers also highlighted the need for information in areas (such as male-only forums) where they could get information and exchange viewpoints without the threat of feeling out of place (subtheme 3.3). Fathers spoke positively about getting push notifications delivered to their smart devices, including specific health-related information about their child and simple messages of encouragement. However, the majority of fathers highlighted that daily push notifications would be too excessive, with some fathers preferring weekly or monthly notifications as the child ages (subtheme 3.4).

Theme 4: Aesthetics of the My Baby Now App

This theme provided fathers the opportunity to highlight how the presentation of the MBN app would affect their attraction and potential use of the app. Some fathers found that information in the MBN app can appear cluttered due to the amount of information and the lack of defined sections, such as information presented by age or stages of development. A number of fathers

XSL•FO
RenderX

stated that this could be remedied by the use of more subheadings (subtheme 4.1). In receiving information, fathers found the use of graphics and videos to explain information could facilitate a positive learning experience (subtheme 4.2). However, most fathers had negative perceptions about the distinct lack of visual images of fathers and lack of pictures that fathers would be interested in, such as more meat-based meals (subtheme 4.3).

Theme 5: Perceptions of the Information in the My Baby Now App

When discussing the type of information that they would like to see, fathers consistently made comments that they were appreciative of specific, relevant information that provided them with clear steps to follow, such as age-appropriate play activities and recipes (subtheme 5.1). However, many fathers also highlighted the need to have information in different areas of fatherhood that they were unfamiliar with, such as tips on the social etiquette of using baby change rooms and tips on food storage (subtheme 5.2). The majority of fathers highlighted that helping with the demands of breastfeeding was a constant source of stress and some thought a specific section for fathers and breastfeeding would be advantageous (subtheme 5.3). Fathers highlighted the need for factual information, with some fathers stating that they did not mind if a male or female presented information in videos, just as long as it was factual (subtheme 5.4).

Discussion

Principal Findings

This study adds to a limited pool of research that uses qualitative enquiry to gain fathers perspectives on how parenting apps can be improved to be more engaging for fathers [24]. From conducting focus groups and interviews with fathers, 5 themes emerged; previous parenting information seeking, functionality of the MBN app, fathers' engagement with the MBN app, the aesthetics of the MBN app, and fathers' perceptions of the information in the MBN app. The information gained from fathers about mHealth technology is important, as traditional and typical contemporary domains for fathers to find information on parenting, such as social media and parenting websites have typically targeted mothers, with few father-specific resources [49]. Indeed, some parenting apps to date have portrayed a dismissive attitude to fathers' roles and experiences and what they can contribute as a parent to children in early stages of development [28,50].

Findings from our study revealed that fathers have previously used a variety of traditional and contemporary sources of information, including books, social media, parenting groups, apps, with parenting websites and parenting material on YouTube (Google) being the most prevalent. This is in line with previous Australian research, which also found the web-based activities was the main resource fathers used to find information on their child's health, for reasons of convenience and speed, and this was particularly so in fathers of a higher socioeconomic position (SEP) [51]. Our sample consisted mostly of higher SEP fathers (by education) with over 70% of fathers being university-educated, and the preferences for internet usage highlighted by fathers is in line with a "digital divide" noted by Laws et al [51], whereby higher educated fathers are more likely to use parenting website activities for seeking information on children's health. Understanding differences in mHealth app usage by fathers seeking children's health information, delineated by SEP, remains unclear and will benefit from further research.

Despite being the prominent choice, seeking information through parenting websites and YouTube was widely reported to be a frustrating endeavor for fathers in our study, whereby many highlighted they could not locate what they desired due to being overwhelmed by excessive information of questionable quality. This led to some fathers having a negative perception of internet-based parenting information and resources and avoiding its use [52]. Similar findings were reported in the Australian qualitative study of Walsh et al [10], whereby fathers highlighted a desire to be better informed about their young children's diet and physical activity needs, but felt there was a lack of useable and credible information to guide them. Of fathers who had previously used apps in our study, not only was the convenience of the app in providing prompt information important, but also the value of an app in providing useful and credible information in the one area.

Many fathers in our study highlighted their negative perception of parenting information or imagery encountered previously, and also in the MBN app, that included only maternal content. Such perceptions are important considerations for the engagement of fathers, as it has been found that representations and languages that embed social norms of fathers not being involved in parenting duties, have led to paternal disengagement from parenting programs [53]. For fathers to be motivated to participate in parenting research and programs, research has highlighted the need for stratification, with fathers specifically named and targeted to garner paternal interest [54]. This need was present in the recommendations from fathers to improve the MBN, whereby it was unanimously highlighted that the MBN app needs greater father-specific information and imagery to appeal to and engage with fathers.

Further to the requests for greater father imagery and content, fathers also widely requested for there to be father-only forums. Evidence suggests that fathers engage with other fathers in a different style than mothers do, with more humor and less formality in their social media and chatroom interactions [55]. Their preference for male-only domains in apps may provide them with an opportunity to discuss sensitive matters while maintaining a perception of control through the use of humor while on an equal footing to other fathers [56]. Canadian research into engaging young fathers in parenting programs reveals that they will be more likely to engage if programs initially involve informal meetings in places of comfort with their male peers, such as sports fields [23]. This allows fathers to seek help in an environment of perceived security without looking "weak," as experienced in more formal settings such as traditional health care [55]. It was interesting to note in our focus groups and interviews, how positively and openly fathers engaged with each other, with regular humor evident, in discussing sensitive developmental issues without previous

XSL•FO
RenderX

contact with each other. Another potential benefit of men-only forums is that fathers who have had knowledge and previous experience with other children may be able to pass this knowledge onto younger or less experienced fathers who benefit from guidance [57].

Well-designed tools available through smart technology have the potential to provide fathers with the information they want [15,58], and fathers in our study were mostly able to navigate through app technology when seeking information. Similar to previous research [23,28], the fathers in our study reported that when they were able to find information, they could understand on the MBN app, and improved confidence and enjoyment was noted in their engagement with their child. Receiving notifications through smart phone technology has proven to be beneficial for mothers as well as fathers in gaining information [59,60], and fathers in our study were mostly positive about receiving push notifications from the MBN app, particularly in areas of low knowledge, such as breastfeeding. Push notifications, therefore present as a valuable strategy to deliver desired breastfeeding information to fathers wanting to be supportive, which is vital for mothers to facilitate the demands of breastfeeding [61]. Similar to Australian research into the effects of supportive text messages on new fathers' mental health [15], many of the fathers in our study expressed a belief that messages of support would be beneficial in managing parental pressures and lowering isolation. The pressures of raising young children are a stressful time where new demands are being put on parents [62], and many fathers in our study highlighted the significant impact of feeling useless and isolated had on their mood. In demanding times, if reassurance and guidance are not provided by others, mHealth technology presents as a valuable resource for fathers to use in their parenting journey.

While this paper highlighted the potential benefits of providing fathers with credible, evidence-based mHealth resources, it did not have the scope to explore the feasibility of developing and maintaining a usable app for fathers to use in their everyday lives. Recent American evidence suggests that it can take over 6 months and costs approximately US $ 270,000 for the development of an app, with ongoing maintenance costs an additional expense [63]. It was noteworthy in this study, that rather than advocating the need for father only apps, many fathers instead highlighted their desire to see father specific sections in current parenting apps. By having father specific sections in current parenting apps, the desired resources that fathers have raised in this study, such as positive male imagery, father only forums, and tailored push notifications, could be provided without the financial burden that a stand-alone app would encumber.

Strengths and Limitations

This study has a number of strengths and limitations. A key strength was the qualitative design, which allowed fathers' perspectives to be explored in more detail through focus groups and interviews, thereby providing a deeper understanding of fathers' experiences and viewpoints. The results of this paper provide qualitative evidence from fathers about what is needed in an mHealth resource for them to engage with it and find informative and useful. This is important for the promotion of coparenting, as more traditional methods of providing education to fathers, such as parenting classes, have not been an effective way to provide support fathers in paid employment [15]. Coparenting research has advocated the need for modern technology such as mHealth, to reach parents during the demanding postpartum period to promote greater coparticipation in the promotion of positive health behaviors [62]. Such co-operative parenting behaviors have in turn been shown to lead to such benefits as improving the child's obesity status [4] and the social-emotional well-being of the child [64,65].

In line with noted recruitment difficulties in existing paternal research [17,29,54], the recruitment of a desired number and varied sample of participants proved difficult for this study. In addition, the sample was limited by fathers being mostly higher educated, predominantly Australian-born, who by their interest in this study, were likely to be health conscious and committed fathers. While this may have contributed to social desirability bias in their responses, the fathers in our study were open and forthcoming with divulging their challenges and offered valuable insight and recommendations for improvement of the MBN app. Future research will benefit from the inclusion of a varied sample of participants, including fathers of low SEP and the inclusion of fathers of differing family status, such as single fathers and same sex couples. In addition, as this paper was predominantly made up of a culturally homogenous sample of participants, caution will need to be exercised in extrapolating the results internationally, as approaches and beliefs about fathering varies considerably across cultures [8].

Finally, many fathers were able to make themselves available only at select times, which precluded them from taking part in focus groups with other fathers, and instead took part in a one-on-one interview with a researcher. This denied some fathers the opportunity to engage with other fathers in a positive group setting and may have limited their opportunity to develop their views and opinions through group dynamic. The researchers do not believe that the quality of the information elicited in interviews lacked any of the richness of focus groups.

This qualitative study has provided unique insights from fathers in focus groups and interviews about how an mHealth parenting resource, in the form of app technology, can be improved to enhance the engagement of fathers in early childhood. While current parenting apps, such as MBN, have proved advantageous in delivering factual information to fathers expediently, the information can fail to appeal to the specific needs and wants of fathers. Fathers committed to the promotion of positive health behaviors to their children risk becoming frustrated and potentially disengaged if father-specific material is not provided. Through the promotion of father specific information, use of positive imagery and descriptives of fathers in their role, promoting father exclusive domains such as forums, and using positive reinforcements such as push notifications to support and give guidance to fathers in an area of uncertainty for them, app technology can be a valuable resource for fathers in their parenting journey.

XSL•FO
RenderX

Acknowledgments

The authors would like to thank all the fathers who contributed to this study. MG is supported by a Deakin University PhD scholarship, DUPR-GRANTS (PVC RSP; 0000018832). KDH is supported by a Heart Foundation Future Leader Fellowship (105929).

Data Availability

The datasets used and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

All authors made a substantial contribution to this project and the manuscript. MG and KG conducted data collection. MG contributed to the analytical approach, results interpretation and had primary responsibility for manuscript writing. RL was the principal investigator and together with KW and KH contributed to the study design, analytical approach, and interpretation of results. All authors contributed to drafts and read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional information.
[DOCX File , 23 KB - pediatrics_v8i1e64171_app1.docx]

References

1. Gustafson SL, Rhodes RE. Parental correlates of physical activity in children and early adolescents. Sports Med 2006;36(1):79-97. [doi: 10.2165/00007256-200636010-00006] [Medline: 16445312]
2. Berge JM, Wall M, Loth K, Neumark-Sztainer D. Parenting style as a predictor of adolescent weight and weight-related behaviors. J Adolesc Health 2010;46(4):331-338 [FREE Full text] [doi: 10.1016/j.jadohealth.2009.08.004] [Medline: 20307821]
3. Morgan PJ, Lubans DR, Callister R, Okely AD, Burrows TL, Fletcher R, et al. The 'Healthy Dads, Healthy Kids' randomized controlled trial: efficacy of a healthy lifestyle program for overweight fathers and their children. Int J Obes (Lond) 2011;35(3):436-447. [doi: 10.1038/ijo.2010.151] [Medline: 20697417]
4. Wake M, Nicholson J, Hardy P, Smith K. Preschooler obesity and parenting styles of mothers and fathers: Australian national population study. Pediatrics 2007;120(6):e1520-e1527. [doi: 10.1542/peds.2006-3707] [Medline: 18055667]
5. Walsh AD, Crawford D, Cameron AJ, Campbell KJ, Hesketh KD. Associations between the physical activity levels of fathers and their children at 20 months, 3.5 and five years of age. BMC Public Health 2017;17(1):628 [FREE Full text] [doi: 10.1186/s12889-017-4545-8] [Medline: 28679435]
6. Pleck JH. Paternal involvement: Levels, sources, and consequences. New York, NY: Wiley; 1997.
7. Barber K. The well-coiffed man: Class, race, and heterosexual masculinity in the hair salon. Gender & Society 2008;22(4):455-476. [doi: 10.1177/0891243208321168]
8. Lamb ME. The role of the father in child development. Fifth edition. Hoboken, New Jersey: Wiley; 2010.
9. Gaynor M, Wynter K, Hesketh K, Love P, Laws R. Fathers' perceived role, self-efficacy and support needs in promoting positive nutrition and physical activity in the first 2000 days of life: a mixed methods study. Int J Behav Nutr Phys Act 2024;21(1):23 [FREE Full text] [doi: 10.1186/s12966-024-01575-w] [Medline: 38409057]
10. Walsh AD, Hesketh KD, van der Pligt P, Cameron AJ, Crawford D, Campbell KJ. Fathers' perspectives on the diets and physical activity behaviours of their young children. PLoS One 2017;12(6):e0179210 [FREE Full text] [doi: 10.1371/journal.pone.0179210] [Medline: 28604810]
11. Morgan PJ, Collins CE, Plotnikoff RC, Callister R, Burrows T, Fletcher R, et al. The 'Healthy Dads, Healthy Kids' community randomized controlled trial: a community-based healthy lifestyle program for fathers and their children. Prev Med 2014;61:90-99. [doi: 10.1016/j.ypmed.2013.12.019] [Medline: 24380796]
12. Quattrin T, Roemmich JN, Paluch R, Yu J, Epstein LH, Ecker MA. Efficacy of family-based weight control program for preschool children in primary care. Pediatrics 2012;130(4):660-666 [FREE Full text] [doi: 10.1542/peds.2012-0701] [Medline: 22987879]
13. Mallan KM, Nothard M, Thorpe K, Nicholson JM, Wilson A, Scuffham PA, et al. The role of fathers in child feeding: perceived responsibility and predictors of participation. Child Care Health Dev 2014;40(5):715-722. [doi: 10.1111/cch.12088] [Medline: 23902382]
14. Walsh AD, Hesketh KD, van der Pligt P, Cameron AJ, Crawford D, Campbell KJ. Fathers' perspectives on the diets and physical activity behaviours of their young children. PLoS One 2017;12(6):e0179210 [FREE Full text] [doi: 10.1371/journal.pone.0179210] [Medline: 28604810]

XSL•FO
RenderX

15. Fletcher R, Kay-Lambkin F, May C, Oldmeadow C, Attia J, Leigh L. Supporting men through their transition to fatherhood with messages delivered to their smartphones: a feasibility study of SMS4dads. BMC Public Health 2017;17(1):953 [FREE Full text] [doi: 10.1186/s12889-017-4978-0] [Medline: 29237439]
16. Hull MJ, Gunn KM, Smith AE, Jones M, Dollman J. "We're Lucky to Have Doctors at All"; a qualitative exploration of Australian farmers' barriers and facilitators to health-related help-seeking. Int J Environ Res Public Health 2022;19(17):11075 [FREE Full text] [doi: 10.3390/ijerph191711075] [Medline: 36078793]
17. Rhodes A, Smith AD, Llewellyn CH, Croker H. Investigating partner involvement in pregnancy and identifying barriers and facilitators to participating as a couple in a digital healthy eating and physical activity intervention. BMC Pregnancy Childbirth 2021;21(1):450 [FREE Full text] [doi: 10.1186/s12884-021-03917-z] [Medline: 34182953]
18. Lowenstein LM, Perrin EM, Berry D, Vu MB, Pullen Davis L, Cai J, et al. Childhood obesity prevention: fathers' reflections with healthcare providers. Child Obes 2013;9(2):137-143 [FREE Full text] [doi: 10.1089/chi.2012.0111] [Medline: 23472966]
19. Marshall A, Wilson C, Dale A. New pathways to crisis resilience: solutions for improved digital connectivity and capability in rural Australia. Media Int. Aust 2023;189(1):24-42. [doi: 10.1177/1329878x231183292]
20. Thakkar S, Muhammad T, Maurya C. An investigation of the longitudinal association of ownership of mobile phones and having internet access with intimate partner violence among young married women in India. J Public Health (Berl.) 2023. [doi: 10.1007/s10389-023-02106-w]
21. Bastawrous A, Hemming B, Livingstone I. mHealth possibilities in a changing world. Distribution of global cell phone subscriptions. Journal of Mobile Technology in Medicine 2013;2(1S):22-25. [doi: 10.7309/jmtm.2.1.4]
22. Ericsson TL. Ericsson mobility report. Stockholm, Sweden: Ericsson Mobility Report: Ericsson; 2021.
23. Sevigny PR, Loutzenhiser L, Oriet C. Canadian fathers' preferences for support during the transition to fatherhood. Can J Commun Ment Health 2021;40(2):49-70. [doi: 10.7870/cjcmh-2021-011]
24. Virani A, Duffett-Leger L, Letourneau N. Parents' perspectives of parenting app use. J. Inform. nursing 2020;5(1):8-18 [FREE Full text]
25. Remick AP, Kendrick JS. Breaking new ground: the text4baby program. Am J Health Promot 2013;27(3 Suppl):S4-S6 [FREE Full text] [doi: 10.4278/ajhp.27.3.c2] [Medline: 23286662]
26. Laws RA, Cheng H, Rossiter C, Kuswara K, Markides BR, Size D, et al. Perinatal support for breastfeeding using mHealth: a mixed methods feasibility study of the My Baby Now app. Matern Child Nutr 2023;19(2):e13482 [FREE Full text] [doi: 10.1111/mcn.13482] [Medline: 36725007]
27. Gebremariam KT, Mulugeta A, Gallegos D. Theory-based mHealth targeting fathers and mothers to improve exclusive breastfeeding: a quasi-experimental study. Int Breastfeed J 2023;18(1):2 [FREE Full text] [doi: 10.1186/s13006-022-00537-x] [Medline: 36604757]
28. Thomas GM, Lupton D, Pedersen S. 'The appy for a happy pappy': expectant fatherhood and pregnancy apps. Journal of Gender Studies 2017;27(7):759-770. [doi: 10.1080/09589236.2017.1301813]
29. Moura AF, Philippe K. Where is the father? Challenges and solutions to the inclusion of fathers in child feeding and nutrition research. BMC Public Health 2023;23(1):1183 [FREE Full text] [doi: 10.1186/s12889-023-15804-7] [Medline: 37337169]
30. Jansen E, Harris H, Daniels L, Thorpe K, Rossi T. Acceptability and accessibility of child nutrition interventions: fathers' perspectives from survey and interview studies. Int J Behav Nutr Phys Act 2018;15(1):67 [FREE Full text] [doi: 10.1186/s12966-018-0702-4] [Medline: 29996867]
31. White B, Giglia RC, White JA, Dhaliwal S, Burns SK, Scott JA. Gamifying breastfeeding for fathers: process evaluation of the milk man mobile app. JMIR Pediatr Parent 2019;2(1):e12157 [FREE Full text] [doi: 10.2196/12157] [Medline: 31518324]
32. Lee SJ, Walsh TB. Using technology in social work practice: the mDad (Mobile Device Assisted Dad) case study. ASW 2015;16(1):107-124. [doi: 10.18060/18134]
33. Campbell KJ, Lioret S, McNaughton SA, Crawford DA, Salmon J, Ball K, et al. A parent-focused intervention to reduce infant obesity risk behaviors: a randomized trial. Pediatrics 2013;131(4):652-660. [doi: 10.1542/peds.2012-2576] [Medline: 23460688]
34. Netting MJ, Campbell DE, Koplin JJ, Beck KM, McWilliam V, Dharmage SC, Centre for FoodAllergy Research, the Australasian Society of Clinical ImmunologyAllergy, the National Allergy Strategy,the Australian Infant Feeding Summit Consensus Group. An Australian consensus on infant feeding guidelines to prevent food allergy: outcomes from the australian infant feeding summit. J Allergy Clin Immunol Pract 2017;5(6):1617-1624 [FREE Full text] [doi: 10.1016/j.jaip.2017.03.013] [Medline: 28499774]
35. Okely AD, Ghersi D, Hesketh KD, Santos R, Loughran SP, Cliff DP, et al. A collaborative approach to adopting/adapting guidelines - the Australian 24-hour movement guidelines for the early years (Birth to 5 years): an integration of physical activity, sedentary behavior, and sleep. BMC Public Health 2017;17(Suppl 5):869 [FREE Full text] [doi: 10.1186/s12889-017-4867-6] [Medline: 29219094]
36. Russell CG, Taki S, Azadi L, Campbell KJ, Laws R, Elliott R, et al. A qualitative study of the infant feeding beliefs and behaviours of mothers with low educational attainment. BMC Pediatr 2016;16:69 [FREE Full text] [doi: 10.1186/s12887-016-0601-2] [Medline: 27209010]

XSL•FO
RenderX

37. Laws R, Campbell KJ, van der Pligt P, Ball K, Lynch J, Russell G, et al. Obesity prevention in early life: an opportunity to better support the role of maternal and child health nurses in Australia. BMC Nurs 2015;14:26 [FREE Full text] [doi: 10.1186/s12912-015-0077-7] [Medline: 25972765]
38. Laws RA, Denney-Wilson EA, Taki S, Russell CG, Zheng M, Litterbach E, et al. Key lessons and impact of the growing healthy mHealth program on milk feeding, timing of introduction of solids, and infant growth: quasi-experimental study. JMIR Mhealth Uhealth 2018;6(4):e78 [FREE Full text] [doi: 10.2196/mhealth.9040] [Medline: 29674313]
39. Tashakkori A, Teddlie C. Handbook of mixed methods in social & behavioral research. Second edition. London: SAGE; 2016.
40. Bradshaw C, Atkinson S, Doody O. Employing a qualitative description approach in health care research. Glob Qual Nurs Res 2017;4:2333393617742282 [FREE Full text] [doi: 10.1177/2333393617742282] [Medline: 29204457]
41. Braun V, Clarke V. Reflecting on reflexive thematic analysis. Qual. Res. Sport Exerc. Health 2019;11(4):589-597. [doi: 10.1080/2159676x.2019.1628806]
42. Creswell JW, Clark VL. Designing and conducting mixed methods research. Third ed. London: SAGE; 2018.
43. Stoyanov SR, Hides L, Kavanagh DJ, Wilson H. Development and validation of the user version of the mobile application rating scale (uMARS). JMIR Mhealth Uhealth 2016;4(2):e72 [FREE Full text] [doi: 10.2196/mhealth.5849] [Medline: 27287964]
44. Interactive survey maker: create surveys for free. Mentimeter. URL: https://www.mentimeter.com/features/surveys [accessed 2025-01-27]
45. Braun V, Clarke V. Conceptual and design thinking for thematic analysis. Qual. Psychol 2022;9(1):3-26. [doi: 10.1037/qup0000196]
46. Edhlund BM, McDougall AG. NVivo 11 essentials : your guide to the world's most powerful data analysis software. Stallarholmen, Sweden: Form & Kunskap AB; 2016.
47. Rostron A. Who do they think we are? Reflexivity and participant constructions of the researcher. J. Manag. Inq 2023;33(5):284-299. [doi: 10.1177/10564926231193374]
48. Teychenne M, Apostolopoulos M, Ball K, Olander EK, Opie RS, Rosenbaum S, et al. Key stakeholder perspectives on the development and real-world implementation of a home-based physical activity program for mothers at risk of postnatal depression: a qualitative study. BMC Public Health 2021;21(1):361 [FREE Full text] [doi: 10.1186/s12889-021-10394-8] [Medline: 33593324]
49. Dworkin J, Connell J, Doty J. A literature review of parents' online behavior. Cyberpsychology 2013;7(2):1-10. [doi: 10.5817/CP2013-2-2]
50. Johnson SA. "Maternal Devices", social media and the self-management of pregnancy, mothering and child health. Societies 2014;4(2):330-350. [doi: 10.3390/soc4020330]
51. Laws R, Walsh AD, Hesketh KD, Downing KL, Kuswara K, Campbell KJ. Differences between mothers and fathers of young children in their use of the internet to support healthy family lifestyle behaviors: cross-sectional study. J Med Internet Res 2019;21(1):e11454 [FREE Full text] [doi: 10.2196/11454] [Medline: 30674450]
52. He Y, Dworkin J. Cyber dads: What are fathers doing online? Fathering: A Journal of Theory, Research & Practice about Men as Fathers 2015;13(3):219-230. [doi: 10.3149/fth.1303.219]
53. Panter-Brick C, Burgess A, Eggerman M, McAllister F, Pruett K, Leckman JF. Practitioner review: engaging fathers--recommendations for a game change in parenting interventions based on a systematic review of the global evidence. J Child Psychol Psychiatry 2014;55(11):1187-1212 [FREE Full text] [doi: 10.1111/jcpp.12280] [Medline: 24980187]
54. Leach LS, Bennetts SK, Giallo R, Cooklin AR. Recruiting fathers for parenting research using online advertising campaigns: evidence from an Australian study. Child Care Health Dev 2019;45(6):871-876. [doi: 10.1111/cch.12698] [Medline: 31216596]
55. Niela-Vilén H, Axelin A, Salanterä S, Melender H. Internet-based peer support for parents: a systematic integrative review. Int J Nurs Stud 2014;51(11):1524-1537. [doi: 10.1016/j.ijnurstu.2014.06.009] [Medline: 24998788]
56. Deslauriers JM, Kiselica MS. An ecological approach to understanding the paternal commitments of young fathers: from the pregnancy test to the child's first birthday. Child Adolesc Soc Work J 2022;41(2):249-268. [doi: 10.1007/s10560-022-00845-5]
57. Kiselica MS, Rotzlen A, Doms J. Preparing teenage fathers for parenthood: a group psychoeducational approach. J. Spec. Group Work 1994;19(2):83-94. [doi: 10.1080/01933929408413767]
58. Doty JL, Dworkin J. Online social support for parents: a critical review. Marriage & Family Review 2014;50(2):174-198. [doi: 10.1080/01494929.2013.834027]
59. Hearn L, Miller M, Fletcher A. Online healthy lifestyle support in the perinatal period: what do women want and do they use it? Aust J Prim Health 2013;19(4):313-318. [doi: 10.1071/PY13039] [Medline: 23899373]
60. Downing KL, Best K, Campbell KJ, Hesketh KD. Informing active play and screen time behaviour change interventions for low socioeconomic position mothers of young children: what do mothers want? Biomed Res Int 2016;2016:2139782 [FREE Full text] [doi: 10.1155/2016/2139782] [Medline: 28053979]
61. Johnson KM, Slauson-Blevins KS. "Perfectly supportive in theory…": Women's perceptions of partner support while breastfeeding. J Soc Pers Relat 2022;39(9):2869-2889. [doi: 10.1177/02654075221090185]

XSL•FO
RenderX

62. Xiao X, Loke AY. The effects of co-parenting/intergenerational co-parenting interventions during the postpartum period: a systematic review. Int J Nurs Stud 2021;119:103951. [doi: 10.1016/j.ijnurstu.2021.103951] [Medline: 34023796]
63. Jake-Schoffman DE, Silfee VJ, Waring ME, Boudreaux ED, Sadasivam RS, Mullen SP, et al. Methods for evaluating the content, usability, and efficacy of commercial mobile health apps. JMIR Mhealth Uhealth 2017;5(12):e190 [FREE Full text] [doi: 10.2196/mhealth.8758] [Medline: 29254914]
64. Young MD, Lubans DR, Barnes AT, Eather N, Pollock ER, Morgan PJ. Impact of a father-daughter physical activity program on girls' social-emotional well-being: a randomized controlled trial. J Consult Clin Psychol 2019;87(3):294-307. [doi: 10.1037/ccp0000374] [Medline: 30640483]
65. Neshteruk CD, Jones DJ, Skinner A, Ammerman A, Tate D, Ward DS. Understanding the role of fathers in children's physical activity: a qualitative study. J Phys Act Health 2020;17(5):540-547. [doi: 10.1123/jpah.2019-0386] [Medline: 32283541]

Abbreviations

INFANT: Infant Feeding Activity and Nutrition Program
MBN: My Baby Now
mHealth: mobile health
SEP: socioeconomic position
uMars: end user version of the mobile rating scale

Edited by A Nguyen; submitted 11.07.24; peer-reviewed by H LaMonica, F Yang, M Eisenstadt; comments to author 19.10.24; revised version received 20.11.24; accepted 30.11.24; published 21.02.25.

Please cite as:
Gaynor M, Hesketh K, Gebremariam K, Wynter K, Laws R
Practicality of the My Baby Now App for Fathers by Fathers: Qualitative Case Study
JMIR Pediatr Parent 2025;8:e64171
URL: https://pediatrics.jmir.org/2025/1/e64171
doi:10.2196/64171
PMID:39982774

©Mathew Gaynor, Kylie Hesketh, Kidane Gebremariam, Karen Wynter, Rachel Laws. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 21.02.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

The Added Value of Parents Practicing in Virtual Reality to Illustrate the Use of Innovative Methods in Parent-Child Interaction Therapy: Single-Case Experimental Design

Iza C A Scherpbier[1,2,3], PhD; Mariëlle E Abrahamse[1,2,4], PhD; Samantha Bouwmeester[5], PhD; Robert G Belleman[6], PhD; Arne Popma[2,3,7], MD, PhD; Ramón J L Lindauer[1,2,3], MD, PhD

[1]Child and Adolescent Psychiatry, Amsterdam University Medical Center Location University of Amsterdam, Amsterdam, The Netherlands

[2]Academic Center for Child and Adolescent Psychiatry, Levvel, Amsterdam, The Netherlands

[3]Mental Health, Amsterdam Public Health, Amsterdam, The Netherlands

[4]Child Care and Protection Board, Ministry of Justice and Security, The Hague, The Netherlands

[5]Department of Developmental Psychology, University of Tilburg, Tilburg, The Netherlands

[6]Computational Science Lab, University of Amsterdam, Amsterdam, The Netherlands

[7]Amsterdam University Medical Center location Vrije Universiteit Amsterdam, Child and Adolescent Psychiatry & Psychosocial Care, Amsterdam, The Netherlands

Corresponding Author:
Iza C A Scherpbier, PhD
Child and Adolescent Psychiatry
Amsterdam University Medical Center Location University of Amsterdam
Meibergdreef 9
Amsterdam, 1105AZ
The Netherlands
Phone: 31 20 890 1000
Email: i.c.a.scherpbier@amsterdamumc.nl

Abstract

Background: Throughout years of research, the well-known behavioral parent training program, Parent-Child Interaction Therapy (PCIT), has been adapted and enhanced to tailor the treatment to the needs of families in community-based clinical care. This study wished to evaluate an add-on to PCIT that could be engaging for parents. As a way to enlarge practice opportunity and potentially allow parents to achieve positive treatment effects sooner, this study added virtual reality (VR) to PCIT.

Objective: This study aimed to increase positive parenting skills at a faster pace with the use of PCIT-VR, on the basis that practicing positive parenting skills in the VR tool would increase parents' overall practice time, thus leading to more confidence in their skills, which could consequently increase the pace of skill acquisition. Furthermore, we hypothesized that due to the overall increase in positive parenting skills, PCIT treatment effects such as diminishment of child disruptive behavior and parenting stress would decrease at a faster pace when VR was introduced.

Methods: Families were recruited from a specialized child and adolescent psychiatry clinical practice in the Netherlands. Using a single-case experimental design, 11 families, equating to 18 participants, signed informed consent forms and received the staggered introduction of VR to treatment. As is common with a single-case experimental design, visual inspection analyses and randomization tests were conducted. Group differences were evaluated with nonparametric tests and reliable change indices.

Results: Overall, our study reaffirmed that PCIT is an effective intervention for this population as there were positive treatment effects found in almost all cases. Nevertheless, there did not seem to be a clear relationship between the use of the VR tool and PCIT treatment effects, although positive parenting skills seemed to increase when VR was introduced to treatment for some parents. For all parents, questions and comments decreased with the introduction of VR. These findings tentatively suggest that practicing with VR could potentially increase positive parenting skills and also have an impact on other treatment-related outcomes, such as child disruptive behavior and parenting stress.

Conclusions: This was the first time that PCIT has been supplemented with VR. We provide preliminary evidence of its added value. We cautiously suggest that VR could provide added value to PCIT and increase confidence in parenting skills for certain parents, although there are complex factors that play into treatment success that must simultaneously be considered. These factors

XSL•FO
RenderX

include parents having the motivation and mental capacity to change and the complex psychological problems some families face. Although promising, we believe that due to the novelty of our VR practice tool and the variety of results from our study, more research is necessary into PCIT-VR to draw further conclusions on its effects.

(JMIR Pediatr Parent 2025;8:e60752) doi:10.2196/60752

KEYWORDS

Parent-Child Interaction Therapy; virtual reality; single-case experimental design; innovation; parenting

Introduction

Background

Behavioral parent training (BPT) programs are an effective way to treat child disruptive behavior [1,2]. It is important to intervene at a young age for children exhibiting disruptive behavior to limit adverse outcomes later in life. Child disruptive behavior can lead to higher risks of aggressive behavior, criminality, internalizing problems, and other mental health–related problems later on [3]. Moreover, if persistent, long-term problems can arise in child development, family functioning, and other broader social factors, such as in parent-child relationships or educational delays [3,4]. We know that parents are the most important people in children's early lives [5-7], which indicates the importance of including parents in treatment. Parents should function as sensitive, responsive support figures for children. Furthermore, we know that child disruptive behavior can greatly increase parenting stress and strain the parent-child relationship [8]. Hence, BPT programs aim to diminish child disruptive behavior and parenting stress by focusing on the parent-child relationship with positive parenting skills [9].

With more than 40 years of evidence, Parent-Child Interaction Therapy (PCIT) is considered an effective BPT program for young children between the ages of 2 and 7 years and their parents, and has been widely disseminated [10]. PCIT aims to diminish child disruptive behavior and parenting stress, increase parents' positive parenting skills, and better the quality of the parent-child relationship [1,11]. Overall, PCIT is known to impactfully improve parental responsiveness and warmth [12]. PCIT includes 2 phases, the first phase is the child-directed interaction (CDI) phase and the second phase is the parent-directed interaction (PDI) phase. In the CDI phase, parents are taught to use positive parenting skills that affirm their child's behavior, which helps to build up the quality of the parent-child relationship. This phase lays the foundation for effective behavior change. In the PDI phase, parents are taught to set safe, consistent, and effective boundaries for their child's behavior. In this phase, the positive parenting skills that were previously taught still play an important role, allowing the parent-child relationship to continue improving over the course of the treatment [12]. To allow families to go at their own pace, PCIT has a nontime limited character, which means that treatment is completed only when certain parenting skills are met and parents feel confident in being able to manage behavior at home without the support of therapists [11].

Throughout the years, PCIT has been adapted and enhanced to tailor the treatment to the needs of families in community-based clinical care, though, for example, shortened versions of treatment or by adding incentives [13-18]. These studies demonstrated decreases in child disruptive behavior, a reduction in reports of child maltreatment posttreatment, and more positive parenting outcomes within community-based clinical samples. Notwithstanding, these studies commonly experienced high dropout rates that suggested only around 50% of families completed treatment [18]. When specifically looking at the difference between treatment completers and treatment dropouts, several factors were found that potentially predicted the dropout. These factors associated with the dropout were a lower education level, especially in combination with a female child gender, one-parent households, and internalizing problems for the mother [19,20]. Furthermore, a 3-year follow-up study showed that treatment completers reported substantially less child disruptive behavior and parenting stress than treatment dropouts [21]. It was also found that positive parenting skills increased more and negative parenting skills decreased more between pre and posttreatment when treatment was completed [19]. In addition, a crucial aspect of improving the parent-child relationship is parents using positive parenting skills [9] and skill practice was shown to be a good predictor for treatment outcomes [22]. Taken together, these studies infer that treatment should focus on increasing practice time for parents' skill use. This could in turn lead to better treatment outcomes, such as decreasing parenting stress and thereby dropout rates. With this in mind, this study strived to adapt PCIT in an attempt to increase skill practice at home. In other words, we attempted to tailor PCIT to the needs of this community-based clinical sample treatment receivers through creating an additional practice opportunity.

Adaptations to PCIT have previously been made with the common assumption that the treatment as is, did not fully extend to the needs of a target population, such as for clinical samples [23]. In addition, as there is a high attrition rate in community-based clinical samples, it is important to enlarge engagement opportunities for this target population and engage them in treatment right from the start. We know that positive treatment effects in PCIT can already be found if at least 4 treatment sessions are attended by families [17]. Accordingly, it could be helpful to prolong the effects of these sessions through, for example, a technological tool. In more recent years, digital adaptations, such as online PCIT and Pocket PCIT (ie, a web-based PCIT resource platform) have increasingly been used to better reach parents [12,24,25]. Pocket PCIT is a passive PCIT augmentation that provides an online and on-demand resource to families to practice CDI skills [24]. The first findings of Pocket PCIT indicated that the CDI phase was completed in fewer sessions when families had access to Pocket PCIT, although they did not complete the entire treatment in fewer sessions [12]. Moreover, parents were open to completing

XSL•FO
RenderX

additional homework in the form of Pocket PCIT, provided that the content was engaging, which indicates a high satisfaction rate with such a digital add-on [25]. Nonetheless, treatment-related outcomes such as child disruptive behavior and parenting stress did not differ significantly from standard PCIT, suggesting that there are only partial benefits gained from this on-demand resource [25]. This study wished to similarly create an add-on to PCIT that could be engaging for parents, but we decided to augment PCIT in a different way. As a way to enlarge treatment engagement through practice opportunity and potentially allow parents to achieve positive treatment effects sooner, this study sought to add virtual reality (VR) to PCIT [26]. VR can provide a sense of realness through immersion, which watching a video cannot. Therefore, practicing in VR would allow parents to not only be probed to think about the skills (similarly to previous digital add-ons), but it would also allow them to virtually experience using the skills [27].

In recent years, there has been an extreme increase in the use of VR in mental health care [28]. VR has been developed for new treatments but has also been used to boost or modernize treatments [29,30]. Among others, it has increasingly been implemented as a tool for internalizing problems in adults and children, such as the treatment of phobias, posttraumatic stress disorder, eating disorders, and anxiety disorders [31,32]. In these studies, VR has shown promising results with effect sizes varying from moderate to large [31,32]. Most commonly, VR has been used for exposure therapies and skills training [33]. Specifically, when VR was used as a skills trainer, a meta-analysis showed positive results in creating practice opportunities to increase knowledge-based skills [34]. Furthermore, a meta-analysis that supported the addition of VR to a variety of psychological treatments showed promising results and that it has the potential to support clinical populations [33]. In line with these findings, this study investigated the added value of VR to PCIT in a community-based clinical sample as a way to increase their practice opportunity [26].

Due to the novelty of the VR tool and the fact that PCIT is measurement-driven and a nontime limited intervention, we used a single-case experimental design (SCED) to assess the added value of VR to PCIT. Using an SCED to evaluate a novel tool has multiple advantages. First, it is perfect to use in clinical practice as it can take into account individual changes because it compares the participant with him or herself [35]. More specifically, this can help take into account the variation of problems that are seen in a highly specialized clinical mental health care sample. Second, in an SCED, there are repeated measurements of the independent variable for one individual in different treatment phases, instead of evaluating the independent variable by assigning multiple individuals to different treatment groups. Third, in addition to prepost measurement strategies, an SCED can extensively examine the impact of an intervention due to its repeated measurements approach, not only within an individual, but also through repetition across participants. This allows for an insight into how, why, and when change happens during the intervention, which is done both individually and on a group level [36].

Objective

Therefore, through this SCED study, we evaluated the added value of VR to PCIT. Aside from measuring the effectiveness of PCIT in a community-based clinical sample, we took a closer look at individual patterns and how the staggered introduction of VR could influence treatment-related outcomes. We expected that PCIT-VR would increase positive parenting skills at a faster pace and increase treatment engagement. This is because if parents practiced positive parenting skills in the VR tool, we hypothesized that their overall practice time would increase, which could consequently increase the pace of skill acquisition. Moreover, we expected that with the addition of the VR tool, the scope would be enlarged (eg, it could be beneficial for split families with separated parents), as it provided the opportunity to practice in the absence of their child. Furthermore, we hypothesized that due to the overall increase in positive parenting skills, PCIT treatment effects such as diminishment of child disruptive behavior and parenting stress would also decrease at a faster pace when VR was introduced. Finally, we expected that the effects of PCIT-VR would be further maintained and engrained in the long run due to the additional skill training provided by our VR tool.

Methods

The Single-Case Reporting Guideline in Behavioral Interventions (SCRIBE), 2016 was followed to explain the design, methodology, and the results of this study [37,38].

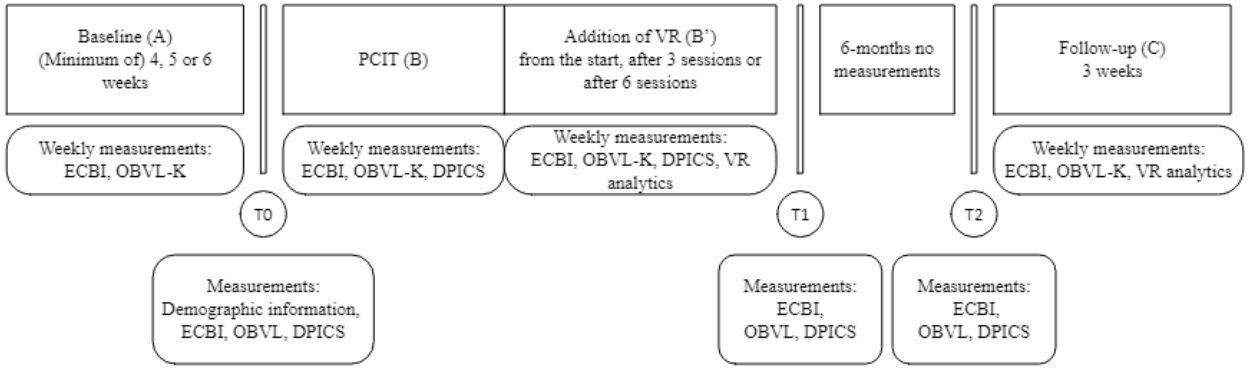
Design

Type of Design

A randomized, nonconcurrent, multiple-baseline SCED across single participants (Figure 1) was applied. Intersubject replication, with weekly repetition, was used in this study [37]. Participants completed weekly measurements during a baseline phase (phase A, a minimum of 4, 5, or 6 measurements), an intervention period (phase B [PCIT] and phase B' [PCIT with the addition of VR]), and a follow-up phase (phase C with 3 measurements) that took place 6 months posttreatment. Between phases, a more extensive measurement took place as a way to assess pretreatment, posttreatment, and follow-up group differences as well (Figure 1). Researchers, therapists, and participants were not blinded to any components of the study. Nobody was blinded because researchers had to administer the VR component at the correct time, therapists could refer to the VR component during treatment, and participants were allowed to know when they would receive the add-on.

XSL•FO
RenderX

Figure 1. Set up of the design with phases and measurements per phase. DPICS: Dyadic Parent-Child Interaction Coding System; ECBI: Eyberg Child Behavior Inventory; OBVL-K: Dutch Parenting Stress Questionnaire-shortened version (Opvoedingsbelastingvragenlijst-Kort); PCIT: Parent-Child Interaction Therapy; T0: pretreatment measurement; T1: posttreatment measurement; T2: follow-up measurement; VR: virtual reality.



Randomization

Participants were randomized twice at the start of the study (Figure 1). As the waitlist for the treatment typically varied between 4 to 12 weeks, participants were randomized to phase A (ie, baseline) for a minimum of 4, 5 or 6 weeks, which means a multiple baseline design was used. Participants were contacted for participation while on the waitlist to start treatment. In this study, participants never remained on the waitlist longer to finish phase A, meaning clinical practice was not obstructed. Moreover, to allow for random sequencing of the intervention phase, the reception of VR was also randomized. Participants received VR either straight away, after 3 sessions, or after 6 sessions. This way, we could assess the added value of VR as we expected to see a direct difference in treatment results when VR was added. This limited the possibility of change occurring due to maturation and we could most relevantly attribute change to VR. In other words, both the baseline and intervention randomizations were done to control for potential time-related confounders [39]. The randomization of phases A and B/B' was done by a noninvolved researcher from the department, who would let the researcher know what randomization the participants had received. Phase C was not randomized, as all participants were contacted 6 months after treatment.

Procedural Changes

The original study protocol stated that 15 children would be included [26]. However, due to factors such as the COVID-19 pandemic; attrition; and losing therapists to, for example, other jobs; we were unable to include 15 children who completed all measurements. However, with an SCED, the amount of data per phase (ie, at least 3 to 5 data points) per participant are more important than the number of participants, as participants are merely compared within themselves. This amount of data per phase were adhered to in most cases. Refer to the *Participants* section for the final inclusion number and number of data points per phase per participant.

Moreover, in the original study protocol, there were no weekly measurements incorporated in the follow-up phase; this phase originally consisted of 1 single follow-up measurement. However, the third author (SB), who has expertise in SCED analyses, suggested adding additional weekly measurements to be able to compare that phase with previous phases. Accordingly, an amendment was written and subsequently granted by the medical ethical committee. This meant participants who had previously joined the study were asked to sign another informed consent form if they agreed to have 3 additional weekly measurements in phase C after the single follow-up measurement (Figure 1).

Participants

Participants Characteristics and Selection Criteria

Participants were recruited from a specialized child and adolescent psychiatry clinical practice in the Netherlands, after being referred through community channels. For the full selection procedure, please consult the study protocol [26]. The inclusion criteria for the study were as follows: (1) child disruptive behavior problems were a reason for referral, (2) children were aged between 2 and 7 years old, and (3) parents spoke Dutch or English. Participants were excluded from participation if any of the following criteria were met: (1) a child had a severe physical impairment, such as deafness; (2) a child had a mental disability (IQ <60); (3) an unsafe home situation, where home displacement was indicated; (4) a child or parent with problems requiring personal health care, such as suicidality, or parents with aggression regulation or addiction problems; and (5) parents known to have severe problems with motion sickness.

In total, 23 participants were screened to participate, of which 20 (87%) were approached as they met inclusion criteria. A total of 18 (78%) parents of 11 children were willing to participate in the study. Participants signed informed consent after receiving verbal and written information about the study, and after being able to ask all questions regarding the study to the researchers. If there was no wish to participate in the study, families would receive treatment as usual (PCIT without the addition of VR). A total of 1 (11%) couple dropped out during baseline. In total, we obtained data from all phases from 6 (33%) participants. The remaining 10 (56%) participants missed data in at least 1 phase of a measurement point, but were included in the analyses, nonetheless. In the *Results* section, we will go into detail on reasons for dropout per family.

Context

Setting

The specialized child and adolescent psychiatry clinical practice in the Netherlands used in this study has multiple locations in

XSL•FO
RenderX

and around Amsterdam. Depending on where participants lived and what team they were referred to, they were in clinical care in 1 of 3 locations. Another option was that they received treatment in-home, which was the case for 3 (%) families. All sessions were conducted by certified PCIT therapists according to PCIT International criteria. All pretreatment, posttreatment, and follow-up observations were conducted in-home by the first author (ICAS), and all the questionnaires were obtained digitally.

Ethical Considerations

This study was approved by the independent medical ethics committee of the Academic Medical Center of Amsterdam, the Netherlands (2020_143/NL74210.018.20). Furthermore, the principles of the World Medical Association Declaration of Helsinki [40], and the Medical Research Involving Human Subjects Act were adhered to.

Written informed consent was obtained from participants before the study and participation was voluntary. Data were anonymized. Participants received no compensation for participation apart from being able to keep the VR headset placeholder.

Intervention

PCIT Treatment

PCIT is an evidence-based treatment for young children with disruptive behavior problems aged between 2 and 7 years and their parents [1,11]. During the treatment, which consists of 2 phases, parents are coached live by therapists from behind a one-way screen through an earpiece. In the first phase, the CDI phase, parents follow their child's play while being coached to use child-centered interaction skills. In this phase, parents are being taught to use positive parenting skills, which include labeled and unlabeled praises, reflections, and behavior descriptions, as this positively reinforces the behavior their child is displaying. Parents are also taught to limit using questions, commands, and criticisms, as this can negatively impact the parent-child interaction. Ultimately, using positive parenting skills and limiting unwanted verbalizations leads to an improvement in the parent-child relationship. The second phase, the PDI phase, is reached when parents achieve the set amount of child-centered verbal skills (statements including 10 labeled praises, 10 reflective statements, and 10 behavior descriptions, and no questions, commands, or criticisms). During the PDI phase, parents learn to set effective and safe limits for their children. They are taught to give effective commands and how to respond consistently to their child's compliance and noncompliance. This allows for their child's behavior to be structured in a developmentally appropriate way. The treatment requires for parents to practice "special time" with their children 5 minutes every day at home. PCIT does not have a set number of sessions, parents rather progress at their own pace and naturally reach a subsequent phase when meeting the required skill criteria.

VR Component

As an additional skill training tool, parents could practice with VR at home. The VR component consisted of prerecorded 360-degree videos that portrayed a child actor playing with PCIT-appropriate toys in a PCIT playroom. The video showed the child playing, after which the fragment stopped and called for the parents to respond to a multiple-choice question. An instruction video explaining how the VR environment worked was optionally available to watch before starting to practice. In a VR practice session, parents were posed statements so they could practice positive parenting skills taught in PCIT (ie, labeled praises, reflective statements, behavior descriptions, and ignoring unwanted behavior). An example was "Describe her behavior," for which they had 2 options to answer with, such as "You put the yellow block on the green block," or "Put the block on the tower." An answer would only be selected when the pointer circle visible in the VR environment would increase in size for 3 seconds, as a way to warn participants about their imminent selection. Moreover, the selection was based on head movement rather than eye movement. After having selected an answer, parents received feedback on their respective answers. In the aforementioned example, if they selected the first option, they would see the following feedback: "That was a good behavior description." If they selected the second option, they would see, "That was a command. Try to describe her behavior. For example, 'you put the yellow block on the green block.'" The video resumed to the next fragment showing the child playing. The more the parents selected the correct answers that depict a positive parenting skill, the less examples they were offered of that particular positive parenting skill. Parents received more elaborate feedback (such as in the aforementioned example) if they did not select correct answers. After parents saw a few different scenarios, they were encouraged to practice different positive parenting skills out loud, without receiving feedback on every possibility. A VR practice session lasted approximately 10 to 15 minutes, depending on the answers given by parents.

Measures and Materials

Measures

All primary measures were completed weekly. The Dyadic Parent-Child Interaction Coding System (DPICS) [41], the Eyberg Child Behavior Inventory (ECBI) [42,43], and the Dutch Parenting Stress Questionnaire [44] were also completed before treatment, after treatment, and at 6 months follow-up. All measures apart from the DPICS were digitally obtained via Castor Electronic Data Capture (Castor Research Inc), which is a secure data management platform [45]. Demographic information was filled out solely at pretreatment.

Demographic Information

Parents were required to fill out a questionnaire regarding background information about their child and his or her family. Information regarding sex, age, origin, family composition, parental work situation, and education level were included.

DPICS Tool

The DPICS [41] is a reliable and valid behavioral observation coding system. It evaluates the quality of the parent-child interactions by coding open verbal and physical behaviors of both parents and children. The following DPICS categories were used: labeled praise, unlabeled praise, reflection, behavior

XSL•FO
RenderX

description, question, direct command, indirect command, and negative talk. These were subsequently categorized into the following 2 categories for the CDI phase: "positive following," which consists of labeled praise, unlabeled praise, reflection, and behavior description, and "negative leading," which consists of question, direct command, indirect command, and negative talk. To code with the DPICS, researchers must be trained to be able to achieve an 80% agreement rate on scored behaviors. All observations were transcribed verbatim to monitor interrater reliability. In this study, there are 2 ways the DPICS was used. First, researchers used the DPICS during the pretreatment, posttreatment, and follow-up assessment. Here, coding was done through 3 standard 5-minute play situations (child-led play, parent-led play, and clean-up). There was an average of 86% agreement between coders. Second, therapists scored a weekly 5-minute standardized observation moment at the start of every CDI session to monitor skill acquisition.

VR User Analytics

Each parent received a personalized link that automatically registered their use and progress in VR. The number of times (per week) that VR was used was monitored by the first author (ICAS) through a secure platform.

ECBI Questionnaire

The ECBI [42] is a questionnaire that addresses child disruptive behavior for children aged 2 to 16 years and is filled out by parents. The ECBI consists of 2 scales—one measuring the frequency of the problem behavior (Intensity scale: 7-point scale from 1 [never] to 7 [always]) and another that records the extent to which parents experience the behavior as a problem (problem scale: yes or no). The psychometric properties of the Dutch-translated version of the ECBI are good [43,46]. The ECBI was filled out weekly, in addition to being filled out at pretreatment, posttreatment, and follow-up assessments.

Dutch Parenting Stress Questionnaire (Shortened Version)

The Dutch Parenting Stress Questionnaire (Opvoedingsbelasting vragenlijst-Kort [OBVL-K]) [44] contains 34 questions that address 5 aspects of parenting stress. These are problems in the parent-child relationship, problems in parenting, depressed moods, role restriction, and health complaints. The total parenting burden score is calculated with a T-score. The psychometric properties of the questionnaire are good [44]. In the shortened version of the OBVL (ie, OBVL-K), there are 10 questions about the different aspects of parenting that together give a total score on parenting burden. The OBVL-K is used to assess weekly parenting burden, whereas the normal version is used before treatment, after treatment, and at follow-up.

VR Equipment

A head-mounted display that can house a smartphone was bought for all participants [47]. This study chose to use 360-degree videos that could be played on a smartphone device. This meant that participants could place their device into the headset and look around 360 degree from a singular point in the virtual environment, which in technical terms refers to 3 degrees of freedom. In other words, users could move their heads in all directions, simulating a natural look around, but did not have the capability of moving in a direction within the virtual space. This form of VR was inexpensive, easy to use with a protected personalized weblink, and allowed participants to practice in the comfort of their own homes. The videos were streamed over a network and played on a web browser, which allowed almost all devices with access to internet to be able to run the content. The raw videos were edited into fragments with key events that showed a multiple-choice question at the end of each fragment. The answer was selected by looking at the answer box with a built-in eye bullet for 3 seconds. The fragments were given in a nonlinear sequence, determined by the user's responses. This was done in a web-based scenario editor created by ICAS, the fourth author (RGB), and bachelor and master students from technology-based studies [48-52]. Before inclusion, a small amount of preliminary work was done. The product was tested by therapists before full development and use. Nonetheless, this study is the first to explore the addition of VR to PCIT with clinical participants.

Procedural Fidelity

Adherence to the treatment procedure was accomplished using the standard PCIT protocol for treatment sessions. Furthermore, ICAS was responsible for sending weekly questionnaires, which could be automatically done electronically via Castor Electronic Data Capture. A data monitor appointed by the Amsterdam University Medical Center was appointed to monitor the process with 2 monitoring visits throughout the project. The observational parts of the pretreatment, posttreatment, and follow-up assessments were also planned and coordinated by ICAS with the families. Although they received weekly reminders to fill out the questionnaires and practice with VR, it was the parents' responsibility to do this at home.

Analyses

Overview

Visual inspection analyses and randomization tests were conducted on a shiny app Single Case Design website [53]. Other analyses were conducted via R Statistical Software (version 4.2.1; R Core Team 2022) and SPSS Statistics (version 28; IBM Corp) [54]. We split the analyses up into 2 parts. First, we assessed the treatment effects of PCIT. Second, we analyzed the effects VR had on treatment outcomes.

Primary Measures

To evaluate the effects of the treatment per person, we conducted visual inspection analyses per person for the ECBI, OBVL-K, and DPICS. We expected to find that scores would decrease on the total score of the ECBI Intensity Scale and the T-score of the OBVL-K over time. For the DPICS, we expected an increase in positive following and a decrease in negative leading over time. Second, to evaluate the effect of the intervention on ECBI Intensity Scale and OBVL-K scores, randomization tests were performed complementarily to statistically test the difference in means [55,56]. First, for each individual participant the effect size, Cohen *d*, was calculated. Next, 1000 random samples were drawn from the individual scores, and for each of these samples, the Cohen *d* was calculated. The *P* value for the individual was defined as the number of random samples that had an effect size Cohen *d* that was as large or larger than the observed Cohen *d*

XSL•FO
RenderX

divided by 1000. To calculate *P* value for the group, the sum of the individual *P* values was calculated. The *P* value for the group was defined as the probability of finding the sum of *P* values given that the H0 (null hypothesis) distribution where the individual *P* values were uniformly distributed between 0 and 1. We calculated the overall *P* value for both the entire group and for the group of treatment completers.

Furthermore, to assess the added value of VR, vertical lines indicating the start of when parents received the addition of VR were added in the visual inspection analyses of the DPICS. We expected to find that when VR was added to treatment, the next measured positive following score would be higher and the next measured negative leading score would be lower. Therefore, we evaluated the hypotheses that the mean and median difference score between positive following before and after the use of VR was positive, while the mean difference score between negative leading before and after the use of VR was negative.

Secondary Measures

We secondarily evaluated the mean group differences from pretreatment to posttreatment and to follow-up in the DPICS categories of positive following and negative leading through a nonparametric Wilcoxon signed rank test. Effect sizes were calculated with Cohen *d*. We expected to find that positive following would significantly increase from pretreatment to posttreatment and remain stable at follow-up. Similarly, we expected to find that negative leading would significantly decrease from pretreatment to posttreatment and remain stable at follow-up. To evaluate DPICS per person, we evaluated their raw scores from pretreatment to posttreatment and to follow-up. Furthermore, reliable change indices (RCIs) were calculated to illustrate the change in the total scores of the Intensity and Problem scales in the ECBI and the total T-score on the OBVL-K from pretreatment to posttreatment and to follow-up. We expected to find that all 3 would reliably diminish from pretreatment to posttreatment and remain stable at follow-up. We expected scores to be less than the clinical range at posttreatment and at follow-up.

Results

Overview

First, we described the sample population with demographics, description per family, treatment trajectory, and research participation. Second, we analyzed the primary measures through visual inspection analyses and randomization tests. Third, we reported the secondary measures from pretreatment to posttreatment and to follow-up. We examined group outcomes of PCIT to show the effectiveness of the treatment for this entire sample. We looked at how often parents practiced with VR and what their DPICS scores were. In addition, we assessed their ECBI and OBVL scores through RCI.

Demographic Sample Population

Overview

To gain an understanding of the sample characteristics, see Table 1 for the relevant demographic information per participant. Moreover, Multimedia Appendix 1 presents an overview of per participant at baseline and VR randomization, what measurements were completed, and how many measurements were missed per phase as per the SCRIBE guidelines [37,38]. No participants reported adverse events during the study.

Table 1. Participants' demographics showing gender, relationship, custody status, family income, and child's gender and age.

Participant	Parent gender (per participant)	Relationship status	Custody status	Family income (€ per month[a])	Child's gender	Child's age (y)
01[b]	Female	Single parent	Sole	1000-2000	Male	4
02 and 03	Male and female	Divorced	Shared	Participant 02: >5000; participant 03: 2000-3000	Female	5
04	Female	Divorced	Sole	1000-2000	Male	6
05 and 06	Male and female	Married	Shared	3000-4000	Male	3
09	Female	Single parent	Shared	4000-5000	Male	6
10[b] and 11[b]	Male and female	Cohabiting	Shared	<1000	Male	5
12[c]	Female	Single parent	Sole	<1000	Male	5
13[b] and 14[b]	Male and female	Married	Shared	4000-5000	Female	4
15 and 16	Male and female	Married	Shared	>5000	Female	2
17[d] and 18[d]	Male and female	Divorced	Shared	Unknown	Male	7

[a]€1=US $1.08 on average.

[b]Dropped out fully.

[c]Dropped out of intervention but remained in the study.

[d]The information collected from casefile due to missing pretreatment assessment.

XSL•FO
RenderX

Description of Each Participating Family

Reasons for referral and experiences with PCIT and VR are described per participant. All cases were referred for highly specialized clinical mental health care. Details of any family dropouts or significant events are also provided. Multimedia Appendix 1 supports the information for each trajectory.

Participant 01: a single mother who participated alone in the treatment with her 4-year-old boy. The child had contact with his father once a week and had 2 half-siblings that lived under the same roof. The mother had a history of psychiatric problems and was declared unfit to work. The child was clinically diagnosed with attention-deficit/hyperactivity disorder (ADHD), overall developmental delay, and parent-child relationship problems. Reason for referral was the child's disruptive behavior. He was impulsive, did not listen, and did not respond to punishment. The mother practiced with VR once, but indicated she was too tired to do it more often. The mother and child dropped out of treatment after 3 CDI sessions because it caused too much psychological burden and stress for the mother. She indicated willingness to be contacted for research purposes 6 months after treatment, but due to the child temporarily being placed out of home, no measurement took place. Due to dropping out, only descriptive and visual inspection was included from this family. They were excluded from pretreatment, posttreatment, and follow-up measurement analyses.

Participants 02 and 03: a divorced (with shared custody) father and mother participated together in treatment with their 5-year-old girl. The child, together with her sibling, alternated every 3 nights between her father and mother. The mother had a history of personal psychiatric problems for which she had been and still was in treatment. The child was clinically diagnosed with early relation-specific traumatic experiences, parent-child relationship problems (specifically with the mother), and disruptive behavior at home. These were also the reasons for referral. The father was positive about VR, although he experienced technological problems at first. The mother did not feel immersed in VR and stopped practicing with it due to that. Due to psychological stress, the mother only filled out questionnaires at the 6-month follow-up. Unfortunately, clinical DPICS scores were not registered for research purposes by the therapist and were therefore unavailable for this research project.

Participant 04: a single mother who participated alone in the treatment with her 6-year-old boy. Neither the mother nor the child had contact with the father. The child had no siblings. The mother had a history of psychiatric problems and had previously been in treatment. The child was clinically diagnosed with separation anxiety disorder (later in remission) and there were parent-child relationship problems. Reasons for referral were the diagnosed attachment problems and manipulative behavior of the child. They completed PCIT. The mother was positive about the results of PCIT and expressed VR helped her to constructively practice parenting skills. The therapist recorded 10 DPICS scores during the CDI phase and 2 DPICS scores during the PDI phase.

Participants 05 and 06: a married father and mother who participated together in treatment with their 3-year-old boy. The child had 1 sibling. The mother was recovering from burnout (ie, extreme physical and emotional exhaustion with mental health repercussions) at the start of the treatment. The father had a history of psychiatric problems for which he received treatment in the past. The child was clinically diagnosed with disruptive behavior and language delay. There were suspicions of autism spectrum disorder (ASD) and ADHD, but these were not officially diagnosed. The reason for referral was to lessen disruptive behavior and regain tranquility in the home environment. Upon completion of PCIT, the parents were positive about the results; their child's language had improved because of reflective statements and they saw that positive reinforcement helped in contact with their child. Both the parents practiced with VR, especially at the beginning of treatment. Later, they felt they gained more from practicing live. Due to the parents feeling overwhelmed with psychological care for their child, they only completed questionnaires at the 6-month follow-up. Unfortunately, clinical DPICS scores were not registered for research purposes by the therapist and were therefore unavailable for this research project.

Participants 07 and 08: while on the waitlist (baseline measurements, ie, phase A), the father and mother received intermediate psychological care for their child. This first caused PCIT to be postponed, and subsequently, it was concluded that PCIT was no longer necessary. No further information is known as they did not complete the T0 measurement. They will not be further discussed.

Participant 09: a single mother (with shared custody) participated alone in treatment with her 6-year-old boy. The father was aware and consented to the treatment, but did not want to fully commit. He participated in a few treatment sessions to gain an understanding of PCIT. The child was diagnosed early on with a genetic defect that could lead to neurological consequences. He was later clinically diagnosed with unspecified ADHD and unspecified intellectual disability. Originally, the child was referred by a pediatrician to diagnose ADHD and to treat it accordingly. Besides PCIT, the child also received medication (methylphenidate and melatonin) for his concentration problems. Upon completion of PCIT, the mother was positive about the reduced disruptive behavior and she was able to set effective limits for her child. She expressed that VR helped her to learn and practice the skills during the CDI phase, but that she missed the continuity of VR during the PDI phase. Unfortunately, clinical DPICS scores were not registered for research purposes by the therapist and were therefore unavailable for this research project.

Participants 10 and 11: a married father and mother participated in treatment together with their 5-year-old boy. The child had 2 half-siblings who he did not live with. The mother was simultaneously in treatment for personal psychological problems. The child was clinically diagnosed with ADHD combined type, a language delay, and there were parent-child relationship problems. The national institution that offers advice and support on matters concerning domestic violence and child abuse (in Dutch: "Veilig Thuis") was involved with this family due to reports of potential in-home violence. The reason for referral was to improve the parent-child relationship and to decrease behavior and parenting problems. The parents were

XSL•FO
RenderX

meant to receive VR but expressed that their burden and stress were too high to fit in time to practice with VR. They successfully completed the CDI phase of PCIT, but the intervention was temporarily paused. They did not restart PCIT due to experiencing a high psychological burden. No contact was achieved for T1 or T2. The therapist recorded 7 DPICS scores from the CDI phase. Due to dropping out, only descriptive and visual inspection was included from this family. They were excluded from pretreatment, posttreatment, and follow-up measurement analyses.

Participant 12: a single mother participated alone in treatment with her 5-year-old boy. The child was an only child and there was no contact with his father. The mother has a history of psychiatric problems for which she had been in treatment. During treatment, she was recovering from a recurring hernia. The child was clinically diagnosed with a disorganized attachment style, disruptive behavior, sleeping problems, and pica. The reason for the referral was to diagnose problem behavior and subsequently treat the respective diagnosed behavior with PCIT. The child had weekend foster care every 3 weeks. The mother and child dropped out of PCIT after a few CDI sessions, as the mother felt her child's behavior and their relationship had largely improved. Overall, the mother was positive about the treatment. She attempted practicing with VR but experienced nausea and dizziness. Even though she dropped out of treatment, she still completed both T1 and T2 measurements but did not want to complete the questionnaires in phase C anymore. The therapist recorded 5 DPICS scores from the CDI phase, with many weeks between sessions.

Participants 13 and 14: a married father and mother participated in treatment together with their 4-year-old girl. The father followed the treatment in Dutch and the mother in English due to her non-Dutch background. The father had a history of medical problems and substance abuse. The mother had psychological problems for which she started treatment during the PCIT trajectory. The child was clinically diagnosed with severe disruptive behavior, parent-child relationship problems, and parenting problems and there were suspicions of ASD. The child went to school 3 days a week upon request of the school due to hindrance from the disruptive behavior. They were referred to PCIT due to disruptive behavior at home and in school. The CDI phase was successfully completed (partially at home) and there were a few PDI sessions. The therapist recorded 5 DPICS scores from the CDI phase. The mother practiced with VR twice early on and said it helped her understand examples of how to use the skills. However, she later said it was not useful anymore. The father practiced once. Over the summer holidays, the child returned to their home country for 2 months, and PCIT was paused accordingly. In between, the parents were asked to practice with VR; however, they were unable to make time for this. PCIT was not restarted as they experienced enough improvement. Thus, they dropped out of treatment and the study. Due to drop out, only descriptive and visual inspection was included from this family. They were excluded from the pretreatment, posttreatment, and follow-up measurement analyses.

Participants 15 and 16: a married father and mother participated together in treatment with their 2-year-old girl. They received in-home PCIT. The parents experienced friction due to different views on parenting. The child had temper tantrums and exhibited crying fits and disruptive behavior. There were problems in the parent-child relationships. The reasons for referral were to lessen child disruptive behavior and parenting stress and the parents wished to improve their ability to react sensitively and responsively to their child. Upon completion of PCIT, they were positive about the results, although hesitant about some skills during the PDI phase. The father practiced a few times with VR but was not engaged in it. The mother was positive about practicing the skills in VR but found it difficult to make time for it. They both felt VR did not match their needs during the PDI phase. The therapist recorded 16 DPICS scores, all from the CDI phase.

Participants 17 and 18: a divorced father and mother participated together in treatment with their 7-year-old girl. The father was recovering from burnout and other psychological problems at the start of treatment. The mother had previously experienced burnout. The child was clinically diagnosed with ADHD, combined type, for which he received medication that was still being stabilized during the first few sessions of PCIT. There were parent-child relationship problems. Moreover, there were suspicions of oppositional defiance disorder and ASD. The child was referred for diagnostic assessment of oppositional defiance disorder and ASD and treatment for disruptive behavior. The parents originally did not want to participate in the study, but they did wish to practice with VR when their child was with the other parent. Upon completion of PCIT, the parents were positive about the results as the disruptive behavior decreased immensely, the child listened better, and parents were able to better understand their child. Moreover, both parents felt that the parent-child relationship had bettered during treatment. They mentioned that sudden changes or adaptations remained difficult for their child posttreatment. The father was positive about VR, although he experienced technological problems at first. The mother experienced nausea and dizziness when practicing in VR, so tried to do the videos on her phone without the head-mounted display headset. However, she did not feel it helped her and found the scenarios too simple. The parents were willing to participate in posttreatment and follow-up measurements and in phase C. The therapist recorded 11 DPICS scores, all from the CDI phase.

Primary Measures

Visual Inspection Analyses: VR, DPICS, ECBI, and OBVL-K

Multimedia Appendix 2 shows the visual inspection analyses per participant. In all figures, the horizontal axis represents the time in treatment expressed in weeks and the vertical lines represent the separation between subsequent phases and the addition of VR. Specifically, the gray line separates the baseline and CDI phase, the blue line separates the CDI and PDI phases, the purple line separates the PDI and follow-up phases, and the red dotted line represents the addition of VR. The visual inspection analysis of VR is shown for all participants except for participants 10 and 11 as they did not want to receive the addition of VR any longer. However, when they would have received VR is vertically presented. The visual inspection

XSL•FO
RenderX

analyses were only done for DPICS positive following and negative leading when DPICS scores were archived during treatment. This means that all participants except for participants 02, 03, 05, 06, and 09 were shown. We hypothesized that there would be a visible increase in positive following and a visible decrease in negative leading as soon as VR was introduced in treatment. For the ECBI and OBVL-K, visual inspection analyses were shown for all participants except for participant 14, as this participant did not fill out questionnaires due to the language barrier. We expected that the ECBI and OBVL-K would visually decrease over time, with a potential lag of 2 or 3 weeks behind the DPICS scores dependent on the respective increasing of positive following scores and decreasing negative leading scores.

Following visual inspection of the plots, little discernable change was apparent when looking at the moment VR was added to the treatment and the following DPICS scores. When examining the plots, participants 04, 17, and 18 appeared to show an increase in DPICS positive following scores when VR was added to treatment. Furthermore, participant 15 appeared to start using VR at around increment 10, and when looking at the DPICS positive following it appeared to increase at around the same time point. There was a visible upward trend in DPICS positive following (where everything >30 is considered good) for participants 04, 11, 12, 13, 14, 15, 16, 17, and 18. Participant 10 appeared not to show a steady pattern in DPICS positive following. There was also a visible downward trend in DPICS negative leading (where everything <5 is considered good) for participants 04, 10, 11, 12, 13, 14, 15, 16, and 18. No discernable change was visible for participant 17 in DPICS negative leading.

Following visual inspection of the plots for the ECBI, a visible decline in scores appeared for participants 01, 02, 03, 09, 12, 17, and 18. Participant 06 and 15 seemed to first decrease, but subsequently fluctuate in scores. There seemed no noteworthy changes in ECBI scores for participants 04, 05, 11, and 16. For participants 10 and 13, there appeared to be an increase in ECBI scores over time. No discernable change appeared between the use of VR and ECBI through visual inspection.

Following visual inspection of the plots for the OBVL-K, a visible decline in scores appeared for participants 01, 02, 06, 09, 12, 15, 17, and 18. The scores on the OBVL-K seemed to increase for participants 05, 10, and 13. There were no visible changes for participants 03, 04, 11, and 16 as scores seemed to remain stable or fluctuated a lot over time. No discernable change appeared between the use of VR and OBVL-K through visual inspection.

Randomization Tests: ECBI and OBVL-K

Table 2 shows the randomization tests of the ECBI Intensity Scale and the OBVL-K of all scores visible per participant in Multimedia Appendix 2. The effect size and individual *P* values are shown for both questionnaires. Only participants with at least 2 measurement points in phases A (baseline) and B (intervention) were included to assess treatment effects. This means that participants 17 and 18 were excluded as they did not participate in phase A.

The randomization test for the ECBI Intensity Scale revealed that there was no overall group significance in reports of child disruptive behavior for the entire group, nor solely for treatment completers. Only participant 09 showed a very large effect size complemented by a statistically significant decrease in reports of child disruptive behavior. Moreover, large or very large positive effect sizes were also found for participants 01, 02, 06, 11, 12, and 15, indicating that there were observed positive effects of their reports of child disruptive behavior, but these were not statistically significant. Nonetheless, this means that treatment positively impacted the reported levels of child disruptive behavior for a large number of participants. Participants 05 and 10 showed large to very large contratherapeutic effects in their reports of child disruptive behavior, although again not statistically significant. However, this means that for these 2 participants, their reports of child disruptive behavior were overall higher during the treatment phase than in the baseline phase, potentially due to amounting stressful circumstances described earlier.

The randomization test for the OBVL-K revealed that there were no overall group significance in reports of parenting stress. Again, participant 09 showed a very large effect size, complemented by a statistically significant decrease in parenting stress. Very large effect sizes were found for participants 06, 11, and 15, indicating that there were observed therapeutic effects of their reports of parenting stress, although these were not statistically significant. Nonetheless, this means that treatment positively impacted their reported levels of parenting stress. Participant 10 (who dropped out) demonstrated a nonsignificant very large contratherapeutic effect size in his reports of parenting stress, meaning that his parenting stress was higher during the treatment phase than in the baseline phase, potentially due to amounting stressful circumstances described earlier.

XSL•FO
RenderX

Table 2. Randomization tests per participant showing effect size and significance of the Eyberg Child Behavior Inventory (ECBI) Intensity Scale and the Dutch Parenting Stress Questionnaire, shortened version (Opvoedingsbelasting vragenlijst-Kort; OBVL-K).

Participant	ECBI Intensity Scale		OBVL-K	
	Cohen *d*	*P* value	Cohen *d*	*P* value
01[a]	3.59[b]	.84	3.59[c]	.82
02	0.80[d,e,f]	.20	0.69	.15
03	0.394	.68	0.48	.49
04	0.002	.50	0.06	.46
05	−0.925[d,e,f]	.92	−0.47	.81
06	1.44[c]	.24	1.60[c]	.14
09	1.36[c]	.001[g]	1.39[c]	.001[e]
10[a]	−2.17[b]	.10	−1.77[c]	.10
11[a]	1.74[c]	.18	1.76[c]	.07
12[h]	0.86[d,e,f]	.25	0.88[d,e,f]	.13
13[a]	0.20	.48	0.217	.43
15	2.04[b]	.27	2.04[b]	.20
16	0.49	.28	0.32	.32
Treatment completers	__[i]	.14	—	.14
Total	—	.27	—	.24

[a]Dropped out fully.

[b]Cohen *d* effect size: huge=2.00.

[c]Cohen *d* effect size: very large=1.20.

[d]Cohen *d* effect size:large=0.80.

[e]Cohen *d* effect size:medium=0.50.

[f]Cohen *d* effect size*:* very small=0.01 to small=0.20

[g]Significance at <.05.

[h]Dropped out of intervention but remained in study.

[i]Not applicable.

Virtual Reality

To investigate whether there was a visible effect in the use of parenting skills from one PCIT session to the next when parents used VR, we subtracted the number of tallied skills in a session from its previous session. As parents need to achieve a preestablished amount of positive parent skills, including 10 labeled praises, 10 behavior descriptions, and 10 reflections, we corrected for 30 tallied skills. This means that any number >30, was considered the same. All participants who had practiced with VR between 2 PCIT sessions, and where DPICS scores during the 5-minute observation at the start of both sessions were available, are included in Table 3. This table reflects how practicing with VR in between sessions contributes to the positive following and negative leading scores of parents. As DPICS scores were archived from varying sessions and parents practiced at varying moments in time, this table does not provide information regarding specific sessions and the effects of VR on those sessions. It does consider the number of times practiced between 2 sessions. Both the mean and median are shown. The median is more sensitive to outliers, which made it a more cautious analysis.

Table 3 shows that when parents used VR, all their negative leading scores decreased from one session to the next, both when looking at the median difference and the mean difference. In addition, only for 2 parents, the positive following skills increased from one session to the next when VR was used. This suggests that when parents practiced with VR in between sessions, it especially led to a decreased use of negative leading statements in the following session.

XSL•FO
RenderX

Table 3. Median and mean difference in positive following and negative leading skills from one session to the next when virtual reality was used in between sessions[a].

Participant	Median difference		Mean difference	
	Positive following	Negative leading	Positive following	Negative leading
04	7.00	0.00	3.00	−0.56
15	−14.50	−5.00	−9.00	−6.75
16	0.00	−2.00	−6.33	−0.33
17	0.00	−1.50	−1.13	−1.30
18	4.00	−2.00	4.00	−1.75

[a]Positive following is supposed to increase for wanted change to occur, and negative leading is supposed to decrease for wanted change to occur.

Secondary Measures

DPICS Group Outcomes

As the sample was too small to perform *t* tests, a nonparametric test (the Wilcoxon signed rank test) was performed to illustrate the changes in positive following and negative leading during the CDI phase according to the DPICS from pretreatment to posttreatment and follow-up (Table 4). Effect sizes were demonstrated with Cohen *d* [57].

Significant effects were found both in positive following and in negative leading from pretreatment to posttreatment, and from pretreatment to follow-up. No significant effects were found from posttreatment to follow-up. There was a general increase in mean in the use of positive following skills and a general decrease in the use of negative leading statements. Moreover, the effect sizes according to Cohen *d* indicated very large effects from pretreatment to posttreatment and from pretreatment to follow-up for positive following, as well as very large effect size for pretreatment to follow-up in negative leading.

Table 4. Changes in positive following and negative leading during the child-directed interaction phase in pretreatment, posttreatment, and follow-up measurements for parents who completed Parent-Child Interaction Therapy[a].

Measurements	Sample size, n	Wilcoxon signed rank test, mean (SD; range)	*P* value	Cohen *d*
Positive following				
T0[b]	9	5.11 (5.64; 0-18)	T0 to T1[c]=.01[d]	T0 to T1=1.84[e]
T1	10	32.10 (22.87; 11-89)	T0 to T2[f]=.04[d]	T0 to T2=2.96[e]
T2	7	32.00 (13.49; 13-51)	T1 to T2=.40	T1 to T2=0.01
Negative leading				
T0	9	30.44 (15.06; 5-56)	T0 to T1=.05[d]	T0 to T1=1.02[g,h,i]
T1	10	14.40 (16.41; 0-57)	T0 to T2=.04[d]	T0 to T2=2.27[e]
T2	7	6.43 (4.86; 1-15)	T1 to T2=.06	T1 to T2=0.68

[a]Positive following must increase and negative leading must decrease for wanted change to have occurred.

[b]T0: pretreatment measurement.

[c]T1: posttreatment measurement.

[d]Significance at <.05.

[e]Cohen *d* effect size: very large=1.20.

[f]T2: follow-up measurement.

[g]Cohen *d* effect size: large=0.80.

[h]Cohen *d* effect size: medium=0.50.

[i]Cohen *d* effect size: very small=0.01 to small=0.20.

VR, DPICS, and RCIs for ECBI and OBVL

To illustrate the number of times participants practiced with VR and whether this affected the primary outcomes of positive parenting skills, child disruptive behavior, and parenting stress, we examined the raw scores per person. Reliable change was not calculated for the DPICS, because there was not enough published information for the calculation of reliable change. Therefore, we have merely shown the raw scores of positive following and negative leading per measurement point. As this is a clinical sample, we deemed it important to show raw total scores and demonstrate whether or not participants fell into the clinical range at different time points (Multimedia Appendix 3; Table 5). To further illustrate changes in child disruptive behavior and parenting stress, we also performed RCIs (Table 6). We only included the participants who had completed ≥2

XSL•FO
RenderX

measurement points, which meant that participants who had dropped out of treatment and the study were not included (ie, participants 01, 10, 11, 13, and 14).

To assess whether there were differences on the DPICS, ECBI, and OBVL scores when VR was practiced, we split the group in 2 based on the median use of VR in the group. The median of practicing with VR was 6. Therefore, we split the group into participants who practiced with VR 6 or less times (group A) and who practiced with VR 7 or more times (group B; Tables 5 and 6). With this, we provided preliminary observations regarding practice time and treatment outcomes, but more evidence is necessary to draw any conclusions on relations with one another, as other factors may also have been of influence.

First, we observed that 3 of the 5 (60%) participants from group A did not participate in the follow-up measurement, whereas all participants from group B participated in posttreatment and follow-up. Second, results show that group A started with higher scores in positive following and negative leading than group B. Group A consistently scored higher in positive following than group B, but only group B showed progression in positive following from posttreatment to follow-up. However, for negative leading, group B showed lower scores on pretreatment and posttreatment than group A. Both groups decreased in negative leading from posttreatment to follow-up. Third, group A also started with higher reports on the ECBI Intensity Scale than group B and only group B had all scores less than the clinical cutoff score at posttreatment and at follow-up. Fourth, although group B started with a higher overall score on the ECBI Problem Scale, they diminished more than group B and remained below the clinical cutoff score at posttreatment and follow-up. Fifth, group A showed higher reports of total parenting stress in all 3 measurement points than group B. Overall, we observed more improvement for group B than for group A in child disruptive behavior and parenting stress, but group A applied more parenting skills than group B.

These results show that there are little discernable differences in terms of reliable change for the ECBI scales when splitting the group in 2 based on the median VR use. A total of 4 of 11 (36%) parents experienced a reliable change from pretreatment to posttreatment on the ECBI Intensity Scale. Two parents (both who practiced with VR >6 times) maintained that significant change at follow-up as well. For the ECBI Problem Scale, we observed that there were 6 (55%) parents with a reliable change from pretreatment to follow-up. Participant 16 experienced an increase in problems, which indicated contratherapeutic treatment effects. We were privy to the information that the child had experienced impetigo and chicken pox in the weeks before filling out the questionnaires, thus elevating her disruptive behavior, which could have influenced parent's reports. Participant 06 also experienced a deterioration from posttreatment to follow-up. Participants 02, 09, and 12 had reliable changes from pretreatment to follow-up and participant 02 also showed a large reliable change from posttreatment to follow-up, indicating that the treatment seemed to continue its effects.

For the OBVL, we observed that in the group that practiced with VR <6 times, all parents experienced a large significant change in parenting stress from pretreatment to follow-up. Participant 06 showed a significant negative reliable change from posttreatment to follow-up, indicating deterioration. This is in line with the fact that parents were unable to make time for the observation at follow-up, due to increased psychological burden at that moment in time. Her partner, participant 05, although not significantly changed, reported even higher levels of parenting stress at follow-up than participant 06. In the group that practiced with VR >6 times, all participants showed a reliable change from pretreatment to follow-up, except participant 04 who experienced contratherapeutic treatment effects. As mentioned before, participant 04 started working full time at the end of treatment and expressed feeling parenting stress as a result. Although participant 18 showed a negative reliable change from posttreatment to follow-up, the parent gave us relevant information that could have influenced the change index. Namely, in the specific week that the questionnaires were filled out, 3 family members had celebrated their birthdays, which meant that the normal routine had been disturbed. The parent expressed that her child was tired and irritable as a result, which in her eyes, was not representative of the months posttreatment.

XSL•FO
RenderX

Table 5. The total number of times practiced with virtual reality (VR) and the raw scores in pretreatment, posttreatment, and follow-up measurements in the Dyadic Parent-Child Coding System (DPICS), Eyberg Child Behavior Inventory (ECBI), and Opvoedingsbelasting vragenlijst (OBVL) per participant.

Participant	VR	DPICS						ECBI						OBVL		
	Total	Positive following[a]			Negative leading[b]			Intensity scale			Problem scale			Total parenting stress		
		T0[c]	T1[d]	T2[e]	T0	T1	T2	T0	T1	T2	T0	T1	T2	T0	T1	T2
VR practice group A (practiced with VR ≤6 times)																
03	4	3	89	—[f]	14	0	—	140	143	132	17	20	21	72	68	66
05	3	10	23	—	41	57	—	159	161	131	18	22	5[g]	79	79	75
06	3	6	28	—	36	19	—	155	109[g]	150	16	1[g]	14	75	55[g]	66
15	4	0	11	36	32	12	8	165	115[g]	129[g]	20	0[g]	0[g]	63	53[g]	48[g]
16	5	18	51	37	56	10	1	137	124[g]	135	15	1[g]	20	77	76	72
VR practice group B (practiced with VR ≥7 times)																
02	7	2	24	51	5	3	3	117[g]	63[g]	62[g]	29	20	0[g]	56[g]	54[g]	48[g]
04	24	2	17	24	30	8	10	123[g]	119[g]	131	13	17	18	72	72	76
09	14	2	35	43	37	22	15	145	128[g]	128[g]	21	7[g]	2[g]	70	68	66
12[h]	7	3	3	1	51	18	18	164	88[g]	87[g]	19	6[g]	7[g]	72	53[g]	51[g]
17	24	—	26	13	—	6	4	—	52[g]	51[g]	—	0[g]	0[g]	—	58[g]	50[g]
18	8	—	17	20	—	7	4	—	78[g]	101[g]	—	0[g]	2[g]	—	49[g]	59[g]

[a]Positive following must increase.

[b]Negative leading must decrease.

[c]T0: pretreatment.

[d]T1: posttreatment.

[e]T2: follow-up.

[f]Not applicable.

[g]Raw scores below the clinical range (ECBI Intensity Scale <60; OBVL total T score <60).

[h]Dropped out of intervention but remained in study.

XSL•FO
RenderX

Table 6. Reliable change indices for the Eyberg Child Behavior Inventory (ECBI) and the Opvoedingsbelastingvragenlijst (OBVL) from pretreatment to posttreatment and to follow-up per participant.

Participants	ECBI Intensity Scale			ECBI Problem Scale			OBVL Total Parenting Stress		
	T0[a] to T1[b]	T0 to T2[c]	T1 to T2	T0 to T1	T0 to T2	T1 to T2	T0 to T1	T0 to T2	T1 to T2
VR[d] practice group A (practiced with VR ≤6 times)									
03	−0.14	0.37	0.50	−0.64	−0.85	−0.21	2.44[e]	3.66[e]	1.22
05	−0.09	1.29	1.38	−0.85	2.77[e]	3.62[e]	0.00	2.38[e]	2.38[e]
06	2.11[e]	0.23	−1.88	3.20[e]	0.43	−2.77[e]	11.90[e]	5.36[e]	−6.55[d]
15	2.29[e]	7.57[e]	5.28[e]	4.26[e]	4.26[e]	0.00	5.95[e]	8.93[e]	2.98[e]
16	0.60	0.09	−0.50	−0.43	−25.57[e]	−25.14[e]	0.60	2.98[e]	2.38[e]
VR practice group B (practiced with VR ≥7 times)									
02	2.48[e]	2.52[e]	0.05	1.92	6.18[e]	4.26[e]	1.22	4.88[e]	3.66[e]
04	0.18	−0.37	−0.55	−0.85	−1.07	−0.21	0.00	−2.44[e]	−2.44[e]
09	0.78	0.78	0.00	2.98[e]	4.05[e]	1.07	1.22	2.44[e]	1.22
12	3.49[e]	3.53[e]	0.05	2.77[e]	2.56[e]	−0.21	11.59[e]	12.80[e]	1.22
17	—[f]	—	0.05	—	—	0.00	—	—	4.88[e]
18	—	—	−1.06	—	—	0.43	—	—	−6.10[e]

[a]T0: pretreatment.

[b]T1: posttreatment.

[c]T2: follow-up.

[d]VR: virtual reality.

[e]Significant reliable change indices (RCI) values (ECBI RCI ≥1.96 or RCI ≤−1.96; OBVL RCI ≥1.645 and RCI ≤−1.645).

[f]Not available.

Discussion

Principal Findings

We experimentally examined the staggered addition of VR to PCIT with parents who followed treatment with their child who displayed child disruptive behavior. Our findings are presented in an SCED study on PCIT-VR in a community-based clinical sample. As this was the first time that VR was used supplementary to PCIT, we sought to give initial insights into the added value of this skill practice tool, and we examined the effects of additional practice time in VR and other treatment-related outcomes. Accordingly, we expected that the introduction of VR would increase positive parenting skills at a faster pace, and that this increase would subsequently lead to a faster diminishment of child disruptive behavior and parenting stress. This was partially confirmed as the relationship between practicing in VR and treatment-related outcomes varied among participants. Some participants seemed to benefit from the addition of VR, whereas it did not seem to impact treatment-related outcomes for other participants. We discuss the most important individual and group findings subsequently, after which we review strengths and limitations of the study and suggest future directions for research. Finally, we discuss clinical implications and conclude our findings.

With regards to the visual inspection plots and randomization tests, we found that overall, there did not seem to be a clear relationship between the use of the VR tool and PCIT treatment effects, as positive parenting skills did not noticeably change when VR was added in most of the cases. However, in 3 cases, positive parenting skills visibly seemed to increase when VR was introduced to treatment. This was confirmed through median and mean differences in skills between 2 sessions. Specifically, our study demonstrated that there seemed to be meaningful differences for more parents in changes in negative leading statements (ie, questions, commands, and negative talk) than in positive parenting skills (eg, labeled praises, reflective statements, and behavioral descriptions). Although our VR tool specifically targeted scenarios aimed at practicing positive parenting skills, some scenarios also targeted practicing ignoring unwanted behavior, while using positive parenting skills to re-engage the child in play. Although there is no clear reasoning behind why practicing in VR seemed to be associated more with decreased questions and commands in the following session, we can venture a guess as to why this pattern emerged. When parenting skills were sequenced, visible changes in increased positive parenting skills and decreased negative leading statements were seen during treatment sessions in a study by Hakman et al [58]. That study attributed this change to therapists providing immediate feedback to the parent to appropriately respond to child behaviors, and the therapist being able to tailor

XSL•FO
RenderX

the application of skills when problems arose during sessions. That described mechanism of feedback and tailoring responses is incorporated into our VR tool. Parents receive immediate positive feedback for correctly choosing to use positive skills and receive suggestions for alternative skill application when choosing to use questions and commands. Therefore, although they may not yet be fully proficient in applying positive parenting skills, practicing in VR may have given them enough alternatives to negative leading statements to limit those in the following sessions. While this was an incidental finding, we deem it an important benefit that pleads for practicing in VR as we know that negative parenting strategies can increase or maintain child disruptive behavior and other adverse outcomes [59].

Considering the number of missing questionnaires from parents and the amount of times VR was practiced with, our results indicate that the effect of VR may potentially be dependent on the level of engagement from parents in treatment. Parents who filled out >70% of questionnaires and did not drop out of either the treatment or the study, seemed to practice with VR more. This insinuates that when families have the drive, motivation, and capacity to change, in addition to having the mental space to take on the responsibility of change, they seem to take accountability for that change to happen. In other words, when they feel accountable for change, they do everything in their power, including increasing their practice time through VR, for the desired change to happen. This finding emphasizes treatment engagement of parents, which is considered an important predictor for treatment success [60]. In line with our study, previous research showed that lower income and high levels of parental stress were associated with lower treatment engagement [61,62]. Moreover, the more engaged parents were in treatment, the lower the child's disruptive behavior was at posttreatment and the more parents expressed understanding skills and how to use them appropriately [61]. In addition, Pocket PCIT found that treatment engagement was stimulated through their web-based resource platform for parents and they suggested this as a point of interest for future research [24]. Although we attempted to enhance treatment engagement through practicing with skills in VR, it may be that when the psychological burden is too high, parents are unable to benefit enough from the additional services offered to them. Another possibility is that due to the use of 360-degree videos and thus creating a 3-degree of freedom virtual environment, VR may not have been engaging enough for some participants who had previous experiences with VR. Where VR could have been perceived as an engaging way to practice skills, the static storyline could have quickly led to boredom [63]. This, in turn, could have led to less practice time in the virtual environment. Taken together, we believe that the VR practice could potentially work best as a suggested additional practice tool tailored to the needs, capacity, and motivation of individuals, rather than a mandatory addition to treatment.

We did not uncover conclusive changes between practicing with VR and child disruptive behavior, nor between practicing with VR and parenting stress, although therapeutic trends are visible in parenting skills, child disruptive behavior, and parenting stress. These were complemented by large effect sizes after receiving PCIT in most (n/N, %) cases. One parent, who had dropped out before treatment completion, showed contra therapeutic treatment-related outcomes, where both child disruptive behavior and parenting stress increased over time. These individual changes were also confirmed in the pretreatment, posttreatment, and follow-up measurements. Here, we found significant changes in increased positive parenting skills and decreased questions and commands from pretreatment to posttreatment as well as from pretreatment to follow-up for treatment completers. These were again complemented by very large effect sizes for receiving PCIT (-VR) in general. Our findings are in line with treatment effects found in other PCIT studies, including findings from a study in a similar Dutch community-based clinical sample [1,13,64]. This suggests that, regardless of the addition of VR, PCIT had the wanted therapeutic effects on the children and parents from this community-based clinical sample.

Furthermore, reliable decreases were found in parenting stress for all but 1 of the 11 (91%) treatment completers from pretreatment to follow-up, regardless of the number of times they had practiced with VR. This means that parenting stress decreased for all parents in our sample because of following PCIT (-VR). There was variability in reliable decreases of child disruptive behavior from pretreatment to posttreatment and to follow-up, where 5 (45%) parents reported reliable decreases from pretreatment to follow-up, and 1 (9%) parent reported a reliable increase, which was contra-therapeutic. Moreover, the participants who practiced with VR >6 times, reported their child's disruptive behavior to be below the clinical range at posttreatment, and all but 1 (83%) participant (who scored 131) remained below the clinical range at follow-up. This means that PCIT positively affected child disruptive behavior, but when VR was practiced along with it more than 6 times, the child disruptive behavior remained manageable at follow-up. These results were in line with treatment protocol because when positive parenting skills are correctly implemented, treatment-related outcomes such as child disruptive behavior should also decrease [11]. Although no group comparisons were statistically made and we must be very careful with this interpretation, participants that practiced with VR <6 times had higher initial reports of child disruptive behavior and parenting stress, and remained higher at posttreatment and follow-up, which could suggest that these participants represented more complex problems. When there are more complex problems, families in community-based samples are known to have lower homework completion rates, which is postulated to be related to barriers such as high levels of stress and busy schedules [19,65]. This confirms the trends seen in the individual outcomes, where treatment engagement may be contingent on the complexity of problems and their (mental) capacity. These findings suggest that the VR practice tool may not be the solution to engage these specific families in PCIT. This group might, for example, benefit more from other types of additional care, such as financial aid, to reduce life stressors. Moreover, more research is warranted to confirm the speculatory relationship between the complexity of problems and less practice time in VR.

XSL•FO
RenderX

Furthermore, we can see that skill acquisition largely increased at posttreatment and follow-up when VR was practiced >6 times. This is in line with the deliberate practice theory, which states that additional practice time can contribute to increased skill learning [66-68]. However, we cannot attribute this solely to practicing in VR, as parents who practiced <6 times with VR equally showed large increases in skills at posttreatment and follow-up. Moreover, PCIT is already known to stimulate increases in skill acquisition [1]. It is possible that the increased practice time in VR led to increased confidence in parenting in general, which was suggested by qualitative findings in PCIT-VR, which was a part of the study but published as a separate qualitative paper [63]. This implies that practicing parenting skills and receiving feedback in VR may have been beneficial for the confidence in skill application of these parents, which was reflected in showing more lasting treatment outcomes than the participants that practiced less with VR. Consequently, we believe that tailoring VR to the needs of parents could be of clinical relevance in PCIT because some parents from our sample visibly benefited from the additional practice time.

Strengths, Limitations, and Future Directions

This study allowed us to take an in-depth look at the varying change trajectories in the treatment-related outcomes in PCIT, while also investigating the novel VR practice tool. We uncovered interesting trends that demonstrated the complexity of a community-based clinical sample. Moreover, through VR, split families received an opportunity to practice in-treatment taught skills without the presence of their child. In our sample, we had 4 (participants for whom this was relevant and who profited from this. This was facilitated by the strong design that an SCED provides, as we could individually follow both parents and report their progress separately, but simultaneously. In addition, the simplicity of our VR tool with 360 degrees videos readily available on a personal smartphone meant that it was very accessible and easy to use. These points highlight the potential of VR to be tailored to an individual's needs, and that it could be implemented as an optional skill strengthener when necessary.

Although this study provides valuable initial insights into the added value of VR to PCIT, there are some limitations that must be addressed. We must first acknowledge that because of using an SCED design, parents were required to fill out weekly questionnaires at home, in their own time, rather than in the PCIT room before the start of treatment. Although this meant that we had data about child disruptive behavior and parenting stress from weeks that sessions did not take place, it also meant that this could be seen as additional homework by parents. In other words, on top of giving them additional practice time through VR, they may have felt that the weekly SCED questionnaires were an additional task or burden as well. This could potentially have influenced their practice time, because if they were short on time, they may have picked questionnaires over VR practice time. Moreover, we know that homework completion rates are already lower in community-based clinical samples [19,65], so adding questionnaires as a task may have impacted practice time, albeit live or in VR.

Another limitation was that a lot of DPICS data were missing in our sample due to archiving problems. Therefore, although we can very carefully draw conclusions about the effects practicing in VR had on treatment, we cannot say that it was the case for our entire sample, as we do not know. As mentioned, there seemed to be a trend that indicated that the more dedicated parents were to fill out questionnaires, which was translated into fewer missed values, the more they seemed to practice with VR. However, we missed DPICS data from some of these participants too (eg, participants 02 and 09). It would have been interesting to be able to report their change in positive following skills and negative leading behavior alongside VR as well. In the future, a better system for archiving DPICS data should be implemented.

Finally, this study had originally planned to evaluate the staggered addition of VR at the start of treatment, after 3 sessions or after 6 sessions. While the idea of such a design was strong, as we would be able to attribute changes in treatment outcomes on VR and not because of maturation, we were unable to include enough participants to be able to say anything on this in this study. Nonetheless, qualitative findings of PCIT-VR suggested that parents found particular added value in using VR at the start of treatment, as it provided them with a visual learning opportunity that complimented the verbal instructions from therapists. It also gave them examples of how to use specific skills, which they found helpful to apply to special time with their child [63]. With this knowledge, we believe in the potential VR has as a complementary tool to the instruction session. Therefore, it would be valuable to offer VR from the start for parents. A follow-up study with a similar design where DPICS scores are archived could help us confirm the initial suggestions that VR could help improve treatment outcomes.

Conclusions

First, our study provides additional evidence that PCIT in a community-based clinical sample results in positive treatment effects. Moreover, we gave valuable first insights into the added value of VR to PCIT. Although this study alone does not provide strong enough evidence to clearly state that there was added value of VR to PCIT, we believe that there are interesting trends that plead for a further investigation into PCIT-VR. These findings tentatively suggest that practicing with VR could potentially increase positive parenting skills, and it could potentially also have an impact on other treatment-related outcomes, such as child disruptive behavior and parenting stress. However, individual differences, such as treatment engagement, accountability, capacity for change, and complexity of problems, may play a role both in the number of times VR was practiced with over the course of the treatment and on individual treatment effects. In other words, creating a practical add-on for such a clinical target population is beneficial if it fits their respective complex and stressful lives, as this increases the chances of them being (able to be) engaged, and thus achieving treatment success. Overall, we can preliminarily suggest that VR could be of added value to PCIT to increase confidence in parenting skills for certain parents, while simultaneously considering complex factors that play into treatment success.

XSL•FO
RenderX

Acknowledgments

This research was funded by a grant from the Dutch Ministry of Health, Welfare, and Sport (in Dutch: Ministerie van Volksgezondheid, Welzijn en Sport). Information regarding the project funding can be found in the Amsterdam Medical Center, Amsterdam Medical Research B.V. (code 23378). The funding body had no role in the process of the study. In addition, the study protocol has not undergone peer review by the funding body.

The authors would like to thank all parents, children, and therapists who participated in the study. They would also like to thank the students who helped create the virtual reality tool and the students who helped code the Dyadic Parent-Child Interaction Coding System.

Data Availability

The datasets generated and analyzed during this study are not publicly available to protect the privacy of the participants and follow ethical guidelines, but they are available from the corresponding author on reasonable request.

Authors' Contributions

ICAS participated in conceptualization, data curation, data analysis, and writing the original draft, as well as reviewing and editing. MEA contributed to supervision and writing, major reviewing, and editing the manuscript. SB participated in the single-case experimental design experience; data analysis; and writing, reviewing, and editing the manuscript. RGB contributed to the virtual reality experience as well as writing, reviewing, and editing. AP was responsible for reviewing and editing. RJLL was responsible for funding acquisition and supervision, as well as reviewing and editing. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Number of measurements completed and missing per participant per phase.
[DOCX File , 28 KB - pediatrics_v8i1e60752_app1.docx]

Multimedia Appendix 2
Visual inspection analysis for all participants.
[DOCX File , 1719 KB - pediatrics_v8i1e60752_app2.docx]

Multimedia Appendix 3
The total number of times practiced with virtual reality and the raw scores in pretreatment, posttreatment, and follow-up measurements in the Dyadic Parent-Child Interaction Coding System, Eyberg Child Behavior Inventory, and the Dutch Parenting Stress Questionnaire per participant.
[DOCX File , 27 KB - pediatrics_v8i1e60752_app3.docx]

References

1. Thomas R, Abell B, Webb HJ, Avdagic E, Zimmer-Gembeck M. Parent-child interaction therapy: a meta-analysis. Pediatrics 2017 Sep;140(3):20. [doi: 10.1542/peds.2017-0352] [Medline: 28860132]
2. Thomas R, Zimmer-Gembeck MJ. Behavioral outcomes of parent-child interaction therapy and triple p-positive parenting program: a review and meta-analysis. J Abnorm Child Psychol 2007 Jun 27;35(3):475-495. [doi: 10.1007/s10802-007-9104-9] [Medline: 17333363]
3. Bodden DH, Deković M. Multiproblem families referred to youth mental health: what's in a name? Fam Process 2016 Mar 07;55(1):31-47. [doi: 10.1111/famp.12144] [Medline: 25754003]
4. Overbeek MM, Gudde LM, Rijnberk C, Hempel R, Beijer D, Maras A. Multi‐problem families in intensive specialised multi‐family therapy: theoretical description and case study report. J Fam Ther 2021 Jan 10;45(1):81-93. [doi: 10.1111/1467-6427.12320]
5. Bronfenbrenner U. Ecological models of human development. In: Gauvain M, Cole M, editors. International Encyclopedia of Education. 2nd edition. Oxford, UK: Eburon Academic Publishers; 1994:37-43.
6. Bandura A. Social-learning theory of identificatory processes. In: Grusec JE, Hastings PD, editors. Handbook of Socialization Theory and Research. New York, NY: The Guilford Press; 1969:213-262.
7. Krishnan V. Early child development: a conceptual model. In: Proceedings of the 2010 Annual Conference on Childhood Council. 2010 Presented at: CCAC '10; May 7-9, 2010; Christchurch, New Zealand p. 2-17 URL: https://tinyurl.com/5d6ykxtj

XSL•FO
RenderX

8. Pesonen A, Räikkönen K, Heinonen K, Komsi N, Järvenpää AL, Strandberg T. A transactional model of temperamental development: evidence of a relationship between child temperament and maternal stress over five years. Soc Dev 2008 Jan 20;17(2):326-340. [doi: 10.1111/j.1467-9507.2007.00427.x]
9. Kaminski JW, Valle LA, Filene JH, Boyle CL. A meta-analytic review of components associated with parent training program effectiveness. J Abnorm Child Psychol 2008 May 19;36(4):567-589. [doi: 10.1007/s10802-007-9201-9] [Medline: 18205039]
10. Niec LN. Parent–child interaction therapy: a transdiagnostic intervention to enhance family functioning. In: Niec LN, editor. Handbook of Parent-Child Interaction Therapy: Innovations and Applications for Research and Practice. Cham, Switzerland: Springer; 2018:3-15.
11. Eyberg S, Funderburk B. Parent-child interaction therapy protocol. In: Rubin A, editor. Programs and Interventions for Maltreated Children and Families at Risk: Clinician's Guide to Evidence-Based Practice. Hoboken, NJ: John Wiley & Sons; 2011:61-63.
12. Niec LN. Handbook of Parent-Child Interaction Therapy: Innovations and Applications for Research and Practice. Cham, Switzerland: Springer; 2018.
13. Abrahamse ME, Junger M, van Wouwe MA, Boer F, Lindauer RJ. Treating child disruptive behavior in high-risk families: a comparative effectiveness trial from a community-based implementation. J Child Fam Stud 2016 Nov 26;25(5):1605-1622 [FREE Full text] [doi: 10.1007/s10826-015-0322-4] [Medline: 27110086]
14. Abrahamse ME, Tsang VM, Lindauer RJ. Home-based parent-child interaction therapy to prevent child maltreatment: a randomized controlled trial. Int J Environ Res Public Health 2021 Aug 04;18(16):8244 [FREE Full text] [doi: 10.3390/ijerph18168244] [Medline: 34444004]
15. Kohlhoff J, Morgan S, Briggs N, Egan R, Niec LN. Parent-child interaction therapy with toddlers: a community-based randomized controlled trial with children aged 14-24 months. J Clin Child Adolesc Psychol 2021 Feb 20;50(3):411-426. [doi: 10.1080/15374416.2020.1723599] [Medline: 32078379]
16. Lanier P, Kohl PL, Benz J, Swinger D, Moussette P, Drake B. Parent-child interaction therapy in a community setting: examining outcomes, attrition, and treatment setting. Res Soc Work Pract 2011 Nov 01;1(6):689-698 [FREE Full text] [doi: 10.1177/1049731511406551] [Medline: 24839378]
17. Lieneman CC, Quetsch LB, Theodorou LL, Newton KA, McNeil CB. Reconceptualizing attrition in parent–child interaction therapy: “dropouts” demonstrate impressive improvements. Psychol Res Behav Manag 2019 Jul;Volume 12:543-555. [doi: 10.2147/prbm.s207370]
18. Stokes JO, Wallace NM, McNeil CB. Effectiveness of community-delivered parent-child interaction therapy compared to usual care. Child Fam Behav Ther 2018 Oct 09;40(4):279-305. [doi: 10.1080/07317107.2018.1522232]
19. Danko CM, Garbacz LL, Budd KS. Outcomes of Parent–Child Interaction Therapy in an urban community clinic: a comparison of treatment completers and dropouts. Child Youth Serv Rev 2016 Jan;60:42-51 [FREE Full text] [doi: 10.1016/j.childyouth.2015.11.007]
20. Abrahamse ME, Niec LN, Junger M, Boer F, Lindauer RJ. Risk factors for attrition from an evidence-based parenting program: findings from the Netherlands. Child Youth Serv Rev 2016 May;64:42-50. [doi: 10.1016/j.childyouth.2016.02.025]
21. Boggs SR, Eyberg SM, Edwards DL, Rayfield A, Jacobs J, Bagner D, et al. Outcomes of parent-child interaction therapy: a comparison of treatment completers and study dropouts one to three years later. Child Fam Behav Ther 2005 Jan 11;26(4):1-22. [doi: 10.1300/j019v26n04_01]
22. Stokes JO, Jent JF, Weinstein A, Davis EM, Brown TM, Cruz L, et al. Does practice make perfect? The relationship between self-reported treatment homework completion and parental skill acquisition and child behaviors. Behav Ther 2016 Jul;47(4):538-549. [doi: 10.1016/j.beth.2016.04.004] [Medline: 27423169]
23. Campbell SM, Hawes T, Swan K, Thomas R, Zimmer-Gembeck MJ. Evidence-based treatment in practice: PCIT research on addressing individual differences and diversity through the lens of 20 years of service. Psychol Res Behav Manag 2023;16:2599-2617 [FREE Full text] [doi: 10.2147/PRBM.S360302] [Medline: 37465048]
24. Jent JF, Rothenberg WA, Weinstein A, Stokes J, Barnett M, Srivatsa N, et al. Comparing traditional and eBook-augmented parent-child interaction therapy (PCIT): a randomized control trial of pocket PCIT. Behav Ther 2021 Nov;52(6):1311-1324. [doi: 10.1016/j.beth.2021.02.013] [Medline: 34656188]
25. Jent JF, Brown TM, Weinstein A. Using technology to expand the reach of PCIT. In: Niec LN, editor. Handbook of Parent-Child Interaction Therapy: Innovations and Applications for Research and Practice. Cham, Switzerland: Springer; 2018:375-390.
26. Scherpbier IC, Abrahamse ME, Belleman RG, Popma A, Lindauer RJ. Implementation of virtual reality to parent-child interaction therapy for enhancement of positive parenting skills: study protocol for single-case experimental design with multiple baselines. JMIR Res Protoc 2022 May 20;11(5):e34120 [FREE Full text] [doi: 10.2196/34120] [Medline: 35594138]
27. Slater M. Place illusion and plausibility can lead to realistic behaviour in immersive virtual environments. Philos Trans R Soc Lond B Biol Sci 2009 Dec 12;364(1535):3549-3557 [FREE Full text] [doi: 10.1098/rstb.2009.0138] [Medline: 19884149]
28. Pawassar CM, Tiberius V. Virtual reality in health care: bibliometric analysis. JMIR Serious Games 2021 Dec 01;9(4):e32721 [FREE Full text] [doi: 10.2196/32721] [Medline: 34855606]

XSL•FO
RenderX

29. Botella C, Fernández-Álvarez J, Guillén V, García-Palacios A, Baños R. Recent progress in virtual reality exposure therapy for phobias: a systematic review. Curr Psychiatry Rep 2017 Jul 24;19(7):42. [doi: 10.1007/s11920-017-0788-4] [Medline: 28540594]
30. Hilty DM, Randhawa K, Maheu MM, McKean AJ, Pantera R, Mishkind MC, et al. A review of telepresence, virtual reality, and augmented reality applied to clinical care. J Technol Behav Sci 2020 Feb 20;5(2):178-205. [doi: 10.1007/s41347-020-00126-x]
31. Mishkind MC, Norr AM, Katz AC, Reger GM. Review of virtual reality treatment in psychiatry: evidence versus current diffusion and use. Curr Psychiatry Rep 2017 Sep 18;19(11):80. [doi: 10.1007/s11920-017-0836-0] [Medline: 28920179]
32. Grochowska A, Wichniak A, Jarema M. Virtual reality – a valuable tool to advance treatment of mental disorders. Arch Psych Psych 2019 Mar 24;21(1):65-73. [doi: 10.12740/app/101654]
33. Turner WA, Casey LM. Outcomes associated with virtual reality in psychological interventions: where are we now? Clin Psychol Rev 2014 Dec;34(8):634-644. [doi: 10.1016/j.cpr.2014.10.003] [Medline: 25455627]
34. Howard MC, Gutworth MB. A meta-analysis of virtual reality training programs for social skill development. Compute Educ 2020 Jan;144:103707. [doi: 10.1016/j.compedu.2019.103707]
35. Kazdin AE. Single-case experimental designs. Evaluating interventions in research and clinical practice. Behav Res Ther 2019 Jun;117:3-17. [doi: 10.1016/j.brat.2018.11.015] [Medline: 30527785]
36. Aydin O. Rise of single-case experimental designs: a historical overview of the necessity of single-case methodology. Neuropsychol Rehabil 2024 Apr 22;34(3):301-334. [doi: 10.1080/09602011.2023.2181191] [Medline: 36811612]
37. Tate RL, Perdices M, Rosenkoetter U, McDonald S, Togher L, Shadish W, et al. The single-case reporting guideline in BEhavioural interventions (SCRIBE) 2016: explanation and elaboration. Arch Sci Psychol 2016 Apr 14;4(1):10-31. [doi: 10.1037/arc0000027]
38. Tate R, Perdices M, Rosenkoetter U, Shadish W, Vohra S, Barlow D, et al. The single-case reporting guideline in BEhavioural interventions (SCRIBE) 2016 statement. Phys Ther 2016 Jul;96(7):e1-10. [doi: 10.2522/ptj.2016.96.7.e1] [Medline: 27371692]
39. Kratochwill TR, Hitchcock J, Horner RH, Levin JR, Odom SL, Rindskopf DM, et al. The what works clearinghouse single-case design pilot standards. Remedial Spec Educ 2014 Jan 28;35(3):145-152. [doi: 10.1177/0741932513518979]
40. World Medical Association. World medical association declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013 Nov 27;310(20):2191-2194. [doi: 10.1001/jama.2013.281053] [Medline: 24141714]
41. Eyberg S, Nelson M, Ginn N, Bhuiyan N, Boggs S. Dyadic Parent-Child Interaction Coding System (DPICS) Comprehensive Manual for Research Training. Fourth Edition. Gainesville, FL: PCIT International; 2013.
42. Eyberg S, Pincus D. ECBI and SESBI-R: Eyberg Child Behavior Inventory and Sutter-Eyberg Student Behavior Inventory-Revised: Professional Manual. Psychological Assessment Resources. 1999. URL: https://www.parinc.com/products/ECBI [accessed 2024-04-29]
43. Weeland J, van Aar J, Overbeek G. Dutch norms for the Eyberg Child Behavior Inventory: comparisons with other Western countries. J Psychopathol Behav Assess 2018 Dec 2;40(2):224-234 [FREE Full text] [doi: 10.1007/s10862-017-9639-1] [Medline: 29937620]
44. Vermulst A, Kroes G, De Meyer R, Nguyen L, Veerman J. Handleiding OBVL. Delft, Netherlands: Eburon Academic Publishers; 2015.
45. van Linschoten RC, Knijnenburg S, West R, van Noord D. CastorEDC API: a python package for managing real world data in castor electronic data capture. J Open Res Softw 2023:11. [doi: 10.5334/jors.436]
46. Abrahamse ME, Junger M, Leijten PH, Lindeboom R, Boer F, Lindauer RJ. Psychometric properties of the Dutch Eyberg Child Behavior Inventory (ECBI) in a community sample and a multi-ethnic clinical sample. J Psychopathol Behav Assess 2015 Mar 25;37(4):679-691 [FREE Full text] [doi: 10.1007/s10862-015-9482-1] [Medline: 26640320]
47. Wilson CJ, Soranzo A. The use of virtual reality in psychology: a case study in visual perception. Comput Math Methods Med 2015;2015:151702 [FREE Full text] [doi: 10.1155/2015/151702] [Medline: 26339281]
48. Schrijver P. The Application of Virtual Reality Technology of PCIT [thesis]. Amsterdam, the Netherlands: University of Amsterdam; 2018.
49. Bras C. Ontwikkelomgeving voor 360 Graden VR voor Training en Therapie [thesis]. Amsterdam, the Netherlands: University of Amsterdam; 2021.
50. Vermeulen M. Towards a Production-Ready Framework for PCIT-VR [thesis]. Amsterdam, the Netherlands: University of Amsterdam; 2020.
51. van VE. A Visual Editor for Creating Non-Linear Timelines for PCIT-VR [thesis]. Amsterdam, the Netherlands: University of Amsterdam; 2021.
52. Monk S. Designing a Visual Analytics Dashboard to Assess User Data from PCIT-VR Research [thesis]. Amsterdam, the Netherlands: University of Amsterdam; 2021.
53. Bouwmeester S. Single case designs. Shiny Apps. URL: https://architecta.shinyapps.io/SingleCaseDesignsv02/ [accessed 2024-04-29]
54. Meyers LS, Gamst GC, Guarino A. Performing Data Analysis using IBM SPSS. Hoboken, NJ: John Wiley & Sons; 2013.

XSL•FO
RenderX

55. Bouwmeester S, Jongerling J. Power of a randomization test in a single case multiple baseline AB design. PLoS One 2020 Feb 6;15(2):e0228355 [FREE Full text] [doi: 10.1371/journal.pone.0228355] [Medline: 32027683]
56. Bulté I, Onghena P. Randomization tests for multiple-baseline designs: an extension of the SCRT-R package. Behav Res Methods 2009 May;41(2):477-485. [doi: 10.3758/brm.41.2.477]
57. Cohen J. Statistical Power Analysis for the Behavioral Sciences. New York, NY: Academic Press; 2013.
58. Hakman M, Chaffin M, Funderburk B, Silovsky JF. Change trajectories for parent-child interaction sequences during parent-child interaction therapy for child physical abuse. Child Abuse Negl 2009 Jul;33(7):461-470. [doi: 10.1016/j.chiabu.2008.08.003] [Medline: 19581001]
59. Warren JM, Halpin SA, Hanstock TL, Hood C, Hunt SA. Outcomes of Parent-Child Interaction Therapy (PCIT) for families presenting with child maltreatment: a systematic review. Child Abuse Negl 2022 Dec;134:105942. [doi: 10.1016/j.chiabu.2022.105942] [Medline: 36368165]
60. Dixon LB, Holoshitz Y, Nossel I. Treatment engagement of individuals experiencing mental illness: review and update. World Psychiatry 2016 Feb;15(1):13-20 [FREE Full text] [doi: 10.1002/wps.20306] [Medline: 26833597]
61. Joseph HM, Farmer C, Kipp H, Kolko D, Aman M, McGinley J, et al. Attendance and engagement in parent training predict child behavioral outcomes in children pharmacologically treated for attention-deficit/hyperactivity disorder and severe aggression. J Child Adolesc Psychopharmacol 2019 Mar;29(2):90-99 [FREE Full text] [doi: 10.1089/cap.2018.0119] [Medline: 30592635]
62. Bode AA, George MW, Weist MD, Stephan SH, Lever N, Youngstrom EA. The impact of parent empowerment in children's mental health services on parenting stress. J Child Fam Stud 2016 Jun 6;25(10):3044-3055. [doi: 10.1007/S10826-016-0462-1]
63. Scherpbier IC, Abrahamse ME, Widdershoven GA, Belleman RG, Popma A, Lindauer RJL. The added value of virtual reality to parent–child interaction therapy: a qualitative study with parents and therapists. BMC Digit Health 2024 May 14;2(1):e370. [doi: 10.1186/S44247-024-00079-8]
64. Valero-Aguayo L, Rodríguez-Bocanegra M, Ferro-García R, Ascanio-Velasco L. Meta-analysis of the efficacy and effectiveness of parent child interaction therapy (PCIT) for child behaviour problems. Psicothema 2021 Nov 01;33(4):544-555. [doi: 10.7334/psicothema2021.70] [Medline: 34668468]
65. Quetsch LB, Girard EI, McNeil CB. The impact of incentives on treatment adherence and attrition: a randomized controlled trial of Parent-Child Interaction Therapy with a primarily Latinx, low-income population. Child Youth Serv Rev 2020 May;112:104886. [doi: 10.1016/j.childyouth.2020.104886]
66. Ericsson KA. The influence of experience and deliberate practice on the development of superior expert performance. In: Ericsson KA, Charness N, Feltovich PJ, Hoffman RR, editors. The Cambridge Handbook of Expertise and Expert Performance. Cambridge, MA: Cambridge University Press; 2006:683-704.
67. Ericsson KA, Krampe RT, Tesch-Römer C. The role of deliberate practice in the acquisition of expert performance. Psychol Rev 1993;100(3):363-406. [doi: 10.1037//0033-295X.100.3.363]
68. Macnamara BN, Maitra M. The role of deliberate practice in expert performance: revisiting Ericsson, Krampe and Tesch-Römer (1993). R Soc Open Sci 2019 Aug 21;6(8):190327 [FREE Full text] [doi: 10.1098/rsos.190327] [Medline: 31598236]

Abbreviations

ADHD: attention-deficit/hyperactivity disorder
ASD: autism spectrum disorder
BPT: behavioral parent training
CDI: child-directed interaction
DPICS: Dyadic Parent-Child Interaction Coding System
ECBI: Eyberg Child Behavior Inventory
OBVL: Dutch Parenting Stress Questionnaire (Opvoedingsbelastingvragenlijst)
PCIT: Parent-Child Interaction Therapy
PDI: parent-directed interaction
RCI: reliable change index
SCED: single-case experimental design
SCRIBE: Single-Case Reporting Guideline in Behavioral Interventions
VR: virtual reality

XSL•FO
RenderX

Edited by S Badawy; submitted 20.05.24; peer-reviewed by EM Davis, KA Hails; comments to author 06.07.24; revised version received 16.11.24; accepted 23.12.24; published 23.07.25.

Please cite as:
Scherpbier ICA, Abrahamse ME, Bouwmeester S, Belleman RG, Popma A, Lindauer RJL
The Added Value of Parents Practicing in Virtual Reality to Illustrate the Use of Innovative Methods in Parent-Child Interaction Therapy: Single-Case Experimental Design
JMIR Pediatr Parent 2025;8:e60752
URL: https://pediatrics.jmir.org/2025/1/e60752
doi:10.2196/60752
PMID:40699889

©Iza C A Scherpbier, Mariëlle E Abrahamse, Samantha Bouwmeester, Robert G Belleman, Arne Popma, Ramón J L Lindauer. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 23.07.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Immediate Kangaroo Mother Care for Sick Newborns: Quality Improvement Implementation and Feasibility Study

Belén Fernández-Monteaguado[1], MD; Ana Peña-Moreno[1], MD; Inés Ramírez-de Andrés[1], MD; Patricia Barbero-Casado[2], PhD; Eduardo Zarzuela-NÚñez[3], PhD; Beatriz Bellón-Vaquerizo[1], RN; Cristina Martin Arriscado-Arroba[4], MSc; María Teresa Moral-Pumarega[1,5], PhD; Salvador Piris-Borregas[1,5*], PhD; Carmen Rosa Pallás-Alonso[1,5*], PhD

[1]Neonatology Department, Hospital Universitario 12 De Octubre, Madrid, Spain

[2]Obstetrician Department, Hospital Universitario 12 de Octubre, Madrid, Spain

[3]Obstetric Reanimation, Hospital Universitario 12 de Octubre, Madrid, Spain

[4]Research institute, Hospital Universitario 12 de Octubre, Madrid, Spain

[5]Maternal and Child Health and Development Research Network (RICORS-SAMID Network), Madrid, Spain

[*]these authors contributed equally

Corresponding Author:
Salvador Piris-Borregas, PhD
Neonatology Department
Hospital Universitario 12 De Octubre
Gta. Málaga, 11, Usera
Madrid, 28041
Spain
Phone: 34 913908972 ext 8972
Email: piris.salvador@gmail.com

Abstract

Background: A systematic separation of late preterm and/or sick newborns from their mothers and families continues to occur in most neonatal units around the world.

Objective: The aim of this study was to implement immediate kangaroo mother care for sick newborns from birth.

Methods: This study comprised preterm newborns at ≥34 weeks of gestational age and weighing ≥1800 g, term newborns with noninvasive ventilation, and newborns at ≥34 weeks of gestational age and weighing ≥1800 g with congenital anomalies that did not require urgent medical or surgical attention. Newborns were excluded in cases of advanced resuscitation or at medical discretion. The newborns in this study were maintained skin-to-skin for 120 minutes, preferably with the mother, and then transferred skin-to-skin to their destination unit.

Results: In this study, 60 newborns were included. The median time for immediate kangaroo mother care was 120 minutes for all newborns; 100% of the time was spent with the mother, even when respiratory support was required. Immediate kangaroo mother care was interrupted for 13 of the 60 newborns, and this was more frequent in newborns with heart disease (9/13, 69%), with the main cause being the neonatologist's concern. No causes of separation were related to maternal issues, hypoglycemia, or temperature instability, and no incidents such as hypothermia were observed during kangaroo mother care, either at birth or during transport.

Conclusions: Kangaroo mother care during the first 120 minutes of life in late premature or sick newborns is a safe and feasible practice.

(JMIR Pediatr Parent 2025;8:e78207) doi:10.2196/78207

KEYWORDS

kangaroo mother care method; premature newborns; respiratory distress syndrome; newborn; congenital abnormalities; heart defects; congenital

XSL•FO
RenderX

Introduction

An increasing body of evidence supports maintaining the nuclear family unit at birth by promoting early newborn stabilization, prolonged uninterrupted immediate kangaroo mother care (iKMC) as soon as possible after birth, and initiating breastfeeding on the mother's bare chest, which is known as iKMC [1-3]. iKMC for preterm newborns has been associated with reduced mortality, nosocomial infections, and hypothermia in those weighing less than 1500 g [4]. It also improves breastfeeding rates [5,6], reduces parental stress and health care costs [7], and enhances long-term health outcomes [8]. Hence, the World Health Organization (WHO) recommends iKMC for neonates born after 28 weeks of gestation [9].

There is evidence regarding the feasibility and safety of iKMC in very premature newborns [10]. Nevertheless, there is a lack of clinical protocols or experiences explaining how to implement iKMC in other groups of ill newborns, particularly, late premature newborns, those requiring noninvasive respiratory support, or those with prenatal diagnoses. In many cases, there is very little evidence for these groups. This study aims to evaluate the feasibility and safety of iKMC at birth for sick newborns, thereby bringing the benefits of iKMC to a greater number of sick newborns and their families.

Methods

Study Design

This is a quality improvement study. The inclusion criteria comprised 3 gestational groups: (1) preterm newborns between ≥34+0 and <37+0 weeks of gestational age (GA) and weighing ≥1800 g with or without respiratory distress requiring or not noninvasive ventilation (group 1); (2) term neonates ≥37+0 weeks of GA with respiratory distress (group 2); and (3) term newborns ≥37+0 weeks of GA and preterm newborns ≥34 weeks of GA, weighing ≥1800 g, and having a prenatal congenital anomaly not requiring immediate medical or surgical intervention (group 3). The exclusion criteria were neonates needing intubation, cardiac massage, advanced resuscitation, noninvasive ventilation with FiO_2 (fraction of inspired oxygen) >40%, or with heart rate <100 beats per minute, as well as those excluded based on clinical judgment by the attending team. The iKMC protocol established a standardized duration of 120 minutes, irrespective of the delivery mode and was conducted in either the labor/recovery unit or the obstetric resuscitation area. Continuation of iKMC was permitted in the assigned maternal or neonatal unit depending on clinical stability. All training sessions were multidisciplinary, attended by neonatologists, resident doctors, neonatal nurses, midwives, and anesthetists.

A neonatologist or neonatal nurse was present at the initiation of skin-to-skin contact. In delivery rooms, newborns could be assessed either directly or via telemetry. Monitoring with pulse oximetry and temperature or glucose measurement was recommended, as appropriate. In cases of asymptomatic early mild hypoglycemia, breastfeeding during iKMC was encouraged to avoid mother-newborn separation. For cesarean deliveries, the physical presence of both a neonatologist and a neonatal nurse was mandatory. In all cases, the umbilical cord was cut after 1 minute. The temperature was measured immediately after birth and upon arrival at the neonatal intensive care unit. If at any time the temperature was below 36 °C, iKMC was interrupted. When the temperature was between 36 °C and 36.5 °C, additional measures were initiated, such as preheated cloths or increasing the maternal temperature with air convection blankets. Ideally, transport to the destination unit was performed with the mother using a bed or a wheelchair depending on her physical condition at the time. If the mother was not available, iKMC transport with the father or the other authorized caregiver was encouraged. A wheelchair was used for this purpose.

The primary outcome was the duration of uninterrupted iKMC (in minutes). Additional variables included patient demographics, the individual providing the care, need for respiratory support, and its discontinuation during iKMC. A formal sample size calculation was not conducted; however, a target of 50 patients was deemed sufficient to assess feasibility. Ultimately, 60 patients were included. Quantitative variables were summarized using mean and standard deviation or median (p50) and interquartile range (p25-p75), depending on the distribution assessed by the Shapiro-Wilk test. Categorical variables were reported as absolute counts and percentages. Group comparisons were performed using analysis of variance, Kruskal-Wallis, Mann-Whitney *U* test, 2-sided Student *t* test, chi-square, or Fisher exact test, as appropriate. Bonferroni adjustment was applied for comparisons among the 3 inclusion groups. All analyses were conducted using SAS software (version 9.4, SAS Institute), with statistical significance set at $P \leq .05$ and 95% CI.

Ethical Considerations

This study is a subproject of a larger project called “zero separation.” The larger zero separation project was submitted to the research ethics committee with all the subprojects. The ethics committee of the 12 de Octubre University Hospital approved the global project (approval 25/542). All families, including mothers and fathers, were informed verbally. No informed consent was required according to the recommendations of the ethics committee, and participants could opt out anytime. Data were anonymized, and no compensation was given to any participant.

Results

Between January and August 2024, 89 eligible newborns were admitted to the unit. Of these, 29 (33%) were excluded: 52% (15/29) were excluded due to respiratory distress with FiO_2 >40%, 35% (10/29) due to maternal factors, and 14% (4/29) for reasons such as advanced resuscitation or care overload. The final sample comprised 60 newborns.

The characteristics of the included newborns are shown in Table 1. Significant differences were observed among groups 1, 2, and 3 in the gestational weeks (median 35+0 [IQR 34+2 to 36+0] weeks vs 40+2 [IQR 39+2 to 40+6] weeks vs 40+0 [IQR 38+5 to 40+4] weeks, respectively; $P<.01$) and birth weight (2350 [IQR 2080-2940] g vs 3290 [IQR 3130-3660] g vs 3230 [IQR 2970-3550] g, respectively; $P<.01$). Among the different

XSL•FO
RenderX

congenital anomalies, 60% (14/24) were congenital heart diseases such as Tetralogy of Fallot or aortic coarctation, 20% (4/24) were neurological problems, and 10% (3/24) were other anomalies.

The characteristics of iKMC are presented in Table 2. The median duration was 120 minutes for all newborns, with no differences among the groups. All newborns received iKMC with their mothers. Notably, newborns in the respiratory distress group (group 2) more frequently required continuous positive airway pressure (CPAP) than groups 1 and 3 during iKMC (17/19, 90% vs 6/17, 35% vs 1/24, 4%, respectively; *P*<.01) and were more frequently transported in iKMC (16/19, 84% vs 8/17, 47% vs 10/24, 42%, respectively; *P*=.01).

Table 1. General characteristics of the sample of newborns recruited based on the inclusion criteria.

Variables	Late preterm newborns (n=17)	Term newborns with respiratory distress (n=19)	Newborns with congenital pathology (n=24)	*P* value
Gestational age (weeks), median (IQR)	35+0 (34+2 to 36+0)	40+2 (39+2 to 40+6)	40+0 (38+5 to 40+4)	<.01
Weight (g), median (IQR)	2350 (2080 to 2940)	3290 (3130 to 3660)	3230 (2970 to 3550)	<.01
Sex (male), n (%)	8 (47)	11 (58)	13 (54)	.80
Twin pregnancy (yes), n (%)	3 (18)	0 (0)	1 (4)	.08
Type of delivery (eutocic), n (%)	13 (77)	13 (68)	17 (71)	.55
Intrauterine growth retardation, n (%)	1 (6)	1 (5)	0 (0)	.50
Need for resuscitation with positive pressure ventilation, n (%)	3 (18)	5 (26)	1 (4)	.12
Shift in which immediate kangaroo mother care was performed, n (%)				.22
Morning	9 (53)	7 (37)	5 (21)	
Afternoon	2 (12)	6 (32)	7 (29)	
Night	6 (35)	6 (32)	12 (50)	

Table 2. Characteristics of the immediate kangaroo mother care in the contact protocol patients.

Variables	Late preterm newborns (n=17)	Term newborns with respiratory distress (n=19)	Newborns with congenital pathology (n=24)	*P* value
Median (IQR) time (min) of uninterrupted kangaroo care	120 (120-120)	120 (120-120)	120 (30-120)	.23
With whom kangarooing was performed (with mother), n (%)	17 (100)	19 (100)	24 (100)	>.99
CPAP[a] in kangaroo care (yes), n (%)	6 (35)	17 (90)	1 (4)	<.01
Possibility to remove CPAP during kangaroo care	0 (0)	4 (24)	0 (0)	.37
Possibility to remove CPAP after 120 min of kangaroo care	0 (0)	5 (29)	0 (0)	.27
CPAP maintenance for 120 min and subsequent admission	5 (83)	6 (35)	0 (0)	.28
Need to discontinue kangaroo care due to deterioration	1 (17)	2 (12)	1 (100)	.07
Performance of transport in kangaroo care (yes), n (%)	8 (47)	16 (84)	10 (42)	.01
With whom kangaroo transport was performed (with mother), n (%)	8 (100)	13 (81)	8 (80)	.40
Kangaroo transport incidents (yes), n (%)	0 (0)	0 (0)	0 (0)	>.99

[a]CPAP: continuous positive airway pressure.

Table 3 summarizes the characteristics of iKMC among protocol participants. Among those with interrupted kangaroo care, the median duration was 20 (IQR 20-30) minutes. Early separation occurred more often in newborns with prenatal diagnoses of congenital anomalies (9/24, 69% vs 2/17,15% vs 2/19,15%, respectively; *P*=.02), although the median iKMC duration did not differ significantly between the groups.

Temperature instability and hypoglycemia were not reported as the causes of separation. Newborns who experienced iKMC interruption were less likely to be transported in iKMC (3/13,

XSL•FO
RenderX

23% vs 31/47, 66%, respectively; *P*<.01). No significant differences in interruption rates were observed across work shifts (morning: 3/13, 23%; afternoon: 3/13, 23%; night: 7/13, 54%; *P*=.47). Interestingly, newborns requiring positive pressure ventilation at birth (n=9) were less likely to have iKMC interrupted (2/9, 22% vs 7/9, 78%, respectively; *P*=.02). Some details related with the characteristics of breastfeeding during iKMC and at discharge were also studied, which are shown in Table 4.

Table 3. Characteristics of kangaroo care interruption in the contact protocol.

Variables	Late preterm newborns (n=17)	Term newborns with respiratory distress (n=19)	Newborns with congenital pathology (n=24)	*P* value
Kangaroo care interruption at some point (yes), n (%)	2 (15)	2 (15)	9 (69)	.02
Median (IQR) time (min) to interruption	35 (30-40)	17.5 (15-20)	20 (20-30)	.17
Reason for separation, n (%)				.09
Increase in respiratory distress of the newborn	1 (50)	1 (50)	2 (22)	
Obstetrics complications of the mother	0 (0)	0 (0)	0 (0)	
Reason not referred/concern of neonatologist	0 (0)	1 (50)	6 (67)	
Other reasons	1 (50)	0 (0)	1 (11)	

Table 4. Characteristics of breastfeeding during kangaroo care and at discharge.

Variables	Late preterm newborns (n=17), n (%)	Term newborns with respiratory distress (n=19), n (%)	Newborns with congenital pathology (n=24), n (%)	*P* value
Breastfeeding in kangaroo care achieved	5 (29)	5 (26)	8 (33)	.88
How to get colostrum (% attachment to the breast)	17 (100)	19 (100)	24 (100)	>.99
Breastfeeding at discharge	17 (100)	17 (90)	23 (96)	.34
Exclusive breastfeeding at discharge	7 (41)	10 (53)	10 (4)	.76

Discussion

This study represents the first experience published in Europe demonstrating the feasibility and security of iKMC for sick newborns and late premature newborns. Nearly 80% (47/60) of the newborns remained in uninterrupted iKMC for 120 minutes, with 100% of that time spent skin-to-skin with their mothers, even among those requiring positive pressure ventilation or respiratory support. No complications occurred during the process or during skin-to-skin transport.

No studies have been found with which to compare the outcomes of iKMC in patients with prenatally detected congenital anomalies. Walsh et al [11] evaluated singletons born vaginally at 35-36 6/7 weeks gestation who were randomized to be initiated with iKMC with a reported time of immediate kangaroo care of 60 minutes. Our median uninterrupted iKMC duration of 120 minutes is notably longer, likely reflecting heightened staff awareness and targeted training. iKMC was interrupted in 22% (13/60) of the cases, predominantly due to worsening respiratory status (4/13, 31%). No interruptions were related to maternal issues, hypoglycemia, or temperature instability, consistent with prior literature [12,13]. This underscores the role of health care providers, sometimes unintentionally, as the main cause of mother-newborn separation.

Technical or logistical issues accounted for only 2 interruptions. No significant differences in iKMC duration or interruption rates were observed across different shifts or patient subgroups. Numerous studies support the safety and benefits of KMC for newborns requiring respiratory support from birth [13,14]. However, only one prior study comprising premature newborns, including late premature ones, demonstrated safe respiratory stabilization by using noninvasive ventilation during skin-to-skin care, achieving 40.6% stabilization in kangaroo care [13]. In our study, this rate increased to 79% (47/60), with 38% (9/24) of the patients discontinuing CPAP during KMC, thereby reducing admissions. Differences in GAs between studies should be noted.

Notably, newborns requiring respiratory support were more frequently transported skin-to-skin, confirming the feasibility and safety of this method. This study extends existing evidence to preterm and sick newborns. Regarding breastfeeding, iKMC is known to promote early latch and initiation in healthy term newborns [13,15]. Our findings extend this to preterm and sick newborns, with 30% (18/60) achieving early colostrum latch and a greater breastfeeding rate at discharge (57/60, 95%), including exclusive breastfeeding in half of the cohort.

XSL•FO
RenderX

This study is the first to detail the way to apply implementation of iKMC in preterm and sick newborns, achieving greater recruitment and applicability. A limitation is that our study was conducted in a unit with extensive staff training and strong commitment to iKMC, which may limit generalizability without similar institutional support. Indeed, our unit has previously published its experience regarding the implementation of iKMC in preterm newborns born between 28 and 34 weeks of gestation [10].

In conclusion, iKMC with uninterrupted skin-to-skin contact and transport during the first 120 minutes of life in late preterm and sick newborns is safe and feasible. Newborns that required noninvasive ventilation with FiO_2 <40% could be initiated with iKMC. Early mother-newborn contact also improves breastfeeding initiation. This study represents a further step toward zero separation—a goal strongly desired by parents of hospitalized newborns and actively advocated by the Global Foundation for the Care of the Newborn Infant. To date, most scientific literature has focused primarily on very premature newborns. However, extending the practice of iKMC to newborns with higher GAs has the potential to benefit a much larger number of families by preventing unnecessary separation.

Acknowledgments

The authors thank the Support Program for Healthcare Innovation Initiatives (i+12-AY230503-1, Contratos Transforma 12), i+12 Research Institute (Imas 12), and 12 de Octubre University Hospital, Madrid, Spain. The authors would like to express their sincere gratitude to the investigators of the Red Ricors Samid Maternal, Child, and Developmental Health Network (RD24/0013/0008).

Conflicts of Interest

None declared.

References

1. , editor. Baby-Friendly Hospital Initiative: Revised, Updated and Expanded for Integrated Care. Geneva, Switzerland: WHO; May 1, 2009.
2. Durmaz A, Sezici E, Akkaya DD. The effect of kangaroo mother care or skin-to-skin contact on infant vital signs: a systematic review and meta-analysis. Midwifery 2023 Oct;125:103771-103775. [doi: 10.1016/j.midw.2023.103771] [Medline: 37454580]
3. Moore E. Early skin-to-skin contact for mothers and their healthy newborn infants. Cochrane Database Syst Rev 2016 Aug 23;11:174-184. [doi: 10.1002/14651858.cd003519.pub4]
4. Immediate KMC Study Group W. Immediate "kangaroo mother care" and survival of infants with low birth weight. N Engl J Med 2021 May 27;384(21):2028-2038. [doi: 10.1056/nejmoa2026486]
5. Stevens J, Schmied V, Burns E, Dahlen H. Immediate or early skin-to-skin contact after a Caesarean section: a review of the literature. Matern Child Nutr 2014 Oct;10(4):456-473 [FREE Full text] [doi: 10.1111/mcn.12128] [Medline: 24720501]
6. Karimi FZ, Sadeghi R, Maleki-Saghooni N, Khadivzadeh T. The effect of mother-infant skin to skin contact on success and duration of first breastfeeding: a systematic review and meta-analysis. Taiwan J Obstet Gynecol 2019 Jan;58(1):1-9 [FREE Full text] [doi: 10.1016/j.tjog.2018.11.002] [Medline: 30638460]
7. Ionio C, Ciuffo G, Landoni M. Parent-infant skin-to-skin contact and stress regulation: a systematic review of the literature. Int J Environ Res Public Health 2021 Apr 28;18(9):4695 [FREE Full text] [doi: 10.3390/ijerph18094695] [Medline: 33924970]
8. Mclean MA, Scoten OC, Yu W, Ye XY, Petrie J, Church PT, et al. Lower maternal chronic physiological stress and better child behavior at 18 months: follow-up of a cluster randomized trial of neonatal intensive care unit family integrated care. J Pediatr 2022 Apr;243:107-115.e4. [doi: 10.1016/j.jpeds.2021.12.055] [Medline: 34971651]
9. , editor. WHO Recommendations for Care of the Preterm or the Low Birth Weight Infant. Geneva, Switzerland: WHO; Nov 15, 2022.
10. Peña-Moreno A, Fernández-Monteagudo B, Gómez-Montes E, Tebar-Cuesta MI, Martín-Arriscado-Arroba C, Alba-Raya N, et al. Immediate kangaroo mother care was more feasible for preterm infants after vaginal than caesarean deliveries in a Spanish neonatal unit. Acta Paediatr 2025 Jun 14;114(9):2397-2399. [doi: 10.1111/apa.70172] [Medline: 40515612]
11. Walsh R, Payne A, Cossler N, Thompson C, Bhola M. Safety of immediate skin-to-skin contact after vaginal birth in vigorous late preterm neonates – a pilot study. Journal of Neonatal-Perinatal Medicine 2020 Feb 20;14(1):95-100. [doi: 10.3233/npm-190311]
12. Punasanvala PH, Parekh AN, Gohil JR, Pujari S. Kangaroo mother care in Preterm baby receiving assisted respiratory support (CPAP): a case-control trial. Int J Contemp Pediatr 2018 Apr 20;5(3):1008. [doi: 10.18203/2349-3291.ijcp20181531]
13. Marín Gabriel MA, Llana Martín I, López Escobar A, Fernández Villalba E, Romero Blanco I, Touza Pol P. Randomized controlled trial of early skin-to-skin contact: effects on the mother and the newborn. Acta Paediatr 2010 Nov;99(11):1630-1634. [doi: 10.1111/j.1651-2227.2009.01597.x] [Medline: 19912138]

XSL•FO
RenderX

14. Gunnarsdottir K, Falk M, Baldursdottir S, Donaldsson S, Jonsson B, Drevhammar T. Do newborn infants exhale through the CPAP system? Secondary analysis of a randomised cross-over trial. Arch Dis Child Fetal Neonatal Ed 2023 May 19;108(3):232-236 [FREE Full text] [doi: 10.1136/archdischild-2022-324462] [Medline: 36261145]
15. Karimi FZ, Miri HH, Khadivzadeh T, Maleki-Saghooni N. The effect of mother-infant skin-to-skin contact immediately after birth on exclusive breastfeeding: a systematic review and meta-analysis. J Turk Ger Gynecol Assoc 2020 Mar 06;21(1):46-56 [FREE Full text] [doi: 10.4274/jtgga.galenos.2019.2018.0138] [Medline: 30905140]

Abbreviations

CPAP: continuous positive airway pressure
FiO2: fraction of inspired oxygen
GA: gestational age
iKMC: immediate kangaroo mother care
WHO: World Health Organization

Edited by S Badawy; submitted 16.06.25; peer-reviewed by BH Eriksen, M Narvey; comments to author 05.08.25; revised version received 11.08.25; accepted 13.08.25; published 26.09.25.

Please cite as:
Fernández-Monteaguado B, Peña-Moreno A, Ramírez-de Andrés I, Barbero-Casado P, Zarzuela-NÚñez E, Bellón-Vaquerizo B, Martin Arriscado-Arroba C, Moral-Pumarega MT, Piris-Borregas S, Pallás-Alonso CR
Immediate Kangaroo Mother Care for Sick Newborns: Quality Improvement Implementation and Feasibility Study
JMIR Pediatr Parent 2025;8:e78207
URL: https://pediatrics.jmir.org/2025/1/e78207
doi:10.2196/78207
PMID:41004243

©Belén Fernández-Monteaguado, Ana Peña-Moreno, Inés Ramírez-de Andrés, Patricia Barbero-Casado, Eduardo Zarzuela-NÚñez, Beatriz Bellón-Vaquerizo, Cristina Martin Arriscado-Arroba, María Teresa Moral-Pumarega, Salvador Piris-Borregas, Carmen Rosa Pallás-Alonso. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 26.09.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

The Practice of Shaking in Disciplining Young Children in Lower-Income Communities of Bangladesh: Cross-Sectional Exploratory Study

Fahmida Tofail[1], PhD

International Centre for Diarrhoeal Disease Research, Bangladesh, Dhaka, Bangladesh

Corresponding Author:
Fahmida Tofail, PhD
International Centre for Diarrhoeal Disease Research, Bangladesh
68, Shaheed Tajuddin Ahmed Sarani, Mohakhali
Dhaka, 1212
Bangladesh
Phone: 880 (0)2 2222 77001
Email: ftofail@icddrb.org

Abstract

Background: Disciplining a child is a complex, multidimensional aspect of parenting, involving emotional guidance, behavioral correction, and consistent communication. Disciplinary practices applied to children may vary due to social, cultural, and geographic contexts. Among these practices, child shaking and its potentially severe consequences, including traumatic brain injury and long-term neurodevelopmental impairments, are more frequently documented in high-income countries. Although child shaking also occurs in low- and middle-income countries, particularly among infants, where it is primarily triggered by persistent crying, it is rarely reported in formal studies. Moreover, primary caregivers, particularly mothers, may not perceive shaking as a form of punitive discipline, and maternal depression is often associated with their caregiving attitude toward children. Furthermore, notable functional variations are also observed in the parenting practices of low-income urban and rural mothers, often influenced by divergent socioeconomic and environmental factors.

Objective: This study aims to explore caregivers' use of shaking as a disciplinary practice with young children in lower-income urban and rural communities in Bangladesh and identify the underlying factors associated with this behavior.

Methods: This was a cross-sectional study in which we randomly interviewed 800 caregivers of children (aged <2 y) admitted to the hospitals of the International Centre for Diarrhoeal Disease Research, Bangladesh, in urban Dhaka (n=520, 65%) and rural Matlab (n=280, 35%). We collected detailed information on how they disciplined their young children (index children), with particular emphasis on shaking behavior. The questionnaires also explored perceived causes and common beliefs related to child shaking, in addition to collecting information on sociodemographic characteristics and caregivers' depression. All analyses were conducted using SPSS software.

Results: Child shaking was higher in lower-income communities of Dhaka compared to rural Matlab (n=265, 51% vs n=52, 19%; *P*<.001). Mothers, as the primary caregivers, mostly used shaking as a disciplinary practice with their young children (n=491, 61%). Overall, 27% (n=214) of primary caregivers reported ever shaking a child below 2 years; among these, 62% (n=133) reported shaking at least 3 to 5 times. Crying and fussing were the main triggering factors (Dhaka: n=107, 62% vs Matlab: n=26, 67%) for shaking behavior, particularly in infants aged younger than 6 months. Approximately 56.6% (n=99) of the mothers in Dhaka and 28.2% (n=11) of the mothers in Matlab believed that shaking was either definitely or probably harmless. Maternal depression was significantly correlated (adjusted odds ratio 1.03, 95% CI 1.01-1.04; *P*=.001) with shaking practices used by mothers.

Conclusions: Shaking young children as a form of discipline is quite prevalent in lower-income communities of Bangladesh, where poverty and other stressors are common. Caregivers are not fully aware of the harmful side effects of infant shaking. Positive parenting programs need to be strengthened to reduce these harmful behaviors toward children to support their developmental potential.

(JMIR Pediatr Parent 2025;8:e64474) doi:10.2196/64474

XSL•FO
RenderX

KEYWORDS

infant shaking; behavior; depression; urban slum; Matlab; Dhaka, Bangladesh

Introduction

Background

Shaking infants, commonly reported in Western countries, is a practice used by caregivers as a form of physical discipline or parenting for young infants and children. However, shaking can be the primary risk behavior for shaken baby syndrome (SBS) or abusive head trauma (AHT). Shaking infants or young children can cause a range of harms, from mild and transient effects to severe and potentially life-threatening injuries. Studies estimate that 10% to 12% of the infant deaths related to child abuse are attributable to SBS, with approximately 1 in 4 deaths due to grave injuries [1,2]. SBS is a severe form of child abuse caused by violent shaking, leading to brain injuries, such as subdural hematomas, diffuse axonal injury, and retinal hemorrhages, as well as fractures of the long bones or ribs, even when there might be little or no evidence of trauma [3]. Infants are particularly susceptible to injuries due to their anatomical and physiological characteristics, including a heavy head, weak neck muscles, a soft and rapidly growing brain, and a thin skull wall. With less control over their head and neck and limited mobility, they face an increased risk of permanent injuries. Globally, shaking is recognized as a common disciplinary act for children. In the United States, 2.6% of the parents of children aged younger than 2 years acknowledge shaking their child as an act of “discipline.” This indicates that the ratio of reported shaking to severe or fatal cases of SBS or AHT is 152:1 [4]. When data from 60 countries were analyzed, it was found to be 33% more common [5]. Despite the mortality rate for SBS and AHT ranging from 13% to 30% in high-income countries such as the United States [6-8] and Canada [9], its prevalence and long-term impacts in low- and middle-income countries (LMICs) remain underexplored. In Japan, the prevalence of self-reported shaking behavior at 1 month post partum was 16.8%, with caregivers continuing this behavior until the infants were aged 6 years [10]. Although several systematic reviews have been conducted on the impact and prevalence of SBS injuries in high-income countries, evidence from LMICs is unavailable. A parallel survey was conducted on parental child-discipline practices in 6 different countries that included a high-income country (the United States), upper–middle-income countries (Brazil and Chile), and lower–middle-income countries (Egypt, Philippines, and India). The study showed that almost half of the surveyed communities practiced shaking as a typical caregiving act, and more than 20% indicated using shaking to discipline their children before they were aged 2 years [11].

The consequences of such harsh punishments, particularly child shaking, are not well understood in LMICs, where poverty and other psychosocial stressors, such as violence, aggression, and caregivers’ depression, are quite common [12]. The long-term public health implications of child shaking remain largely unknown, emerging evidence suggests that it may contribute to the prevalence of learning disabilities and intellectual impairments in these settings [13]. Social and economic adversities may amplify the risks associated with such harsh caregiving practices, underscoring the need for further research and culturally appropriate interventions.

Common risk factors for the perpetrators of child shaking include an inability to cope with stress, poor impulse control, unrealistic child-rearing expectations, and rigid attitudes. In addition, caring for premature or high-needs infants may lead to heightened frustration, reduced tolerance, and resentment, increasing the likelihood of harmful responses [14]. In these situations, parents and caregivers often consider shaking to be less harmful than spanking. Environmental factors, such as low socioeconomic status, poverty, unemployment, low education, unsafe neighborhoods, poor prenatal care, single marital status, frequent moves, and the lack of social support, further compound the risk of infant shaking [15].

The long-term consequences of SBS are severe. Children exposed to SBS before the age of 2 years have exhibited developmental delays in 11% to 47% of the cases by the age of 5 years [16].

Objectives

Bangladesh, a densely populated, low-income country with more than 165 million people, is facing unique challenges in addressing harmful caregiving practices. In this study, we aimed to explore the descriptive epidemiology of caregiver-executed shaking behavior among young children residing in lower-income, resource-constrained urban and rural communities of Bangladesh.

The specific objectives of this study were to (1) estimate the overall burden of shaking in children aged between 0 and 24 months, (2) identify the common triggering factors for such behavior, and (3) understand caregivers’ descriptions of the act of shaking and their awareness of its potentially harmful effects.

Methods

Design

This cross-sectional survey was conducted among the mothers and other caregivers of children aged younger than 2 years who were admitted to the 2 big charity hospitals of the International Centre for Diarrhoeal Disease Research, Bangladesh. The 2 hospitals are situated in urban Dhaka and rural Matlab. Both hospitals primarily serve the economically disadvantaged surrounding communities. This study was conducted over 7 months, from June to December 2009. Children aged younger than 2 years with less severe diarrhea were enrolled in this study. We excluded all children who were critically ill (eg, children experiencing convulsions and those with tuberculosis, encephalitis, and meningitis) and those with obvious physical congenital anomalies or developmental abnormalities. Due to the variation in patient flow between the 2 hospitals, 2 interviewers at the Dhaka Hospital recruited up to 6 mother-child dyads per day (n=520), while one interviewer at Matlab Hospital recruited up to 3 dyads per day (n=280).

XSL•FO
RenderX

Measures

A questionnaire was adapted that included both open- and closed-ended items, designed to capture the experiences of caregivers with child discipline, specifically focusing on shaking behavior and their associated mental states, such as the extent of anger or frustration during these incidents.

A structured socioeconomic and demographic questionnaire was used to collect information on the number of family members, parental education and occupation, number of children aged younger than 5 years in the family, and the birth order of the index child. In addition, participants were asked about household income and expenditure balances over the previous months. The financial status of the families was classified into 4 categories: constant deficits, occasional deficits, balanced income, and surplus (excess of income over expenditure). The occupation categories were classified into 3 groups based on skill level and employment regularity: unskilled (eg, unemployed individuals and day laborers), low-skilled and irregular (eg, mechanics, electricians, and rickshaw pullers), and high-skilled job categories.

Questions on child discipline practices assessed whether the caregivers had ever disciplined their child and, if so, who else had been involved in the disciplinary process and what methods were used. *To capture caregiver-reported child-shaking behavior,* 5 *items were adapted* from the "Parent-Child Conflict Tactics Scale (CTSPC)" [17]. CTSPC includes subscales assessing various dimensions of the parent-child relationship, such as communication, power dynamics, discipline strategies, emotional expression, and relationship quality. Items are typically rated on a Likert-type scale (eg, from "never" to "always"), and subscale scores are calculated by summing the individual item responses.

The selected questions from this questionnaire included: (1) "Has anyone in the household ever shaken the child to discipline?" (2) "If yes, how many times in the past year or since birth was the child shaken?" and (3) "What was the mental status of the caregiver or others while they shook the baby?" Two additional items from a previous study were incorporated to assess contextual factors, assessed by the question, "What was the child doing right before you shook them?" and awareness of the potential consequences of shaking, assessed by the question, "Thinking about when you shook your child, did you think you might have hurt the child?" These items had previously been field-tested in the United States and other countries [11,17]. Maternal mental status and emotional well-being were assessed using 6 questions adapted from the Center for Epidemiological Studies Depression scale [5,18], which is widely used in community-based mental health research. In addition, caregiver-child interactions were assessed using the "Family Care Indicators," developed by the United Nations Children's Fund [19], which measure the frequency and type of stimulation and engagement provided by caregivers.

Data Collection

Once the children were settled after hospital admission and had received initial management, a trained interviewer briefed the caregivers about the project and built rapport. The interviewers were university graduates with previous experience in child health–related research. Informed written consent (signature or fingerprint) was obtained from the caregiver who agreed to participate in the study. Care was taken to organize the questionnaire to minimize the likelihood of caregivers feeling guilty, ashamed, or offended when responding to questions about shaking. For example, caregivers were first informed about common parental habits for disciplining their children. Then they were asked whether they had ever disciplined their children and, if so, how. The conversation was gradually guided to include shaking as one possible disciplinary behavior, after which the interviewer asked whether they had ever shaken their child as a form of discipline. Typical shaking was described as "back and forth" shaking, as used in the CTSPC. If the interviewers were convinced that a shaking incident was being described, additional details were collected. However, "mild" shaking, such as soothing, rocking, or tossing the child up in the air, was not counted as "typical shaking." The interviews were conducted in a private location in the ward, and the caregivers were offered snacks. One designated health worker or attendant looked after the child during the interview. The collected data were cross-checked by the supervisors on the day of the interview or the following day for any inconsistencies or missing information before data entry.

Analysis

Data were analyzed using SPSS software for Windows (version 20.0, IBM Corp). A simple descriptive analysis was conducted for this pilot study. Frequency distributions of all the items in the questionnaire were determined. The dichotomous "yes or no" information on whether the child had ever been shaken was calculated by combining the shaking histories reported by the primary caregiver and other family members. Sometimes a child was shaken, either by a caregiver or other family members, in the past year or since birth (if aged <1 year), and these instances were combined to calculate the total number of times the child had been shaken by someone. This variable was not normally distributed. Therefore, the Spearman correlation was conducted separately for the urban (n=520) and the rural (n=280) samples to examine the associations between various sociodemographic and maternal factors and the frequency of shaking the index child. An independent sample 2-tailed *t* test was conducted to compare the populations of the urban and rural areas. Finally, multiple logistic regression was computed to examine the factors associated with shaking as a disciplinary practice with young children. The model considered the following covariates in the analysis: family members (ie, number of persons eating from the same pot), number of children aged younger than 5 years in the household, family income-expenditure deficit, maternal depression, and geographic location (urban and rural). All statistical tests were performed using 2-tailed *t* tests.

Ethical Considerations

The institutional review board at the International Centre for Diarrhoeal Disease Research, Bangladesh, reviewed and approved this study (2009-007). We obtained verbal informed consent from all parents, and the principles of confidentiality and anonymity were upheld throughout the study. All participants were informed in Bengali about their rights

XSL•FO
RenderX

regarding voluntary participation and their freedom to withdraw from the interview at any point during the process.

Results

Description of the Population

A total of 800 mother-child dyads were enrolled from both hospitals (Dhaka: n=520, 65%; Matlab: n=280, 35%). Almost all (n=786, 98.3%) of the caregivers were biological mothers of the index children. A significantly higher proportion of fathers in rural areas were engaged in unskilled occupations compared to their urban counterparts (n=34, 10% vs n=45, 18%; *P*=.04). Multimedia Appendix 1 presents the socioeconomic, maternal, and child characteristics of the study populations. In addition, rural families tended to be slightly larger, and the fathers in these areas reported lower household incomes relative to those in urban settings. Across both groups, the mothers generally had a low level of educational attainment, reflecting limited access to formal education in these lower-income communities.

Approximately 15% (n=78) of the urban mothers and 19% (n=53) of the rural mothers completed education beyond high school. Although the mothers in the rural area were significantly better educated than their urban counterparts, they were more likely to be housewives. Approximately 29% (n=151) of the urban fathers and 30% (n=85) of the rural fathers studied beyond high school. Despite the urban-rural differences in living conditions, the monthly income and expenditure balances were not significantly different between the 2 groups. The percentage of mothers with higher depression scores (ie, median >25) was similar in both urban and rural contexts. A higher number of male children were admitted to and enrolled from the rural Matlab hospital than from the urban Dhaka hospital during the study period.

Shaking Practices in the Communities

In response to the question whether the child had ever been shaken to discipline them by anyone, 51% (n=265) of the respondents in Dhaka and 21% (n=60) of the respondents in Matlab hospital said “yes,” and the percentage was significantly higher (*P*<.001) in the lower-income urban communities of Dhaka compared to rural Matlab. The median number of shaking episodes reported in the past year was 5 (IQR 3-7) in Dhaka and 4 (IQR 2-7) in Matlab.

Responses to the question “How many times in the past year [or since birth if aged <1 year] have you shaken the child?” are illustrated in Multimedia Appendix 2, according to the percentage of children in different age groups who were shaken in Dhaka and Matlab.

Factors Triggering Shaking

To identify the source of disturbances that triggered shaking behavior, whether originating from the child or the caregiver, we asked specific questions to the caregivers. In most cases, caregivers reported that the shaking was triggered by the child’s behavior: 50.6% (n=134) in Dhaka and 18.3% (n=11) in Matlab. However, 12% (n=32) of the caregivers in Dhaka and 50% (n=30 in Matlab reported that there was no provocation from the child; rather, they were disturbed and stressed for some other familial reasons and expressed their frustrations by shaking the child.

When we asked about specific activities of a child that elicited shaking behavior, caregivers from both Dhaka and Matlab reported that crying and fussing were the most common triggers (n=133, 62.4%) for shaking, particularly in infants approximately aged 6 months (Multimedia Appendix 3). Disruptive behavior of children during feeding (eg, not eating and throwing food) and playing (eg, hitting other children or making a mess) also appeared to be important triggers.

Persons Involved in Shaking Behavior

In these communities, children’s biological mothers, as the primary caregivers, shook their children the most (Multimedia Appendix 4). Approximately 43% (n=113) of the mothers in urban Dhaka and 60% (n=36) of the mothers in rural Matlab acknowledged that they were the only caregivers who shook the child. Sometimes more than 1 caregiver shook the child (n=77, 29.1% of the cases in Dhaka vs n=4, 6.7% of the cases in Matlab), and in most cases, these caregivers were fathers, grandparents, older siblings, or neighbors, along with the mothers.

A comparatively smaller proportion of biological fathers reported shaking their children: only 8% (n=21) in Dhaka and 5% (n=3) in Matlab. In Dhaka, 20% (n=54) of the children were shaken by nonparent caregivers; among them, 14% (n=37) were siblings, cousins, neighbors, and housemaids, 4% (n=12) were aunts and 2% (n=5) were grandmothers. Similarly, in Matlab, 28% (n=17) of the children were shaken by nonparent caregivers; among them, 10% (n=6) were siblings, 17% (n=10) were aunts, and 2% (n=1) were grandmothers.

Caregivers’ Beliefs Regarding Child Shaking Behavior

When caregivers were asked about their beliefs regarding shaking, 56.6% (n=85) of the mothers in Dhaka and 28.2% (n=10) of the mothers in Matlab stated that they considered shaking to be harmless for children (Multimedia Appendix 5).

Factors Associated with Shaking

Finally, to identify the factors associated with shaking as a disciplinary practice in young children, we conducted a multiple logistic regression analysis (Multimedia Appendix 6). The variables included were age and sex of child, parental education (ie, years of schooling), parental occupation, and total number of family members. After adjusting for potential covariates, child age in months was significantly associated with increased odds of being shaken (adjusted odds ratio [AOR] 1.06, 95% CI 1.02-1.10; *P*=.001), showing that older children were more likely to be subjected to this form of discipline. No significant associations were found for child sex, parental occupation, family size, number of children, and parental education. Although male children had higher odds of being shaken compared to female children (AOR 1.13, 95% CI 0.83-1.55; *P*=.44), the association was not statistically significant. Similarly, low-skilled paternal occupation (AOR 1.07, 95% CI 0.75-1.51; *P*=.72) and maternal housewife status (AOR 1.23, 95% CI 0.77-1.98; *P*=.39) were not statistically significant predictors. However, maternal depressive symptoms were

XSL•FO
RenderX

positively associated with shaking behavior; each 1-point increase in the depression score was associated with a 3% increase in the odds of shaking (AOR 1.03, 95% CI 1.01-1.04; *P*=.001). In addition, children residing in Dhaka had significantly higher odds (5 times more) of being shaken compared to those in Matlab (AOR 5.32, 95% CI 3.62-7.82; *P*<.001).

Discussion

Principal Findings

The practice of shaking as a form of disciplining children, particularly those aged between 6 and 12 months, was found to be unexpectedly high in lower-income rural and urban households. Around 27% (n=214) of the primary caregivers (mothers) of the children surveyed had practiced it. This study was designed to document the occurrence of shaking and not its severity.

One possible explanation for the high prevalence of caregiver-reported shaking behavior among those aged between 6 and 12 months is the increased caregiving demands during this developmental period, including heightened crying, mobility, and feeding difficulties. Children require more attention and care during this critical time as they transition to complementary feeding; learn new developmental skills, such as motor activities (eg, crawling and sitting); and begin to explore their surroundings. Moreover, infants at this age experience frequent illnesses (eg, diarrhea, respiratory infections, and fever) due to the waning of maternally acquired immunity and increased exposure to infectious agents. Consequently, caregivers become increasingly anxious and stressed, which can contribute to “shaking” as a response to perceived child distress or behavioral challenges. Unlike studies from high-income countries, shaking behavior does not appear to be prevalent during early infancy (ie, aged <6 months). One explanation could be the culture and social structure that exists between neighboring families in Bangladesh. Families in these communities tend to live closely together, offer mutual support, and form very intimate bonds. Such connections may serve as a buffer against caregiver stress during the first months of childcare. In rural Matlab, 3 to 5 households share a common courtyard [20], and in Dhaka slums, as many as 8 to 10 individuals share a 1-room dwelling [21]. Thus, there are several household members available to help with childcare during the early months.

The peak prevalence of shaking is similar in urban and rural households, although the practice was significantly higher in the slums of Dhaka city. Both groups have experienced extreme poverty, but there are important differences as well. Urban mothers are more likely to be wage earners and have a higher level of education. Unlike in other LMICs, where maternal education had a negative correlation with shaking behavior [22], we found no significant association between maternal education and shaking practices, although it was higher in urban mothers. However, maternal depressive symptoms showed a significant association with shaking practices for disciplining [23]. This indicates the importance of maternal mental well-being as the primary caregiver.

Similar to other studies, we found crying and fussing to be common triggering factors for shaking, particularly in young children. However, the timing of crying is outside the normal cry curve, which peaks at around 3 months of age in high-income countries [24]. Among 33 infants aged younger than 3 months, only 4 (12%) in Dhaka and none in Matlab experienced shaking.

We also tried to assess the mental status of the caregivers during shaking by asking questions about how frustrated or angry they were and why. Approximately 50% (n=162) of the mothers reported that they were disturbed or frustrated at the time of their last shaking episode due to different reasons (eg, a quarrel with their husband or mother-in-law). In our study, depression was positively correlated with the shaking behavior of mothers.

According to one study in Ethiopia, female primary caregivers were significantly associated with a higher use of harsh physical punishment compared to male caregivers [23]. We found female caregivers (eg, mothers, aunts, sisters, and grandmothers) to be the main perpetrators of shaking behavior. This contrasts with studies published from high-income countries, where in 65% to 90% of the cases, young male individuals—either the baby’s father or the mother’s boyfriend—are the main perpetrators [25]. This could be due to the cultural norms in this part of the world, where mothers and other female relatives are expected to look after children at an early age.

However, consistent with studies from many other countries, half (n=85, 56.6%) of the mothers in Dhaka hospital and a third (n=10, 28.2 %) of the mothers in Matlab believed that infant shaking is harmless. Interestingly, when we interviewed mothers to learn how they discipline their children, not a single mother spontaneously mentioned shaking as a disciplining behavior. However, when asked specifically whether they shook their child for discipline, they reported that they did so sometimes. This indicates that, culturally, shaking is not considered a very dangerous or cruel behavior in child-rearing in Bangladesh.

In general, this pilot study aimed to explore the prevalence of shaking behavior among caregivers toward their young children residing in lower-income communities as well as the possible biological and sociodemographic factors associated with it. We collected information from the aforementioned 2 popular diarrhea hospitals because a large number of people from lower-income communities with mild to moderate illnesses are admitted to these hospitals. Therefore, selecting cases from these hospitals allowed us to estimate the prevalence of shaking in lower-income, stressed, and vulnerable communities of urban and rural Bangladesh.

Limitations

Our main limitation was the selection of a biased sample of mothers of children who were hospitalized with illness. To minimize this, we included only the mothers of children with less severe illness who were admitted to longer-stay units, so that after settling their children, they could talk to us. Most of the reported studies on infant shaking interviewed mothers of children diagnosed with SBS and thus were easier to interpret. Here, based on the mother’s report, we do not know how severe the shaking was and whether it impacted the child. The report

XSL•FO
RenderX

of maternal depression was also confounded by the concurrent illnesses of the children.

Apart from these limitations, this quick exploratory study on 720 participants revealed the context of infant-shaking behavior in an LMIC such as Bangladesh. The key observations were that shaking behavior exists in lower-income communities in Bangladesh and is alarmingly high, but the patterns are different from those reported in high-income countries. The age range for children who were shaken is different from that in the Western context, as shaking occurs when children are slightly older. Although similar to other countries, crying and fussing triggered shaking behavior in most cases; this does not fall within the normal crying curve of infants aged 2 to 3 months. Mothers are the main perpetrators of infant shaking because of their frequent contact with children, and in many cases, they are unaware of the hazardous outcomes.

Furthermore, qualitative and quantitative studies are needed to determine the actual burden of this problem. In Bangladesh, child abuse and neglect are becoming a growing concern [26]. A screening program on 2576 children in Bangladesh showed that up to 70% of the children are living with mild to moderate disabilities [27]. It is also important to examine the relationship between early shaking and future child development in low-income countries to understand the long-term consequences of infant shaking and the resulting social and public health burden.

Comparison with Prior Work

There has been no study conducted in Bangladesh with which we can compare our results.

Conclusions

This study provides insights into the differences in disciplinary acts experienced by children from their caregivers in 2 types of communities in Bangladesh. We recommend more research on this topic, considering cultural beliefs or social practices. It is very important to examine the association between shaking behavior and child development. In addition, we found that maternal depression was correlated with certain disciplining practices, which, as we hypothesize, may affect child development. Children living in lower-income urban communities are more prone to these practices. However, the long-term effects of disciplining children through shaking practices are still unknown. We need to help parents understand how such behavior impacts their children. As the world shifts into a new era, some social aspects of raising children need to be revised for the betterment of society.

Acknowledgments

I extend my heartfelt gratitude to Centre for Community Child Health Research of the Child and Family Research Institute, and BC Children's Hospital, Canada for their generous financial assistance. I am also grateful to Dr Hasanat Alamgir (Simon Fraser University) and Dr Charles Larson (British Columbia Children's Hospital, Canada) for their invaluable support throughout this work. My sincere thanks go to Dr Ron Barr (Department of Pediatrics, UBC Faculty of Medicine, Canada), and Drs Adam J Zolotor and Desmond K Runyan (The University of North Carolina, USA) for their extensive guidance and technical support. Great appreciation to Nur-E Salveen, Goutam Kumar Dutta, Mahbub Elahi, Sk Rafia Islam Mitu, and Kaniz Fatima for their support in preparing the manuscript. The author is grateful to the study participants who gave their valuable time and information for this research. icddr,b is also grateful to the Governments of Bangladesh and Canada for providing core/unrestricted support.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Socioeconomic and child characteristics of the population studied.
[DOCX File , 14 KB - pediatrics_v8i1e64474_app1.docx]

Multimedia Appendix 2
Percentage of children ever shaken by caregivers, by age group, in Dhaka and Matlab hospitals.
[DOCX File , 13 KB - pediatrics_v8i1e64474_app2.docx]

Multimedia Appendix 3
Triggers for shaking behavior (child's activities).
[DOCX File , 15 KB - pediatrics_v8i1e64474_app3.docx]

Multimedia Appendix 4
Child-shaking by caregivers in Dhaka and Matlab.
[DOCX File , 13 KB - pediatrics_v8i1e64474_app4.docx]

Multimedia Appendix 5

XSL•FO
RenderX

Mothers' perception of shaking.
[DOCX File , 13 KB - pediatrics_v8i1e64474_app5.docx]

Multimedia Appendix 6
Factors linked to shaking as discipline among young children.
[DOCX File , 14 KB - pediatrics_v8i1e64474_app6.docx]

References

1. Altimier L. Shaken baby syndrome. J Perinat Neonatal Nurs 2008;22(1):68-77. [doi: 10.1097/01.JPN.0000311877.32614.69] [Medline: 18287904]
2. Newton AW, Vandeven AM. Unexplained infant and child death: a review of sudden infant death syndrome, sudden unexplained infant death, and child maltreatment fatalities including shaken baby syndrome. Curr Opin Pediatr 2006 Apr;18(2):196-200. [doi: 10.1097/01.mop.0000193296.32764.1e] [Medline: 16601503]
3. Case ME, Graham MA, Handy TC, Jentzen JM, Monteleone JA, National Association of Medical Examiners Ad Hoc Committee on Shaken Baby Syndrome. Position paper on fatal abusive head injuries in infants and young children. Am J Forensic Med Pathol 2001 Jun;22(2):112-122. [doi: 10.1097/00000433-200106000-00002] [Medline: 11394743]
4. Theodore AD, Chang JJ, Runyan DK, Hunter WM, Bangdiwala SI, Agans R. Epidemiologic features of the physical and sexual maltreatment of children in the Carolinas. Pediatrics 2005 Mar;115(3):e331-e337. [doi: 10.1542/peds.2004-1033] [Medline: 15741359]
5. Ward KP, Grogan-Kaylor A, Ma J, Pace GT, Lee S. Associations between 11 parental discipline behaviours and child outcomes across 60 countries. BMJ Open 2023 Oct 30;13(10):e058439 [FREE Full text] [doi: 10.1136/bmjopen-2021-058439] [Medline: 37903610]
6. Keenan HT, Runyan DK, Marshall SW, Nocera MA, Merten DF, Sinal SH. A population-based study of inflicted traumatic brain injury in young children. JAMA 2003 Aug 06;290(5):621-626. [doi: 10.1001/jama.290.5.621] [Medline: 12902365]
7. Dias MS, Smith K, DeGuehery K, Mazur P, Li V, Shaffer ML. Preventing abusive head trauma among infants and young children: a hospital-based, parent education program. Pediatrics 2005 Apr;115(4):e470-e477. [doi: 10.1542/peds.2004-1896] [Medline: 15805350]
8. Risen SR, Suskauer SJ, Dematt EJ, Slomine BS, Salorio CF. Functional outcomes in children with abusive head trauma receiving inpatient rehabilitation compared with children with nonabusive head trauma. J Pediatr 2014 Mar;164(3):613-9.e1 [FREE Full text] [doi: 10.1016/j.jpeds.2013.10.075] [Medline: 24321537]
9. King WJ, MacKay M, Sirnick A, Canadian Shaken Baby Study Group. Shaken baby syndrome in Canada: clinical characteristics and outcomes of hospital cases. CMAJ 2003 Jan 21;168(2):155-159 [FREE Full text] [Medline: 12538542]
10. Sakakihara A, Masumoto T, Kurozawa Y. The association between maternal shaking behavior and inappropriate infant parenting: the Japan environment and children's study. Front Public Health 2022 Apr 12;10:848321 [FREE Full text] [doi: 10.3389/fpubh.2022.848321] [Medline: 35480586]
11. Runyan DK. The challenges of assessing the incidence of inflicted traumatic brain injury: a world perspective. Am J Prev Med 2008 Apr;34(4 Suppl):S112-S115. [doi: 10.1016/j.amepre.2008.01.011] [Medline: 18374259]
12. Runyan DK, Shankar V, Hassan F, Hunter WM, Jain D, Paula CS, et al. International variations in harsh child discipline. Pediatrics 2010 Sep;126(3):e701-e711. [doi: 10.1542/peds.2008-2374] [Medline: 20679301]
13. Grantham-McGregor S, International Child Development Committee. Early child development in developing countries. Lancet 2007 Mar 10;369(9564):824. [doi: 10.1016/S0140-6736(07)60404-8] [Medline: 17350449]
14. Caffey J. On the theory and practice of shaking infants. Its potential residual effects of permanent brain damage and mental retardation. Am J Dis Child 1972 Aug 01;124(2):161-169. [doi: 10.1001/archpedi.1972.02110140011001] [Medline: 4559532]
15. Carbaugh SF. Understanding shaken baby syndrome. Adv Neonatal Care 2004 Apr;4(2):105-117. [doi: 10.1016/S1536-0903(04)00031-1]
16. Jackson JE, Beres AL, Theodorou CM, Ugiliweneza B, Boakye M, Nuño M. Long-term impact of abusive head trauma in young children: outcomes at 5 and 11 years old. J Pediatr Surg 2021 Dec;56(12):2318-2325 [FREE Full text] [doi: 10.1016/j.jpedsurg.2021.02.019] [Medline: 33714452]
17. Straus MA, Hamby SL, Finkelhor D, Moore DW, Runyan D. Identification of child maltreatment with the parent-child conflict tactics scales: development and psychometric data for a national sample of American parents. Child Abuse Negl 1998 Apr;22(4):249-270. [doi: 10.1016/s0145-2134(97)00174-9] [Medline: 9589178]
18. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Appl Psychol Manag 1977 Jun 01;1(3):385-401. [doi: 10.1177/014662167700100306]
19. Abusive head trauma (shaken baby syndrome). Nemours KidsHealth. URL: https://kidshealth.org/en/parents/shaken.html [accessed 2025-09-15]
20. Alam N, Ali T, Razzaque A, Rahman M, Zahirul Haq M, Saha SK, et al. Health and Demographic Surveillance System (HDSS) in matlab, Bangladesh. Int J Epidemiol 2017 Jun 01;46(3):809-816. [doi: 10.1093/ije/dyx076] [Medline: 28637343]

XSL•FO
RenderX

21. Podymow T, Turnbull TJ, Islam MA, Ahmed M. Health and social conditions in the Dhaka slums. SCRIBD. URL: https://www.scribd.com/document/44220155/Health-and-Social-Conditions-in-the-Dhaka-Slums [accessed 2025-05-29]
22. Ashford JB, Lortie K. Human Behavior in the Social Environment: A Multidimensional Perspective. 4th edition. New York, NY: Brooks/Cole; 2009.
23. Desta M, Deyessa N, Hailu Y, Baye A, Rodriguez N, Fish I, et al. Harsh physical discipline: prevalence and associated factors among primary caregivers of pre-school children in Ethiopia. Int J Child Maltreat 2022 Jun 21;5(3):355-374 [FREE Full text] [doi: 10.1007/s42448-022-00118-9] [Medline: 35757599]
24. Barr RG, Trent RB, Cross J. Age-related incidence curve of hospitalized Shaken Baby Syndrome cases: convergent evidence for crying as a trigger to shaking. Child Abuse Negl 2006 Jan;30(1):7-16. [doi: 10.1016/j.chiabu.2005.06.009] [Medline: 16406023]
25. Norton DR, Firestone JM, Vega A. Changes in awareness of shaken baby syndrome in the San Antonio metropolitan statistical area: 2001–2002. J Appl Sociol 2004;6(2):112-134 [FREE Full text]
26. Khan NZ, Lynch MA. Recognizing child maltreatment in Bangladesh. Child Abuse Negl 1997 Aug;21(8):815-818. [doi: 10.1016/s0145-2134(97)00041-0] [Medline: 9280385]
27. Zaman SS, Khan NZ, Islam S, Banu S, Dixit S, Shrout P, et al. Validity of the 'Ten Questions' for screening serious childhood disability: results from urban Bangladesh. Int J Epidemiol 1990 Sep;19(3):613-620. [doi: 10.1093/ije/19.3.613] [Medline: 2148168]

Abbreviations

AHT: abusive head trauma
AOR: adjusted odds ratio
CTSPC: Parent-Child Conflict Tactics Scale
LMIC: low- and middle-income country
SBS: shaken baby syndrome

Edited by S Badawy; submitted 24.07.24; peer-reviewed by Q Zhou, D Poddighe; comments to author 23.12.24; revised version received 07.05.25; accepted 18.07.25; published 14.10.25.

Please cite as:
Tofail F
The Practice of Shaking in Disciplining Young Children in Lower-Income Communities of Bangladesh: Cross-Sectional Exploratory Study
JMIR Pediatr Parent 2025;8:e64474
URL: https://pediatrics.jmir.org/2025/1/e64474
doi:10.2196/64474
PMID:41085998

©Fahmida Tofail. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 14.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

The Maternal Support Framework Studying Mothers' Perceived Understanding and Support During Excessive Infant Crying: Exploratory Qualitative Study

Oona Janssens[1], PhD; Anna Galle[1], PhD; Ineke De Kruijff[2], PhD, Dr med; Katrijn Brenning[3], Prof Dr

[1]Department of Public Health and Primary Care, Faculty of Medicine and Health Sciences, Ghent University, Ghent, Belgium

[2]Department of Pediatrics, St Antonius Ziekenhuis, Utrecht, The Netherlands

[3]Department of Developmental, Personality and Social Psychology, Faculty of Psychology and Educational Sciences, Ghent University, Ghent, Belgium

Corresponding Author:
Oona Janssens, PhD
Department of Public Health and Primary Care
Faculty of Medicine and Health Sciences
Ghent University
Corneel Heymanslaan 10
Ghent, 9000
Belgium
Phone: 32 470861351
Email: oona.janssens@ugent.be

Abstract

Background: Excessive infant crying affects approximately 20% of families and can lead to parental distress, anxiety, and strained relationships. Despite its prevalence, many parents report feeling misunderstood and unsupported during these challenging periods.

Objective: This study aimed to gain in-depth insight into mothers' perceptions of being understood and supported in the context of excessive infant crying, focusing on three key stakeholder groups: partners, the personal network, and health care professionals. Based on these results, the study sought to develop a maternal support framework regarding excessive crying that could guide future research and practice, as well as support strategies.

Methods: Using a qualitative approach supplemented by quantitative measures, through an online survey, three open-ended questions were included on how mothers would like to be understood and supported by the three stakeholder groups (ideal situation) and six 6-point Likert scales on mothers' current perceived understanding and support regarding the three stakeholder groups (current situation). Descriptive statistics were used to examine current levels of understanding and support, and an inductive thematic analysis was applied to identify the ideal key support elements.

Results: Data were collected from 432 mothers (n=238, 55.1% Dutch; n=194, 44.9% Flemish; mean age 33 years, range 21-45 years). Regarding the current situation, mothers rated health care professionals lowest in perceived understanding and support, with 50.6% (n=219) feeling little or no understanding and 47.1% (n=203) reporting little or no support. Similar patterns were found in the personal network (n=184, 42.6%, and n=164, 38%, respectively). Partners were perceived as most supportive, with only 17.6% (n=76) of mothers reporting little or no understanding and 21.8% (n=94) reporting little or no support. Based on the thematic analysis of the qualitative data, the ideal situation was framed in the newly developed maternal support framework. This framework identifies 25 distinct support forms, of which 12 (48%) are common support forms (partner, personal network, health care professionals, eg, listen actively), 6 (24%) are related to partners (eg, be physically present), 6 (24%) concern the support of health care professionals (eg, refer appropriately), and 1 (4%) is specific to the personal network (cope with the crying).

Conclusions: This study underscores the need for holistic, family-centered approaches to supporting families with excessively crying infants. The proposed maternal support framework offers a foundation for developing tailored interventions that reflect the diverse roles of partners, personal networks, and health care professionals in maternal well-being.

(JMIR Pediatr Parent 2025;8:e75669) doi:10.2196/75669

XSL•FO
RenderX

KEYWORDS

excessive crying; infant; maternal support; parental distress; framework; maternal support framework

Introduction

Infant crying is an essential aspect of early development, serving as the primary mode of communication during the first months of life [1,2]. Although crying is typical behavior, it becomes a concern when approximately 20% of infants exhibit excessive crying [3]. Traditionally, excessive crying has been defined using objective criteria, such as Wessel's rule of threes (crying for at least 2 hours per day, 3 days per week, for 3 consecutive weeks [4]), and, more recently, the ROME-IV criteria (recurrent, unexplained crying or irritability in infants under 5 months old that cannot be soothed by caregivers [5]). Although ROME-IV incorporates caregiver reports, its focus remains on observable infant behavior and colic specifically, offering limited attention to parental distress or the broader psychosocial context. Recent research emphasizes the limitations of such symptom-based classifications, highlighting the need to consider parents' subjective experiences, such as stress and helplessness [6,7]. Indeed, Reijneveld et al [7] emphasize the importance of definitions that integrate both crying duration and the distress experienced by parents. Additionally, some researchers distinguish between "excessive crying," which is based on parents' subjective perception that their baby cries too much and signals a potential problem, and "prolonged crying," which refers to a measurable duration [8]. This dual perspective highlights the growing recognition of parental perceptions and the intricate interplay between infant behavior and parental mental health. This is a positive development, as it underscores the importance of adopting a biopsychosocial perspective and approach to excessive crying [9], particularly given that a medical cause is identified in fewer than 5% of cases [1].

The experience of having an excessively crying infant can profoundly affect parents, leading to heightened levels of distress, anxiety, and depression, as well as difficulties bonding with their child [3,6,10-12]. These psychological challenges are often compounded by practical issues, such as early cessation of breast feeding, overfeeding, and, in some cases, long-term developmental risks for the infant. Although more research is still needed on the long-term consequences of excessive crying, excessively crying infants seem to be at increased risk of developing psychological, behavioral, and allergic disorders. In addition, there might be a higher incidence of headache and migraine later in life in children who cry excessively [13]. In severe instances, excessive crying might also increase the risk of shaken infant syndrome [9-11,14]. These far-reaching effects underline the necessity of addressing excessive crying, not merely as an infant issue, but also as a family-centered concern that prioritizes the well-being of parents [6].

A qualitative study by Garratt et al [6] explored UK parents' experiences of having an excessively crying baby. Their study showed that parents often have disrupted expectations and experiences of parenthood, perceive stigma and social isolation, and seek support and validation of their experience [6]. This sense of isolation is further amplified by dissatisfaction with health care; research shows that 55% of the participating Dutch mothers in a study by van der Veek et al [15] felt that they received inadequate information about their infant's crying and available health care support. Therefore, proactively providing comprehensive information during pregnancy or shortly after birth might better equip parents to manage the challenges associated with excessive crying [6]. In the same vein, Harskamp et al [16] explored the types and format of health care support parents with excessively crying infants need. They identified four key themes: (1) the need for confidence in health care professionals, (2) the need to investigate potential somatic causes of crying, (3) the need for acknowledgment of their baby's crying, and (4) the need for support to break the cycle of exhaustion and self-doubt [16]. These findings underscore the importance of holistic, family-centered care that addresses not only the crying itself but also the emotional and practical challenges faced by parents. Providing tailored support is essential for preventing cascading difficulties and fostering positive parent-infant interactions [17].

Even though health care professionals are thus critical in providing support and care for parents with an excessively crying baby, an integrative approach involving the entire support system of parents with an excessively crying baby is essential. Moreover, existing research often isolates specific aspects of excessive crying, such as health care interventions, for example, manual therapy [18,19], probiotics [20], parental coping [6], or soothing techniques (eg, swaddling [21]). Furthermore, studies on excessive crying are often small in scale, and an integrative care framework for parents with excessively crying infants is lacking.

To optimally identify the needs of parents with excessively crying infants, it is crucial to assess both their current experiences and their perceptions of an ideal support situation. Previous research has shown that mothers often feel they are not taken seriously or that the severity of their situation is not adequately understood or acknowledged [15]. Additionally, receiving insufficient or inadequate support has been highlighted as a key issue by van der Veek et al [15]. Importantly, being understood and receiving support represent two distinct but interrelated needs for families facing excessive infant crying. Building on this, this survey study investigated mothers' perceived understanding and support from their partners, personal networks, and health care professionals (current situation). Moreover, building on the needs for support expressed by mothers (ideal situation), this study aimed to develop a comprehensive conceptual framework—the maternal support framework—that can serve as a foundation for future research and interventions designed to support families with excessively crying babies.

Methods

Sample

Recruitment began in January 2024. Using a cluster sampling technique, invitations to participate were distributed via specific Facebook groups for parents, such as "Mama's," "Mama's onder

XSL•FO
RenderX

elkaar," and "Onder mama's." Additionally, invitations were also shared in more specialized groups focusing on excessively crying infants, such as "Reflux Baby," "Crying Baby Parents," "Crying Baby Support Center," and similar communities. A link was available to participate in the study. The relatively homogeneous sample, including only mothers who had experienced having a crying baby themselves (without a specific quantification of the crying amount, as our main focus was on parental perception) allowed for an in-depth exploration of the phenomenon of excessive crying and, more specifically, parents' perceptions of understanding and support during this life phase. Although there is no gold standard for determining the sample size in qualitative research, we aimed to recruit and collect data until we reached data saturation. However, 432 participants completed the survey within a week, which could be seen as an exceptional response rate, so we decided to include all data, thereby further strengthening the validity of the study.

Ethical Considerations

When interested mothers wanted to participate, they could click an anonymous link that directed them to a questionnaire. The study received approval from the Ethics Committee of Ghent University (reference number: 2023-141W). Prior to commencement of the questionnaire survey, written informed consent was obtained from all participants after providing them with comprehensive information about the study goals, study flow, etc. Additionally, participants acknowledged a privacy statement at the beginning of the questionnaire, which provided comprehensive information regarding General Data Protection Regulation (GDPR) compliance and the handling of their data. No incentives were provided. A brief overview of the sample can be found in the *Results* section.

Data Collection

A questionnaire was developed in Qualtrics. The questionnaire was based on previous research indicating a gap in knowledge about the perceived understanding and support of mothers' direct environment (partners, personal networks, and health care professionals). First, the invitation was posted in the aforementioned Facebook groups to test the questionnaire and ensure the questions are clear. Three mothers pilot-tested the questionnaire using a think-aloud procedure where they could write down their concerns regarding the questions. However, no ambiguities was identified, as expected, as the questions were straightforward and concise. Therefore, the final questionnaire consisted of 11 questions that were a combination of qualitative and quantitative measures. Nine items concerned perceptions of the current (six items) and the ideal (three items) situation, one item was an open-ended question on which health care professionals they consulted during this period, and one item was on the general daily duration of crying. Participants were included based on maternal characteristics—specifically, having experienced a baby who cried excessively at the time of the study or in the past.

Qualitative Measures

To encourage deep insights and strengthen our qualitative research approach by data triangulation, a combination of open-ended questions and Likert scales was used. The qualitative part existed of asking participants how they wanted to be understood and supported by each of the groups (partners, personal networks, and health care professionals in general=ideal situation). Finally, they were asked which health care professionals they consulted during this period.

Quantitative Measures

In addition to answering the open-ended questions, participants scored six Likert scales that assessed their perceptions (current situation) of understanding (three questions) and support (three questions) from their (1) partners, (2) personal networks (parents, grandparents, friends, colleagues, etc), and (3) consulted health care professionals (health care disciplines not specified). These questions used a 6-point Likert scale with the following verbal anchors: perfect (1), very good (2), good (3), fair (4), poor (5), and none (6). The use of these verbal anchors avoids numeric values and clearly defines the scale in verbal terms. We chose 6 points to prevent consistently selecting the neutral midpoint [22-25]. Finally, a scale with predefined time categories (in hours) was used to assess the duration of crying in different parts of the day as part of the demographic data. The complete questionnaire can be found in Multimedia Appendix 1.

Data Analysis

This study used a qualitative research approach (open-ended questions) supplemented by quantitative measures (Likert scales).

Qualitative Measures

Open-ended questions that explored how participants wished to be supported and understood were analyzed using an inductive content analysis approach in NVivo [26]. Given the exploratory nature of the study and the straightforward structure of the data, a single experienced coder conducted the initial coding. Thereby, the data were first thoroughly read multiple times to gain a deep understanding of the content. Following this, the organizing process began, which included open coding, theme development, and abstraction [27]. The final phase of abstraction involved creating overarching concepts. Afterward, an independent reviewer examined the themes to eliminate ambiguity, overlap, and potential misinterpretations, thereby enhancing credibility and reducing potential bias. This approach ensured a balance between analytical consistency and critical validation. Additionally, the frequency with which each theme emerged in the data was calculated to assess how well the integration of themes resonated with participants. This approach allowed for an estimation of the importance and prevalence of the identified themes, ultimately contributing to the development of a framework for the overarching concept of "care for parents with an excessively crying baby," referred to as the maternal support framework [28].

Quantitative Measures

Analysis of the Likert scales involved descriptive statistics to calculate frequencies, as well as minimum, maximum, and mean values.

XSL•FO
RenderX

Results

Participant Details

A total of 432 mothers fully completed the questionnaire. Of these, 55.1% (n=238) resided in the Netherlands, while 44.9% (n=194) were from Flanders (Belgium). Additionally, 0.5% (n=2) of the participants reported living in other countries, specifically France or Italy. The average age of the participants was 33 years (range 21-45). The number of children per participant varied from 1 to 5, with a mean of 1.77 children per parent.

Descriptive analyses showed that the 432 participating mothers consulted a total of 1111 different health care professionals at least once during the period their baby cried excessively. On average, each mother consulted 2.7 health care professionals due to their infant's excessive crying. These health care professionals included pediatricians, general practitioners, midwives, child health nurses, osteopaths, pharmacists, physiotherapists, psychologists, chiropractors, dentists, radiologists, parenting coaches, lactation consultants, surgeons, dietitians, and occupational therapists. The most frequently consulted health care professionals were pediatricians (305/408, 74.8%, mothers), general practitioners (212/408, 52%, mothers), child health nurses (153/408, 37.5%, mothers), osteopaths (121/408, 29.7%, mothers), and midwives (112/408, 27.5%, mothers). Table 1 provides a detailed overview of consulted health care professionals and the number of mothers who consulted them.

Excessive crying, on average, began approximately 2 weeks and 1 day after birth. Parents reported that they typically noticed their baby's crying was above average around 4 weeks and 2 days after birth. Participants estimated that their babies cried for nearly 12 hours (mean 11.97 hours, SD 5.2) each day, with the most significant crying occurring in the evening, averaging 6.6 hours (SD 5.3). This was followed by crying in the afternoon, which averaged 5.5 hours (SD 5), while mornings saw the least crying, averaging about 4.4 hours (SD 4.7).

XSL•FO
RenderX

Table 1. Overview of consulted health care professionals (N=1111).

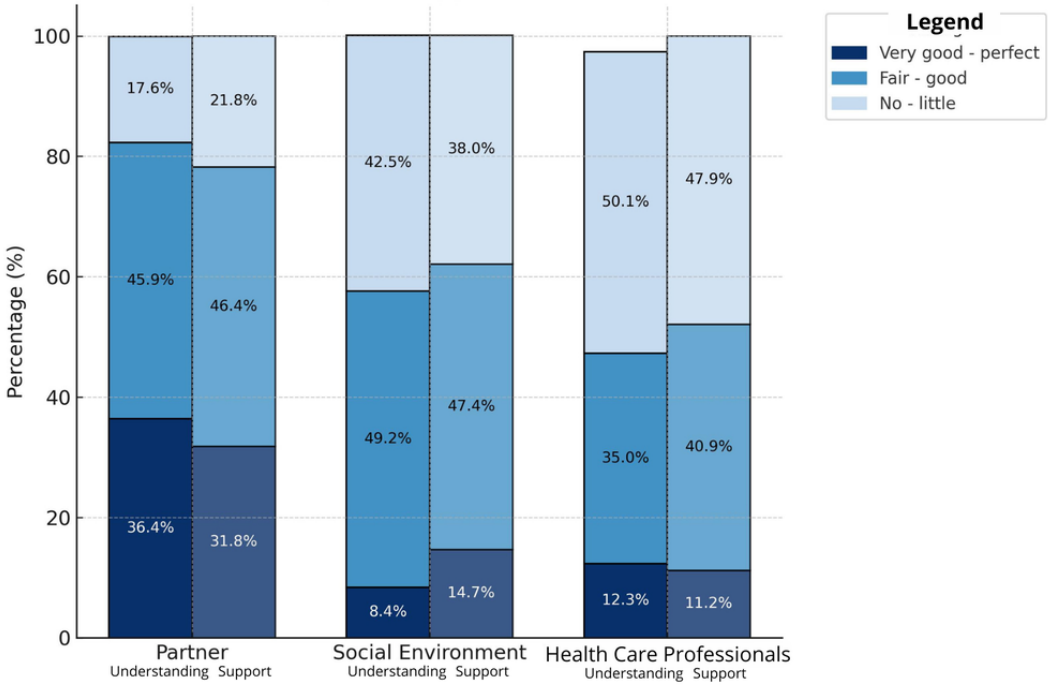
Health care professionals	Mothers (N=432), n (%)
Missing (participant did not specify consulted health care professionals)	24 (5.6)
None	1 (0.2)
Pediatrician	305 (70.6)
General practitioner	212 (49.1)
Child health nurse: *Kind en Gezin* (Belgium) or *Consultatiebureau* (the Netherlands)	153 (35.4)
Osteopath	121 (28.0)
Midwife	112 (25.9)
Child physiotherapist	31 (7.2)
Other alternative medicine practitioner (eg, homeopath, acupuncturist)	27 (6.3)
Emergency doctor	23 (5.3)
Lactation consultant	22 (5.1)
Psychologist	22 (5.1)
Chiropractor	12 (2.8)
Dietitian	9 (2.1)
Manual therapist	6 (1.4)
Allergist	6 (1.4)
Baby therapist	5 (1.2)
Sleep coach	5 (1.2)
Manual therapist	5 (1.2)
Nurse	5 (1.2)
Foot reflexologist	5 (1.2)
Speech therapist	5 (1.2)
Dermatologist	3 (0.7)
Ear, nose, and throat specialist	3 (0.7)
Mesologist	3 (0.7)
Neurologist	2 (0.5)
Dentist	2 (0.5)
Psychiatrist	2 (0.5)
Pedagogue	2 (0.5)
Neonatologist	1 (0.2)
Orthomolecular therapist	1 (0.2)

Current Situation of Understanding and Support

Based on the quantitative measures, mothers' perception of understanding and support from *health care professionals* was the lowest, with a score of 4.4 and 4.3, respectively, on a 6-point Likert scale (ranging from 1=perfect understanding/support to 6=no understanding/support). Half of the parents (n=216, 50%) felt they perceived no to little understanding from their health care professionals. The same was seen for perceived support, where 47% (n=203) of the parents felt they perceived little to no support. However, it is important to note that no differentiation was made among the health care professionals involved. The results therefore offer a general overview of health care professionals as a whole. Although parents' perceptions of understanding and support from health care professionals were the lowest, there is also room for improvement in the understanding and support from parents' partners and personal networks. A large group of parents reported receiving little to no understanding (n=76, 17.6%; mean=3.1/6) and support (n=94, 21.8%; mean score=3.3/6) from their *partners*, as well as little to no understanding (n=184, 42.6%; mean score=4.2/6) and support (n=164, 38%; mean score=4/6) from their *personal networks*. An overview can be found in Figure 1.

XSL•FO
RenderX

Figure 1. Visualization of mothers' perceptions.



Ideal Situation of Understanding and Support

Of the 432 participants, 423 (97.2%) responded to the open-ended questions about how they want understanding and support from their partners, personal networks, and health care professionals to be improved. It was striking that when people were asked to name their needs, they tended to focus not on their active needs but rather on negative experiences in which their needs had not been met. These narratives shed light on the unmet expectations and frustrations of mothers navigating the challenges of excessive infant crying. For example, one mother shared:

> *I wish certain people would have acknowledged it. And that they wouldn't accuse me of keeping my child away from family while I was acting in my child's best interest, and they were unwilling to adapt.* [The Netherlands, 29 years old, consulted a general practitioner, a child health nurse, a pediatrician, and a dermatologist]

Another mother noted:

> *They dismissed me as a young mom, ignorant, first child, and all that.* [Belgium, 26 years old, consulted several pediatricians and general practitioners]

These experiences, although painful, were crucial in identifying the gaps in support and helped shape the themes and subthemes, after which the overarching themes were transformed to support forms. Overall, the findings revealed that although some forms of support were shared across groups and incorporated as fundamental principles, others were more specific to the roles of partners, personal networks, or health care professionals. These forms of support were integrated through an in-depth analysis into the maternal support framework presented in Figure 2.

A total of 25 support forms or themes were identified, of which 12 (48%) were common across all three groups and were therefore labeled as *fundamental principles*, such as "communicate openly and break down taboos." A participant's quote below emphasizes the taboo around admitting struggles during early parenthood while she points out a lack of support options:

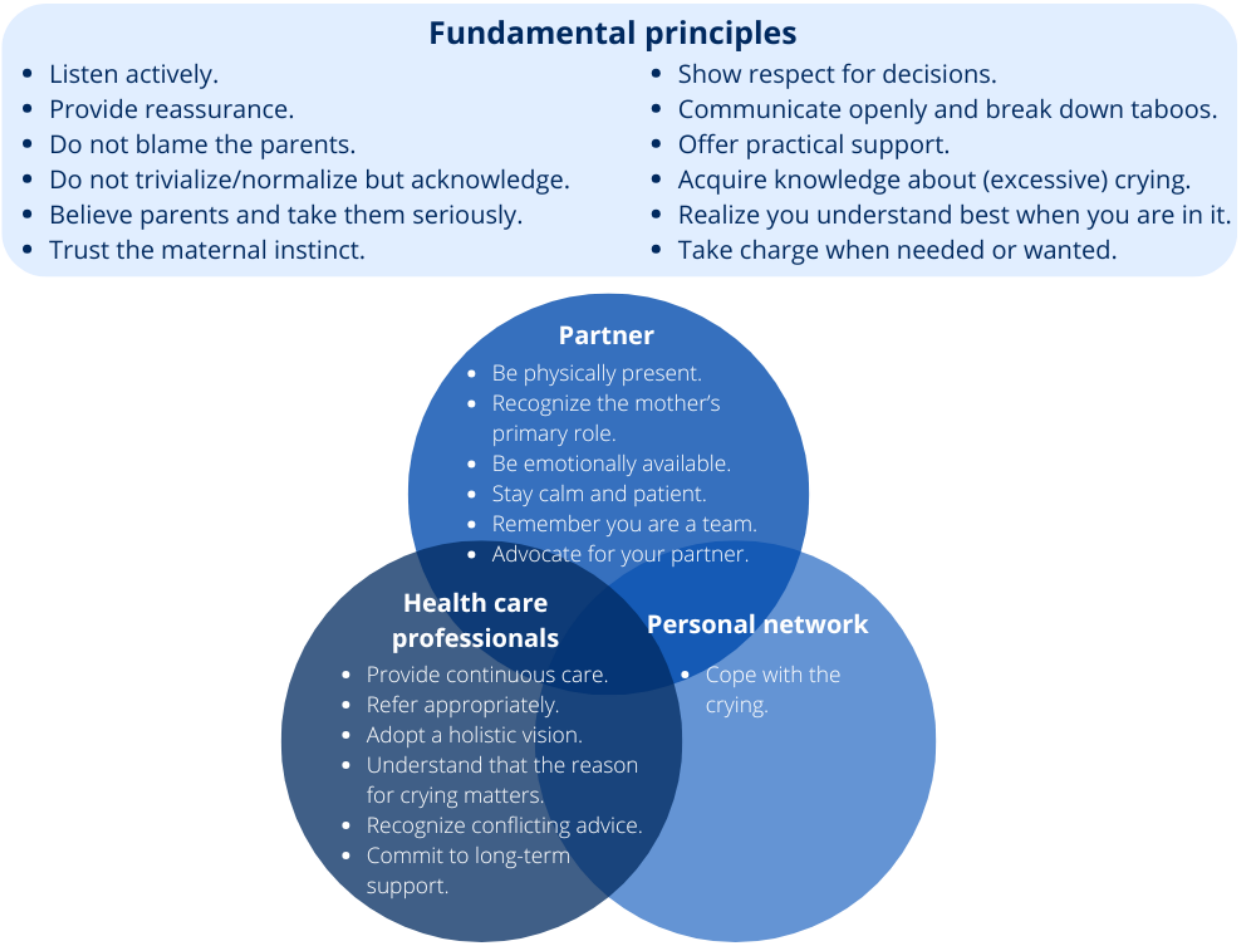
> *It's a shame that there is still so much taboo around this, and that having a baby is still expected to be mostly "joyful," while in reality, when you truly talk to people, you realize that many parents struggle and that for a lot of them, their "cloud" is more gray than pink. It's also frustrating that society expects you to be back at work three months after giving birth, functioning just as before—whether you have a high-needs baby, sleep deprivation, or not. Additionally, there are very few support options or places where you can seek help for yourself and your baby. You can talk to a psychologist, but even there, waiting lists are always an issue.* [Belgium, 35 years old, consulted a midwife, a general practitioner, and a psychologist]

Another lamented the lack of acknowledgment of their struggles:

> *Since the baby was growing well, there was no problem. My own struggles were not acknowledged.* [Belgium, 38 years old, consulted a pediatrician]

XSL•FO
RenderX

Figure 2. Maternal support framework.



Although many support forms were shared across groups (fundamental principles), some were specific to particular groups. For example, mothers expressed distinct expectations from their *partners*, such as "stay calm and patient" and "remember you are a team." This resulted in the development of six specific partner support forms. One mother recounted:

> *My partner had no patience with our crying baby. It frustrated him a lot, and he took it out on me. It would have been really helpful if he could have stepped in with patience and acceptance sometimes.* [The Netherlands, 29 years old, consulted a child health clinic]

Another mother highlighted the value of teamwork, stating:

> *My partner and I have really been a team during this challenging time. He has pulled me through, and I have done the same for him.* [The Netherlands, 27 years old, consulted a child health clinic, a general practitioner, and a pediatrician]

These accounts underscore the critical role of partners in alleviating the mental and emotional burden of excessive infant crying.

Similarly, the support forms directed at *health care professionals* were particularly distinct, with six support forms specific to this group, for example, "provide continuous care" and "refer appropriately." One mother expressed frustration, saying:

> *It is important that these parents feel heard. Don't let them struggle on their own. I only realized later that my baby was a high-needs baby, even though I had asked the consultation clinic for help so many times. I felt so alone. It turned out that our hospital had a special clinic for crying babies—they probably could have helped much sooner. This might have spared me from depression.* [The Netherlands, 37 years old, consulted a general practitioner and a pediatrician "too late"]

These examples highlight the need for health care professionals to go beyond surface-level assessments and consider both parents' and infants' physical and emotional well-being.

The *personal network*, although less distinctive and showing more overlap with the other support forms, is also a critical source of either comfort or frustration. The most important theme related to the personal network that distinguished itself from the other two groups was to cope with crying. This was illustrated, for example, in the following quote:

> *When they came to visit and saw that he wouldn't stop crying, they often couldn't leave fast enough.* [Belgium, 38 years old, consulted a midwife, a pediatrician, and a general practitioner]

However, concerning their personal networks, mothers also called for several fundamental principles such as "offer practical support." For example, one mother shared:

XSL•FO
RenderX

> *Avoid giving generic advice—just listening is enough. Offer to watch the baby for a few hours so they can recharge, take over household chores, or prepare dinner.* [Belgium, 28 years old, consulted a general practitioner, a pediatrician, an osteopath, a homeopath, and a physiotherapist]

Discussion

Principal Findings

This study, using a qualitative approach supplemented with quantitative measures, explored maternal perceptions of understanding and support when faced with an excessively crying baby (current situation), as well as the key forms of support the mothers would like to receive (ideal situation). With 432 participants, it offered a robust and diverse dataset, enabling nuanced insights into support needs and identifying potential forms of support from partners, personal networks, and health care professionals. These findings informed the development of the maternal support framework.

Crying Duration

The reported average of nearly 12 hours of infant crying per day appears unusually high compared to existing epidemiological data, even for excessively crying infants. This likely reflects a combination of recall bias, parental misinterpretation of crying versus fussing or general wakefulness, and the low coping ability of parents. Parent-reported measures, although practical for large-scale studies, are known to diverge from objective recordings. The Barr's Baby Diary validation study found moderate correlations between diary reports and audio recordings for crying (r=0.67) but low or no correlation for fussing (r=0.45 for crying+fussing; r=0.01 for fussing alone [29]). As Vermillet et al [6] noted, this may be due to parents' sensitivity to visual signs of distress not captured by audio, as well as the more fragmented nature of fussing behavior. As capturing the objective crying duration of these infants was not the main purpose of this study, these findings reflect perceived, not actual, cry durations, yet they remain valuable for understanding parental experience, which plays a crucial role in early caregiving and stress [2].

Consulted Health Care Professionals

Before turning to the study's central research questions on current and desired support, we highlight one key finding regarding health care use among mothers of excessively crying infants. The level of health care use, reflected in an average of 2.7 health care professionals consulted during periods of excessive crying, was relatively high in this study and aligns with previous research [15]. One reason for this is that many mothers feel a strong need to find an explanation for their baby's excessive crying. However, in 95% of cases, no medical cause is found [1,30], and crying often decreases by the time the baby is 3-4 months old [31,32]. This suggests that the reduction in crying may be due to other factors, not just the health care professionals parents consult, and "finding the cause" of excessive crying is not the primary reason for its reduction [1,33,34]. For example, the months wherein parents consult different health care professionals might cover the natural peak of infant crying [2]. Consulting various health care professionals likely gives parents a sense of control, as they hope for a quick fix, which for them often means receiving a medical label [35]. However, this high health care consumption in combination with the low satisfaction of parents regarding health care delivery also highlights a lack of continuous and solid support, leaving parents feeling that they must take charge in the search for a cause, since they seem to believe that without a medical cause, there is no solution to excessive crying.

As for the specific health care professionals consulted, mothers most frequently sought help from a pediatrician, a general practitioner, child health nurses, an osteopath, or a midwife. Remarkably, no mother mentioned consulting an infant mental health (IMH) specialist—a health care professional with additional training, skills, and experience in working intensively with young children and families through a comprehensive, relationship-based approach [36]. One possible explanation is that parents, given the recent development of this field, are not yet aware of the existence of these specialized professionals. Another possibility is that parents are aware of a professional's IMH training but simply do not specify it. Lastly, parents may have consulted such specialists without realizing their additional expertise. However, future research could help demonstrate the added value of such specialists in cases of excessive crying, as current research lacks a clear link to this issue, even though the existence and role of these specialists are increasingly being acknowledged [37].

Current and Ideal Situations of Understanding and Support

Mothers of excessively crying babies reported the lowest levels of understanding and support from health care professionals, with half feeling they received little to no understanding and support. These numbers are in accordance with previous research indicating that 55% of mothers feel they receive inadequate information regarding their baby's crying and their caregiving role [15]. Although health care professionals showed the greatest need for improvement, mothers also experienced significant gaps in support and understanding from their partners and personal networks. This suggests widespread challenges in securing sufficient support networks for mothers.

This brings us to the qualitative data, which provided deeper insight into mothers' perceived support needs. An in-depth analysis of the data led to the development of a maternal support framework consisting of 25 maternal support forms divided into common maternal support forms or fundamental principles and specific maternal support forms. Twelve general maternal support forms were identified, which applied to each of the groups (partners, personal networks, and health care professionals). Six maternal support forms were only detected toward health care professionals, six were identified toward mothers' partners, and one was specified for their personal networks.

First, *common maternal support forms* were identified. The support forms identified in this qualitative study generally align with various needs previously reported in the literature. For example, the theme *communicate openly and break down taboos* corresponds to the stigma surrounding excessive crying, often

XSL•FO
RenderX

exacerbated by societal taboos, which leaves mothers feeling isolated and unsupported. Clearly, insufficient social recognition and a lack of open communication can significantly increase maternal distress [6,7]. Moreover, prior research states that excessive crying often disrupts parental identity and generates stigma [6]. This highlights the critical need to explicitly address the taboo and blame surrounding infant crying in intervention programs, as doing so may reduce stigma, foster parental acceptance, and encourage seeking support. Furthermore, *practical support*, such as household tasks or caregiving assistance, was another recurrent theme. Many mothers reported that small gestures, such as offering to babysit or prepare a meal, could have alleviated their overwhelming burden. This resonates with studies advocating for community-based interventions to enhance family resilience during challenging periods [16].

Second, the findings regarding current and ideal levels of understanding and support by *health care professionals* highlight critical areas for improving health care delivery. Indeed, mothers expressed dissatisfaction with fragmented or dismissive health care, where excessive crying was trivialized or attributed to "normal" infant behavior without thorough investigation. Despite frequent consultations, health care professionals seem to underperform in meeting parental needs during episodes of excessive infant crying. This may be due to a predominant biomedical approach focused on ruling out disease or normaliz*ing* the crying behavior, rather than addressing the emotional and informational needs of parents [15,16]. Harskamp-Van Ginkel et al [16] stated that through the development of eight consecutive steps in the assessment of an excessively crying infant, *taking parents seriously* while demonstrating medical expertise and *offering a practical plan* is the way to go. However, *providing care continuity* with *appropriate referral* to health care professionals who can offer the most appropriate care at the time of the request for help and a *holistic vision* of both the baby's and the mother's well-being can improve mothers' satisfaction and families' well-being, as also shown in previous research [38]. The study underscores the need for a holistic screening approach that goes beyond quantifying crying episodes. Incorporating emotional and contextual factors into assessments could facilitate targeted interventions and foster greater understanding among health care professionals. Such approaches would align with calls in the literature for more family-centered care models that prioritize both infant well-being and parental mental health [7,39]. A great example of such a good practice, where a multidisciplinary approach is used with a focus on continuity of care, is the care model described by de Graaf et al [40], which is currently being further developed at the Sint-Antonius Hospital in the Netherlands. This integrated model supports families with excessively crying infants by combining psychosocial support, timely medical consultation, and structured follow-up across disciplines. It involves early intervention through clear guidance on soothing techniques and access to reliable (digital) information about excessive crying for all parents. In cases where a medical cause is suspected, parents are offered a joint consultation with both a pediatrician and a medical pedagogical professional within 5 working days. This close collaboration ensures that both medical and psychosocial aspects are addressed simultaneously. To safeguard continuity of care, a follow-up handover takes place within 2 weeks via a video call in the presence of the parents, allowing the referring professional to remain involved and ensuring a warm and informed transfer of care [40]. Accordingly, the recently validated Infant Crying and Parent Well-Being (ICPW) screening tool could serve as a starting point for a more nuanced approach to identify parents whom have a problem with the excessive crying of their infant. This ICPW screening tool is a brief, five-item instrument designed to identify parents who are struggling with their infant's crying (example item: "Has your baby's crying or fussing been a problem or upsetting to you recently?" Yes/No). It quickly and efficiently identifies families that are in need of extra support in comforting their child, considering parent-specific stressors, such as parenting stress. Its simplicity and clinical relevance make it well-suited for routine use in early infancy to guide timely support and referrals [41,42].

Third, the findings shed light on the forms of support that mothers consider important to receive from their *partners*. Participants highlighted the importance of a unified approach, where *partners act as advocatesand teammates* in managing the situation. The strain of excessive crying often amplified the mental load for mothers, particularly when partners were perceived as less *present*, *engaged*, or understanding. Conversely, where strong partner support was present, mothers reported greater emotional stability and a sense of shared responsibility. These findings support the literature emphasizing the protective effects of strong partner relationships in mitigating stress [39]. However, having an excessively crying baby might cause marital stress, arguments, and feelings of resentment toward the partner, which confirms our findings [39].

Fourth, the forms of maternal support from the *personal network* were explored. Mothers often felt that their networks failed to grasp the intensity of their experiences, leading to feelings of alienation. *Experiential knowledge* where social contacts had faced similar challenges was perceived as enhancing understanding and empathy. This suggests a potential benefit of peer support programs or initiatives that connect parents with others who have navigated similar challenges [43]. Given that mothers indicated their personal networks often had difficulty *coping with their baby's crying*, and considering the lack of research on this topic, increasing awareness and knowledge, as well as conducting further investigation, may be warranted.

The results of this study also highlight gaps in research and practice. Existing studies often focus on isolated elements of the parent's environment, such as partner support or health care delivery, while neglecting the broader support system. This fragmented nature of current research also limits generalizability. The findings of this study provide a first step in expanding the scope of research to encompass a fuller spectrum of maternal experiences. However, including the role of societal pressure, for instance, could yield valuable insights into developing comprehensive support systems. In addition, the results emphasize the importance of *fostering greater knowledge* and understanding of excessive crying among different central stakeholders—parents, personal networks, and health care professionals. Enhancing awareness could *reduce stigma*, *improve acknowledgment* of parental struggles, and ultimately lead to better care and support. Such efforts could

XSL•FO
RenderX

transform excessive crying from an isolating and distressing experience to an opportunity for building stronger family and community resilience. Finally, the findings of this study underscore the need for a *holistic and context-sensitive approach* to understanding and addressing excessive crying, both in research and in practice.

Practical Implications

The maternal support framework may serve as a valuable foundation for the development of new support programs or the optimization of existing ones. By offering a clear representation of the support needs of the target population, the framework can enable health care professionals and program developers to assess which needs are already being addressed and to identify how to broaden their interventions in line with unmet parental support needs. For example, the framework's emphasis on fundamental principles, such as "listen actively," "believe parents and take them seriously," and "provide reassurance," shows the need for interventions to create safe spaces where parents can share their feelings without judgment, reducing the taboo and blame associated with infant crying; the framework's emphasis on trusting the maternal instinct could help develop family-centered interventions focusing on parent empowerment by validating their choices and providing them with knowledge and tools to make informed decisions.

Limitations

Although this study has several strengths, certain limitations should be acknowledged, alongside some recommendations for future research. First, the study included both participants who currently have an excessively crying baby and parents who experienced excessive crying in the past. Perceptions may differ between mothers currently coping with excessive crying and those reflecting retrospectively on a past experience. Nevertheless, both perspectives are highly relevant: the immediate experience offers insight into present challenges, while retrospective accounts provide valuable reflections. Although this approach introduces certain limitations, the diversity of the sample enriches the findings by incorporating unique viewpoints. These varied experiences offer additional insights that might otherwise be overlooked.

Second, there may be sampling bias, as mothers who were dissatisfied with the perceived understanding and support might have been more likely to participate than those without issues. Moreover, this study only involved *mothers* with excessively crying babies. This might be seen as a limitation as fathers, comothers, and same-sex fathers are equally important groups. Fathers experience a lot of distress and have a high chance of developing depression when having an excessively crying baby [12]. Therefore, future studies and interventions need to include other primary caregivers. However, the focus on mothers did ensure a consistent and homogeneous sample, reducing variability in responses that could arise from differences between mothers and fathers or comothers and same-sex fathers.

Third, we have no information about the age of the babies at the time of the excessive crying complaints. This lack of age-specific data is unfortunate, as perceptions of excessive crying and the need for support are likely to vary depending on the infant's age and developmental stage. Not accounting for this variable may have affected how mothers reflected on their experiences and expressed their needs. However, this broad inclusion strategy was a deliberate choice, as it allowed us to explore general themes that are widely shared across the population. Given the exploratory nature of this study, capturing a broad range of experiences was valuable in identifying common patterns and concerns among mothers.

A fourth limitation is that we did not collect information about the cultural or ethnic backgrounds of the participants. Although the recruitment strategies (eg, Dutch language online communities in Belgium and the Netherlands) suggest that most participants were likely part of a Western European cultural context, we cannot draw firm conclusions about the cultural diversity within the sample. This limits the transferability of the findings to mothers from other cultural backgrounds, whose perceptions and support needs around excessive infant crying may differ. Future research should aim to include and differentiate between diverse cultural perspectives to gain a more inclusive understanding [44,45].

Finally, another potential limitation is related to the measurement instrument. Specifically, the use of "perfect" as the positive anchor on the Likert scale is less common in previous research. Although we deliberately chose to capture participants' perceptions of an ideal or optimal experience, the word "perfect" may have been perceived as an unattainable ideal and therefore selected less frequently. Future research might consider using a more moderate and relatable term (such as "excellent") to capture positive evaluations more accurately.

Finally, we did not use any existing/adapted items from validated tools as we believed there did not exist any fitting items in existing tools. However, as a compensation, we used a pilot test (n=3).

In addition to the aforementioned limitations, several final recommendations for future research can be proposed to further advance understanding in this field. For instance, future studies could investigate the association between perceived understanding and support and the specific type of health care professional involved. Given the considerable variation in approaches, treatment methods, and patient interactions across health care disciplines, such an examination would clarify the unique contributions and challenges associated with each. Further, future research might focus on the validation of the conceptual maternal support framework, while considering the previously stated stakeholder groups, so that the maternal support framework can be expanded to the parental support framework.

Conclusion

This study highlighted the significant challenges faced by mothers of excessively crying infants, emphasizing the critical role of understanding and support from their partners, personal networks, and health care professionals. Findings indicate that health care professionals provide the least understanding and support, followed by personal networks, while partners offer more consistent support and understanding.

XSL•FO
RenderX

Qualitative insights further underscore the emotional and practical support needs of mothers, including a desire for more empathy, respect for their decisions, and tangible support. The maternal support framework developed in this study offers a comprehensive guide to understanding and addressing maternal support forms. It calls for greater collaboration among partners, personal networks, and health care professionals to alleviate the mental and emotional burdens of parents, ultimately improving the well-being of both parents and infants. Future interventions should focus on bridging the gaps in understanding and support, fostering a more supportive environment for families dealing with excessive crying.

Data Availability

The complete codebook, including the fundamental principles (shared support forms) and specific support forms, supplemented with the ad verbatim codes, which stayed close to the original words, will be available upon request. A list of support forms and subforms, each with a verbatim quote, will also be available upon request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire.
[DOCX File , 17 KB - pediatrics_v8i1e75669_app1.docx]

References

1. Akhnikh S, Engelberts AC, van Sleuwen BE, L'Hoir MP, Benninga MA. The excessively crying infant: etiology and treatment. Pediatr Ann 2014 Apr;43(4):e69-e75 [FREE Full text] [doi: 10.3928/00904481-20140325-07] [Medline: 24716561]
2. Vermillet AQ, Tølbøll K, Litsis Mizan S, C Skewes J, Parsons CE. Crying in the first 12 months of life: a systematic review and meta-analysis of cross-country parent-reported data and modeling of the "cry curve". Child Dev 2022 Jul 19;93(4):1201-1222 [FREE Full text] [doi: 10.1111/cdev.13760] [Medline: 35438798]
3. Adam-Darque A, Freitas L, Grouiller F, Sauser J, Lazeyras F, Van De Ville D, et al. Shedding light on excessive crying in babies. Pediatr Res 2021 Apr 06;89(5):1239-1244 [FREE Full text] [doi: 10.1038/s41390-020-1048-6] [Medline: 32629458]
4. Wessel MA, Detwiler AC, Cobb JC, Jackson EB, Harris, Jr GS. Paroxysmal fussing in infancy, sometimes called "colic". Pediatrics 1954 Nov 1;14(5):421-435 [FREE Full text] [doi: 10.1542/peds.14.5.421]
5. ROME IV diagnostic criteria for disorders of gut-brain interaction (DGBI). Rome Foundation. 2016 Jan 16. URL: https://theromefoundation.org/wp-content/uploads/Rome-Foundation-Diagnostic-Criteria-Booklet-2019.pdf [accessed 2025-10-22]
6. Garratt R, Bamber D, Powell C, Long J, Brown J, Turney N, et al. Parents' experiences of having an excessively crying baby and implications for support services. J Health Visit 2019 Mar 02;7(3):132-140 [FREE Full text] [doi: 10.12968/johv.2019.7.3.132]
7. Reijneveld S, Brugman E, Hirasing R. Excessive infant crying: the impact of varying definitions. Pediatrics 2001 Oct;108(4):893-897 [FREE Full text] [doi: 10.1542/peds.108.4.893] [Medline: 11581441]
8. Long J, Powell C, Bamber D, Garratt R, Brown J, Dyson S, et al. Development of materials to support parents whose babies cry excessively: findings and health service implications. Prim Health Care Res Dev 2018 Jan 10;19(04):320-332 [FREE Full text] [doi: 10.1017/s1463423617000779]
9. Zeifman DM, St James-Roberts I. Parenting the crying infant. Curr Opin Psychol 2017 Jun;15:149-154 [FREE Full text] [doi: 10.1016/j.copsyc.2017.02.009] [Medline: 28685155]
10. Kurth E, Spichiger E, Zemp Stutz E, Biedermann J, Hösli I, Kennedy HP. Crying babies, tired mothers - challenges of the postnatal hospital stay: an interpretive phenomenological study. BMC Pregnancy Childbirth 2010 May 13;10(1):21 [FREE Full text] [doi: 10.1186/1471-2393-10-21] [Medline: 20462462]
11. Stifter CA, Moding KJ. Infant temperament and parent use of food to soothe predict change in weight-for-length across infancy: early risk factors for childhood obesity. Int J Obes (Lond) 2018 Sep 30;42(9):1631-1638 [FREE Full text] [doi: 10.1038/s41366-018-0006-4] [Medline: 29463917]
12. de Kruijff I, Veldhuis MS, Tromp E, Vlieger AM, Benninga M, Lambregtse-van den Berg MP. Distress in fathers of babies with infant colic. Acta Paediatr 2021 Aug 18;110(8):2455-2461 [FREE Full text] [doi: 10.1111/apa.15873] [Medline: 33840149]
13. Indrio F, Dargenio VN, Francavilla R, Szajewska H, Vandenplas Y. Infantile colic and long-term outcomes in childhood: a narrative synthesis of the evidence. Nutrients 2023 Jan 25;15(3):615 [FREE Full text] [doi: 10.3390/nu15030615] [Medline: 36771322]
14. Wolke D, Bilgin A, Samara M. Systematic review and meta-analysis: fussing and crying durations and prevalence of colic in infants. J Pediatr 2017 Jun;185:55-61.e4 [FREE Full text] [doi: 10.1016/j.jpeds.2017.02.020] [Medline: 28385295]

XSL•FO
RenderX

15. van der Veek SMC, van Rosmalen L. Maternal satisfaction with professional health care for excessive infant crying: does it meet maternal needs? Early Child Dev Care 2022 Oct 10;193(4):602-615 [FREE Full text] [doi: 10.1080/03004430.2022.2130903]
16. Harskamp-Van Ginkel MW, Klazema W, Hoogsteder MHH, Chinapaw MJM, van Houtum L. The need of having a plan in excessive infant crying - a qualitative study of parents' experiences of healthcare support. Acta Paediatr 2023 Mar 14;112(3):434-441 [FREE Full text] [doi: 10.1111/apa.16618] [Medline: 36477912]
17. Viragova M, O'Curry S. Understanding persistent crying in infancy. Paediatr Child Health 2021 Mar;31(3):116-121 [FREE Full text] [doi: 10.1016/j.paed.2020.12.004]
18. Holm LV, Vach W, Jarbøl DE, Christensen HW, Søndergaard J, Hestbæk L. Identifying potential treatment effect modifiers of the effectiveness of chiropractic care to infants with colic through prespecified secondary analyses of a randomised controlled trial. Chiropr Man Therap 2021 Apr 19;29(1):16 [FREE Full text] [doi: 10.1186/s12998-021-00373-6] [Medline: 33874964]
19. Carnes D, Plunkett A, Ellwood J, Miles C. Manual therapy for unsettled, distressed and excessively crying infants: a systematic review and meta-analyses. BMJ Open 2018 Jan 24;8(1):e019040 [FREE Full text] [doi: 10.1136/bmjopen-2017-019040] [Medline: 29371279]
20. Dorreh F, Hashemi SM, Salehi S, Taheri M, Almasi-Hashiani A. The effect of probiotic in treatment of infantile colic: a randomized clinical trial. Int J Pediatr 2017;5(7):5295-5303 [FREE Full text] [doi: 10.22038/ijp.2017.22530.1884]
21. Blom MA, van Sleuwen BE, de Vries H, Engelberts AC, L'hoir MP. Health care interventions for excessive crying in infants: regularity with and without swaddling. J Child Health Care 2009 Jun 20;13(2):161-176 [FREE Full text] [doi: 10.1177/1367493509102476] [Medline: 19458170]
22. Schneider P, Evaniew N, Rendon JS, McKay P, Randall RL, Turcotte R, PARITY Investigators. Moving forward through consensus: protocol for a modified Delphi approach to determine the top research priorities in the field of orthopaedic oncology. BMJ Open 2016 May 24;6(5):e011780 [FREE Full text] [doi: 10.1136/bmjopen-2016-011780] [Medline: 27221129]
23. Vogel C, Zwolinsky S, Griffiths C, Hobbs M, Henderson E, Wilkins E. A Delphi study to build consensus on the definition and use of big data in obesity research. Int J Obes (Lond) 2019 Dec 17;43(12):2573-2586 [FREE Full text] [doi: 10.1038/s41366-018-0313-9] [Medline: 30655580]
24. Ab Latif R, Dahlan A, Ab Mulud Z, Mat Nor MZ. The Delphi technique as a method to obtain consensus in health care education research. Educ Med J 2017 Sep 30;9(3):89-102 [FREE Full text] [doi: 10.21315/eimj2017.9.3.10]
25. De Meyer D, Kottner J, Beele H, Schmitt J, Lange T, Van Hecke A, et al. Delphi procedure in core outcome set development: rating scale and consensus criteria determined outcome selection. J Clin Epidemiol 2019 Jul;111:23-31 [FREE Full text] [doi: 10.1016/j.jclinepi.2019.03.011] [Medline: 30922885]
26. Drisko JW, Maschi T. Content Analysis. New York: Oxford University Press; 2016.
27. Elo S, Kyngäs H. The qualitative content analysis process. J Adv Nurs 2008 Apr;62(1):107-115 [FREE Full text] [doi: 10.1111/j.1365-2648.2007.04569.x] [Medline: 18352969]
28. Raskind IG, Shelton RC, Comeau DL, Cooper HLF, Griffith DM, Kegler MC. A review of qualitative data analysis practices in health education and health behavior research. Health Educ Behav 2019 Feb 18;46(1):32-39 [FREE Full text] [doi: 10.1177/1090198118795019] [Medline: 30227078]
29. Barr RG, Kramer MS, Boisjoly C, McVey-White L, Pless IB. Parental diary of infant cry and fuss behaviour. Arch Dis Child 1988 Apr;63(4):380-387 [FREE Full text] [doi: 10.1136/adc.63.4.380] [Medline: 3365007]
30. Freedman S, Al-Harthy N, Thull-Freedman J. The crying infant: diagnostic testing and frequency of serious underlying disease. Pediatrics 2009 Mar;123(3):841-848 [FREE Full text] [doi: 10.1542/peds.2008-0113] [Medline: 19255012]
31. Kim JS. Excessive crying: behavioral and emotional regulation disorder in infancy. Korean J Pediatr 2011 Jun;54(6):229-233 [FREE Full text] [doi: 10.3345/kjp.2011.54.6.229] [Medline: 21949516]
32. Halpern R, Coelho R. Excessive crying in infants. J Pediatr (Rio J) 2016 May;92(3 Suppl 1):S40-S45 [FREE Full text] [doi: 10.1016/j.jped.2016.01.004] [Medline: 26994450]
33. Sarasu JM, Narang M, Shah D. Infantile colic: an update. Indian Pediatr 2018 Jun 13;55(11):979-987 [FREE Full text] [doi: 10.1007/s13312-018-1423-0] [Medline: 29941700]
34. Biagioli E, Tarasco V, Lingua C, Moja L, Savino F. Pain-relieving agents for infantile colic. Cochrane Database Syst Rev 2016 Sep 16;9(9):CD009999 [FREE Full text] [doi: 10.1002/14651858.CD009999.pub2] [Medline: 27631535]
35. Dahlen HG, Foster JP, Psaila K, Spence K, Badawi N, Fowler C, et al. Gastro-oesophageal reflux: a mixed methods study of infants admitted to hospital in the first 12 months following birth in NSW (2000-2011). BMC Pediatr 2018 Feb 12;18(1):30 [FREE Full text] [doi: 10.1186/s12887-018-0999-9] [Medline: 29429411]
36. Weatherston DJ. A qualitative study of the practice of infant mental health: practitioners' and parents' voices. Wayne State University ProQuest. 2000. URL: https://www.proquest.com/openview/68e40627c5bc64c6da67568cd9f22457/1?pq-origsite=gscholar&cbl=18750&diss=y [accessed 2025-10-22]
37. Lakatos PP, Rodas NV, Matic T, Williams ME, Samora LL, Carson MC. Providing continuity in infant mental health services for medically fragile infants and their families. J Clin Psychol Med Settings 2024 Mar 31;31(1):5-18 [FREE Full text] [doi: 10.1007/s10880-023-09957-1] [Medline: 37000305]

XSL•FO
RenderX

38. McCallum SM, Rowe HJ, Gurrin L, Quinlivan JA, Rosenthal DA, Fisher JR. Unsettled infant behaviour and health service use: a cross-sectional community survey in Melbourne, Australia. J Paediatr Child Health 2011 Nov 17;47(11):818-823 [FREE Full text] [doi: 10.1111/j.1440-1754.2011.02032.x] [Medline: 21679331]
39. Botha E, Joronen K, Kaunonen M. The consequences of having an excessively crying infant in the family: an integrative literature review. Scand J Caring Sci 2019 Dec 06;33(4):779-790 [FREE Full text] [doi: 10.1111/scs.12702] [Medline: 31058351]
40. de Graaf K, Gustafsson-Oberink E, Alofs L, Klazema W, Sprenkelder K, de Kruijff I. Huilbaby's: een multidisciplinaire (samen)werkwijze. Prakt Pediatr 2023 Sep 1;3:16-24 [FREE Full text] [doi: 10.1007/s12452-022-00293-8]
41. Katch LE, Burkhardt T. Development and validation of the infant crying and parent well-being screening tool. J Community Psychol 2021 Aug 25;49(6):1579-1597 [FREE Full text] [doi: 10.1002/jcop.22599] [Medline: 34033694]
42. de Graaf K, Kwakman YE, de Kruijff I, Tromp E, Staal II, Katch LE, et al. Validation of the Dutch Infant Crying and Parent Well-Being (ICPW) screening tool in parents of infants less than 12 months of age. J Pediatr 2025 Jan;276:114326 [FREE Full text] [doi: 10.1016/j.jpeds.2024.114326] [Medline: 39343132]
43. Santos IS, Matijasevich A, Capilheira MF, Anselmi L, Barros FC. Excessive crying at 3 months of age and behavioural problems at 4 years age: a prospective cohort study. J Epidemiol Community Health 2015 Jul 19;69(7):654-659 [FREE Full text] [doi: 10.1136/jech-2014-204568] [Medline: 25700531]
44. Vermillet AQ, Parsons CE, Skewes JC. Parental perspectives on infant crying. Int J Birth Parent Educ 2024 Apr 1;11(3):4-8 [FREE Full text]
45. Abdulrazzaq YM, Al Kendi A, Nagelkerke N. Soothing methods used to calm a baby in an Arab country. Acta Paediatr 2009 Feb 12;98(2):392-396 [FREE Full text] [doi: 10.1111/j.1651-2227.2008.01029.x] [Medline: 19143669]

Abbreviations

ICPW: Infant Crying and Parent Well-Being
IMH: infant mental health

Edited by S Badawy; submitted 08.04.25; peer-reviewed by E Möller, J Zhang, E Tella; comments to author 31.05.25; revised version received 22.09.25; accepted 14.10.25; published 28.10.25.

Please cite as:
Janssens O, Galle A, De Kruijff I, Brenning K
The Maternal Support Framework Studying Mothers' Perceived Understanding and Support During Excessive Infant Crying: Exploratory Qualitative Study
JMIR Pediatr Parent 2025;8:e75669
URL: https://pediatrics.jmir.org/2025/1/e75669
doi:10.2196/75669
PMID:

©Oona Janssens, Anna Galle, Ineke De Kruijff, Katrijn Brenning. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 28.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Analysis of Cough Factors and Quality of Life Score Among Children With Protracted Bacterial Bronchitis: Cross-Sectional Study

Haonan Ning[1], MM; Wenyu Zheng[2], MM; Jinghui Zhang[3], MM; Fuhai Li[3], MD; Nana Qiao[3], MD

[1]Department of Pediatrics, Qingdao Central Hospital, University of Health and Rehabilitation Sciences, Qingdao, China

[2]Department of Pediatrics, Linyi People's Hospital, Linyi, China

[3]Department of Pediatrics, Qilu Hospital of Shandong University, No. 107, Wenhua West Road, Lixia District, Jinan, Shandong Province, China

Corresponding Author:
Nana Qiao, MD
Department of Pediatrics, Qilu Hospital of Shandong University, No. 107, Wenhua West Road, Lixia District, Jinan, Shandong Province, China

Abstract

Background: Protracted bacterial bronchitis (PBB) is a leading cause of chronic wet cough in children. Misdiagnosis and inadequate treatment may lead to the progression of diseases.

Objective: The objective of this paper was to analyze factors influencing the cough duration prior to the diagnosis and assess health-related quality of life in children with PBB.

Methods: Children diagnosed with PBB in the Qilu Hospital of Shandong University from November 2021 to November 2022 were included in this study. Clinical data were collected; parents completed the Parent-Proxy Cough-Specific Quality of Life (PC-QOL) questionnaire and the simplified Cough Symptom Score. Children aged 6 years and older completed the Leicester Cough Questionnaire in Mandarin-Chinese (LCQ-MC).

Results: As of November 2022, we enrolled 88 patients. Place of residence (B=9.35, 95% CI 0.36-18.35; *P*=.04) and rest status during the coughing episode (B=7.87, 95% CI 0.36-15.38; *P*=.04) were significantly associated with cough duration prior to the diagnosis. PC-QOL scores (physical: mean 3.10, SD 1.36; psychological: mean 3.32, SD 1.57; social: mean 3.67, SD 1.53; total: mean 10.09, SD 4.21) showed physical-social differences (t_{174}=−2.58, *P*=.01). PC-QOL posttreatment scores were significantly higher than pretreatment scores (physical: t_{18}=–6.05, *P*<.001; psychological: t_{18}=–4.42, *P*<.001; social: t_{18}=−4.79, *P*<.001; total: t_{18}=–5.25, *P*<.001). However, the scores of each PC-QOL domain were significantly lower than those of the LCQ-MC (physical: t_{34}=8.31, *P*<.001; psychological: t_{34}=6.58, *P*<.001; social: t_{34}=5.09, *P*<.001; total: t_{34}=8.11, *P*<.001).

Conclusions: Place of residence and rest status during the coughing episode were significantly associated with cough duration prior to the diagnosis**.** Furthermore, PBB significantly reduces quality of life in physical, psychological, and social aspects.

(JMIR Pediatr Parent 2025;8:e82887) doi:10.2196/82887

KEYWORDS

protracted bacterial bronchitis; duration of cough; sCSS; PC-QOL; LCQ-MC; simplified Cough Symptom Score; Parent-Proxy Cough-Specific Quality of Life; Leicester Cough Questionnaire in Mandarin-Chinese

Introduction

Cough is a prevalent symptom of respiratory disorders among children, with children presenting with cough constituting 70% of primary complaints in outpatient visits to pediatric respiratory clinics. Notably, chronic cough, defined as a cough lasting more than 4 weeks, accounts for 10% of these outpatient cases [1-3]. Chronic cough in children originates from various factors, and its etiology varies based on the child's age. Common causes of cough include respiratory infections, postinfectious cough, cough variant asthma, upper airway cough syndrome, and protracted bacterial bronchitis (PBB) [4-6].

PBB was initially proposed in 2006 [7], representing a chronic bacterial infection of the endobronchial membrane. This condition manifests as a persistent wet cough in children and may account for up to 42% of chronic cough cases [8,9]. Studies have indicated that the protracted duration of chronic cough is linked to respiratory dysfunction, impaired lung function, and potential development of bronchiectasis [10-13]. The incidence of cough-related complications escalates with both the prolongation of the disease and increased cough frequency, with a more than 2-fold increase in complication rates when symptoms persist beyond 8 weeks [14]. Inadequate treatment of PBB can result in irreparable damage to the bronchial mucosa,

XSL•FO
RenderX

potentially progressing into chronic suppurative lung disease or bronchiectasis [15]. A recent study [16] indicates that a significant proportion of children experience respiratory symptoms many years later; some have an objectively reduced lung function and structural changes of the bronchial wall despite adequate initial therapy. Additionally, PBB profoundly affects the quality of life of both affected children and their families [17].

Therefore, PBB not only affects the physical health of children but also undermines their psychological, social, and familial functioning. The Clinical Practice Guide for Diagnosis and Treatment of Cough in Chinese Children underscores the significance of pediatricians in China focusing on children's quality of life, advocating for the development and validation of a Cough-Specific Quality of Life Scale tailored for domestic children [18]. According to the 2015 Chest Guidelines [19], the Leicester Cough Questionnaire (LCQ) [20] and Parent-Proxy Cough-Specific Quality of Life (PC-QOL) questionnaire [21] have emerged as reliable and efficacious metrics for assessing quality of life in children experiencing chronic cough. Presently, there are few reports addressing the quality of life of children experiencing PBB. Highlighting this aspect of cough management is crucial for raising clinical awareness. To gain a deeper insight into PBB, this study dissected the clinical profiles of children with PBB, delved into the reasons behind their protracted disease trajectory, and evaluated the detrimental effects of chronic cough on their quality of life.

Methods

Participants

A comprehensive study was conducted on 88 pediatric patients diagnosed with PBB, who were admitted to the Pediatrics Department of Qilu Hospital, Shandong University, between November 2021 and November 2022. In total, 88 pediatric patients were included from outpatient and inpatient departments, and we obtained written consent from their guardians. All enrolled participants must meet the diagnostic criteria for PBB established by the American College of Chest Physicians (CHEST) Guidelines and Expert Panel [22].

The relevant definitions are as follows:

- Clinically based PBB: children aged ≤14 years with chronic wet or productive cough unrelated to an underlying disease and without any specific cough pointers (eg, coughing with feeding and digital clubbing) and whose cough resolves within 2 weeks of treatment with antibiotics targeted to local antibiotic sensitivities.
- Microbiologically based PBB: children aged ≤14 years with PBB with lower airway (bronchoalveolar lavage or sputum) confirmation of clinically important density of respiratory bacteria (≥10^4 CFU/mL).

The exclusion criteria were as follows: (1) the presence of acute respiratory symptoms, such as fever or rapid breathing before enrollment; (2) chest X-ray or chest CT scans indicating pneumonia after hospitalization; (3) specific cough symptoms or signs, such as chest pain, suspected history of foreign body inhalation, hemoptysis, repeated sinus lung infections, history of tuberculosis exposure, dyspnea, chest deformities, wet rales on lung auscultation, changes in chest imaging, abnormal lung function, etc; (4) the coexistence of severe underlying diseases, including but not limited to neuromuscular disorders, immunodeficiency, chronic corticosteroid use, congenital heart disease, and delayed growth and development; and (5) inability to obtain written informed consent from the children or their legal guardians.

General Information

The characteristics of the included children, such as their age, sex, duration of coughing prior to the diagnosis, characteristics of their cough (eg, wet, dry, or accompanied by wheezing), residential area, the presence of siblings, their parents' age and educational attainment, their primary caregiver's status, underlying health issues, exposure to smoking environments, and previous medical diagnoses and treatments, were comprehensively collected. Furthermore, the diagnoses and treatments provided to the children both in and out of the hospital during our research, including the type of antibiotics, length of treatment, and the efficacy of antibiotic therapy (Multimedia Appendix 1). For pediatric patients with PBB who showed inadequate response to empirical antibiotic therapy administered externally, electronic bronchoscopy was performed after hospitalization to identify pathogens and rule out potential underlying diseases. The pathogens found in bronchoalveolar lavage fluid were recorded.

Simplified Cough Symptom Score

The simplified Cough Symptom Score (sCSS; Table S1 in Multimedia Appendix 2) [23], which is determined based on the description of the frequency and intensity of daytime and nocturnal coughing, and its effect on daily activities and sleep patterns, is categorized into 4 distinct grades based on symptom severity. This scale is a simplified version developed based on the Cough Symptom Score (Table S2 in Multimedia Appendix 2). Research [24] shows that the sCSS is a reliable and valid instrument for assessing cough symptoms. A higher sCSS indicates a more severe cough, which negatively affects children. Using the sCSS obtained during the initial visit, guardians were subsequently contacted through outpatient follow-ups and telephone interviews to monitor the fluctuations in the sCSS over 2 and 4 weeks of treatment, including at night. The scores were interpreted as follows:

1. A score of 0 meant the complete resolution of cough symptoms.
2. A decrease in the sCSS compared to the initial visit without reaching 0 indicated improvement in the cough symptoms.
3. No change in sCSS meant no significant change in cough symptoms.
4. An increase in the sCSS compared to the initial visit indicated a worsening of the cough symptoms.

The Quality of Life Scale

The Leicester Cough Questionnaire in Mandarin-Chinese (LCQ-MC) [25] and PC-QOL questionnaire [21] were used to evaluate the impact of cough and disease experience on both children's and parents' overall quality of life (Tables S3-S5 in Multimedia Appendix 2).

XSL•FO
RenderX

The LCQ-MC and PC-QOL questionnaires were used to evaluate the frequency and severity of coughing episodes, their impact on the sleep patterns of both patients and parents, and the overall quality of life in children. The LCQ-MC scale is validated for children aged 6 - 14 years old and consists of 19 items, and the PC-QOL is validated for children aged 0 - 14 years old and consists of 27 items; both assess physical, psychological, and social functioning domains. The total score is calculated by summing the scores from each domain. The higher the accumulated score, the better the quality of life and the less the detrimental effects of coughing on children.

Statistical Analysis

Measurement data with normal distribution are presented as means and SDs, and between-group comparisons were conducted using an independent sample *t* test or ANOVA. Measurement data without normal distribution are expressed as median (IQR), and nonparametric tests were used for intergroup comparisons. Count data are expressed as percentages, and chi-square tests were used for intergroup comparisons. Normally distributed variables were analyzed using Pearson correlation analysis, whereas variables without normal distribution were subjected to Spearman correlation analysis. Difference analysis and multivariate linear regression analysis were used to investigate the factors affecting the cough duration prior to the diagnosis in children. *P* values obtained from univariate comparisons were adjusted for multiple testing using the Benjamini-Hochberg false discovery rate (FDR) correction method, with a significance threshold set at Q<.05. Statistical analysis was conducted using IBM SPSS 26.0 software, with a *P* value of less than .05 exhibiting statistical significance. The FDR correction was carried out using the R statistical programming language (version 4.5.1; R Core Team).

Ethical Considerations

This study was approved by the Ethics Committee of Qilu Hospital, Shandong University, under the ethical number KYLL-202111-118-1. Written informed consent was meticulously obtained from all participating children or their guardians. All data are anonymous.

Results

Sample Characteristics

As of November 2022, we enrolled 88 patients with PBB. Among these 88 enrolled children, there was a male predominance, with a male-to-female ratio of 1.84:1 and a median age of 60 (IQR 48 - 78) months. The median cough duration prior to inclusion in this study was 8 (IQR 4.5 - 16) weeks. Overall, 38% (33/88) of patients lived in rural areas, while 63% (55/88) of patients lived in urban areas. Furthermore, 51% (45/88) of patients had siblings and 49% (43/88) were only children. Parental education levels indicated that 28% (25/88) of patients had a high school education or below. In contrast, 72% (63/88) of patients had postsecondary education. The cohort analysis further demonstrated that 24% (21/88) of children were primarily cared for by their grandparents, while 76% (67/88) of children received primary care from their parents. Environmental tobacco smoke exposure was reported in 16% (14/88) of children, contrasting with 84% (74/88) of children without such exposure. Furthermore, regarding activity patterns during illness, 63% (55/88) of children continued attending school and physical activities despite cough symptoms, whereas 38% (33/88) rested at home. Parents' assessment of the nature of the cough indicated that 16% (14/88) of parents mistook a wet cough (a cough producing phlegm) for a dry cough. Meanwhile, 84% (74/88) of parents correctly identified it.

All 88 children had prior outpatient visits at external health care facilities before enrollment in this study. Health care–seeking behavior analysis showed that 49% (43/88) of children visited a municipal-level or higher hospital, 13% (11/88) of children had more than 5 repeated visits. Diagnostic accuracy assessment revealed that 33% (29/88) of cases were initially misdiagnosed with cough variant asthma or bronchial asthma, and 65% (57/88) of children were incorrectly diagnosed with bronchitis or bronchopneumonia and were treated with antibiotics and Chinese patent medicine before study participation (Table S1 in Multimedia Appendix 3).

Complete pre-enrollment medication records were unavailable for some participants in this study. Of the 73 children with documented antibiotic use, 48 (66%) received β-lactam antibiotics (amoxicillin, clavulanate potassium, cefaclor, etc), with only 4 (5%) having treatment durations longer than 2 weeks. Additionally, 33 (45%) children were treated with macrolides, including azithromycin and erythromycin; among them, only 5 (7%) had a treatment duration exceeding 2 weeks (Table S2 in Multimedia Appendix 3).

As for microbiological findings, following enrollment in this study, 63 pediatric patients were hospitalized for treatment and underwent bronchoscopy and bronchoalveolar lavage. Pathogen tests, such as bronchoalveolar lavage fluid culture, polymerase chain reaction, and metagenomic next-generation sequencing analysis, were also conducted. Of the 63 patients, 39 (62%) were positive for pathogenic bacteria. Of the 39 patients, 17 *Streptococcus pneumoniae* (44%), 7 *Haemophilus influenzae* (18%), and 6 *Staphylococcus aureus* (15%) were the most frequently detected pathogens. Additionally, 36% (18/39) of patients were coinfected with viral infections. Rhinovirus had the highest detection rate among viruses. Fungi were detected in 2 patients, namely Candida albicans; Pseudomonas aeruginosa, a bacterium, was also identified (Table S3 in Multimedia Appendix 3).

All the children were prescribed oral antibiotic therapy after enrollment in this study. Forty-seven patients were treated with Cefditoren Pivoxil Granules (3 mg/kg, 3 times a day), with a mean treatment duration of 2.7 (SD 0.7) weeks; 27 patients received Faropenem Sodium Tablets (5 mg/kg, 3 times a day), with a mean duration of 3.0 (SD 1.1) weeks; and 22 patients were administered Linezolid Tablets (10 mg/kg, 3 times a day), with a mean treatment course of 2.5 (SD 1.3) weeks. Among these cases, 2 patients who showed inadequate response to Cefditoren Pivoxil Granules achieved cough resolution after switching to Faropenem Sodium Tablets; 4 patients who failed initial Cefditoren Pivoxil Granules therapy successfully transitioned to Linezolid Tablets with subsequent symptom disappearance; 2 patients received combination therapy with

XSL•FO
RenderX

Faropenem Sodium Tablets and Linezolid Tablets, and 1 patient required antifungal medication. The median duration of anti-infective therapy after evaluation at our institution was 3 (IQR 2 - 4) weeks. Treatment duration distribution was as follows: 31% (27/88) of children received 2 weeks of therapy, 33% (29/88) completed 3 weeks, 27% (24/88) required 4 weeks, and 9% (8/88) needed extended therapy beyond 4 weeks. Complete resolution of cough symptoms was achieved in all cases (Tables S4 and S5 in Multimedia Appendix 3).

Analysis of Factors Affecting Cough Duration Prior to the Diagnosis

Ten potential influencing factors were screened through univariate analysis. Given that multiple comparisons increase the risk of Type I error, we applied the Benjamini-Hochberg method to control the FDR by adjusting the *P* values. A Q value <.05 after correction was considered statistically significant. The corrected results demonstrated statistically significant differences among groups for the following 4 factors: place of residence (z=−2.72; P=.006; Q=.045), parental education level (z=−2.37; P=.02; Q=.045), parental assessment of the nature of the cough (z=−2.46; P=.01; Q=.045), and whether the individual rested during the cough episode (z=−2.50; P=.01; Q=.045). In contrast, no significant differences were observed for other variables; detailed data are presented in Table 1.

XSL•FO
RenderX

Table . Analysis of the factors affecting the cough duration prior to the diagnosis (N=88).[a]

Variable and Group	Duration of cough (weeks), median (IQR)	*z* score	*P* value	Q value
Sex		−0.25	.81	.896
Male	8 (6 - 14)			
Female	8 (4 - 16)			
Residence		−2.72	.006	.045
City	8 (4 - 12)			
Village	14 (8-26)			
Siblings		−1.92	.06	.110
Yes	12 (8-16)			
No	8 (4 - 12)			
Parental education level		−2.37	.02	.045
Postsecondary education	8 (4 - 12)			
High school education or below	12 (8-24)			
Judgment of the nature of cough		−2.46	.01	.045
Yes	8 (4 - 12)			
No	14 (8-36)			
Rest at disease period		−2.50	.01	.045
Yes	8 (4 - 12)			
No	12 (8-16)			
Primary caregiver		−0.07	.94	.944
Parents	8 (4 - 16)			
Grandparents	8 (5 - 14)			
Environmental exposure to smoking		−0.26	.79	.896
Yes	8 (4 - 16)			
No	8 (5.5 - 16)			
Treatment of asthma		−1.66	.10	.139
Yes	12 (8-20)			
No	8 (4 - 12)			
Treatment with antibiotics		−1.71	.09	.139
Yes	12 (4-16)			
No	8 (6 - 8)			

[a]The nonparametric test was conducted with the duration of cough prior to the diagnosis as the dependent variable.

To explore the independent effects of each variable on cough duration prior to the diagnosis after controlling for other factors, the 4 variables that showed significant associations ($P<.05$) in the univariate analysis (including residence, parental education level, parental assessment of the nature of the cough, and rest status at disease period) were included in a multivariate linear regression analysis model. The assignment of each variable is presented in Table 2. Specifically, place of residence (B=9.35, 95% CI 0.36-18.35; $P=.04$) and rest status during the coughing episode (B=7.87, 95% CI 0.36-15.38; $P=.04$) were significantly associated with cough duration prior to the diagnosis. In contrast, parental educational level (B=2.83, 95% CI −6.36 to 12.01; $P=.54$) and parental assessment of the nature of the cough (B=7.39, 95% CI −2.59 to 17.38; $P=.15$) were not significantly associated with the outcome. The analysis revealed that the regression model was statistically significant ($F_{4,83}=3.98$; $P=.005$). The 4 predictor variables collectively explained 12.1% of the variance in the interval between symptom onset and diagnosis (adjusted $R^2=0.121$) (Table 2).

XSL•FO
RenderX

Table . The factors affecting cough duration in multivariate linear regression analysis (N=88).[a]

Independent variable	B (SE)[b]	Standardized β coefficient	*t* value (*df*)	*P* value	VIF[c]
Constant	5.75 (3.26)	—[d]	1.77 (83)	.08	—
Residence	9.35 (4.52)	.24	0.07 (83)	.04	1.30
Education level of parents	2.83 (4.62)	.07	0.61 (83)	.54	1.32
Judgment of the nature of cough	7.39 (5.02)	.15	1.47 (83)	.15	1.03
Rest at disease period	7.87 (3.78)	.21	2.08 (83)	.04	1.02

[a]Variable description: Residence (city=0, village=1); education level of parents (postsecondary education=0, high school education or below=1); judgment of the nature of cough (correct=0, wrong=1); rest at disease period (rest=0, no rest=1)

[b]R^2=0.161; adjusted R^2=0.121; F_1-score=3.98; *P*=.005; D-W value=1.81.

[c]VIF: variance inflation factor.

[d]Not available.

Correct Antibiotics Significantly Reduced Daytime and Nocturnal Cough Scores

At the first visit, all 88 children were scored by their parents based on the symptoms. At the first visit, 5% (4/88) of patients only had night cough, 23% (20/88) of patients only had daytime cough, and 20% (18/88) of patients had frequent daytime cough affecting their daytime life. There were 32% (28/88) patients with frequent nocturnal cough affecting sleep, and 13% (11/88) patients with frequent daytime and nocturnal cough affecting daily life (Table S6 in Multimedia Appendix 3). At the first visit, there was no significant difference in daytime cough symptom score and nocturnal cough symptom score between the two groups (z=−0.52; *P*=.60; Table S7 in Multimedia Appendix 3).

The daytime and nocturnal scores at 2 weeks and 4 weeks after diagnosis were assessed via outpatient examination and telephone follow-up. Fortunately, all parents and caregivers of the enrolled patients completed the assessment of their children's cough symptom scores at both the 2nd and 4th weeks of treatment. At the 2nd week of follow-up, daytime cough disappeared in 38% (33/88) of patients, nocturnal cough disappeared in 70% (62/88) of patients, and the cough symptoms completely disappeared in 31% (27/88) of patients. At the 4th week of follow-up, daytime cough symptoms disappeared in 90% (79/88) of patients, night cough symptoms disappeared in 98% (86/88) of patients, and cough symptoms completely disappeared in 90% (79/88) of patients (Tables S8 and S9 in Multimedia Appendix 3).

Daytime cough did not completely disappear in 9 patients after 4 weeks of treatment. Cough disappeared in 7 patients after 5 to 6 weeks of antibiotic therapy, aggravated in 1 patient and improved after adding antifungal drugs in the hospital, and 1 child did not continue treatment. The nocturnal cough did not completely disappear in 2 children at 4 weeks of treatment, and the duration of treatment was prolonged to 5 weeks (Tables S8 and S9 in Multimedia Appendix 3).

PBB Reduced the Quality of Life in Children

In total, 35 PBB children older than 6 years old completed the LCQ-MC. The results showed no significant difference in the physical, psychological, and social scores of LCQ-MC among children with PBB ($F_{2,102}$=0.13; *P*=.88; Table S10 in Multimedia Appendix 3 and Table 3).

XSL•FO
RenderX

Table . Score of the Leicester Cough Questionnaire in Mandarin-Chinese (LCQ-MC) and Parent-Proxy Cough-Specific Quality of Life (PC-QOL).

Scale and domain	Score, mean (SD)	*F* test (*df*)	*P* value
LCQ-MC (n=35)		0.13 (2,102)	.88
Physical	4.90 (0.89)		
Psychological	4.99 (1.28)		
Social	4.85 (1.37)		
PC-QOL (n=88)		3.20 (2,261)	.04
Physical	3.10 (1.36)[a]		
Psychological	3.32 (1.57)[a,b]		
Social	3.67 (1.53)[b]		

[a]Data were analyzed by repeated-measures ANOVA followed by Bonferroni post hoc test. Within each scale, different superscript letters denote statistically significant differences at $P<.05$ in the post hoc pairwise comparisons.

[b]Data were analyzed by repeated-measures ANOVA followed by Bonferroni post hoc test. Within each scale, different superscript letters denote statistically significant differences at $P<.05$ in the post hoc pairwise comparisons.

The reliability and validity of the PC-QOL scale were measured among 88 children at the first visit. Cronbach α coefficient was higher than 0.8, suggesting good internal consistency and high reliability. Cronbach α coefficients of physical, psychological, and social components were all higher than 0.8, suggesting that the scale had high reliability. Kaiser-Meyer-Olkin (KMO) >0.8 was suitable for factor analysis. The overall KMO of PC-QOL was 0.90, and the KMOs of physical, psychological, and social components were all >0.8, suggesting that the scale exhibited good construct validity (Table S11 in Multimedia Appendix 3). The results showed a significant difference between the scores of the physical domain and social domain among children with PBB ($t_{174}=-2.58$, $P=.01$; Table 3), and the score of the physical domain was significantly lower than that of the social domain.

In total, 19 parents of children with PBB completed the PC-QOL scale at baseline and after treatment. The results showed significant differences in the overall distribution of each domain and the total score of PC-QOL between baseline and after treatment (Table 4). The scores of physical ($t_{18}=-6.05$, $P<.001$), psychological ($t_{18}=-4.42$, $P<.001$), and social domains ($t_{18}=-4.79$, $P<.001$) and total scores ($t_{18}=-5.25$, $P<.001$) after treatment were significantly higher than those before treatment.

Table . Parent-Proxy Cough-Specific Quality of Life scores were compared before and after treatment using the paired samples *t* test (n=19).

Domain	Before treatment, mean (SD)	After treatment, mean (SD)	*t* test (df)	*P* value
Physical	2.86 (1.35)	5.48 (1.24)	−6.05 (18)	<.001
Psychological	3.38 (1.54)	5.69 (1.17)	−4.42 (18)	<.001
Social	3.63 (1.60)	5.89 (1.06)	-4.79 (18)	<.001
Sum	9.87 (4.26)	17.06 (3.22)	-5.25 (18)	<.001

Thirty-five children with PBB aged more than 6 years were included in this study. Pearson correlation analysis and difference analysis showed a good correlation between the scores and total scores of PC-QOL and LCQ-MC (physical: $r=0.57$, $P<.001$; psychological: $r=0.48$, $P=.004$; social: $r=0.58$, $P<.001$; total: $r=0.66$, $P<.001$) (Table S12 in Multimedia Appendix 3). The scores and total scores of PC-QOL were significantly lower than those of LCQ-MC (physical: $t_{34}=8.31$, $P<.001$; psychological: $t_{34}=6.58$, $P<.001$; social: $t_{34}=5.09$, $P<.001$; total: $t_{34}=8.11$, $P<.001$) (Table 5).

Table . Paired sample *t* test was used for the Leicester Cough Questionnaire in Mandarin-Chinese (LCQ-MC) and Parent-Proxy Cough-Specific Quality of Life (PC-QOL) among children aged ≥6 years (n=35).

Domain	LCQ-MC, mean (SD)	PC-QOL, mean (SD)	*t* test (df)	*P* value
Physical	4.90 (0.89)	3.24 (1.43)	8.31 (34)	<.001
Psychological	4.99 (1.28)	3.38 (1.53)	6.58 (34)	<.001
Social	4.85 (1.37)	3.73 (1.49)	5.09 (34)	<.001
Sum	14.74 (3.11)	10.35 (4.21)	8.11 (34)	<.001

XSL•FO
RenderX

Discussion

Principal Findings

This study examined factors contributing to the prolonged clinical course of PBB and evaluated the impact of chronic cough on quality of life in children with PBB. Using multiple regression analysis, this study identified place of residence and whether the child was resting or active during coughing episodes as significantly associated with prediagnosis cough duration. Furthermore, PBB substantially impairs multiple dimensions of children's well-being, including physical, psychological, and social functioning.

Analysis of Factors Affecting Cough Duration Prior to the Diagnosis

PBB is a common cause of chronic wet cough among preschool children aged 0 - 6 years [26,27]. The 2019 multicenter study on the proportion of the causes of chronic wet cough in children [28] showed that PBB was the 4th cause of chronic wet cough among children in China. It was also the leading cause of chronic wet cough among children younger than 1 year. Early diagnosis and treatment of PBB can reduce the duration of persistent cough, improve clinical symptoms, prevent its progression to bronchiectasis, and reduce morbidity and mortality [27,29].

Residence in rural areas demonstrated the strongest correlation with prolonged cough duration prior to PBB diagnosis, underscoring a core issue of inequitable distribution of medical resources. Compared to urban residents, rural families likely face several barriers, including limited access to specialized diagnostic facilities and expertise. PBB was recognized as a diagnostic name worldwide in 2008 [30]. In 2013, PBB was first included in the guidelines for chronic cough in China [4]. However, the Australian scholar Laird et al [31] conducted a survey of local medical workers in towns and remote communities and found that approximately one-third of local medical workers did not know the guidelines for chronic wet cough and had little knowledge about chronic wet cough, PBB, and chronic suppurative lung disease. They normalized chronic wet cough. The long-term complications of chronic wet cough and the need for timely assessment and therapeutic intervention have been largely neglected. Therefore, the cough duration of children with PBB who live in rural areas is longer than that of those living in urban areas, which is closely associated with the lack of knowledge about PBB in primary medical institutions in rural areas of China. Residents in rural areas may experience significant delays within the local health care system. They often undergo multiple rounds of ineffective empirical treatments at primary care facilities before receiving a definitive diagnosis. A study including 190 children with PBB diagnosed after referral to secondary care institutions [32] reported that more than 80% of the children had visited a doctor 5 or more times in the past 12 months, and 53% (101/190) had visited a doctor 10 or more times before referral. Therefore, there is a lack of awareness of PBB-related treatment options in primary care institutions. Geographical barriers: accessing medical centers that provide specialized pediatric respiratory care requires considerable financial resources and time; this poses a substantial barrier to timely diagnosis. The family in rural residents had insufficient awareness of disease prevention and control and had less knowledge about chronic diseases of the respiratory system. Due to the economic conditions of families, parents more often choose the nearby diagnosis and treatment facilities or buy drugs based on their choice rather than going to professional medical institutions for treatment. When the child's condition does not improve, they will seek more professional treatment. In addition, parents in rural areas have less energy to take care of their children, which limits the implementation of medical advice and affects the treatment effect. Perhaps in the future, we will be able to introduce advanced technology such as cough sound classifiers [33], eHealth systems and interventions [34,35] to offer a promising solution for the early detection and efficient management of PBB in primary care institutions.

Prior to the diagnosis of PBB, inadequate rest during the coughing episode was significantly linked to a prolonged duration of the cough. In this study, 63% (55/88) of the children continuously went to school after the onset of cough symptoms. Among daycare children, those who receive care because of a cough are 13 times more likely to develop a chronic cough than those who stop caring for children at home [36]. The incidence of infectious diseases among children in daycare or preschool education is 2 to 3 times that of ordinary children [37,38], and the large population density in the classroom can easily lead to cross-infection of viruses among children. Common respiratory pathogens, such as respiratory syncytial virus, influenza A virus, and rhinovirus, upregulate the bacterial adhesion molecules of epithelial cells in children, which can also lead to mucociliary clearance disorders and damage epithelial cells, affect the clearance efficiency, promote bacterial invasion of host cells and tissues, and enhance bacterial growth and colonization. This damage can take weeks to repair [39-41]. Cross-infection provides insufficient time to repair the airway mucosa, and repeated infection worsens airway inflammation, further exacerbating airway inflammation, thus forming a vicious circle, which is conducive to the formation of bacterial biofilm [42], promotes the development and progression of PBB, and prolongs cough symptoms. However, due to work requirements and social and family tasks, it is difficult in many families in our country for parents to terminate school and nursery care for children with a persistent cough. In contemporary society, seeking medical care for children often entails practical constraints such as taking time off work or arranging leave from school. Consequently, families tend to prioritize health care visits only when symptoms become sufficiently severe to cause significant functional impairment, that is, when the child must rest and daily routines are substantially disrupted.

Parents play critical roles in the treatment of children with respiratory diseases [43]. Studies have found that the low education level of primary caregivers is a risk factor for the incidence of recurrent upper respiratory tract infections among children [44,45]. A low education level is a risk factor for the low awareness of respiratory infection prevention and control among parents of preschool children [46]. At the same time, in the process of treatment, parents with higher education levels will provide accurate information, have better compliance, and

XSL•FO
RenderX

will not arbitrarily stop the drug. Nevertheless, parental education showed no significant association with diagnostic delay in the multivariate model. One possible explanation is that parental education influences the disease course indirectly through various health behaviors and environmental factors. Research shows that a mother's education level is a factor influencing children's susceptibility to illnesses [47-49]. Families with higher levels of parental education are more likely to seek professional medical care when their children are ill, possibly because higher education enhances health knowledge and the ability to access health care resources. This influence may be reflected in variables such as urban versus rural residence and the frequency or severity of cough symptoms. When variables such as residence and cough characteristics are included in statistical models, the independent effect of parental education becomes attenuated or statistically insignificant.

Moreover, this study indicated that parental judgment of the nature of the cough was not significantly associated with the duration of cough prior to diagnosis. Like parental education level, parental judgment may be influenced by mediating effects and potential collinearity with other variables. These factors could reduce its independent explanatory power. Furthermore, this result suggests that even when parents are able to recognize key symptoms such as "wet cough," this recognition does not necessarily translate into timely health-seeking behavior. Foreign studies have shown that local Australian residents believe that isolated chronic wet cough does not need medical management [50], which often delays treatment. Some parents may also rely on self-management approaches based on previous illness experiences. Specifically, a productive cough may be mistaken for a mild condition that resolves on its own, such as the recovery phase of a common cold, rather than being recognized as a symptom that requires professional medical evaluation.

Quality of Life Score Among Children With PBB

Frequent cough during the daytime can affect children's learning and life, and nocturnal cough can affect children's sleep, lower daytime energy levels, and affect children's health. Long-term cough can also lead to anxiety, embarrassment, and other psychological problems, and repeated medical treatment and physical discomfort can also affect the progress of school life. Chronic cough affects children's physical, sleep, and mental health and school performance. It can also cause anxiety in parents, interfere with work and other plans, and increase family expenditure. The decreased quality of life caused by cough may be the direct cause of patients' visits.

The LCQ scale [20] was first proposed by SSB in 2003, which assesses the effects of chronic cough on 19 items across 3 domains: physical, psychological, and social domains. The LCQ scale is highly reproducible and responsive to change. It is a reliable and valid measurement tool for assessing cough-specific health status and can be used to evaluate the effects of cough on different aspects over time, with a minimal clinically important difference of 1.3 [51]. Gao et al [25] translated the LCQ scale into Mandarin Chinese in 2014 using the forward-backward translation method, creating the LCQ-MC. There were no significant differences in the conceptual content between the back-translation and the original English version. This was verified by S.S. Birring (SSB), the author of the English LCQ. This study confirmed that the LCQ-MC effectively assessed the severity of cough symptoms in patients with bronchiectasis. Research by Xu et al [52] indicated that the LCQ-MC can assess cough severity after thoracoscopic surgery in patients with pulmonary disease. The Chinese National Guideline on Diagnosis and Management of Cough (2021) [53] also recommends using LCQ-MC to assess cough-related quality of life, supporting these findings.

The PC-QOL scale [21] was developed by Newcombe PA in 2008. The questionnaire was set according to the opinions of experts in child respiratory medicine and psychology. It comprises 27 items involving physical, psychological, and social aspects. The parents' feelings (15 items) and concerns (12 items) about the severity of cough in children with chronic cough were evaluated to reflect the effect of children's cough on parents and parents' perception of their children's quality of life. In 2010, Newcombe et al [54] confirmed that the questionnaire was a reliable and valid measure, with a minimally important difference of 0.9 [55], capable of assessing childhood cough-related quality of life over specified periods. But over the last 10 years, minimal research has been conducted on the creation, application, and cultural modification of QOL evaluation instruments for chronic cough in children [56].

The scores of 35 children who completed both LCQ-MC and PC-QOL at the first visit were analyzed to explore the consistency of quality of life assessment between children and their parents. Correlation analysis showed a good correlation between PC-QOL and LCQ-MC in physical, psychological, and social domains and total scores. After cough remission, the scores of each domain and the total score of the PC-QOL scale significantly increased in children with PBB, suggesting that the scale has good therapeutic responsiveness and can be used to assess treatment effects. A randomized controlled trial [57] also showed that the PC-QOL score of children with PBB increased by 2.1 and 1.9 after 2 or 4 weeks of treatment with amoxicillin clavulanate potassium, respectively. A study [58] also indicated that PC-QoL scores were significantly improved postintervention. The improvement in the PC-QOL score suggests an improvement in the quality of life of children and their caregivers. The pressure and concerns of parents will disappear when the children's cough stops [32]. The treatment of PBB not only relieves the cough symptoms of children and solves the physical discomfort of children but also significantly improves the psychological and social effects of cough on children and their caregivers.

In this study, the average scores of the physical, psychological, and social domains of the LCQ-MC scale were mean 4.90 (SD 0.89), mean 4.99 (SD 1.28), and mean 4.850 (SD 1.37), respectively, and the average total score of each domain was mean 14.74 (SD 3.11). In the study conducted by Reynolds et al [59], the average scores of physical, psychological, and social domains of LCQ were mean 6.53 (SD 0.39), mean 6.83 (SD 0.34), and mean 6.87 (SD 0.27), respectively. The total scores of LCQ ranged from 17.05 to 21, with an average score of mean 20.23 (SD 0.85). The study suggested the following scores as the lower limits of a normal LCQ score: physical domain: 5.36; psychological domain: 5.81; social domain: 6.06; and total

XSL•FO
RenderX

score: 17.68. In our study, the scores of each domain and the total score of the LCQ-MC scale among children with PBB were lower than the lower limit of normal scores suggested by the above studies, suggesting that PBB can decrease the physical, psychological, and social quality of life in children.

The scores of PC-QOL were significantly lower than those of LCQ-MC. The differences in scores between PC-QOL and LCQ-MC could be attributed to the characteristics of parents and children in families. Parents' response is affected by their expectations and attention to their children, the burden of care, their own mental health, and family responsibility [60]. Children's quality of life score was higher than that of parents' evaluation. Consistently, previous studies have found that the self-rated quality of life scores of children with attention-deficit hyperactivity disorder syndrome, sickle cell anemia [61], and ataxia telangiectasia [62] were higher than those of their parents.

On the LCQ-MC scale, the lowest score was observed in the social domain, and the highest score was observed in the psychological domain. However, on the PC-QOL scale, the lowest score was observed in the physical domain and the highest score was observed in the social domain. Parents are more concerned about the effects of cough on the body of children, while the social function of children is more affected, suggesting that parents of children with PBB may ignore the effect of chronic cough on the social function of children. For children, it is critical to achieve good peer relationships, and children with chronic diseases more frequently report that their health problems impair their participation in group activities and affect their quality of life [63-65]. For children with PBB, chronic cough is often considered a sign of being unhealthy and infected. Children themselves worry about the effect of cough on peers, care about the views of classmates and teachers, and are unwilling to go to school. In addition, frequent absences in school and group activities due to repeated medical visits and exacerbation of cough symptoms subsequent to respiratory tract infection also limit the time of children to participate in social and recreational activities, thus decreasing their social communication skills. At the same time, the parent-child relationship between the children and their parents will also be affected, and the parents' requirements, control, and overprotection of the children will increase, and parents of the children will have to complete work tasks to earn sufficient money for taking care of their children, which can induce a negative feeling. Negative attitudes toward children can affect communication with children, and some parents even give their children to others because they cannot cope with their children's diseases, which affects children's psychosocial function [66]. Based on the bio-psycho-social medical model, people's health not only represents their normal physical function, but also the health and harmony of physiological, psychological, and social functions. Medical workers should not only solve the physical pain of patients but also improve their quality of life.

Therefore, clinicians should pay more attention to children with PBB who live in rural areas and whose parents have a low education level. Parents should consider the rest time at home for children with PBB to shorten the duration of the cough. PBB can seriously affect the physical, mental, and social functions of children. While treating the physical diseases of children, doctors and parents should also pay attention to the detrimental effects of cough on the psychological and social functions of children and strengthen psychological counseling and communication to help children improve their quality of life.

Limitations

Of course, this study has several limitations. First, the adjusted R^2 value of 0.121 suggests that a considerable proportion of the variance in cough duration remains unexplained. This indicates the potential role of unmeasured confounding factors, such as specific pathogens, the child's atopic predisposition, and variations in both the accuracy of primary care diagnoses and the level of awareness among primary care providers. Additionally, only Chinese participants were included in this study. No analysis of cultural or social influences related to racial or ethnic differences was conducted. Second, all measures, including symptom data and clinical assessments, relied on subjective information, which is susceptible to measurement bias, such as recall or reporting bias. Third, the relatively small sample size may limit the statistical power of the analyses, and the cross-sectional design precludes causal inference between variables. As a result, the findings are preliminary. Future studies should use longitudinal designs and recruit larger samples. They should also incorporate laboratory-confirmed bacterial diagnoses and environmental assessments to validate these findings and better elucidate the biological and sociobehavioral mechanisms influencing the course of PBB in children.

Conclusions

Based on univariate analysis, 4 variables potentially associated with cough duration prior to PBB diagnosis were identified and included in the multivariate regression model. The final model revealed that "place of residence" and "rest status during the coughing episode" were significantly associated with cough duration. Nevertheless, the model also indicated that a substantial proportion of the variance remains unexplained, suggesting the involvement of additional unmeasured factors that warrant further investigation. Moreover, our findings indicate that PBB significantly impairs children's physical, psychological, and social quality of life. Notably, changes in social functioning are often overlooked by both clinicians and parents during the diagnosis, treatment, and daily care of affected children.

Acknowledgments

The authors thank the patients and families whose data were enrolled in the study. The authors thank the entire pediatric team of Qilu Hospital of Shandong University. The authors thank the original developer of the Leicester Cough Questionnaire (LCQ),

XSL•FO
RenderX

Prof Birring, S.S. and the Copyright Clearance Center of BMJ Group for the use of the LCQ. We have applied for and obtained official permission for the LCQ scale from BMJ Group [67]; the order number is 6133160551337.

Funding

This work was supported by the horizontal research projects, Qilu Hospital, Shandong University (grant 6010124007).

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: FL (lead), NQ (equal)
Data curation: HN
Formal analysis: WZ (lead), JZ (supporting)
Funding acquisition: JZ
Investigation: HN (lead), WZ (supporting)
Writing – original draft: HN (lead), NQ (supporting)
Writing – review & editing: HN (lead), NQ (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Patients' demographics assessments with a case report form.
[PDF File, 326 KB - pediatrics_v8i1e82887_app1.pdf]

Multimedia Appendix 2
Questionnaires of simplified cough symptom score, cough symptom score, Leicester Cough Questionnaire, Leicester Cough Questionnaire in Mandarin-Chinese, and Parent-Proxy Cough-Specific Quality of Life.
[PDF File, 237 KB - pediatrics_v8i1e82887_app2.pdf]

Multimedia Appendix 3
Characteristics of 88 children, usage of antibiotics outside the hospital, pathogen detection in the bronchoalveolar lavage fluid, antibiotic use, duration of antimicrobial therapy, sCSS at first visit, comparison of CSS between day and night, efficacy evaluation of daytime cough, efficacy evaluation of nocturnal cough, LCQ-MC score, the reliability and validity of PC-QOL, and correlation analysis of LCQ-MC and PC-QOL scores among children aged ≥6 years. LCQ-MC: Leicester Cough Questionnaire in Mandarin-Chinese; PC-QOL: Parent-Proxy Cough-Specific Quality of Life; sCSS: simplified Cough Symptom Score.
[PDF File, 168 KB - pediatrics_v8i1e82887_app3.pdf]

References

1. Lai K, Pan J, Chen R, Liu B, Luo W, Zhong N. Epidemiology of cough in relation to China. Cough 2013 Jul 8;9(1):18. [doi: 10.1186/1745-9974-9-18] [Medline: 23835047]
2. Li L, Liu EM, Hao CL, Chen Q, Hu CL, Zhang F, et al. A prospective multicenter study on the clinical diagnosis and treatment of children and protracted bacterial bronchitis [Article in Chinese]. Jiangxi Med J 2021 Feb;56(2):168-172. [doi: 10.3969/j.issn.1006-2238.2021.02.014]
3. Peek R, Walker L, Singleton R. Chronic cough in preschool aged children. BMJ 2024 Sep 2;386:e079747. [doi: 10.1136/bmj-2024-079747] [Medline: 39222970]
4. Clinical Research Coordination Group of Chronic Cough, The Subspeciality Group of Respiratory Diseases, The Society of Pediatrics, Chinese Medical Association, Editorial Board, Chinese Journal of Pediatrics. Guideline for diagnosis and treatment of chronic cough in Chinese children. Zhonghua Er Ke Za Zhi 2014 Mar;52(3):184-188. [Medline: 24824387]
5. Weinberger M. Chronic cough and causes in children. J Clin Med 2023 Jun 9;12(12):3947. [doi: 10.3390/jcm12123947] [Medline: 37373643]
6. Mallet MC, Elmiger A, Glick S, et al. Diagnosis in children with prolonged or recurrent cough: findings from the Swiss Paediatric Airway Cohort. Pediatr Pulmonol 2025 Feb;60(2):e27499. [doi: 10.1002/ppul.27499] [Medline: 39936634]
7. Chang AB, Landau LI, Van Asperen PP, et al. Cough in children: definitions and clinical evaluation. Med J Aust 2006 Apr 17;184(8):398-403. [doi: 10.5694/j.1326-5377.2006.tb00290.x] [Medline: 16618239]

XSL•FO
RenderX

8. Chang AB, Robertson CF, Van Asperen PP, et al. A multicenter study on chronic cough in children: burden and etiologies based on a standardized management pathway. Chest 2012 Oct;142(4):943-950. [doi: 10.1378/chest.11-2725] [Medline: 22459773]
9. Chang AB, Robertson CF, van Asperen PP, et al. A cough algorithm for chronic cough in children: a multicenter, randomized controlled study. Pediatrics 2013 May;131(5):e1576-e1583. [doi: 10.1542/peds.2012-3318] [Medline: 23610200]
10. Douros K, Alexopoulou E, Nicopoulou A, et al. Bronchoscopic and high-resolution CT scan findings in children with chronic wet cough. Chest 2011 Aug;140(2):317-323. [doi: 10.1378/chest.10-3050] [Medline: 21415129]
11. Baines KJ, Upham JW, Yerkovich ST, et al. Mediators of neutrophil function in children with protracted bacterial bronchitis. Chest 2014 Oct;146(4):1013-1020. [doi: 10.1378/chest.14-0131] [Medline: 24874501]
12. King PT, Holdsworth SR, Farmer M, Freezer N, Villanueva E, Holmes PW. Phenotypes of adult bronchiectasis: onset of productive cough in childhood and adulthood. COPD 2009 Apr;6(2):130-136. [doi: 10.1080/15412550902766934] [Medline: 19378226]
13. Xu L, Ji X, Lin M, Chen X, Su C. Respiratory microbiota diversity and composition in recurrent protracted bacterial bronchitis: a cross-sectional study. Front Cell Infect Microbiol 2025;15:1524116. [doi: 10.3389/fcimb.2025.1524116] [Medline: 40792104]
14. Irwin RS, Boulet LP, Cloutier MM, et al. Managing cough as a defense mechanism and as a symptom. A consensus panel report of the American College of Chest Physicians. Chest 1998 Aug;114(2 Suppl Managing):133S-181S. [doi: 10.1378/chest.114.2_supplement.133s] [Medline: 9725800]
15. Chang AB, Redding GJ, Everard ML. Chronic wet cough: protracted bronchitis, chronic suppurative lung disease and bronchiectasis. Pediatr Pulmonol 2008 Jun;43(6):519-531. [doi: 10.1002/ppul.20821] [Medline: 18435475]
16. Hermann J, Brückner K, Koerner-Rettberg C, et al. Long-term pulmonary sequelae 5-14 years after protracted bacterial bronchitis in early childhood. Pediatr Pulmonol 2025 May;60(5):e71111. [doi: 10.1002/ppul.71111] [Medline: 40325918]
17. Newcombe PA, Sheffield JK, Chang AB. Parent cough-specific quality of life: development and validation of a short form. J Allergy Clin Immunol 2013 Apr;131(4):1069-1074. [doi: 10.1016/j.jaci.2012.10.004] [Medline: 23146374]
18. Subspecialty Group of Pharmacology, the Society of Pediatrics, Chinese Medical Association, National Clinical Research Center for Child Health and Disorders, Subspecialty Group of Respiratory Diseases, the Society of Pediatrics, Chinese Medical Association, Children's Respiratory Professional Committee, the Society of Pediatrics of Chinese Medical Doctor Association, Editorial Board, Chinese Journal of Pediatrics. Clinical practice guidelines for the diagnosis and management of children with cough in China (version 2021). Zhonghua Er Ke Za Zhi 2021 Sep 2;59(9). [doi: 10.3760/cma.j.cn112140-20210513-00423]
19. Boulet LP, Coeytaux RR, McCrory DC, et al. Tools for assessing outcomes in studies of chronic cough: CHEST guideline and expert panel report. Chest 2015 Mar;147(3):804-814. [doi: 10.1378/chest.14-2506] [Medline: 25522203]
20. Birring SS, Prudon B, Carr AJ, Singh SJ, Morgan MDL, Pavord ID. Development of a symptom specific health status measure for patients with chronic cough: Leicester Cough Questionnaire (LCQ). Thorax 2003 Apr;58(4):339-343. [doi: 10.1136/thorax.58.4.339] [Medline: 12668799]
21. Newcombe PA, Sheffield JK, Juniper EF, et al. Development of a parent-proxy quality-of-life chronic cough-specific questionnaire: clinical impact vs psychometric evaluations. Chest 2008 Feb;133(2):386-395. [doi: 10.1378/chest.07-0888] [Medline: 18252913]
22. Chang AB, Oppenheimer JJ, Weinberger MM, et al. Management of children with chronic wet cough and protracted bacterial bronchitis. Chest 2017 Apr;151(4):884-890. [doi: 10.1016/j.chest.2017.01.025] [Medline: 28143696]
23. Chinese Medical Association Respiratory Diseases Branch Asthma Group. Cough diagnosis and treatment guidelines (2015 Edition) [Article in Chinese]. Chin J Tubercul Respirat Dis 2016;39(5):323-354. [doi: 10.3760/cma.j.issn.1001-0939.2016.05.003]
24. Lin R, Zhu L, Pan X. Validation of the simplified cough symptom score in non-small cell lung cancer patients after surgery. Gen Thorac Cardiovasc Surg 2022 Aug;70(8):735-739. [doi: 10.1007/s11748-022-01791-w] [Medline: 35224703]
25. Gao YH, Guan WJ, Xu G, et al. Validation of the Mandarin Chinese version of the Leicester Cough Questionnaire in bronchiectasis. Int J Tuberc Lung Dis 2014 Dec;18(12):1431-1437. [doi: 10.5588/ijtld.14.0195] [Medline: 25517807]
26. Gallucci M, Pedretti M, Giannetti A, et al. When the cough does not improve: a review on protracted bacterial bronchitis in children. Front Pediatr 2020;8:433. [doi: 10.3389/fped.2020.00433] [Medline: 32850546]
27. Wiltingh H, Marchant JM, Goyal V. Cough in protracted bacterial bronchitis and bronchiectasis. J Clin Med 2024 Jun 4;13(11):3305. [doi: 10.3390/jcm13113305] [Medline: 38893016]
28. Chen Q, Hu CL, Shen KL, Jian CM, Liu EM, Shen ZB, et al. A multicenter clinical study on the cause constituent ratio of chronic wet cough in children [Article in Chinese]. Chin J Pract Pediatr 2019 Sep;34(9):757-762. [doi: 10.19538/j.ek2019090609]
29. Chang AB, Bush A, Grimwood K. Bronchiectasis in children: diagnosis and treatment. Lancet 2018 Sep 8;392(10150):866-879. [doi: 10.1016/S0140-6736(18)31554-X] [Medline: 30215382]
30. Shields MD, Bush A, Everard ML, McKenzie S, Primhak R, British Thoracic Society Cough Guideline Group. BTS guidelines: recommendations for the assessment and management of cough in children. Thorax 2008 Apr;63 Suppl 3:iii1-iii15. [doi: 10.1136/thx.2007.077370] [Medline: 17905822]

XSL•FO
RenderX

31. Laird P, Walker R, Lane M, Chang AB, Schultz A. We won't find what we don't look for: identifying barriers and enablers of chronic wet cough in Aboriginal children. Respirology 2020 Apr;25(4):383-392. [doi: 10.1111/resp.13642] [Medline: 31344317]
32. Marchant JM, Newcombe PA, Juniper EF, Sheffield JK, Stathis SL, Chang AB. What is the burden of chronic cough for families? Chest 2008 Aug;134(2):303-309. [doi: 10.1378/chest.07-2236] [Medline: 18641100]
33. Isangula KG, Haule RJ. Leveraging AI and machine learning to develop and evaluate a contextualized user-friendly cough audio classifier for detecting respiratory diseases: protocol for a diagnostic study in rural Tanzania. JMIR Res Protoc 2024 Apr 23;13:e54388. [doi: 10.2196/54388] [Medline: 38652526]
34. Bakema R, Smirnova D, Biri D, Kocks JWH, Postma MJ, de Jong LA. The use of eHealth for pharmacotherapy management with patients with respiratory disease, cardiovascular disease, or diabetes: scoping review. J Med Internet Res 2023 Sep 26;25:e42474. [doi: 10.2196/42474] [Medline: 37751232]
35. Xiao YZ, Chen XJ, Sun XL, et al. Effect of implementing an informatization case management model on the management of chronic respiratory diseases in a general hospital: retrospective controlled study. JMIR Med Inform 2024 Jun 19;12:e49978. [doi: 10.2196/49978] [Medline: 38904478]
36. Au-Yeung YT, Chang AB, Grimwood K, et al. Risk factors for chronic cough in young children: a cohort study. Front Pediatr 2020;8:444. [doi: 10.3389/fped.2020.00444] [Medline: 32903491]
37. Baroudy NRE, Refay ASE, Hamid TAA, Hassan DM, Soliman MS, Sherif L. Respiratory viruses and atypical bacteria co-infection in children with acute respiratory infection. Open Access Maced J Med Sci 2018 Sep 25;6(9):1588-1593. [doi: 10.3889/oamjms.2018.332] [Medline: 30337970]
38. Nesti MMM, Goldbaum M. Infectious diseases and daycare and preschool education. J Pediatr (Rio J) 2007;83(4):299-312. [doi: 10.2223/JPED.1649] [Medline: 17632670]
39. Yu MF, Zhang HL. Microbiology progress of protracted bacterial bronchitis in children [Article in Chinese]. Chin J Pract Pediatr 2021;36(8):634-636. [doi: 10.3760/cma.j.cn101070-20191211-01234]
40. Wong JYW, Rutman A, O'Callaghan C. Recovery of the ciliated epithelium following acute bronchiolitis in infancy. Thorax 2005 Jul;60(7):582-587. [doi: 10.1136/thx.2004.024638] [Medline: 15994267]
41. Budden KF, Shukla SD, Rehman SF, et al. Functional effects of the microbiota in chronic respiratory disease. Lancet Respir Med 2019 Oct;7(10):907-920. [doi: 10.1016/S2213-2600(18)30510-1] [Medline: 30975495]
42. Principi N, Esposito S. Biofilm production and its implications in pediatrics. Microorganisms 2024 Jul 25;12(8):1522. [doi: 10.3390/microorganisms12081522] [Medline: 39203365]
43. Jijo A, Jijo M, Manoj S, Veerachamy A. Assessing the suitability of ChatGPT and DeepSeekAI for parent's education on common pediatric respiratory diseases. Cureus 2025 Sep;17(9):e92434. [doi: 10.7759/cureus.92434] [Medline: 41111876]
44. Wang J, Li XH. Analysis of related factors and countermeasures of recurrent upper respiratory tract infection in 86 children [Article in Chinese]. Ant Inf Pharm 2020;17(4):552-554. [doi: 10.13493/j.issn.1672-7878.2020.04-029]
45. Bai SY, Guo SX, Chen H. Meta-analysis of risk factors for recurrent respiratory infections in children [Article in Chinese]. Chin J Nosocomiol 2021;31(12):1811-1816. [doi: 10.11816/cn.ni.2021-203798]
46. Wang MR, Qi J, Huang XL. The investigation of the awareness of respiratory infection prevention and control among parents of preschool children and its influencing factors [Article in Chinese]. Chin Matern Child Health Care 2019;34(11):2582-2584 [FREE Full text]
47. Ndugwa RP, Zulu EM. Child morbidity and care-seeking in Nairobi slum settlements: the role of environmental and socio-economic factors. J Child Health Care 2008 Dec;12(4):314-328. [doi: 10.1177/1367493508096206] [Medline: 19052189]
48. Islam MS, Chowdhury MRK, Bornee FA, et al. Prevalence and determinants of diarrhea, fever, and coexistence of diarrhea and fever in children under-five in Bangladesh. Children (Basel) 2023 Nov 20;10(11):1829. [doi: 10.3390/children10111829] [Medline: 38002920]
49. Kurt G, Serdaroğlu HU. Prevalence of infectious diseases in children at preschool education institutions and stakeholder opinions. Children (Basel) 2024 Apr 8;11(4):447. [doi: 10.3390/children11040447] [Medline: 38671664]
50. Laird P, Walker R, Lane M, Totterdell J, Chang AB, Schultz A. Recognition and management of protracted bacterial bronchitis in Australian aboriginal children: a knowledge translation approach. Chest 2021 Jan;159(1):249-258. [doi: 10.1016/j.chest.2020.06.073] [Medline: 32673622]
51. Raj AA, Pavord DI, Birring SS. Clinical cough IV:what is the minimal important difference for the Leicester Cough Questionnaire? Handb Exp Pharmacol 2009(187):311-320. [doi: 10.1007/978-3-540-79842-2_16] [Medline: 18825348]
52. Xu Z, Lin R, Che G, et al. Validation of the Mandarin Chinese version of the Leicester Cough Questionnaire in patients undergoing lung resection for patients with lung disease. Zhongguo Fei Ai Za Zhi 2017 Jun 20;20(6):389-394. [doi: 10.3779/j.issn.1009-3419.2017.06.04] [Medline: 28641696]
53. Asthma Group of Chinese Thoracic Society. Chinese national guideline on diagnosis and management of cough (2021). Zhonghua Jie He He Hu Xi Za Zhi 2022 Jan 12;45(1):13-46. [doi: 10.3760/cma.j.cn112147-20211101-00759] [Medline: 35000304]

XSL•FO
RenderX

54. Newcombe PA, Sheffield JK, Juniper EF, Petsky HL, Willis C, Chang AB. Validation of a parent-proxy quality of life questionnaire for paediatric chronic cough (PC-QOL). Thorax 2010 Sep;65(9):819-823. [doi: 10.1136/thx.2009.133868] [Medline: 20805179]
55. Newcombe PA, Sheffield JK, Chang AB. Minimally important change in a Parent-Proxy Quality-of-Life questionnaire for pediatric chronic cough. Chest 2011 Mar;139(3):576-580. [doi: 10.1378/chest.10-1476] [Medline: 20947650]
56. Cao B, Wang T, Zhai S, Zhang S, Yuan B. Quality of life assessment tools for chronic cough in children: a systematic review. Front Public Health 2025;13:1515858. [doi: 10.3389/fpubh.2025.1515858] [Medline: 40469618]
57. Ruffles TJC, Goyal V, Marchant JM, et al. Duration of amoxicillin-clavulanate for protracted bacterial bronchitis in children (DACS): a multi-centre, double blind, randomised controlled trial. Lancet Respir Med 2021 Oct;9(10):1121-1129. [doi: 10.1016/S2213-2600(21)00104-1] [Medline: 34048716]
58. Laird PJ, Chang AB, Walker R, et al. Evaluation of the implementation and clinical effects of an intervention to improve medical follow-up and health outcomes for Aboriginal children hospitalised with chest infections. Lancet Reg Health West Pac 2023 May;34(100708):100708. [doi: 10.1016/j.lanwpc.2023.100708] [Medline: 37283983]
59. Reynolds JE, Jetté ME, Wright ML, Sundar KM, Gillespie AI, Slovarp LJ. Normative values for the Leicester Cough Questionnaire in healthy individuals. Ann Otol Rhinol Laryngol 2023 Jun;132(6):705-708. [doi: 10.1177/00034894221112517] [Medline: 35833581]
60. Lee YC, Yang HJ, Chen VCH, et al. Meta-analysis of quality of life in children and adolescents with ADHD: by both parent proxy-report and child self-report using PedsQL. Res Dev Disabil 2016;51-52(160-72):160-172. [doi: 10.1016/j.ridd.2015.11.009] [Medline: 26829402]
61. Blake A, Guthrie-Dixon N, Grindley M, Barton-Gooden A, Knight-Madden J, Asnani M. Level of agreement between adolescents' self-assessment and parent proxy report of health-related quality of life in adolescents with sickle cell disease. Pediatr Blood Cancer 2020 Apr;67(4):e28198. [doi: 10.1002/pbc.28198] [Medline: 32020725]
62. McGlashan HL, Blanchard CV, Luscombe C, et al. Quality of life and neurological disability in children and young people with ataxia telangiectasia. Eur J Paediatr Neurol 2022 Sep;40(34-9):34-39. [doi: 10.1016/j.ejpn.2022.07.004] [Medline: 35932633]
63. Sawyer MG, Reynolds KE, Couper JJ, et al. A two-year prospective study of the health-related quality of life of children with chronic illness--the parents' perspective. Qual Life Res 2005 Mar;14(2):395-405. [doi: 10.1007/s11136-004-0786-y] [Medline: 15892428]
64. James C, Corman H, Noonan K, Reichman NE, Jimenez ME. Chronic health conditions and adolescents' social connectedness. Am J Orthopsychiatry 2024;94(3):235-245. [doi: 10.1037/ort0000712] [Medline: 38300587]
65. Meurillon R, Stheneur C, Le Roux E. Discrimination against adolescents with chronic diseases: a systematic review. Eur J Pediatr 2024 Dec 10;184(1):74. [doi: 10.1007/s00431-024-05829-4] [Medline: 39658646]
66. Cousino MK, Hazen RA. Parenting stress among caregivers of children with chronic illness: a systematic review. J Pediatr Psychol 2013 Sep;38(8):809-828. [doi: 10.1093/jpepsy/jst049] [Medline: 23843630]
67. Rights and licensing. BMJ Group. URL: https://bmjgroup.com/licensing/ [accessed 2025-12-08]

Abbreviations

KMO: Kaiser-Meyer-Olkin
LCQ: Leicester Cough Questionnaire
LCQ-MC: Leicester Cough Questionnaire in Mandarin-Chinese
PBB: protracted bacterial bronchitis
PC-QOL: Parent-Proxy Cough-Specific Quality of Life
sCSS: simplified Cough Symptom Score

Edited by S Badawy; submitted 24.08.25; peer-reviewed by JY Oh, R Lin; revised version received 02.11.25; accepted 27.11.25; published 19.12.25.

Please cite as:
Ning H, Zheng W, Zhang J, Li F, Qiao N
Analysis of Cough Factors and Quality of Life Score Among Children With Protracted Bacterial Bronchitis: Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e82887
URL: https://pediatrics.jmir.org/2025/1/e82887
doi:10.2196/82887

© Haonan Ning, Wenyu Zheng, Jinghui Zhang, Fuhai Li, Nana Qiao. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 19.12.2025. This is an open-access article distributed under the terms of the Creative Commons

XSL•FO
RenderX

Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Evaluation of the Use of a Novel Intelligent Diagnosis and Cost Control System on Pediatric Bronchopneumonia Outcomes: Retrospective Cohort Study

Yanjun Wu[1,2], MM; Kaijie Liu[1], MAM; Xinli Mao[3], MD; Danjie Wu[4*], MM; Feng Zhu[1*], BAM

[1]Department of Medical Affairs, Taizhou Hospital of Zhejiang Province, 150 Ximen Street, Linhai City, China

[2]Department of Pediatrics, Taizhou Hospital of Zhejiang Province, Linhai City, Zhejiang Province, China

[3]Department of Gastroenterology, Taizhou Hospital of Zhejiang Province, Linhai City, Zhejiang Province, China

[4]Department of Stomatology, Taizhou Hospital of Zhejiang Province, Linhai City, Zhejiang Province, China

[*]these authors contributed equally

Corresponding Author:
Feng Zhu, BAM
Department of Medical Affairs, Taizhou Hospital of Zhejiang Province, 150 Ximen Street, Linhai City, China

Abstract

Background: Health care systems face challenges of inconsistent quality, inefficiency, and rising costs. Fragmented applications of clinical decision support systems (CDSSs), clinical pathways (CPs), and diagnosis-related group (DRG) payment systems have limited their synergistic potential.

Objective: This study proposed a CDSS-CP-DRG closed-loop model enabled by digital health technologies; specifically, the CDSS optimized CP execution through real-time data, the CP standardized workflows to support DRG cost control, and DRG payment pressures drove iterative improvements in both technology and processes. This research aimed to validate the model's effectiveness in clinical efficacy, cost control, and standardized diagnosis and treatment of bronchopneumonia in children and provide evidence for value-based health care transformation.

Methods: A total of 4543 children with bronchopneumonia were selected and divided into the experimental or control group based on whether the intelligent diagnosis and cost control system was used in the diagnostic process. Chi-square test, 1-way analysis of variance, paired *t* test, multiple regression analysis, and other mathematical statistical methods were used to verify the difference between the outcomes of the two groups of patients.

Results: This study demonstrated comparably high cure rates in both groups ($P>.05$). However, the experimental group exhibited a 0.4-day reduction in average length of stay, 12.3% lower total hospitalization costs, RMB 135.3 (US $19) higher medical insurance reimbursement surplus, and a reduction of 0.16 defined daily doses of antibiotic use intensity versus the control group ($P<.05$ for all significant differences).

Conclusions: The novel intelligent diagnosis and cost control system demonstrated significant improvement in clinical effect, cost control, and standardized treatment for pediatric bronchopneumonia, but the CP for pediatric pneumonia requiring intensive care still needs further attention and adjustment.

(JMIR Pediatr Parent 2025;8:e74964) doi:10.2196/74964

KEYWORDS

intelligent diagnosis and cost control system; clinical decision support system; clinical pathway; diagnosis-related group; pediatric bronchopneumonia; evaluation; medical expenses; treatment outcomes

Introduction

Background

Bronchopneumonia, a prevalent lower respiratory tract infection, exhibits high incidence in children globally [1], with approximately 150 million annual cases among those aged 0‐5 years. Severe cases requiring hospitalization account for 12.82% of affected children [2,3], imposing substantial health burdens and socioeconomic costs [4].

Clinical decision support systems (CDSSs) integrate patient-specific data with computerized knowledge bases to generate evidence-based recommendations through software algorithms, representing a pivotal advancement in health informatics [5,6]. Pediatric applications demonstrate the capacity of CDSSs to enhance diagnostic accuracy, reduce errors, and improve workflow efficiency via intelligent alerts [7]. In addition, standardization of treatment through the use of clinical pathways (CPs) has proven to be an effective way to streamline

XSL•FO
RenderX

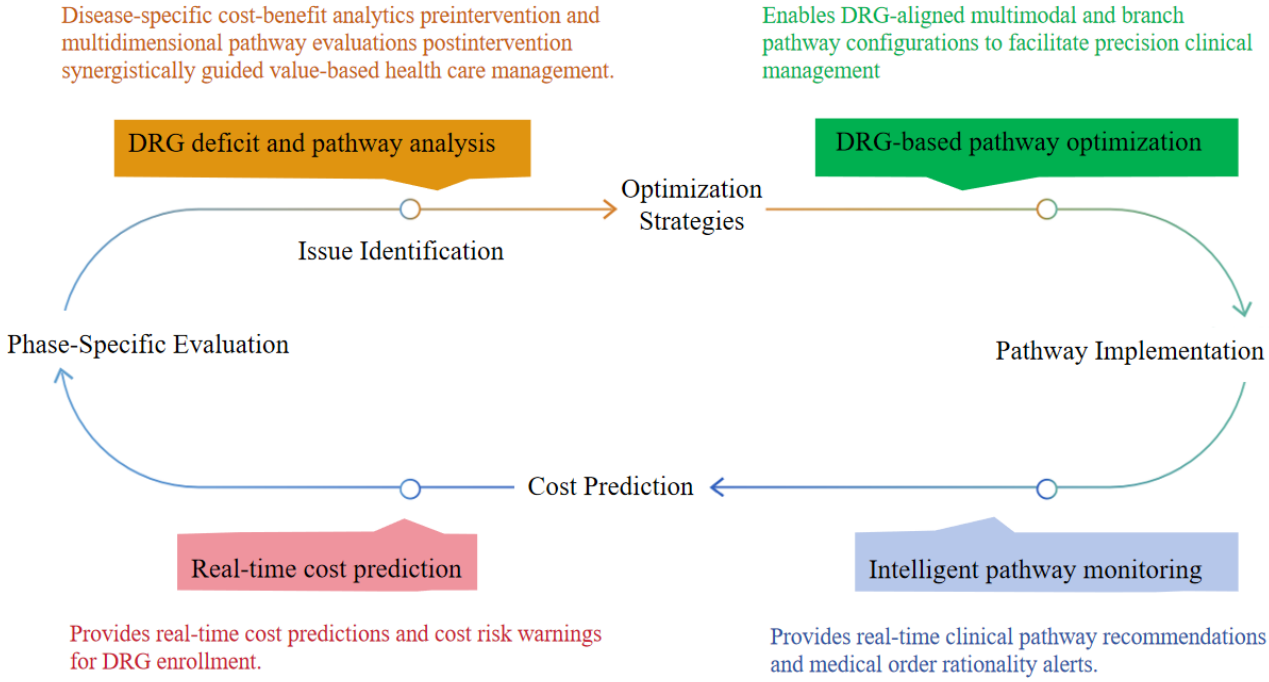
care in a way that minimizes errors and cost while improving outcomes [8].

Although these information-based systems hold transformative potential for global health care digitalization, rigorous economic evaluations and real-world effectiveness analyses remain scarce, with most evidence derived from narrative reviews rather than empirical data.

The Design and Implementation Path of a Novel Intelligent Diagnosis and Cost Control System

As shown in Figure 1, the artificial intelligence (AI)–driven CP optimization and cost containment system uses generalizable identification mechanisms and data-intelligent decision-making, integrating natural language processing, data mining, and machine learning technologies. It is integrated with core hospital information systems including electronic medical records, the laboratory information system, and the picture archiving and communication system. The system constructs disease-specific smart CPs that synchronize treatment quality assurance with expenditure control. This machine learning–powered architecture enables granular diagnosis-related group (DRG) adaptation, achieving precision treatment protocols (dynamic pathway optimization based on real-time patient status monitoring), intelligent cost governance (automated detection of billing deviations through natural language processing–based charge item analysis), and quality-cost balance (continuous learning from multisource clinical data to maintain care standards while reducing low-value services).

Figure 1. Closed-loop management framework of the intelligent decision and cost control system. DRG: diagnosis-related group.



Implementation Pathway and Core Functions

The intelligent diagnosis and cost control system (IDCCS) operates through a streamlined workflow, integrating multisource data from hospital systems (eg, hospital information system, laboratory information system, picture archiving and communication system, electronic medical records), followed by automated data cleaning and standardization. It features customizable CPs with DRG-based treatment branches and preimplementation cost simulations using historical data. The system establishes baselines through retrospective data analysis, then automatically enrolls eligible patients into pathways. During treatment, it provides real-time clinical decision support with deviation alerts requiring clinician confirmation, while monitoring prescription appropriateness and forecasting costs with early warnings. Posttreatment multidimensional analytics evaluate pathway efficacy, supporting continuous optimization.

Study Goal

This retrospective study analyzed the clinical outcomes, cost containment, and treatment standardization metrics of children with bronchopneumonia in a tertiary hospital in Eastern China (May 2023 to November 2024) and compared the difference of using or not using the IDCCS on these treatment outcome indicators. The findings provided empirical evidence for developing specialized and systematic intelligent CDSSs integrating cost-effective quality control in pediatric respiratory treatment.

Methods

Study Design

We designed a retrospective cohort study to analyze the differences in the results of 3 dimensions of treatment outcomes of hospitalized children with pneumonia for whom the IDCCS was used or was not used. The specific indicators of the 3 dimensions were as follows. The indicator of clinical efficacy was whether the disease improved. The economic indicators included length of hospital stay, total hospitalization expenses, proportion of drugs and consumables in expenses, and medical insurance settlement balance. The standardized diagnosis and treatment index was the volume of antibiotics dispensed (defined daily dose [DDD]).

XSL•FO
RenderX

Antibiotic therapy remains pivotal in pediatric pneumonia management [9]. The selection of DDD for evaluating antibiotic therapy compliance and normative treatment aligns with international guidelines [10,11]. This metric demonstrates superior validity in quantifying adherence to evidence-based protocols while balancing clinical relevance, operational feasibility, and comparability across multicenter studies [12]. The quantitative indicators including length of stay and health care costs can serve as economic end points to further validate the IDCCS's beneficial effects on treatment outcomes through cost analysis and resource utilization evaluation. These metrics' integration with CDSSs enables real-time feedback.

IDCCS Evaluation

Participants and Setting

This study was carried out at a tertiary hospital in Eastern China. The deployment of the IDCCS in December 2023 served as a natural intervention. Accordingly, patients retrospectively enrolled from the preimplementation phase (January to November 2023) comprised the control group. Conversely, patients from the postimplementation phase (the corresponding period in 2024) comprised the experimental group.

Information was collected for patients admitted to the hospital with the diagnosis of "bronchial pneumonia" and aged <14 years. The experimental group consisted of patients for whom the IDCCS was used (n=1658), and the control group consisted of patients for whom the IDCCS was not used (n=2885).

Cases were excluded if their medical records had home pages with incomplete information or important fields missing, home pages with errors, hospitalization expenses with outliers, hospitalization expenses below 100 yuan (US $13.95), hospitalization days below 0.1 days; ultimately, records for 4543 children were retained.

Data Collection

All the data were extracted from the hospital's internal database. To describe the population included in the study, the following variables were extracted at baseline: age, sex, diagnosis, with coinfection or not, and treatment result.

Statistical Analysis

Statistical analyses were conducted using SPSS for Windows (version 23.0; IBM Corp). Categorical data were denoted in numbers and percentages, while continuous variables were represented as means and SDs. Data normality and homoscedasticity were preliminarily verified before executing each statistical analysis.

The χ^2 test was used to compare the differences in categorical variable indicators between the experimental group and the control group (gender, diagnosis results of disease severity, concurrent infections, treatment outcomes). Paired *t* test and 1-way ANOVA were used to test the differences in continuous variables of the research subjects (length of hospital stay, total hospitalization cost, proportion of drug and consumable costs in the total cost, balance of medical insurance settlement, DDD).

For all tests, a *P* value ≤.05 was considered statistically significant.

Furthermore, in the comparison of treatment outcome differences, we not only conducted the analysis of the overall experimental group and intervention group, but also further divided the patients based on whether they required intensive care and whether they had severe complications or comorbidities, and then conducted further analysis separately.

Ethical Considerations

This study, conducted in accordance with the Declaration of Helsinki, received approval from the institutional review board of Taizhou Hospital of Zhejiang Province (K20250873). As it was a retrospective study involving the analysis of existing, anonymized data, the requirement for informed consent was waived by the ethics committee. To ensure data security and patient confidentiality, all personally identifiable information was removed prior to analysis. The data were accessed strictly for research purposes and stored on secure, password-protected hospital servers [13].

Results

Overview

Among the 4543 patients included in the study, 1658 were in the IDCCS-used (experimental) group, and 2885 were in the IDCCS-without (control) group. Data on demographic characteristics, discharge diagnosis, coinfection with or without, and treatment outcomes of the patients are provided in Table 1. No statistically significant differences were observed in age or sex distribution between the experimental and control groups (*P*>.05).

XSL•FO
RenderX

Table . Characteristics of participants in the study sample (N=4543).

Characteristics		Control (n=2885)	Experimental (n=1658)	Total missing, n (%)	*F* test/chi-square (*df*)
	Age (years), mean (SD)	4.17 (3.16)	3.54 (3.12)	0 (0)	1.9 (1, 4543)[a]
	Sex (female), n (%)	772 (46.6)	596 (48)	1643 (36.2)	0.4 (1, 1368)[b]
Discharge diagnosis					
	Pediatric pneumonia	2577 (89.3)	1648 (99.4)	0 (0)	165.0[c] (2, 4413)[b]
	Pediatric pneumonia requiring intensive care	178 (6.2)	10 (0.6)		
Coinfection					
	Without	2324 (80.6)	1067 (64.4)	0 (0)	146.0[c] (2, 4543)[b]
	With	561 (19.4)	591 (35.6)		
Treatment outcome					
	Improved	2840 (99.27)	1647 (99.34)	24 (0.5)	2.5 (2, 4159)[b]
	Unresolved	22 (0.77)	9 (0.54)		
	Death	0 (0)	1 (0.06)		

[a]*F* test.

[b]Chi-square test.

[c]*P*<.001.

Clinical Efficacy

Participants were stratified into 3 diagnostic subgroups: pediatric pneumonia, pediatric pneumonia requiring intensive care, and pediatric pneumonia with severe comorbidities and complications. Statistical analysis revealed no significant differences in treatment outcomes between the intervention and control groups across these subgroups (*P*>.05) (Table 2).

Table . The differences in treatment outcomes among participants in different diagnostic subgroups.

		Control (n=2554)	Experimental (n=1647)	Chi-square (*df*)
Pediatric pneumonia				
	Improved	2534 (99.2)	1637 (99.4)	2.4 (2)
	Unresolved	20 (69)	9 (31)	
	Death	0 (0)	1 (0.1)	
Pediatric pneumonia requiring intensive care				
	Improved	176 (98.9)	10 (100)	0.1 (1)
	Unresolved	2 (1.1)	0 (0)	
Pediatric pneumonia with severe comorbidities and complications				
	Improved	130 (100)	—[a]	

[a]Not applicable.

Economic Indicators

As shown in the analytical data in Table 3, following the implementation of the IDCCS, the experimental groups demonstrated a statistically significant reduction in the length of stay by 0.4 days (*P*<.001), with total hospitalization expenses decreasing by 12.2% (RMB 508.56 [US $71.43]) and medical insurance settlement balance increasing by RMB 135.3 (US $19; both *P*<.001).

Further group analysis found that the previously mentioned indicators of patients with pneumonia in the experimental group were improved. However, no significant differences were observed in the pediatric pneumonia subgroup requiring intensive care (*P*>.05).

XSL•FO
RenderX

Table . Differences in economic indicators of all participants.

	Control (n=2885)			Experimental (n=1658)				
	Mean	SD	95% CI	Mean	SD	95% CI	*F* test (*df*)	*P* value
Length of hospital stay	6.5	0.0	6.4 to 6.6	6.1	0.0	6.0 to 6.2	32.7 (1)	<.001
Pediatric pneumonia	6.3	0.0	6.2 to 6.4	6.1	0.0	6.0 to 6.2	10.2 (1)	.001
Pediatric pneumonia requiring intensive care	7.9	0.0	7.5 to 8.3	8.9	0.0	7.7 to 10.4	1.4 (1)	.24
Total hospitalization expenses	4153.9	0.2	4086.2 to 4225.9	3645.4	1.1	3588.8 to 3711.6	104.5 (1)	<.001
Pediatric pneumonia	3824.4	–0.3	3770.5 to 3884.0	3610.4	–0.7	3559.0 to 3663.5	28.9 (1)	<.001
Pediatric pneumonia requiring intensive care	7266.5	–3.0	6829.9 to 7748.0	9410.2	20.89	7578.5 to 11,828.3	4.5 (1)	.04
Proportion of drugs and consumables in expenses	0.1	0.0	0.1 to 0.1	0.1	0.0	0.1 to 0.1	0.5 (1)	.49
Pediatric pneumonia	0.1	0.0	0.1 to 0.1	0.1	0.0	0.1 to 0.1	4.0 (1)	.046
Pediatric pneumonia requiring intensive care	0.1	0.0	0.1 to 0.2	0.1	0.0	0.1 to 0.2	1.3 (1)	.25
Medical insurance settlement balance	–457.0	–0.4	–508.6 to –405.1	−321.7	−1.7	–377.0 to –272.0	11.8 (1)	<.001
Pediatric pneumonia	–533.7	–0.7	–581.7 to –485.4	193.6	1.0	–390.8 to –290.1	28.3 (1)	<.001
Pediatric pneumonia requiring intensive care	715.0	–5.0	381.6 to 1052.1	2704.7	12.4	135.8 to 5335.7	6.1 (1)	.01

Standardized Diagnosis and Treatment

Table 4 demonstrates that while the experimental group showed a modest reduction in mean antibiotic prescribing intensity (−0.1 DDD) compared to the control group, this system-wide effect was not statistically significant (*P*=.21). However, in the pediatric pneumonia subgroup that leveraged the clinical decision support features of the IDCCS, we observed a statistically and clinically meaningful reduction in antimicrobial exposure intensity (−0.2 DDD; *P*=.002), representing a 6.8% decrease compared to the control group.

XSL•FO
RenderX

Table . Differences in antibiotic use intensity among participants.

		Control (n=2588)			Experimental (n=1613)				
		Mean	SD	95% CI	Mean	SD	95% CI	*F* test (*df*)	*P* value
All participants		2.3	0.0002	2.3 to 2.4	2.3	−0.0006	2.2 to 2.4	1.6 (1)	.21
Discharge diagnosis		2.3	−0.0004	2.2 to 2.3	2.3	−0.0010	2.2 to 2.3	0.0 (1)	.97
	Pediatric pneumonia	2.3	0.0020	2.1 to 2.6	2.2	−0.0132	2.0 to 2.3	9.8 (1)	.002
	Pediatric pneumonia requiring intensive care	2.4	0.0010	2.3 to 2.5	2.3	0.0004	2.2 to 2.4	1.7 (1)	.19
Coinfection		2.1	0.0029	1.9 to 2.3	2.2	−0.0021	2.1 to 2.3	1.1 (1)	.30
	Without	2.3	0.0002	2.3 to 2.4	2.3	−0.0006	2.2 to 2.4	1.6 (1)	.21
	With	2.3	−0.0004	2.2 to 2.3	2.3	−0.0010	2.2 to 2.3	0.0 (1)	.97

Discussion

Principal Results

Our findings demonstrate that implementing the IDCCS CDSS significantly reduced treatment costs and improved standardized treatment in pediatric pneumonia management [14]. The digital intervention was associated with a reduction in the length of stay, a decrease in total hospitalization expenses, an increase in the medical insurance settlement balance, and a reduction in antibiotic prescribing volumes [15].

These results highlight the dual benefits of AI-driven decision support in enhancing value-based treatment while maintaining normative treatment quality.

However, within our study, in the pediatric pneumonia subgroup requiring intensive care, the aforementioned outcome metrics demonstrated no statistically significant improvement, suggesting that the current CP algorithms in the intelligent diagnosis assistance system require further optimization for use in critically ill patient populations.

Interpretation and Comparison With Prior Work

Extensive international research demonstrates that health information technology, characterized by accessibility, feasibility, and efficiency, significantly reduces antibiotic resistance rates, antimicrobial therapy mortality, and health care costs [16-19].

Christensen et al [20] put forward that CDSSs were designed according to the “Five Rights” principle: delivering the right information to the right recipient at the right time, through the right channel, in the right format. As a tool for auxiliary diagnosis, CDSS can improve the quality and efficiency of diagnosis. Düvel et al [21] demonstrated in a qualitative study that CDSS holds promise for optimizing antibiotic stewardship, while current systems lack AI technology integration.

Umoh et al [22] proposed the future development of CDSS in clinical treatment and management; a comprehensive tool that is precise and user-friendly would improve clinical decisions and efficiency.

Farkas et al [23] revealed that the use of CPs could reduce unnecessary diagnostic testing in hospitalized patients, which is consistent with the conclusion of our study. Jaafar et al [24] found that the implementation of DRG policy and CPs significantly enhanced health care resource utilization. However, evidence evaluating the effectiveness of CPs using real-world data remains limited in current literature. As noted by Bakel et al [25], most hospitals were unable to measure their pathway outcomes or demonstrate improvement in care.

In these prior studies, CDSS, CP, and DRG payment systems were mostly applied and evaluated separately, and the fragmented application greatly limited their synergy potential. Current literature lacks real-world data studies investigating the integration of CDSSs with CPs.

This study innovatively proposed a CDSS-CP-DRG closed-loop model enabled by digital health technologies, where CDSS optimized CP execution through real-time data, CPs standardized workflows to support DRG cost control, and DRG payment pressures drove iterative improvements in both technology and processes. Their integration promoted evidence-based practice, reduced clinical variation, and curbed overutilization, particularly in resource-sensitive pediatric settings.

Strengths and Limitations

DRG is a well-known type of hospital payment system that aims to establish the reference interval of medical expenses. It can effectively reduce costs, decrease the difficulty of standardized management of the medical diagnosis and treatment, and facilitate the macroprediction and control of medical expenses.

The ultimate goal of the DRG cost pathway is to achieve optimal medical value [26]. In this study, we integrated CDSS with CP systems using AI technology to develop the IDCCS, and the framework established a closed-loop quality and cost control process spanning preimplementation DRG-based deficit analysis and CP optimization, intraimplementation execution with real-time alerts, and postimplementation statistical analytics. This system ensures standardized diagnosis and treatment while managing and controlling health care costs for hospitalized patients through the establishment of defined insurance payment

XSL•FO
RenderX

quotas. As a result, hospitals are incentivized to reduce medical costs proactively, shorten hospital stays, and minimize unnecessary expenditures in pursuit of economic profitability. This approach facilitates cost control and promotes the rational and standardized use of medical resources [27]. Ultimately, it aims to achieve low-cost, high-quality, efficient, and health-oriented value-based treatment [28,29].

Conclusion

This study innovatively integrated a CDSS with CPs to optimize DRG-based case management. An AI-driven CDSS-CP framework was developed for pediatric pneumonia, demonstrating scalability for diverse clinical contexts. AI-optimized CPs enhanced cost-effectiveness (ie, reduced medical expenditures) and care standardization, further validating its role in health care system reform. The model contributed to evidence-based global health care practices and population health improvement. However, CPs for critical cases or other diseases require continuous optimization and adaptation to enhance health care resource utilization and standardize clinical practices.

Acknowledgments

Our heartfelt thanks to all the reviewers for reviewing the manuscript. This research was supported by the Scientific Research Program of Zhejiang Health Information Society (2024XHZN-Y01), Taizhou Science and Technology Plan Project (Category B, grant number 24ywb10), the Enze Medical Center (Group) Scientific Research Fund (grant number 2025EZAI09), and the Enze Hospital Management Research (Youth) Fund (grant number ENHM2020024). This article did not receive sponsorship.

Data Availability

All the data are accessible and available from the corresponding author upon request.

Authors' Contributions

All authors contributed to the design, execution, and writing of this manuscript and approved the submitted version. YW and KL designed the study, performed experiments, and wrote the manuscript. FZ and DW supervised the project, analyzed data, revised the manuscript, and coordinated revisions. XM participated in the research design, project support, and paper revision. YW and KL contributed equally to this work as co-first authors. FZ and DW contributed equally to this work as co-corresponding authors. Danjie Wu can be reached at wudj10039@enzemed.com and 17857149701. All authors approved the final version.

Conflicts of Interest

None declared.

References

1. Rudan I, Boschi-Pinto C, Biloglav Z, Mulholland K, Campbell H. Epidemiology and etiology of childhood pneumonia. Bull World Health Organ 2008 May;86(5):408-416. [doi: 10.2471/blt.07.048769] [Medline: 18545744]
2. Zhao S. The influence of DR examination on the diagnostic accuracy rate of children with bronchopneumonia [Article in Chinese]. Heilongjiang Journal of Traditional Chinese Medicine 2024;53(3):33-35 [FREE Full text]
3. Yao W, Zhang X, Xu F, Cao C, Liu T, Xue Y. The therapeutic effects of naringenin on bronchial pneumonia in children. Pharmacol Res Perspect 2021 Aug;9(4):e00825. [doi: 10.1002/prp2.825] [Medline: 34310866]
4. Pei D. Data mining and analysis of pediatric bronchopneumonia inpatients in a hospital in Northern China [Article in Chinese]. China Medical University 2019 [FREE Full text]
5. Huang A, Bu I, Mengting X. Evaluation research on nursing clinical decision support system [Article in Chinese]. Chinese Health Quality Management 2021;28(1):42-45 [FREE Full text]
6. Huang N, Zhou Y, Wang K, et al. Application of clinical decision support system on the management of gestational diabetes mellitus: a review [Article in Chinese]. Journal of Nurses Training 2021;36(17):1581-1585. [doi: 10.16821/j.cnki.hsjx.2021.17.009]
7. Xiaomin C, Yaqin D, Huiping Y. Building and application of a smart nursing interactive system. Chinese Journal of Hospital Administration 2018(6):493-496. [doi: 10.3760/cma.j.issn.1000-6672.2018.06.014]
8. Demczko MM, Ganetzky RD, Tormey C, et al. Improving acute care for primary mitochondrial disease: development of a publicly available clinical care pathway. Mol Genet Metab 2025 Apr;144(4):109058. [doi: 10.1016/j.ymgme.2025.109058] [Medline: 40020324]
9. National Health Commision of China. Diagnosis and treatment guidelines for mycoplasma pneumonia in children (2023 edition) [Article in Chinese]. Infectious Disease Information 2023;36(4):291-297 [FREE Full text]
10. Wang B. Antibiotic use in pneumonia treatment and management during the recovery period [Article in Chinese]. Health Must-Read 2024:34-35 [FREE Full text]
11. Liao L, Shen X, Zhu L. Study on the effect of rational drug use intervention in hospitals through the prescription pre-review system [Article in Chinese]. Chinese Journal of Clinical Rational Drug Use 2025(8):136-139 [FREE Full text]

XSL•FO
RenderX

12. Lena P, Karageorgos SA, Loutsiou P, et al. Multidrug-resistant bacteria on healthcare workers' uniforms in hospitals and long-term care facilities in Cyprus. Antibiotics (Basel) 2021 Dec 31;11(1):49. [doi: 10.3390/antibiotics11010049] [Medline: 35052926]
13. Notice on issuing the ethical review measures for human life sciences and medical research (state health and education development document no4 [2023])[EB/OL]. Chinese National Health Commission. URL: https://www.waizi.org.cn/doc/140518.html [accessed 2025-8-10]
14. Dhombres F, Maurice P, Guilbaud L, et al. A novel intelligent scan assistant system for early pregnancy diagnosis by ultrasound: clinical decision support system evaluation study. J Med Internet Res 2019 Jul 3;21(7):e14286. [doi: 10.2196/14286] [Medline: 31271152]
15. Jeanmougin P, Larramendy S, Fournier JP, Gaultier A, Rat C. Effect of a feedback visit and a clinical decision support system based on antibiotic prescription audit in primary care: multiarm cluster-randomized controlled trial. J Med Internet Res 2024 Dec 18;26:e60535. [doi: 10.2196/60535] [Medline: 39693139]
16. Baysari MT, Lehnbom EC, Li L, Hargreaves A, Day RO, Westbrook JI. The effectiveness of information technology to improve antimicrobial prescribing in hospitals: a systematic review and meta-analysis. Int J Med Inform 2016 Aug;92:15-34. [doi: 10.1016/j.ijmedinf.2016.04.008] [Medline: 27318068]
17. Gates PJ, Meyerson SA, Baysari MT, Westbrook JI. The prevalence of dose errors among paediatric patients in hospital wards with and without health information technology: a systematic review and meta-analysis. Drug Saf 2019 Jan;42(1):13-25. [doi: 10.1007/s40264-018-0715-6] [Medline: 30117051]
18. Jones BE, Collingridge DS, Vines CG, et al. CDS in a learning health care system: identifying physicians' reasons for rejection of best-practice recommendations in pneumonia through computerized clinical decision support. Appl Clin Inform 2019 Jan;10(1):1-9. [doi: 10.1055/s-0038-1676587] [Medline: 30602195]
19. Curtis CE, Al Bahar F, Marriott JF. The effectiveness of computerised decision support on antibiotic use in hospitals: a systematic review. PLoS One 2017;12(8):e0183062. [doi: 10.1371/journal.pone.0183062] [Medline: 28837665]
20. Christensen B, Rotegård AK. Clinical decision support: evaluating the development of a tool for nurses. Stud Health Technol Inform 2023 May 18;302:531-535. [doi: 10.3233/SHTI230199] [Medline: 37203742]
21. Düvel JA, Lampe D, Kirchner M, et al. An AI-based clinical decision support system for antibiotic therapy in sepsis (KINBIOTICS): use case analysis. JMIR Hum Factors 2025 Mar 4;12:e66699. [doi: 10.2196/66699] [Medline: 40036494]
22. Umoh I, Xia X, Winblad B, et al. Deciphering perspectives: a European survey on clinical decision support tools for dementia and Alzheimer's disease. Dement Geriatr Cogn Disord 2025 Feb 25;2025:1-10. [doi: 10.1159/000544801] [Medline: 39999809]
23. Farkas A, Turner T, Sherman K, Pavlic A. Implementation of a clinical pathway for the evaluation of asymptomatic hypertension in the emergency department. Am J Emerg Med 2024 Dec;86:37-40. [doi: 10.1016/j.ajem.2024.09.042] [Medline: 39321674]
24. Jaafar H, Berahim N, Said MA, et al. HSD124 application of diagnosis-related group (DRG) in measuring the impact of clinical pathway on resource utilization for patients suspected with acute coronary syndrome in the emergency department. Value Health 2024 Dec;27(12):S349. [doi: 10.1016/j.jval.2024.10.1807]
25. Bakel LA, Waynik IY, Starmer AJ, Berkwitt AK, Ziniel SI. Clinical pathways programs in children's hospitals. Pediatrics 2024 Dec 1;154(6):e2023065553. [doi: 10.1542/peds.2023-065553] [Medline: 39533867]
26. Yang L. A DRG pathway study on hospitalization costs of pediatric pneumonia based on the E-CHAID decision tree algorithm [Article in Chinese]. Army Medical University 2020 [FREE Full text]
27. Guo J. A study on the grouping of inpatients with digestive system diseases in a tertiary hospital in Dalian by using the method of Beijing BJ-DRGs [Article in Chinese]. Dalian Medical University 2017 [FREE Full text]
28. Huo Z, Dong Z, Fan J. Research on the diagnosis related groups of hospitalization expenses for patients undergoing cardiac surgery based on regression tree model [Article in Chinese]. Chinese Health Economics 2017(9):32-34 [FREE Full text]
29. Vogl M, Schildmann E, Leidl R, et al. Redefining diagnosis-related groups (DRGs) for palliative care - a cross-sectional study in two German centres. BMC Palliat Care 2018 Apr 5;17(1):58. [doi: 10.1186/s12904-018-0307-3] [Medline: 29622004]

Abbreviations

AI: artificial intelligence
CDSS: clinical decision support system
CP: clinical pathway
DDD: defined daily dose
DRG: diagnosis-related group
IDCCS: intelligent decision and cost control system

XSL•FO
RenderX

Edited by S Badawy; submitted 26.03.25; peer-reviewed by D Poddighe, SA Dezfouli; revised version received 12.09.25; accepted 20.09.25; published 15.10.25.

Please cite as:
Wu Y, Liu K, Mao X, Wu D, Zhu F
Evaluation of the Use of a Novel Intelligent Diagnosis and Cost Control System on Pediatric Bronchopneumonia Outcomes: Retrospective Cohort Study
JMIR Pediatr Parent 2025;8:e74964
URL: https://pediatrics.jmir.org/2025/1/e74964
doi:10.2196/74964

© Yanjun Wu, Kaijie Liu, Xinli Mao, Danjie Wu, Feng Zhu. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 15.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Hospitalization and Mortality in Brazilian Children and Adolescents Due to COVID-19: Retrospective Study

Ana Carolina Pereira de Godoy[1*], MD; Reinaldo Bulgarelli Bestetti[2*], Prof Dr Med

[1]Hospital da Criança e Materinade de Sao José do Rio Preto-Brazil, Rua Floriano Peixoto 2950, Sao José do Rio Preto, Brazil

[2]Faculdade de Medicina de Sao José do Rio Preto-Brazi, University of Ribeirão Preto, Sao José do Rio Preto, Brazil

[*]all authors contributed equally

Corresponding Author:
Ana Carolina Pereira de Godoy, MD
Hospital da Criança e Materinade de Sao José do Rio Preto-Brazil, Rua Floriano Peixoto 2950, Sao José do Rio Preto, Brazil

Abstract

Background: COVID-19 is currently one of the most important medical challenges as it affects the entire population, with children and adolescents being infected as easily as adults.

Objective: The objective of this study was to evaluate the prevalence of mortality in children and adolescents aged <19 years, compared to that of adults.

Methods: This retrospective, observational study analyzed the medical records of all patients diagnosed with COVID-19 by real-time reverse transcription–quantitative polymerase chain reaction who were hospitalized at Hospital de Base and the Infant and Maternal Hospital of São José do Rio Preto, São Paulo, Brazil. Out of a total of 8986 hospitalized patients who were COVID-19 positive, 383 (4.26%) were children and adolescents aged <19 years (group 1), and 8603 (95.74%) were adults (group 2).

Results: Overall, mortality was significantly higher (P<.001) in group 2 (2185/8603, 25.4%) compared to group 1 (12/383, 3.1%). A total of 11 (92%) of the 12 patients in group 1 that died had associated diseases. The mortality rates by age group were as follows: infants aged <1 year, 1.6% (2/123); children aged 1-4 years, 4% (4/95); children aged 5-9 years, 2% (1/47); adolescents aged 10-14 years, 2% (1/40); and adolescents aged 15-19 years, 5% (4/78).

Conclusions: Mortality from COVID-19 in children and adolescents was significantly lower than that in adults and was associated with other comorbidities.

(JMIR Pediatr Parent 2025;8:e67546) doi:10.2196/67546

KEYWORDS

COVID-19; children; mortality; Brazil; retrospective study; morbidity; hospitalization

Introduction

COVID-19 is currently one of the most important medical challenges as it affects the entire population, with children and adolescents being infected as easily as adults; children and adolescents often remain asymptomatic or have mild complaints due to their immature immune systems [1]. Advanced age and comorbidities such as hypertension, diabetes, ischemic heart disease, vascular disease, renal failure, obesity, dyspnea, and dementia have been reported to be associated with a greater risk of death among older people infected with COVID-19. Some studies have described pathophysiological insights into COVID-19–induced coagulopathy, endothelium disease, and angiogenesis-associated defects [2-4]. Most children and adolescents with COVID-19 have mild symptoms; however, coagulopathies have been associated with multisystem inflammatory syndrome—a postinfectious complication—in young patients [2].

A study in Sergipe, Brazil, describing COVID-19 cases and deaths in children and adolescents reported 37 deaths before September 20, 2020, corresponding to a rate of 4.87 deaths per 100,000 of the population aged <19 years. Most children and adolescents had comorbidities such as chronic neurological diseases (n=7, 19%) and prematurity (n=4, 11%). Furthermore, most children and adolescents who died (n=18, 49%) were not admitted to intensive care units. This was possibly related to the great regional inequalities in health care [5].

A study in England reported that 4% (1408/35,200) of tests performed in children and adolescents aged <16 years were positive for SARS-CoV-2, compared to 19.1% to 34.9% in adults [3]. A review of pregnant women with COVID-19 reported that SARS-CoV-2 was detected in 4.3% (19/444) of newborns at birth. Elevated levels of immunoglobulin M and G serum antibodies were reported in one case, but the swab test was negative [4]. Mortality in children is higher in those with existing diseases compared to those without comorbidities [6].

XSL•FO
RenderX

Regarding the prognosis, metabolic acidosis, hyperlactatemia, hyperglycemia, altered liver function parameters, and hypoproteinemia are biochemical markers associated with the severity of the disease in children infected with SARS-CoV-2. Anemia and ketoacidosis are important risk factors for death in the pediatric patient population who are infected [7]. Gastrointestinal involvement is common in children hospitalized for acute COVID-19 infection and multisystem inflammatory syndrome, but gastrointestinal involvement is not associated with critical illness, length of hospital stay, or mortality in acute cases of COVID-19 [8].

In a study of pediatric COVID-19 epidemiology, Sousa et al [9] highlighted the presence of comorbidities in patients aged <2 years, in particular those related to congenital heart disease, Down syndrome, obesity, and asthma. Furthermore, these authors reported differences in morbidity and mortality due to regional disparities, with higher rates in regions with less resources, as is the case in the economically less favored northern and northeastern regions of Brazil. In their analysis of 2020 deaths of children that occurred throughout Brazil, 42% occurred in children aged <2 years and 43% occurred in adolescents aged 10 - 19 years, with children aged 2 - 10 years being relatively protected. A total of 58% of deceased patients had at least one comorbidity. It is noteworthy that 69% of deaths were observed in Black or multiracial patients, 25.5% in White patients, and 5% in Indigenous patients, with approximately 60% occurring in the northern and northeastern regions of Brazil.

It is also worth remembering the prolonged symptoms that are associated with COVID-19—notably, fatigue, headaches, drowsiness, and difficulty concentrating—as well as the impact of social isolation, which can cause psychosocial disorders and learning gaps that can have a major impact on children's education [10,11].

An American study reports that pediatric patients with a recent relapse of cancer have a higher chance of all-cause mortality when infected with COVID-19 [12].

The objectives of this study were to evaluate the mortality of children and adolescents and compare it with that of adults in a cohort of 8986 patients hospitalized for COVID-19 in a university hospital complex in Brazil.

Methods

Patients and Setting

A retrospective, observational study was performed to analyze the medical records of all patients diagnosed with COVID-19 who were hospitalized at Hospital de Base and the Infant and Maternal Hospital of São José do Rio Preto, São Paulo, Brazil, from March 2020 to July 2023.

All patients diagnosed with COVID-19 by reverse transcription–quantitative polymerase chain reaction and admitted to these hospitals were included in this study. Patients hospitalized for other illnesses and those who tested negative for COVID-19 during this period were excluded.

Patients aged <19 years were categorized as children or adolescents (group 1), and those aged ≥19 years were categorized as adults (group 2). Group 1 was further subdivided by age: <1 year, 1 - 4 years, 5 - 9 years, 10 - 14 years, and 15 - 19 years. The monthly occurrence of COVID-19 was evaluated, with mortality in children and adolescents being compared to that in adults. Existing diseases and the occurrence of other viral infections were identified over the same period in patients aged <19 years who were COVID-19 positive.

Ethical Considerations

The study was approved by the ethics committee of the Medical School in São José do Rio Preto under approval 6.086.468 (CAAE 67915723.3.0000.5415; date approved: May 29, 2023).

For this study, the institution permitted the analysis of these records, guaranteeing the use of data only in this research protocol. Absolute confidentiality was maintained during the data collection and use thereof. Safeguards were taken to collect data from medical records in the institution's own archives department; patient charts were not removed for any reason.

The signed consent form was authorized by the ethics committee to be waived, because these were medical records and due to the impossibility of contacting family members and those who have died. Thus, the authors guaranteed the privacy and confidentiality of the data obtained, fully preserving the anonymity of the participants in accordance with the Declaration of Helsinki.

Statistical Analysis

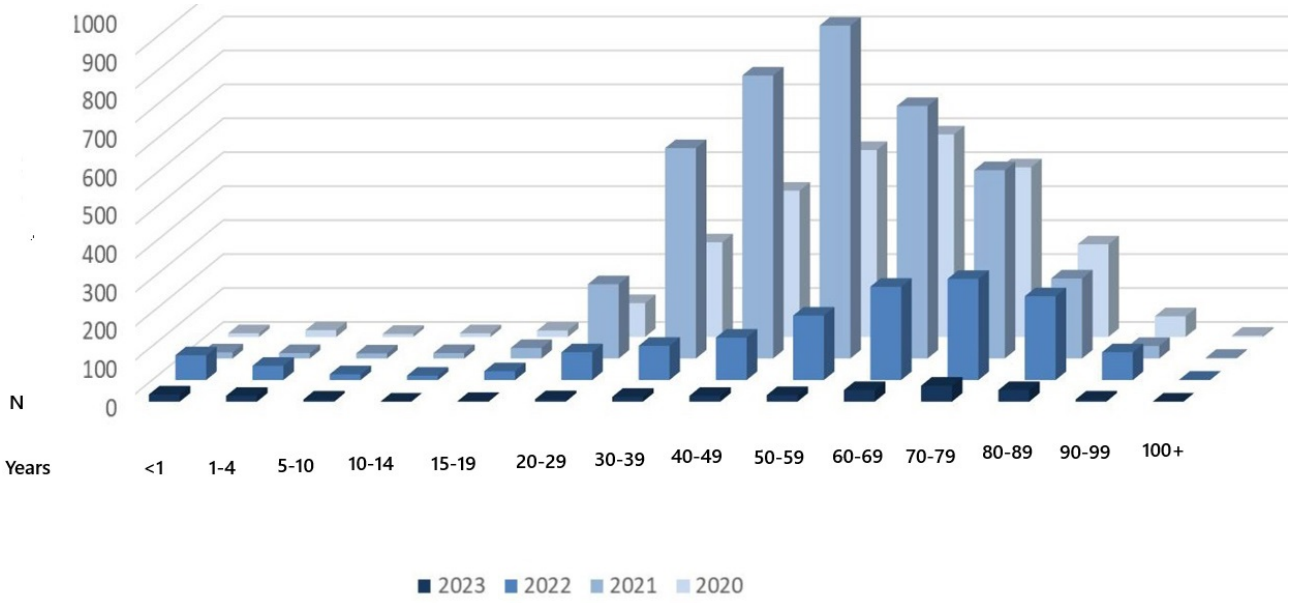
Data were tabulated in Microsoft Excel spreadsheets, with statistical analysis conducted using StatsDirect 3 software (StatsDirect Ltd). Descriptive statistics, Fisher exact test, chi-square test, and odds ratio were used considering an α error of 5% ($P \leq .05$).

Results

Between March 2020 and July 2023, a total of 8986 patients who were COVID-19 positive were hospitalized, 383 (4.26%) of whom were aged <19 years and 8986 (95.74%) were aged ≥19 years (mean age 57.66 y; Figure 1). Overall, 12 children and adolescents died, that is, 3.1% of the 383 patients in this age group. The number of deaths in group 2 (adults) was 2185, that is, equivalent to 25.4% of the 8603 hospitalized adults and 99.45% (2185/2197) of overall deaths. Mortality was significantly higher for adults than children and adolescents aged <19 years (Yates-corrected χ^2 test=98.127501, $P<.001$; odds ratio 10.317, 95% CI 5.793 - 18.374).

XSL•FO
RenderX

Figure 1. Patients hospitalized with COVID-19 by age group and year.



Regarding the different age groups of children and adolescents, the mortality rates were as follows: infants aged <1 years, 1.6% (2/123); children aged 1-4 years, 4% (4/95); children aged 5-9 years, 2% (1/47); adolescents aged 10-14 years, 2% (1/40); and adolescents aged 15-19 years, 5% (4/78). There were no statistical differences between the different age groups (Fisher exact test: *P*=.30; Table 1 and Figure 2). Figure 3 shows the main viral infections of the patients who were COVID-19 positive in the 2 hospitals, emphasizing the importance of this disease. Table 2 shows the associated diseases of the 12 children who died from COVID-19.

Table . Hospitalizations and deaths for different age groups from March 2020 to July 2023.

Age group (years)	2020		2021		2022		2023		Total	
	Hospitalizations, n	Deaths, n	Hospitalizations, n	Deaths, n	Hospitalizations, n	Deaths, n	Hospitalizations, n	Deaths, n	Hospitalizations, n	Deaths, n
<1	11	0	18	1	73	1	21	0	123	2
1 - 4	20	1	16	1	42	2	17	0	95	4
5 - 9	9	0	15	1	17	0	6	0	47	1
10 - 14	11	1	16	0	13	0	0	0	40	1
15 - 19	19	2	31	0	26	2	2	0	78	4
20 - 29	100	8	219	20	82	4	7	1	408	33
30 - 39	279	13	620	76	101	8	14	2	1014	99
40 - 49	431	27	834	125	125	11	17	3	1407	166
50 - 59	551	85	981	241	190	23	19	3	1741	352
60 - 69	597	147	744	287	275	71	34	11	1650	516
70 - 79	500	187	555	257	298	90	47	11	1400	545
80 - 89	273	141	236	136	247	94	34	6	790	377
90 - 99	61	43	37	22	82	28	6	0	186	93
>100	4	3	2	1	1	0	0	0	7	4
Total	2866	658	4324	1168	1572	334	224	37	8986	2197

XSL•FO
RenderX

Figure 2. Hospitalizations and deaths of children and adolescents who were COVID-19 positive.

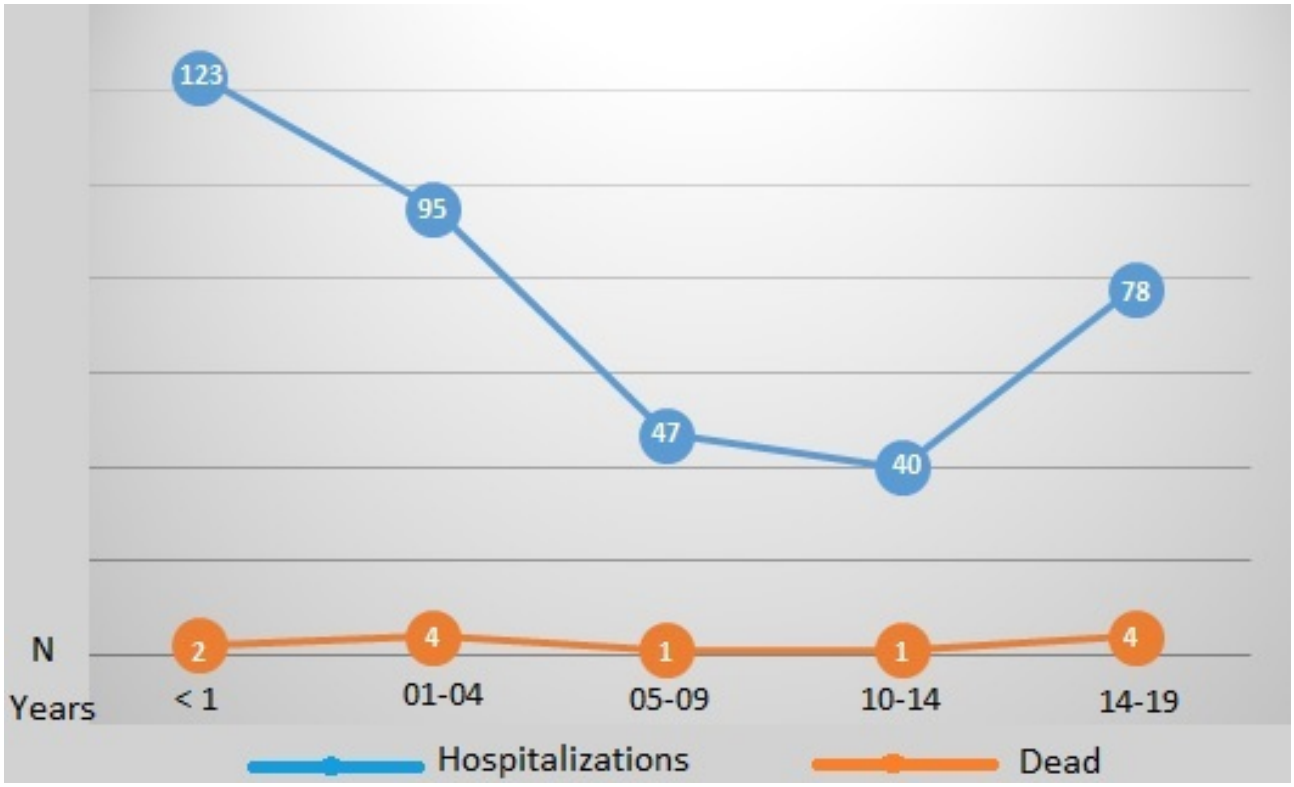
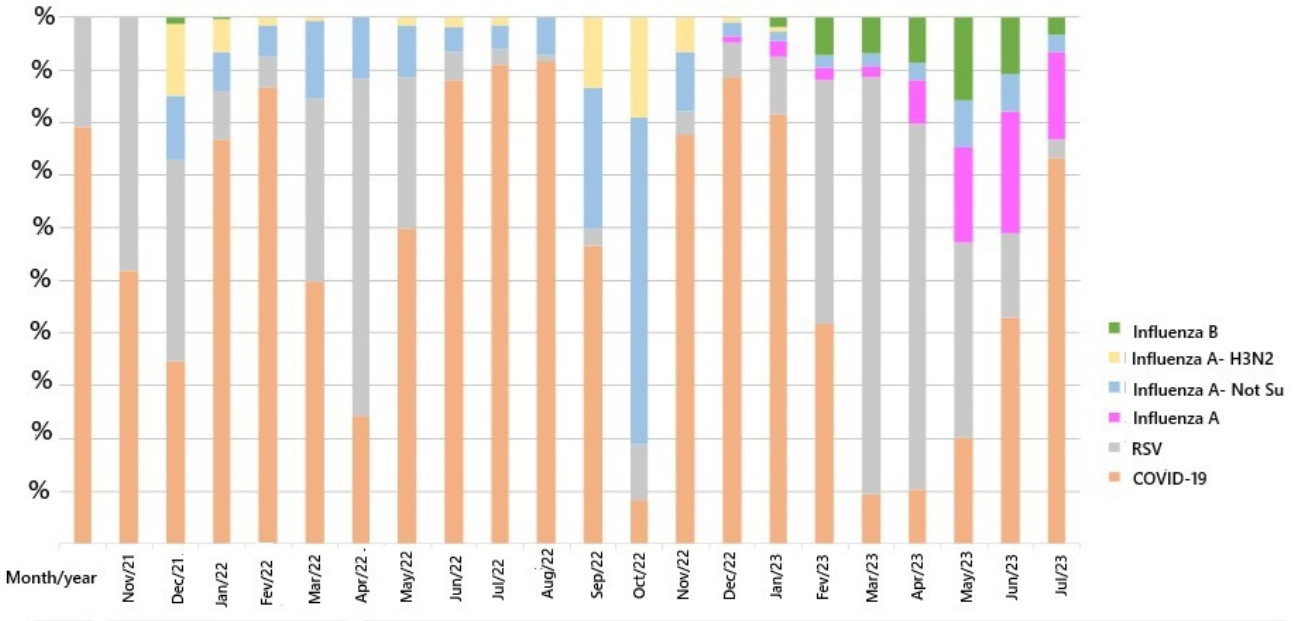


Figure 3. Percentage of hospitalized cases for COVID-19, influenza, and respiratory syncytial virus (RSV) at the hospital complex in São José do Rio Preto, according to month and etiological agent from October 1, 2021, to July 24, 2023.



XSL•FO
RenderX

Table . Chief comorbidities associated with COVID-19 that led to the deaths of children and adolescents.

Age (y)	Sex	Comorbidity	Infection	Antibiotics	Image	Vasoactive drugs	Mechanical ventilation	Intensive care unit	Dialysis support	Time in hospital (mo)
19	Female	Hodgkin lymphoma	Yes	Yes	CT[a] 25% compromised (ground-glass opacity)	Yes	Yes	Yes	Yes	45
14	Female	Down syndrome	Yes	Yes	CT 70%	Yes	Yes	Yes	Yes	12
2	Male	Down syndrome and heart disease	Yes	Yes	Rx[b]	Yes	Yes	Yes	Yes	5
19	Female	Down syndrome, schizophrenia, asthma, and corrected heart disease	Yes	Yes	CT 50% compromised	Yes	Yes	Yes	Yes	5
0	Male	None	Yes	Yes	Rx infiltrated	Yes	Yes	Yes	Yes	5
2	Male	Encephalopathy	Yes	Yes	Rx	Yes	Yes	Yes	Yes	24
5	Male	Renal transplant	Yes	Yes	CT >50% infiltrated (ground-glass opacity)	Yes	Yes	Yes	No	20
3	Male	Congenital heart disease	Yes	Yes	Rx	Yes	Yes	Yes	No	3
16	Female	Tumor in the central nervous system	Yes	Yes	CT >50% infiltrated (ground-glass opacity)	Yes	Yes	Yes	Yes	10
17	Female	Lupus	Yes	Yes	CT <25%	Yes	Yes	Yes	No	55
3	Female	Hydranencephaly	Yes	Yes	Rx	No	Yes	Yes	Yes	1
1	Female	Congenital heart disease	No	No	Rx	Yes	Yes	No	No	1

[a]CT: computed tomography.

[b]Rx: x-ray.

Discussion

Principal Findings

This study reports on the general mortality of children and adolescents aged <19 years and adult patients in a single university hospital complex from March 2020 to July 2023. Of the 8986 patients hospitalized with COVID-19, a total of 383 (4.26%) were children and adolescents treated at the children's hospital. Deaths in this age group represented 0.55% (12/2197) of all deaths from COVID-19 in the institution and 3.1% (12/383) of all hospitalized patients aged <19 years. No significant difference was detected in mortality between the age groups of children and adolescents. A multicenter study in Latin America reported a mortality rate of 14% in 210 children, with

XSL•FO
RenderX

67% of those who died being treated in an intensive care unit [13].

Observational studies in the pediatric population have shown that the presence of comorbidities is a risk factor for severe disease. Obesity, genetic disorders (such as sickle cell anemia), neurological disorders, hematological diseases, congenital heart diseases, diabetes, chronic kidney disease, asthma, and other lung diseases are pathologies that have already been associated with the severity of COVID-19 in previous studies [14]. In this study, heart disease was the main disorder reported in the children and adolescents who died.

Regarding the age of the children and adolescents, there is no consensus on which age group has the highest or lowest severity of disease, included mortality; however, severity does seem to be linked to the presence of preexisting clinical factors. A review study reported that younger children and those with specific comorbidities, such as obesity, diabetes, heart diseases, chronic lung diseases, epilepsy, and immunocompromised conditions, are at higher risk of infection and potentially more severe consequences of COVID-19 [15,16].

One interesting Brazilian study that analyzed a large nationwide database of hospitalized children and adolescents with laboratory-confirmed COVID-19 showed that death was associated with being aged younger than 2 years or between 12 and 19 years. Indigenous ethnicity, living in the poorest microregions, and the presence of comorbidities were also correlated with the severity of the disease. Therefore, health care disparities and social inequalities, exacerbated by interweaving comorbidities, might have contributed synergistically to magnifying the COVID-19 burden for more socioeconomically deprived and vulnerable individuals [17]. Due to uncertainties in epidemiological data on children, there is still much to learn about the manifestations of COVID-19 in this population.

In this study, no significant differences with respect to mortality were detected between age groups of the children and adolescents; however, the number of patients is too small to arrive at any definite conclusion.

In North America, mortality was higher in children younger than 1 year, followed by adolescents aged between 15 and 19 years [18]. In 2021 and 2022, a study in Java, Indonesia, analyzed 6441 patients aged ≤18 years who were positive for COVID-19 and reported that 2.7% of deaths occurred with other associated factors; in this study, the rate was 91.67%—a difference that may be related to the different conditions (socioeconomic factors and access to health care) in the 2 countries [19].

Regarding mortality, since the beginning of the pandemic, newborns, children, and adolescents are less prone to this emerging condition compared to adults. Most of them experience mild symptoms; hospitalization and death of pediatric patients are rare, with deaths usually being explained by associated complications [20].

In Ecuador, a study on mortality from 2020 to 2021 reported that out of 34,001 confirmed cases of COVID-19, a total of 258 were children and adolescents aged between 0 and 19 years and that 127 died due to COVID-19. In the same period, the study found that most deaths occurred in children aged 0 to 1 year, representing 44% (n=114) of the total deaths reported [21].

In Brazil, in 2020, a total of 14,638 children were diagnosed with SARS, resulting in 1180 (8.06%) deaths. Being younger than 2 years was a risk factor for higher hospitalization and mortality rates [22]. In 2021, an increase in the number of cases of pediatric patients was noted; according to data from the Brazilian Ministry of Health, there were 17,644 occurrences of SARS-CoV-2 with 1263 (7.15%) deaths. This rise is related to greater knowledge of the disease, a simpler diagnosis, the larger quantity of diagnostic tests performed, and the emergence of new variants (Delta and Omicron) [9].

Pediatric patients with comorbidities are at higher risk for hospitalization and mortality. Among the reported comorbidities, the following should be highlighted: Down syndrome, asthma, obesity, immunosuppression, and heart disease. Morbidity and mortality due to COVID-19 are not similar to other etiologies of acute respiratory distress syndrome. This is because fulminant activation of coagulation cascades can occur in COVID-19, resulting in widespread microvascular thrombosis and the consumption of clotting factors [9,22-25]. It appears that inflamed lung tissues and pulmonary endothelial cell damage may result in the formation of microthrombi that contribute to the high incidence of thrombotic complications, such as deep vein thrombosis, pulmonary embolism, and arterial thrombotic complications.

Another important factor that must be highlighted is the possibility of long-term symptoms such as fatigue, headaches, drowsiness, and difficulty concentrating, all of which have implications in social and educational spheres, leading to important concerns regarding the impact of the pandemic on future education levels.

Another point to be considered is related to the risk of the long-term effects of COVID-19 on the health of the general population. Post–COVID-19 coronary changes and the presence of multisystem inflammatory syndrome were identified in some pediatric patients. Therefore, although children and adolescents represent a low percentage of COVID-19 cases in Latin America and worldwide, major social, economic, and cultural implications are linked to the disease in this population. In truth, COVID-19 has disrupted all spheres of life, including country risk factors, such as exposure to multidimensional risk drivers.

Socioeconomic and political factors significantly influence health care conditions and directly impact the response to pandemics, including the allocation of resources for immediate health care needs. Studies analyzing the influence of demographic, economic, and political conditions in different countries and continents show a significant difference between countries with a low Human Development Index and those with a high Human Development Index. This has influenced, and continues to directly influence, human health care [26,27].

It should be remembered that the dynamics of infections and deaths related to COVID-19 differ from country to country and are constantly changing throughout Latin America. Management requires political leadership, financial resources, and social

XSL•FO
RenderX

equality, as well as the existence of informal and regional economies directed toward disadvantaged populations that traditionally have had limited access to health services. In this study, COVID-19 was the most common viral infection identified in this period. Mortality from COVID-19 in children and adolescents was lower than that in adults and was generally associated with existing diseases, with the main one being heart disease.

This study shows results consistent with our hypothesis and with the results of studies published in MEDLINE. Thus, predicting the outcome of COVID-19 is of vital clinical importance to better allocate medical resources and provide individualized treatment for patients. The availability of clinical characteristics and parameters with potential prognostic implications will be of value for effective prevention and intervention.

Conclusion

Mortality from COVID-19 in children and adolescents was lower than that in adults. A second interesting finding was that these deaths were generally associated with existing diseases.

Data Availability

All data generated and analyzed during this study have been included within the paper.

Authors' Contributions

ACPdG and RBB contributed to the concept and design, acquisition of data, analysis and interpretation of data, drafting of the paper, and revising it critically for important intellectual content. ACPdG and RBB provided final approval of the version to be published.

Conflicts of Interest

None declared.

References

1. Frenkel LD, Gomez F, Bellanti JA. COVID-19 in children: pathogenesis and current status. Allergy Asthma Proc 2021 Jan 3;42(1):8-15. [doi: 10.2500/aap.2021.42.200104] [Medline: 33404385]
2. Kumar R, Aktay-Cetin Ö, Craddock V, et al. Potential long-term effects of SARS-CoV-2 infection on the pulmonary vasculature: multilayered cross-talks in the setting of coinfections and comorbidities. PLoS Pathog 2023 Jan 12;19(1):e1011063. [doi: 10.1371/journal.ppat.1011063] [Medline: 36634048]
3. Smadja DM, Mentzer SJ, Fontenay M, et al. COVID-19 is a systemic vascular hemopathy: insight for mechanistic and clinical aspects. Angiogenesis 2021 Nov;24(4):755-788. [doi: 10.1007/s10456-021-09805-6] [Medline: 34184164]
4. Connors JM, Levy JH. COVID-19 and its implications for thrombosis and anticoagulation. Blood 2020 Jun 4;135(23):2033-2040. [doi: 10.1182/blood.2020006000] [Medline: 32339221]
5. de Siqueira Alves Lopes A, Fontes Vieira SC, Lima Santos Porto R, et al. Coronavirus disease-19 deaths among children and adolescents in an area of Northeast, Brazil: why so many? Trop Med Int Health 2021 Jan;26(1):115-119. [doi: 10.1111/tmi.13529] [Medline: 33217116]
6. Tsankov BK, Allaire JM, Irvine MA, et al. Severe COVID-19 infection and pediatric comorbidities: a systematic review and meta-analysis. Int J Infect Dis 2021 Feb;103:246-256. [doi: 10.1016/j.ijid.2020.11.163] [Medline: 33227520]
7. Belu A, Trandafir LM, arcă E, et al. Variations in biochemical values under stress in children with SARS-CoV-2 infection. Diagnostics (Basel) 2022 May 12;12(5):1213. [doi: 10.3390/diagnostics12051213] [Medline: 35626368]
8. Sayed IA, Bhalala U, Strom L, et al. Gastrointestinal manifestations in hospitalized children with acute SARS-CoV-2 infection and multisystem inflammatory condition: an analysis of the VIRUS COVID-19 Registry. Pediatr Infect Dis J 2022 Sep 1;41(9):751-758. [doi: 10.1097/INF.0000000000003589] [Medline: 35622434]
9. Sousa BLA, Silva CA, Ferraro AA. An update on the epidemiology of pediatric COVID-19 in Brazil. Rev Paul Pediatr 2022 Apr 4;40:e2021367. [doi: 10.1590/1984-0462/2022/40/2021367] [Medline: 35442272]
10. Luo X, Lv M, Zhang X, et al. Clinical manifestations of COVID-19: an overview of 102 systematic reviews with evidence mapping. J Evid Based Med 2022 Sep;15(3):201-215. [doi: 10.1111/jebm.12483] [Medline: 35909298]
11. Souza I, Scodro R, Dias Siqueira VL, Fressatti Cardoso R, Caleffi-Ferracioli KR. Comorbidities and deaths by COVID-19 In Brazil. Revista Uningá 2021;58:eUJ4054 [FREE Full text]
12. Quast T, Andel R, Gregory S, Storch EA. Years of life lost associated with COVID-19 deaths in the USA during the first 2 years of the pandemic. J Public Health (Oxf) 2022 Aug 25;44(3):e353-e358. [doi: 10.1093/pubmed/fdac057] [Medline: 35640260]
13. Dominguez-Rojas J, Vásquez-Hoyos P, Pérez-Morales R, et al. Association of cancer diagnosis and therapeutic stage with mortality in pediatric patients with COVID-19, prospective multicenter cohort study from Latin America. Front Pediatr 2022 May 3;10:885633. [doi: 10.3389/fped.2022.885633] [Medline: 35592840]

XSL•FO
RenderX

14. Pathak EB, Salemi JL, Sobers N, Menard J, Hambleton IR. COVID-19 in children in the United States: intensive care admissions, estimated total infected, and projected numbers of severe pediatric cases in 2020. J Public Health Manag Pract 2020;26(4):325-333. [doi: 10.1097/PHH.0000000000001190] [Medline: 32282440]
15. Choi JH, Choi SH, Yun KW. Risk factors for severe COVID-19 in children: a systematic review and meta-analysis. J Korean Med Sci 2022 Feb 7;37(5):e35. [doi: 10.3346/jkms.2022.37.e35] [Medline: 35132841]
16. Siebach MK, Piedimonte G, Ley SH. COVID-19 in childhood: transmission, clinical presentation, complications and risk factors. Pediatr Pulmonol 2021 Jun;56(6):1342-1356. [doi: 10.1002/ppul.25344] [Medline: 33721405]
17. Oliveira EA, Colosimo EA, Simões E Silva AC, et al. Clinical characteristics and risk factors for death among hospitalised children and adolescents with COVID-19 in Brazil: an analysis of a nationwide database. Lancet Child Adolesc Health 2021 Aug;5(8):559-568. [doi: 10.1016/S2352-4642(21)00134-6] [Medline: 34119027]
18. Flaxman S, Whittaker C, Semenova E, et al. Assessment of COVID-19 as the underlying cause of death among children and young people aged 0 to 19 years in the US. JAMA Netw Open 2023 Jan 3;6(1):e2253590. [doi: 10.1001/jamanetworkopen.2022.53590] [Medline: 36716029]
19. Efendi F, Haryanto J, Has EMM, et al. Predictors of mortality among children with confirmed and suspected cases of COVID-19 in East Java, Indonesia. J Multidiscip Healthc 2023 Feb 7;16:355-362. [doi: 10.2147/JMDH.S391917] [Medline: 36785579]
20. Castagnoli R, Votto M, Licari A, et al. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in children and adolescents: a systematic review. JAMA Pediatr 2020 Sep 1;174(9):882-889. [doi: 10.1001/jamapediatrics.2020.1467] [Medline: 32320004]
21. Ortiz-Prado E, Izquierdo-Condoy JS, Fernandez-Naranjo R, et al. The deadly impact of COVID-19 among children from Latin America: the case of Ecuador. Front Pediatr 2023 Apr 21;11:1060311. [doi: 10.3389/fped.2023.1060311] [Medline: 37152328]
22. Ministério da Saúde (Brazil). SRAG 2020 - banco de dados de síndrome respiratória aguda grave - incluindo dados da COVID-19. Open Data SUS. 2020. URL: https://opendatasus.saude.gov.br/dataset/srag-2020 [accessed 2021-10-19]
23. Mucalo L, Brandow AM, Dasgupta M, et al. Comorbidities are risk factors for hospitalization and serious COVID-19 illness in children and adults with sickle cell disease. Blood Adv 2021 Jul 13;5(13):2717-2724. [doi: 10.1182/bloodadvances.2021004288] [Medline: 34196678]
24. Trapani S, Rubino C, Lasagni D, et al. Thromboembolic complications in children with COVID-19 and MIS-C: a narrative review. Front Pediatr 2022 Aug 11;10:944743. [doi: 10.3389/fped.2022.944743] [Medline: 36034557]
25. Conway EM, Mackman N, Warren RQ, et al. Understanding COVID-19-associated coagulopathy. Nat Rev Immunol 2022 Oct;22(10):639-649. [doi: 10.1038/s41577-022-00762-9] [Medline: 35931818]
26. Renzaho AMN. The need for the right socio-economic and cultural fit in the COVID-19 response in sub-Saharan Africa: examining demographic, economic political, health, and socio-cultural differentials in COVID-19 morbidity and mortality. Int J Environ Res Public Health 2020 May 15;17(10):3445. [doi: 10.3390/ijerph17103445] [Medline: 32429123]
27. Heo MH, Kwon YD, Cheon J, Kim KB, Noh JW. Association between the Human Development Index and confirmed COVID-19 cases by country. Healthcare (Basel) 2022 Jul 29;10(8):1417. [doi: 10.3390/healthcare10081417] [Medline: 36011075]

Edited by S Badawy; submitted 14.10.24; peer-reviewed by MM Kostik, SW Lee; revised version received 14.01.25; accepted 15.01.25; published 20.05.25.

Please cite as:
Pereira de Godoy AC, Bulgarelli Bestetti R
Hospitalization and Mortality in Brazilian Children and Adolescents Due to COVID-19: Retrospective Study
JMIR Pediatr Parent 2025;8:e67546
URL: https://pediatrics.jmir.org/2025/1/e67546
doi:10.2196/67546

© Ana Carolina Pereira de Godoy, Reinaldo Bulgarelli Bestetti. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 20.5.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Exploring Stress and Stress-Reduction With Caregivers and Clinicians in the Neonatal Intensive Care Unit to Inform Intervention Development: Qualitative Interview Study

Kristin Harrison Ginsberg[1], MSW; Jane Alsweiler[2], PhD; Jenny Rogers[3], RN; Phoebe Ross[4], PhD; Anna Serlachius[1], PhD

[1]Department of Psychological Medicine, Faculty of Medical and Health Sciences, University of Auckland, Private Bag 92019, Auckland, New Zealand

[2]Department of Paediatrics: Child and Youth Health, Faculty of Medical and Health Sciences, University of Auckland, Auckland, New Zealand

[3]Liggins Institute, University of Auckland, Auckland, New Zealand

[4]Department of Medicine, Faculty of Medical and Health Sciences, University of Auckland, Auckland, New Zealand

Corresponding Author:
Kristin Harrison Ginsberg, MSW
Department of Psychological Medicine, Faculty of Medical and Health Sciences, University of Auckland, Private Bag 92019, Auckland, New Zealand

Abstract

Background: Parents and caregivers with preterm babies in the neonatal intensive care unit (NICU) experience high levels of distress and are at an increased risk of anxiety, depression, and acute stress disorders. Effective interventions to reduce this distress are well described in the literature, but this research has been conducted primarily in Europe and North America. To our knowledge, few interventions of this sort have been developed in Australasia, and none have been developed or tested in Aotearoa New Zealand.

Objective: The primary aims of this study were to explore sources of stress with caregivers and clinicians in a NICU in Aotearoa New Zealand and gather participant ideas on ways to reduce caregiver stress to inform intervention development.

Methods: This qualitative design used an essentialist and realist methodology to generate findings aimed at future intervention development. Overall, 10 NICU clinicians (neonatologists, nurses, and mental health clinicians) and 13 caregivers (mothers, fathers, and extended family members) of preterm babies, either currently admitted or discharged from the NICU within the last 12 months, were recruited to participate in interviews exploring stress and stress-reduction in the NICU.

Results: The 23 participants included 10 clinicians (all female, with an average of 15 years of experience in the NICU) and 13 parents and caregivers (majority of them were female; 10/13, 77%) of preterm babies. We identified 6 themes relevant to intervention development. Three themes focused on caregiver stress: the emotional "rollercoaster" of NICU; lack of support, both culturally and emotionally; and caregivers feeling "left out" and confused. Three themes focused on participant-proposed solutions to reduce stress: caregiver empowerment, improving emotional support, and communication on "my" terms (ie, digitally).

Conclusions: Participants reported high levels of caregiver stress in the NICU, and they proposed a range of stress-reducing solutions, including increasing caregiver empowerment and improving emotional and cultural support. Clinicians and caregivers also strongly agreed on providing more information for caregivers in digital, mobile-friendly formats.

(JMIR Pediatr Parent 2025;8:e66401) doi:10.2196/66401

KEYWORDS

neonatal intensive care unit; NICU; parents; preterm infants; stress; stress reduction; intervention development; digital; neonatology; pediatric; infants; babies; neonatal; toddler; children; caregiver; telemedicine; telehealth; virtual care; virtual health; virtual medicine; remote consultation; qualitative study

Introduction

Parents with babies in the neonatal intensive care unit (NICU) have described the NICU experience as "terrifying" and "traumatic" [1], and they frequently experience high rates of stress, anxiety, depression, and acute stress disorders [2,3]. These effects can last well after discharge, with long-term negative effects including problems with parent-child bonding and attachment [4].

The most common cause of admission to the NICU is preterm birth (born at less than 37 weeks gestational age). Preterm birth affects an estimated 1 in 10 births annually around the world and is the leading cause of death for children under 5 years of age [5]. In Aotearoa New Zealand, a diverse, bicultural country,

XSL•FO
RenderX

preterm birth is estimated to occur in 8.9% of annual births [6]. New Zealand Europeans experience fewer preterm births, perinatal deaths, and maternal deaths than Māori, the Indigenous people of Aotearoa New Zealand who make up 17.3% of the population [7]. They also experience fewer adverse perinatal outcomes than Pacific Peoples and Indian minority groups in Aotearoa New Zealand [8]. Additionally, New Zealand European babies are less likely to be admitted to NICU than these 3 groups [9].

Effective interventions to reduce the distress of parents with babies in the NICU are well described in the literature, but this research has been conducted primarily in Europe and North America, and mostly with Caucasian mothers [10,11]. To our knowledge, few interventions of this sort have been developed in Australasia, and none have been developed or tested in Aotearoa New Zealand. As a recent study of services showed, psychosocial support for caregivers in the NICUs in Aotearoa New Zealand is highly limited, with no formalized support programs, limited cultural support services, and fewer staff members available to provide support to parents with babies in the NICU [12]. Given the limited resources available to support this highly distressed population, clinically feasible and culturally appropriate interventions for use in the NICU should be developed for the Aotearoa New Zealand context.

A few qualitative studies have explored the experiences of families in Aotearoa New Zealand NICUs [13,14], including for Māori whānau (families) [15]. However, no intervention research focused on reducing distress has been conducted with caregivers in the NICUs of Aotearoa New Zealand.

Therefore, the main objectives of this study were to gather feedback from caregivers and clinicians in the NICU on sources of caregiver stress and ways to reduce that stress to inform future intervention development.

Methods

Study Design

We conducted a qualitative study using semistructured interviews with caregivers and clinicians from September 2022 to April 2023 in a level 3 NICU in Auckland, Aotearoa New Zealand. We analyzed the data using thematic analysis (framework method).

Ethical Considerations

The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist was followed to report the qualitative study findings. The Auckland Health Research Committee provided ethical consent (#AH24458). Informed written consent was provided by participants in advance of their participation in this study. Individuals were provided with a NZ $50 (US $28) gift voucher to a local store as thanks for their participation. To ensure confidentiality, all identifying details were removed from the data, and participant transcripts were issued numeric codes.

Setting

This study was conducted at Te Toka Tumai Auckland Starship Child Health NICU, a level 3 NICU and one of Aotearoa New Zealand's largest NICUs. Most rooms are shared, with 40 cots in the unit and an average of 900 infant admissions per year. The unit is a regional specialty center with a diverse patient population. In 2023, 29% of babies in the unit were New Zealand European, 19% were Other Asian, 17% were Indian, 17% were Pacific Peoples, and 16% were Māori. Common causes of admission were preterm birth (42%), respiratory distress (25%), and congenital abnormalities (14%) [16].

All participants in our study had admissions in the NICU during the COVID-19 pandemic. COVID-19–related visitor restrictions in the unit varied during this study's time period, with parents recruited earlier in the study experiencing more restrictive conditions than those recruited later in the study. NICU visitor restrictions included limiting visitors in the NICU to one parent at a time, not allowing extended family visitors without special permission, and requiring all visitors to wear facial masks in the unit.

Participants and Recruitment

We sought to collect a range of perspectives on caregiver stress and support in the NICU, so we recruited both currently admitted and discharged parents and legal guardians of preterm babies in the NICU. We also aimed to include other types of caregivers in this study, such as extended family members who had spent significant time in the NICU. This is important in the Aotearoa New Zealand cultural context, as grandparents and other extended family members (such as aunts and uncles) often play important caregiver roles in many cultures, including Māori [15].

Caregivers were eligible for the study if their baby was currently admitted to the NICU or discharged within the previous 12 months and had an admission lasting at least 2 weeks. Participants also had to be 18 years of age or older and be able to read and speak English.

Clinicians were eligible for the NICU clinician group if they were currently employed by Te Toka Tumai Auckland Starship Hospital and interacted closely with caregivers in the NICU as a standard part of their job. Eligible roles included nurses, neonatologists or pediatricians, and mental health clinicians, including social workers and psychotherapists.

An experienced research nurse in the NICU recruited parents with babies currently admitted in the unit. Parents of discharged babies were introduced to the study by clinicians using convenience sampling in an outpatient follow-up clinic for NICU graduates. Parent participants were encouraged to invite their extended family members to participate if they had spent significant time in the NICU.

Clinicians in the NICU were recruited via voluntary response sampling. Study promotion flyers for clinicians were displayed in the unit staff room and distributed by email.

Recruitment for this study was closed after data saturation was reached in both groups. Data saturation was defined as the point at which little or no relevant new categories were found in the data [17]. The final study sample size (N=23) also met the recommended sample size guidelines for achieving rigor in qualitative research of this type [18].

XSL•FO
RenderX

Interview Schedule

The open-ended interview questions (Multimedia Appendix 1), with a caregiver version and a clinician version, were developed by the research team and based on existing literature about the sources of stress and support for parents with babies in the NICU. In the caregiver interview, part 1 included open-ended questions about sources of stress (ie, "What situations did you find most stressful in the NICU?") and support (ie, "What helped you manage your stress most in the NICU?"). In part 2, caregivers were shown examples (websites, apps, and printed materials) of NICU education materials and evidence-based stress-reduction activities from a range of sources (both local and international) and asked for their feedback on usefulness and feasibility. Questions were a mixture of open and closed questions in part 2 (ie, "Would you have used this type of intervention in the NICU? Why or why not?").

In the clinician interview, in part 1, clinicians were asked questions about their work with caregivers and what was most stressful and supportive from their perspective (ie, "In your experience, what types of support, education, or staff roles are most helpful in reducing stress for parents and family members?"). In part 2, clinicians were asked about their ideas on stress reduction tools and what they would like to see included (ie, "What are some features of a stress-reduction intervention that you would like to see for parents in the NICU?"). They were also asked about potential challenges involved in the implementation and feasibility of a new stress-reduction intervention.

The interview schedules were piloted with a researcher with lived NICU experience and a NICU clinician uninvolved in this study. Based on that feedback, the order of questions was changed to improve the interview flow, and some questions were simplified.

Procedure

After expressing interest in the study, participants were contacted by a researcher who introduced them to the study and sent them a link to study enrollment materials. Participants provided informed consent and completed a demographic survey through the web-based research tool REDCap (Research Electronic Data Capture; Vanderbilt University).

Participants chose their preferred interview method (in-person or on Zoom), and families were invited to participate in interviews either individually or as a group. Each participant was given a voucher as a gift of thanks at the start of the interview.

Interviews lasted an average of 45 minutes for clinicians and 60 minutes for caregivers. Interviews were audio-recorded (if in-person) or via Zoom's recording feature.

Two researchers conducted interviews and had no prior relationship with any of the participants. One interviewer (JR) was an experienced female Māori nurse and qualitative researcher who holds leadership roles in equity and Māori engagement. She is a mother of 5 children and grandmother of 7. The other interviewer (KHG) was a European, female, health psychology PhD candidate, licensed mental health clinician who specializes in perinatal mood disorders, and mother of 2 children.

Participants who self-identified as Māori were offered the choice of being interviewed by the non-Māori or Māori researcher. The Māori researcher conducted interviews in alignment with tikanga Māori (Māori protocols).

Interviews were transcribed using automatic speech recognition tools (Zoom and Whisper.AI [19]) and checked and corrected for accuracy using audio or video recordings. To ensure confidentiality, all identifying details were removed, and participant transcripts were issued numeric codes. Participants could review transcripts if they wished within 2 weeks after completing an interview.

Qualitative Methodology

This study's methodology was grounded in an essentialist and realist epistemology (that a reality exists independently of researcher beliefs or interpretations) [20] and informed by existing stress theory, including the situational stress model [21], on which the validated PSS:NICU (Parental Stress Scale: Neonatal Intensive Care Unit) was developed [22]. We used the framework method of thematic analysis, a qualitative method commonly used in applied health research [23]. The framework method allows for both a deductive approach, led by existing theory and predetermined concepts organized into a "framework," and an inductive approach, exploring new concepts based on the data [17].

Data Analysis

Anonymized interview transcripts were imported into the qualitative data analysis software NVivo (release 1.3, Lumivero). Data were then analyzed using the five-step process of the framework method: (1) familiarization with the data, (2) creating a coding framework, (3) indexing (coding), (4) charting (sorting and grouping of coded data), and (5) mapping and interpreting (creating themes) [23].

The initial coding framework for the caregiver dataset was developed a priori from the interview schedule and existing research on NICU parental stress using a deductive approach. It was piloted on 3 transcripts by KHG and PR. During that process, codes were also added as needed in an inductive, data-driven fashion in accordance with the framework method, which allows for both inductive and deductive approaches [17]. The same method was used to create the clinician framework. All investigators discussed and agreed on the final codes and frameworks.

Working independently and using the frameworks, 2 researchers (KHG and PR) coded transcripts, charted (grouped) the data into categories, and developed initial minor and major themes. Then, they used a collaborative approach to create the final themes, working together to compare theme ideas against transcripts and reevaluate when needed.

Initially, themes were created separately for the caregiver and clinician groups. However, after both researchers identified nearly identical themes in the 2 groups independently and shared the results with the investigative team, the decision was made to merge the datasets together. This agreement between datasets

XSL•FO
RenderX

also provided triangulation, which helps ensure data rigor and credibility in qualitative research [24].

The Māori researcher (JR) also reviewed themes and example quotes for cultural understanding for the Māori participant transcripts. The final themes were reviewed and refined by all coinvestigators.

Results

Participant Characteristics

We interviewed 23 participants, conducting 13 interviews on Zoom (including 2 with couples) and 8 in-person: at a university (n=5), in the NICU (n=1), and, for caregivers, at participants' homes (n=2). Three babies were present during these interviews.

Thirteen caregivers (12 parents and 1 grandparent) completed interviews and experienced NICU stays with 10 infants (8 singletons and 1 set of twins). Although we aimed to recruit multiple types of caregivers (ie, parents, grandparents, aunts, and uncles) in this study, only 1 nonparent caregiver was successfully recruited. This was likely due to COVID-19–related restrictions in the unit that ran throughout the study period and only allowed nonparent or legal guardian family members into the unit with special permission (such as to support a single mother) and did not allow children (siblings). All study families had infants admitted to the NICU due to preterm birth, and the majority of babies (6/10, 60%) had stays of 8 weeks or more.

We also interviewed 10 clinicians, who were all female and who had an average of 15 years of experience in the NICU (Table 1). Seven parents completed enrollment paperwork but did not schedule interviews and were removed from the study.

XSL•FO
RenderX

Table . Participant characteristics.

Variables	Values, n (%)
Parents or family members (n=13)	
Female	10 (77)
Ethnicity	
European	9 (69)
Māori	2 (15)
Other[a]	3 (23)
Age (years)	
21 - 30	3 (23)
31 - 40	7 (54)
41 - 50	2 (15)
51 - 60	1 (8)
Education	
Completed high school	2 (15)
Completed tertiary education	11 (85)
Employment status	
Unemployed	2 (15)
Employed part-time	4 (31)
Employed full-time	2 (15)
On parental leave	5 (38)
Baby admission details (n=10)	
Reason for admission	
Premature birth	10 (100)
Admission status	
Currently admitted	4 (40)
Discharged to home	6 (60)
Discharged: total length of stay	
6-8 weeks	2 (20)
More than 8 weeks	4 (40)
Currently admitted: length of stay	
2 to less than 4 weeks	2 (20)
More than 8 weeks	2 (20)
Clinicians (n=10)	
Female	10 (100)
Ethnicity	
European	8 (80)
Māori	1 (10)
Other[a]	1 (10)
NICU[b] role	
Registered nurse	4 (40)
Nurse specialist or practitioner	3 (30)
Mental health clinician	2 (20)

XSL•FO
RenderX

Variables	Values, n (%)
Neonatologist or pediatrician	1 (10)
Years of experience in the NICU	
1 - 10	4 (40)
11 - 20	2 (20)
21 - 30	4 (40)

[a]Chinese, Indian, Korean, Samoan; participants could select multiple ethnicities, so totals may add up to more than 100%.

[b]NICU: neonatal intensive care unit.

Themes

Stress and Support Themes

We identified 6 themes centered on stress and stress-reduction that we considered relevant to future intervention development. Three themes focused on caregiver stress: (1) the emotional "rollercoaster" caused by the NICU experience, (2) insufficient emotional and cultural support, and (3) caregivers feeling "left out" and confused. Participant-proposed solutions to reduce stress were to (1) empower caregivers through education, (2) improve emotional support, and (3) communicate on "my" terms (ie, digitally) (Textbox 1).

Textbox 1. Themes.

Sources of stress*Emotional "rollercoaster"*

- Fear and anxiety
- Overwhelmed and helpless
- Grief and loss

Left out and confused

- Mixed messages
- Not informed about medical care
- Lack of information

Unsupported

- Forgotten fathers
- Limited emotional and cultural support
- Lack of empathy

Participant-proposed solutions

Empower caregivers

- Provide basics about premature birth, the neonatal intensive care unit, and common medical procedures
- Educate on how to care for premature babies

Communicate on "my terms"

- Deliver information digitally
- Make mobile phone-compatible
- Simplify information

Improve emotional support

- Peer support, including father- and cultural-specific support
- Foster online forums and support groups
- Teach stress-reduction skills

XSL•FO
RenderX

Theme 1: Emotional "Rollercoaster" of the NICU

Nearly all the parent participants in our study described their time in the NICU as significantly stressful and highly distressing.

> *It's an emotional rollercoaster, with lots of crying.* [Mother #9]

Multiple participants described it as the most stressful event of their lives.

> *It's a massive test of your emotional resources, certainly the biggest of my life, and I felt like I was having an existential crisis.* [Mother #1]

Many parents reported ongoing episodes of fear in the NICU, related to the highly medicalized NICU environment and concerns about their babies' survival.

> *It's terrifying to be in NICU. It's terrifying because of so many things…seeing my baby in pain and needing so much life support to keep him alive.* [Mother #13]

Consistently, parent participants also reported feeling overwhelmed and helpless in the NICU because of the intensity of the environment and their inability to help their babies. Fathers also shared explicit feelings of helplessness.

> *My partner gave birth and can express [milk] and do all that stuff, and I can't do any of that.* [Father #10]

Participants also reported feelings of grief and loss throughout the NICU experience. While parents whose babies died in the unit were not part of our study, 4 participants reported sharing rooms with or befriending other families whose babies died in the unit.

> *I feel like being in NICU, you not only have your own experiences, which can be quite scary, but you are also forced to take on other family's difficult experiences too.* [Mother #1]

Some participants also felt cultural traditions were not considered after a baby's death.

> *We felt quite unstable after a baby had passed [in the same room], and another baby just turned up. For us, it's very tapu [sacred, with complex spiritual restrictions] when someone's passed away. So spiritually... we felt unsafe.* [Mother #5]

Theme 2: Insufficient Cultural and Emotional Support

While some parents stated they felt emotionally supported by staff in the NICU, most reported that they felt their needs were secondary.

> *If you weren't dying, you weren't a priority.* [Mother #1]

Clinicians agreed that they often do not spend much time talking to parents about their well-being.

> *We don't finish a visit by saying [to parents], "How are you feeling? Are you doing ok?" We just don't have time.* [Clinician #8]

Multiple parents also felt that some medical staff did not respond to their emotional needs in helpful ways.

> *Something had gone wrong and the doctor told me about it. And then he went on to talk about other things that could go wrong [in the future]. And I was like, that was information I needed to know, but it wasn't information I needed to know right then. Eventually, I was like, "I want you to leave because I want to get upset in private."* [Mother #12]

Additionally, 3 fathers participated in our study, and most reported they felt "forgotten" and treated differently than mothers.

> *I felt like [some staff] didn't expect the dad to ask questions or be involved. Gender expectations were quite out of date.* [Father #2]

A few mothers also commented on this, expressing frustration on behalf of their babies' fathers about a lack of consideration for them.

> *I used to joke to [baby's dad], "you're at the bottom, no one really cares about you." It's terrible, actually, I mean, talk about the gender disparity.* [Mother #1]

All the Māori and minority participants in this study reported mixed levels of cultural support in the NICU. Three parents reported speaking their first or Indigenous language to their babies in the NICU and all expressed concerns that they were making English-speaking staff uncomfortable by doing so. The Māori participants in our study also reported concerns that staff did not understand cultural practices that were important to them.

> *Because I'm brown, I felt like people were thinking, "Oh, is she capable?" I also wondered if they were treating me differently because of my skin color.* [Mother #1]

One clinician (#5) commented on unconscious bias as a barrier to appropriate Māori cultural support, which she noted is a requirement of the Te Tiriti o Waitangi (Treaty of Waitangi), New Zealand's founding document signed by Māori and the British Crown in 1840.

> *I'm always reminding staff that we work within Te Tiriti, and that's the place we need to start from, particularly for Māori.* [Clinician #5]

Some participants also detailed gaps in cultural support for Asian families, including limited translation services and a lack of understanding about some cultural practices.

> *So we have this cultural thing that for the first 30 days after delivery we are not supposed to go out of the house, but immediately I'm traveling between NICU and home, so that's gone out of the window. And on the days when I wasn't going, the nurses were ringing me like, "Are you coming today?" And I was like, "I will come tomorrow." You have this pressure on you.* [Mother #8]

XSL•FO
RenderX

Theme 3: Caregivers "Left Out" and Confused

Caregivers reported significant confusion and uncertainty in the NICU due to a lack of information, which they reported increased their stress. Many reported having unanswered questions about day-to-day procedures in the NICU, who the staff were that cared for their babies, and what they could expect in the future.

> *When I went into labour, I didn't know how early you could have a baby, or what the survival rate was. I didn't know what NICU was! I wish someone had explained it all to me more clearly.* [Mother #6]

A few caregivers also noted that it was difficult for them to take in information early in their baby's admission due to the suddenness of their baby's birth and the feelings of fear and overwhelm they were experiencing.

> *We're almost three months into our admission, and I'm probably only now just getting to a point where I can mentally understand everything that happens in NICU and communicate about it clearly. It was just a real shit show for a long time, and of course I had to recover from birth. It probably took me eight weeks to feel like myself.* [Mother #12]

Some mothers also reported feeling nervous about asking questions of the medical team.

> *I know at the start, I remember sitting there and wanting to say things [to the doctors]. But even just asking something was nerve-wracking and overwhelming.* [Mother #8]

Similarly, a few clinicians expressed the concern that the information they were providing was not always understood by caregivers, and they attributed this to both a lack of time they had available to talk to families and potential power differentials between medical providers and caregivers.

> *The [medical] hierarchy is sometimes an issue for people to speak up and ask more questions. They may come back later and say, "Look, I actually didn't understand a word." Or they may come back and ask a nurse but not the doctor.* [Clinician #4]

Participants also mentioned feeling more stressed when they received conflicting information from different staff members.

> *[My baby] couldn't latch properly, and the machine would start beeping [about his oxygen], and I had different messages from the nurses. So some nurses say "it's totally fine," and then some nurses will say, "If he drops then you need to stop breastfeeding and let him breathe." The mixed messages gave me a lot of anxiety.* [Mother #8]

Concerningly, many parents also reported stressful situations in which they were not informed about their babies' medical care. One mother (#6) reported a "really scary" incident when she was not told that her baby had stopped breathing, which she reported "made me lose my mind." Additionally, 2 participants reported being told "at the last minute" or without their knowledge that their babies were moved to a different section of the unit.

> *So before we moved from Level 3 to Level 2, we were told, "It's not going to happen for a while." But then we're told over the phone that now she's in Level 2. That was very stressful for us. The doctor had given us clear plans, yet the transition happened without us.* [Mother #5]

Clinicians also reported stressful situations when parents were "left out of the conversation," attributing this to time constraints and frequent staff changes.

> *If we had more staff, that would give me more time to talk to parents, rather than thinking, "Oh, but I've got these 3 other babies to think about." If the staff is not stressed, then everybody can be less stressed.* [Clinician #3]

Theme 4: Empower Parents

Overwhelmingly, participants expressed an interest in learning more about the NICU and learning how to better care for and respond to their preterm babies in the NICU. Generally, caregivers wanted information that would help them feel more confident and empowered in the NICU.

> *The things at the top of my education wish-list would be on breastfeeding and pumping, which was so stressful; how to hold your baby; the importance of skin-to-skin and any other developmental tools I could use; and understanding your baby's behaviour.* [Mother #9]

Clinicians echoed this idea and felt it important to emphasize the importance of caregiver involvement and partnership with the medical team in the NICU.

> *I think an intervention that would include solid medical information and highlight ways for parents to be involved in NICU would be really helpful. It needs to have a big focus on what parents can do, because there's so much already taken away from them. And focus much more on the message, 'this is your baby,' and emphasize that they are part of the medical team.* [Clinician #4]

Participants also had many specific ideas about the types of NICU information that would be helpful to them, as well as a desire to receive personalized information about their babies.

> *I wanted to know more about everything. How long does my baby need to be on the incubator, how long for the overall stay, the timing of things. Also, their growth, their weight, are they on track?* [Mother #8]

Some participants had specific information requests, from standard medical procedure timelines to developmental week-by-week guides.

> *It would be nice to have a brief timeline of when babies will get the brain scans, when they'll get their first eye checks. It would be good to know when things are going to happen before, instead of after, so you can ask if you should be there and know to ask about the results.* [Mother #11]

XSL•FO
RenderX

Some parent participants also commented on the lack of information available to them about their babies' medical care through the hospital's electronic health record system, and one suggested an "integrated" web-based approach to include both NICU education and updates about their babies' medical care.

> *It'd be great to have education about NICU in an app form that also includes the doctor's notes from the day. I'd like to have more information that keeps you updated when you aren't there.* [Mother #11]

Theme 5: Provide More Emotional Support

Most participants stated they wanted more emotional support, including more empathy from staff and more ways to destress. Participants also mentioned a desire to connect with other caregivers "like me," such as fathers or caregivers from the same cultural group.

> *It would have been nice to chat with a few more dads. If there was some way that brought people together in a casual format, that'd interest me.* [Father #10]

Some participants expressed a desire to connect both in-person and via online support groups with caregivers from the same NICU.

> *It'd be great if there was an online forum or group for parents from this NICU. I found connecting to other NICU parents helped online, even if their baby is no longer in NICU or was in another city. Also, if they can invite some ex-NICU parents [to the unit], I think that would be really good too.* [Mother #8]

Clinicians also commented on the strength of support parents could provide to each other.

> *It's all very well for us as professionals to say "I've been here for years, and this is what 25-week-old babies do." But that doesn't make a parent feel better sometimes. But if another parent who had a 25-week-old maybe two years ago can say, "Look, now I have a healthy child," that's hugely helpful.* [Clinician #1]

In addition to peer-support as a source of stress reduction, many caregivers also expressed an interest in learning specific stress-reduction skills that they could use while in the NICU.

> *It would be quite nice to put on headphones and do some breathing exercises or to listen to a guided meditation.* [Caregiver #7]

Clinicians expressed an interest in having more ways to help parents reduce stress.

> *We know parents are really stressed, and it'd be great to be able to say, "Here are some tools to reduce your stress."* [Clinician #2]

A few participants also noted that there is a lot of downtime in the NICU, and having stress-reducing activities to try would be more helpful than "doom scrolling" on a phone.

> *Based on my experience, I spent a lot of time in NICU just sitting there not doing anything, especially in my baby's early days. So I would have tried some stress-reduction activities if someone had given them to me, because hopefully they'd help me feel better, but also to give me something to do.* [Mother #9]

One mother stated that she and her partner had a session with a psychotherapist during their baby's admission, which she reported helped reduce her stress. However, she noted that scheduling these sessions was challenging and privacy was limited within the unit. (Clinicians also noted similar challenges in this regard.) She recommended complementing this type of in-person therapy with resources and activities that could be done at home.

> *The therapist gave us self-reflective questions to think about, and those were really helpful for us to talk about later. Like, what was most important to us as parents in NICU? It's hard to get perspective when you are in the midst of it, and those reflective questions really helped us do that. I think a list of those types of questions could be really useful for other parents, too.* [Mother #12]

Participants also recommended ways to improve cultural support, including more diverse staffing and staff training on cultural traditions.

> *I think it'd be helpful to have really good information in different languages and then basic info for staff [on cultural traditions], like this is something a family might want to do, and here's how to support them.* [Clinician #1]

Two Māori participants also recommended specific cultural practices around stress reduction.

> *I'm always interested in karakia (Māori ritual chants/incantations) and ones to do with breathing. For me, it's really helpful in stressful situations and really important that I keep doing it in the NICU.* [Mother #13]

Theme 6: Communicate on "My" Terms (ie, Digitally)

Many caregivers and clinicians expressed an interest in authoritative, reliable web-based resources for information about the NICU and premature baby development, and they commented that the printed resources currently provided in the unit were "not helpful."

> *I've spent more than a decade dedicated to the NICU, and I wouldn't read our pamphlets. Also, we're all on our phones. That's how we communicate. So I think digital is way better.* [Clinician #6]

Another clinician agreed, observing that younger parents in particular prefer digital information.

> *Digital is the way to go. The younger parents never read a printed pamphlet. They take out their phone, and they find their answers, good or bad. I think content needs to be short, sharp, and ideally, more video rather than lots of text. I think it should also be easy to navigate so that when they are hopefully sitting at the bedside or expressing milk, they can look at it when they have a few minutes.* [Clinician #4]

XSL•FO
RenderX

While 2 caregivers preferred printed materials over web-based, the majority of caregivers wanted information delivered in digital formats and specifically mobile-friendly.

> *I never open my laptop. I'm always on my phone. You want it to be easy to read and less words and more videos. But you do want to find the right information that's accurate for your baby.* [Mother #12]

Three participants brought specific app and blog ideas they had brainstormed to their study interviews because they felt "so frustrated" by the lack of information they felt they received about the NICU and premature babies. They also noted they wanted to be able to access information regardless of the time of day.

> *I want more information about my baby and NICU, and I want to be able to work things out in my own time, online, even if it's at 2 am.* [Father #2]

Discussion

Principal Findings

Our study explored caregiver stress in the NICU and solicited participant ideas on ways to reduce stress to inform future intervention development. Broadly, our stress themes highlight how the majority of caregivers felt devalued in the NICU and that their emotional needs were not a priority. They expressed a desire to be treated as partners in their babies' medical care and seen as individuals, with unique values and strengths that were vital to their babies' health and well-being.

These findings align with stress theory, which posits that stress occurs in response to specific components of a situation as well as an individual's perceptions of that environment and their ability to cope within it [21]. The PSS:NICU [22], which was developed based on this theory, measures parental perceptions' of stress in response to four specific components of the NICU environment: (1) "sights and sounds of the NICU," (2) "infant behavior and appearance," (3) "parental role alteration" (with examples such as "not being able to hold my baby" and "feeling helpless"), and (4) "staff communication and behaviors."

Our study data contain examples of all of the categories measured by the PSS:NICU. Importantly, the majority of our data about parental stress can be organized within the category of "parental role alteration." In particular, our themes around parents feeling left out of decisions about their babies' medical care, uniformed, and unsupported emotionally highlight how parents felt disempowered in the NICU. This is important, as a meta-analysis of studies from around the world using the PSS:NICU found that "parental role alteration" is the most significant factor in parental stress in the NICU, with higher perceptions of changes in the parental role leading to higher rates of parental stress [25].

The stress themes in our study highlight problematic gaps in emotional and cultural support for families that led to feelings of parental isolation and disempowerment. While some parents stated they were supported in the NICU, the majority reported stressful interactions that made them feel devalued, confused, or judged as parents. Fathers, in particular, reported feeling "less important" than mothers in the NICU. Fathers' needs have long been understudied in the NICU, with many studies focusing exclusively on mothers [5]. However, recent studies have demonstrated that fathers can experience high levels of distress in the NICU, including elevated rates of depression and posttraumatic stress disorder compared to non-NICU fathers, and specialized interventions in the NICU can help [26].

In total, 30% (7/23) of our study participants self-identified from Māori and other minority cultures. These participants all reported mixed experiences of cultural safety (such as feeling judged by speaking a non-English language to their baby in front of medical staff), which are similar to findings reported in previous studies internationally with minority families [27] and in Aotearoa New Zealand with Māori families in the NICU [15].

Cultural support is a critical area for improvement and should be considered an important component of parental empowerment in the NICU [28] and an avenue for future intervention development. As a systematic review of Indigenous populations' birth outcomes in New Zealand, Australia, Canada, and the United States found, Indigenous groups experience significantly higher rates of preterm birth and neonatal death than non-Indigenous populations [29], and a growing body of international research has also documented a strong dose-dependent relationship between experiences of discrimination and health outcomes [30]. Few studies have explored experiences of discrimination and health outcomes within the NICU [31] or how cultural support can affect outcomes, and these are much-needed avenues of future research.

All participants shared ideas on ways to reduce parental stress in the NICU and what they felt would be helpful in a future intervention. Participants overwhelmingly agreed on the need for caregivers to feel more confident and empowered in the NICU. This idea has significant support in the literature, with decades of evidence documenting the benefits for parents and babies of increased parental involvement and engagement in the NICU [32]. As our study highlights, however, this knowledge can be difficult to translate into practice. Formalized "empowerment" interventions in the NICU have been designed to address this challenge, and most involve multimodal intervention programs that include hands-on caregiver education and changes in clinical practices. These have been found effective in reducing parental stress and depression [32].

Caregiver participants were interested in learning about education topics in 2 categories: how to care for their baby in the NICU and understanding the NICU environment, which was new and unfamiliar to all the families in our study. This desire is backed by research: educational interventions for parents with babies in the NICU have been shown to improve parenting confidence and decrease parental anxiety [33]. Clinicians echoed this need, and most participants wanted information to be provided in "short and sharp," easy-to-understand text and video. Participants also overwhelmingly agreed on the need for digital, mobile-friendly delivery of information (both for education and about their babies).

XSL•FO
RenderX

Digital interventions are a worthwhile avenue for future exploration, as evidence has demonstrated the effectiveness of digital interventions with pregnant and postnatal women. A 2024 meta-analysis examined 31 randomized controlled trials testing digital intervention effects on postpartum anxiety and depression and found significant reductions in symptoms compared to treatment as usual, particularly for interventions that incorporated psychotherapy such as cognitive behavioral therapy or mindfulness [34]. Despite this evidence base, to our knowledge, no digital mental health interventions have been evaluated for parents with babies in the NICU.

Participants also proposed a range of strategies to improve emotional support, including through parent-to-parent support (both in-person and through online support groups). Participants also wanted improved cultural support, including increased staff training on diverse cultural traditions, hiring more Māori and minority staff, and creating more ways for parents to connect with other parents from similar cultures. This personal connection aligns with the Māori concept of whakawhanaungatanga, which emphasizes building meaningful, trusting relationships.

Strengths, Limitations, and Future Research

To inform future intervention development, this study explored sources of stress and solicited ideas about ways to reduce stress with caregivers and clinicians in a level 3 NICU in Aotearoa New Zealand. Soliciting participants' ideas on caregiver stress reduction in the NICU is an uncommon approach in the literature and a strength of the study.

This study is qualitative, and therefore its findings are not generalizable but may be transferable to similar populations. Our results are reflective of one participant group, in which the majority of participants were female, self-identified as European in ethnicity, and most were tertiary-level educated and employed. The study interviews were also conducted during the COVID-19 pandemic, which may have influenced participants' perceptions of stress and contributed to their ideas about stress reduction (such as more interest in digital sources of information).

In the recruitment process, 7 parent participants completed enrollment paperwork but did not schedule interviews. We do not know the reasons for this change in participation interest; however, we were aware of possible barriers, including parental hospitalization, a transfer out of the unit, and a lack of access to a mobile phone, limiting interview scheduling.

Future studies should strive to reduce barriers to participation in research for all caregivers with babies in the NICU, and they should aim to recruit more fathers and minority participants, who are underrepresented in the literature [5]. Caregivers and clinicians in the NICU are also valuable, knowledgeable resources for intervention development and design. Involving stakeholders such as parents, extended family members, and clinicians in intervention development is likely to improve patient-centered care, improve engagement in interventions, reduce inefficiencies in research, and improve research outcomes [35].

Conclusions

This study explored sources of parental stress in the NICU with caregivers and clinicians, and gathered participants' ideas and feedback on ways to reduce stress to inform future intervention development. Proposed solutions by participants focused on increasing parental empowerment, improving emotional and cultural support, and providing information in digital, mobile-friendly formats. This formative study was essential in identifying the unique needs and views of both caregivers and clinicians working in the NICU. It has since informed the development of a digitally delivered psychoeducational program that we are currently evaluating in a randomized controlled trial [36].

Acknowledgments

We would like to thank the participants in this study for sharing their stories and opinions with us. We would also like to thank Sabine Huth for her assistance in recruitment.

Conflicts of Interest

Coauthor AS is Associate Editor of *JMIR Pediatrics and Parenting*.

Multimedia Appendix 1
Semistructured interview outlines.
[DOCX File, 19 KB - pediatrics_v8i1e66401_app1.docx]

References

1. Loewenstein K, Barroso J, Phillips S. The experiences of parent dyads in the neonatal intensive care unit: a qualitative description. J Pediatr Nurs 2021;60:1-10. [doi: 10.1016/j.pedn.2021.01.023] [Medline: 33567394]
2. Lefkowitz DS, Baxt C, Evans JR. Prevalence and correlates of posttraumatic stress and postpartum depression in parents of infants in the neonatal intensive care unit (NICU). J Clin Psychol Med Settings 2010 Sep;17(3):230-237. [doi: 10.1007/s10880-010-9202-7] [Medline: 20632076]
3. Yildiz PD, Ayers S, Phillips L. The prevalence of posttraumatic stress disorder in pregnancy and after birth: a systematic review and meta-analysis. J Affect Disord 2017 Jan 15;208:634-645. [doi: 10.1016/j.jad.2016.10.009] [Medline: 27865585]

XSL•FO
RenderX

4. Lean RE, Rogers CE, Paul RA, Gerstein ED. NICU hospitalization: long-term implications on parenting and child behaviors. Curr Treat Options Pediatr 2018 Mar;4(1):49-69. [doi: 10.1007/s40746-018-0112-5] [Medline: 29881666]
5. Ohuma EO, Moller AB, Bradley E, et al. National, regional, and global estimates of preterm birth in 2020, with trends from 2010: a systematic analysis. Lancet 2023 Oct 7;402(10409):1261-1271. [doi: 10.1016/S0140-6736(23)00878-4] [Medline: 37805217]
6. Report on maternity: further information. Health New Zealand. 2024 Jun. URL: https://www.tewhatuora.govt.nz/assets/Our-health-system/Data-and-statistics/Maternity-web-tools/report-on-Maternity-further-information.pdf [accessed 2025-03-26]
7. 2023 census. Statistics New Zealand. 2023. URL: https://www.stats.govt.nz/2023-census/ [accessed 2025-03-26]
8. Sixteenth Annual Report of the Perinatal and Maternal Mortality Review Committee: Reporting Mortality and Morbidity 2021 [Te Pūrongo ā-Tau Tekau mā Ono o te Komiti Arotake Mate Pēpi, Mate Whaea Hoki: Te Tuku Pūrongo mō te Mate me te Whakamate 2021]. : Te Tāhū Hauora Health Quality & Safety Commission; 2024 Jun URL: https://www.hqsc.govt.nz/assets/Our-work/Mortality-review-committee/PMMRC/Publications-resources/16thPMMRCReport_FINAL.pdf [accessed 2025-03-26]
9. Review of neonatal care in New Zealand. : Malatest International; 2019 Jan URL: https://www.health.govt.nz/system/files/2019-08/review-of-neonatal-care-in-new-zealand-aug2019.pdf [accessed 2025-03-26]
10. Sabnis A, Fojo S, Nayak SS, Lopez E, Tarn DM, Zeltzer L. Reducing parental trauma and stress in neonatal intensive care: systematic review and meta-analysis of hospital interventions. J Perinatol 2019 Mar;39(3):375-386. [doi: 10.1038/s41372-018-0310-9] [Medline: 30659239]
11. Mendelson T, Cluxton-Keller F, Vullo GC, Tandon SD, Noazin S. NICU-based interventions to reduce maternal depressive and anxiety symptoms: a meta-analysis. Pediatrics 2017 Mar;139(3):e20161870. [doi: 10.1542/peds.2016-1870] [Medline: 28223373]
12. Ginsberg KH, Serlachius A, Rogers J, Alsweiler J, Australian and New Zealand Neonatal Network. Psychosocial support provided to parents of infants in neonatal intensive care units: an international survey. J Pediatr 2023 Aug;259:113456. [doi: 10.1016/j.jpeds.2023.113456] [Medline: 37172808]
13. Dodge A, Gibson C, Williams M, Ross K. Exploring the needs and coping strategies of New Zealand parents in the neonatal environment. J Paediatr Child Health 2022 Jun;58(6):1060-1065. [doi: 10.1111/jpc.15908] [Medline: 35178796]
14. Ichijima E, Kirk R, Hornblow A. Parental support in neonatal intensive care units: a cross-cultural comparison between New Zealand and Japan. J Pediatr Nurs 2011 Jun;26(3):206-215. [doi: 10.1016/j.pedn.2009.10.003] [Medline: 21601144]
15. Adcock A, Cram F, Edmonds L, Lawton B. He Tamariki Kokoti Tau: families of indigenous infants talk about their experiences of preterm birth and neonatal intensive care. Int J Environ Res Public Health 2021 Sep 18;18(18):9835. [doi: 10.3390/ijerph18189835] [Medline: 34574759]
16. Annual clinical report—National Women's Health 2023. Health New Zealand. 2025 Feb 19. URL: https://www.tewhatuora.govt.nz/publications/nat-womens-annual-report-2023 [accessed 2025-03-31]
17. Ritchie J, Lewis J. Qualitative Research Practice: A Guide for Social Science Students and Researchers: Sage; 2003.
18. Hennink M, Kaiser BN. Sample sizes for saturation in qualitative research: a systematic review of empirical tests. Soc Sci Med 2022 Jan;292:114523. [doi: 10.1016/j.socscimed.2021.114523]
19. Chen G, Chai S, Wang GB, et al. GigaSpeech: an evolving, multi-domain ASR corpus with 10,000 hours of transcribed audio. Proc Interspeech 2021;2021:3670-3674. [doi: 10.21437/Interspeech.2021-1965]
20. Maxwell JA. A Realist Approach for Qualitative Research: Sage; 2012.
21. Magnusson D, Ekehammar B. Perceptions of and reactions to stressful situations. J Pers Soc Psychol 1975 Jun;31(6):1147-1154. [doi: 10.1037/h0077032] [Medline: 1142064]
22. Miles MS, Funk SG, Carlson J. Parental stressor scale: neonatal intensive care unit. Nurs Res 1993;42(3):148-152. [Medline: 8506163]
23. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol 2013 Sep 18;13(1):117. [doi: 10.1186/1471-2288-13-117] [Medline: 24047204]
24. Johnson JL, Adkins D, Chauvin S. A review of the quality indicators of rigor in qualitative research. Am J Pharm Educ 2020 Jan;84(1):7120. [doi: 10.5688/ajpe7120] [Medline: 32292186]
25. Caporali C, Pisoni C, Gasparini L, et al. A global perspective on parental stress in the neonatal intensive care unit: a meta-analytic study. J Perinatol 2020 Dec;40(12):1739-1752. [doi: 10.1038/s41372-020-00798-6] [Medline: 32901116]
26. Ocampo MJ, Tinero JA, Rojas-Ashe EE. Psychosocial interventions and support programs for fathers of NICU infants: a comprehensive review. Early Hum Dev 2021 Mar;154:105280. [doi: 10.1016/j.earlhumdev.2020.105280] [Medline: 33221029]
27. Beck AF, Edwards EM, Horbar JD, Howell EA, McCormick MC, Pursley DWM. The color of health: how racism, segregation, and inequality affect the health and well-being of preterm infants and their families. Pediatr Res 2020 Jan;87(2):227-234. [doi: 10.1038/s41390-019-0513-6] [Medline: 31357209]
28. Nyaloko M, Lubbe W, Moloko-Phiri SS, Shopo KD. Exploring cultural determinants to be integrated into preterm infant care in the neonatal intensive care unit: an integrative literature review. BMC Pregnancy Childbirth 2023 Jan 9;23(1):15. [doi: 10.1186/s12884-022-05321-7] [Medline: 36624421]

XSL•FO
RenderX

29. Smylie J, Crengle S, Freemantle J, Taualii M. Indigenous birth outcomes in Australia, Canada, New Zealand and the United States: an overview. Open Womens Health J 2010(4):7-17. [doi: 10.2174/1874291201004010007] [Medline: 23390467]
30. Cobbinah SS, Lewis J. Racism & health: a public health perspective on racial discrimination. J Eval Clin Pract 2018 Oct;24(5):995-998. [doi: 10.1111/jep.12894] [Medline: 29508479]
31. Franck LS, O'Brien K. The evolution of family-centered care: from supporting parent-delivered interventions to a model of family integrated care. Birth Defects Res 2019 Sep 1;111(15):1044-1059. [doi: 10.1002/bdr2.1521] [Medline: 31115181]
32. Zhang Q, Wu J, Sheng X, Ni Z. Empowerment programs for parental mental health of preterm infants: a meta-analysis. Patient Educ Couns 2021 Jul;104(7):1636-1643. [doi: 10.1016/j.pec.2021.01.021] [Medline: 33526337]
33. Springer C, Elleman B, Cooper O. The effectiveness of parental education programs within neonatal intensive care units: a systematic review. RDTS 2023;2(1). [doi: 10.53520/rdts2023.10578]
34. Lewkowitz AK, Whelan AR, Ayala NK, et al. The effect of digital health interventions on postpartum depression or anxiety: a systematic review and meta-analysis of randomized controlled trials. Am J Obstet Gynecol 2024 Jan;230(1):12-43. [doi: 10.1016/j.ajog.2023.06.028] [Medline: 37330123]
35. Slattery P, Saeri AK, Bragge P. Research co-design in health: a rapid overview of reviews. Health Res Policy Syst 2020 Feb 11;18(1):17. [doi: 10.1186/s12961-020-0528-9] [Medline: 32046728]
36. Ginsberg KH, Alsweiler J, Rogers J, Cavadino A, Douglas M, Serlachius A. A digital acceptance and commitment therapy and education intervention targeting stress of parents and caregivers with preterm babies in the neonatal intensive care unit: a randomised controlled cluster trial protocol. Contemp Clin Trials 2024 May;140:107519. [doi: 10.1016/j.cct.2024.107519] [Medline: 38547962]

Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
NICU: neonatal intensive care unit
PSS:NICU: Parental Stress Scale: Neonatal Intensive Care Unit
REDCap: Research Electronic Data Capture

Edited by S Badawy; submitted 11.09.24; peer-reviewed by B Eshrati, P Geller; revised version received 02.12.24; accepted 23.12.24; published 02.04.25.

Please cite as:
Ginsberg KH, Alsweiler J, Rogers J, Ross P, Serlachius A
Exploring Stress and Stress-Reduction With Caregivers and Clinicians in the Neonatal Intensive Care Unit to Inform Intervention Development: Qualitative Interview Study
JMIR Pediatr Parent 2025;8:e66401
URL: https://pediatrics.jmir.org/2025/1/e66401
doi:10.2196/66401

© Kristin Harrison Ginsberg, Jane Alsweiler, Jenny Rogers, Phoebe Ross, Anna Serlachius. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 2.4.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Implementing Diabetes Distress Screening in a Pediatric Endocrinology Clinic Using a Digital Health Platform: Quantitative Secondary Data Analysis

Nicole A Kahhan, PhD; Larry A Fox, MD; Matthew Benson, MD; Susana R Patton, PhD, ABPP

Nemours Children's Health- Jacksonville, 807 Children's Way, Jacksonville, FL, United States

Corresponding Author:
Nicole A Kahhan, PhD
Nemours Children's Health- Jacksonville, 807 Children's Way, Jacksonville, FL, United States

Abstract

Background: Type 1 diabetes (T1D) management requires following a complex and constant regimen relying on child or caregiver behaviors, skills, and knowledge. Psychological factors such as diabetes distress (DD), depression, and burnout are pertinent considerations in the treatment of pediatric T1D. Approximately 40% of youth and 61% of caregivers experience DD. Implementation of DD screening as part of clinical best practice is recommended and may facilitate treatment referral, perhaps leading to improved health or well-being for youth with T1D and their caregivers. By building on existing institutional infrastructure when available, screening via digital health platforms (applications, or "apps") may allow for timely screening of, and response to, DD.

Objective: This work details the creation, implementation, and refinement of a process to screen for DD in youth and their caregivers in the context of routine T1D care using a digital health platform.

Methods: DD screening was implemented in an outpatient endocrinology clinic over 1 year as part of a larger screen-to-treat trial for children aged 8 - 12.99 years and their caregivers. Validated measures were sent via digital health platform to be completed prior to the clinic visit. Results were initially reviewed manually, but a digital best practice alert (BPA) was later built to notify staff of elevated scores. Families experiencing DD received resources sent via the digital health platform. For this secondary analysis, child demographics and glycated hemoglobin A_{1c} (HbA_{1c}) were collected.

Results: During the screening period, absolute completion rates were 36.78% and 38.83%, with adjusted screening rates at 52.02% and 54.48%, for children and caregivers, respectively. A total of 21 children (mean HbA_{1c} 8.04%, SD 1.39%) and 26 caregivers (child mean HbA_{1c} 8.04%, SD 1.72%) reported elevated DD. Prior to BPA development, resources were sent to all but 1 family. After BPA implementation, all families were sent resources.

Conclusions: Early findings indicate that DD education, screening, and response can be integrated via digital platforms in a freestanding outpatient endocrinology clinic, thereby facilitating timely treatment referral and provision of resources for those identified with distress. Notably, in the observed 1-year screening period, screening rates were low, and barriers to implementation were identified. While some implementation challenges were iteratively addressed, there is a need for future quality improvement initiatives to improve screening rates and the identification of, or response to, DD in our pediatric patients and their families.

Trial Registration: ClinicalTrials.gov NCT05268250; https://clinicaltrials.gov/study/NCT05268250

(JMIR Pediatr Parent 2025;8:e65107) doi:10.2196/65107

KEYWORDS

type 1 diabetes; diabetes mellitus, type 1; pediatric; child; children; youth; parents; diabetes distress; eHealth; screening; digital health; diabetes; diabetic; type 1; DM; T1D; endocrinology; alert; best practice alert; BPA; patient education

Introduction

Rates of type 1 diabetes (T1D) in youth aged 19 years or younger have been increasing in recent years, from approximately 1.48 per 1000 youth in 2001 to 2.15 per 1000 youth in 2017 [1]. Rates increased at the highest levels in non-Hispanic White and non-Hispanic Black children [1]. Health-promoting management of T1D requires following a complex and constant treatment regimen with tasks relying on child and caregiver behaviors, skills, and knowledge [2]. Given the complexity and constancy of diabetes management, it is not surprising that psychological factors such as distress, depression, anxiety, and burnout are highlighted as pertinent to consider in the management of pediatric T1D [2-4].

Diabetes distress (DD) is the "emotional distress that results from living with diabetes and the burden of relentless daily

XSL•FO
RenderX

self-management" that can be seen across the life span, as well as in caregivers of those with diabetes [5]. It occurs at rates of approximately 25% in adults with T1D [6]. In children aged 8 - 12 years, as many as 40% of youth and 61% of their parents or caregivers experience at least some DD [7]. Notably, DD is occurring at higher rates, on average, than depression in pediatric populations with diabetes [8,9]. Increased levels of DD relate to deficits in diabetes self-management behaviors, increased glycated hemoglobin A_{1c} (HbA_{1c}), and negative impacts on mental health and well-being [4,6]. DD differs from burnout, defined as the physical or emotional exhaustion associated with continuous DD and management needs, and depression, although these can co-occur [10,11]. Implementation of DD screening (and subsequently, treatment of DD) as part of clinical best practice may facilitate treatment referral and could lead to improved health and well-being for youth and their caregivers [6].

The American Diabetes Association (ADA) Standards of Care in Diabetes recommends DD screening starting at 8 years of age, with the parent, child, and adolescent versions of the Problem Areas in Diabetes (PAID) highlighted as validated assessment tools in this domain [2]. Similarly, the International Society for Pediatric and Adolescent Diabetes (ISPAD) recommends that age-appropriate and validated assessment tools be used routinely to monitor and guide conversations specific to the psychosocial well-being of all youth with diabetes as well as their caregivers [4]. Despite these recommendations, 1 recent publication reported that less than half of surveyed pediatric diabetes clinics screened for mental health problems of any kind using a validated tool [12]. In contrast, another survey of T1D exchange participants reported that 96% of pediatric centers included use at least 1 standardized measure of patient reported symptoms or needs. However, measures included in this study were more broadly inclusive of mental health, transition readiness, and structural determinants of health, among other domains, with <30% of centers reporting screening for DD [13].

In line with best practice recommendations, we sought to implement standardized DD screening for youth aged 8 - 12 years and their caregivers in an outpatient endocrinology clinic in a large, freestanding, pediatric medical center. Screening was completed using validated surveys sent prior to children's clinical visit via digital health platform. Thus, by building on existing infrastructure, it was possible to conduct DD screening and deliver a response to elevated scores using the institutional app, which we anticipated would be a highly scalable process.

Methods

Participants

This project occurred in the pediatric endocrinology clinic at Nemours Children's Health-Jacksonville, which serves more than 1000 children with T1D. The reported results focus on screening procedures initiated and tested from April 1, 2022, through March 31, 2023. Children eligible for screening were aged between 8 and 12.99 years, with any diagnosis of diabetes (broadly identified by visit type, because at the time of implementation, the system could not differentiate between T1D, type 2 diabetes, or another diabetes), and able to read and understand English. Adolescents aged 13 years and older were excluded from DD screening because they were already participating in another screening initiative at our institution (depression screening). Eligible parents or caregivers had a child who met the eligibility criteria, were signed up to use the Nemours app for health care management, and were able to read and understand English. The Nemours app is a stand-alone app created by the larger Nemours Children's Health system. Families were encouraged to sign up for this app beginning in August 2019 to access child health records, manage appointments, message providers, complete paperwork and payments, receive resources, and participate in telehealth visits. At the start of the screening period (April 2022), approximately 68% of families followed in the endocrinology clinic were signed up for the Nemours app, although this increased to 78% by month 12 (Table 1). Of note, 30.7% of families on average who started previsit questionnaires in the app (the "GetReady" process) did not complete their questionnaires and were able to attend clinic visits despite outstanding paperwork.

XSL•FO
RenderX

Table . Application use data and completion of pre–check-in paperwork over 1-year implementation period.

	Month of screening implementation											
	1	2	3	4	5	6	7	8	9	10	11	12
Percentage of patients seen with active app accounts (enterprise-wide)	51.5	52.4	53.3	54.2	55.2	56.0	56.8	57.6	58.4	59.1	59.7	60.5
Percentage of patients seen with active app accounts (division/location-specific)	68.0	69.1	70.6	71.5	73.0	73.3	74.4	75.3	75.9	76.6	77.5	78.0
Percentage of appointments where GetReady was started but not completed (division/location-specific)	34.9	29.3	24.7	31.6	26.1	30.6	33.9	30.5	30.3	32.1	33.6	30.9

Ethical Considerations

Given the use of retrospective chart reviews for data collection, the authors obtained institutional review board approval (2057003) for secondary (exempt) research prior to the collection of data. The institutional review board determined based on the methods, proposed analyses, and the researcher's ability to work with deidentified data that informed consent or assent was not required for this project. Compensation was not provided as part of this secondary research.

Procedure

In line with standard of care recommendations from the ADA and ISPAD [2,4], and as part of a larger screen-to-treat trial, the pediatric endocrinology clinic at Nemours Children's Health-Jacksonville, implemented a screening program to detect symptoms of DD in school-aged children and their parents. The clinic used automated processes, a digital health platform, and validated screening tools to minimize any negative impact on clinic flow and to capitalize on the existing system for paperwork completion via the Nemours app. Per the screening protocol, the automated system assigned the DD screening tools to children, aged at least 8 years and younger than 13 years, with a visit type "Diabetes NP (new patient) w/Care Team" or "Diabetes FP (follow up patient) w/Care Team" and the clinic location in Jacksonville, Florida. Children and parents received the DD screeners every 6 months via the Nemours app "GetReady" feature along with other clinic surveys (eg, intake form) up to 10 days before their scheduled clinic visit. Regular reminders to complete paperwork were provided prior to the visit through an automated messaging system. Once completed, the Nemours app automatically scored the DD screeners and uploaded the screener results into the child's electronic health record (EHR). Initially, each week, a diabetes psychologist would manually review the completed DD screeners and send messages in the EHR to the visit provider when a child or parent had an elevated DD screen. Furthermore, for each elevated DD screen, the psychologist manually sent families a message via the EHR, which (1) thanked the family for completing screening; (2) defined and normalized DD; and (3) listed local resources including community diabetes groups and camps, web-based resources, relevant web pages, ways to access mental health services (including within their institution from psychology and social work providers), and information about the larger

XSL•FO
RenderX

screen-to-treat DD trial so that families could reach out to learn more if interested. This resource list was created collaboratively between endocrinology physicians, psychologists, and a licensed clinical social worker assigned part-time to the endocrinology clinic. Eventually, to automate the process more fully, the clinic technology team built a best practice alert (BPA) into the EHR so that clinical providers associated with an upcoming visit and the diabetes psychologist would receive an automated alert flag for elevated DD scores. This feature made it possible for providers to engage in standard of care practices to address elevated DD screening results with families directly during the clinic visit and to include a resource list in their electronic after-visit summary. The psychologist also continued to review screening BPAs and send families a local resource list via an EHR message.

Measures

We selected 2 validated DD screening tools, the Problem Areas in Diabetes-Child (PAID-C) and the Parent Problem Areas in Diabetes-Child (P-PAID-C) to screen for child and parent symptoms of DD, respectively. The PAID-C is an 11-item survey of DD symptoms specifically designed and validated for children aged 8 - 12 years [7]. The PAID-C yields a total score that ranges from 11 to 66, with higher scores reflecting more distress. The P-PAID-C is a 16-item survey of DD symptoms specifically designed and validated for parents of school-aged children [7]. Like the child form, the P-PAID-C yields a single total score. The P-PAID-C total score can range from 16 to 96, and higher scores reflect more distress.

We collected child demographics (eg, age, biological sex, race, and ethnicity) and examined these within the larger eligible clinic population; the subpopulation who participated in the screening program; and the group who had elevated DD screening results. We also collected child HbA_{1c} levels from the visit associated with DD screening captured between April 1, 2022, and March 31, 2023. For children's HbA_{1c}, the clinic uses instruments certified by the National Glycohemoglobin Standardization Program and traceable to reference methods from the Diabetes Control and Complications Trial.

Data Analyses

We used approved tools to retrieve all EHR data. We report the percentage of eligible families screened for DD out of all eligible families in the clinic population (absolute percentage screened) and the percentage of eligible families screened for DD out of all eligible families with a completed clinic visit between April 1, 2022, and March 31, 2023 (adjusted percentage screened). To analyze these data, we examined the screening rate by each month and the average across the year. We also examined the rate of EHR documentation of follow-up resources being sent to families with elevated screening results. To identify elevated DD, the clinic applied a clinical cut point of ≥41 for children and a cut point of ≥64 for parents or caregivers [7]. Descriptive statistics and HbA_{1c} were examined for both the population who completed DD screening and the families who had elevated screening results. Given that the screening period took place over a 12-month period, some families received and completed the screening measures on more than 1 occasion. If a child or a caregiver was identified as having elevated DD on multiple screenings, he or she was sent resources each time; however, for the purposes of data analysis, only the first elevated screen that also had a clinic visit with an associated HbA_{1c} was included for analyses.

Results

Participants

Children who completed any DD screening (eg, child and parent or caregiver completed, child-only completed, and parent or caregiver-only completed) were 55.2% female, 44.8% male, and had a mean age of 10.22 (SD 1.36) years. With respect to their self-reported race, 1.8% were Asian American and Pacific Islander, 0.75% were American Indian or Alaskan Native, 0.8% were Asian Indian, 19.6% were Black or African American, 64.16% were White, 5.0% reported more than 1 race, 8.0% reported other/unspecified, and 1.0% reported "prefer not to say." For their self-reported ethnicity, 12.1% identified Hispanic/Latinx, 86.4% identified not Hispanic/Latinx, and 1.5% reported "prefer not to say" (Table 2).

XSL•FO
RenderX

Table . Demographic information.

	Participants, n (%)
Ethnicity	
Hispanic/Latinx	49 (12.1)
Not Hispanic/Latinx	349 (86.4)
Prefer not to answer	6 (1.5)
Race	
AAPI[a]	7 (1.8)
American Indian or Alaskan Native	3 (0.8)
Asian Indian	3 (0.8)
Black or African American	78 (19.6)
White	256 (64.2)
More than 1 race	20 (5.0)
Other/unspecified	32 (8.0)
Prefer not to say	4 (1.0)
Age (years)	
8	70 (14.3)
9	77 (16.4)
10	102 (21.8)
11	117 (25.0)
12	103 (22.0)
Sex	
Female	223 (55.2)
Male	181 (44.8)

[a]AAPI: Asian American and Pacific Islander.

Primary Outcomes

Screening Completion Rates

During the 1-year screening period, the institutional app system automatically assigned a total of 590 PAID-C questionnaires and 649 P-PAID-C questionnaires to children aged 8 - 12.99 years and their caregivers, respectively. A higher number of caregiver questionnaires than pediatric questionnaires were assigned, as some pediatric patients had multiple caregivers associated with their account in the institutional app. Of those, 396 PAID-C and 435 P-PAID-C questionnaires assigned were associated with attended clinic visits. Absolute percentage screened (questionnaire completion out of all assigned) were 36.78% (217/590) and 38.83% (252/649), respectively. Screening rates (questionnaire completion) for those who attended their clinic visits (adjusted percentage screened) for children or caregivers were 52.02% (206/396) and 54.48% (237/435), respectively. Completion rates were relatively stable over the 12 months of DD screening.

DD Rates and Resource Provision

In total, 10.2% (21/206) PAID-C and 11.0% (26/237) P-PAID-C surveys scored as elevated during the 1-year screening period, with 1 child and 3 caregivers completing the measure with an elevated score at multiple clinic visits. During this period, 11 child and caregiver dyads scored as elevated on both measures of DD, with 4 of these dyads including a child with a diagnosis of type 2 diabetes or prediabetes, and the remaining dyads with a child diagnosed with T1D. All other elevated screens were present in only a caregiver or a child, who was not part of a parent and child dyad. Of those who were identified as having DD, resources were sent in the app to families in response to 91.7% of elevated PAID-C scores and 100% of elevated P-PAID-C scores; only 1 patient who screened as elevated was not flagged by manual processes and did not receive resources. This occurred before the automated BPA system was put in place. After the BPA was established, all families with elevated parent or child DD scores were sent resources electronically.

DD, Demographics, and HbA_{1c}

Mean HbA_{1c} was calculated for youth with T1D who also attended the clinic visit associated with the date of elevated DD screening (15 PAID-C and 17 P-PAID-C scores were included). Youth with type 2 diabetes or prediabetes were not included in this subsample. For this subsample including all youth with DD, mean HbA_{1c} was 8.04% (SD 1.39%) and mean child HbA_{1c} for those with caregivers screening elevated for DD was 8.04% (SD 1.72%). This subsample of youth was 68% female (17/25),

XSL•FO
RenderX

32% male (8/25), and had a mean age of 10.4 (SD 1.44) years. With respect to their self-reported race, 8.3% were Black or African American (2/24), 70.8% were White (17/24), 8.3% reported more than 1 race (2/24), and 12.5% reported other/unspecified (3/24). For their self-reported ethnicity, 12.5% identified as Hispanic/Latinx (3/24) and 87.5% identified as not Hispanic/Latinx (21/24).

Discussion

Principal Findings

This study details the creation, implementation, and refinement of a process to routinely screen for DD in youth with T1D and their caregivers using a digital health platform. Furthermore, we present descriptive information for those who completed screening. During the 1-year screening period, screening rates for DD were relatively stable, and lower than our initial goals. Approximately 10% of youth and 11% of caregivers who completed screening were identified as having elevated DD. Most of these families were appropriately sent resources via EHR when DD was identified, with 1 patient not flagged prior to an automated BPA being placed. Iterative processes allowed for improvements to be made in the way families with DD were screened and identified using our institutional app, and for resources to be appropriately shared in the families through the digital health platform. Additional suggestions for quality improvement (QI) processes to increase DD screening as well as relevant clinical implications can now be trialed based on findings and lessons learned during this initial 1-year screening period.

Challenges with Screening Implementation

We identified several challenges to screening families using our institutional app, some that were corrected and others that inform future QI initiatives and clinical research. First, while the automated system was coded to assign the DD screening tools to children aged at least 8 years and those younger than 13 years, for a brief period the questionnaires were incorrectly sent to all pediatric patients or parents seen for diabetes associated visit types in endocrinology. Once identified, this error was corrected. However, the error reoccurred following a later system update and because the system assigns questionnaires at the time an appointment is scheduled (sometimes 6 or more months in advance), the clinic experienced a backlog of incorrectly assigned questionnaires intermittently throughout the first 9 months of the screening period. For the current analyses, children and parent or caregivers who incorrectly received the questionnaires due to age were not included. Nevertheless, the error had clinical implications in that some children and parents or caregivers who were outside of the PAID-C normative age range were identified as distressed and sent electronic resources in line with our procedures.

Second, with our institutional app and its supporting automated system, we could only assign the DD screening tools to children aged 8 - 12.99 years (and their caregiver) with a visit type "Diabetes NP w/Care Team" or "Diabetes FP w/Care Team". These visit types are not coded to differentiate between different diabetes diagnoses. Although DD is also observed in persons with type 2 diabetes, the screening tools we used are not validated for families of youth with type 2 diabetes. In the 1-year screening period, there were 4 elevated PAID-C surveys and 4 elevated P-PAID-C surveys associated with youth with type 2 diabetes or prediabetes. These could represent false-positive results. Thus, if using an automated system to assign a clinical screening tool, it may be important to identify a solution for assigning screeners with greater specificity.

Third, while the initial system for manually reviewing screening results and sending electronic resources to families who had an elevated screen was generally effective, 1 child was not immediately identified and therefore did not receive resources in response to his or her elevated score in a timely manner. Although this represented <5% of total population that screened as elevated, it highlighted the need for an automated BPA process in the EHR to promote greater accuracy and improve response time when sending resources to families. Unfortunately, upon implementing the automated BPA, we identified a new problem, as clinical providers had the ability to close the BPAs without sending families electronic resources. Thus, the lesson learned was also the value of providing ongoing provider education about screening processes in clinic so that these alerts could be appropriately responded to.

Fourth, while 73.6% of families in the endocrinology division were signed up for the Nemours app during the screening year, 30.6% of families who started the "GetReady" paperwork did not complete it before their appointment, thus limiting the number of families screened for DD. While specific reasons for incomplete paperwork were not collected, it can be hypothesized that the length of time to complete "GetReady" paperwork, which included our DD screeners, as well as other standardized paperwork, may have exceeded family availability. Also, as part of the "GetReady" system, we learned that new surveys added to the system are placed at the end of the queue and the order cannot by adjusted. Thus, it is likely that the DD screeners were at the end or near the end of the package of surveys assigned to families. It may be more effective to use an institutional app for routine DD screening if it is possible to toggle the order of surveys so that the clinic can ensure that families receive the screeners earlier in their web-based paperwork.

Notably, the number of families signed up for our institutional app has increased in 3 years since becoming available (from about 25% of families enrolled to current rates). In part, the Covid-19 pandemic and related concerns [14] spurred enrollment, as telehealth functionality is built directly into the app; and many divisions at this institution, including endocrinology, have set annual goals to increase app enrollment. However, it warrants comment that to create and support a process to routinely screen for DD in youth with T1D and their caregivers using a digital health platform, it is important to select a digital health platform that families are willing to use.

Future Directions

We plan to (1) implement a series of QI cycles to increase DD screening rates (these QI cycles will focus on current screening processes in the institutional app, as well as processes that are not app reliant if feasible, for example, integrating screening during clinic appointments); (2) expand screening to other

XSL•FO
RenderX

endocrinology clinic locations within our multisite medical system; (3) create and implement a system to track follow-through on resources or recommendations sent to those with elevated DD; and (4) include options for Spanish-language speakers to receive and complete DD screening, with the eventual goal for this to be integrated into the institutional app when the app is available in Spanish. Our third goal is of particular importance given the increasing rates of T1D among Hispanic/Latinx children [1], and Hispanic youth have been identified as having the highest rates of mental health needs per Youth Risk Behavior Surveillance data [15]. The Problem Areas in Diabetes Survey—Pediatric Version (PAID-Peds) was recently normed for Spanish speakers [16], with the Spanish version of the Problem Areas in Diabetes Survey—Parent Revised (PAID-PR) also validated [17]. Improving distress screening in Spanish-speaking youth and families may assist in decreasing disparities in treatment access for mental health needs.

Relatively low rates of elevated DD were observed for the children or the caregivers in the current report. In the future, a less stringent cutoff for DD may be needed to better identify families and direct provision of referrals and resources; cut point studies may be warranted. Furthermore, given challenges previously noted specific to completion rates, it is possible that those families experiencing higher levels of distress were less likely or able to complete GetReady paperwork. Alternative methods to screen families who do not complete previsit paperwork may be necessary to improve completion rates and to identify or respond to DD. It will be important to increase buy-in at the institutional and provider level to increase opportunities to complete screening during clinical visits.

Conclusions

DD screening is recommended by the ISPAD and the ADA as part of standards of care [2]; however, it is not consistently applied across institutions (currently, the US News & World Report review of pediatric health systems tracks only the inclusion of depression screening in youth aged 13 - 18 years [18]). Given that depression is identified at lower rates than DD in populations with T1D, especially for preadolescent age groups [8,9], that DD and depression screening are not interchangeable, and that DD may play a stronger role in predicting HbA_{1c}, many pediatric endocrinology clinics are missing valuable screening opportunities to direct patient care and impact health outcomes if they are screening only for depression. Our findings indicate that DD education, screening, and response can be integrated via digital platforms in a pediatric endocrinology clinic, facilitating timely treatment referral and provision of resources for those identified with distress. Of note, mean child HbA_{1c} for those with elevated DD in our sample (mean 8.04%, SD 1.72%) was higher than the mean HbA_{1c} for the larger sample of youth aged 8 - 12.99 years with T1D seen in the endocrinology clinic (mean 7.75%, SD 1.46%), and higher than the clinical target of <7.0% recommended by the ADA [2]. This further emphasizes the importance of evaluating DD and providing appropriate resources and interventions in pediatric endocrinology settings.

Acknowledgments

The authors acknowledge the support of the US National Institutes of Health and the National Institute of Diabetes and Digestive and Kidney Diseases (grant R01DK127493). They thank the collaborators on this project as well as the Digital Health Product team at Nemours Children's Health for their support and contributions.

Authors' Contributions

NAK collected and analyzed data and wrote the first draft of the manuscript. NAK and SRP collaboratively reviewed and edited the manuscript. LAF and MB contributed to discussions and manuscript review.

Conflicts of Interest

LAF receives material research support from Dexcom unrelated to this protocol. LAF is an advisory board member for Ki Health and receives honoraria and stock options. MB is a consultant for Arbor and Tolmar Pharmaceuticals. He receives salary and stock options as an advisory board member of Ki Health and receives research support from Novo-Nordisk, Sanofi/Provention-Bio, Beta Bionics, and Diurnal. The remaining authors report no conflicts of interest.

References

1. Lawrence JM, Divers J, Isom S, et al. Trends in prevalence of type 1 and type 2 diabetes in children and adolescents in the US, 2001-2017. JAMA 2021 Aug 24;326(8):717-727. [doi: 10.1001/jama.2021.11165] [Medline: 34427600]
2. ElSayed NA, Aleppo G, Aroda VR, et al. 14. Children and adolescents: standards of care in diabetes—2023. Diabetes Care 2023 Jan 1;46(Suppl 1):S230-S253. [doi: 10.2337/dc23-S014] [Medline: 36507640]
3. Delamater AM, de Wit M, McDarby V, et al. ISPAD Clinical Practice Consensus Guidelines 2018: psychological care of children and adolescents with type 1 diabetes. Pediatr Diabetes 2018 Oct;19(Suppl 27):237-249. [doi: 10.1111/pedi.12736] [Medline: 30058247]
4. de Wit M, Gajewska KA, Goethals ER, et al. ISPAD Clinical Practice Consensus Guidelines 2022: psychological care of children, adolescents and young adults with diabetes. Pediatr Diabetes 2022 Dec;23(8):1373-1389. [doi: 10.1111/pedi.13428] [Medline: 36464988]

XSL•FO
RenderX

5. Kreider KE. Diabetes distress or major depressive disorder? A practical approach to diagnosing and treating psychological comorbidities of diabetes. Diabetes Ther 2017 Feb;8(1):1-7. [doi: 10.1007/s13300-017-0231-1] [Medline: 28160185]
6. Hendrieckx C, Halliday JA, Beeney LJ. Diabetes and Emotional Health: A Practical Guide for Health Professionals Supporting Adults with Type 1 or Type 2 Diabetes, 3rd edition: American Diabetes Association; 2021.
7. Evans MA, Weil LEG, Shapiro JB, et al. Psychometric properties of the parent and child problem areas in diabetes measures. J Pediatr Psychol 2019 Jul 1;44(6):703-713. [doi: 10.1093/jpepsy/jsz018] [Medline: 30920628]
8. Silverstein J, Cheng P, Ruedy KJ, et al. Depressive symptoms in youth with type 1 or type 2 diabetes: results of the pediatric diabetes consortium screening assessment of depression in diabetes study. Diabetes Care 2015 Dec 1;38(12):2341-2343. [doi: 10.2337/dc15-0982]
9. Wasserman RM, Eshtehardi SS, Anderson BJ, Weissberg-Benchell JA, Hilliard ME. Profiles of depressive symptoms and diabetes distress in preadolescents with type 1 diabetes. Can J Diabetes 2021 Jul;45(5):436-443. [doi: 10.1016/j.jcjd.2021.01.012] [Medline: 33771448]
10. Abdoli S, Jones DH, Vora A, Stuckey H. Improving diabetes care: should we reconceptualize diabetes burnout? Diabetes Educ 2019 Apr;45(2):214-224. [doi: 10.1177/0145721719829066] [Medline: 30739546]
11. Snoek FJ, Bremmer MA, Hermanns N. Constructs of depression and distress in diabetes: time for an appraisal. Lancet Diabetes Endocrinol 2015 Jun;3(6):450-460. [doi: 10.1016/S2213-8587(15)00135-7] [Medline: 25995123]
12. Guttmann-Bauman I, Thornton P, Adhikari S, et al. Pediatric endocrine society survey of diabetes practices in the United States: what is the current state? Pediatr Diabetes 2018 Aug;19(5):859-865. [doi: 10.1111/pedi.12677] [Medline: 29582520]
13. Corathers S, Williford DN, Kichler J, et al. Implementation of psychosocial screening into diabetes clinics: experience from the type 1 diabetes exchange quality improvement network. Curr Diab Rep 2023 Feb;23(2):19-28. [doi: 10.1007/s11892-022-01497-6] [Medline: 36538250]
14. Monzon A, Kahhan N, Marker A, Patton S. Challenges and considerations for reducing diabetes distress and fear of hypoglycemia in parents of youth with type 1 diabetes during the COVID-19 pandemic. JMIR Pediatr Parent 2021 Apr 23;4(2):e25106. [doi: 10.2196/25106] [Medline: 33848256]
15. Eaton DK, Kann L, Kinchen S, et al. Youth risk behavior surveillance—United States, 2009. MMWR Surveill Summ 2010 Jun 4;59(5):1-142. [Medline: 20520591]
16. Casanovas-Marsal JO, Civitani Monzón E, Ferrer Duce MP, et al. Translation and psychometric evaluation of the Spanish version of the problem areas in diabetes-pediatric version (PAID-Peds) survey. Diabetol Metab Syndr 2023 Oct 30;15(1):219. [doi: 10.1186/s13098-023-01199-3] [Medline: 37899434]
17. Beléndez M. Estrés en madres y padres de niños/as con diabetes: validación de la versión española de la escala Problem Areas in Diabetes (PAID-PR). Stress in mothers and fathers of children with diabetes: validation of the Spanish version of the Problem Areas in Diabetes (PAID-PR) Scale. Ans y Estrés 2018 Jul;24(2-3):136-139. [doi: 10.1016/j.anyes.2018.06.001]
18. Olmsted MG, Powell R, Murphy J, et al. Methodology: U.S. News & World Report 2022-2023 best hospitals: specialty rankings. : U.S. News & World Report; 2022 URL: https://health.usnews.com/media/best-hospitals/BH_Methodology_2022-23 [accessed 2025-01-29]

Abbreviations

ADA: American Diabetes Association
BPA: best practice alert
DD: diabetes distress
EHR: electronic health record
HbA_{1c}: glycated hemoglobin A_{1c}
ISPAD: International Society for Pediatric and Adolescent Diabetes
P-PAID-C: Parent Problem Areas in Diabetes-Child
PAID: Problem Areas in Diabetes
PAID-C: Problem Areas in Diabetes-Child
PAID-Peds: Problem Areas in Diabetes Survey—Pediatric Version
PAID-PR: Problem Areas in Diabetes Survey—Parent Revised
QI: quality improvement
T1D: type 1 diabetes

XSL•FO
RenderX

Edited by A Serlachius; submitted 05.08.24; peer-reviewed by JP Totka; revised version received 09.12.24; accepted 10.12.24; published 06.02.25.

Please cite as:
Kahhan NA, Fox LA, Benson M, Patton SR
Implementing Diabetes Distress Screening in a Pediatric Endocrinology Clinic Using a Digital Health Platform: Quantitative Secondary Data Analysis
JMIR Pediatr Parent 2025;8:e65107
URL: https://pediatrics.jmir.org/2025/1/e65107
doi:10.2196/65107

© Nicole A Kahhan, Larry A Fox, Matthew Benson, Susana R Patton. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 6.2.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Enhancing Effect of eHealth Use on the Associations Between Social Supports and Well-Being in Japanese Employed Women Providing Childcare or Care: Bayesian Structural Equation Modeling Study

Noyuri Yamaji[1,2,3], PhD; Daisuke Yoneoka[4], PhD; Daichi Suzuki[2,5], MNSc; Kiriko Sasayama[6], PhD; Erika Ota[2], PhD; Etsuko Nishimura[2,7], PhD; Hisateru Tachimori[5,8], PhD; Eiko Saito[6], PhD

[1]Institute of Clinical Epidemiology, Showa Medical University, Tokyo, Japan

[2]Global Health Nursing, Graduate School of Nursing, St. Luke's International University, Tokyo, Japan

[3]Department of Family Nursing, Division of Health Sciences and Nursing, Graduate School of Medicine, The University of Tokyo, Tokyo, Japan

[4]Department of Epidemiology, Japan Institute for Health Security, Tokyo, Japan

[5]Institute for Global Health Policy Research, Bureau of Global Health Cooperation, Japan Institute for Health Security, Tokyo, Japan

[6]Sustainable Society Design Center, Graduate School of Frontier Sciences, The University of Tokyo, Chiba, Japan

[7]Faculty of Nursing, Komazawa Women's University, Tokyo, Japan

[8]Department of Health Policy and Management, Keio University School of Medicine, Tokyo, Japan

Corresponding Author:
Noyuri Yamaji, PhD
Institute of Clinical Epidemiology
Showa Medical University
1-5-8 Hatanodai
Shinagawa-ku
Tokyo, 1428555
Japan
Phone: 81 337848892
Email: yamaji.n@med.showa-u.ac.jp

Abstract

Background: The increasing prevalence of information and communication technologies has made health-related information and social support more accessible on the web. However, limited evidence exists on how eHealth and social support affect the well-being of employed women who also serve as caregivers in Japan.

Objective: This study aimed to assess the relationship between social support and well-being among employed Japanese women providing childcare or caregiving and explore eHealth use's role in enhancing this relationship.

Methods: We conducted a cross-sectional study using secondary data analysis from a nationwide web-based questionnaire survey of 10,000 employed women aged 20-65 years, administered from February 28, 2023, to March 7, 2023. The primary study used a quota random sampling approach based on age and geographic area from the research company's panel. For this analysis, we focused on a subgroup of 2456 women who reported either caring for children less than 7 years old or providing other caregiving responsibilities. We employed a Bayesian structural equation model to estimate the enhancing effect of eHealth on the relationship between social support and 4 well-being indicators: life satisfaction, worthwhileness, happiness, and anxiety.

Results: Among the 2456 employed women included, 1784 (72.6%) received social support and 1635 (66.6%) obtained health-related information via eHealth. Bayesian structural equation model analysis revealed that the standardized total effects of social support on well-being were 0.20 (95% CI 0.13-0.27) in the group without eHealth use and 0.47 (95% CI 0.45-0.50) in the group with eHealth use.

Conclusions: The findings suggest that eHealth may enhance the positive impact of social support on the well-being of employed Japanese women providing childcare or caregiving. This study highlights the potential of eHealth interventions in supporting social support and well-being among working women with caregiving responsibilities in Japan.

XSL•FO
RenderX

(JMIR Pediatr Parent 2025;8:e68119) doi:10.2196/68119

KEYWORDS

eHealth; social support; well-being; women's health; caregivers; working women

Introduction

Well-being is defined as a multifaceted concept encompassing happiness, satisfaction, personal growth, fulfillment, and contribution to the community [1]. It includes physical, emotional, and social dimensions and is a key factor in determining women's productivity and quality of life. While employment has been shown to improve women's well-being [2], it also exposes them to adverse effects from work-family conflict [3]. Women in the prime of their working lives face various health challenges, including mental health issues, work-related illnesses, and reproductive health concerns [4]. Working women with childcare or older adult care responsibilities must balance their work and home lives, and this double burden affects their well-being [5,6].

Social support, a key factor in maintaining well-being, traditionally comes from family, friends, and the community [7]. Social support from family and friends plays a pivotal role in maintaining physical and mental health. This multifaceted concept revolves around interpersonal interactions, wherein individuals perceive reliable connections with friends or family members on whom they can depend during favorable and challenging circumstances [8]. Good social relationships provide emotional and practical resources essential for feeling nurtured and esteemed, consequently fostering healthier lifestyles [9]. Social support has protective physical and mental effects [10]. Although social support from partners is essential [11], approximately 90% of households with children in Japan are nuclear families [12]. The traditional sources of social support may be limited for many working women. This situation creates a need for alternative forms of support, particularly for those balancing work with childcare or older adult care responsibilities.

The rapid digitalization of Japanese society has also opened new avenues for addressing this need. In Japan, with over 90% of the working-age population using the internet and about 80% engaging with social networking services [13], eHealth has emerged as a promising solution. eHealth refers to the cost-effective and secure use of information and communication technologies (ICT) to support health and health-related fields [14]. The dissemination of health information via the internet has expanded in recent years and information on social support has also increased [15]. Recent trends indicate that social support is being increasingly accessed and provided on the web through various digital platforms and social networks. For example, several interventions have been developed that incorporate social support content using group phone calls or applications [16,17].

This shift reflects a broader societal change toward digital communication, which enables individuals to access information and community and emotional support without geographical constraints [18]. Internet-based social support has shown potential in enhancing well-being by providing immediate access to resources and reducing social isolation [19]. It is also known as an important form of social support. These eHealth tools may provide crucial social support and be valuable for working women facing time constraints and the social stigma associated with seeking help. However, these tools are primarily designed for specific groups, such as pregnant women or women with health issues. Few studies specifically targeting working women exist.

In addition, cultural differences must be considered when implementing eHealth interventions. Cultural perspectives on the self differ between Western and Eastern societies. In Western cultures, there is a tendency to view individuals as autonomous entities. Conversely, Eastern cultures often conceptualize the self as intrinsically interconnected with others, emphasizing social relationships and collective harmony [20]. This fundamental difference in self-perception influences various aspects of social behavior. A previous study found cultural differences in the emotional correlates of social support receipt across countries, highlighting the importance of considering cultural context when examining social support interventions. In addition, seeking social support might help the Japanese reduce loneliness [21].

Given Japan's unique cultural and societal context, including its high technological adoption rate, it is necessary to understand how social support and eHealth use interact to influence the well-being of working women with caregiving responsibilities. However, there have been limited studies on the relationship between social support and well-being among employed women raising children or caring for them and the relationship between the use of eHealth medical information in Japan. Therefore, this study aimed to fill this gap by evaluating the relationship between social support and well-being among employed women providing childcare or caregiving and the enhancing effect of eHealth use on this relationship. We hypothesized that individuals who use eHealth services will have improved well-being because they receive support from internet-based communities in addition to support from close family and friends. In this study, we hypothesized that the enhancing variable, "eHealth use," would influence the direct effect of "social support" on "well-being."

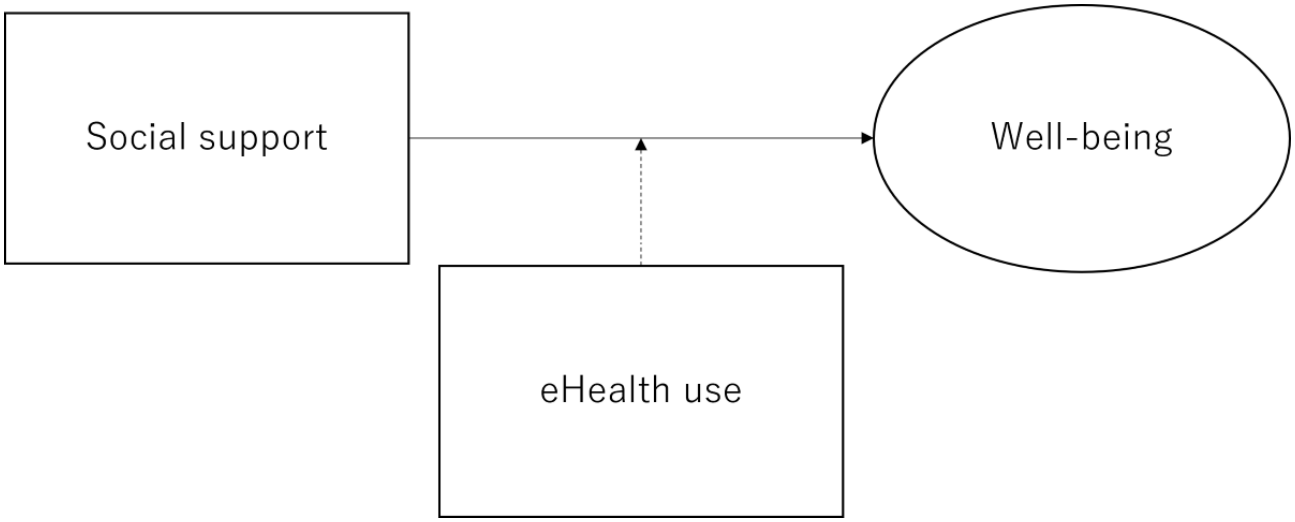
Methods

Study Design

This is a cross-sectional study using secondary data from a web-based nationwide questionnaire survey conducted from February 28, 2023, to March 7, 2023 [22]. Figure 1 illustrates the hypothetical model of the Bayesian structural equation model (BSEM).

XSL•FO
RenderX

Figure 1. Hypothetical model.



Participants and Data

The data used in this study were obtained from a nationwide survey of 10,000 employed women aged 20-65 years in Japan using a questionnaire developed for the previous study [22]. This primary study included participants who met the following criteria: (1) being 20-65 years old, (2) being employed, and (3) being able to provide informed consent. Students were excluded. A research company conducted recruitment and data collection using a web-based questionnaire. This company used its extensive nationwide panel, which includes women from diverse backgrounds across all 47 prefectures of Japan. A link containing the study introduction and the questionnaire was sent to the company's research panel. We stratified the age categories and prefectures for recruitment to improve sample diversity. A questionnaire was distributed using the web-based platform of a professional research company. The first page of the questionnaire contained an informed consent form and the participants could access the questionnaire by checking the agreement button at the end of the page. A structured questionnaire contained questions about demographics (eg, age, sex, and comorbidities), socioeconomic status, social support, health status, well-being, and eHealth. All monetary values originally reported in Japanese yen were converted to US dollars using the average exchange rate at the time of data collection, which was 1 JPY=0.0069 USD. The participants required approximately 10-15 minutes to complete the entire questionnaire. Eligible participants could then choose to respond to the questionnaire.

From the initial 10,000 respondents, participants for this study were selected based on the following criteria: women raising or caring for children aged <7 years were included in the analysis. Those who met these criteria were included in the final analysis.

Measures and Outcomes

Well-Being

The Office for National Statistics (ONS)-4 questionnaire, developed by the United Kingdom Office for National Statistics, was used to measure personal well-being [23]. This questionnaire consists of 4 items: life satisfaction, worthwhileness, happiness, and feelings of anxiety. The participants were instructed to rate their well-being on a scale of 0-10. For life satisfaction, feeling that things done in life are worthwhile and happiness scores are categorized as low (0-4), medium (5-6), high (7-8), and very high (9-10). Feelings of anxiety were categorized as very low (0-1), low (2-3), medium (4-5), or high (6-10). The scores were analyzed using these threshold categories [23].

Social Support

The participants were asked multiple-choice questions about the people or groups who supported them in child and nursing care, which we calculated using dichotomous data: yes or no support.

Usage of eHealth

In this study, eHealth use was defined as obtaining health-related information through ICT. The participants were asked how they obtained health-related information. The choices included medical professionals, health events, books (newspapers, scientific journals, and scientific papers), television, internet news, internet search engines, social network services, medical information sites, blogs, information from the government and local government, family, friends, and others. If the participants selected ICT-enabled health care services from the options (eg, internet news, internet search engines, social network services, medical information sites, and blogs), we recorded them as dichotomous data for eHealth use (yes or no).

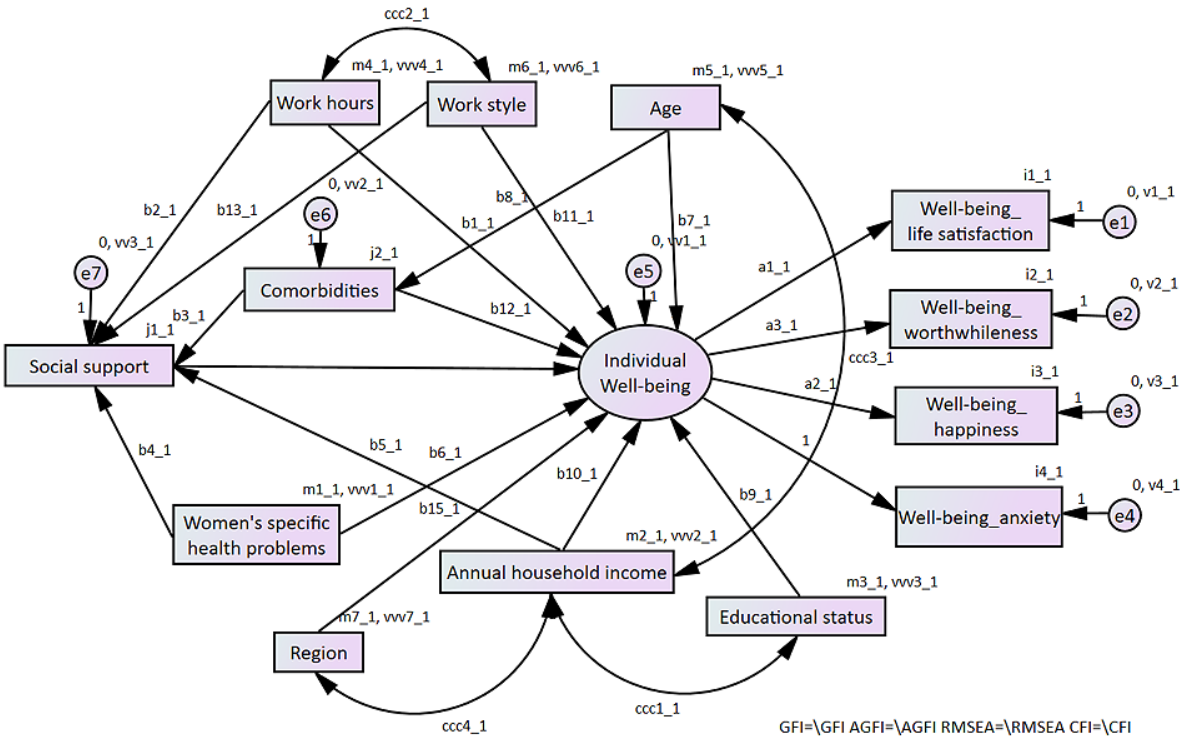
Statistical Analysis

First, a descriptive analysis was performed to examine participant background characteristics and well-being. The Kendall rank correlation coefficient was used to confirm the latent variables that should be considered in addition to the hypothetical model. We selected confounders shown in previous studies to be associated with well-being and social support [24-30], including age, region, educational status, annual household income, work style, work hours, comorbidities, and specific health problems (Figure 2). A BSEM was used to assess the enhancing effect of eHealth usage on the relationship between social support and the 4 well-being items. We adopted

XSL•FO
RenderX

the BSEM approach because it accommodates smaller sample sizes [31] and allows for a natural and explicit representation of Likert scales and binary latent variables [32,33]. The BSEM assumes one latent variable encompassing 4 well-being items and their correlated residuals (Figure 2). Based on the structure, we grouped the participants using eHealth and presented the results separately. We estimated the parameters in the BSEM for the groups with and without eHealth use, respectively. In addition, the ONS-4 data are ordinal scale, and treating them as normally distributed metric values is considered inappropriate. Therefore, we analyzed them using an ordered probit model, assuming the latent variable follows a standard normal distribution, which is appropriate for modeling binary outcomes. The prior distribution was set as a standard normal distribution, reflecting the assumption that the coefficients are centered around zero. We estimated the total standardized effects as path coefficients and their 95% CIs. The standardized total effect normalized the total effect by considering the ratio of the SDs of social support to well-being. The posterior distribution was derived using the Markov Chain Monte Carlo algorithm. The path coefficient was considered significant if the 95% CI excluded zero. The maximum number of iterations was set to 100,000 with 500 burn-in iterations. We judged that the algorithm converged after 100,000 sampling iterations, as determined by a convergence statistic below the threshold of 1.002 [34]. The estimated model was evaluated by the deviance information criterion. Finally, we performed the sensitivity analysis concerning model specifications involved in testing alternative model structures by omitting paths and latent variables to ensure the robustness of the results. Specifically, we confirmed that the standardized coefficients among well-being, eHealth, and other variables did not significantly change by omitting region and work hours and the paths that were linked to them, respectively. All statistical analyses were performed using the SPSS Statistics (version 29.0.1; IBM Corp) software and SPSS Amos (version 29.0; IBM Corp), and a *P* value of <.05 was considered statistically significant.

Figure 2. Preidentified structural model.



Ethical Considerations

This study was approved by the Research Ethics Committee of St. Luke's International University (reference number 22-A089). All participants provided informed consent on the web and the study data were collected anonymously. The research company offered the participants shopping points as rewards.

Results

Demographic Characteristics

Table 1 presents the demographic characteristics of the 2456 women who met the inclusion criteria. The table includes information on age, occupation, region, educational status, annual household income, work style, daily working hours, comorbidities, and women's specific health problems.

XSL•FO
RenderX

Table 1. Demographic characteristics (N=2456).

Variable and classification	Values	eHealth use		*P* value
		With (n=1635)	Without (n=821)	
Age (years), mean (SD)	38.3 (8.9)	37.7 (9.2)	38.6 (8.8)	
Age (years), n (%)				.09
20-30	479 (19.5)	293 (17.9)	186 (22.7)	
30-40	844 (34.4)	572 (35.0)	272 (33.1)	
40-50	860 (35.0)	581 (35.5)	279 (34.0)	
50-60	209 (8.5)	144 (8.8)	65 (7.9)	
60-65	64 (2.6)	45 (2.8)	19 (2.3)	
Occupation, n (%)				.18
Management or executive	26 (1.1)	18 (1.1)	8 (1.0)	
Company employee (full-time)	979 (39.9)	662 (40.5)	317 (38.6)	
Company employee	111 (4.5)	67 (4.1)	44 (5.4)	
Company employee (temporary employee)	80 (3.3)	58 (3.5)	22 (2.7)	
Public employee (excluding teaching staff)	87 (3.5)	54 (3.3)	33 (4.0)	
Faculty member	89 (3.6)	60 (3.7)	29 (3.5)	
Health care provider	209 (8.5)	123 (7.5)	86 (10.5)	
Professional	7 (0.3)	5 (0.3)	2 (0.2)	
Independent business or self-employed workforce	109 (4.4)	80 (4.9)	29 (3.5)	
Part-time work	759 (30.9)	508 (31.1)	251 (30.6)	
Region, n (%)				.30
Hokkaido, Tohoku	342 (13.9)	213 (13.0)	129 (15.7)	
Kanto	879 (35.8)	605 (37.0)	274 (33.4)	
Tokai	326 (13.3)	44 (2.7)	24 (2.9)	
Hokuriku	68 (2.8)	205 (12.5)	121 (14.7)	
Kinki	421 (17.1)	281 (17.2)	140 (17.1)	
Chugoku	137 (5.6)	95 (5.8)	42 (5.1)	
Shikoku	62 (2.5)	45 (2.8)	17 (2.1)	
Kyuusyu, Okinawa	221 (9.0)	147 (9.0)	74 (9.0)	
Educational status, n (%)				.11
Elementary school	34 (1.4)	24 (1.5)	10 (1.2)	
High school	494 (20.1)	314 (19.2)	180 (21.9)	
Associate degree	340 (13.8)	241 (14.7)	99 (12.1)	
Diploma	471 (19.2)	297 (18.2)	174 (21.2)	
University bachelor	1024 (41.7)	693 (42.4)	331 (40.3)	
MSc or PhD	93 (3.8)	66 (4.0)	27 (3.3)	
Annual household income[a], n (%)				.01
<2,000,000 JPY (US $13,800)	171 (7.0)	98 (6.0)	73 (8.9)	
2,000,000-4,000,000 JPY (US $13,800-27,600)	406 (16.5)	263 (16.1)	143 (17.4)	
4,000,000-6,000,000 JPY (US $27,600-41,400)	604 (24.6)	415 (25.4)	189 (23.0)	
6,000,000-8,000,000 JPY (US $41,400-55,200)	513 (20.9)	329 (20.1)	184 (22.4)	
8,000,000-10,000,000 JPY (US $55,200-69,000)	389 (15.8)	257 (15.7)	132 (16.1)	
≥10,000,000 JPY (US $69,000)	372 (15.1)	272 (16.6)	100 (12.2)	

XSL•FO
RenderX

Variable and classification	Values	eHealth use		*P* value
		With (n=1635)	Without (n=821)	
Missing	1 (—[b])	—	—	
Work style, n (%)				.02
Day shift	2252 (91.7)	1513 (92.5)	739 (90.0)	
Night shift	204 (8.3)	122 (7.5)	82 (10.0)	
Daily working hours , n (%)				.40
<8	1908 (77.7)	1262 (77.2)	646 (78.7)	
≥8	548 (22.3)	373 (22.8)	175 (21.3)	
Comorbidities[c], n (%)				.06
Without	1934 (78.8)	1269 (77.7)	665 (81.0)	
With	521 (21.2)	365 (22.3)	156 (19.0)	
Women's specific health problems[d], n (%)				<.01
Without	835 (34.0)	437 (26.7)	398 (48.5)	
With	1620 (66.0)	1197 (73.3)	423 (51.5)	
Missing	1 (—)	—	—	

[a]As of May 2025, a currency exchange rate of 1 JPY=US $0.0069 was applicable.

[b]Not available.

[c]Comorbidities include hypertension, heart disease, atherosclerotic disease, diabetes mellitus, hyperlipidemia, and chronic kidney disease.

[d]Women's specific health problems include menstrual symptoms and illnesses, premenstrual syndrome, cancers common in women (eg, cervical, uterine, ovarian, and breast cancer), pregnancy- and childbirth-related symptoms, menopausal disorders, mental disorders, insomnia, infertility, endometriosis, benign female tumors, blood flow disorders, anemia, gastrointestinal disorders, headaches and migraines, underweight status, nutritional disorders, autoimmune diseases, and pelvic floor symptoms and diseases.

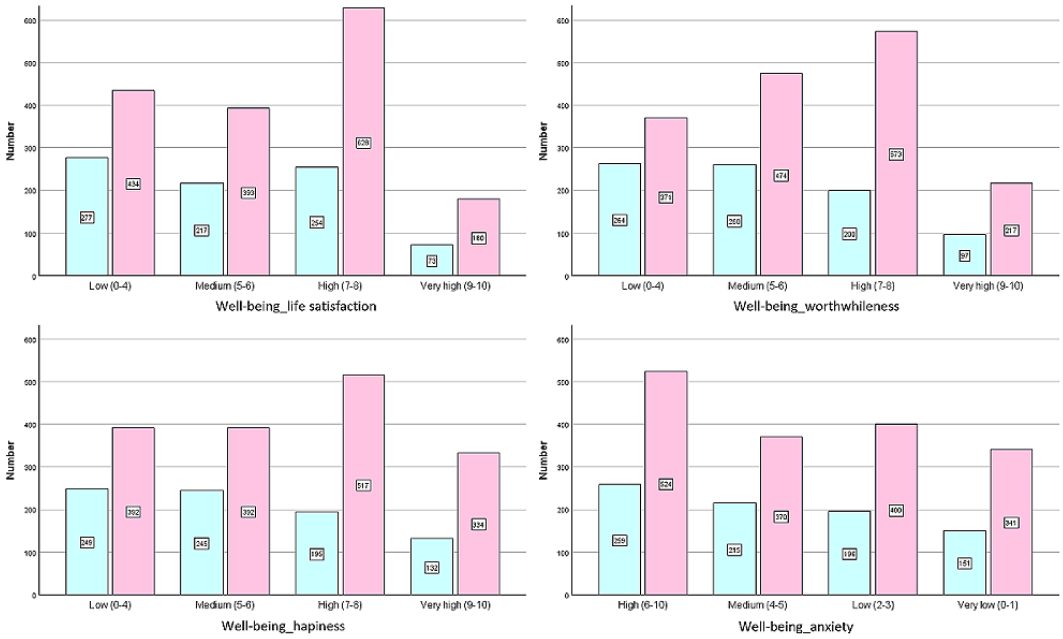
Approximately 70% of the participants were in their 30s and 40s. About 40% of participants were employed by a company and worked full-time. Most participants lived in the Kanto region, followed by Kinki, with the fewest residing in Tokai and Shikoku. Approximately half of the participants had graduated from graduate school or university. Most participants reported middle-class household incomes, with the most common range being upper-middle income (4-6 million yen [US $27,600-41,400] annually). This was followed by households with middle-high income (6-8 million yen [US $41,400–55,200]) and lower-middle income (2-4 million yen [US$ 13,800-27,600]). A notable portion, 372 (15.1%) participants, belonged to high-income households, earning over 10 million yen (over US $69,000) annually. The Kanto region had a higher concentration of high-income households, with 194/879 (22.1%) of participants from this area reporting annual incomes over 10 million yen (over US $69,000). Approximately 204/2456 (8.3%) participants worked night shifts, and 548/2456 (22.3%) participants worked an average of ≥8 hours per day. A total of 521 out of 2456 (21.2%) participants had comorbidities. More than half of the participants (1620/2456, 66% women) answered that they were experiencing symptoms that are common in women, such as premenstrual syndrome, female-specific cancers (uterine cancer and breast cancer), pregnancy-related issues, menopausal disorders, and mental disorders. Of the 2456 participants, 2123 (86.4%) had obtained health-related information in some form, including through means other than the internet, and 1635 out of 2456 (66.6%) had obtained health-related information through eHealth. The breakdown of eHealth sources was as follows: search engines (1003/2456, 40.8%), internet (851/2456, 34.6%), social networking service (744/2456, 30.3%), medical information sites (137/2456, 5.6%), and blogs (126/2456, 5.1%).

Profiles and Correlations of Measures

In terms of well-being, 711 out of 2456 (28.9%) participants reported low life satisfaction, 635 out of 2456 (25.9%) felt their lives were less worthwhile, and 641 out of 2456 (26.1%) had low happiness. Conversely, 253 out of 2456 (10.3%), 314 out of 2456 (12.8%), and 466 out of 2456 (19.0%) participants reported high scores for life satisfaction, feeling worthwhile, and happiness, respectively. In addition, 783 out of 2456 (31.9%) participants experienced high anxiety, whereas 492 out of 2456 (20.0%) reported low anxiety (Figure 3). Social support was reported by 1784 out of 2456 (72.6%) women. Table 2 presents the correlation coefficients between eHealth use, social support, and well-being measures. Significant correlations were found between well-being, social support, and eHealth use, although the effect size was small (Table 2).

XSL•FO
RenderX

Figure 3. Well-being classification by presence or absence of eHealth.



XSL•FO
RenderX

Table 2. Correlation matrix (N=2456).

Variables	Values	1	2	3	4	5	6
eHealth use							
n (%)	1635 (66.6)						
Correlation, tau_b		__[a]					
P value		—					
Social support							
n (%)	1784 (72.6)						
Correlation, tau_b		.165	—				
P value		<.01	—				
Well-being							
Life							
Mean (SD)	2.28 (0.99)						
Correlation, tau_b		.084	.127	—			
P value		<.01	<.01	—			
Value							
Mean (SD)	2.31 (0.99)						
Correlation, tau_b		.105	.123	.715	—		
P value		<.01	<.01	<.01	—		
Happiness							
Mean (SD)	2.40 (1.07)						
Correlation, tau_b		.094	.132	.678	.658	—	
P value		<.01	<.01	<.01	<.01	—	
Anxiety							
Mean (SD)	2.32 (1.12)						
Correlation, tau_b		.02	.112	.188	.152	.196	—
P value		.296	<.01	<.01	<.01	<.01	—

[a]Not available.

Enhancing Effects of eHealth Use

The direct effects of associations between well-being and social support, as BSEM, differed depending on eHealth use. Among participants without eHealth use, the standardized total effects were 0.20 (95% CI 0.13-0.27, SE 0.00, SD 0.03), with a convergence diagnostic value of 1.00. In contrast, for those with eHealth use, the standardized total effect was higher at 0.47 (95% CI 0.45-0.50, SE 0.00, SD 0.01), with the same convergence diagnostic value of 1.00. The posterior predictive distribution *P* value was .50 and the deviance information criterion was 19,262.24, suggesting strong predictive validity of the model. The sensitivity analysis showed that the key relationships in the original model were robust to these changes as the estimated path coefficients and factor loadings varied only marginally. This result suggests that the model's conclusions are not dependent on specific assumptions regarding the model structure.

Discussion

Summary of Study Findings

This study examined the characteristics of participants and the relationship among well-being, social support, and eHealth use among employed women providing childcare or care. In this study, eHealth use enhanced the relationship between social support and well-being, with higher standardized total effects observed in the group that used eHealth compared to those that did not. Our findings align with recent research on eHealth interventions, demonstrating their positive impact on social support and well-being. A study suggested that social media use was positively associated with perceived responsiveness in internet-based social networks, which improved perceived social support and was linked to reduced loneliness and increased life satisfaction [19]. Furthermore, DeHoff et al [35] showed that internet-based social support might enhance participants' belief in being supported, leading to improved health behaviors. These findings suggest that eHealth use may contribute to improved well-being by facilitating access to social support and enhancing

XSL•FO
RenderX

individuals' perception of being supported. It might be particularly effective for working women who have limited time due to childcare or caregiving responsibilities.

Social support refers not only to the receipt of support but also to an individual's perception of support from family, friends, and significant others in their lives [36,37]. Current research suggests that family and close friends are positively associated with emotional well-being, even when they are far away [38]. Furthermore, recent research has shown that internet-based resources allow individuals to connect with and receive social support from people other than family and close friends [18]. The results of this study also support this hypothesis, as internet-based connections with individuals or organizations may lead to social support and improve individual well-being. A study investigating internet-based social support for parents of children with medical needs also showed that, through internet-based support, they receive support from peers, learn the information they need, and acquire the ability to deal with the associated emotional challenges [35]. As nuclear families make up the majority of households in Japan [12], women involved in the care of children and older family members need to be supported effectively using the internet as a tool for exchanging information about these fields and creating social connections for support. For Japanese people, who place great importance on social relationships and group harmony, this intervention might enhance their support-seeking behavior and reduce loneliness [21].

Previous research has demonstrated that cognitive factors such as age [39], education level, income [40], gender, occupational status, and marital status influence eHealth literacy [41]. In addition, a previous study indicated that higher health literacy levels positively influence health-seeking attitudes and social support [42]. Our study found minimal differences between groups based on eHealth usage. This result may be attributed to the data collection method, which was an internet-based survey, and our focused sample of employed Japanese women aged 20-65 years engaged in childcare or caregiving activities [43]. Most participants were in their 30s and 40s, with approximately half having completed higher education. These individuals are not older adults, have a higher level of education, and are employed women. Therefore, they are likely to belong to a group with a relatively high rate of eHealth usage. Regarding income, the participants in this study were employed women whose annual household income exceeded the average income in Japan (5,242,000 yen [US $36,368.68]). This is likely because the survey was conducted among working women, many of whom belong to dual-income households. The lack of comparative data makes it difficult to make a general statement. As many studies have shown a relationship between annual household income and well-being [44,45], the participants in this study may represent a group with a relatively high level of well-being. Health-related conditions, such as high blood pressure and female-specific conditions, were prevalent among the participants. Other well-being surveys in the United Kingdom have shown that the well-being of Japanese people tends to be relatively low [46]. Compared with the British survey using ONS-4, participants had a lower life satisfaction rate and a higher percentage of individuals with high anxiety [46]. As a previous study has pointed out, social support interventions should account for cultural context and cognitive factors and be developed and implemented as tailored eHealth interventions for a similar population.

In addition, when implementing eHealth, factors that might influence its use should be considered. Previous studies have not reached a consensus on the association between eHealth service use, including social media, and well-being. Although some studies have reported a positive association with well-being [36,47], others have suggested that social media use negatively affects well-being [48,49]. Given the complex factors influencing eHealth literacy and well-being, it is important to consider how eHealth service use may impact well-being outcomes across different populations [50]. Previous studies have suggested that interactive methods may have positive effects and that internet-based information exchange and positive social interaction enhance perceived social support and well-being [49]. However, we could not clarify the specific methods for obtaining information via eHealth in this study. Future studies should investigate how individuals obtain information through eHealth services.

Implications for Future Practice and Research

These findings suggest that eHealth use can play a significant role in enhancing well-being among women, particularly those providing childcare or caring for someone else. Labor participation by women has increased globally, benefiting individuals and society worldwide [51]. Japan is no exception, with the number increasing by more than 4 million over the past decade [52]. However, gender inequality exists in Japan's working environment. In 2023, the World Economic Forum assessed the state and evolution of the gender gap across 4 key dimensions (economic participation and opportunity, educational attainment, health and survival, and political empowerment). The World Economic Forum ranks Japan 125th among 146 countries [53]. Various issues were identified, including the gender pay gap, a lack of female executives, and a decline in the number of women in regular employment after their 30s [54]. Women's progress in social advancement is closely linked to changes in daily life and overall well-being. Using internet-based social support to enhance women's well-being could promote their social advancement, improve the next generation's health, and address gender equality. This finding suggests that health care providers and policy makers should consider promoting eHealth platforms to improve mental and physical health outcomes. Moreover, they must support women in accessing required information via eHealth services. Future studies can further explore the mechanisms through which eHealth influences social support and well-being, potentially focusing on the most effective eHealth interventions or platforms. eHealth interventions should be developed to address the specific needs of employed women providing childcare or caregiving and to assess their benefits and harms. In addition, longitudinal studies can provide insights into the long-term effects of eHealth use on well-being and other health outcomes.

Strengths and Limitations

This study is unique in that it examined the relationship among well-being, social support, and eHealth use among a large

XSL•FO
RenderX

sample of working women raising or caring for children. The use of BSEM allowed for a robust analysis of the data, providing CIs and a sensitivity analysis that strengthened the validity of the results. Focus on the use of eHealth provides valuable insights into an emerging area of health intervention that is particularly relevant in today's digital age. However, this study has some limitations. First, the cross-sectional design restricted the ability to infer causality between eHealth use and well-being. Second, our study did not use validated scales specifically designed to measure social support, work-life balance, job satisfaction, and caregiver burden, which could have provided more robust and standardized assessments of these crucial variables. In addition, we did not investigate perceived social support in this study. However, it is important to consider that the mechanisms linking social support and well-being are complex and involve multiple correlated factors. Including perceptions of social support may provide a more comprehensive understanding of how these elements interact and contribute to overall well-being. Third, we only assessed the use of ICT to obtain health-related information, such as the usage of eHealth, and could not evaluate social support through ICT. The frequency or intensity of use was also not evaluated. As eHealth encompasses a broader range of concepts, further studies should include this in evaluating ICT for support in health and health-related fields. Fourth, these data were collected through a self-reported questionnaire, and response biases may be present.

Conclusion

This study suggests that using eHealth services for employed women raising children or caring for someone may enhance the impact of social support on their well-being. However, the complexity of the relationship between eHealth use, social support, and well-being necessitates further investigation. Further studies should investigate the following points while considering cultural contexts and individual differences in eHealth literacy: the mechanisms underlying the relationship among social support, well-being, and eHealth use; the potential benefits and harms of eHealth interventions; and the long-term effects of eHealth interventions on social support and well-being. In addition, further research is needed to develop customized eHealth interventions that address the specific needs of working women with caregiving responsibilities. Deepening our understanding in these areas would allow for the implementation of more effective eHealth interventions, contributing to the improvement of working women's well-being.

Acknowledgments

This study was supported by the Japan Agency for Medical Research and Development (grant 22rea5221030001) and Japan Science and Technology Agency (PRESTO grant JPMJPR21RC, Japan). Funders were not involved in any of the processes, such as study design, participant recruitment, data collection, analysis, or manuscript writing. We thank Editage for editing the English language.

Data Availability

The data used in this study are not publicly available because of privacy and confidentiality concerns. Consequently, external parties cannot share the data.

Authors' Contributions

NY, DY, and KS were responsible for the conceptualization of the study. All members accessed and verified the data. The investigation was conducted by NY, DS, SK, EN, and EO. The methodology was developed by NY, DY, KS, and ES. The original draft was written by NY. Supervision was provided by DY, EO, HT, and ES who reviewed and edited the manuscript. The corresponding author had full access to all the data in the study and assumed the final responsibility for the decision to submit the manuscript for publication.

Conflicts of Interest

None declared.

References

1. Ryff CD. Happiness is everything, or is it? Explorations on the meaning of psychological well-being. J Pers Soc Psychol 1989;57(6):1069-1081. [doi: 10.1037/0022-3514.57.6.1069]
2. Beaufils C, Barbuscia A, Cambois E. Women's employment-family trajectories and well-being in later life: evidence from France. J Aging Health 2023;35(7-8):577-592. [doi: 10.1177/08982643221147637] [Medline: 36630327]
3. Starmer AJ, Frintner MP, Matos K, Somberg C, Freed G, Byrne BJ. Gender discrepancies related to pediatrician work-life balance and household responsibilities. Pediatrics 2019;144(4):e20182926. [doi: 10.1542/peds.2018-2926] [Medline: 31506304]
4. Nomura K, Kitagawa K, Tsuji M, Iida M, Aoki M, Miyauchi K, et al. The quantity and quality of scientific evidence about the health of working women in occupational health of Japan: a scoping review. J Occup Health 2023;65(1):e12427 [FREE Full text] [doi: 10.1002/1348-9585.12427] [Medline: 37845837]

XSL•FO
RenderX

5. Tasnim M, Hossain MZ, Enam F. Work-life Balance: reality check for the working women of Bangladesh. J Hum Resour Sustain Stud 2017;05(01):75-86. [doi: 10.4236/jhrss.2017.51008]
6. Vasumathi A. Work life balance of women employees: a literature review. Int J Serv Oper Manag 2018;29(1):100. [doi: 10.1504/ijsom.2018.10009105]
7. Barrera M, Sandler IN, Ramsay TB. Preliminary development of a scale of social support: studies on college students. Am J Community Psychol 1981;9(4):435-447. [doi: 10.1007/bf00918174]
8. Cooke BD, Rossmann MM, McCubbin HI, Patterson JM. Examining the definition and assessment of social support: a resource for individuals and families. Fam Relat 1988;37(2):211. [doi: 10.2307/584322]
9. World Health Organization. Social Determinants of Health: The Solid Facts. Geneva: World Health Organization; 2003.
10. Passarelli-Araujo H. The association between social support and self-rated health in midlife: are men more affected than women? Cad Saude Publica 2023;39(12):e00106323 [FREE Full text] [doi: 10.1590/0102-311XEN106323] [Medline: 38088736]
11. Baker CN. Social support and success in higher education: the influence of on-campus support on African American and Latino college students. Urban Rev 2013;45(5):632-650. [doi: 10.1007/s11256-013-0234-9]
12. Future estimates of the number of households in Japan (nationwide estimate) (estimate for 2024). National Institute of Population and Social Security Research. URL: https://www.ipss.go.jp/index-e.asp [accessed 2025-05-21]
13. Results of the 2023 telecommunications usage trends survey. Ministry of Internal Affairs and Communications. 2024. URL: https://www.soumu.go.jp/johotsusintokei/statistics/statistics05a.html [accessed 2025-02-27]
14. Guiding optimal development and use of digital health towards improved health outcomes. World Health Organization. 2024. URL: https://www.who.int/westernpacific/activities/guiding-optimal-development-and-use-of-digital-health-towards-improved-health-outcomes [accessed 2025-05-21]
15. Rooij TV, Marsh S. eHealth: past and future perspectives. Per Med 2016;13(1):57-70. [doi: 10.2217/pme.15.40] [Medline: 29749870]
16. El Ayadi AM, Duggal M, Bagga R, Singh P, Kumar V, Ahuja A, et al. A mobile education and social support group intervention for improving postpartum health in Northern India: development and usability study. JMIR Form Res 2022;6(6):e34087 [FREE Full text] [doi: 10.2196/34087] [Medline: 35767348]
17. Perera M, Hawk GS, Nagpal TS, Tinius RA. Social support for exercise from pregnancy to postpartum and the potential impact of a mobile application: a randomized control pilot trial in Southern United States. Prev Med Rep 2023;36:102485 [FREE Full text] [doi: 10.1016/j.pmedr.2023.102485] [Medline: 37954963]
18. Rozzell B, Piercy C, Carr C, King S, Lane B, Tornes M, et al. Notification pending: online social support from close and nonclose relational ties via Facebook. Comput Human Behav 2014;38:272-280 [FREE Full text] [doi: 10.1016/j.chb.2014.06.006]
19. Yue Z, Zhang R, Xiao J. Social media use, perceived social support, and well-being: evidence from two waves of surveys peri- and post-COVID-19 lockdown. J Soc Pers Relat 2023;41(5):1279-1297. [doi: 10.1177/02654075231188185]
20. Strauss J, Goethals G. The self: Interdisciplinary Approaches. Cham: Springer Science & Business Media; 2012.
21. Zheng S, Masuda T, Matsunaga M, Noguchi Y, Ohtsubo Y, Yamasue H, et al. Cultural differences in social support seeking: the mediating role of empathic concern. PLoS One 2021;16(12):e0262001 [FREE Full text] [doi: 10.1371/journal.pone.0262001] [Medline: 34969056]
22. Sasayama K, Nishimura E, Yamaji N, Ota E, Tachimori H, Igarashi A, et al. Current use and discrepancies in the adoption of health-related internet of things and apps among working women in Japan: large-scale, internet-based, cross-sectional survey. JMIR Public Health Surveill 2024;10:e51537 [FREE Full text] [doi: 10.2196/51537] [Medline: 39083338]
23. UK measures of national well-being dashboard. Office for National Statistics. 2024. URL: https://www.ons.gov.uk/peoplepopulationandcommunity/wellbeing/articles/ukmeasuresofnationalwellbeing/dashboard [accessed 2025-05-21]
24. Barrett AE, Toothman EL. Explaining age differences in women's emotional well-being: the role of subjective experiences of aging. J Women Aging 2016;28(4):285-296. [doi: 10.1080/08952841.2015.1017426] [Medline: 27029460]
25. Burger M, Morrison P, Hendriks M, Hoogerbrugge M. Urban-rural happiness differentials across the world. World Happiness Report. 2020. URL: https://worldhappiness.report/ed/2020/urban-rural-happiness-differentials-across-the-world/ [accessed 2025-05-21]
26. Győrffy Z, Dweik D, Girasek E. Workload, mental health and burnout indicators among female physicians. Hum Resour Health 2016;14:12 [FREE Full text] [doi: 10.1186/s12960-016-0108-9] [Medline: 27039083]
27. Killingsworth MA, Kahneman D, Mellers B. Income and emotional well-being: a conflict resolved. Proc Natl Acad Sci U S A 2023;120(10):e2208661120 [FREE Full text] [doi: 10.1073/pnas.2208661120] [Medline: 36857342]
28. What you need to know about education for health and well-being. UNESCO. 2023. URL: http://www.unesco.org/en/health-education/need-know [accessed 2025-08-14]
29. Moreno JC, Ortega M, Conejo-Mir JS, Sanchez-Pedreño P. Palmoplantar pustulosis as a manifestation of cutaneous T cell lymphoma (mycosis fungoides). J Am Acad Dermatol 1990;23(4 Pt 1):758-759. [doi: 10.1016/s0190-9622(08)81083-3] [Medline: 2229510]

XSL•FO
RenderX

30. Xu RH, Chan HH, Shi L, Li T, Wang D. Moderating effect of eHealth literacy on the associations of coronaphobia with loneliness, irritability, depression, and stigma in Chinese young adults: Bayesian structural equation model study. JMIR Public Health Surveill 2023;9:e47556 [FREE Full text] [doi: 10.2196/47556] [Medline: 37773621]
31. MacCallum RC, Browne MW, Sugawara HM. Power analysis and determination of sample size for covariance structure modeling. Psychol Methods 1996;1(2):130-149. [doi: 10.1037/1082-989X.1.2.130]
32. Asparouhov T, Muthén B. Bayesian analysis using MPlus: technical implementation. 2010. URL: http://www.statmodel.com/ [accessed 2025-05-21]
33. Asparouhov TAMB. Bayesian analysis of latent variable models using MPlus. 2010. URL: http://www.statmodel.com/ [accessed 2025-08-14]
34. Gelman A, Carlin J, Stern H, Dunson D, Vehtari A, Rubin D. Bayesian Data Analysis. Boca Raton, Florida: Chapman and Hall/CRC; 2013.
35. DeHoff BA, Staten LK, Rodgers RC, Denne SC. The role of online social support in supporting and educating parents of young children with special health care needs in the United States: a scoping review. J Med Internet Res 2016;18(12):e333 [FREE Full text] [doi: 10.2196/jmir.6722] [Medline: 28007689]
36. Dienlin T, Johannes N. The impact of digital technology use on adolescent well-being . Dialogues Clin Neurosci 2020;22(2):135-142 [FREE Full text] [doi: 10.31887/DCNS.2020.22.2/tdienlin] [Medline: 32699513]
37. Shelley E, Taylor JES, Baum A. Handbook of Psychology and Health. Milton Park: Taylor & Francis; 2022.
38. Johnson AJ, Haigh MM, Becker JAH, Craig EA, Wigley S. College students' use of relational management strategies in email in long-distance and geographically close relationships. J Comp Mediated Comm 2008;13(2):381-404. [doi: 10.1111/j.1083-6101.2008.00401.x]
39. Park SY, Chung S. E-health literacy and associated factors among Korean adults during the COVID-19 pandemic: age-group differences. Health Promot Int 2023;38(5):daad099. [doi: 10.1093/heapro/daad099] [Medline: 37665719]
40. Almoajel A, Alshamrani S, Alyabsi M. The relationship between e-Health literacy and breast cancer literacy among Saudi women. Front Public Health 2022;10:841102 [FREE Full text] [doi: 10.3389/fpubh.2022.841102] [Medline: 35462821]
41. Rezakhani Moghaddam H, Ranjbaran S, Babazadeh T. The role of e-health literacy and some cognitive factors in adopting protective behaviors of COVID-19 in Khalkhal residents. Front Public Health 2022;10:916362 [FREE Full text] [doi: 10.3389/fpubh.2022.916362] [Medline: 35942262]
42. Babazadeh T, Ghaffari-Fam S, Shahnavaz-Yoshanluie F, Ranjbaran S. Psychological well-being and factors affecting it after the COVID-19 pandemic. Front Psychol 2024;15:1295774 [FREE Full text] [doi: 10.3389/fpsyg.2024.1295774] [Medline: 38390417]
43. Comprehensive survey of living conditions. Ministry of Health, Labour and Welfare of Japan. 2023. URL: https://www.mhlw.go.jp/english/database/db-hss/cslc-index.html [accessed 2025-05-21]
44. Deaton A. Income, health, and well-being around the world: evidence from the gallup world poll. J Econ Perspect 2008;22(2):53-72 [FREE Full text] [doi: 10.1257/jep.22.2.53] [Medline: 19436768]
45. Lomas T. Exploring associations between income and wellbeing: new global insights from the Gallup World Poll. J Posit Psychol 2023;19(4):629-646. [doi: 10.1080/17439760.2023.2248963]
46. World happiness report, 2024. WHR Editorial Board. 2024. URL: https://worldhappiness.report/ed/2024/ [accessed 2025-05-21]
47. Clark JL, Algoe SB, Green MC. Social network sites and well-being: the role of social connection. Curr Dir Psychol Sci 2017;27(1):32-37. [doi: 10.1177/0963721417730833]
48. Verduyn P, Gugushvili N, Massar K, Täht K, Kross E. Social comparison on social networking sites. Curr Opin Psychol 2020;36:32-37 [FREE Full text] [doi: 10.1016/j.copsyc.2020.04.002] [Medline: 32387840]
49. Yue Z, Zhang R, Xiao J. Passive social media use and psychological well-being during the COVID-19 pandemic: the role of social comparison and emotion regulation. Comput Human Behav 2022;127:107050 [FREE Full text] [doi: 10.1016/j.chb.2021.107050] [Medline: 34646057]
50. Yang Y, Zhang Y, Xiang A. Information interaction and social support: exploring help-seeking in online communities during public health emergencies. BMC Public Health 2023;23(1):1250 [FREE Full text] [doi: 10.1186/s12889-023-16151-3] [Medline: 37370074]
51. World employment social outlook:trends for women. International Labour Office. 2017. URL: https://www.ilo.org/publications/flagship-reports/world-employment-and-social-outlook-trends-2025 [accessed 2025-05-21]
52. Labour force survey, historical data. Portal Site of Official Statistics of Japan. 2024. URL: https://www.e-stat.go.jp/en/stat-search/files?page=1&toukei=00200531&tstat=000000110001&tclass1=000001040276&tclass2=000001011681 [accessed 2025-05-21]
53. Global gender gap report 2023. World Economic Forum. 2023. URL: https://www.weforum.org/publications/global-gender-gap-report-2023/ [accessed 2025-05-21]
54. Current status and challenges of gender equality in Japan. Gender Equality Bureau Cabinet Office. 2022. URL: https://www.gender.go.jp/english_contents/pr_act/pub/status_challenges/pdf/202205.pdf [accessed 2025-05-21]

XSL•FO
RenderX

Abbreviations

BSEM: Bayesian structural equation model
ICT: information and communication technologies
ONS: Office for National Statistics

Edited by S Badawy; submitted 31.10.24; peer-reviewed by S Ranjbaran, SY Parvar; comments to author 14.02.25; revised version received 06.03.25; accepted 14.04.25; published 26.06.25.

Please cite as:
Yamaji N, Yoneoka D, Suzuki D, Sasayama K, Ota E, Nishimura E, Tachimori H, Saito E
Enhancing Effect of eHealth Use on the Associations Between Social Supports and Well-Being in Japanese Employed Women Providing Childcare or Care: Bayesian Structural Equation Modeling Study
JMIR Pediatr Parent 2025;8:e68119
URL: https://pediatrics.jmir.org/2025/1/e68119
doi:10.2196/68119
PMID:

©Noyuri Yamaji, Daisuke Yoneoka, Daichi Suzuki, Kiriko Sasayama, Erika Ota, Etsuko Nishimura, Hisateru Tachimori, Eiko Saito. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 26.06.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Impact of Digitalization on Pediatric Practice and Childhood Health Care in Spain: Nationwide Survey Study

Alicia Santamaría-Orleans[1], MSc, PhD; Luis Ortiz-González[2], PhD, MD; Maite Pérez-Hernández[3], MSc, MD; Cristóbal Coronel-Rodríguez[4], PhD, MD

[1]Scientific Communication, Laboratorios Ordesa SL, Barcelona, Spain

[2]Biomedical Sciences Department, Medicine and Health Sciences Faculty, Universidad de Extremadura, Badajoz, Spain

[3]Medical Department, Laboratorios Ordesa SL, Barcelona, Spain

[4]Pharmacology, Pediatrics and Radiology Department, Faculty of Medicine, Amante Laffón Health Care Centre, Sevilla, Spain

Corresponding Author:
Alicia Santamaría-Orleans, MSc, PhD
Scientific Communication
Laboratorios Ordesa SL
Paseo de la Zona Franca, 107
Barcelona
Spain
Phone: 34 902105243
Email: orleans1970@gmail.com

Abstract

Background: Health care digitalization and pediatric information and communication technology have facilitated the use of telemedicine and digital communication tools in pediatric practice, improving accessibility and efficiency. Meanwhile, artificial intelligence (AI) is emerging as a promising tool in medicine. However, the rapid adoption of these technologies has raised concerns regarding reliability and ethics.

Objective: This study examines the level of digitalization in pediatric consultations and explores the perspectives of health care professionals (HCPs) on digital technologies in patient care, analyzing differences by age group, health care management, and institution type.

Methods: An observational, cross-sectional survey was conducted among Spanish HCPs dedicated to pediatric care. Participants completed an 18-question web-based questionnaire evaluating their use of digital communication tools, perceptions of online health information, and opinions on AI in clinical practice. Statistical analyses compared responses across age groups, health care management type, and institution type.

Results: A total of 495 pediatric specialists participated (female: 273/495, 58.2%; aged >45 y: 324/495, 69.8%). Most participants worked in urban settings (409/469, 87.2%), in primary care (243/313, 77.6%), and in the public sector (253/464, 54.5%). The telephone remained the most used communication channel (462/481, 96.1%), followed by email (290/481, 60.3%) and WhatsApp (139/481, 28.9%). Private-sector HCPs used digital platforms more frequently than public-sector HCPs, including email (136/206, 66% vs 135/247, 54.7%; *P*=.02), Instagram (23/206, 11.2% vs 5/247, 2%; *P*<.001), WhatsApp (105/206, 51% vs 26/247, 10.5%; *P*<.001), and Facebook (18/206, 8.7% vs 3/247, 1.2%; *P*<.001). Nearly all respondents (417/437, 95.4%) believed that parents were increasingly seeking health information online, yet a considerable proportion (158/458, 34.5%) reported that parents rarely consulted them about reliable sources. Overall, 85.4% (410/480) agreed that the internet and social media raise many questions among parents, while only 7.5% (35/465) believed that the information found is generally reliable. Nearly half of the participants (232/443, 48.5%) proactively suggested trustworthy digital resources, while 44.1% (211/443) did so only when asked. Younger respondents (*P*=.002), public-sector HCPs (*P*=.005), and primary care specialists (*P*=.004) were significantly more likely to offer this guidance, with scientific society resources being the most frequently recommended (402/430, 93.5%). We found that 78.6% (369/470) of participants were familiar with AI, with private-sector HCPs demonstrating greater knowledge than public-sector HCPs (*P*=.003). Overall, 59.6% (279/468) agreed that AI could significantly improve medicine, a view more commonly held by private-sector HCPs (*P*=.005). However, 94.8% (306/323) expressed ethical concerns, and 89.8% (422/470) wished to receive AI-related training.

XSL•FO
RenderX

Conclusions: The survey highlights the increasing use of digital communication tools in pediatric practice, with private-sector HCPs leading adoption. While AI is viewed as promising, ethical dilemmas remain, underscoring the need for training. Limited confidence in online health information highlights the importance of strengthening digital literacy among both HCPs and parents to optimize patient care.

(JMIR Pediatr Parent 2025;8:e75310) doi:10.2196/75310

KEYWORDS

health care digitalization; information and communication technology; ICT; pediatric ICT; artificial intelligence; AI; telemedicine

Introduction

Background

Technological development in recent decades has facilitated digital transformation, defined as the integration of digital solutions to create or modify existing organizational structures, resources, and social relationships [1,2]. Medicine has similarly undergone significant transformation through advances in this field. The adoption of innovative tools in health care, including pediatric information and communication technology (ICT), has expanded the provision of medical services via telecommunications, commonly referred to as telemedicine [3,4]. These services encompass telephone calls, instant messaging apps, videoconferencing, websites, mobile apps, and blogs [5]. These telemedicine options offer substantial benefits and have gained widespread user acceptance by facilitating access to information and enhancing physician-patient communication. In regions with limited health care accessibility, these solutions are particularly valuable, as they reduce travel constraints and optimize time utilization [6-8].

Although telemedicine had been steadily growing, it was the COVID-19 pandemic that triggered its rapid acceleration and widespread implementation [9]. Restrictions on hospital access during the pandemic created major challenges for patient monitoring and treatment adherence, prompting health care professionals (HCPs) to adopt digital solutions within online environments [10,11]. Unfortunately, the increasing use of the internet and social media by patients has generated new concerns. While these platforms can improve access to knowledge, not all content is reliable, which may result in the spread of misinformation. Thus, ensuring content quality control and appropriate regulation of these platforms is crucial [12,13]. In this context, HCPs could play a key role by leveraging social media as educational platforms when appropriate and guiding patients toward reliable sources of information [14].

More recently, the development of artificial intelligence (AI) has emerged as one of the most significant scientific and technological advances of our time, with applications extending across all sectors of society [15]. In medicine, AI is already being used to support specialists in various capacities, including big data analysis, medical image interpretation, workflow management systems, and clinical diagnostics. The implementation of AI has the potential to significantly improve the accuracy, efficiency, and overall quality of patient care [16-18]. Despite these benefits, AI lacks essential human attributes such as empathy and compassion, which are critical skills in health care. These limitations highlight the need for patients to feel that consultations remain under human oversight. As a result, ethical concerns regarding the use of AI continue to persist [19].

Telemedicine in Pediatrics

Pediatrics is among the medical fields most influenced by new ICTs. Parents often seek immediate information and support, for which telemedicine and the internet offer convenient options [20]. During the COVID-19 pandemic, telemedicine use considerably increased in both ambulatory and hospital environments, suggesting that it is likely to become an integral component of routine pediatric care if such services remain available [21,22]. In Spain, most pediatricians reported using digital technologies to communicate with patients during the pandemic and believed that digital consultations would continue to play a role in the future [23].

Therefore, this survey aimed to examine and evaluate the digitalization of pediatric consultations and HCPs' perceptions regarding the use of digital technologies in parenting.

Methods

Study Design

An observational, cross-sectional, descriptive survey was designed to obtain information on pediatric specialists' perspectives regarding communication channels with patients, the quality of information available online, and the potential impact of AI in medicine. In addition, the survey analyzed and compared responses by age group, type of management, and type of institution to identify possible divergences within the system.

HCPs involved in pediatric care, from a sample of 5187 specialists registered in the database of Laboratorios Ordesa, a Spanish company specializing in nutrition and food supplements, were invited to participate. All individuals in this database had previously provided informed consent, in accordance with the Spanish Data Protection and Digital Rights Act, to be contacted by the company for informational purposes. An email invitation describing this study and containing a link to the questionnaire was sent to all members of this database, and the same invitation was also disseminated through the company's social networks (X [formerly known as Twitter] and LinkedIn). No reminders were sent. Of the 5187 HCPs invited to participate, 495 (9.54%) completed the questionnaire. Explicit refusals were not recorded; thus, nonresponders were defined as those who did not reply to the invitation. Participants included HCPs from both the public and private sectors in Spain. No specific inclusion criteria were applied. Participants completed the questionnaire between September 2023 and June 2024.

XSL•FO
RenderX

The survey was developed by a team of HCPs with experience in questionnaire-based studies after a comprehensive literature review (Multimedia Appendix 1).

Since 2017, the research team has progressively explored key topics in communication between pediatricians and families through regular consultations with professionals in the field. This ongoing collaboration helped identify and refine the most relevant questions over time. The final structure and content of the questionnaire were based on a previously published survey that addressed similar topics [23]. In addition, a new section on AI was introduced, given the growing interest and limited existing data in pediatric settings. The questions in this section were developed with input from experts and inspired by recent findings in the field [24].

The questionnaire consisted of 18 questions across 3 sections. The first section included 7 items on sociodemographic data, including workplace location (rural vs urban). This classification was based on population size: rural (<2000 inhabitants), semiurban (2000-10,000 inhabitants), and urban (>10,000 inhabitants).

The second section focused on evaluating the digitalization of pediatric consultations and included 6 closed-ended questions measuring the level of agreement.

The third section assessed the impact of AI in clinical practice through 5 closed-ended questions. Responses regarding the influence of the internet and social media on parenting were rated on a scale ranging from 1 (completely disagree) to 10 (completely agree) and grouped into 4 categories according to Likert scaling: disagreement (1-3), neutral (4-6), agreement (7-10). In parallel, responses were analyzed by age group (29-45 y and >45 y), type of management (public or private), and type of institution (hospital or primary care).

Data Analysis

Descriptive statistics (means and SDs) were calculated for quantitative variables, while frequencies and percentages represented categorical variables to describe the sample characteristics. The Fisher exact test was used to assess associations between qualitative variables, and the Mann-Whitney *U* test was used to compare quantitative variables between 2 independent groups. Statistical analyses were conducted in SAS (version 9.4; SAS Institute), with statistical significance defined as $P<.05$.

Ethical Considerations

This study was exempt from formal ethics committee approval in accordance with the Spanish Organic Law 3/2018, of December 5, on the Protection of Personal Data and the Guarantee of Digital Rights. Participation was entirely voluntary. Pediatricians were informed about the objectives of the study, the voluntary nature of their participation, and the anonymous handling of their data prior to completing the questionnaire. Consent was implied through prior registration in the recruitment database and the voluntary completion of the online survey. No personally identifiable information was recorded, thereby ensuring participant privacy and confidentiality. The study did not involve patients, minors, or other vulnerable populations.

Results

Sociodemographic Data

Of the 5187 HCPs invited to participate, 495 (9.54%) completed the questionnaire. Of the 495 respondents, 273 (58.2%) were female, and the mean age was 52.2 (SD 10.9) years, with 324 (69.8%) aged more than 45 years. Most of the participants (409/469, 87.2%) worked in urban areas; 54.5% (253/464) were public-sector HCPs, while 77.6% (243/313) worked in primary care (Table 1).

XSL•FO
RenderX

Table 1. Sociodemographic characteristics of the study participants (N=495).

Characteristics	Values
Sex (n=469), n (%)	
Male	196 (41.8)
Female	273 (58.2)
Age (years; n=464), mean (SD)	52.2 (10.9)
Age (y; n=464), n (%)	
29-45	140 (30.2)
>45	324 (69.8)
Type of management (n=464), n (%)	
Public	253 (54.5)
Private	211 (45.5)
Type of institution (n=313), n (%)	
Hospital	70 (22.4)
Primary care	243 (77.6)
Workplace location (n=469), n (%)	
Rural	11 (2.3)
Semiurban	49 (10.4)
Urban	409 (87.2)
Medical specialty (n=471), n (%)	
Pediatrics	407 (86.4)
Family medicine	31 (6.6)
Pediatric gastroenterology	15 (3.2)
Other	18 (3.8)

Digitalization of Pediatric Consultations and the Use of the Internet and Social Media

When asked about communication methods with patients, 96.1% (462/481) of the participants reported using the telephone, making it the most common channel. However, nearly 90% (429/481) also relied on ICTs such as email (290/481, 60.3%) and WhatsApp (139/481, 28.9%). Statistically significant differences were observed across subgroups: older HCPs (aged >45 y) were more likely to use WhatsApp (P<.001), while private-sector HCPs more frequently used digital communication methods, including email (P=.02), Instagram (P<.001), WhatsApp (P<.001), and Facebook (P<.001), compared to public-sector HCPs. By contrast, public-sector HCPs primarily relied on telephone communication (P=.01), and specialists working in hospitals used WhatsApp significantly more than those working in primary care (P=.002). These results are summarized in Table 2.

Regarding digitalization in information seeking, most of the respondents (n/N, 95.4%) believed that parents have increased their search for parenting information over the past year (Table 3). Table 4 presents the respondents' recommendations on reliable digital sources of parenting information.

However, 34.5% (158/458) of the participants stated that parents had not consulted them about reliable digital sources of parenting information. The only significant difference was observed by age: younger specialists (aged 29-45 y) were more frequently asked about reliable sources of information (Table 5).

XSL•FO
RenderX

Table 2. Responses of health care professionals in pediatric practice (n=481) to the survey question "Which communication channels are you currently using to communicate with your patients?" Participants could select more than one option. *P* values were calculated with the Fisher exact test. Italicization indicates values that met the threshold for significance.

Communication channels	Total, n (%)	Age group (y), n (%)		*P* value	Type of management, n (%)		*P* value	Type of institution, n (%)		*P* value
		29-45 (n=136)	>45 (n=320)		Public (n=247)	Private (n=206)		Hospital (n=68)	Primary care (n=237)	
Telephone	462 (96)	129 (94.9)	309 (96.6)	.43	243 (98.4)	193 (93.7)	*.01* [c]	62 (91)	229 (96.6)	.09
Email	290 (60.3)	74 (54.4)	198 (61.9)	.15	135 (54.7)	136 (66)	*.02*	46 (68)	134 (56.5)	.12
Blog	11 (2.3)	2 (1.5)	9 (2.8)	.52	3 (1.2)	8 (3.9)	.12	2 (3)	4 (1.7)	.62
Twitter	6 (1.2)	1 (0.7)	5 (1.6)	.67	1 (0.4)	5 (2.4)	.10	1 (2)	3 (1.3)	.99
Instagram	28 (5.8)	7 (5.1)	21 (6.6)	.67	5 (2)	23 (11.2)	*<.001*	7 (10)	14 (5.9)	.27
WhatsApp	139 (28.9)	19 (14)	113 (35.3)	*<.001*	26 (10.5)	105 (51)	*<.001*	30 (44)	57 (24.1)	*.002*
Facebook	21 (4.4)	6 (4.4)	15 (4.7)	.99	3 (1.2)	18 (8.7)	*<.001*	5 (7)	13 (5.5)	.56
Other	62 (12.9)	21 (15.4)	39 (12.2)	.37	37 (15)	25 (12.1)	.41	8 (12)	33 (13.9)	.84

Table 3. Responses of health care professionals in pediatric practice (n=437) to the survey question "Do you believe that in the past year, parents have increasingly sought information on child-rearing through digital media?" *P* values were calculated with the Fisher exact test.

Responses	Total, n (%)	Age group (y), n (%)		*P* value	Type of management, n (%)		*P* value	Type of institution, n (%)		*P* value
		29-45 (n=133)	>45 (n=297)		Public (n=235)	Private (n=198)		Hospital (n=63)	Primary care (n=231)	
Yes	417 (95.4)	129 (97)	282 (94.9)	.45	225 (95.7)	189 (95.5)	.99	63 (100)	225 (97.4)	.35
No	20 (4.6)	4 (3)	15 (5.1)	.45	10 (4.3)	9 (4.5)	.99	0 (0)	6 (2.6)	.35

Table 4. Responses of health care professionals in pediatric practice (n=430) to the survey question "If applicable, what types of sources do you recommend?" Participants could select more than one option. *P* values were calculated with the Fisher exact test. Italicization indicates values that met the threshold for significance.

Responses	Total, n (%)	Age group (y), n (%)		*P* value	Type of management, n (%)		*P* value	Type of institution, n (%)		*P* value
		29-45 (n=82)	>45 (n=148)		Public (n=143)	Private (n=85)		Hospital (n=26)	Primary care (n=131)	
I recommend my own sources	58 (13.5)	8 (9.8)	24 (16.2)	.23	13 (9.1)	20 (23.5)	*.004*	5 (19)	14 (10.7)	.32
I recommend sources from the center where I work	66 (15.3)	13 (15.9)	34 (23)	.23	32 (22.4)	16 (18.8)	.62	3 (12)	30 (22.9)	.29
I recommend sources from scientific societies	402 (93.5)	76 (92.7)	127 (85.8)	.14	126 (88.1)	74 (87.1)	.84	23 (89)	118 (90.1)	.73
I recommend blogs and digital resources from other professionals	142 (33)	43 (52.4)	49 (33.1)	*.005*	52 (36.4)	39 (45.9)	.17	11 (42)	57 (43.5)	.99
I do not recommend digital resources	3 (0.7)	1 (1.2)	6 (4.1)	.43	6 (4.2)	1 (1.2)	.26	0 (0)	0 (0)	—[a]
Other	4 (0.9)	2 (2.4)	2 (1.4)	.62	3 (2.1)	1 (1.2)	.99	0 (0)	3 (2.3)	.99

[a]Not applicable.

XSL•FO
RenderX

Table 5. Responses of health care professionals in pediatric practice to the survey question "Do parents ask you for reliable sources of information to learn about raising their children in the digital media?" *P* values were calculated with the Fisher exact test. Italicization indicates values that met the threshold for significance.

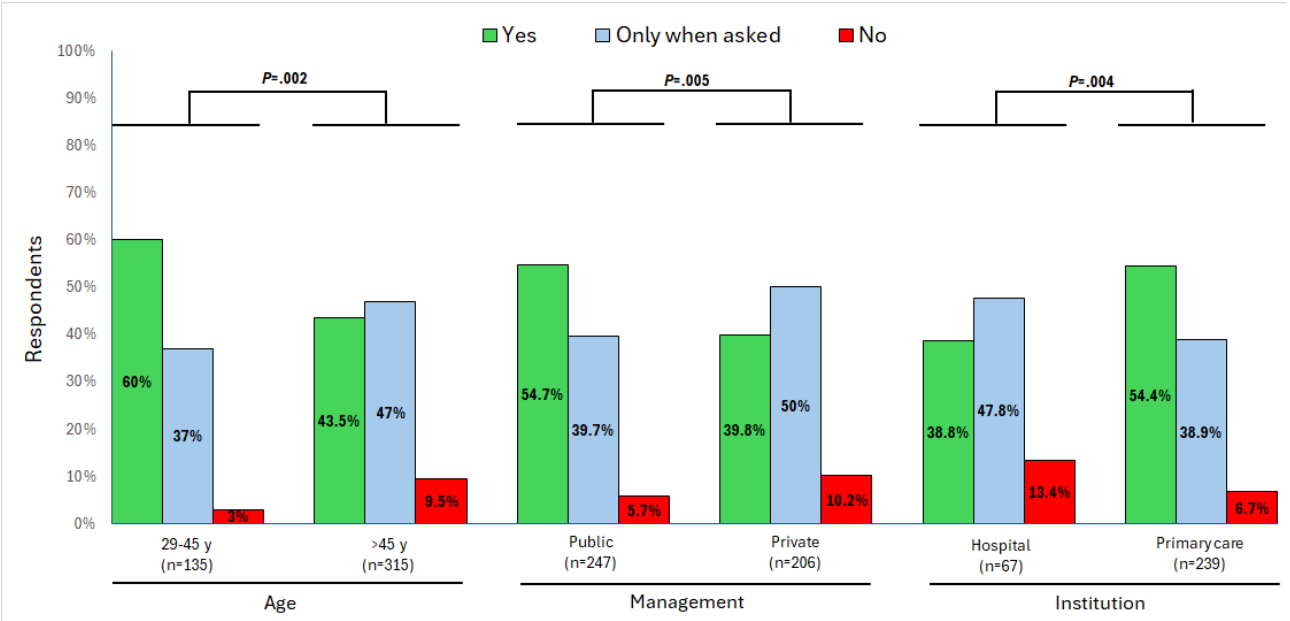
	Total (n=458), n (%)	Analysis by age (y), n (%)		*P* value	Analysis by type of management, n (%)		*P* value	Analysis by type of institution, n (%)		*P* value
		29-45 (n=129)	>45 (n=305)		Public (n=236)	Private (n=198)		Hospital (n=65)	Primary care (n=227)	
Responses				*.03*			.42			.99
Yes	300 (65.5)	95 (73.6)	191 (62.6)		150 (63.6)	134 (67.7)		45 (69)	158 (69.6)	
No	158 (34.5)	34 (26.4)	114 (37.4)		86 (36.4)	64 (32.3)		20 (31)	69 (30)	

When asked whether they recommend "reliable digital sources of parenting information," 48.5% (232/443) of the HCPs responded that they normally do so even if parents do not ask, while 44.1% (211/443) provided recommendations only when asked. Grouped analysis indicated that younger respondents (*P*=.002), public-sector HCPs (*P*=.005), and primary care specialists (*P*=.004) were significantly more likely to provide such recommendations (Figure 1). The most frequently recommended sources were those from scientific societies, cited by 93.5% (402/430) of the HCPs, followed by blogs and digital content (142/430, 33%). Among the recommended options, younger professionals were more likely to propose blogs and digital content from other HCPs (*P*=.005), whereas private-sector physicians were more likely to recommend their own materials (*P*=.004; Table 4).

For the statements "The internet and social media raise many questions among parents" and "In general, the information found on the internet and social media is reliable," the mean scores were 8.10 (SD 0.81) and 3.8 (SD 2.0), respectively. The corresponding percentages are shown in Figure 2.

The only significant differences were observed by type of management, with private-sector HCPs being more likely to believe that the internet and social media raise many questions among parents (*P*=.03; Table 6). Table 7 presents the respondents' perceptions on whether, in general, the information found on the internet and social media is reliable.

Figure 1. Proportions of health care professionals in pediatric practice who proactively recommend, recommend only when asked, or do not recommend trustworthy digital sources to parents, stratified by age group, type of management, and type of institution. Total responses: "yes"=48.5% (232/478); "only when asked"=44.1% (211/478); "no"=7.3% (35/478). The statistically significant *P* values (*P*<.05; Fisher exact test) are shown in bold.



XSL•FO
RenderX

Figure 2. Perceptions of health care professionals in pediatric practice regarding the influence and reliability of the internet and social media in parenting. The bars represent the percentage of health care professionals who agreed, were neutral, or disagreed with each statement (A or B). The numbers indicate response counts. Mean, SD, and total responses are indicated for each statement.

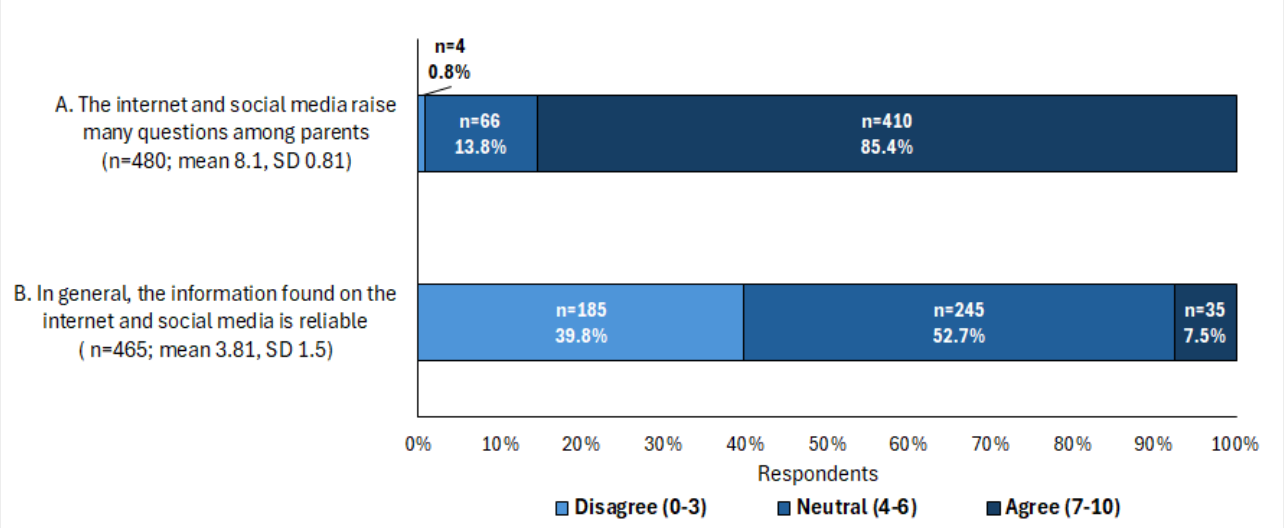


Table 6. Responses of health care professionals in pediatric practice to the survey question "The internet and social media raise many questions among parents." Mann-Whitney U tests and Fisher exact tests were applied to calculate *P* values for quantitative and qualitative variables, respectively.

Variables	Analysis by age (y)		*P* value	Analysis by type of management		*P* value	Analysis by type of institution		*P* value
	29-45 (n=137)	>45 (n=315)		Public (n=248)	Private (n=207)		Hospital (n=68)	Primary care (n=240)	
Scores, mean (SD)	8.08 (1.80)	8.18 (1.74)	.68	8.01 (1.75)	8.31 (1.76)	.03	8.43 (1.51)	8.28 (1.68)	.70
Responses, n (%)			.56			.09			.51
Disagree (1-3)	0 (0)	3 (1)		0 (0)	3 (1.5)		0 (0)	1 (0.4)	
Neutral (4-6), n (%)	24 (17.5)	36 (11.4)		38 (15.3)	24 (11.6)		5 (7)	29 (12.1)	
Agree (7-10), n (%)	113 (82.5)	276 (87.6)		210 (84.7)	180 (87)		63 (93)	210 (87.5)	

Table 7. Responses of health care professionals in pediatric practice to the survey question "In general, the information found on the internet and social media is reliable." Mann-Whitney U tests and Fisher exact tests were applied to calculate *P* values for quantitative and qualitative variables, respectively.

	Age group		*P* value	Type of management, n (%)		*P* value	Type of institution, n (%)		*P* value
	29-45 (n=135)	>45 (n=302)		Public (n=235)	Private (n=205)		Hospital (n=69)	Primary care (n=241)	
Scores, mean (SD)	3.92 (1.85)	3.70 (2.04)	.16	3.61 (1.94)	3.99 (2.02)	.06	4.03 (1.94)	4.05 (1.84)	.67
Responses (y), n (%)			.12			.77			.77
Disagree (1-3)	52 (38.5)	123 (40.7)		96 (40.9)	79 (38.5)		28 (41)	93 (38.6)	
Neutral (4-6)	75 (55.6)	154 (51)		123 (52.3)	109 (53.2)		35 (51)	131 (54.4)	
Agree (7-10)	8 (5.9)	25 (8.3)		16 (6.8)	17 (8.3)		6 (9)	17 (7.1)	

Impact of AI in Medicine

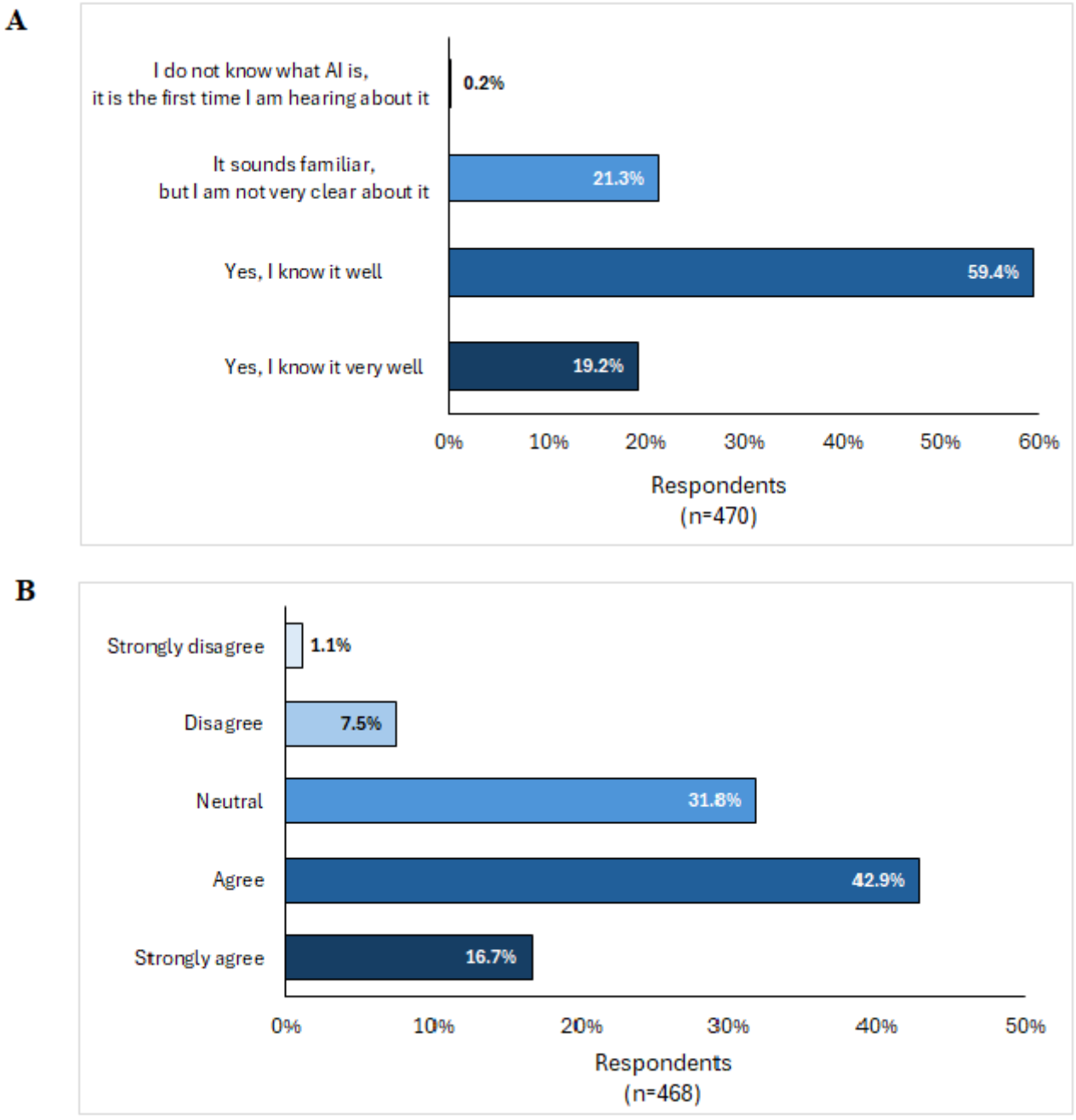
Participants were asked to share their opinions on recent advancements in AI and AI's potential impact in medicine. Nearly 75% (369/470) of the HCPs reported knowing well (279/470, 59.4%) or very well (90/470, 19.2%) what AI is, while 21.3% (100/470) indicated that AI sounded familiar but that they were not very clear on what it entails (Figure 3A). Regarding the statement "I believe AI could lead to significant improvements in medicine," more than half agreed (201/468, 42.9%) or strongly agreed (78/468, 16.7%), while 31.8% (149/468) remained neutral (Figure 3B). Regarding the medical areas where AI is perceived to offer the most improvements, respondents highlighted diagnostic assistance, medical training,

XSL•FO
RenderX

and enhanced health care access in regions lacking specialists. The first 2 options were selected by approximately half of the HCPs (254/472, 53.8% and 228/472, 48.3%, respectively; Table 8).

Grouped analysis revealed several significant differences. Private-sector HCPs demonstrated greater knowledge of AI (*P*=.003; Table 9) and were more convinced than public-sector HCPs that AI could bring important advancements to medicine (*P*=.005), a view also strongly shared by hospital-based HCPs (*P*=.02; Table 10). Regarding areas of improvement, pediatric specialists aged more than 45 years were more likely to believe in AI's potential to assist and contribute to diagnostic support (*P*=.02), as were hospital-based HCPs (*P*=.04); however, public-sector HCPs were more likely to believe that AI could enhance medical training (*P*=.04) and improve treatment adherence (*P*=.02; Table 8).

Figure 3. Health care professionals' perspectives on artificial intelligence (AI) in pediatric practice. (A) Self-reported knowledge of AI among respondents (n=470), expressed as the percentage of participants in each category. (B) Level of agreement (n=468) with the statement "AI will significantly improve medicine."



XSL•FO
RenderX

Table 8. Responses of health care professionals in pediatric practice (n=472) to the survey question "Select the medical areas where you think artificial intelligence (AI) could bring improvements." Participants could select more than one option. *P* values were calculated with the Fisher exact test.

Responses	Total, n (%)	Age group (y), n (%)		*P* value	Type of management, n (%)		*P* value	Type of institution, n (%)		*P* value
		29-45 (n=136)	>45 (n=316)		Public (n=242)	Private (n=210)		Hospital (n=70)	Primary care (n=243)	
Medical training	228 (48.3)	63 (46.3)	156 (49.4)	.61	131 (54.1)	93 (44.3)	.04	29 (41)	91 (37.45)	.58
Better access to health care in areas where specialists are unavailable	169 (35.8)	44 (32.3)	115 (36.4)	.45	96 (39.7)	70 (33.3)	.17	16 (23)	64 (26.3)	.64
Diagnostic assistance	254 (53.8)	61 (44.9)	180 (57)	.02	127 (52.5)	120 (57.1)	.34	41 (59)	107 (44)	.04
Better treatment adherence	78 (16.5)	18 (13.2)	55 (17.4)	.33	50 (20.7)	26 (12.4)	.02	9 (13)	28 (11.5)	.83
Better patient monitoring	116 (24.6)	32 (23.5)	76 (24.1)	.99	62 (25.6)	49 (23.3)	.59	11 (16)	45 (18.5)	.72

Table 9. Responses of health care professionals in pediatric practice to the survey question "You have most likely heard about 'artificial intelligence (AI)' recently, but do you know what AI actually is?" *P* values were calculated with the Fisher exact test. Italicization indicates values that met the threshold for significance.

	Age group (y), n (%)		*P* value	Type of management, n (%)		*P* value	Type of institution, n (%)		*P* value
	29-45 (n=133)	>45 (n=317)		Public (n=244)	Private (n=209)		Hospital (n=69)	Primary care (n=238)	
Responses			.70			*.003*			.44
Yes, I know it very well	28 (21.1)	58 (18.3)		37 (15.2)	49 (23.4)		11 (16)	56 (23.5)	
Yes, I know it well	75 (56.4)	195 (61.5)		142 (58.2)	128 (61.2)		45 (65.2)	130 (54.6)	
It sounds familiar, but I am not very clear about it	30 (22.6)	63 (19.9)		65 (26.6)	31 (14.8)		13 (19)	51 (21.4)	
I do not know what it is, it is the first time I am hearing about it	0 (0)	1 (0.3)		0 (0)	1 (0.5)		0 (0)	1 (0.4)	

Table 10. Responses of health care professionals in pediatric practice to the survey question "I believe that artificial intelligence (AI) could lead to significant improvements in medicine." *P* values were calculated with the Fisher exact test. Italicization indicates values that met the threshold for significance.

	Age (y), n (%)		*P* value	Type of management, n (%)		*P* value	Type of institution, n (%)		*P* value
	29-45 (n=135)	>45 (n=313)		Public (n=246)	Private (n=207)		Hospital (n=67)	Primary care (n=238)	
Responses			.64			*.005*			*.02*
Strongly agree	27 (20)	50 (16)		32 (13)	44 (21.3)		26 (39)	49 (20.6)	
Agree	55 (40.7)	137 (43.8)		96 (39)	99 (47.8)		30 (45)	131 (55)	
Neutral	44 (32.6)	98 (31.3)		93 (37.8)	52 (25.1)		10 (15)	55 (23.1)	
Disagree	7 (5.2)	25 (8)		22 (8.9)	10 (4.8)		1 (2)	3 (1.3)	
Strongly disagree	2 (1.5)	3 (1)		3 (1.2)	2 (1)		0 (0)	0 (0)	

Regarding the ethical and legal aspects of AI, more than half of the participants admitted to being moderately (92/323, 28.5%) or highly (214/323, 66.3%) concerned, with no statistical differences between groups (Figure 4). In addition, most of the HCPs (422/470, 89.8%) stated that they would like to receive

XSL•FO
RenderX

training on AI and its potential applications in medicine (Table 11), again with no significant group differences.

Figure 4. Health care professionals' concerns regarding ethical and legal aspects of artificial intelligence. The bars represent the distribution of responses by age group, type of management, and type of institution. Total responses: "yes, very much"=66.3% (214/323); "yes, somewhat"=28.5% (92/323); "indifferent"=4.6% (15/323); "no, hardly"=0.3% (1/323); "no, not at all"=0.3% (1/323).

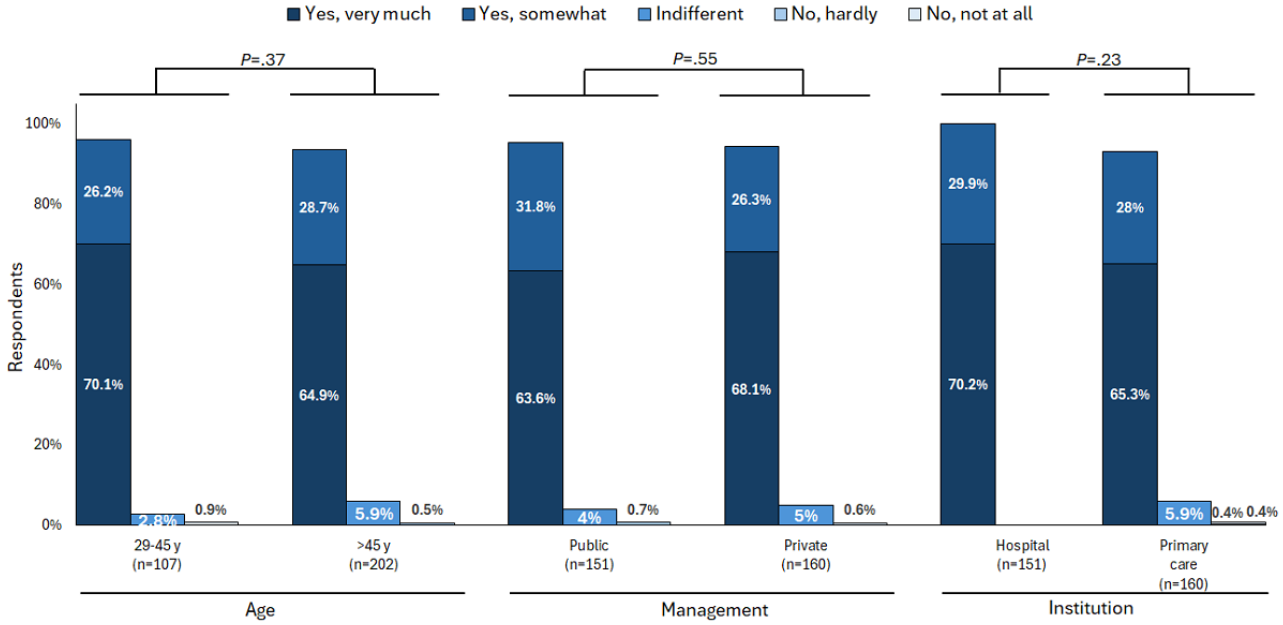


Table 11. Responses of health care professionals in pediatric practice (n=470) to the survey question "Would you like to receive training on AI and its potential applications in the field of medicine?" *P* values were calculated with the Fisher exact test.

	Total, n (%)	Age group (y), n (%)		*P* value	Type of management, n (%)		*P* value	Type of institution, n (%)		*P* value
		29-45 (n=135)	>45 (n=316)		Public (n=247)	Private (n=206)		Hospital (n=67)	Primary care (n=240)	
Responses				.39			.34			.99
Yes	422 (89.8)	119 (88.1)	288 (91.1)		219 (88.7)	189 (91.7)		62 (93)	220 (91.7)	
No	48 (10.2)	16 (11.9)	28 (8.9)		28 (11.3)	17 (8.2)		5 (8)	20 (8.3)	

Discussion

Principal Findings

The integration of AI and digital tools is transforming medical practice, driving advancements in diagnostics, patient management, and health care accessibility [22]. In pediatrics, ICTs have become especially valuable, enhancing physician-parent communication [25] and providing immediate access to medical advice [26].

To the best of our knowledge, this survey is the first to examine the impact of health care digitalization across both public and private sectors and between hospitals and primary care services in Spain. It highlights a high prevalence of telephone use and digital communication tools such as WhatsApp and email among pediatric HCPs. These patterns may reflect the predominantly urban settings of the participants, as urban areas typically offer better digital infrastructure, high-speed internet, and more resources for digital health integration compared to rural regions [27]. Nevertheless, these results emphasize the widespread adoption of virtual communication models between parents and HCPs, consistent with previous reports from Europe [28,29].

Notable variations in digital tool use were observed, aligned with prior research indicating that adoption rates depend on the management system (public vs private) and the age of HCPs [30,31]. According to Rotaru and Edelhauser [30], private health care institutions generally implement digital solutions more quickly than public systems, which often encounter bureaucratic and financial barriers. Supporting this, the *Observatorio de Digitalización en la Sanidad Privada: Madurez Digital y Casos de Éxito* (*Digitalization Observatory in Private Health Care: Digital Maturity and Success Stories*) report underscores that private health care in Spain is leading the charge in digitalization, providing more accessible and personalized services [32]. Indeed, this is reflected in the higher use of digital platforms such as Instagram, WhatsApp, and Facebook by private-sector HCPs. It should be noted that in the Spanish public health care sector, the use of informal communication channels such as WhatsApp or Instagram between HCPs and patients is generally discouraged due to concerns regarding

XSL•FO
RenderX

confidentiality, data protection, and professional boundaries [33].

Interestingly, private-sector HCPs preferred email communication more frequently than public-sector HCPs. This preference may be related to email's ability to maintain formal records, align with structured consultation schedules, easily transfer digital images and documents, and facilitate asynchronous communication [34]. Nevertheless, telephone use remained dominant among public-sector HCPs, possibly due to centralized call systems or accessibility for families with limited digital resources. In addition, primary care physicians demonstrated a lower tendency to use digital tools overall compared to hospital-based HCPs, suggesting existing barriers or constraints in the use of digital health [35]. Notably, the Spanish Ministry of Health has implemented a digital health strategy aimed at transforming primary and community care in Spain, which is expected to help address these challenges [36].

Age has long been considered a key factor in the adoption of digital tools, with younger physicians typically seen as digitally literate and comfortable using digital platforms [31]. However, middle-aged adults (those aged 30-60 years) now also exhibit varying but significant levels of digital literacy, depending on their exposure to technological tools [31]. The simplicity and widespread use of WhatsApp, which has become an integral part of daily life for most people [37,38], likely explains its higher adoption among older HCPs.

Regarding parental use of digital media, most of the participants (417/437, 95.4%) reported that parents are increasingly turning to digital platforms for child-rearing advice. This finding aligns with previous research [39-41] indicating that social media is becoming a primary source of health information for both parents and HCPs [40]. This shift underscores the growing responsibility of HCPs to guide parents toward evidence-based resources. At the same time, concerns about misinformation have escalated, with many participants expressing skepticism about the reliability of online content, often due to the overwhelming volume of unverified information [25,40]. As a result, HCPs must strengthen their presence on social media, recommending curated and credible resources to counter misinformation and improve child health outcomes.

Most of the HCPs (402/430, 93.5%) reported recommending resources from scientific societies. This could be expected, as these institutions provide peer-reviewed, evidence-based information, which ensures content accuracy, reliability, and absence of commercial bias, making them trusted sources of medical advice [42]. Interestingly, private-sector HCPs, in addition to recommending scientific societies, were more likely than their public-sector counterparts to recommend their own online sources. This trend can be attributed to the fact that private hospitals often focus on increasing patient numbers and adherence [43]. Unlike their public-sector counterparts, who usually rely on institutional platforms and officially endorsed guidelines, private HCPs often operate in settings that require greater autonomy and visibility. Recommending personal or practice-specific resources may allow them to reinforce patient trust, provide tailored information, and enhance professional identity, while also compensating for the lack of centralized institutional tools available in the public system.

Evaluating how pediatric specialists are adapting to this digital era is critical for identifying areas of improvement and optimizing integration to ensure high-quality, patient-centered care. Indeed, the survey found that private-sector HCPs are generally more familiar with AI than their public-sector counterparts, likely due to greater investment in AI tools [32], more access to training [43,44], higher patient demand for technologically advanced services, and fewer bureaucratic obstacles to AI adoption [30].

Nearly half of the participants (82/135, 60.7%) believed that AI could significantly enhance medicine, especially in diagnostics and medical training. These results align with previous studies highlighting the role of machine learning in pediatric health care, particularly in supporting complex diagnoses and improving clinical decision-making [45]. However, this study identified differences in preferred areas of AI improvement: public-sector HCPs valued AI more for medical training and treatment adherence, whereas hospital-based HCPs (vs those working in primary care) prioritized diagnostic assistance. This trend was also seen among older HCPs. The reasons for these differences were not explored in the survey, but they may be explained by (1) AI's role in continuing education, especially in underfunded public health systems; (2) AI's potential to support treatment adherence—through automated reminders and multilingual resources—in populations considered vulnerable and attending public hospitals; (3) the ability of AI to automate monitoring; and (4) the potential to democratize access to therapeutic support tools in public health systems. Among older HCPs or those based in hospitals, the preference possibly reflects the need to address more complex or rare cases.

Previous studies have highlighted several concerns among HCPs regarding the integration of AI into health care. Key issues include fears of job displacement, particularly in specialties such as radiology, where AI may reduce the need for human workers. Such concerns are often linked to a lack of understanding of AI, with HCPs reporting superficial knowledge of this technology but still expressing skepticism about its potential. In addition, specialists lack trust in AI's ability to address human emotions, which may degrade the patient-physician relationship, and they worry that overreliance on AI could undermine critical thinking, especially among younger professionals who may not have enough practical experience [46-49]. In this study, although approximately 90% (422/470) of the participants expressed interest in receiving AI training, concern about the legal and ethical aspects of AI was unanimous, regardless of age and type of management. Furthermore, a large proportion of respondents (30/133, 22.6%) reported neutral opinions regarding their knowledge of AI. These findings underscore the need for structured outreach, more reliable educational resources, and awareness campaigns on the role of AI in medicine.

Given the increasing role of digital tools and AI in pediatric care, integrating structured training programs for HCPs is essential to optimize their effective and ethical use. This could

XSL•FO
RenderX

enhance health care efficiency, improve patient outcomes, and help address existing disparities among professional groups. Moreover, efforts should be directed toward establishing guidelines to ensure the reliability of online health information, given its growing influence on parental decision-making. Pediatricians should play a key role in this process by guiding families toward evidence-based resources.

Although this study focuses on Spain, its findings are in line with international trends in pediatric digitalization and AI adoption. Future research should explore cross-country comparisons to identify best practices and potential areas for policy improvement. In addition, further studies should evaluate the long-term impact of digitalization on pediatric health outcomes, as well as the effectiveness of AI-driven solutions in improving clinical decision-making and patient education.

Strengths and Limitations

This study benefits from a large sample size that includes HCPs from different regions, age groups, health care settings, and professional backgrounds, providing a broad overview of current practices and perceptions regarding digital communication and AI in pediatrics. The questionnaire was specifically designed to capture both the use of digital tools and attitudes toward AI, and the stratified analyses offer valuable insights into differences by age, type of management, and type of institution. Although digital health technologies evolve rapidly, the survey was conducted over a relatively short period (September 2023-June 2024), making it unlikely that substantial shifts in professional perceptions occurred during data collection.

However, some limitations should be acknowledged. Recruitment through Laboratorios Ordesa's database and social media channels may have introduced selection bias, favoring HCPs with higher digital literacy or stronger professional ties to the private sector. In addition, the relatively low response rate (495/5187, 9.54%) raises the possibility of nonresponse bias, as participants who completed the survey may differ from nonrespondents in their engagement with digital tools or interest in AI. This could limit the generalizability of the findings to those less engaged with digital platforms. To mitigate this, the study sought participation from professionals across diverse health care settings and sectors, aiming to capture a heterogeneous sample.

Reliance on self-reported data may have introduced recall bias or social desirability bias, potentially leading to overestimation of AI knowledge or frequency of digital tool use. The cross-sectional design also limits the ability to establish causal relationships between variables, as it captures data at a single point in time. Nonetheless, the survey provides a valuable snapshot of current perceptions and practices among HCPs, allowing for the identification of relevant trends and areas for future longitudinal research. In addition, rural HCPs were underrepresented (11/469, 2.3%), which may limit the applicability of the results to rural practice contexts, where resources, infrastructure, and digital adoption present greater challenges. Public-sector participants were also underrepresented, which may not fully reflect their predominance in Spain [50]. There are no similar published works with which our data can be directly compared. Finally, the absence of a mandatory requirement to respond to all questions may have introduced some data gaps, potentially biasing the results.

Conclusions

The findings of this study highlight a significant level of digitalization in pediatric consultations, with widespread adoption of ICTs among pediatric specialists, particularly in urban settings. In addition, AI knowledge among HCPs seems to be relatively high, with many recognizing its potential benefits in diagnostics and medical training. However, concerns about misinformation as well as the ethical and legal aspects of AI continue to persist.

To enhance health care efficiency, improve patient outcomes and education, and help address existing disparities among professional groups, structured training programs on digital tools and AI, together with guidelines to ensure the reliability of online health information, are warranted.

Acknowledgments

This research was funded by Laboratorios Ordesa SL. The funder had no role in the study design; data collection, analysis, and interpretation; or manuscript preparation. The authors thank all pediatricians who participated in this study, K Access Health Projects for support with statistical analysis, and Meisys for assistance with manuscript editing and editorial support.

Data Availability

The datasets generated and analyzed in this study are available from the corresponding author on reasonable request.

Authors' Contributions

All authors made substantial contributions to this study. AS-O and CC-R conceptualized the study and oversaw the project. LO-G and AS-O contributed to the study design. LO-G, AS-O, MP-H, and CC-R oversaw data collection and interpretation. LO-G performed data analysis. LO-G, AS-O, MP-H, and CC-R contributed to manuscript preparation and interpretation. All authors approved the final manuscript.

Conflicts of Interest

AS-O and MP-H are employees of Laboratorios Ordesa SL. All other authors declare no conflicts of interest.

XSL•FO
RenderX

Multimedia Appendix 1
Clinical practice questionnaire.
[DOCX File , 21 KB - pediatrics_v8i1e75310_app1.docx]

References

1. Plekhanov D, Franke H, Netland TH. Digital transformation: a review and research agenda. Eur Manag J 2023 Dec;41(6):821-844. [doi: 10.1016/j.emj.2022.09.007]
2. Van Veldhoven Z, Vanthienen J. Digital transformation as an interaction-driven perspective between business, society, and technology. Electron Mark 2022 Mar 10;32(2):629-644 [FREE Full text] [doi: 10.1007/s12525-021-00464-5] [Medline: 35602117]
3. Barbosa W, Zhou K, Waddell E, Myers T, Dorsey ER. Improving access to care: telemedicine across medical domains. Annu Rev Public Health 2021 Apr 01;42(1):463-481 [FREE Full text] [doi: 10.1146/annurev-publhealth-090519-093711] [Medline: 33798406]
4. Ezeamii VC, Okobi OE, Wambai-Sani H, Perera GS, Zaynieva S, Okonkwo CC, et al. Revolutionizing healthcare: how telemedicine is improving patient outcomes and expanding access to care. Cureus 2024 Jul;16(7):e63881. [doi: 10.7759/cureus.63881] [Medline: 39099901]
5. Liverpool S, Mota CP, Sales CM, Čuš A, Carletto S, Hancheva C, et al. Engaging children and young people in digital mental health interventions: systematic review of modes of delivery, facilitators, and barriers. J Med Internet Res 2020 Jun 23;22(6):e16317 [FREE Full text] [doi: 10.2196/16317] [Medline: 32442160]
6. Aledia AS, Dangodara AA, Amin AA, Amin AN. Implementation of inpatient electronic consultations during the COVID-19 crisis and its sustainability beyond the pandemic: quality improvement study. J Med Internet Res 2024 May 16;26:e55623 [FREE Full text] [doi: 10.2196/55623] [Medline: 38754103]
7. Kruse CS, Krowski N, Rodriguez B, Tran L, Vela J, Brooks M. Telehealth and patient satisfaction: a systematic review and narrative analysis. BMJ Open 2017 Aug 03;7(8):e016242 [FREE Full text] [doi: 10.1136/bmjopen-2017-016242] [Medline: 28775188]
8. Bashshur RL, Howell JD, Krupinski EA, Harms KM, Bashshur N, Doarn CR. The empirical foundations of telemedicine interventions in primary care. Telemed J E Health 2016 May;22(5):342-375 [FREE Full text] [doi: 10.1089/tmj.2016.0045] [Medline: 27128779]
9. Shaver J. The state of telehealth before and after the COVID-19 pandemic. Prim Care 2022 Dec;49(4):517-530. [doi: 10.1016/j.pop.2022.04.002] [Medline: 36357058]
10. Wosik J, Fudim M, Cameron B, Gellad ZF, Cho A, Phinney D, et al. Telehealth transformation: COVID-19 and the rise of virtual care. J Am Med Inform Assoc 2020 Jun 01;27(6):957-962 [FREE Full text] [doi: 10.1093/jamia/ocaa067] [Medline: 32311034]
11. North S. Telemedicine in the time of COVID and beyond. J Adolesc Health 2020 Aug;67(2):145-146 [FREE Full text] [doi: 10.1016/j.jadohealth.2020.05.024] [Medline: 32605827]
12. Jeyaraman M, Ramasubramanian S, Kumar S, Jeyaraman N, Selvaraj P, Nallakumarasamy A, et al. Multifaceted role of social media in healthcare: opportunities, challenges, and the need for quality control. Cureus 2023 May;15(5):e39111 [FREE Full text] [doi: 10.7759/cureus.39111] [Medline: 37332420]
13. Bravo Acuña J, Merino Moína M. [Use of new technologies for communicating with patients: their usefulness and their risks]. An Pediatr (Engl Ed) 2020 May;92(5):251-252 [FREE Full text] [doi: 10.1016/j.anpedi.2020.02.010] [Medline: 32241652]
14. Chen J, Wang Y. Social media use for health purposes: systematic review. J Med Internet Res 2021 May 12;23(5):e17917 [FREE Full text] [doi: 10.2196/17917] [Medline: 33978589]
15. Medicine in the digital age. Nat Med 2019 Jan 7;25(1):1. [doi: 10.1038/s41591-018-0322-1] [Medline: 30617338]
16. Rajpurkar P, Chen E, Banerjee O, Topol EJ. AI in health and medicine. Nat Med 2022 Jan 20;28(1):31-38. [doi: 10.1038/s41591-021-01614-0] [Medline: 35058619]
17. Esteva A, Robicquet A, Ramsundar B, Kuleshov V, DePristo M, Chou K, et al. A guide to deep learning in healthcare. Nat Med 2019 Jan 7;25(1):24-29. [doi: 10.1038/s41591-018-0316-z] [Medline: 30617335]
18. Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. Nat Med 2019 Jan 7;25(1):44-56. [doi: 10.1038/s41591-018-0300-7] [Medline: 30617339]
19. Buch VH, Ahmed I, Maruthappu M. Artificial intelligence in medicine: current trends and future possibilities. Br J Gen Pract 2018 Mar;68(668):143-144 [FREE Full text] [doi: 10.3399/bjgp18X695213] [Medline: 29472224]
20. Castelló Egea A, Roqueta del Riego M, Minguella García I, García García A, Macias Castellví M, García Bordes L. Fuentes de información de los padres respecto a la salud de sus hijos. Acta Pediatr Esp 2011;69(10):450-454 [FREE Full text] [doi: 10.2307/jj.5076229.153]
21. Curfman A, McSwain SD, Chuo J, Yeager-McSwain B, Schinasi DA, Marcin J, et al. Pediatric telehealth in the COVID-19 pandemic era and beyond. Pediatrics 2021 Sep;148(3):e2020047795 [FREE Full text] [doi: 10.1542/peds.2020-047795] [Medline: 34215677]

XSL•FO
RenderX

22. Haynes SC, Marcin JP. Pediatric telemedicine: lessons learned during the coronavirus disease 2019 pandemic and opportunities for growth. Adv Pediatr 2022 Aug;69(1):1-11 [FREE Full text] [doi: 10.1016/j.yapd.2022.04.002] [Medline: 35985702]
23. Martín-Masot R, Diaz-Martin JJ, Santamaría-Orleans A, Navas-López VM. Impact of the COVID-19 pandemic on the digitization of routine pediatric practice in Spain: a nationwide survey study. Front Pediatr 2023 Feb 14;11:1106488 [FREE Full text] [doi: 10.3389/fped.2023.1106488] [Medline: 36865698]
24. Perrier E, Rifai M, Terzic A, Dubois C, Cohen JF. Knowledge, attitudes, and practices towards artificial intelligence among young pediatricians: a nationwide survey in France. Front Pediatr 2022 Dec 23;10:1065957 [FREE Full text] [doi: 10.3389/fped.2022.1065957] [Medline: 36619510]
25. Schmitz A, Díaz-Martín AM, Yagüe Guillén MJ. Telemedicine beyond borders: a mixed-methods approach to understanding cross-national usage intention. Telemed J E Health 2024 Aug 01;30(8):e2344-e2352. [doi: 10.1089/tmj.2023.0678] [Medline: 38752866]
26. Hollander JE, Carr BG. Virtually perfect? Telemedicine for Covid-19. N Engl J Med 2020 Apr 30;382(18):1679-1681. [doi: 10.1056/NEJMp2003539] [Medline: 32160451]
27. Borges do Nascimento IJ, Abdulazeem H, Vasanthan LT, Martinez EZ, Zucoloto ML, Østengaard L, et al. Barriers and facilitators to utilizing digital health technologies by healthcare professionals. NPJ Digit Med 2023 Sep 18;6(1):161. [doi: 10.1038/s41746-023-00899-4] [Medline: 37723240]
28. Van de Belt TH, Berben SA, Samsom M, Engelen LJ, Schoonhoven L. Use of social media by Western European hospitals: longitudinal study. J Med Internet Res 2012 May 01;14(3):e61 [FREE Full text] [doi: 10.2196/jmir.1992] [Medline: 22549016]
29. Williams SA, Terras M, Warwick C. How Twitter is studied in the medical professions: a classification of Twitter papers indexed in PubMed. Med 2 0 2013;2(2):e2. [doi: 10.2196/med20.2269] [Medline: 25075237]
30. Rotaru N, Edelhauser E. Digital transformation: a challenge for the Romanian health system. Systems 2024 Sep 14;12(9):366. [doi: 10.3390/systems12090366]
31. Subhan Amir A, Mulyana D, Dida S, Suminar JR. Enhancing doctor-patient communication through digital media platforms: a study on innovation in health interaction. Proc Int Conf Innov Sci Technol Educ Child Health 2024;4(2):172-189 [FREE Full text] [doi: 10.62951/icistech.v4i2.99]
32. Observatorio de Digitalización en la sanidad privada: madurez digital y casos de éxito. Instituto para el Desarrollo e Integración de la Sanidad. 2025. URL: https://www.fundacionidis.com/uploads/informes/[IDIS]Observatorio_de_Digitalizacin_en_la_sanidad_privada_-_Informe_Final_.pdf [accessed 2025-09-24]
33. El ICOMEM recuerda a los médicos que comunicar los datos de salud de los pacientes por whatsapp no garantiza la confidencialidad de la información. Médicos y Pacientes. 2018 Jun 18. URL: https://www.medicosypacientes.com/articulo/el-icomem-recuerda-los-medicos-que-comunicar-los-datos-de-salud-de-los-pacientes-por/ [accessed 2025-08-13]
34. Ginn S. Email in healthcare: pros, cons and efficient use. BJPsych Adv 2024;30(3):195-201. [doi: 10.1192/bja.2023.49]
35. Luchowska K, Chmielewska M, Byszek K, Olearczyk A, Gawrońska A, Więckowska B. Contextual factors influencing the use of digital health by patients and physicians in primary care: a scoping review protocol. BMJ Open 2024 Dec 20;14(12):e088169. [doi: 10.1136/bmjopen-2024-088169] [Medline: 39806600]
36. Estrategia de Salud Digital 2021-2026. Ministerio de Sanidad. 2024 Dec. URL: https://www.sanidad.gob.es/areas/saludDigital/doc/Presentacion_avances_de_la_Estrategia_de_Salud_Digital_web.pdf [accessed 2025-02-01]
37. Mutch S. What's up with using WhatsApp in the workplace? People Management. 2023 Sep 7. URL: https://www.peoplemanagement.co.uk/article/1836432/whats-using-whatsapp-workplace [accessed 2025-02-01]
38. Rosales A, Fernández-Ardèvol M. Beyond WhatsApp: older people and smartphones. Rom J Commun Public Relat 2016;18(1):27-47. [doi: 10.21018/rjcpr.2016.1.200]
39. Frey E, Bonfiglioli C, Brunner M, Frawley J. Parents' use of social media as a health information source for their children: a scoping review. Acad Pediatr 2022 May;22(4):526-539 [FREE Full text] [doi: 10.1016/j.acap.2021.12.006] [Medline: 34906742]
40. Bella SL, Ludovico AD, Parri N, Mauro AD, Corsello A. How social media are changing pediatricians and pediatrics? - A claim for regulation. Ital J Pediatr 2024 Nov 25;50(1):251 [FREE Full text] [doi: 10.1186/s13052-024-01822-7] [Medline: 39587655]
41. Freberg K, Palenchar MJ, Veil SR. Managing and sharing H1N1 crisis information using social media bookmarking services. Public Relat Rev 2013 Sep;39(3):178-184. [doi: 10.1016/j.pubrev.2013.02.007]
42. Kington RS, Arnesen S, Chou WY, Curry SJ, Lazer D, Villarruel AM. Identifying credible sources of health information in social media: principles and attributes. NAM Perspect 2021 Jul 16;2021. [doi: 10.31478/202107a] [Medline: 34611600]
43. Busto-Salinas L. Comunicar desde el ámbito público o privado: el caso de los hospitales. Prof Inf 2016 Nov 14;25(6):923-930. [doi: 10.3145/epi.2016.nov.09]
44. Sacristan FR. Fundación IDIS destaca el rol de la sanidad privada en la era digital de la salud. Gaceta Médica. 2025. URL: https://gacetamedica.com/profesion/fundacion-idis-destaca-el-rol-de-la-sanidad-privada-en-la-era-digital-de-la-salud/ [accessed 2025-02-01]

XSL•FO
RenderX

45. Ganatra HA. Machine learning in pediatric healthcare: current trends, challenges, and future directions. J Clin Med 2025 Jan 26;14(3):807 [FREE Full text] [doi: 10.3390/jcm14030807] [Medline: 39941476]
46. Weber S, Wyszynski M, Godefroid M, Plattfaut R, Niehaves B. How do medical professionals make sense (or not) of AI? A social-media-based computational grounded theory study and an online survey. Comput Struct Biotechnol J 2024 Dec;24:146-159 [FREE Full text] [doi: 10.1016/j.csbj.2024.02.009] [Medline: 38434249]
47. Ramasawmy M, Sunkersing D, Poole L, Blandford A, Gill P, Khunti K, et al. Healthcare professionals' attitudes towards digital health interventions and perspectives on digital health inequalities in cardiometabolic care: a qualitative study. BMJ Open 2025 Feb 26;15(2):e091018. [doi: 10.1136/bmjopen-2024-091018] [Medline: 40010817]
48. Pal N, Syed J, Madhan R, Patil V, Shambhu SK, Chalasani SH. Attitude and perceptions of healthcare professionals towards digital health technologies: a cross-sectional study. SSRN. Preprint posted online on January 24, 2025 2025 [FREE Full text] [doi: 10.2139/ssrn.5101084]
49. Yousif M, Asghar S, Akbar J, Masood I, Arshad MR, Naeem J, et al. Exploring the perspectives of healthcare professionals regarding artificial intelligence; acceptance and challenges. BMC Health Serv Res 2024 Oct 08;24(1):1200 [FREE Full text] [doi: 10.1186/s12913-024-11667-9] [Medline: 39379939]
50. Castaño Alegre S, Celaya Fernández I, Corbato García Á, Martínez Suárez V. Encuesta sobre la situación profesional de la pediatría en España. Pediatr Integral 2020;24(5):285-294 [FREE Full text]

Abbreviations

AI: artificial intelligence
HCP: health care professional
ICT: information and communication technology

Edited by S Badawy; submitted 14.04.25; peer-reviewed by H Sadia, F López Segui; comments to author 08.08.25; revised version received 29.08.25; accepted 10.09.25; published 15.10.25.

Please cite as:
Santamaría-Orleans A, Ortiz-González L, Pérez-Hernández M, Coronel-Rodríguez C
Impact of Digitalization on Pediatric Practice and Childhood Health Care in Spain: Nationwide Survey Study
JMIR Pediatr Parent 2025;8:e75310
URL: https://pediatrics.jmir.org/2025/1/e75310
doi:10.2196/75310
PMID:41092390

©Alicia Santamaría-Orleans, Luis Ortiz-González, Maite Pérez-Hernández, Cristóbal Coronel-Rodríguez. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 15.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Using WhatsApp for Nutrition Surveillance Among Children Under 5 Years in West Java, Indonesia: Cross-Sectional Survey and Feasibility Study

Dewi Nur Aisyah[1,2,3,4*], PhD; Chyntia Aryanti Mayadewi[2*], MSc; Astri Utami[2*], BSc; Fauziah Mauly Rahman[2,5*], BSc; Nathasya Humaira Adriani[2*], BSc; Erlangga Al Farozi[2*], MTI; Meldi Hafizh Sayoko[6*], MSc; Aulia Chairunisa[2*], BSc; Liza Restiana[7*], MD; Logan Manikam[1,3*], PhD; Zisis Kozlakidis[8*], PhD

[1]Department of Epidemiology and Public Health, Institute of Epidemiology and Health Care, University College London, 1-19 Torrington Place, London, United Kingdom

[2]Digital Transformation Office, Ministry of Health, Republic of Indonesia, Jakarta, Indonesia

[3]Aceso Global Health Consultants Pte Limited, #32-02, International Plaza, Singapore, Singapore

[4]Department of Public Health, Monash University Indonesia, Tangerang, Indonesia

[5]School of Computer Science, Faculty of Engineering, University of Sydney, Camperdown, NSW, Australia

[6]Department of Science, Technology and Innovation Studies, School of Social and Political Science, University of Edinburgh, Edinburgh, United Kingdom

[7]Ciderum Community Health Center, Caringin Subdistrict, Bogor, Indonesia

[8]International Agency for Research on Cancer World Health Organization, Lyon, France

[*]all authors contributed equally

Corresponding Author:
Logan Manikam, PhD
Department of Epidemiology and Public Health, Institute of Epidemiology and Health Care, University College London, 1-19 Torrington Place, London, United Kingdom

Abstract

Background: Large-scale programs involving nutrition-specific interventions have been carried out in Indonesia as a community-based approach at the primary care level across cities and districts, throughout the age-specific target population (ie, children under 5 years).

Objective: The aim of this paper is to describe the potential use of WhatsApp as a tool for recording and monitoring the growth of children under 5 years by Posyandu (Pos Pelayanan Terpadu or community-based health service post), investigating its potential in enhancing health programs and services.

Methods: Data were collected from Posyandu cadres in Bogor District, West Java, from March to June 2022. The anthropometric measurement data were reported in real time through a WhatsApp chatbot, automatically analyzed by the system, and presented in a structured dashboard. A qualitative assessment was carried out using a cross-sectional survey conducted from March to July 2022.

Results: The study involved 42 Posyandu in 3 villages, engaging 282 staff, and the WhatsApp chatbot recorded anthropometric data for 4571 children under 5 years. The qualitative assessment indicated widespread system utilization, with 50% (45/90) affirming comprehensive data input. Additionally, 66.4% (83/129) found the system easy to use, and 66.7% (82/123) expressed clarity in comprehending variables. Moreover, 75.6% (93/123) found the data input flow easily understood, and 74% (91/123) suggested that the system contributed to enhancing Posyandu activities and the quality of data reporting. Regarding staff proficiency, 63.5% (80/126) affirmed their adeptness in using the system, and 71% (88/124) asserted their high capability in providing training to colleagues.

Conclusions: The potential use of WhatsApp as a surveillance tool for recording children's nutritional status is promising, suggesting broader applications within health programs. Nonetheless, this expansion requires additional improvements, including human resource preparation, Posyandu infrastructure development, and strong regulatory support.

(JMIR Pediatr Parent 2025;8:e58752) doi:10.2196/58752

XSL•FO
RenderX

KEYWORDS

WhatsApp; Posyandu; nutrition surveillance; nutrition; nutritional; mHealth; mobile health; app; anthropometric; data collection; surveillance; chatbots; digital; digital health; digital technology; digital intervention; pediatric; infant; baby; neonatal; toddler; child

Introduction

Stunting is a condition described as a linear growth failure in which children are too short for their age, and it has been deemed a significant public health issue globally [1-3]. Children with stunted growth are at heightened risk of irreversible loss of growth, suboptimal cognitive development, and elevated risk of morbidities and mortalities in adulthood [3,4]. Suboptimal cognitive development leads to lower cognitive skills, resulting in poor academic performance and lower incomes [4,5]. Although there was a significant decrease in prevalence within the last decade, 148.1 million (22.3%) children under 5 years (CU5) were estimated as having stunted growth in 2022 [1]. According to the Indonesian Nutritional Status Survey (Survei Status Gizi Indonesia) in 2023, the prevalence of children with stunted growth in Indonesia in 2022 was 21.6%, thus similar to the global burden [1,6,7].

To accurately describe a population's nutritional status, particularly the at-risk groups, establishing a nutritional surveillance system becomes pivotal [8]. Such a nutritional surveillance system needs to collect data on nutrition risk factors in a regular and timely manner from various sources, such as growth monitoring in health facilities, nutrition surveys for the population, as well as community-based sentinel monitoring [8-10]. In Indonesia, community-based sentinel sites for growth monitoring for CU5 are conducted through Posyandu (Pos Pelayanan Terpadu; community-based health service post), where the anthropometry measurements are done routinely to help obtain cohort nutritional status information of the children [11,12]. Posyandu serves as a community-based public health outreach initiative, managed and organized in partnership with the community, linking the latter to public health centers (Pusat Kesehatan Masyarakat [Puskesmas]), with the goal of improving access to basic health services, particularly for reducing maternal and child mortality rates [13]. Posyandu itself is integrated into the village social institutions, contributing to enhanced health services for the community [14].

Posyandu undertakes a comprehensive range of health services, consisting of but not limited to maternal and child health care, including immunization services; adolescent reproductive health services; older adult health services; disease control; environmental sanitation; promotion of healthy lifestyles; and diversification of food consumption [11]. These activities are carried out by dedicated and trained community health workers, also referred to as cadres, who are community members voluntarily devoting their time and efforts to organizing Posyandu activities [11]. Indonesia currently possesses a substantial network of more than 213,000 Posyandu, with an estimated 1,039,684 active volunteers nationwide [15]. Trained community health workers play a crucial role in the success of Posyandu and the reduction of malnutrition [16]. In 2021, a presidential decree by the Indonesian government focused on the acceleration of stunting reduction and emphasized the importance of growth and development monitoring services at Posyandu [17].

In general, the reporting process in Posyandu begins with the cadre registering the children and mother in the Posyandu's registration book. It is then followed by the measurement of the height and body weight of the children, which are recorded in the Maternal and Child Health book as well as the Posyandu book [11,12]. After the child and the mother are given health education and other health services as needed, the data are input into an Excel file (Microsoft Corp). The file is then sent to the Puskesmas (public health center), where the workers begin inputting the data into the nutrition surveillance system. This process creates a delay in generating the nutritional status of the children and presents challenges such as difficulty for the cadres to plot the growth chart, possibility of loss of records, and potential inclusion of errors.

Mobile phones and internet usage are increasingly used for health programs, service delivery, and public health messaging [18]. Young adults are very likely to use mobile apps and the internet for health purposes [19]. Furthermore, in low- and middle-income countries (LMICs), mobile phone technologies are promising tools for enhancing primary health care services [20]. In 2021, 125.6% of the total population in Indonesia possessed a mobile phone (ie, there is more than 1 phone per person) [21], while in 2022, 66% of the population had used the internet [22], with the majority of apps used falling within the social and communication spectrum [23]. As of 2023, WhatsApp reached 120.35 million users in Indonesia with an average use time of 29 hours per month, making it the most used app nationally [24]. Aside from being a communication tool, WhatsApp is used for other purposes such as facilitating education (as a supporting tool for e-learning), as well as for health purposes such as for diagnostic and telemedicine support [25-31], though WhatsApp's use as a survey tool remains limited.

Indonesia is considered a digital force in Southeast Asia [32], with highly advanced digital health services integration. With the launch of the Digital Health Transformation Blueprint, the government committed to enhancing public health through the means of digitization [33]. One of these digitization programs involves improving the quality and reach of surveillance of the nutritional status of CU5 conducted by community health workers. To this end, the Digital Transformation Office – Pusat Data dan Informasi (DTO-Pusdatin) team at the Ministry of Health carried out a pilot project using WhatsApp as a data input tool to monitor the growth status of CU5 during Posyandu activities. This paper investigates the potential use of WhatsApp as a tool for recording and monitoring the growth of CU5 in Posyandu and evaluates its application within the national framework of providing an improved national surveillance service.

XSL•FO
RenderX

Methods

Using WhatsApp for CU5 Nutrition Surveillance

Overview

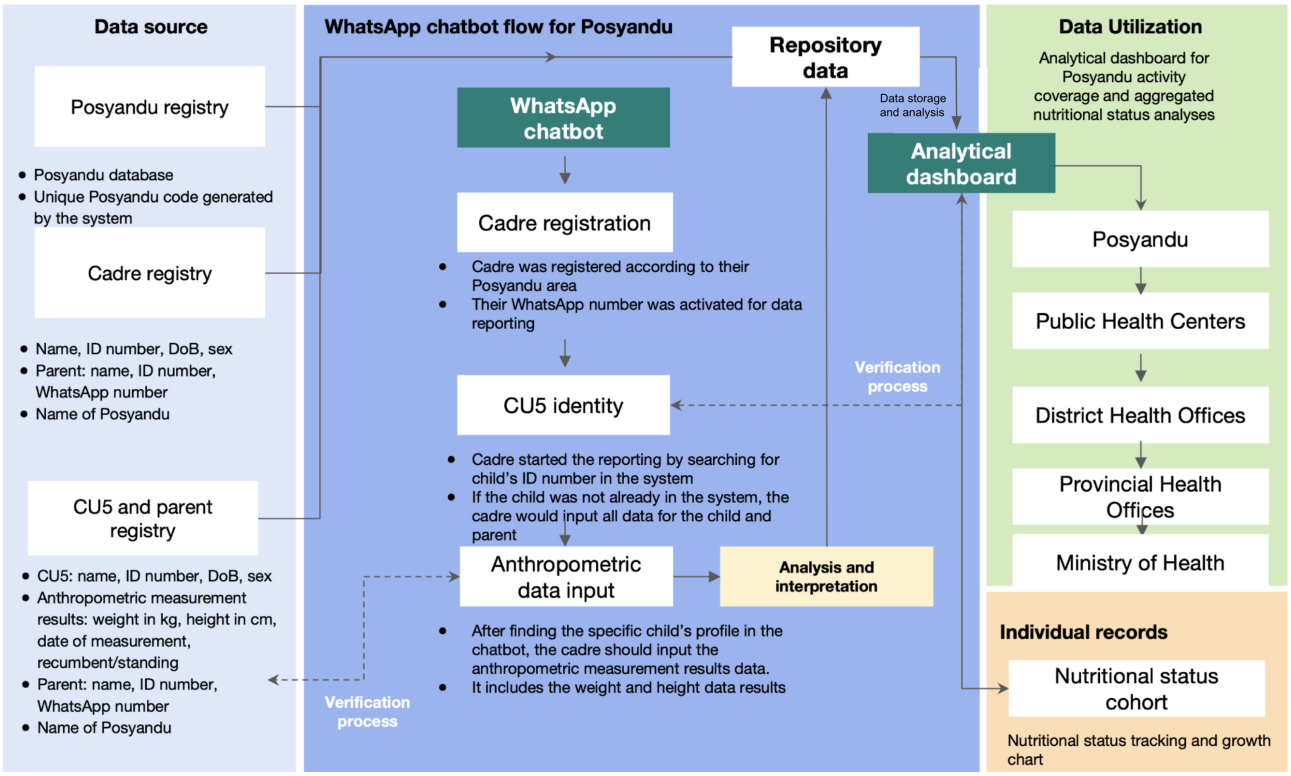
There are varying capacities among Posyandu's cadres in Indonesia with respect to technology; not all are acquainted with or adept at using mobile apps or information systems for nutrition surveillance recording and reporting. To address this, a novel approach is required to simplify the process of recording and reporting nutrition surveillance in Posyandu, especially that which is to be done by the cadres. In response to this need, the DTO-Pusdatin Ministry of Health introduced an innovation by creating a WhatsApp chatbot specifically designed for inputting CU5 measurement results by the cadres at Posyandu. A feasibility study to test the reporting system through the WhatsApp chatbot was conducted from March to June 2022 at the Ciderum Puskesmas, located in Bogor District, West Java Province, Indonesia.

The process of recording the nutritional data using the WhatsApp chatbot involved several stages (Figure 1).

Gathering the Basic Data of CU5 and Parents or Caregivers

Basic data were gathered about the CU5 and their parents, including the child's full name, national identification number (Nomor Identitas Kependudukan; NIK), date of birth, gender, parent's name and ID number, and lastly the Posyandu ID. For the parent's data, it was only asked that either the father or mother's information was entered; in some cases, this information would be that of a grandmother or another caregiver. This manual dataset was then imported into the system.

Figure 1. Input, process, and output flow of the WhatsApp chatbot system for nutrition surveillance in Posyandu. CU5: children under 5 years; DoB: date of birth.



Cadre Registration

The account registration was done to enable the cadres to record the data in the WhatsApp chatbot. The registration required the cadres' data including their full name, ID number, date of birth, the name of Posyandu they work in, and an active WhatsApp number. This data already existed at Puskesmas, and it was used to validate the input data. The registered cadres' profiles could be monitored through the operational dashboard, which also served as the user management feature for the WhatsApp chatbot. Only DTO-Pusdatin Ministry of Health and Puskesmas Ciderum Teams had the authority to register and edit the cadres' accounts.

Data Input and Validation

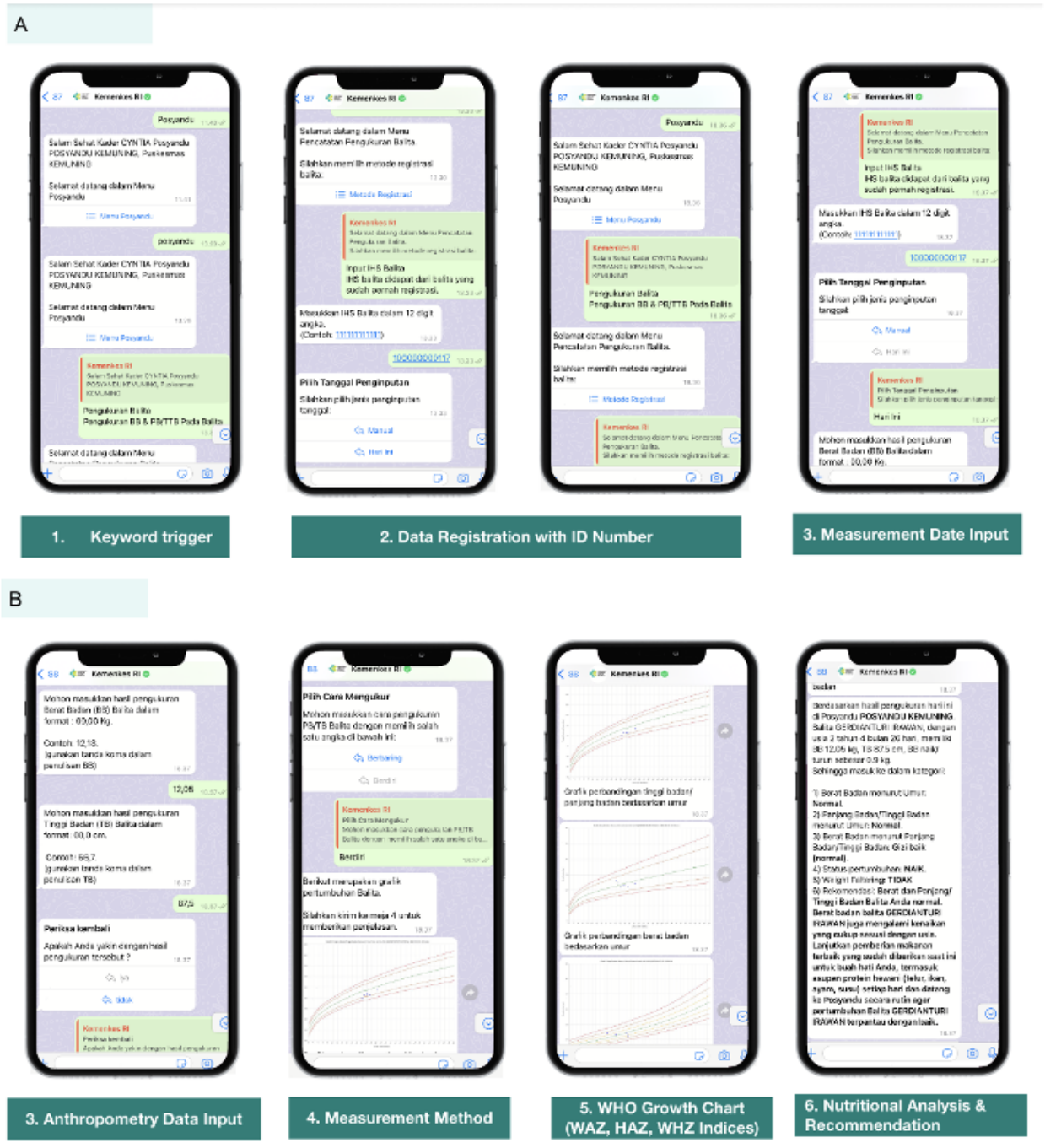
After the cadres were registered and their WhatsApp number was activated, the cadres could start to report data by sending "posyandu" as the trigger keyword to activate the data reporting flow of the chatbot (Figure 2). Once the flow started, the variables that should be filled in by the cadres were separated into 3 main sections: child's data, parent/caregiver's data, and measurement data. For each variable, automatic validations were set in order to prevent human error in data recording.

For the first section, the child's name, ID number, date of birth, and sex were required. For the parent's section, their name, their ID number, and an active WhatsApp number were required. Both the child's and parent's ID number were nonmandatory, as some of them may not have had an ID number. Lastly, the measurement section required the date of measurement, weight

XSL•FO
RenderX

result (kg, 2 decimals), height result (cm, 1 decimal), and method of measuring height (recumbent or standing).

Figure 2. The WhatsApp chatbot interface including (A) starting the flow and child identity data input and (B) anthropometry data input, WHO growth chart, and results analysis. HAZ: height-for-age z-score; WAZ: weight-for-age z-score; WHO: World Health Organization; WHZ: weight-for-height z-score.



Individual Nutritional Status Analysis

After the cadres completed inputting the requested data, the chatbot system automatically sent the results of 3 nutritional status indices, which included the weight-for-age z-score (WAZ), height-for-age z-score (HAZ), and weight-for-age height z-score (WHZ) (Textbox 1).

Each recorded CU5 was provided with an evaluation of their nutritional status using 3 nutritional indices, accompanied by a growth chart for each index. These growth charts are similar to the World Health Organization (WHO) growth chart, making it easy for the cadres to quickly determine the child's nutritional status by plotting the growth chart.

XSL•FO
RenderX

Textbox 1. Nutritional indices and the classifications for each index according to the Ministry of Health Decree Number 2/2020 about Children Anthropometry Standard.

1. Weight-for-age z-score (WAZ)

- Severely underweight (less than –3 SD)
- Underweight (–3 SD to less than –2 SD)
- Normal (–2 SD to +1 SD)
- Risk of overweight (greater than +1 SD)

2. Height-for-age z-score (HAZ)

- Severely stunted (less than −3 SD)
- Stunted (–3 SD to less than –2 SD)
- Normal (–2 SD to +3 SD)
- Tall (greater than +3 SD)

3. Weight-for-height z-score (WHZ)

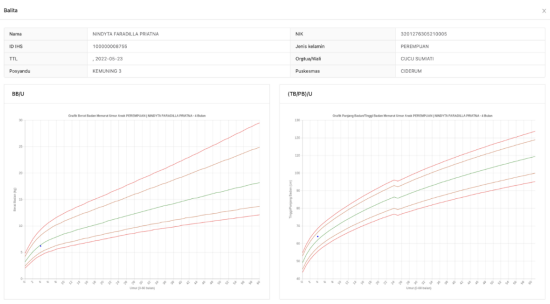
- Severely wasted (less than –3 SD)
- Wasted (3 SD to less than –2 SD)
- Normal (–2 SD to +1 SD)
- Overweight (greater than +2 SD to +3 SD)
- Obese (greater than +3 SD)

Analytics Dashboard

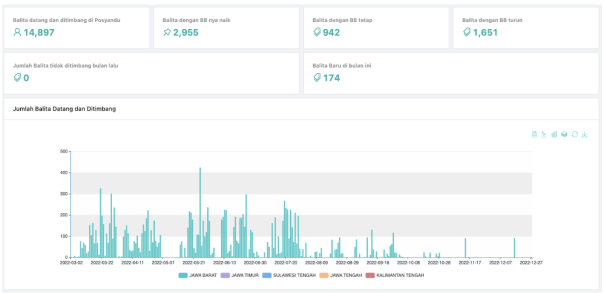
In order to provide nutritional status interpretations, the reporting system offered individual recording outcomes and aggregate analyses through a dashboard (Figure 3). The analysis dashboard was divided into four sections, including (1) cohort of individual measurement results, (2) aggregated measurement analysis, (3) analysis of nutritional problem magnitudes, and (4) malnutrition management feature (Figure 3).

Figure 3. Analytical dashboard features.

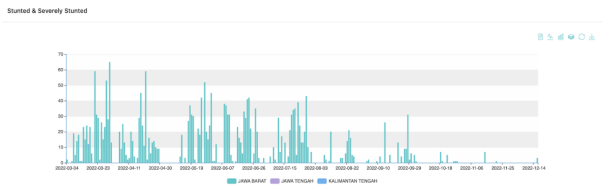
(A) Cohort of individual measurement results



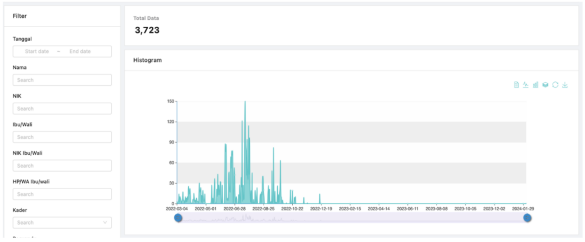
(B) Aggregated measurement analysis



(C) Nutrition problem magnitude analysis



(D) Malnutrition management feature



Excel Download for Cadres

For cadres who completed inputting weighing results at Posyandu, the chatbot flow offered the option to download the recorded data in Excel format. Selecting “YES DOWNLOAD” prompted the system to send an Excel file containing weighing results not only from one cadre but from all cadres who input data for all CU5 attending the same Posyandu within the same

XSL•FO
RenderX

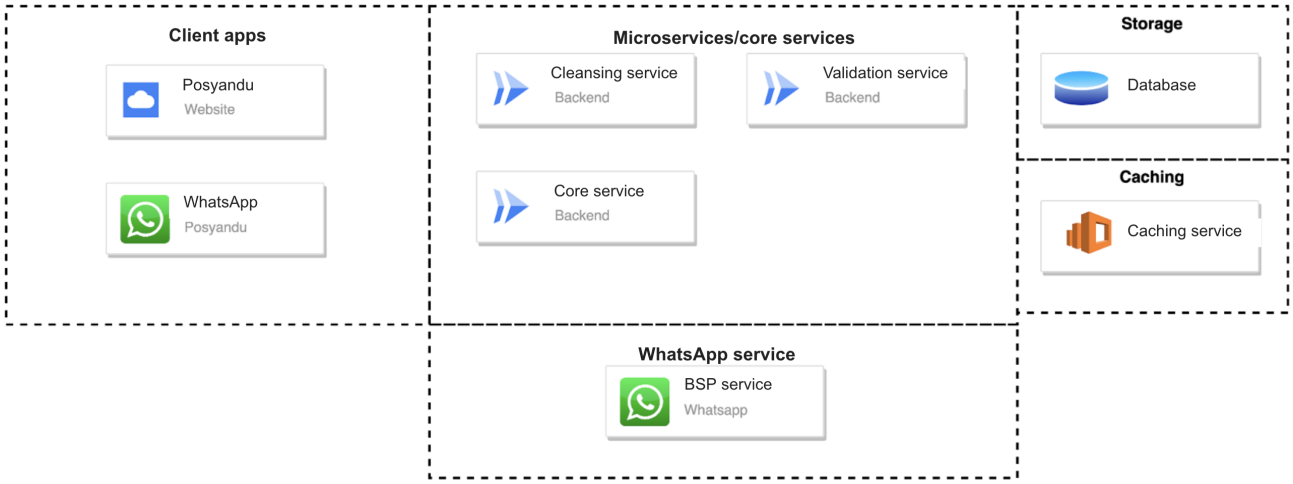
time frame. This excel data served as a simple way to check the number of recorded CU5 in the system, especially for the Puskesmas, which mostly required timely reports of recent Posyandu activity.

System Architecture

Client applications, microservices, and the WhatsApp service, storage, and caching are the 5 components that make up the architecture used for this chatbot development (Figure 4). A website and a WhatsApp client (chatbot) are the components that make up the client apps. For the purpose of facilitating the submission of data from the WhatsApp chatbot, the website functions as a front-facing interface for cadres and system administrators. Additionally, it is able to process and change the master data that is going to be used by the WhatsApp chatbot, such as Posyandu data. The information that is stored in each of these front-facing interfaces is stored in a MySQL database. As a result of the large amount of data that is processed, an additional caching service was designed in order to speed up the look up and processing of data within the database.

The microservices model allows for communication between the storage and the front-facing interface. The front-facing client and the database are connected through a number of microservices, which act as the gateway for the exchange of data between the two. In addition, these services incorporate logics and rules that are in accordance with the standards set forth by the World Health Organization (WHO) in order to process the information that is received from the front-facing interface before saving it in the database. Additionally, WhatsApp possesses its very own microservice, which is responsible for communicating the outcome of the computation and the data from the database to the chatbot before it is displayed to the user.

Figure 4. WhatsApp chatbot system architecture. BSP: business service provider.



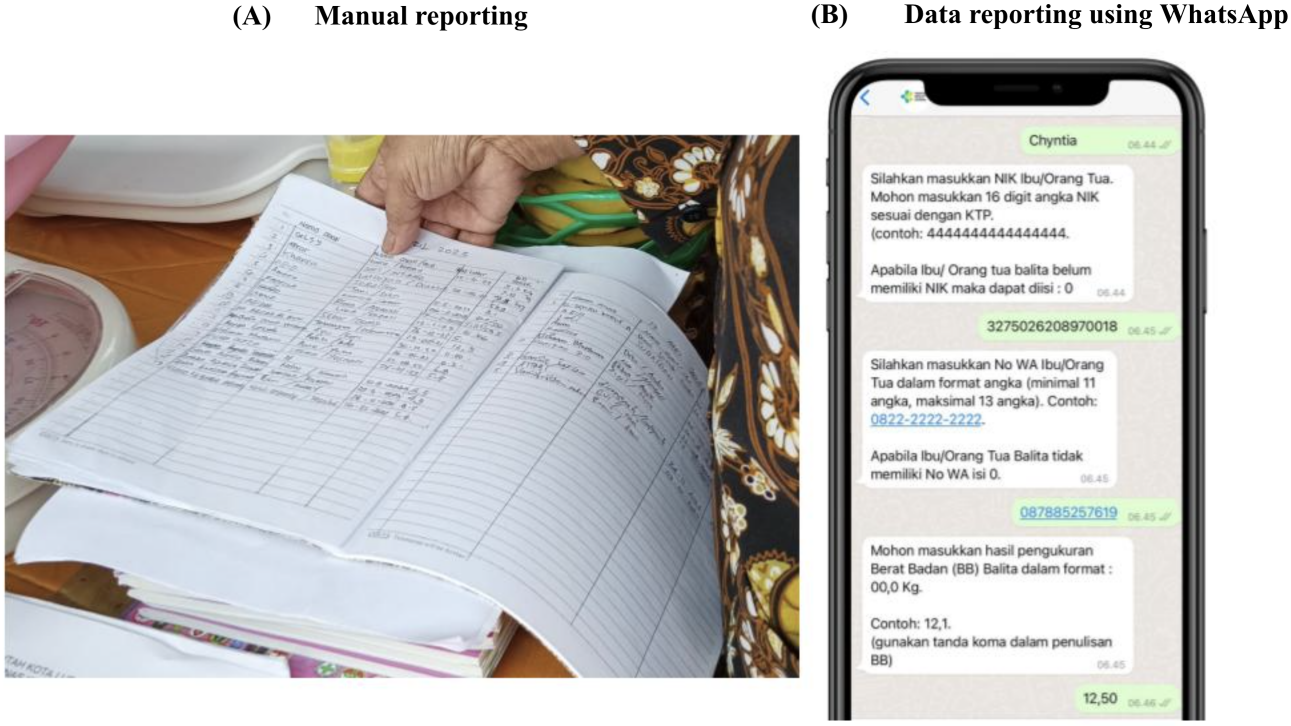
Data Analysis

The cadre entered individual data by entering the child's 16-digit NIK or Individual Health Status (IHS) number. The cadre was then asked to enter the child's height and weight measurements, as well as how the measurements were taken (standing or recumbent). After all the data were entered, the system calculated the measurement results to be included in the growth chart (Figure 5): based on body height/length and body weight, based on body height/length and age, and based on body weight and age [34]. After that, recommendations for parents were displayed based on the child's nutritional status. Data collection was carried out from March 1 to June 30, 2022, at 42 Posyandu in 3 villages in the Puskesmas Ciderum work area in Bogor District, namely Ciderum Village, Ciherang Pondok Village, and Pancawati Village.

Before the recording was carried out by cadres, a training session was carried out for one cadre from each Posyandu, with a total of 42 participants, in February 2022. To make it easier for cadres to carry out training for other Posyandu cadres, a booklet and tutorial video were provided. The system trial phase was carried out for 1 month by visiting the Posyandu in each village and an evaluation was carried out at the end of March. In the following 3 months, assistance was provided at 42 Posyandu with 2 evaluation processes through a WhatsApp coordination group with cadres. The Puskesmas officers monitored the input results through the analysis dashboard.

XSL•FO
RenderX

Figure 5. Posyandu reporting before (left) and after (right) using the WhatsApp chatbot.



The results of anthropometric data (weight and height) were automatically processed by the system and presented in a structured dashboard, accessible for Puskesmas, District Health Offices, Provincial Health Offices, and the Ministry of Health at the national level. The data could be queried using a set of predetermined variables. The analyses generated were the frequency and percentage of children being measured based on demographic characteristics (sex, age, domicile address), nutritional status (WAZ, HAZ, WHZ), and spatial analysis on nutritional burden. Trends in service outcome were depicted using time series graphs. The comparative results of Posyandu services at the village level were generated, including analysis by sex and age groups.

Qualitative Assessment

To collect feedback from users, a series of qualitative assessments were carried out on March 31, May 31, and July 4, 2022, using a roundtable discussion method with a total of 48, 41, and 42 participants in the sessions, respectively [35]. This qualitative assessment was done during monitoring evaluation meetings with health cadres who had been trained and joined the pilot program since February 2022.

The participants of the survey were health cadres from 3 villages (Ciderum, Ciherang Pondok, and Pancawati) in Bogor District. The qualitative assessments started 1 month after the pilot project was implemented, and they were repeated at monthly intervals an additional 2 times. The survey used the Mentimeter online platform, enabling participants to answer and show the cumulative, anonymized results directly. The questionnaire consisted of four sections: (1) system usage, (2) data input, (3) overall user feedback, and (4) cadre's ability.

Ethical Considerations

We declare that the data collected for this paper do not require ethical approval as no individual data are presented and informed consent was obtained during the survey implementation. The participants were able to opt out at any point during participation in this study. This exemption is regulated in Indonesia Ministry of Health's National Guidelines and Standards for Ethical Research and Development in Health year 2017, which states that studies are exempt from the ethical review process due to no or minimal potential risk/harm of the studies, and if the information being used was publicly available, including procedures such as surveys or interviews or observations of public behavior. It further specifies that research that is conducted by a department or agency, with the purpose of studying, evaluating, or assessing the benefits of public programs or services, does not require ethics approval [36]. This study ensured that the entire process adhered to ethical principles, including respecting participants' autonomy, promoting their well-being, and avoiding any harm. These principles were upheld by obtaining informed consent, maintaining the confidentiality of participants' information, and minimizing any potential risks. Additionally, no compensation was provided to the participants involved in this study.

Results

Overview

This study of a WhatsApp chatbot for nutrition surveillance data recording and reporting was done in 3 villages in Bogor District, West Java Province, Indonesia, specifically Ciherang Pondok, Ciderum, and Pancawati. These 3 villages have different characteristics in terms of sociodemographics, facilities, and level of support by local leaders (Table 1).

XSL•FO
RenderX

Table . Characteristics of the 3 study area villages.

Characteristics	Ciherang Pondok	Ciderum	Pancawati	Total
Children under 5 years, n (%)	1642 (36)	1352 (30)	1577 (34)	4571
Number of Posyandu	13	14	15	42
Number of cadres	65	56	60	282
Internet infrastructure	Good	Fair	Poor	N/A
Support from village leader	Very good	Neutral	Neutral	N/A

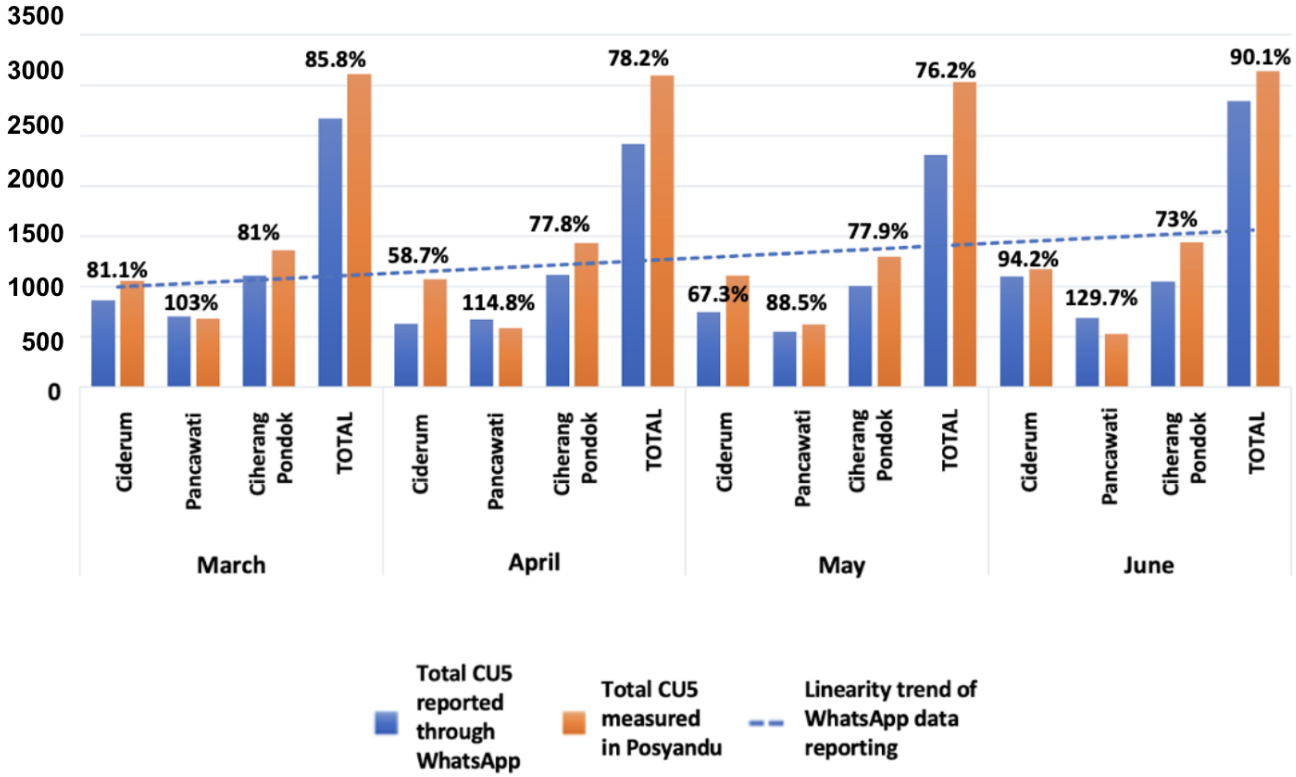
[a]N/A: not applicable.

Results of CU5 Posyandu Weight and Height Measurement Services

During the study, cadres successfully adapted to the new WhatsApp chatbot for reporting CU5 height and weight measurements, transitioning from manual to digital recording. Implementing the WhatsApp chatbot for data reporting presented a novel experience for the cadres.

Generally, it was found that the total number of CU5 measurements input into the chatbot was lower than the total number of children weighed at the Posyandu (Figure 6). The highest proportion of measurements input was in June (n=3144, 90.1%), followed by March (n=3113, 85.8%), April (n=3095, 78.2%), and May (n=3032, 76.2%). In April and May, fewer results were entered due to Ramadan and Eid al-Fitr affecting how well cadres could input data. Toward the study's end, a reminder was sent to cadres by DTO-Pusdatin Ministry of Health and village leaders about data entry.

Figure 6. The comparison of total CU5 being measured and those reported through WhatsApp, and the linearity trend of total WhatsApp data reporting month by month. CU5: children under 5 years.



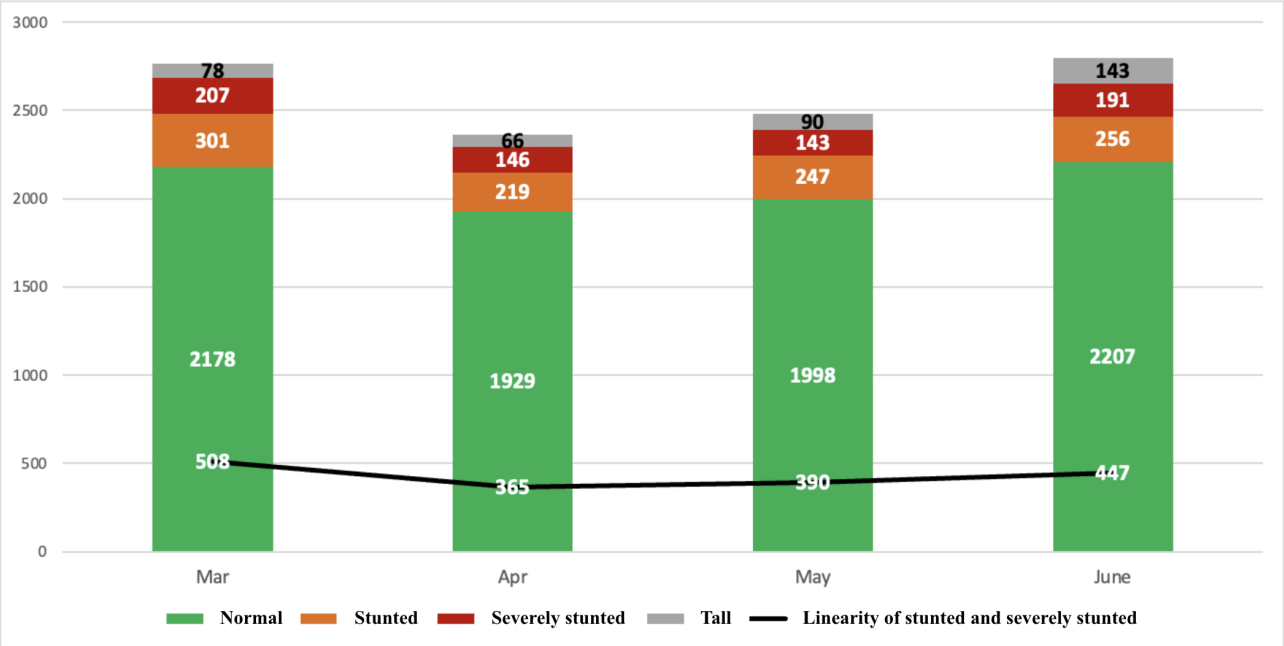
In terms of each village's performance of inputting data, Pancawati had the highest number, followed by Ciherang Pondok and Ciderum. However, the data show that Pancawati had more children entered into the system than the number of children actually weighed. In March, April, and June, the percentage of CU5 weighed exceeded 100%, possibly because the chatbot recorded CU5 not just from the monthly weighing but also from those weighed outside the Posyandu area. Additionally, some data might have been entered twice, thus increasing the total number of records, but not affecting individual recordings.

Further analysis on HAZ was done, categorizing children into severely stunted, stunted, normal, and tall according to the Ministry of Health Decree Number 2/2020 about Children Anthropometry Standard guidelines (Figure 7). In general, the majority of CU5 had a normal nutritional status based on their HAZ compared to other nutritional statuses. Following the "normal" status, the next highest counts were for "stunted,"

XSL•FO
RenderX

"severely stunted," and "tall" statuses. This sequence of HAZ nutritional statuses remained consistent throughout the 4-month observation period.

Figure 7. Measurement result data analysis based on the height-per-age z-score.



User Feedback on WhatsApp Usage for the Posyandu Reporting System From Cadres

The qualitative exploration of the system usage shows that all participants used the system (129/129, 100%). Regarding the data input, half the users (45/90) self-reported that all data had been input into the system, followed by 25.6% (23/90) reporting that three-quarters of the data had been input into the system, and 24.4% (22/90) reporting that half or less of the data had been input into the system.

Most respondents suggested the system was easy to use (118/125, 94.4%) and only 5.6% of respondents (7/125) stated that the system was difficult to use. Regarding the variable in the system, none of the respondents stated that the variable (data required including child and parent identity and weight and height measurements) was difficult to understand. Two-thirds (82/123, 66.7%) of the respondents stated the variable was easy to understand, and 33.3% (41/123) stated the variable was very easy to understand. None of the respondents stated that the flow of data input was difficult to understand. Most respondents (93/123, 75.6%) suggested that the flow of data input was easy to understand and 24.4% (30/123) of respondents said that the flow of data input was very easy to understand. Related to the impact of the usage of the system, 74% (91/123) of respondents suggested that the system was improving Posyandu activities and data reporting quality, while 26% (32/123) suggested that the system only improved data reporting quality.

The other aspects explored in the assessment were about the cadre's ability to train other cadres about the system. In general, 36.5% (46/126) of respondents stated that they were fairly competent at using the system, and 63.5% (80/126) stated that they were proficient at using the system. Regarding the ability to train the other cadres, 0.8% (1/124) of respondents stated that they were uncertain about their ability to train the other cadres, while 28.2% (35/124) stated that they were capable of training other cadres with preparation. The other 71% (88/124) stated that they were very capable at giving training to the other cadres (Table 2).

XSL•FO
RenderX

Table . Qualitative exploration about the WhatsApp implementation (N=129).

Characteristics		Values, n (%)
System usage by cadres (n=129)		
	Have used the system	129 (100)
	Never	0 (0)
Total data input (n=90)		
	One-third of the data	12 (13.3)
	Half of the data	10 (11.1)
	Three-quarters of the data	23 (25.6)
	All data	45 (50)
Overall user feedback on system		
Ease of use (n=125)		
	Very difficult to use	0 (0)
	Difficult to use	7 (5.6)
	Neutral	0 (0)
	Easy to use	83 (66.4)
	Very easy to use	35 (28)
Variable (n=123)		
	Very difficult to understand	0 (0)
	Difficult to understand	0 (0)
	Neutral	0 (0)
	Easy to understand	82 (66.7)
	Very easy to understand	41 (33.3)
Flow of data input (n=123)		
	Very difficult to understand	0 (0)
	Difficult to understand	0 (0)
	Neutral	0 (0)
	Easy to understand	93 (75.6)
	Very easy to understand	30 (24.4)
Impact of system usage (n=123)		
	Make things more complicated	0 (0)
	Neutral	0 (0)
	Improving data reporting quality	32 (26)
	Improving Posyandu activities and data reporting quality	91 (74)
Cadres' ability		
Ability to use the system (n=126)		
	Having difficulty	0 (0)
	Still confused	0 (0)
	Fairly competent	46 (36.5)
	Proficient/skillful	80 (63.5)
Ability to train the other cadres (n=124)		
	Unable	0 (0)
	Uncertain	1 (0.8)

XSL•FO
RenderX

Characteristics		Values, n (%)
	Capable with preparation	35 (28.2)
	Very capable	88 (70)

SWOT Analysis

The use of WhatsApp for recording and reporting Posyandu results means that cadres do not need to download new apps, but instead can use a popular existing app. This makes Posyandu recording using WhatsApp easy to use and easy to teach to cadres, thereby speeding up the Posyandu monthly reporting process. This is in line with the evaluation results where, in the first evaluation, cadres still had difficulty inputting Posyandu data; conversely, in the next two evaluations, cadres found it easy to use WhatsApp to report the results of weighing CU5.

Cadres can also input data on toddlers from different Posyandu in the same subdistrict. The Excel data input over the last month remains downloadable and this makes it easier for cadres to report to the village midwife and Puskesmas. Moreover, the digital record helps cadres to plot CU5's nutritional status in a precise manner, allowing them to produce an accurate plot.

Based on the evaluation results, connection problems are the number one challenge in Posyandu reporting using WhatsApp; Table 3 presents a SWOT (strengths, weaknesses, opportunities, threats) analysis. Limited internet connectivity and the absence of an offline input feature prevented cadres from reporting. Additionally, some cadres could not input data in real time, especially for areas with high target data, with a large volume of work related to inputting data in real time. Finally, there are several features that should be considered for future updates, such as a reminder feature for inputting Posyandu results data, or other features that suit the program's reporting needs.

XSL•FO
RenderX

Table . WhatsApp chatbot SWOT[a] analysis.

Category	Strength	Weakness	Opportunity	Threat
Data input process	Cadres can input data for children from different Posyandu within the same subdistrict (Puskesmas).	It depends on the signal; offline data input is not yet possible.	In cases where the number of target children is not high, real-time data input by cadres is feasible.	Slow responses from the chatbot can discourage cadres from inputting a large amount of data.
System utilization	No need to download an app, simply save the chatbot WhatsApp number.	Limitation on providing various features for user through chatbot flow mechanism	Additional features can be introduced based on the reporting program's needs.	If incorrect information—such as birth date, gender, and weighing results—is input, it can lead to inaccurate interpretation of nutritional status.
Sustainability	Easy to be taught to cadres with low digital literacy	N/A[b]	The sustainability of Posyandu nutritional surveillance data reporting depends on cross-sectoral collaborations from related ministries and stakeholders to support the Puskesmas and Posyandu in implementing the Maternal and Child Health program and recording and reporting data while ensuring data quality. Stakeholders include the National Population and Family Planning Board, the Ministry of Public Works, and the Ministry of Villages, Development of Disadvantaged Regions, and Transmigration.	Depending on server capacity, scalability considerations are essential for national implementation.
Data quality	Validation and verification during data input to minimize errors	Regular data monitoring and evaluation are necessary to support data reporting.	After completing data entry, there is an Excel file containing the weighing results for the last month, facilitating reporting to the village midwife and Puskesmas.	Cadres often input child data with different national identification numbers and Individual Health Status numbers, leading to potential data duplication for a single child in the database.
Significance of innovation	Data security is maintained as cadres can only input data and cannot edit it.	N/A	The interpretation of nutritional status provided at the end of each recording helps cadres to plot nutritional status accurately.	The performance of the chatbot is influenced by the specifications of the cadre's mobile phone.

[a]SWOT: strengths, weaknesses, opportunities, threats.

[b]N/A: not applicable.

Both support from local regional leaders to encourage cadres to input data and regular monitoring and evaluation of reporting are necessary to encourage cadres to input measurement data. If the recording is complete, cadres can report individual weighing results that have not been reported yet.

Cadres' ability to carry out anthropometric measurements in the correct way and anthropometric tools that are not available or have not been calibrated were some of the challenges in this trial. Not all cadres have devices with high specifications, which slows down the chatbot's response. This makes cadres unwilling to input large amounts of data. Double data also often occurs because there are discrepancies when inputting the NIK and IHS numbers. If a cadre enters the wrong gender or date of birth, there will be an error in the nutritional interpretation such that the information obtained will be incorrect. In addition, regarding server capacity, it is necessary to consider how such a program could scale up and be implemented nationally.

Discussion

Principal Findings

WhatsApp has been used for various health-related purposes [28-34]. This paper demonstrates the feasibility of WhatsApp as a tool for data input and data recording in childhood health programs in Indonesia, where it can be used for inputting data, real-time monitoring of nutritional status, generating plotted growth charts, and automatically generating reports on the activities and performance of the cadres in Posyandu.

XSL•FO
RenderX

Current WhatsApp utilization includes aiding in the preparation for professional medical licensing examinations and facilitating online-mediated learning [37,38]. It serves as a data collection tool for health questionnaires related to conditions like Williams-Beuren syndrome and acts as a survey tool for patients with COVID-19 and cancer [39,40]. In biomedical and health care settings, it is used to support processes like neurosurgery assessments, to monitor the application of braces for clubfoot, in laboratory management systems, and to facilitate patient-related communication [41-44]. Additionally, it plays a role in health programs, including initiatives for smoking cessation, patient follow-up care, online health information services for the prevention of stunting, and various peer-support interventions [45-48]. Despite its demonstrated versatility in many contexts, there is currently limited utilization of WhatsApp as a data input tool.

During the 4 months of this pilot study, there was a significant narrowing of the gap between the number of CU5 receiving measurements at Posyandu and the number of data points reported by cadres through WhatsApp. Recording Posyandu activities with WhatsApp can be considered user-friendly and practical because the cadres are already familiar with the app, as are large parts of the population [49,50]. The frequent use of WhatsApp has made cadres accustomed to its interface, features, and services, making it easier for them to follow recording and reporting instructions.

Any app featuring a well-designed user interface contributes to user comfort when using the app and WhatsApp has been shown to fulfill the memorability and usability aspect of an app [51]. The architectural design of the WhatsApp client is also crafted to deliver a seamless and user-friendly experience [52,53]. From an economic perspective, WhatsApp provides an easily adoptable alternative solution. The majority of cadres are housewives [54,55]. Although employment status does not affect the motivation of cadre contributions, it can pose a challenge because they tend to have limited resources, such as owning a smartphone with limited internet data for digital recording. WhatsApp is a freely downloadable app, so cadres do not need to incur subscription costs to use it [56,57].

During the final stage of the pilot, 15.9% (n=447) of CU5 were reported as having stunted growth. This number was lower than the 2022 estimated prevalence of children with stunted growth obtained through a national survey in Indonesia, which amounted to 21.6% at the national level and 20.2% for West Java Province [7]. The number was also lower than the prevalence of children with stunted growth in Bogor District, which was reported to have reached 24.9% in 2022 [58]. It is unclear if this discrepancy was due to a more accurate reporting methodology, a lack of recording for the more affected children, or other reasons. However, it demonstrates that, even within a pilot application, the use of this tool provides a representative picture.

However, there are several challenges to its nationwide implementation: access to an internet connection, data validity, system capacity, hardware support, and external support. To activate a conversation with the chatbot, an adequate internet connection needs to be established. Despite the increasing adoption of 4G networks and up to 73% internet penetration, disparities in internet access persist in the eastern part of Indonesia [59].

To mitigate challenges related to internet access, it is crucial to support efforts to expand internet quality across all provinces. Efforts that could reduce this gap in the digital divide include but are not limited to: partnering with local business to provide internet in low-resource settings, engaging with multisectoral stakeholders to develop policy frameworks and funding support for targeted areas, as well as encouraging innovation in technology related to internet access [60,61]. Currently, the Indonesian Ministry of Health is exploring the possibility of cooperation with Starlink (a satellite internet provider) to provide internet access in Puskesmas located in remote, frontier, and outermost areas [62]. Aside from that, continuous collaboration with relevant stakeholders such as the Ministry of Communication and Information Technology is needed.

As an alternative, developing offline features would allow for data entry without an internet connection. A previous study showed that offline features in a mobile app could aid data collection in a decentralized registry [63]. Mobile apps with offline functionality such as Research Electronic Data Capture (REDCap) have also been tested for their usefulness in collecting field survey data in areas with low access to the internet [64]. Additionally, offline functionality could also be used for educational purposes to inform mothers in rural areas about their children's nutrition status [65].

Several studies pointed out the need for attention to the standard operating procedure for anthropometric measurements (especially for body height, which had the highest technical error of measurement), maintenance of instruments, training, and measurement resampling to ensure the accuracy of the data [62,66,67].

To tackle the disparities in anthropometric instruments across the country, the Ministry of Health is striving to equip all Posyandu with anthropometric devices, aiming to distribute 313,737 anthropometric devices to 303,416 Posyandu nationwide by the end of 2024 [68]. Regular calibration must be carried out by an assigned technician to ensure instrument quality; equipment such as infantometers and stadiometers must be calibrated weekly [69]. Another study showed that, to achieve the same accuracy of anthropometric measurement as a medical student, cadres must be trained intensively and receive regular education [70,71]. Capacity building can be carried out as a means to train cadres to conduct anthropometric measurements and digitally report data [72,73].

In order to record individual data, having a NIK number is an integral part of the reporting process. This identification number is able to provide information on location such as province, city/district, and subdistrict, as well as date of birth [74]. Even so, a subpopulation of around 5.3 million people in Indonesia still do not have access to NIK as an identification number [75]. A study by the Ministry of Home Affairs highlights that disadvantaged groups such as individuals living in poverty, indigenous communities, religious or ethnic minorities, remote populations, older individuals, persons with disabilities, refugees, and individuals with nonpermanent housing or high

XSL•FO
RenderX

mobility are those having a hard time accessing and obtaining digital identification [76]. Providing legal identification since birth is an area of focus of the Sustainable Development Goals; therefore, to tackle the gap mentioned above, as well as part of a strategy to participate in providing legal identity for all, civil registration data can be linked and integrated with vital statistics such as birth registration data [77,78].

To prevent data duplication, the government shall implement a central database that connects a unique identifier generated by the Ministry of Home Affairs (NIK), Ministry of Health (IHS number), and Immigration Directorate General (passport number) [79-81]. The system shall implement robust data validation mechanisms that could include automated cross-checking against a central database before final submission. This interoperable check of the central database ensures that an individual's data are recorded through a single, streamlined thread, effectively reducing the risk of duplication and maintaining health data quality [82].

Considering that anthropometric measurement is carried out as a routine activity in Posyandu, it is crucial to ensure that the system is capable of meeting user needs related to inputting data, and that it has the capability to store, file, abstract, and retrieve records seamlessly [83]. Server availability is also one of the crucial components of infrastructure readiness [84]. Another technicality that needs to be considered is the compatibility of the hardware to the software, meaning that to use WhatsApp, potential users need to at least have a device that supports Android OS 5.0 or iOS 12 [85]. Consequently, older devices that were released before 2015 might not be compatible with WhatsApp [85-87].

Taking into consideration that ease of use affects the adoption of apps and/or health systems, developers also need to ensure that the data reporting flow remains simple and the app size is compact [88,89]. Adding features like reminders for data input and providing visual feedback on data consistency could motivate cadres and improve adherence to data entry protocols. Studies have shown that electronic reminders had a great impact on health worker adherence to implementing certain health protocols [90]. Adding monitoring features and feedback loops can also help in identifying cadres who are facing challenges and ensuring targeted support [90].

Aside from the technical support aspect, external support is also pivotal for the implementation of the data input process. Support from the village midwife, Puskesmas, as well as the village leader plays a role in motivating cadres to use the WhatsApp chatbot and input data. It is undeniable that stakeholders such as professional health workers and governmental bodies have a role to play in adequately managing health information systems [91]. Legislative, regulatory, and coordination support are also deemed to be a prerequisite step for optimal and functional health information systems [83]. Having strong cross-sectoral collaborations with relevant ministries and stakeholders, such as the Ministry of Villages, Development of Disadvantaged Regions, and Transmigration; the Ministry of Home Affairs, the National Population and Family Planning Board, and the National Development Planning Agency (Bappenas), will strengthen the broader implementation.

Strengths and Limitations

The strength of this study lies in its pioneering exploration of digitizing Posyandu records through WhatsApp, representing the first-ever development of such a method with substantial potential for diverse data input approaches, particularly in low- and middle-income countries. However, certain limitations must be acknowledged: (1) data input at Posyandu is dependent on internet access, (2) data validation relies on the standards of measurement tools and the capacity of the cadre, and (3) there exists a potential for record duplication due to discrepancies in the input of NIK and IHS numbers by the cadres. Nevertheless, this study provides a nuanced understanding of the potential application of WhatsApp as a tool for monitoring the nutritional status of CU5 in developing countries such as Indonesia.

Conclusions

The utilization of WhatsApp holds promise as a tool for recording surveillance data related to the nutritional status of children. This study provides the first evidence of the implementation of such a tool in community-driven health care settings. In the future, there is potential for expanding the application of WhatsApp to encompass broader data recording functions within health programs. However, such an expansion requires concurrent enhancements in features, involving the preparation of human resources, infrastructure at Posyandu, and robust regulatory support. This entails a comprehensive approach that addresses not only the technological aspects but also considers the human, infrastructural, and regulatory dimensions for the effective integration of WhatsApp into health programs, ensuring its optimal and sustainable use.

Acknowledgments

The authors would like to thank the Digital Transformation Office, Ministry of Health, Republic of Indonesia for supporting the study implementation and developing the WhatsApp (Meta) chatbot. The authors also thank Posyandu Desa Ciherang Pondok, Posyandu Desa Ciderum, Posyandu Desa Pancawati, Ciderum Public Health Centres, and Bogor District Health Office in West Java Province, who participated in the study.

Data Availability

The datasets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

XSL•FO
RenderX

Authors' Contributions

DNA led the study design and built the paper concept, main structure, and methodology. CAM, AU, FMR, NHA, LR conducted quantitative and qualitative assessment and accessed and analyzed the data. DNA, CAM, AU, FMR, and NHA wrote the first draft of the paper. EAF developed the chatbot infrastructure. MHS and AC provided support in chatbot development. ZK and LM validated the study and critically revised the manuscript content. DNA, CAM, and LR had primary responsibility for the final content. All authors read and contributed to reviewing the study data and manuscript design. All authors provided approval of the final manuscript.

Conflicts of Interest

Although 2 authors are affiliated with Aceso Global Health Consultants Pte Limited, a private company, we declare that this research project did not receive funding from Aceso Global Health Consultants. The company did not have a role in the study design; data collection and analysis; decision to publish; or preparation of the manuscript. LM is the director of the company and DNA is a consultant of the company. However, both of them contributed to this paper on a pro bono basis. Where authors are identified as personnel of the International Agency for Research on Cancer/World Health Organization, the authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy or views of the International Agency for Research on Cancer/World Health Organization. The other authors declare no conflicts of interest.

References

1. Levels and trends in child malnutrition child malnutrition: UNICEF / WHO / World Bank Group Joint Child Malnutrition Estimates: Key findings of the 2023 edition. : World Health Organization; 2023 URL: https://iris.who.int/bitstream/handle/10665/368038/9789240073791-eng.pdf?sequence=1 [accessed 2025-04-26]
2. Wild CP, Miller JD, Groopman JD. CHAPTER 2. Child stunting in developing countries. In: Mycotoxin Control in Low- and Middle-Income Countries: NCBI Bookshelf; 2015. URL: https://www.ncbi.nlm.nih.gov/books/NBK350567 [accessed 2025-04-26]
3. Sanctis VD, Soliman A, Alaaraj N, Ahmed S, Alyafei F, Hamed N. Early and long-term consequences of nutritional stunting: from childhood to adulthood. Acta Biomedica Atenei Parmensis 2021;92(1):11346-11346. [doi: 10.23750/abm.v92i1.11346]
4. Ekholuenetale M, Barrow A, Ekholuenetale CE, Tudeme G. Impact of stunting on early childhood cognitive development in Benin: evidence from Demographic and Health Survey. Egypt Pediatric Association Gaz 2020 Dec;68(1). [doi: 10.1186/s43054-020-00043-x]
5. Prendergast AJ, Humphrey JH. The stunting syndrome in developing countries. Paediatr Int Child Health 2014 Nov;34(4):250-265. [doi: 10.1179/2046905514Y.0000000158] [Medline: 25310000]
6. Galasso E, Wagstaff A. The aggregate income losses from childhood stunting and the returns to a nutrition intervention aimed at reducing stunting. : The World Bank; 2018 URL: https://hdl.handle.net/10986/30108 [accessed 2023-12-24] [doi: 10.1596/1813-9450-8536]
7. Hasil Survei Status Gizi Indonesia (SSGI). Badan Kebijakan Pembangunan Kesehatan. 2023. URL: https://ayosehat.kemkes.go.id/pub/files/files46531._MATERI_KABKPK_SOS_SSGI.pdf [accessed 2023-12-27]
8. Food and nutrition surveillance systems: technical guide for the development of a food and nutrition surveillance system. : World Health Organization; 2013 URL: https://applications.emro.who.int/dsaf/EMROPUB_2013_EN_1576.pdf [accessed 2025-04-26]
9. ENU SPOTLIGHT. Nutrition surveillance. : World Vision; 2010 URL: https://www.wvi.org/sites/default/files/ENU-Issue-5-Jan-Mar2010.pdf
10. Nutrition surveillance systems: their use and value. : Save The Children UK; 2016 URL: https://resourcecentre.savethechildren.net/pdf/nutrition_surveillance_systems.pdf/ [accessed 2025-04-26]
11. Peraturan Menteri Dalam Negeri (Permendagri) Nomor 19 Tahun 2011. Pedoman Pengintegrasian Layanan Sosial Dasar Di Pos Pelayanan Terpadu [Website in Indonesian]. Indonesia Ministry of Home Affairs. 2011. URL: https://peraturan.bpk.go.id/Details/111821/permendagri-no-19-tahun-2011 [accessed 2023-12-23]
12. Faza A, Rinawan FR, Mutyara K, et al. Posyandu application in Indonesia: from health informatics data quality bridging bottom-up and top-down policy implementation. Informatics (MDPI) 2022;9(4):74. [doi: 10.3390/informatics9040074]
13. Pedoman Umum Pengelolaan Posyandu [Website in Indonesian]. Kementerian Kesehatan RI. 2011. URL: https://ayosehat.kemkes.go.id/pub/files/files72087Pedoman_Umum_Pengelolaan_Posyandu.pdf [accessed 2023-12-23]
14. Peraturan Menteri Dalam Negeri Nomor 18 Tahun 2018 Tentang Lembaga Kemasyarakatan Desa Dan Lembaga Adat [Website in Indonesian]. Kementerian Dalam Negeri RI. 2018. URL: https://peraturan.bpk.go.id/Details/143587/permendagri-no-18-tahun-2018 [accessed 2023-12-23]
15. Data Perkembangan Posyandu 2022 [Website in Indonesian]. Kementerian Dalam Negeri RI. 2022. URL: https://e-prodeskel.kemendagri.go.id/v/2022/data-integrasi/9/data-perkembangan-posyandu [accessed 2023-12-23]
16. Ti Ripan RA. The role of Posyandu cadres in efforts to improve the nutritional status of toddlers in Suka Makmur village, Patilanggio district. JHTS 2021;2(1):37-43. [doi: 10.47918/jhts.v2i1.151]

XSL•FO
RenderX

17. Peraturan Presiden (PERPRES) Nomor 72 Tahun 2021 Tentang Percepatan Penurunan Stunting [Website in Indonesian]. Presiden Republik Indonesia. 2021. URL: https://peraturan.bpk.go.id/Details/174964/perpres-no-72-tahun-2021 [accessed 2023-12-23]
18. MHealth: use of mobile wireless technologies for public health. World Health Organization. 2016. URL: https://apps.who.int/gb/ebwha/pdf_files/EB139/B139_8-en.pdf [accessed 2023-12-23]
19. Bach RL, Wenz A. Studying health-related internet and mobile device use using web logs and smartphone records. PLOS One 2020;15(6):e0234663. [doi: 10.1371/journal.pone.0234663] [Medline: 32530937]
20. Uddin J, Biswas T, Adhikary G, et al. Impact of mobile phone-based technology to improve health, population and nutrition services in rural Bangladesh: a study protocol. BMC Med Inform Decis Mak 2017 Jul 6;17(1):101. [doi: 10.1186/s12911-017-0502-9] [Medline: 28683742]
21. Kemp S. Digital in Indonesia: All the Statistics You Need in 2021 — DataReportal – Global Digital Insights. DataReportal – Global Digital Insights. 2021. URL: https://datareportal.com/reports/digital-2021-indonesia [accessed 2023-12-27]
22. Individuals using the internet (% of population) - Indonesia. World Bank. 2023. URL: https://data.worldbank.org/indicator/IT.NET.USER.ZS?locations=ID [accessed 2023-12-23]
23. Nurhayati-Wolff H. Topic: mobile apps in Indonesia. Statista. 2023. URL: https://www.statista.com/topics/9983/mobile-internet-and-apps-in-indonesia/#topicOverview [accessed 2023-12-27]
24. Nurhayati-Wolff H. Indonesia: leading android social media apps by monthly hours used 2023. Statista. 2023. URL: https://www.statista.com/statistics/1253240/indonesia-leading-android-social-media-apps-by-monthly-hours-used/ [accessed 2023-12-27]
25. Raiman L, Antbring R, Mahmood A. WhatsApp messenger as a tool to supplement medical education for medical students on clinical attachment. BMC Med Educ 2017 Jan 6;17(1):7. [doi: 10.1186/s12909-017-0855-x] [Medline: 28061777]
26. Usman YD, Bukar A. Students' usage of WhatsApp instant messenger as a supporting tool for learning in Kaduna State, Nigeria. IJEDICT 2022;18(3):147-158.
27. Meeuwis IHM, van Rooijen EM, Verhagen WIM. The use of WhatsApp Messenger: an important tool in modern neurological examination. Acta Neurol Belg 2020 Oct;120(5):1045-1049. [doi: 10.1007/s13760-020-01435-x] [Medline: 32647971]
28. Gulacti U, Lok U, Hatipoglu S, Polat H. An analysis of WhatsApp usage for communication between consulting and emergency physicians. J Med Syst 2016 Jun;40(6):130. [doi: 10.1007/s10916-016-0483-8] [Medline: 27083574]
29. Rahu ZA, Bhanbhro H, Chohan R, Muhammad H. A study on use of WhatsApp Messenger among students for their academic achievements: a case study. IJATCSE 2021;10(3):2607-2610. [doi: 10.30534/ijatcse/2021/154032021]
30. Berewot J, Fibra A. Whatsapp Messenger among higher education students: a study on Whatsapp Messenger usage for project learning. J Phys: Conf Ser 2020 Mar 1;1477(4):042018. [doi: 10.1088/1742-6596/1477/4/042018]
31. Dhahir DF. The usability of Whatsapp Messenger as online teaching-learning media. JITU 2020;3(2):48. [doi: 10.30818/jitu.3.2.3629]
32. Cheah A. Think with Google. 2017. URL: https://www.thinkwithgoogle.com/intl/en-apac/consumer-insights/consumer-journey/indonesia-new-frontier-mobile-marketing [accessed 2023-12-27]
33. Blueprint for digital health transformation strategy Indonesia 2024. Kementerian Kesehatan Republik Indonesia. 2021. URL: https://oss2.dto.kemkes.go.id/artikel-web-dto/Digital-Transformation-Strategy-2024.pdf [accessed 2023-12-23]
34. The WHO child growth standards. World Health Organization. 2006. URL: https://www.who.int/tools/child-growth-standards/standards [accessed 2023-12-23]
35. Bridgeman PA. Round table discussion: an effective public engagement strategy. 2010. URL: https://www.nacsw.org/Publications/Proceedings2010/BridgemanPRoundTable.pdf [accessed 2024-02-15]
36. National guidelines and ethical standards for health research and development [Report in Indonesian]. Ministry of Health. 2021 URL: https://repository.badankebijakan.kemkes.go.id/id/eprint/4214/1/Pedoman%20dan%20Standar%20Etik%20Penelitian%20dan%20Pengembangan%20Kesehatan%20Nasional.pdf [accessed 2025-04-26]
37. Hidayat Y, Hidayat T, Mariawati A, Rosmiati R, Haq VN. WhatsApp group: online media for early childhood learning during the Covid-19 pandemic. JCELL 2022;2(2):140-148. [doi: 10.54012/jcell.v2i2.76]
38. Tunjera N. Adopting WhatsApp to reduce transactional distance during the COVID-19 pandemic. EJEL 2023;21(2):110-120. [doi: 10.34190/ejel.21.2.2752]
39. Pires LVL, Ribeiro RL, de Sousa A, et al. Nationwide questionnaire data of 229 Williams-Beuren syndrome patients using WhatsApp tool. Arq Neuropsiquiatr 2021 Nov;79(11):950-956. [doi: 10.1590/0004-282X-ANP-2020-0450] [Medline: 34816986]
40. Gebbia V, Piazza D, Valerio MR, Borsellino N, Firenze A. Patients with cancer and COVID-19: a WhatsApp Messenger-based survey of patients' queries, needs, fears, and actions taken. JCO Glob Oncol 2020 May;6(6):722-729. [doi: 10.1200/GO.20.00118] [Medline: 32412811]
41. Kankane VK, Jaiswal G, Gupta TK. Apply of WhatsApp: a quick, simple, smarty and cost competent method of communication in neurosurgery. Romanian Neurosurgery 2016;30(2):306-312. [doi: 10.1515/romneu-2016-0049]
42. Dharmshaktu GS. Use of WhatsApp to monitor proper brace application and compliance in a case of clubfoot: a feasibility report. Int J Res Orthop 2018;4(5):808. [doi: 10.18203/issn.2455-4510.IntJResOrthop20183686]

XSL•FO
RenderX

43. Dorwal P, Sachdev R, Gautam D, et al. Role of WhatsApp Messenger in the laboratory management system: a boon to communication. J Med Syst 2016 Jan;40(1):14. [doi: 10.1007/s10916-015-0384-2] [Medline: 26573651]
44. Khanna V, Sambandam SN, Gul A, Mounasamy V. "WhatsApp"ening in orthopedic care: a concise report from a 300-bedded tertiary care teaching center. Eur J Orthop Surg Traumatol 2015 Jul;25(5):821-826. [doi: 10.1007/s00590-015-1600-y] [Medline: 25633127]
45. Cheung YTD, Chan CHH, Ho KS, et al. Effectiveness of WhatsApp online group discussion for smoking relapse prevention: protocol for a pragmatic randomized controlled trial. Addiction 2020 Sep;115(9):1777-1785. [doi: 10.1111/add.15027] [Medline: 32107817]
46. Abusin S. Using WhatsApp smartphone application to monitor INR in patients on Warfarin: first experience with 21 patients. Sudan Heart J 2019;7 [FREE Full text]
47. Puspitarini R. Co-designing health intervention by using WhatsApp for preventing the stunting in toddlers during the COVID-19 pandemic [Article in Indonesian]. J Keskom 2022;8(3):536-545. [doi: 10.25311/keskom.Vol8.Iss3.1240]
48. Weaver NS, Roy A, Martinez S, Gomanie NN, Mehta K. How whatsapp is transforming healthcare services and empowering health workers in low-and middle-income countries. Presented at: 2022 IEEE Global Humanitarian Technology Conference (GHTC); Sep 8-11, 2022; Santa Clara, CA. [doi: 10.1109/GHTC55712.2022.9911048]
49. Indonesia's smartphone market ended 2022 down 143%, IDC reports IDC: the premier global market intelligence company. International Data Corporation. 2022. URL: https://my.idc.com/getdoc.jsp?containerId=prAP53189225 [accessed 2025-04-26]
50. Syaharani M. Aplikasi yang Paling Banyak Digunakan Masyarakat Pada [Website in Indonesian]. GoodStats Data. 2023. URL: https://data.goodstats.id/statistic/melasyhrn/10-aplikasi-yang-paling-banyak-digunakan-masyarakat-pada-2023-MosyK [accessed 2023-12-27]
51. Pratama MAT, Cahyadi AT. Effect of user interface and user experience on application sales. IOP Conf Ser: Mater Sci Eng 2020 Jul 1;879(1):012133. [doi: 10.1088/1757-899X/879/1/012133]
52. Ike UK, Orji EC, Durunna IL, Okorie JI. An indepth analysis of social media application; exploring WhatsApp's tech stack and functionalities. Int J Appl Sci Math 2023;9(3). [doi: 10.4324/9781003351962-2]
53. Seelam NP, Palisetti V. Comparative research of whatsapp and telegram by using heuristic principles. Thesis.: Blekinge Institute of Technology; 2022 URL: https://bth.diva-portal.org/smash/get/diva2:1707558/FULLTEXT02.pdf [accessed 2023-12-27]
54. Djuhaeni H, Gondodiputro S, Suparman R. Motivasi Kader Meningkatkan Keberhasilan Kegiatan Posyandu. mkb 2010;42(4):140-148. [doi: 10.15395/mkb.v42n4.26]
55. Rohayu SB. Beberapa Faktor Yang Berhubungan Dengan Partisipasi Kader Posyandu Di Wilayah Puskesmas Kedung Solo Kab. Sidoarjo Jawa Timur [Website in Indonesian]. Thesis.: Universitas Airlangga; 2017 URL: https://repository.unair.ac.id/36042/ [accessed 2023-12-23]
56. LLC W. WhatsApp Messenger.: Apps on Google Play URL: https://play.google.com/store/apps/details?id=com.WhatsApp&hl=en&gl=US [accessed 2023-12-27]
57. Nardo B, Cannistrà M, Diaco V, et al. Optimizing patient surgical management using WhatsApp application in the Italian healthcare system. Telemed J E Health 2016 Sep;22(9):718-725. [doi: 10.1089/tmj.2015.0219] [Medline: 27027211]
58. Fitriani N. Data terbaru! Prevalensi stunting di Jabar menurun 4,3%, pencapaian target WHO semakin dekat [Website in Indonesian]. Open Data Jabar. 2023. URL: https://opendata.jabarprov.go.id/id/artikel/data-terbaru-prevalensi-stunting-di-jabar-menurun-43-pencapaian-target-who-semakin-dekat [accessed 2023-12-27]
59. Drury P, Lazuardi L. Telehealth and digital inclusion in Indonesia. 2022. URL: https://www.heart-resources.org/doc_lib/telehealth-and-digital-inclusion-in-indonesia/ [accessed 2023-12-23]
60. Mony PK, Swaminathan S, Gajendran JK, Vaz M. Quality assurance for accuracy of anthropometric measurements in clinical and epidemiological studies: [errare humanum est = to err is human]. Indian J Community Med 2016;41(2):98-102. [doi: 10.4103/0970-0218.173499] [Medline: 27051083]
61. Turcios Y. Digital access: a super determinant of health. SAMHSA. 2023. URL: https://www.samhsa.gov/blog/digital-access-super-determinant-health#5 [accessed 2024-03-23]
62. Advancing broadband connectivity as a social determinant of health. Federal Communications Commission. 2022. URL: https://www.fcc.gov/health/SDOH [accessed 2025-04-26]
63. Reichold M, Heß M, Kolominsky-Rabas P, Gräßel E, Prokosch HU. Usability evaluation of an offline electronic data capture app in a prospective multicenter dementia registry (digiDEM Bayern): mixed method study. JMIR Form Res 2021 Nov 3;5(11):e31649. [doi: 10.2196/31649] [Medline: 34730543]
64. McIntosh S, Pérez-Ramos J, Demment MM, et al. Development and implementation of culturally tailored offline mobile health surveys. JMIR Public Health Surveill 2016 Jun 2;2(1):e28. [doi: 10.2196/publichealth.5408] [Medline: 27256208]
65. Sosanya ME, Samuel FO, Bashir S, Omoera VO, Freeland-Graves JH. A mobile gaming app to train teenage mothers on appropriate child feeding practices: development and validation study. J Med Internet Res 2024 Sep 26;26:e53560. [doi: 10.2196/53560] [Medline: 39326044]
66. Rokom Kemenkes RI. Menkes Temui Elon Musk Untuk Bangun Akses Internet di Puskesmas Terpencil [Website in Indonesian]. Sehat Negeriku. 2023. URL: https://sehatnegeriku.kemkes.go.id/baca/rilis-media/20230806/2643614/menkes-temui-elon-musk-untuk-bangun-akses-internet-di-puskesmas-terpencil [accessed 2024-03-23]

XSL•FO
RenderX

67. Carsley S, Parkin PC, Tu K, et al. Reliability of routinely collected anthropometric measurements in primary care. BMC Med Res Methodol 2019 Apr 24;19(1):84. [doi: 10.1186/s12874-019-0726-8] [Medline: 31014250]
68. Astuti SD, Janardhana A, Sulistyarini A, et al. Comparison between anthropometric measurement results by cadres and medical profession students using tips (Tikar Pendeteksi Stunting). JOCHAPM 2023;3(1):1-8. [doi: 10.21776/ub.jochapm.2023.003.01.1]
69. Malonda N, Engkeng S, Sanggelorang Y. Edukasi Pemantauan Pertumbuhan Anak Balita pada Kader Posyandu di Puskesmas Wenang Kota Manado [Website in Indonesian]. JPAI: Jurnal Perempuan dan Anak Indonesia 2023;5(2). [doi: 10.35801/jpai.5.2.2023.51846]
70. Anthropometry procedures manual. CDC. 2004. URL: https://stacks.cdc.gov/view/cdc/50333 [accessed 2024-03-22]
71. Govt aims to equip all healthcare centers with anthropometric tools. Tempo.co. 2023. URL: https://en.tempo.co/read/1680412/govt-aims-to-equip-all-healthcare-centers-with-anthropometric-tools [accessed 2023-12-27]
72. Framework and standards for country health information systems. Health Metrics Network. 2008. URL: https://www.afro.who.int/sites/default/files/2017-06/AHO_Country_H_Infos_Systems_2nd_edition.pdf [accessed 2023-12-27]
73. Rahmadi A, Rusyantia A. Kecamatan Bukit Kemuning, Kabupaten Lampung Utara [Website in Indonesian]. JKAM 2023;3(6):1811-1818. [doi: 10.54082/jamsi.1027]
74. Syefudin S, Nugroho BI, Murtopo AA, et al. Sosialisasi Dan Pelatihan Penerapan Aplikasi E-Posyandu Bagi Kader Posyandu Desa Bandasari Di Kabupaten Tegal. J Masy Madani Indones 2023;2(4):462-469. [doi: 10.59025/js.v2i4.161]
75. Presiden Republik Indonesia. Peraturan Pemerintah (PP) Nomor 37 Tahun 2007 Tentang Pelaksanaan Undang Undang Nomor 23 Tahun 2006 Tentang Administrasi Kependudukan. 2007. URL: https://peraturan.bpk.go.id/Details/4759/pp-no-37-tahun-2007 [accessed 2024-03-22]
76. Tangkilisan W, Meidy Enyke Sjam J, Supriadi T, Marota R. Legal problems of the misuse of electronic identification card (E-Ktp) data in the Indonesian general election. J Posit Sch Psychol 2022;6(6).
77. ID for inclusive service delivery and digital transformation in Indonesia. Republic of Indonesia Ministry of Home Affairs. 2022. URL: https://dukcapil.kemendagri.go.id/files/DOK/2022/1666320013SEP_Digital%20ID_20Oct2022.pdf [accessed 2024-03-22]
78. Identification for development. World Bank Group. URL: https://www.worldbank.org/content/dam/Worldbank/Governance/GGP%20ID4D%20flyer.pdf
79. Peraturan Presiden Nomor 83 Tahun 2021 Tentang Pencantuman Dan Pemanfaatan Nomor Induk Kependudukan Dan/Atau Nomor Pokok Wajib Pajak Dalam Pelayanan Publik [Report in Indonesian]. : Sekretariat Negara Republik Indonesia; 2021.
80. Patient resource documentation: FHIR implementation guide. Ministry of Health of the Republic of Indonesia [Website in Indonesian].: SATUSEHAT URL: https://satusehat.kemkes.go.id/platform/docs/id/fhir/resources/patient [accessed 2024-12-16]
81. Undang-Undang Republik Indonesia Nomor 6 Tahun 2011 Tentang Keimigrasian. : Sekretariat Negara Republik Indonesia; 2011.
82. Agboola SO, Scott PJ, Hopgood AA. Automating electronic health record data quality assessment: scoping review of current approaches. J Med Internet Res 2023 Jan;25. [doi: 10.2196/42013] [Medline: 36781551]
83. Economic Commission for Africa, World Health Organization, African Union Commission, United Nations International Children's Emergency Fund, United Nations Population Fund, United Nations. High Commissioner for Human Rights Birth Registration as an Opportunity to Integrate Civil Registration and Identity Management Systems. 2017. URL: https://repository.uneca.org/handle/10855/24048 [accessed 2024-03-22]
84. Ajami S, Ketabi S, Isfahani SS, Heidari A. Readiness assessment of electronic health records implementation. Acta Inform Med 2011 Dec;19(4):224-227. [doi: 10.5455/aim.2011.19.224-227] [Medline: 23407861]
85. About supported devices. WhatsApp Help Center. URL: https://faq.WhatsApp.com/2366980643469578/?cms_platform=iphone&helpref=platform_switcher [accessed 2023-12-27]
86. Android 5.0 Compatibility Definition. Android. 2015. URL: https://source.android.com/docs/compatibility/5.0/android-5.0-cdd [accessed 2023-12-27]
87. Eadicicco L. Here are all of the phones that can get Google's massive new Android update today. Insider. 2015. URL: https://www.businessinsider.com/android-lollipop-release-date-update-2015-2 [accessed 2023-12-27]
88. Cheryan Tjandra Y, Wiradinata T. The effect of perceived usefulness, perceived ease of use, and public figure endorser towards the adoption of convo application. Presented at: The 6th International Conference on Entrepreneurship; Aug 28-29, 2019; Universitas Ciputra Surabaya, Indonesia p. 141-146 URL: https://icoen.org/wp-content/uploads/conference_doc/icoen6/THE%20EFFECT%20OF%20PERCEIVED%20USEFULNESS,%20PERCEIVED%20EASE%20OF%20USE,%20AND%20PUBLIC%20FIGURE%20ENDORSER%20TOWARDS%20THE%20ADOPTION%20OF%20CONVO%20APPLICATION.pdf [accessed 2025-04-26]
89. Garavand A, Mohseni M, Asadi H, Etemadi M, Moradi-Joo M, Moosavi A. Factors influencing the adoption of health information technologies: a systematic review. Electron Physician 2016 Aug;8(8):2713-2718. [doi: 10.19082/2713] [Medline: 27757179]
90. Zwicker P, Meng M, Friesecke S, et al. An interactive feedback system for increasing hand antisepsis adherence in stationary intensive care. J Hosp Infect 2023 Mar;133:73-80. [doi: 10.1016/j.jhin.2022.12.017] [Medline: 36646137]

XSL•FO
RenderX

91. Winter A, Ammenwerth E, Haux R, Marschollek M, Steiner B, Jahn F. Health Information Systems: Technological and Management Perspectives: Springer Nature; 2023. URL: https://library.oapen.org/bitstream/id/5f31db6d-5945-49ad-ac3a-78cb2037af5b/978-3-031-12310-8.pdf [accessed 2023-12-27]

Abbreviations

CU5: children under 5 years old
DTO: Digital Transformation Office
HAZ: height-for-age z-score
IHS: Individual Health Status
NIK: national identification number
Posyandu: Pos Pelayanan Terpadu (community-based health service post)
Puskesmas: Pusat Kesehatan Masyarakat
REDCap: Research Electronic Data Capture
WAZ: weight-for-age z-score
WHZ: weight-for-height z-score

Edited by A Nguyen; submitted 23.03.24; peer-reviewed by F Carrouel, T Chumachenko; revised version received 17.02.25; accepted 22.02.25; published 15.05.25.

Please cite as:
Aisyah DN, Mayadewi CA, Utami A, Rahman FM, Adriani NH, Al Farozi E, Sayoko MH, Chairunisa A, Restiana L, Manikam L, Kozlakidis Z
Using WhatsApp for Nutrition Surveillance Among Children Under 5 Years in West Java, Indonesia: Cross-Sectional Survey and Feasibility Study
JMIR Pediatr Parent 2025;8:e58752
URL: https://pediatrics.jmir.org/2025/1/e58752
doi:10.2196/58752

© Dewi Nur Aisyah, Chyntia Aryanti Mayadewi, Astri Utami, Fauziah Mauly Rahman, Nathasya Humaira Adriani, Erlangga Al Farozi, Meldi Hafizh Sayoko, Aulia Chairunisa, Liza Restiana, Logan Manikam, Zisis Kozlakidis. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 15.5.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Parent-Child Mutual Influences on Sugar-Sweetened Beverage Consumption Behaviors: Actor-Partner Analysis

May O Lwin[1], PhD; Allison Seet[1], BA; Seraphina Leo[1], MA; Peter J Schulz[1,2], PhD

[1]Wee Kim Wee School of Communication and Information, Nanyang Technological University, Singapore, Singapore

[2]Institute of Communication and Health, Università della Svizzera italiana, Lugano, Switzerland

Corresponding Author:
Allison Seet, BA
Wee Kim Wee School of Communication and Information
Nanyang Technological University
31 Nanyang Link
Singapore, 637718
Singapore
Phone: 1 67905966
Email: allison.seet@ntu.edu.sg

Abstract

Background: Childhood obesity remains a significant global public health issue, with consumption of sugar-sweetened beverages (SSBs) recognized in scientific studies as a key contributing factor. While family influences on children's dietary behaviors and their effects on obesity risk are well-documented, the dynamics between parents and children in shaping SSB consumption remain underexplored.

Objective: Drawing on social influence theory, this study examines how parent-child perceptions and consumption intentions regarding SSBs are interrelated and the potential mediating role of attitudes. We also studied how engagement with food-related content on social media may relate to consumption intentions.

Methods: We conducted a face-to-face survey of 250 parent-child dyads (N=500) living in public housing in Singapore, a country tackling overweight in its population. Dichotomous items were used to measure cognitive perceptions and attitudes toward SSBs. Both parent and child participants self-reported their intention to consume SSBs. Based on the World Health Organization (WHO) definition of SSBs, visuals of culturally relevant drink products were used in the survey to visualize SSBs. Dyadic data analysis using the MEDYAD tool was conducted to test the actor-partner interdependence model (APIM) and examine the impact of the parent-child dyadic relationship on individuals' intention to consume sugary drinks.

Results: Pearson correlation results indicated positive associations between parent and child cognitive perceptions and intentions to consume SSBs. Path analysis revealed strong actor effects with both parents' (β=.52, *P*<.001) and children's (β=.43, *P*<.001) own perceptions predicting their attitudes and subsequent intentions to consume SSBs (parent: β=.32, *P*<.001; child: β=.31, *P*<.001). Partner effects also emerged: parental perceptions influenced children's intentions (β=.20, *P*=.01), while children's perceptions shaped parental attitudes (β=.20, *P*=.02), highlighting the reciprocal nature of influence. While digital food media engagement was positively associated with consumption intentions, its effects were relatively modest and not central to the dyadic pathways.

Conclusions: Our study findings highlight the reciprocal effects of both parents and children in influencing healthier behaviors and hence provide insights to aid obesity prevention efforts. By addressing the interdependent associations of parent-child dynamics, this research bridges theory and health communication practice, offering a novel framework for combating obesity through family-centered approaches.

(JMIR Pediatr Parent 2025;8:e76943) doi:10.2196/76943

KEYWORDS

Parent-child influence; parental mediation; healthy behavior; sugar-sweetened beverages; Singapore health promotion

XSL•FO
RenderX

Introduction

Background

The rising prevalence of childhood obesity has become a significant public health issue, with rates among Singapore's school-aged children (aged 6-18 years) increasing from 11% in 2013 to 16% in 2021 [1]. This rapid upward trend is evident even among primary 1 (grade 1) students, the youngest entrants into Singapore's school system, where national data from the Singapore Department of Statistics indicate a steady increase in the proportion of overweight and severely overweight children in this age group—from 9.8% in 2014 to 12.1% in 2022 [2]. As childhood obesity becomes more prevalent, it is no longer solely a pediatric issue, but a pressing public health crisis at the national level.

Among the various dietary contributors, the frequent consumption of sugar-sweetened beverages (SSBs) has been consistently identified as a major risk factor for childhood obesity, with growing scientific evidence linking high sugar intake to adverse weight outcomes in early childhood [3-5]. This concern is similarly echoed in national dietary data showing that Singaporean adults consume an average of 60 grams of sugar daily—exceeding the recommended intake by 10 grams—with more than half of this sugar derived from SSBs [6]. Excessive sugar consumption, particularly through SSBs, has been associated with increased caloric consumption, greater adiposity, and a higher risk of developing noncommunicable and metabolic diseases such as type 2 diabetes, hypertension, and nonalcoholic fatty liver disease [7-9]. With these dietary patterns, unsurprisingly, Singapore has reported one of the highest rates of diabetes among developed countries [10]. The implications are far-reaching—from higher hospitalization rates to reduced work productivity and an increased risk of developing other chronic diseases [11]—and place a burden on public health resources.

Globally, the intake of SSBs among children and adolescents is also rising, increasing alarmingly by 23% over the past 3 decades [12]; this trend is raising concerns over the impact of SSB consumption on nutritional quality and future health outcomes. Frequent consumption of SSBs during childhood is associated with elevated blood pressure, dental caries, and unhealthy dietary habits, factors that, as discussed earlier, can contribute to the early onset of noncommunicable and metabolic diseases such as obesity and type 2 diabetes. Moreover, these patterns often persist into adulthood [12,13], potentially reinforcing a life-course trajectory of poor health outcomes. In Singapore, the widespread popularity of sugar-laden drinks—such as the highly popular bubble tea (often sweetened with high-fructose corn syrup), carbonated soft drinks, and sweetened fruit juices—coupled with pervasive advertising of SSBs has contributed substantially to the growing burden of childhood obesity [14]. Children and adolescents today are immersed in social media environments saturated with food-related content, often encountered passively through algorithm-driven feeds, influencer promotions, and peer sharing. Evidence suggests that such incidental exposure can subtly shape adolescents' cravings, food preferences, and consumption behaviors over time, including increased inclination toward energy-dense, nutrient-poor products such as SSBs [5,15]. Considering this, reducing SSB consumption through key socializing agents is critical for obesity prevention and health promotion strategies targeted at younger populations.

Children's dietary behaviors are not formed in isolation but rather through complex social interactions embedded within their daily environments. While social influence theory highlights the role of multiple agents (eg, peers, teachers, and the media), the family unit is considered one of the earliest and most influential socializing agents in shaping children's health behaviors [16-20]. Parent-child interactions related to broader dietary norms and health-related behaviors serve as a foundation through which children begin to interpret, model, and internalize parental attitudes, beliefs, and practices about food, nutrition, and health [21]. As primary socialization agents, parents play a critical role, often acting as gatekeepers of the home food environment and influencing children's eating patterns and dietary choices from an early age; in this way, parents provide guidance and set expectations for healthy consumption. As such, parental attitudes and behaviors toward SSBs can directly affect children's consumption patterns.

Previous studies have investigated the links between parental modeling and children's food consumption, as well as between media exposure and dietary intake in parent-child dyads [18,22]. However, most existing research has focused on unidirectional influences from parents to children, with comparatively less attention given to bidirectional or reciprocal effects such as how children's own preferences, attitudes, or media exposure might influence parental perspectives and behaviors surrounding SSB consumption. Moreover, studies that systematically examine the bidirectional dynamics in parent-child dyads specifically in the context of SSB consumption are lacking. In particular, the psychological mechanisms that drive and sustain these dynamics, such as the role of cognitive perceptions and positive attitudes toward SSBs, are still unclear.

Emerging perspectives informed by social influence theory challenge the notion that children are passive recipients of parental influence [23], instead highlighting their active role in shaping and responding to social cues related to food and health behaviors. This includes influencing household norms and practices through reciprocal interactions with their parents. Building on Kelman's foundational work [23], contemporary social influence research has expanded to encompass a broader set of cognitive mechanisms, including normative-informational influence, central-peripheral information processing, and unconscious or automatic pathways [24-26]. These developments underscore the multifaceted nature of social influence, which operates at both conscious and subconscious levels, shaping children's dietary behaviors across diverse interpersonal contexts.

There is a clear gap in knowledge regarding the reciprocal influence between parents and children in understanding parents' and children's dietary behaviors in the current age of digital media. In today's media-saturated environment, children and adolescents' food preferences and consumption habits are increasingly shaped—and often reinforced—by food-related

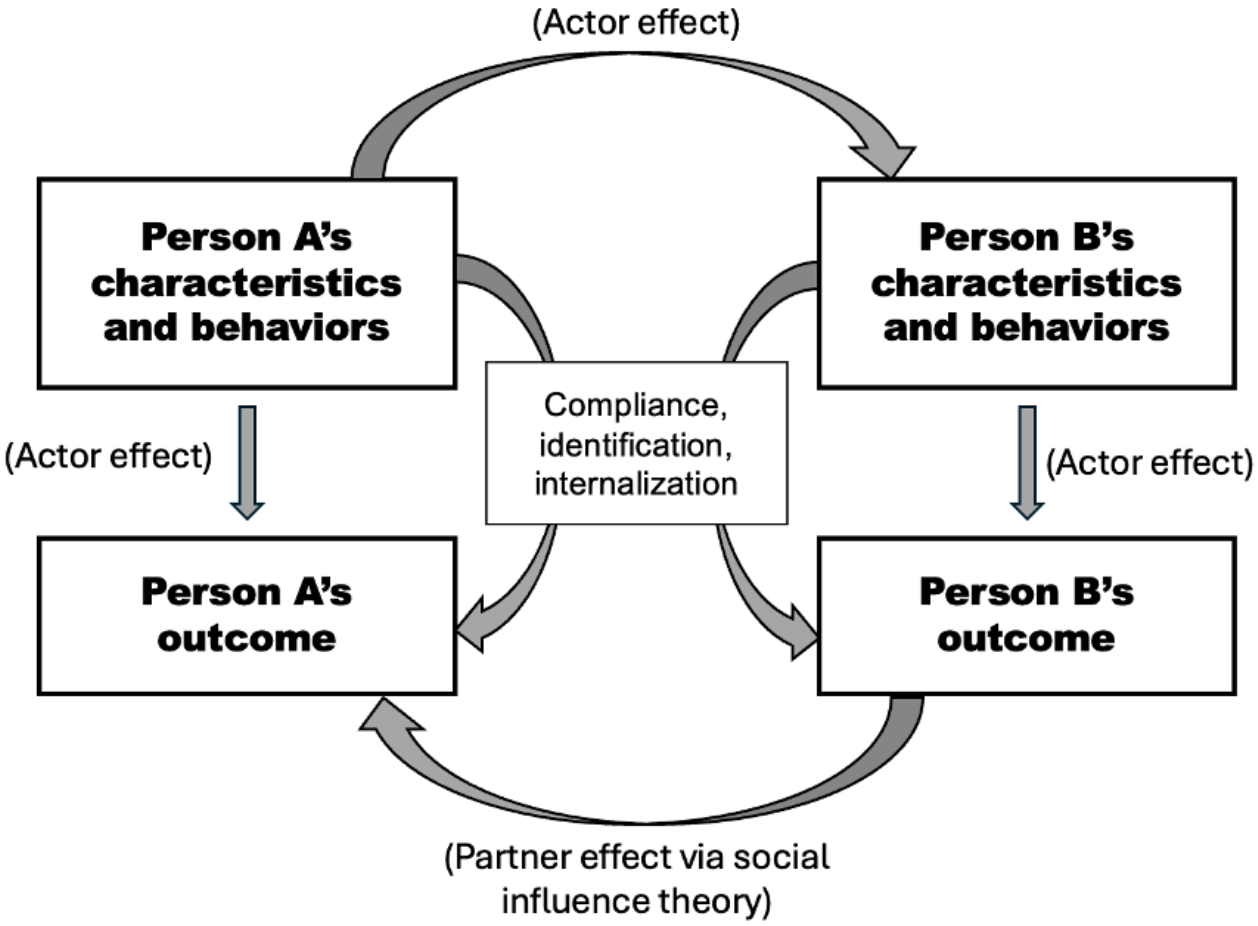
XSL•FO
RenderX

content on social media. As children mature and become more independent, their opinions and preferences can contribute to household decision-making, including food-related choices such as grocery selections and meal planning. Such exposure not only influences their own individual consumption patterns, but can also indirectly influence parental attitudes, grocery purchasing decisions, and potentially shift household dietary norms. In the Singaporean context, where educational milestones are closely tied with distinct social development stages, children's evolving roles within the family—across primary, secondary, and post-secondary levels—may reflect varying degrees of influence over family dietary behaviors and food-related decision-making, and vice versa.

Objectives

To examine the reciprocal nature of influence within parent-child actor-partner relationships, this research draws upon the actor-partner interdependence model (APIM), situated within the broader theoretical lens of social influence theory. APIM allows us to disentangle the extent to which an individual's perceptions affect their own behavior (*actor effects*), as well as how those perceptions influence the behavior of the other dyad member (*partner effects*). In the context of SSB consumption, this framework enables a more granular understanding of how attitudes, perceptions, and intentions for SSB purchase are shaped by parent-child relationships across different stages of social development. Figure 1 presents a self-developed conceptual framework illustrating potential actor-partner effects in dyadic relationships using APIM [27,28].

Figure 1. Conceptual framework depicting potential actor-partner effects in dyadic relationships using the actor-partner interdependence model.



The overarching aim of this study is to examine how SSB-related attitudes, perceptions, and behavior intentions are associated within parent-child dyads in Singapore, exploring patterns of mutual influence using a cross-sectional dyadic framework. It further examines how the influence of the parent-child dynamic on SSB consumption intent varies across children's developmental stages and social media exposure. This research is thus guided by the following overarching research questions: (1) how do parents' and children's perceptions of SSBs influence each other's attitudes and behavioral intentions, and (2) how do these effects vary across developmental stages and digital media exposure levels.

Hypotheses

To address the research objectives, the following hypotheses were proposed based on social influence theory:

Hypothesis 1

Hypothesis 1 (H1) is related to actor effects via intrapersonal pathways:

XSL•FO
RenderX

- H1a (parent actor effect) is that parents' perceptions of SSBs relate to their behavioral intentions to consume these beverages, with this relationship mediated by their attitudes toward SSBs.
- H1b (child actor effect) is that children's perceptions of SSBs relate to their own behavioral intentions to consume these beverages, with this relationship mediated by their attitudes toward SSBs.

Hypothesis 2

Hypothesis 2 (H2) is related to partner effects via interpersonal pathways:

- H2a (parent-to-child partner effect) is that parents' perceptions of SSBs are expected to predict their children's behavioral intentions to consume these beverages, with this relationship mediated by the children's attitudes toward SSBs.
- H2b (child-to-parent partner effect) is that children's perceptions of SSBs are expected to predict their parents' behavioral intentions to consume these beverages, with this relationship mediated by the parents' attitudes toward SSBs.

Hypothesis 3

Hypothesis 3 (H3) is related to moderators of partner effects:

- H3a (moderation by developmental stage) is that the child-to-parent partner effect is expected to be stronger for older children than younger children.
- H3b (moderation by social media exposure) is that the child-to-parent partner effect is expected to be stronger for children with higher levels of social media exposure.

Methods

Study Design and Population

The cross-sectional, in-person survey was conducted in Singapore, targeting parent-child dyads. Participants were recruited using a multistage cluster sampling procedure based on a compiled list of government primary and secondary schools, stratified by region according to the Singapore Urban Redevelopment Authority's zoning. This approach ensured geographic diversity and representation across urban planning districts in Singapore. The targeted child age range (8-19 years) corresponds to key developmental stages from late childhood through adolescence, during which independent dietary preferences begin to form and parental influence remains critical.

Within each region of the country, schools were randomly selected. The public housing estates feeding the selected schools were then identified, and data collection began from the top floor of the lowest-numbered apartment block adjacent to each school, proceeding door-to-door. From there, participants were recruited through snowball sampling. Eligibility criteria included (1) being a Singaporean citizen or having permanent resident status, (2) parents and children residing in the same household, and (3) children being aged between 8 and 19 years. Each household contributed one parent-child dyad. In families with more than one eligible child in the targeted age range, the participating parent was given the discretion to select one child to take part in the study. While this approach may introduce some selection bias, no additional controls were applied for within-household selection, consistent with protocols in comparable dyadic studies prioritizing feasibility in field-based recruitment.

Both parents and children completed parallel versions of the survey assessing their perceptions, attitudes, and intentions regarding SSB consumption. The survey was administered in person in English. Survey items were designed to be age appropriate, with simple and clear language used throughout to accommodate younger participants. Prior to data collection, the research team conducted internal pilot testing and cognitive walk-throughs to ensure item clarity and relevance. Where necessary, terminology was simplified or rephrased to enhance understanding. For younger participants, researchers were present to guide them through the survey to ensure they could complete it independently, thereby minimizing parental influence on the children's responses.

As part of the survey, both parents and children were shown 4 unbranded images of commonly consumed beverages in Singapore: a glass of cola, bubble tea, a sports drink, and a bottle of orange juice (Multimedia Appendix 1). These images were presented simultaneously at the start of the relevant survey section and served as visual references for participants when responding to questions on cognitive perceptions and attitudes toward SSBs. The images were selected based on the WHO definition of SSBs and adapted for cultural relevance [29].

Ethical Considerations

Informed consent was obtained from both parents and children prior to participation. Participants were informed that they could withdraw from the study at any point during data collection without any consequences, and that doing so would not affect their relationship with the university. The study protocol was approved by the University's Institutional Review Board (IRB-2022-320) and data collection took place between 2023 and 2024. No personal identifiers were collected. Instead, each dyad was assigned a unique identification code used during data analysis to maintain confidentiality. Upon completion of both the parent and child surveys, each household received a $40 supermarket voucher.

Survey Measures

The measurement of parent-child dyads' perceptions and attitudes toward SSBs was adapted from previous validated studies [30-32]. Perceptions toward SSBs were measured using 4 dichotomous items on a 5-point semantic differential scale ("unhealthy" to "healthy," "unsafe" to "safe," "unnatural" to "natural"). One item with low factor loading was excluded from the analysis. Internal consistency for the final 3-item scale was acceptable, with the McDonald ω values exceeding the commonly recommended threshold of 0.70 (ω=0.71 for parents, ω=0.76 for children). In comparable samples of children aged 9-12 years, Lwin et al [31] reported high reliability for a similar 4-item scale assessing views on unhealthy foods, including sugary drinks (Cronbach α=0.93).

Positive attitudes toward SSBs were measured with four 5-point semantic differential items ("not at all happy" to "very happy," "not at all satisfied" to "very satisfied"). Internal consistency

XSL•FO
RenderX

was excellent in the current sample (ω=0.96 for parents; ω=0.94 for children). In another comparable study by Lwin et al [32] involving 210 parent-child dyads (children aged 9-15 years), a similar attitude scale toward healthy food yielded Cronbach α=0.87.

Intention to consume SSBs was measured using a single item, adapted from previously validated instruments [32], asking participants to rate their agreement with the statement "I intend to drink these beverages in the next week" on a 5-point Likert scale from "strongly disagree" to "strongly agree." This item had previously demonstrated predictive validity in studies of adolescent dietary behavior.

In addition, children's exposure to food-related content on social media was measured by their self-reported frequency of seeking such content, using a 5-point Likert scale ranging from "strongly disagree" to "strongly agree."

Demographic data were collected from both parents and children, including age, sex, and ethnicity. Children's school grade levels were used to classify them into three social age groups reflective of the Singapore education system: (1) ages 8-12 years, (2) ages 13-16 years, and (3) ages 17-19 years. This categorization captures key educational transitions in Singapore and was used as a covariate in regression analyses to account for developmental differences in autonomy, social influence, and decision-making relevant to dietary behaviors.

Statistical Analysis

Data analyses were conducted using SPSS Statistics (version 29; IBM Corporation) along with the MEDYAD tool developed by Coutts et al [33]. Descriptive statistics were computed to summarize participant demographics. Pearson correlation coefficients were calculated to explore bivariate associations among key study variables.

To examine the dyadic associations between perceptions, attitudes, and consumption intentions, the APIM was applied using path analysis with 1000 bootstrap samples [33,34]. Standardized regression coefficients (β) were reported for all effects. A 2-tailed significance level of $P<.05$ was used to determine statistical significance.

Results

Sample Characteristics

A total of 250 parent-child dyads participated in the study, totaling 500 respondents (Table 1). The average age of parent participants was 43.7 (SD 5.77) years, with 82% (205/250) being female and 86.8% (217/250) being of Chinese ethnicity. Among child participants, the mean age was 12.1 (SD 3.52) years, with almost equal sex distribution (female: 126/250, 50.4%; male: 124/250, 49.6%). The majority of children were Chinese (219/250, 87.6%), followed by Indian (18/250, 7.2%), Malay (8/250, 3.2%), and other ethnicities (including Burmese, Eurasian, Filipino, and Indonesian; 5/250, 2%).

Children's grade levels, classified by social age groups, showed that 141 of 250 (56.4%) were in primary school (grades 1-6), 77 of 250 (30.8%) were in secondary school (grades 7-10), and 32 of 250 (12.8%) were in post-secondary school (grades 11 and 12).

Table 1. Demographic information of study participants.

Characteristics	Parents (n=250)	Children (n=250)
Age (years), mean (SD)	43.7 (5.77)	12.1 (3.52)
Sex, n (%)		
Female	205 (82)	126 (50.4)
Male	45 (18)	124 (49.6)
Ethnicity, n (%)		
Chinese	217 (86.8)	219 (87.6)
Malay	8 (3.2)	8 (3.2)
Indian	18 (7.2)	18 (7.2)
Other[a]	7 (2.8)	5 (2.0)
Grade, n (%)		
1-6	—[b]	141 (56.4)
7-10	—	77 (30.8)
11-12	—	32 (12.8)

[a]Other ethnicities included Burmese (n=1), Eurasian (n=1), Filipino (n=2), Indonesian (n=2), and Russian (n=1) for parents and Burmese (n=1), Eurasian (n=2), Filipino (n=1), and Indonesian (n=1) for children.

[b]Not applicable.

Correlations Between Variables

Table 2 summarizes Pearson correlation coefficients between key study variables. Notably, parents' cognitive perceptions of SSBs were positively associated with their positive attitudes toward ($r=0.35$, $P<.001$) and intentions to consume ($r=0.21$, $P<.001$) SSBs. A similar pattern was observed among children:

XSL•FO
RenderX

children's perceptions were positively correlated with their attitudes (r=0.36, P<.001) and intentions (r=0.14, P=.03).

Table 2. Correlations between study variables (n=250).

Variable	Parents' perception toward SSBs[a]	Parents' positive attitudes toward SSBs	Parents' intention to consume SSBs	Children's perception toward SSBs	Children's positive attitudes toward SSBs	Children's intention to consume SSBs	Children's social age group	Children's food media exposure
Parents' perception toward SSBs								
r	1	0.354[b]	0.214[b]	0.151[c]	0.026	0.102	0.033	0.009
P value	—[d]	<.001	<.001	.02	.68	.11	.61	.89
Parents' positive attitudes toward SSBs								
r	0.354[b]	1	0.353[b]	0.151[c]	0.220[b]	0.206[b]	–0.257[b]	0.039
P value	<.001	—	<.001	.02	<.001	.001	<.001	.54
Parents' intention to consume SSBs								
r	0.214[b]	0.353[b]	1	0.127[c]	0.068	0.325[b]	–0.081	0.184[b]
P value	<.001	<.001	—	.045	.29	<.001	.21	.004
Children's perception toward SSBs								
r	0.151[c]	0.151[c]	0.127[c]	1	0.363[b]	0.136[c]	0.154[c]	0.073
P value	.02	.02	.045	—	<.001	.03	.02	.25
Children's positive attitudes toward SSBs								
r	0.026	0.220[b]	0.068	0.363[b]	1	0.275[b]	0.056	0.061
P value	.68	<.001	.29	<.001	—	<.001	.39	.34
Children's intention to consume SSBs								
r	0.102	0.206[b]	0.325[b]	0.136[c]	0.275[b]	1	0.081	0.169[b]
P value	.11	.001	<.001	.03	<.001	—	.21	.008
Children's social age group								
r	0.033	–0.257[b]	–0.081	0.154[c]	0.056	0.081	1	0.167[b]
P value	.61	<.001	.21	.02	.39	.21	—	.01
Children's food media exposure								
r	0.009	0.039	0.184[b]	0.073	0.061	0.169[b]	0.167[b]	1
P value	.89	.54	.004	.25	.34	.008	.01	—

[a]SSBs: sugar-sweetened beverages.

[b]The correlation is significant at the P<.01 level (2-tailed).

[c]The correlation is significant at the P<.05 level (2-tailed).

[d]Not applicable.

Our overarching research objective questioned the links between parents' and children's perceptions of SSBs and their influences on each other's attitudes and behavioral intentions. The data revealed that significant associations between parents and children emerged in their perceptions and behaviors. Parents' and children's perceptions of SSBs were weak but still significantly correlated (r=0.15, P=.02), while their consumption intentions showed moderate correlation (r=0.33, P<.001). Children's social age group showed a positive correlation with their perceptions of SSBs (r=0.15, P=.02), suggesting that older children held more favorable views of these beverages. Interestingly, social age was negatively correlated with parents' positive attitudes toward SSBs (r= –0.26, P<.001), indicating potential shifts in parental attitudes as children mature. Although children's food-related media exposure was positively correlated with both their parents' (r=0.18, P=.004) and their own (r=0.17, P=.008) intentions to consume SSBs, the effect sizes were small. While these findings indicate some individual-level associations, the food media exposure variable was not directly tied to the dyadic framework central to the APIM. To preserve the theoretical integrity and parsimony of the APIM, which is designed to capture reciprocal interpersonal effects within dyads, children's food-related media exposure was excluded from the final model, as its role as an individual-level predictor was not

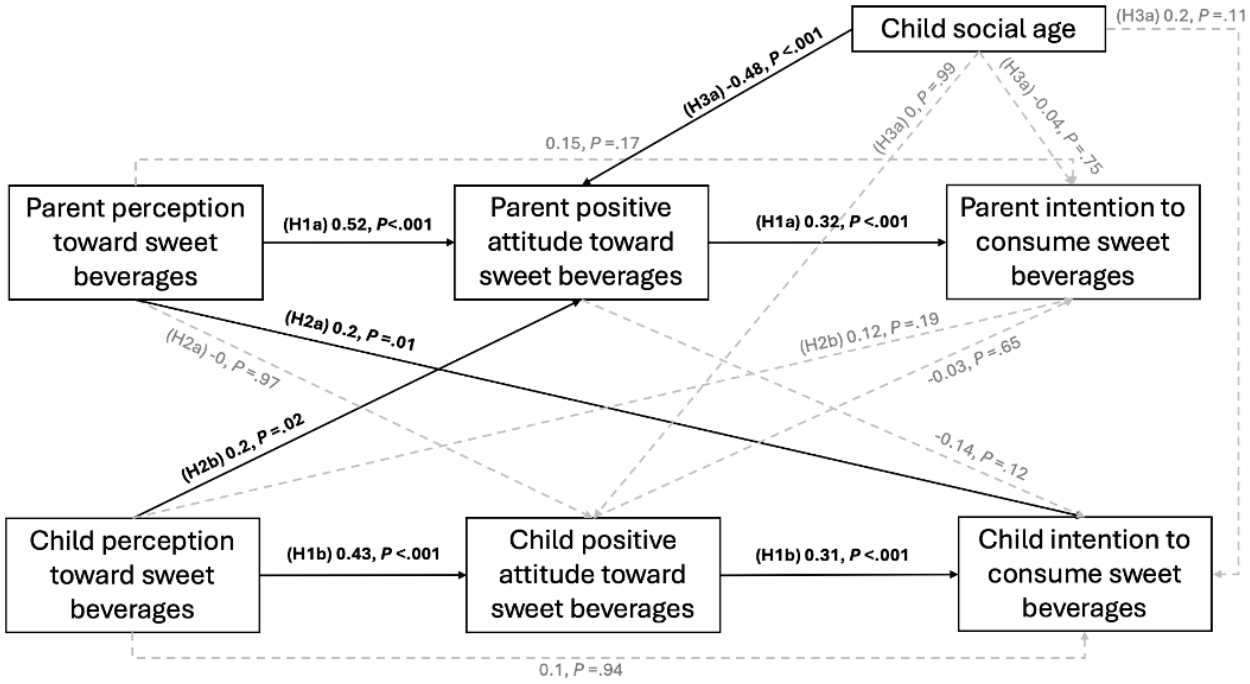
XSL•FO
RenderX

conceptually aligned with the model's core assumptions. Hence, H3b, which aimed to assess the influence of social media exposure, was excluded from further analysis.

Path Analysis (APIM) and Regression Analysis

To examine H1a (parent actor effect), H1b (child actor effect), H2a (parent-to-child partner effect), and H2b (child-to-parent partner effect), we conducted path analysis of our APIM model. Additional regression analysis was further conducted to the test moderation effects of H3a (moderation by developmental stage). The results are summarized in Figure 2.

Figure 2. Path analysis results using the actor-partner interdependence model. Standardized regression coefficients and P values are reported. H1: hypothesis 1; H2: hypothesis 2; H3: hypothesis 3.



H1 proposed actor effects via intrapersonal pathways for both parents (H1a) and children (H1b). Actor effects demonstrated that both parents' and children's cognitive perceptions strongly predicted their own positive attitudes toward SSBs (parent: β=.52, *P*<.001; child: β=.43, *P*<.001). In turn, these positive attitudes were significantly associated with higher intentions to consume SSBs (parent: β=.32, *P*<.001; child: β=.31, *P*<.001).

H2 proposed partner effects via interpersonal pathways, with H2a predicting a parent-to-child partner effect and H2b predicting a child-to-parent partner effect. Data analysis showed that partner effects further illuminated patterns of mutual associations between parents and children. Specifically, parents' cognitive perceptions significantly predicted their children's intentions to consume SSBs (β=.20, *P*=.01). Notably, children's perceptions also positively influenced their parents' attitudes toward SSBs (β=.20, *P*=.02), highlighting the reciprocal nature of influence within the dyad. Overall, the model supports the hypothesized pathways of H1 and H2, with both actor and partner effects influencing SSB consumption intentions in parent-child dyads.

To further explore how parents' and children's perceptions relate to consumption intentions, we ran multiple regression analyses, as shown in Table 3. Initially, we included both parents' income and education level as covariates to control for socioeconomic status. However, neither variable was statistically significant (income: β=–.008, *P*=.52; education level: β=–.062, *P*=.12), and their inclusion did not meaningfully change the results. Therefore, these covariates were excluded from the final model.

When it came to predicting the intention of parents to consume SSBs, both their own perceptions (β=.214, *P*<.001) and their child's perceptions (β=.127, *P*=.05) were significant predictors. Like findings from the APIM analysis, this suggests that parents who view SSBs in a more positive light, and whose children also hold favorable views, are more likely to intend to consume such beverages. In contrast, when predicting children's intention to consume SSBs, only the child's own perception was a significant predictor (β=.136, *P*=.03), while the parent's perception was not statistically significant (β=.102, *P*=.11).

XSL•FO
RenderX

Table 3. Regression analysis.

	B	SE	β	*t* (*df*)	*P*
Dependent variable: parents' intention to consume SSBs					
Parents' perception of SSBs	.341	.099	.214	3.45 (245)	<.001
Children's perception of SSBs	.179	.089	.127	2.01 (245)	.045
Dependent variable: children's intention to consume SSBs					
Parents' perception of SSBs	.175	.109	.102	1.61 (245)	.11
Children's perception of SSBs	.208	.096	.136	2.16 (245)	.03

Discussion

Principal Findings

This study set out to examine the interdependent associations between parents and children in shaping intentions to consume SSBs, drawing on social influence theory and using APIM. Our findings confirmed significant actor and partner effects (H1 and H2), underscoring the reciprocal nature of influence within parent-child dyads. Notably, children's cognitive perceptions of SSBs significantly influenced their parents' attitudes, providing novel insight into the evolving role of children as active contributors to family health behaviors.

While active engagement with food-related content on social media was positively associated with both parent and child SSB consumption intentions, these effects were relatively small and outside the primary scope of our dyadic model (proposed H3b). To preserve the conceptual integrity of the APIM, which is designed to assess reciprocal interpersonal influence, this variable was excluded from the final model. Instead, our focus remained on mutual influences within the parent-child relationship, where actor and partner effects provide a more meaningful framework for understanding shared dietary behavior.

To our knowledge, this is the first study to apply APIM to investigate the reciprocal pathways underlying SSB consumption within parent-child dyads. By simultaneously modeling actor and partner effects, APIM offers a more nuanced understanding of intrapersonal and interpersonal processes than traditional unidirectional models. When integrated with social influence theory, this approach was able to capture both the mechanisms of behavioral persuasion and the dynamic flow of influence between family members. This is especially relevant in contemporary applications of the theory, which now recognizes the roles of normative versus informational influence, central versus peripheral processing, and unconscious social mimicry. These mechanisms are especially salient in family contexts, where both overt communication and subtle social cues co-shape health behaviors.

Our findings reaffirm established evidence that individual cognitive perceptions strongly predict positive attitudes and behavioral intentions (H1a and H1b were supported), consistent with health behavior models such as the theory of planned behavior [22,35-37]. These effects underscore the enduring role of individual beliefs in shaping dietary intentions and reinforce the need to address personal cognition in health promotion efforts.

Importantly, our results extend the current literature by quantifying interpersonal dynamics using data from dyadic sources. While previous studies examined the impact of parental influence on children's dietary choices, they typically relied on unidirectional frameworks, where children are treated as passive recipients of parental modeling [17,38,39]. By contrast, this study demonstrates that children's perceptions can shape parental attitudes, supporting the idea of upward social influence within the family. This finding offers a statistically grounded contribution to an emerging body of work that recognizes children as socializing agents rather than passive recipients of health messaging.

Parents' perceptions were positively associated with their children's intentions to consume SSBs (H2a was supported), a finding consistent with the literature on parental modeling and household food norms [18,40]. More strikingly, children's positive perceptions also influenced parental attitudes (H2b was supported), suggesting a shift in traditional influence patterns. As children develop preferences and exert greater autonomy, particularly for popular drinks like bubble tea or isotonic beverages, parents may recalibrate their attitudes to accommodate their child's views, consciously or otherwise [35,36].

These patterns are especially relevant in the context of Singapore, where children's educational levels correspond with key developmental stages. Our data show that older children tended to hold more favorable views of SSBs, potentially amplifying their influence on household attitudes (H3a was supported). This aligns with social development theory, which posits that adolescents become more persuasive in family decision-making as they gain autonomy [37]. For health promotion and communication practitioners, this suggests that behavior interventions may benefit from tailoring content by age group while recognizing children's emerging role in shaping household consumption norms.

Implications

Our findings contribute to the broader application of social influence theory by empirically demonstrating interdependent associations in family health decision-making. While earlier applications of the theory have predominantly emphasized top-down parental influence (parental modeling), more recent expansions have acknowledged reciprocal and automatic forms of influence. By applying APIM, we capture both actor and

XSL•FO
RenderX

partner effects within the same analytical framework, offering a more complete understanding of shared health behaviors and extending the application of social influence theory beyond individual-level outcomes.

From a practical perspective, these insights carry implications for obesity prevention strategies. Family-centered interventions that engage both parents and children simultaneously may be more effective than those targeting individuals in isolation. This could include school-based nutrition programs, multigenerational health workshops, or community-based campaigns. Specifically, empowering children with nutrition knowledge and fostering critical thinking around beverage choices could generate spillover effects that reshape parental attitudes and, by extension, household norms. Our findings are also potentially relevant for existing public health policies such as Singapore's Nutri-Grade labeling system, introduced in 2022 to inform consumers about sugar and saturated fat levels in beverages [41]. While the Nutri-Grade framework targets individual decision-making at the point of purchase, our results suggest that its impact could be magnified through family-based educational efforts. By incorporating parent-child dialogue into nutrition labeling initiatives, health authorities could promote more meaningful engagement with the system and improve long-term dietary behaviors.

Limitations and Future Research

Some limitations should be considered when interpreting the findings of this study. First, the cross-sectional design limits the ability to draw causal inferences. While the APIM offers a powerful framework for assessing dyadic associations, longer-term observations via longitudinal or experimental designs would allow for a more precise understanding of how the strength and directionality of influence evolve over time, particularly as children mature and gain autonomy and parental control shifts.

Second, the use of self-reported measures may be subject to recall bias or social desirability effects, especially in relation to dietary intentions and perceptions. Future research could benefit from incorporating objective consumption data (eg, food diaries or purchase records) to complement self-reports and enhance measurement accuracy.

Third, although culturally relevant images of SSBs were used to aid recognition, the omission of specific brand names or labels may have influenced participants' perceptions and engagement with the stimuli. Future studies could experimentally manipulate branding or use ecologically valid consumption scenarios to examine how commercial cues interact with attitudes and intentions.

Additionally, while this study focused specifically on SSBs within parent-child dyads, it is important to consider how other types of familial relationships—such as siblings or grandparents—as well as peer networks may shape children's dietary behaviors. These wider social influences warrant further exploration in future dyadic or network-based analyses.

Furthermore, our exclusive focus on SSBs represents only one aspect of children's dietary patterns linked to obesity. Other food categories associated with excess calorie intake and poor nutrition, such as fast food or ultraprocessed snacks, were not examined but may be equally or more salient in shaping health risks. Future research could extend the dyadic framework to examine how parent-child interactions influence consumption of these foods and how such patterns contribute to broader dietary and obesity-related outcomes.

Conclusion

Despite its limitations, this study strongly advances the current understanding of the reciprocal dynamics between parents and children regarding SSB consumption intentions. By identifying both actor and partner effects, the findings underscore children's active role in shaping parental attitudes and contribute valuable insights for designing more holistic, family-centered health communication strategies. As childhood obesity continues to challenge an already-strained global public health system, leveraging reciprocal family influences offers a meaningful and actionable pathway for promoting sustainable behavior change related to beverage consumption.

With this study's findings, we aim to extend existing knowledge on family dynamics in dietary behaviors and present practical insights for health communication strategies targeting both parents and children, particularly within the Singaporean context, with potential for adaptation across other health care systems. By applying the APIM to a health communication context, this study contributes to the broader effort to develop family-centered interventions for obesity prevention, focusing on the interplay of perceptions, attitudes, and intentions that shape beverage consumption decisions.

Looking forward, future research could explore how these parent-child dynamics operate across dietary domains beyond SSBs, such as fast-food consumption or snacking behaviors, which are also known contributors to childhood obesity. Additionally, examining diverse family structures and extending dyadic analyses to peer or sibling relationships could offer deeper insight into the broader social networks that influence children's eating behaviors. As digital media continues to shape youth culture and food choices, future studies could also investigate how digital exposure intersects with family influence over time, particularly through longitudinal designs that capture developmental shifts in autonomy and influence.

Acknowledgments

This project was supported by the Singapore Ministry of Health's National Medical Research Council under NMRC grant 10042.

XSL•FO
RenderX

Authors' Contributions

MOL is the lead principal investigator in this study and planned the overall research strategy. AS, MOL, and SL conceptualized the study. AS and SL drafted the literature review and paper. AS, PJS, and SL performed statistical analyses. MOL and PJS provided critical feedback and edits to the paper. All authors have read and approved the manuscript for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Images of sugar-sweetened beverages.
[PNG File , 141 KB - pediatrics_v8i1e76943_app1.png]

References

1. Tham K, Lim AL, Baur L. The global agenda on obesity: what does this mean for Singapore? Singapore Med J 2023;64(3):182. [doi: 10.4103/singaporemedj.smj-2023-018] [Medline: 36876624]
2. Overweight and severely overweight (obesity) prevalence among primary one children, annual. Singapore Department of Statistics. 2024. URL: https://data.gov.sg/datasets/d_564a0412bb7d7b1f228d15aefe8f41d7/view [accessed 2025-04-18]
3. Apolzan JW, Carmichael OT, Kirby KM, Ramakrishnapillai SR, Beyl RA, Martin CK. The effects of the form of sugar (solid vs. beverage) on body weight and fMRI activation: a randomized controlled pilot study. PLoS One 2021;16(5):e0251700 [FREE Full text] [doi: 10.1371/journal.pone.0251700] [Medline: 33999960]
4. Lara-Castor L, Micha R, Cudhea F, Miller V, Shi P, Zhang J, Global Dietary Database. Intake of sugar sweetened beverages among children and adolescents in 185 countries between 1990 and 2018: population based study. BMJ 2024 Aug 07;386:e079234 [FREE Full text] [doi: 10.1136/bmj-2024-079234] [Medline: 39111807]
5. Yu L, Zhou H, Zheng F, Song J, Lu Y, Yu X, et al. Sugar is the key cause of overweight/obesity in sugar-sweetened beverages (SSB). Front Nutr 2022;9:885704 [FREE Full text] [doi: 10.3389/fnut.2022.885704] [Medline: 35836588]
6. Public consultation on possible measures for pre packaged sugar sweetened beverages. Ministry of Health - Epidemiology & Disease Control Division. 2019. URL: https://www.reach.gov.sg/latest-happenings/public-consultation-pages/2018/public-consultation-on-possible-measures-for-pre-packaged-sugar-sweetened-beverages [accessed 2025-04-18]
7. Costa D, Warkentin S, Oliveira A. Sugar-sweetened beverages, effects on appetite and public health strategies to reduce the consumption among children: a review. Porto Biomed J 2022;7(1):e172 [FREE Full text] [doi: 10.1097/j.pbj.0000000000000172] [Medline: 35146179]
8. Tran QD, Nguyen THH, Le CL, Hoang LV, Vu TQC, Phan NQ, et al. Sugar-sweetened beverages consumption increases the risk of metabolic syndrome and its components in adults: Consistent and robust evidence from an umbrella review. Clin Nutr ESPEN 2023 Oct;57:655-664. [doi: 10.1016/j.clnesp.2023.08.001] [Medline: 37739720]
9. Lara-Castor L, O'Hearn M, Cudhea F, Miller V, Shi P, Zhang J, Global Dietary Database. Burdens of type 2 diabetes and cardiovascular disease attributable to sugar-sweetened beverages in 184 countries. Nat Med 2025 Feb;31(2):552-564. [doi: 10.1038/s41591-024-03345-4] [Medline: 39762424]
10. Public consultation on measures to reduce sugar intake from pre-packaged sugar-sweetened beverages. Ministry of Health Singapore. 2018. URL: https://www.moh.gov.sg/newsroom/public-consultation-on-measures-to-reduce-sugar-intake-from-pre-packaged-sugar-sweetened-beverages [accessed 2025-04-18]
11. Ling J, Chen S, Zahry NR, Kao TA. Economic burden of childhood overweight and obesity: a systematic review and meta-analysis. Obes Rev 2023 Feb;24(2):e13535 [FREE Full text] [doi: 10.1111/obr.13535] [Medline: 36437105]
12. Bleich SN, Vercammen KA. The negative impact of sugar-sweetened beverages on children's health: an update of the literature. BMC Obes 2018;5:6 [FREE Full text] [doi: 10.1186/s40608-017-0178-9] [Medline: 29484192]
13. Malik VS, Popkin BM, Bray GA, Despre´s J, Hu FB. Sugar-sweetened beverages, obesity, type 2 diabetes mellitus, and cardiovascular disease risk. Circulation 2010 Mar 23;121(11):1356-1364. [doi: 10.1161/circulationaha.109.876185] [Medline: 20308626]
14. Baker JA. Sweeter than soda? The hidden sugars in bubble tea. Channel News Asia. URL: https://www.channelnewsasia.com/singapore/bubble-tea-sugar-content-sweeter-than-coke-soda-916016 [accessed 2025-07-03]
15. Fleming-Milici F, Harris JL. Adolescents' engagement with unhealthy food and beverage brands on social media. Appetite 2020 Mar 01;146:104501. [doi: 10.1016/j.appet.2019.104501] [Medline: 31669579]
16. Hübner HL, Bartelmeß T. Associations of sugar-related food parenting practices and parental feeding styles with prospective dietary behavior of children and adolescents: a systematic review of the literature from 2017 to 2023. Front Public Health 2024;12:1382437 [FREE Full text] [doi: 10.3389/fpubh.2024.1382437] [Medline: 39206011]
17. Liu X, Xiong J, Xu Y, Zhao L, Libuda L, Cheng G. Prospective association of family members' sugar-sweetened beverages intake with children's sugar-sweetened beverages consumption in China. Eur J Nutr 2023 Feb;62(1):175-184 [FREE Full text] [doi: 10.1007/s00394-022-02971-3] [Medline: 35931834]

XSL•FO
RenderX

18. Mahmood L, Flores-Barrantes P, Moreno LA, Manios Y, Gonzalez-Gil EM. The influence of parental dietary behaviors and practices on children's eating habits. Nutrients 2021 Mar 30;13(4):1138 [FREE Full text] [doi: 10.3390/nu13041138] [Medline: 33808337]
19. Couch SC, Glanz K, Zhou C, Sallis JF, Saelens BE. Home food environment in relation to children's diet quality and weight status. J Acad Nutr Diet 2014 Oct;114(10):1569-1579.e1 [FREE Full text] [doi: 10.1016/j.jand.2014.05.015] [Medline: 25066057]
20. Savage JS, Fisher JO, Birch LL. Parental influence on eating behavior: conception to adolescence. J Law Med Ethics 2021 Jan 01;35(1):22-34. [doi: 10.1111/j.1748-720x.2007.00111.x] [Medline: 17341215]
21. Frosch CA, Schoppe-Sullivan SJ, O'Banion DD. Parenting and child development: a relational health perspective. Am J Lifestyle Med 2021;15(1):45-59 [FREE Full text] [doi: 10.1177/1559827619849028] [Medline: 33447170]
22. Lu J, Cayabyab YM, Malik S, Lwin MO. The associations between mobile media use and food consumption in parent-child dyads. J Child Fam Stud 2022 Feb 02;31(7):2005-2014. [doi: 10.1007/s10826-022-02241-0]
23. Kelman HC. Compliance, identification, and internalization three processes of attitude change. J Confl Resolut 1958 Mar 01;2(1):51-60. [doi: 10.1177/002200275800200106]
24. Bargh JA, Chartrand TL. The unbearable automaticity of being. Am Psychol 1999 Jul;54(7):462-479 [FREE Full text] [doi: 10.1037/0003-066X.54.7.462]
25. Petty R, Cacioppo J. The elaboration likelihood model of persuasion. In: Communication and Persuasion. New York: Springer; 1986:1-24.
26. Christakis NA, Fowler JH. Connected: The Surprising Power of Our Social Networks and How They Shape Our Lives. New York: Little, Brown Spark; 2009.
27. Kenny DA. Dyadic Analysis. davidakenny.net. 2015. URL: https://davidakenny.net/dyad.htm [accessed 2025-05-01]
28. Ledermann T, Macho S, Kenny DA. Assessing mediation in dyadic data using the actor-partner interdependence model. Struct Equ Modeling 2011 Oct 17;18(4):595-612. [doi: 10.1080/10705511.2011.607099]
29. Guideline: sugars intake for adults and children. World Health Organization. 2015. URL: https://www.who.int/publications/i/item/9789241549028 [accessed 2025-05-01]
30. Aikman SN, Crites SL, Fabrigar LR. Beyond affect and cognition: identification of the informational bases of food attitudes. J Applied Social Pyschol 2006 Mar 30;36(2):340-382. [doi: 10.1111/j.0021-9029.2006.00011.x]
31. Lwin MO, Shin W, Yee AZH, Wardoyo RJ. A parental health education model of children's food consumption: influence on children's attitudes, intention, and consumption of healthy and unhealthy foods. J Health Commun 2017 May;22(5):403-412. [doi: 10.1080/10810730.2017.1302523] [Medline: 28362215]
32. Lwin MO, Malik S, Lau J. Association between food availability and young people’s fruits and vegetables consumption: understanding the mediation role of the theory of planned behaviour. Public Health Nutr 2020 May 26;23(12):2155-2164. [doi: 10.1017/s1368980019005263] [Medline: 32450936]
33. Coutts JJ, Hayes AF, Jiang T. Easy statistical mediation analysis with distinguishable dyadic data. J Commun 2019;69(6):612-649. [doi: 10.1093/joc/jqz034]
34. Ledermann T, Kenny DA. A toolbox with programs to restructure and describe dyadic data. J Soc Pers Relatsh 2014 Nov 02;32(8):997-1011. [doi: 10.1177/0265407514555273]
35. Park SH, Park H. Relationship between motivations and dietary behaviours within parent-adolescent dyads: application of actor-partner interdependence models. Pediatr Obes 2024 Oct;19(10):e13153. [doi: 10.1111/ijpo.13153] [Medline: 39099236]
36. Dwyer LA, Bolger N, Laurenceau J, Patrick H, Oh AY, Nebeling LC, et al. Autonomous motivation and fruit/vegetable intake in parent-adolescent dyads. Am J Prev Med 2017 Jun;52(6):863-871 [FREE Full text] [doi: 10.1016/j.amepre.2017.01.011] [Medline: 28526363]
37. Litchford A, Savoie Roskos MR, Wengreen H. Influence of fathers on the feeding practices and behaviors of children: a systematic review. Appetite 2020 Apr 01;147:104558. [doi: 10.1016/j.appet.2019.104558] [Medline: 31870933]
38. Talati Z, Charlesworth J, Mackenzie K, McAlpine T, Myers G, Miller C, et al. Exploring sugary drink consumption and perceptions among primary-school-aged children and parents in Australia. Nutrients 2024 Sep 30;16(19):3320. [doi: 10.3390/nu16193320] [Medline: 39408287]
39. Thomson JL, Hennessy E, Landry AS, Goodman MH. Patterns of food parenting practices regarding junk foodsugary drinks among parent-child dyads. Nutr J 2020;19(1):91. [doi: 10.21203/rs.3.rs-21160/v3] [Medline: 32847599]
40. Ravikumar D, Spyreli E, Woodside J, McKinley M, Kelly C. Parental perceptions of the food environment and their influence on food decisions among low-income families: a rapid review of qualitative evidence. BMC Public Health 2022 Jan 05;22(1):9 [FREE Full text] [doi: 10.1186/s12889-021-12414-z] [Medline: 34983469]
41. Measures for Nutri-Grade. Health Promotion Board. URL: https://hpb.gov.sg/healthy-living/food-beverage/nutri-grade [accessed 2025-04-18]

Abbreviations

APIM: actor-partner interdependence model
H1: hypothesis 1

XSL•FO
RenderX

H2: hypothesis 2
H3: hypothesis 3
SSB: sugar-sweetened beverage
WHO: World Health Organization

Edited by S Badawy; submitted 05.05.25; peer-reviewed by T Baranowski; comments to author 09.06.25; revised version received 21.06.25; accepted 01.07.25; published 24.07.25.

Please cite as:
Lwin MO, Seet A, Leo S, Schulz PJ
Parent-Child Mutual Influences on Sugar-Sweetened Beverage Consumption Behaviors: Actor-Partner Analysis
JMIR Pediatr Parent 2025;8:e76943
URL: https://pediatrics.jmir.org/2025/1/e76943
doi:10.2196/76943
PMID:40705441

©May O Lwin, Allison Seet, Seraphina Leo, Peter J Schulz. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 24.07.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Monetary Valuation of Congenital Heart Disease in Indonesia: Economic Modeling Study

Muhammad Iqhrammullah[1], MSci, MPH, PhD; Derren DCH Rampengan[2], BMedSci; Ikhwan Amri[3], BSc, MSci; Surna Lastri[4], MSci, PhD; Starry H Rampengan[5], MD, Prof Dr Med, PhD; Radityo Prakoso[6], MD; Muhammad Habiburrahman[7], BMedSci, MD

[1]Postgraduate Program of Public Health, Universitas Muhammadiyah Aceh, Banda Aceh, Indonesia

[2]Faculty of Medicine, Sam Ratulangi University, Manado, Indonesia

[3]Department of Geography Education, Faculty of Teacher Training and Education, Samudra University, Langsa, Indonesia

[4]Postgraduate Program of Management, Universitas Muhammadiyah Aceh, Banda Aceh, Indonesia

[5]Division of Interventional Cardiology, Department of Cardiology and Vascular Medicine, R.D. Kandou Central General Hospital, Faculty of Medicine, Sam Ratulangi University, Manado, Indonesia

[6]Division of Paediatric Cardiology and Congenital Heart Disease, Department of Cardiology and Vascular Medicine, National Cardiovascular Centre Harapan Kita, Faculty of Medicine, University of Indonesia, Jakarta, Indonesia

[7]Faculty of Medicine, Imperial College London, London, United Kingdom

Corresponding Author:
Muhammad Habiburrahman, BMedSci, MD
Faculty of Medicine
Imperial College London
4th Floor IRDB, Hammersmith Campus
Du Cane Road
London, W12 0NN
United Kingdom
Phone: 44 (0)20 7380 1730
Email: h.habiburrahman23@imperial.ac.uk

Abstract

Background: Congenital heart disease (CHD) constitutes a significant health and economic burden in low- and middle-income countries, including Indonesia. However, its macroeconomic impact across provinces remains poorly quantified.

Objective: This study aims to estimate the economic burden associated with premature death and disability due to CHD in Indonesia, with a focus on regional and gender disparities.

Methods: Using data from the Global Burden of Disease 2019 study, we assessed the value of lost welfare (VLW) attributable to CHD across all 34 Indonesian provinces. Economic valuation was conducted using 3 approaches: the US Department of Transportation model, a method based on the Organisation for Economic Co-operation and Development, and a national wage–based estimate. Analyses were stratified by sex and derived from both disability-adjusted life years (DALYs) and years of life lost. We examined disparities using two approaches: (1) gender disparity was measured as the relative difference in VLW between males and females, and (2) geographical disparity was quantified using both location quotients (for raw VLW) and a disparity index (for VLW-to–gross domestic product ratios).

Results: The national CHD-related VLW derived from DALYs was estimated at US $16.83 billion (US Department of Transportation), US $11.41 billion (Organisation for Economic Co-operation and Development), and US $9.03 billion (wage-based). West Java recorded the highest provincial VLW (US $1.60 billion), followed by East Java (US $0.83 billion), North Sumatra (US $0.80 billion), and Central Java (US $0.79 billion), indicating a concentration of burden in populous provinces. In contrast, Yogyakarta (US $0.04 billion), North Kalimantan (US $0.04 billion), and West Papua (US $0.06 billion) had the lowest estimates. In several provinces, male-attributed VLW was more than 150% higher than female VLW, with extreme gaps observed in Riau Islands (281.25%), Aceh (166.10%), and Banten (145.86%). These patterns were consistent across both DALY- and years-of-life-lost-based estimates. Based on the location quotients, provinces such as Papua (2.42), West Sulawesi (2.37), Maluku (1.78), East Nusa Tenggara (1.75), and Central Sulawesi (1.66) bore VLW burdens far greater than their population share. The

XSL•FO
RenderX

burden was disproportionately high in several eastern provinces, including East Nusa Tenggara (3.35%), Maluku (2.61%), and West Sulawesi (2.66%).

Conclusions: CHD is a macroeconomically manageable burden across most of Indonesia. However, the presence of deep gender disparities and geographically concentrated burdens in eastern and underserved provinces calls for targeted pediatric cardiac health investments.

(JMIR Pediatr Parent 2025;8:e80696) doi:10.2196/80696

KEYWORDS

burden of disease; economic burden; health economics; health equity; pediatric cardiology

Introduction

Despite a 56.2% global reduction in mortality, congenital heart disease (CHD) continues to cause more than 200,000 childhood deaths annually, remaining one of the leading contributors to mortality among children younger than 5 years worldwide [1]. This global progress, however, has not been equitably realized across all nations. In Indonesia, CHD-associated disability-adjusted life years (DALYs) rose from 96.3 (72.4-126.8) per 100,000 population in 2019 to 113.2 (86.6-143.7) in 2021, indicating a concerning reversal of global trends [2].

Clinical data from a national registry of 1012 pediatric patients identified secundum atrial septal defect as the predominant diagnosis, accounting for more than 70% of cases, with over three-quarters already exhibiting signs of pulmonary hypertension at the time of diagnosis [3]. The consequences of CHD extend beyond cardiovascular morbidity, encompassing significant impairments in growth and development. Previous studies have shown that children with CHD frequently present with underweight, stunting, and wasting [4]. Independent risk factors for undernutrition include cyanotic CHD, delayed diagnosis, congestive heart failure, and pulmonary hypertension [4]. In a separate cohort, nearly half of the children were aged 0-2 years, with 18.5% demonstrating developmental delays; cyanotic CHD was significantly associated with poor nutritional status [5].

Despite well-documented clinical, developmental, and survival implications, the long-term economic burden of CHD—particularly the loss of productivity due to premature mortality and disability—remains underexamined in Indonesia's national health planning. Valuing lost life years provides a critical framework to translate disease burden into economic terms. Previous research has demonstrated the applicability of value of lost welfare (VLW) approaches to quantify the economic impact of mortality shifts in low- and middle-income countries (LMICs), reinforcing its utility in appraising health sector investments [6].

The VLW, derived from the broader concept of the value of a statistical life (VSL), provides a standardized monetary valuation for years lost to premature death or morbidity. When applied to DALYs and years of life lost (YLLs), VLW enables the conversion of epidemiological estimates into economic burden, thereby enhancing the evidence base for strategic resource allocation and policy prioritization. The increasing use of disease burden estimates in shaping national policy, such as in the European Union's legislative decisions, underscores their practical influence [7].

Several methodologies for estimating the VSL exist, each carrying distinct policy implications. The US Department of Transportation (US DOT) model reflects valuations typical of high-income settings [8], the Organisation for Economic Co-operation and Development (OECD)–based model offers a global median, and wage-based models generate context-specific estimates more aligned with national economic realities [9]. In Indonesia, where regional disparities in income and health care access remain pronounced, disaggregating VLW by province and valuation model allows for a more nuanced understanding of both absolute and relative economic burden [10,11]. For macroeconomic assessments, Global Burden of Disease (GBD) estimates can capture regional inequalities, as reported previously in studies quantifying disparities in population health [12,13]. Previous studies have used GBD estimates to capture the trend in various causes of death in global, regional, and even national contexts [12-16]. Accordingly, this study sought to quantify the economic burden of CHD in Indonesia by estimating VLW and VLW-to–gross domestic product (GDP) per capita ratios across provinces using GBD 2019 data and 3 established VSL frameworks.

Methods

Ethical Considerations

This study used publicly available, deidentified data from the Global Burden of Disease 2019 study. As all data were anonymized and aggregated, no additional ethical approval was required. The data were used in accordance with the Global Burden of Disease data use policy.

Study Design

This study quantified the economic burden associated with congenital heart anomalies (CHAs) in Indonesia by monetizing health losses using the VLW framework. We drew upon the GBD 2021 dataset, which provides comprehensive and methodologically harmonized estimates of disease burden across countries and regions. Two principal health metrics were used: DALYs—a composite of years lived with disability (YLDs) and YLLs due to premature mortality—and YLLs alone, to isolate mortality-specific economic losses. VLW was estimated by applying 3 established benchmarks of the VSL. Analyses were conducted at both national and provincial levels, stratified by sex, to examine geographic and demographic variation in the health-related economic burden.

XSL•FO
RenderX

Data Sources

Burden estimates were extracted from GBD 2021, focusing specifically on the CHAs subcategory. YLDs were calculated by multiplying condition-specific prevalence by disability weights reflective of the severity of health loss. YLLs were estimated from mortality counts and the GBD standard life expectancy for each age group. DisMod-MR 2.1, a Bayesian meta-regression framework, was used to ensure epidemiological consistency across parameters. Additionally, Spatiotemporal Gaussian Process Regression was used to account for spatial and temporal heterogeneity in disease patterns. All estimates were disaggregated by gender and province. In provinces with limited empirical data, estimates were refined using covariate adjustments and comparisons with analogous regions. Full methodological specifications are available in the GBD technical documentation [17,18]. To contextualize the economic burden, 2021 provincial GDP per capita data were sourced from Badan Pusat Statistik (BPS, Indonesian Statistic Agency). Reported values in Indonesian Rupiah (IDR) were converted to US$ using the average 2021 exchange rate (IDR 14,308=US $1) and expressed in trillions to match the national economic scale. DALYs and YLLs of CHD and GDP per capita across Indonesian provinces are available in Multimedia Appendix 1.

VSL Benchmarks and Economic Valuation

To monetarily quantify the societal burden associated with premature mortality from CHAs, we applied 3 benchmark estimates of the VSL. The primary benchmark was a nationally derived, wage-based VSL specific to Indonesia, estimated at US $950,000. This estimate reflects labor market trade-offs between income and occupational fatality risk, as captured through a hedonic wage model [19]. The model used data from the 2019 Survei Angkatan Kerja Nasional National (Labor Force Survey) conducted by BPS, alongside occupation-specific fatality rates provided by the Badan Penyelenggara Jaminan Sosial Kesehatan Ketenagakerjaan (Social Security Administrator for Labor) [20,21].

Multivariable linear regression was used to estimate wage differentials associated with varying levels of occupational risk, adjusting for confounding factors including industry classification, educational attainment, and demographic characteristics. To address potential selection bias—where individuals may self-select into higher-risk or better-compensated occupations—a Heckman [22] 2-stage correction model was applied. The choice of 2019 as the base year was intentional, ensuring that VSL estimates reflect stable labor market conditions before disruptions caused by the COVID-19 pandemic.

Two additional benchmarks were adapted from international reference values originating in high-income countries: one from the OECD and another from the US DOT. Both were recalibrated to the Indonesian context using the income transfer method, which adjusts VSL values according to relative national income levels. This ensures that the transferred VSLs remain consistent with Indonesia's economic reality. Specifically, the recalibrated values were derived using the standard benefit transfer formula (equation 1):



(1)

In this equation $VSL_{Indonesia}$ denotes the income-adjusted value of a statistical life for Indonesia; $VSL_{Reference}$ corresponds to the original benchmark value from either the OECD or the US DOT; $GDP_{Indonesia}$ and $GDP_{Reference}$ represent per capita GDP values (in purchasing power parity terms) for Indonesia and the reference country, respectively; and ε (elasticity coefficient) indicates the income elasticity of VSL. Following established methodological practice for LMIC settings, we assumed an ε of 1.0, consistent with World Bank and OECD recommendations for cross-national health valuation exercises.

Using 2021 GDP per capita data, the income-adjusted VSL estimates for Indonesia were calculated as US $1.2 million (based on the OECD benchmark) and US $1.77 million (from the US DOT benchmark). These adjusted values reflect economic conditions specific to Indonesia while preserving the relative scale of the original reference values. Each of the 3 benchmark VSLs—including the nationally derived, wage-based VSL—was subsequently transformed into a VLW by dividing the respective VSL by the standard age-specific life expectancy at death, enabling alignment with GBD metrics. These VLWs were applied to DALY- and YLL-derived estimates of CHAs to produce monetized estimates of VLW, stratified by province and sex. This dual disaggregation enabled a granular evaluation of the economic burden and its association with geographic and demographic disparities.

Monetization of DALYs and YLLs Through VLW

To quantify the economic burden associated with CHAs in Indonesia, we used a monetization approach anchored in the concept of the VLW, applying it to both DALYs and YLLs in absolute counts. To convert DALY and YLL rates into absolute counts, we multiplied them by the population estimated by the GBD (Multimedia Appendix 1). This approach leverages DALYs and YLLs as proxies for health-adjusted life years lost, facilitating economic valuation based on the VSL framework [23,24]. Following established methodological conventions [24,25], we used the inherent age stratification provided by the GBD study to retain age-specific granularity in estimating disease burden. For each province (*i*), sex (*s*), and valuation model (*m*), we derived VLW estimates by multiplying age-disaggregated DALYs or YLLs with a standardized value of a statistical life year (VSLY), which was computed by dividing VSL by life expectancy at age of death. We used separate life expectancy estimates for males and females, allowing sex-specific adjustment of VSLY in accordance with the demographic profile of each death. According to BPS, the average life expectancy in 2021 was 73.5 years for the total population, with sex-specific values of 60.67 years for males and 73.55 years for females. Three VSLY estimates were applied, corresponding to the VSL benchmarks sourced from the US DOT, the OECD, and the nationally derived wage-based estimate. The economic valuation formula is expressed as follows (equations 2 and 3):



XSL•FO
RenderX

(2)

or,



(3)

Where α denotes the age group; $DALY_{i,s,\alpha}$ or $YLL_{i,s,\alpha}$ represent the disease burden (ie, DALYs or YLLs) in age group α for province *i* and sex *s* and $VSLY_m$ corresponds to the life-year valuation under model (USDOT, OECD, or wage-based). Finally, to contextualize these figures within local economic capacity, we calculated the VLW-to-GDP ratio for each province, defined as follows (equation 4):



(4)

Disparity Estimation

We estimated gender and geographic disparities in the economic impact of CHD across Indonesia. Gender disparity was quantified using the male–female relative difference in VLW, expressed as a percentage (equation 5). This gender disparity metric reflects the proportional excess burden among males relative to females. Geographic disparity was assessed using 2 measures. First, we calculated the location quotient (LQ), defined as the ratio of a province's share of national VLW to its share of the national population (equation 6). This metric is suitable for raw VLW data because both the numerator and denominator represent shares of national totals, allowing a valid comparison of economic burden relative to population size. An LQ greater than 1 indicates that a province bears a disproportionate share of VLW relative to its population. Second, we computed a disparity index by dividing the provincial VLW-to-GDP ratio by the national average. This approach is more appropriate for ratio-based metrics such as VLW-to-GDP, as using an LQ on these values can lead to inflated results due to the low national reference value. The disparity index quantifies how much greater (or lesser) the economic burden is in a province relative to the national benchmark, offering a stable basis for interprovincial comparisons.



(5)



(6)



(7)

Data Processing and Visualization

All calculations and data integration were performed using Python 3.11, with the Pandas library used for structured data manipulation, including the aggregation and merging of health burden estimates (from GBD 2021) and provincial economic indicators. Final estimates of VLW were expressed in billion US$, computed under both DALY- and YLL-based paradigms, and stratified by sex (male, female, and combined) to reflect sex-specific differentials in health-related economic loss. To classify provinces by levels of disparity, we applied k-means clustering on both gender and geographic disparity indices, allowing unsupervised grouping into quartile-based clusters. To visually convey the geographic heterogeneity of the burden, we used Tableau Desktop 2024.1 (Tableau Software, LLC) to develop spatially resolved choropleth maps, highlighting provincial-level VLW and VLW-to-GDP ratios. This visual framework enabled the identification of regions exhibiting disproportionately high economic losses relative to their GDP, facilitating targeted policy interpretation and public health planning.

Results

Economic Burden Based on DALY-Derived Estimates

The DALY-based VLW estimates for CHD in Indonesia are presented in Table 1. At the national level, the total VLW burden reaches US $16.825 billion using the US DOT benchmark, US $11.407 billion using the OECD benchmark, and US $9.03 billion using the national wage benchmark. Based on the national wage–based estimates, West Java reported the highest provincial VLW at US $1.599 billion, followed by East Java (US $0.831 billion), North Sumatra (US $0.797 billion), and Central Java (US $0.793 billion). Together, these 4 provinces accounted for over 44% of the national burden. Other notable contributors include Banten (US $0.475 billion), Papua (US $0.381 billion), and South Sumatra (US $0.363 billion). In contrast, provinces such as North Kalimantan (US $0.036 billion), Yogyakarta (US $0.042 billion), and West Papua (US $0.055 billion) reported the lowest VLW.

XSL•FO
RenderX

Table 1. Economic burden of congenital heart disease in Indonesia estimated from disability-adjusted life year (DALY), using the US Department of Transportation (US DOT), Organisation for Economic Co-operation and Development (OECD), and wage-based models (value of lost welfare [VLW] in billion US$).

Province	VLW (US DOT)			VLW (OECD)			VLW (national wage)		
	Both	Males	Females	Both	Males	Females	Both	Males	Females
Aceh	0.352	0.293	0.110	0.239	0.199	0.075	0.189	0.157	0.059
Bali	0.179	0.121	0.079	0.121	0.082	0.053	0.096	0.065	0.042
Bangka-Belitung Islands	0.116	0.089	0.043	0.079	0.060	0.029	0.062	0.048	0.023
Banten	0.886	0.720	0.292	0.601	0.488	0.198	0.475	0.386	0.157
Bengkulu	0.127	0.101	0.044	0.086	0.068	0.030	0.068	0.054	0.024
Central Java	1.477	1.123	0.550	1.002	0.761	0.373	0.793	0.603	0.295
Central Kalimantan	0.210	0.141	0.093	0.142	0.096	0.063	0.113	0.076	0.050
Central Sulawesi	0.306	0.243	0.106	0.208	0.165	0.072	0.164	0.130	0.057
East Java	1.548	1.182	0.572	1.049	0.801	0.388	0.831	0.634	0.307
East Kalimantan	0.196	0.149	0.073	0.133	0.101	0.049	0.105	0.080	0.039
East Nusa Tenggara	0.574	0.405	0.240	0.389	0.275	0.162	0.308	0.217	0.129
Gorontalo	0.146	0.103	0.061	0.099	0.070	0.041	0.078	0.055	0.033
Indonesia	16.825	12.917	6.164	11.407	8.753	4.179	9.030	6.931	3.309
Jakarta	0.356	0.281	0.125	0.241	0.190	0.084	0.191	0.151	0.067
Jambi	0.183	0.139	0.068	0.124	0.094	0.046	0.098	0.075	0.037
Lampung	0.572	0.465	0.189	0.388	0.315	0.128	0.307	0.250	0.101
Maluku	0.209	0.145	0.090	0.142	0.098	0.061	0.112	0.078	0.048
North Kalimantan	0.067	0.053	0.024	0.046	0.036	0.016	0.036	0.028	0.013
North Maluku	0.162	0.122	0.061	0.110	0.083	0.042	0.087	0.065	0.033
North Sulawesi	0.201	0.167	0.063	0.136	0.113	0.043	0.108	0.090	0.034
North Sumatra	1.486	1.209	0.488	1.007	0.819	0.331	0.797	0.649	0.262
Papua	0.710	0.569	0.241	0.482	0.385	0.163	0.381	0.305	0.129
Riau	0.352	0.287	0.114	0.238	0.195	0.077	0.189	0.154	0.061
Riau Islands	0.122	0.113	0.029	0.083	0.076	0.020	0.065	0.061	0.016
South Kalimantan	0.324	0.245	0.122	0.220	0.166	0.083	0.174	0.132	0.066
South Sulawesi	0.608	0.475	0.216	0.412	0.322	0.147	0.326	0.255	0.116
South Sumatra	0.676	0.531	0.238	0.458	0.360	0.161	0.363	0.285	0.128
Southeast Sulawesi	0.326	0.262	0.110	0.221	0.178	0.075	0.175	0.141	0.059
West Java	2.979	2.219	1.147	2.020	1.504	0.778	1.599	1.191	0.616
West Kalimantan	0.295	0.189	0.139	0.200	0.128	0.094	0.158	0.101	0.075
West Nusa Tenggara	0.403	0.295	0.160	0.273	0.200	0.108	0.216	0.158	0.086
West Papua	0.103	0.076	0.040	0.070	0.051	0.027	0.055	0.041	0.022
West Sulawesi	0.209	0.153	0.083	0.142	0.104	0.056	0.112	0.082	0.044
West Sumatra	0.285	0.192	0.127	0.193	0.130	0.086	0.153	0.103	0.068
Yogyakarta	0.078	0.060	0.028	0.053	0.041	0.019	0.042	0.032	0.015

Economic Burden Based on YLL-Derived Estimates

Indonesia's overall estimated VLW reaches US $16.13 billion using the US DOT benchmark, US $10.936 billion under the OECD benchmark, and US $8.658 billion based on the national wage model (Table 2). To reflect local relevance, the national wage benchmark is prioritized in the following interpretation. The highest provincial VLW was observed in West Java (US $1.533 billion), followed by East Java (US $0.777 billion), North Sumatra (US $0.776 billion), and Central Java (US $0.742

XSL•FO
RenderX

billion). Collectively, these 4 provinces contributed more than 40% of the national burden. Other significant contributors include Banten (US $0.459 billion), South Sumatra (US $0.351 billion), and Papua (US $0.374 billion). In contrast, provinces such as North Kalimantan (US $0.035 billion), Yogyakarta (US $0.037 billion), and West Papua (US $0.054 billion) reported the lowest VLW estimates (Table 2).

Table 2. Economic burden of congenital heart disease in Indonesia estimated from years of life lost (YLL), using the United States Department of Transportation (US DOT), Organisation for Economic Co-operation and Development (OECD), and wage-based models (value of lost welfare [VLW] in billion US$).

Province	VLW (US DOT)			VLW (OECD)			VLW (national wage)		
	Both	Males	Females	Both	Males	Females	Both	Males	Females
Aceh	0.339	0.285	0.104	0.230	0.193	0.070	0.182	0.153	0.056
Bali	0.167	0.114	0.073	0.113	0.077	0.050	0.090	0.061	0.039
Bangka-Belitung Islands	0.112	0.086	0.041	0.076	0.058	0.028	0.060	0.046	0.022
Banten	0.856	0.701	0.278	0.580	0.475	0.188	0.459	0.376	0.149
Bengkulu	0.122	0.098	0.042	0.083	0.066	0.028	0.066	0.052	0.022
Central Java	1.383	1.063	0.506	0.938	0.720	0.343	0.742	0.570	0.272
Central Kalimantan	0.203	0.137	0.090	0.137	0.093	0.061	0.109	0.073	0.048
Central Sulawesi	0.299	0.238	0.102	0.202	0.161	0.069	0.160	0.128	0.055
East Java	1.447	1.117	0.525	0.981	0.757	0.356	0.777	0.599	0.282
East Kalimantan	0.186	0.143	0.068	0.126	0.097	0.046	0.100	0.077	0.037
East Nusa Tenggara	0.560	0.396	0.233	0.379	0.269	0.158	0.300	0.213	0.125
Gorontalo	0.143	0.101	0.060	0.097	0.068	0.040	0.077	0.054	0.032
Indonesia	16.130	12.472	5.837	10.936	8.451	3.957	8.658	6.692	3.134
Jakarta	0.330	0.264	0.112	0.224	0.179	0.076	0.177	0.142	0.060
Jambi	0.174	0.133	0.064	0.118	0.090	0.044	0.094	0.071	0.035
Lampung	0.550	0.450	0.178	0.373	0.305	0.121	0.295	0.241	0.096
Maluku	0.204	0.141	0.088	0.139	0.096	0.059	0.110	0.076	0.047
North Kalimantan	0.066	0.052	0.023	0.044	0.035	0.016	0.035	0.028	0.012
North Maluku	0.159	0.120	0.060	0.108	0.081	0.041	0.085	0.064	0.032
North Sulawesi	0.194	0.162	0.060	0.132	0.110	0.041	0.104	0.087	0.032
North Sumatra	1.446	1.183	0.469	0.980	0.802	0.318	0.776	0.635	0.252
Papua	0.696	0.559	0.235	0.472	0.379	0.159	0.374	0.300	0.126
Riau	0.335	0.277	0.107	0.227	0.188	0.072	0.180	0.149	0.057
Riau Islands	0.116	0.109	0.026	0.079	0.074	0.018	0.062	0.058	0.014
South Kalimantan	0.314	0.239	0.118	0.213	0.162	0.080	0.169	0.128	0.063
South Sulawesi	0.584	0.460	0.205	0.396	0.312	0.139	0.313	0.247	0.110
South Sumatra	0.655	0.517	0.228	0.444	0.350	0.155	0.351	0.277	0.122
Southeast Sulawesi	0.320	0.258	0.107	0.217	0.175	0.072	0.172	0.138	0.057
West Java	2.856	2.141	1.089	1.936	1.451	0.738	1.533	1.149	0.584
West Kalimantan	0.281	0.180	0.133	0.191	0.122	0.090	0.151	0.097	0.071
West Nusa Tenggara	0.390	0.286	0.153	0.264	0.194	0.104	0.209	0.154	0.082
West Papua	0.100	0.074	0.039	0.068	0.050	0.026	0.054	0.040	0.021
West Sulawesi	0.206	0.151	0.081	0.139	0.102	0.055	0.110	0.081	0.043
West Sumatra	0.271	0.182	0.120	0.183	0.124	0.081	0.145	0.098	0.064
Yogyakarta	0.068	0.054	0.023	0.046	0.037	0.016	0.037	0.029	0.012

XSL•FO
RenderX

In most provinces, the DALY-based values exceeded YLL-based values by less than 5%. For instance, the gaps were 2% in Papua, Maluku, North Maluku, Southeast Sulawesi, and West Sulawesi; 3% in Central Sulawesi, Central Kalimantan, East Nusa Tenggara, North Kalimantan, South Kalimantan, and West Nusa Tenggara; and 4% in Aceh, Bengkulu, Lampung, South Sulawesi, and West Java. Only a few provinces demonstrated higher differences, such as Bali (6%), Central Java (6%), East Java (6%), Jakarta (7%), and Yogyakarta, which had the largest gap at 12%. Nationally, the average DALY–YLL gap was approximately 4%.

Productivity Loss Based on DALYs

The estimated CHD-related economic burden in Indonesia stands at 1.35% of GDP using the US DOT benchmark, 0.91% under the OECD benchmark, and 0.72% using the national wage benchmark (Table 3). Provincial-level insights using the national wage benchmark reveal that East Nusa Tenggara (3.08%), West Sulawesi (2.47%), Maluku (2.40%), and Gorontalo (1.93%) bear the highest CHD-related economic burden relative to their regional GDP. In contrast, Jakarta (0.07%), East Kalimantan (0.13%), Riau (0.22%), and Riau Islands (0.23%) report the lowest VLW-to-GDP ratios. Other populous provinces such as West Java (0.76%), Central Java (0.58%), and East Java (0.35%) fall at or below the national average.

XSL•FO
RenderX

Table 3. Value of lost welfare (VLW)–to-gross domestic product (GDP) ratios for congenital heart disease in Indonesia, based on the United States Department of Transportation (US DOT), Organisation for Economic Co-operation and Development (OECD), and wage-based valuation models (VLW-to-GDP, %).

Province	VLW (US DOT), %			VLW (OECD), %			VLW (national wage), %		
	Both	Males	Females	Both	Males	Females	Both	Males	Females
Estimated from DALY (VLW_{DALY}-to-GDP[a])									
Aceh	2.01	2.75	1.26	1.36	1.87	0.85	1.08	1.48	0.68
Bali	0.82	0.90	0.73	0.55	0.61	0.50	0.44	0.48	0.39
Bangka-Belitung Islands	1.43	1.75	1.10	0.97	1.18	0.74	0.77	0.94	0.59
Banten	1.40	1.85	0.94	0.95	1.25	0.64	0.75	0.99	0.50
Bengkulu	1.67	2.11	1.21	1.13	1.43	0.82	0.90	1.13	0.65
Central Java	1.08	1.35	0.80	0.73	0.91	0.54	0.58	0.72	0.43
Central Kalimantan	1.25	1.33	1.17	0.85	0.90	0.79	0.67	0.71	0.63
Central Sulawesi	1.13	1.43	0.81	0.77	0.97	0.55	0.61	0.77	0.44
East Java	0.65	0.82	0.48	0.44	0.56	0.32	0.35	0.44	0.26
East Kalimantan	0.25	0.30	0.19	0.17	0.20	0.13	0.13	0.16	0.10
East Nusa Tenggara	5.74	6.65	4.83	3.89	4.51	3.27	3.08	3.57	2.59
Gorontalo	3.59	4.05	3.12	2.43	2.74	2.11	1.93	2.17	1.67
Indonesia	0.13	0.16	0.09	0.09	0.11	0.06	0.07	0.09	0.05
Jakarta	0.79	0.97	0.59	0.53	0.66	0.40	0.42	0.52	0.32
Jambi	1.61	2.10	1.09	1.09	1.42	0.74	0.86	1.12	0.58
Lampung	4.47	4.98	3.95	3.03	3.37	2.68	2.40	2.67	2.12
Maluku	0.56	0.68	0.41	0.38	0.46	0.28	0.30	0.37	0.22
North Kalimantan	2.72	3.26	2.15	1.84	2.21	1.46	1.46	1.75	1.16
North Maluku	1.48	1.96	0.98	1.00	1.33	0.66	0.79	1.05	0.52
North Sulawesi	1.84	2.46	1.21	1.24	1.67	0.82	0.99	1.32	0.65
North Sumatra	2.94	3.64	2.13	1.99	2.47	1.45	1.58	1.95	1.14
Papua	0.42	0.55	0.28	0.28	0.38	0.19	0.22	0.30	0.15
Riau	0.42	0.63	0.20	0.28	0.43	0.14	0.23	0.34	0.11
Riau Islands	1.56	1.92	1.18	1.06	1.30	0.80	0.84	1.03	0.64
South Kalimantan	1.16	1.50	0.82	0.79	1.02	0.56	0.62	0.81	0.44
South Sulawesi	1.35	1.71	0.98	0.92	1.16	0.66	0.73	0.92	0.52
South Sumatra	2.46	3.20	1.70	1.67	2.17	1.15	1.32	1.72	0.91
Southeast Sulawesi	1.42	1.72	1.12	0.97	1.17	0.76	0.76	0.92	0.60
West Java	1.32	1.34	1.30	0.90	0.91	0.88	0.71	0.72	0.70
West Kalimantan	3.10	3.71	2.49	2.10	2.51	1.69	1.66	1.99	1.34
West Nusa Tenggara	1.30	1.48	1.11	0.88	1.00	0.75	0.70	0.79	0.59
West Papua	4.60	5.41	3.75	3.12	3.67	2.55	2.47	2.90	2.02
West Sulawesi	1.16	1.28	1.04	0.79	0.87	0.70	0.62	0.69	0.56
West Sumatra	2.01	2.75	1.26	1.36	1.87	0.85	1.08	1.48	0.68
Yogyakarta	0.82	0.90	0.73	0.55	0.61	0.50	0.44	0.48	0.39
Estimated from YLL (VLW_{YLL}-to-GDP[b])									
Aceh	2.35	3.93	1.44	1.59	2.67	0.98	1.26	2.11	0.77
Bali	0.95	1.29	0.84	0.65	0.87	0.57	0.51	0.69	0.45

XSL•FO
RenderX

Province	VLW (US DOT), %			VLW (OECD), %			VLW (national wage), %		
	Both	Males	Females	Both	Males	Females	Both	Males	Females
Bangka-Belitung Islands	1.67	2.49	1.25	1.13	1.69	0.85	0.90	1.34	0.67
Banten	1.64	2.63	1.09	1.11	1.78	0.74	0.88	1.41	0.58
Bengkulu	1.93	3.00	1.36	1.31	2.04	0.92	1.04	1.61	0.73
Central Java	1.24	1.89	0.91	0.84	1.28	0.62	0.67	1.02	0.49
Central Kalimantan	1.44	1.87	1.33	0.98	1.26	0.90	0.77	1.00	0.72
Central Sulawesi	1.32	2.04	0.93	0.90	1.38	0.63	0.71	1.10	0.50
East Java	0.74	1.15	0.54	0.50	0.78	0.37	0.40	0.62	0.29
East Kalimantan	0.29	0.42	0.22	0.20	0.29	0.15	0.16	0.23	0.12
East Nusa Tenggara	6.79	9.61	5.64	4.60	6.51	3.82	3.64	5.16	3.03
Gorontalo	4.25	5.90	3.60	2.88	4.00	2.44	2.28	3.17	1.93
Indonesia	1.35	2.06	0.99	0.91	1.40	0.67	0.72	1.11	0.53
Jakarta	0.15	0.23	0.10	0.10	0.16	0.07	0.08	0.12	0.05
Jambi	0.91	1.36	0.68	0.61	0.92	0.46	0.49	0.73	0.37
Lampung	1.88	3.00	1.25	1.28	2.03	0.85	1.01	1.61	0.67
Maluku	5.28	7.22	4.59	3.58	4.89	3.11	2.84	3.87	2.46
North Kalimantan	0.67	1.00	0.50	0.46	0.68	0.34	0.36	0.54	0.27
North Maluku	3.20	4.71	2.48	2.17	3.19	1.68	1.72	2.52	1.33
North Sulawesi	1.72	2.81	1.10	1.17	1.90	0.74	0.92	1.51	0.59
North Sumatra	2.16	3.53	1.40	1.46	2.39	0.95	1.16	1.90	0.75
Papua	3.45	5.21	2.49	2.34	3.53	1.69	1.85	2.80	1.34
Riau	0.49	0.79	0.32	0.33	0.54	0.22	0.26	0.42	0.17
Riau Islands	0.50	0.92	0.23	0.34	0.62	0.16	0.27	0.49	0.12
South Kalimantan	1.82	2.72	1.38	1.23	1.84	0.93	0.98	1.46	0.74
South Sulawesi	1.36	2.15	0.94	0.92	1.46	0.64	0.73	1.16	0.51
South Sumatra	1.60	2.47	1.13	1.08	1.67	0.77	0.86	1.32	0.61
Southeast Sulawesi	2.91	4.63	1.98	1.98	3.14	1.34	1.56	2.48	1.06
West Java	1.67	2.47	1.29	1.13	1.67	0.88	0.90	1.32	0.69
West Kalimantan	1.55	1.93	1.51	1.05	1.30	1.02	0.83	1.03	0.81
West Nusa Tenggara	3.60	5.28	2.84	2.44	3.58	1.92	1.93	2.83	1.52
West Papua	1.53	2.15	1.27	1.04	1.45	0.86	0.82	1.15	0.68
West Sulawesi	5.44	7.85	4.36	3.69	5.32	2.96	2.92	4.21	2.34
West Sumatra	1.34	1.79	1.19	0.91	1.21	0.81	0.72	0.96	0.64
Yogyakarta	0.58	0.93	0.39	0.39	0.63	0.26	0.31	0.50	0.21

[a]VLW_{DALY}: value of lost welfare–disability-adjusted life years.

[b]VLW_{YLL}: value of lost welfare–years of life lost.

Productivity Loss Based on YLLs

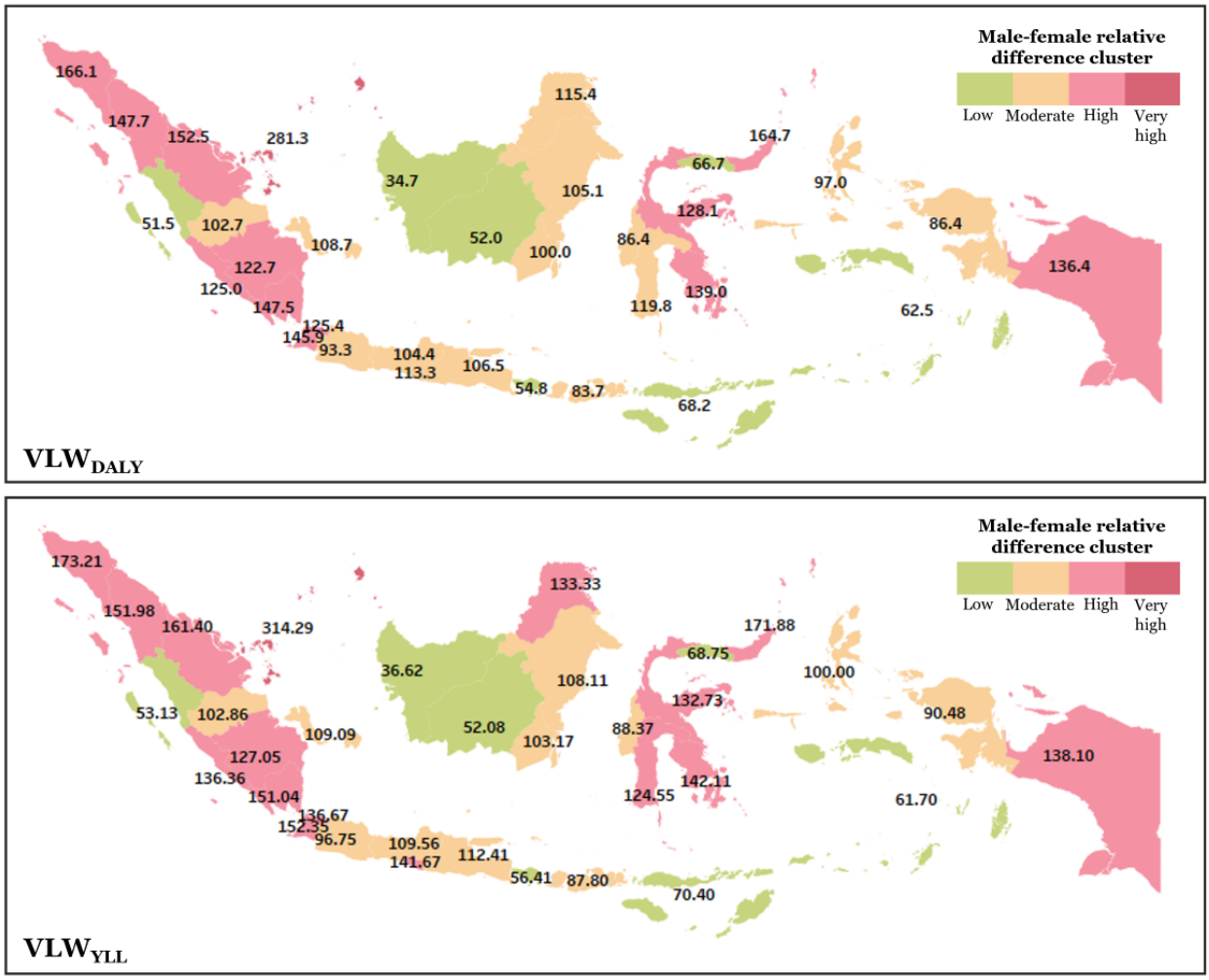
Corresponding estimates based on YLL are detailed in Table 3. Nationally, CHD-related productivity loss accounts for 1.35% of GDP using the US DOT benchmark, 0.91% with the OECD benchmark, and 0.72% under the national wage model. According to the national wage benchmark, East Nusa Tenggara records the highest VLW-to-GDP ratio at 3.64% (males=5.16% and females=3.03%), followed by West Sulawesi (2.92%), Maluku (2.84%), Gorontalo (2.28%), and West Nusa Tenggara (1.93%). In contrast, Jakarta (0.08%), East Kalimantan (0.16%), Riau (0.26%), and Riau Islands (0.27%) exhibit much lower VLW-to-GDP ratios. As populous provinces, West Java (0.90%), Central Java (0.67%), and East Java (0.40%) fall at or below the national average.

XSL•FO
RenderX

Gender Disparity

High gender disparities across Indonesian provinces, revealed by the male–female relative difference, are presented in Figure 1 and Multimedia Appendix 2. Based on the gender disparity in VLW_{DALY} (value of lost welfare–disability-adjusted life years), provinces such as Riau Islands (281.25%) stand out in the very high disparity category. A significant number of provinces fall into the high disparity cluster, including Aceh (166.10%), Banten (145.86%), Lampung (147.52%), North Sumatra (147.71%), and Papua (136.43%), reflecting consistently male-dominated VLW in both western and eastern regions. The moderate disparity group encompasses provinces such as Central Java (104.41%), East Java (106.51%), South Kalimantan (100%), and Yogyakarta (113.33%). Meanwhile, the low disparity cluster, with relative differences below 70%, includes Bali (54.76%), Central Kalimantan (52.00%), West Kalimantan (34.67%), Maluku (62.50%), and East Nusa Tenggara (68.22%).

Figure 1. Male-female relative difference showing gender disparities across Indonesia, estimated from VLW_{DALY} (value of lost welfare–disability-adjusted life years) and VLW_{YLL} (value of lost welfare–years of life lost).



The VLW_{YLL} (value of lost welfare–years of life lost) gender disparity reveals substantial variation in male-to-female differences across Indonesia. The most extreme case is seen in the Riau Islands, with a relative difference of 314.29%. A large group of provinces falls into the high disparity category, including Aceh (173.21%), Banten (152.35%), North Sumatra (151.98%), Lampung (151.04%), Papua (138.10%), and Yogyakarta (141.67%). The moderate disparity group features provinces such as Central Java (109.56%), East Java (112.41%), South Kalimantan (103.17%), and North Maluku (100%). In contrast, the very low disparity cluster includes Bali (56.41%), Central Kalimantan (52.08%), West Kalimantan (36.62%), and East Nusa Tenggara (70.40%). The gender disparity patterns in VLW_{DALY} and VLW_{YLL} for CHD are consistent. However, North Kalimantan and Yogyakarta are 2 provinces categorized as moderate disparity in the VLW_{DALY} but rise to high disparity in the VLW_{YLL}.

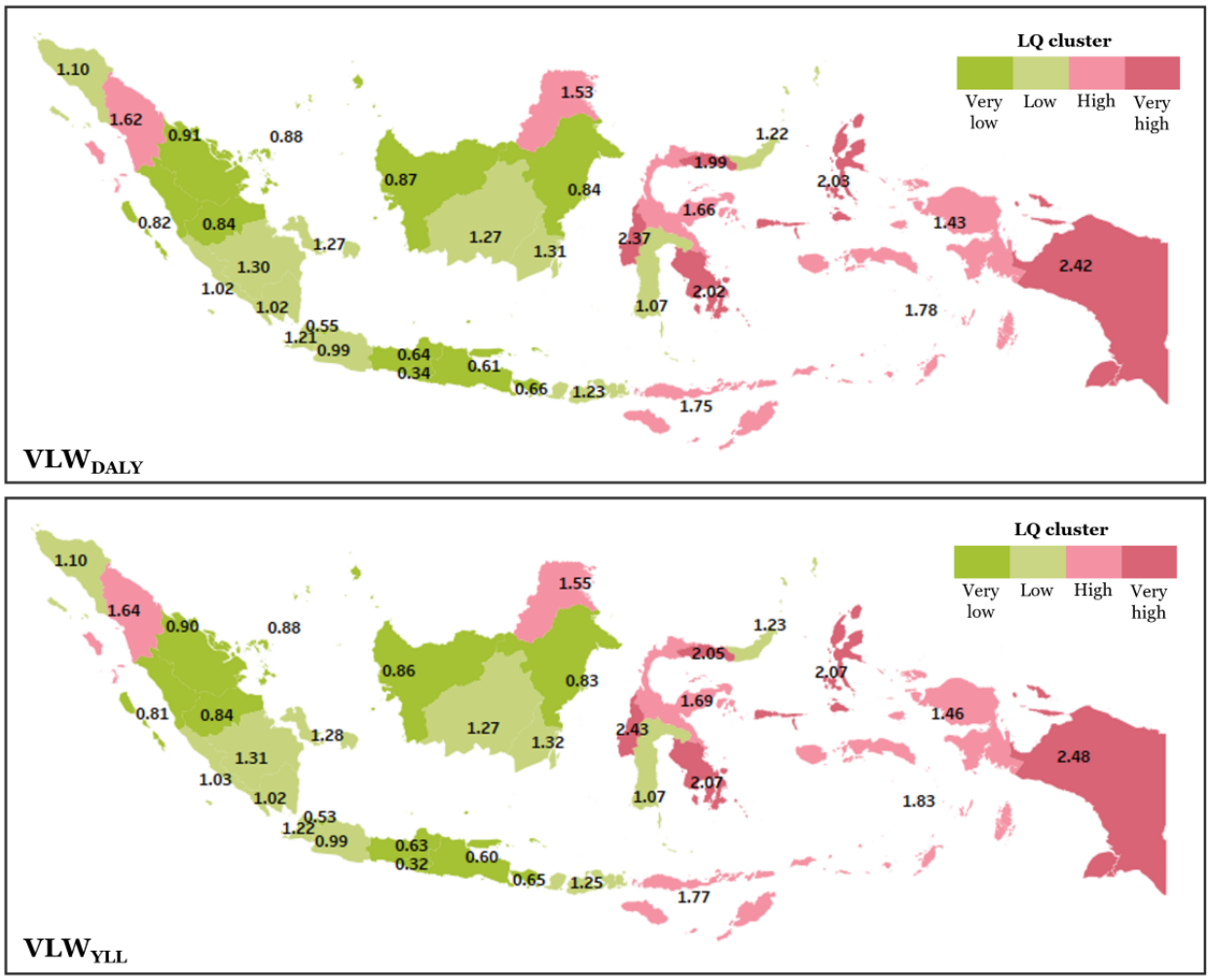
Geographical Disparity

The geographical analysis of economic CHD burden in Indonesia reveals notable spatial disparities in the VLWs (Figures 2 and 3; Multimedia Appendix 2). Based on the VLW_{DALY} LQ, most provinces fall into the low (LQ=1.0-1.3) and very low (<1.0) categories, indicating that their share of CHD-related welfare loss is roughly proportional—or even lower—than their population size. Notably, Yogyakarta (0.34), Jakarta (0.55), East Java (0.61), Central Java (0.64), and Bali (0.66) fall under the very low group. In contrast, provinces such

XSL•FO
RenderX

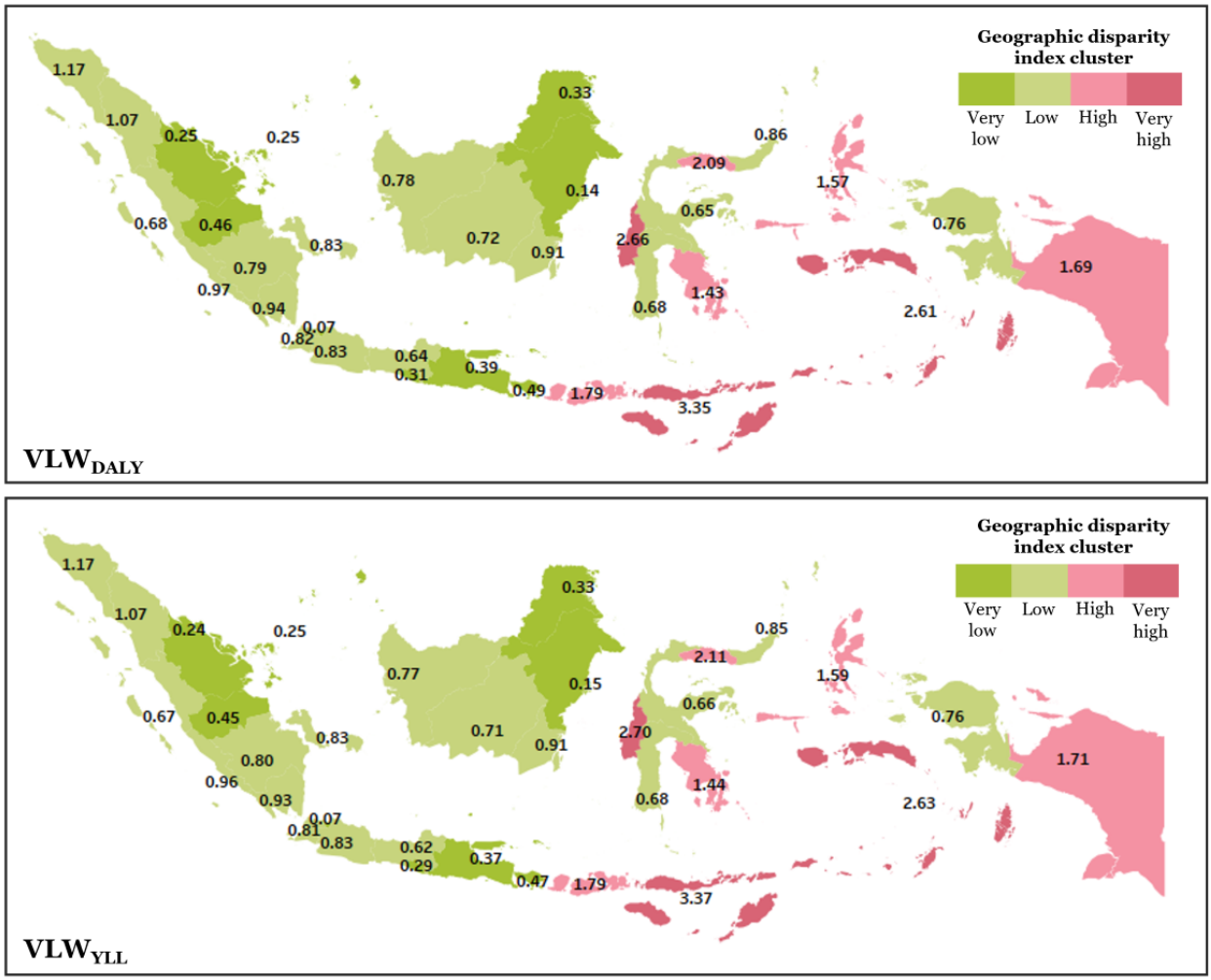
as Central Sulawesi (1.66), East Nusa Tenggara (1.75), Maluku (1.78), and North Sumatra (1.62) are in the high group, while Gorontalo (1.99), North Maluku (2.03), Papua (2.42), Southeast Sulawesi (2.02), and West Sulawesi (2.37) are in the very high group. Similarly, the VLW_{YLL} LQ follows a consistent trend. Provinces with very low LQs include Yogyakarta (0.32), Jakarta (0.53), East Java (0.60), Central Java (0.63), and Bali (0.65). Meanwhile, high disparity is observed in Central Sulawesi (1.69), East Nusa Tenggara (1.77), Maluku (1.83), and North Sumatra (1.64). The very high group again includes Gorontalo (2.05), North Maluku (2.07), Papua (2.48), Southeast Sulawesi (2.07), and West Sulawesi (2.43).

Figure 2. Location quotient (LQ) showing the economic burden of congenital heart disease (CHD) relative to the share population across Indonesia, estimated from VLW_{DALY} (value of lost welfare–disability-adjusted life years) and VLW_{YLL} (value of lost welfare–years of life lost). An LQ greater than 1 indicates a disproportionately higher economic burden relative to population share.



XSL•FO
RenderX

Figure 3. Geographic disparity index of the CHD economic burden across Indonesia, estimated from VLW_{DALY} (value of lost welfare–disability-adjusted life years) and VLW_{YLL} (value of lost welfare–years of life lost).



VLW_{DALY}-to-GDP disparity revealed that the majority of provinces in Indonesia (20 of 34) fall into the "low disparity" group, with ratios ranging from 0.636 in Central Java to 1.174 in Aceh, indicating that while the burden exists, it is proportionate to local GDP. Provinces such as Banten (0.816), North Sumatra (1.067), and West Java (0.834) also belong to this group. The "very low disparity" cluster includes 9 provinces, such as Jakarta (0.072), East Kalimantan (0.143), Riau and Riau Islands (both 0.251), and Yogyakarta (0.314), showing minimal economic strain from CHD-related welfare loss. In contrast, 5 provinces fall into the "high disparity" category, including West Nusa Tenggara (1.793), Papua (1.694), and North Maluku (1.569), where the economic burden is disproportionately high relative to GDP. Most critically, East Nusa Tenggara (3.352), Maluku (2.608), and West Sulawesi (2.662) are classified under "very high disparity."

Even though similar to the VLW_{DALY}-to-GDP, where the indices of most provinces (21 of 34) fall into the "low disparity" category, discrepancies exist in the trend. The value was lowest in Central Java (0.620) and in highest in Aceh (1.166). Provinces such as Banten (0.814), Lampung (0.935), and North Sumatra (1.073) belong to this group. The "very low disparity" cluster includes 9 provinces, including Jakarta (0.074), East Kalimantan (0.148), Riau (0.241), and Yogyakarta (0.287). Conversely, 5 provinces are classified under "high disparity," with indices ranging from 1.444 in Southeast Sulawesi to 2.110 in Gorontalo, indicating a disproportionate burden relative to their GDP. Notably, 3 eastern provinces—East Nusa Tenggara (3.369), Maluku (2.628), and West Sulawesi (2.702)—fall into the "very high disparity" group.

Discussion

Overview

This study estimated the economic burden of CHD across all 34 Indonesian provinces, highlighting substantial national losses as well as marked regional and gender disparities. The VLW-to-GDP ratio across provinces exceeds 1 million ($\times 10^{-}$), underscoring the significant burden of premature mortality and disability associated with CHD. This widespread productivity loss represents not only an urgent public health challenge but also a constraint on equitable economic development. High-income provinces such as Jakarta, East Kalimantan, and the Riau Islands reported some of the largest absolute VLW estimates, frequently exceeding US $10 billion even under conservative wage-based valuations. However, their

XSL•FO
RenderX

VLW-to-GDP ratios remain modest due to their larger economic output. Nonetheless, the absolute magnitude of these losses highlights a substantial, and perhaps underappreciated, burden of disease. The persistence of CHD-related productivity losses in economically advantaged provinces points to systemic inefficiencies in health care delivery; despite higher income levels and relatively advanced health infrastructure, these regions continue to experience significant losses in human capital.

Overall, the CHD-related VLW-to-GDP ratio remains under 5% in most provinces, suggesting a modest economic burden nationally. However, the relative burden is considerably higher in economically vulnerable eastern provinces, where limited health infrastructure and geographic barriers amplify the impact of premature mortality and disability. In contrast, higher-income provinces such as West Java, East Java, North Sumatra, and Jakarta reported the highest absolute VLW_{DALY} estimates, ranging from US $0.79 billion to US $1.60 billion under wage-based valuations. However, due to their stronger economic output, these areas exhibited modest VLW-to-GDP ratios. These provinces also had LQ values <1.0, suggesting their share of VLW is proportionate to—or even smaller than—their population size. Nonetheless, the absolute magnitude of these losses—despite higher health infrastructure—suggests systemic inefficiencies in health care delivery and delays in diagnosis or treatment within CHD care pathways.

This phenomenon aligns with the Preston Curve, in which higher GDP does not automatically translate into better health outcomes without commensurate health system performance [26]. Similar patterns have been observed in coronary heart disease, where economic losses persisted despite macroeconomic gains, estimated at US $33.3 billion nationally [27]. In this context, the high VLW in affluent provinces may reflect missed opportunities in prevention, early detection, or effective intervention—rather than resilience. Conversely, resource-limited provinces, particularly in eastern Indonesia—East Nusa Tenggara (3.35%), Maluku (2.61%), and West Sulawesi (2.66%)—though reporting lower absolute VLW (US $0.1-US $0.3 billion), experienced disproportionately high relative burden and LQ values (2.4-2.7). This suggests structural fragility: limited pediatric cardiology services, fragmented referral networks, and geographic barriers all magnify the consequences of delayed care [28,29]. The findings thus illuminate a dual burden: in wealthier, urbanized provinces, absolute VLW losses suggest inefficiencies in service delivery, whereas in poorer, rural areas, high VLW-to-GDP ratios and elevated LQ values highlight acute economic vulnerability from preventable losses. Collectively, these patterns underscore the need for nuanced, region-specific policy responses.

Burden Patterns: DALYs Versus YLLs

Our provincial analysis in this study revealed that the difference between VLW_{DALY} and VLW_{YLL} is small—generally under 5% across most regions, with only Yogyakarta exceeding a 10% gap. This finding indicates that premature mortality remains the dominant contributor to productivity loss from CHD in Indonesia, rather than chronic morbidity. It also suggests that while rehabilitation and long-term care are important, the most immediate policy priority in many provinces remains the prevention of early deaths through improved detection and timely intervention. Many infants do not survive CHD—largely due to late diagnosis, limited surgical access, and insufficient intensive neonatal and postoperative care [4,30]. In remote regions, care-seeking is often delayed due to low health literacy, poor transportation, financial hardship, and cultural beliefs [28,31]. As a result, many congenital anomalies remain undetected until they cause serious complications or early death [31]. In line with the previously reported economic evaluations of congenital anomalies, strengthening early detection and intervention is thus essential to reduce VLW_{DALY} [27]. In Bali, Central Java, East Java, or Jakarta, persistent premature mortality likely affects marginalized subgroups within otherwise well-equipped provinces. Similar patterns have been reported in the United States, where CHD mortality remains unequally distributed despite overall health system strength [32,33]. Yogyakarta's relatively higher DALY-to-YLL difference likely reflects both effective early detection and follow-up care systems [34,35], as well as a sociodemographic structure with a lower concentration of underserved populations compared to megacities such as Jakarta [36].

Geographic Divide

This study introduces 2 complementary indicators of geographic burden: the VLW-to-GDP disparity index and the VLW LQ. While both indicators reveal a consistent east–west divide, they offer distinct perspectives. The VLW-to-GDP disparity index classifies 20 of 34 provinces as "low disparity" and 9 as "very low," indicating that in most regions, the CHD-related economic burden remains relatively proportional to local GDP. However, East Nusa Tenggara (3.35%), Maluku (2.61%), and West Sulawesi (2.66%) fall into the "very high disparity" cluster, pointing to severe strain relative to their limited economic capacity. These findings support previous reports highlighting chronic health care underdevelopment and financial vulnerability in these eastern provinces [37,38]. Residents of Maluku are significantly less likely than even those in Papua to use hospital services, with an adjusted odds ratio (OR) of 0.827 (95% CI 0.820-0.835), reflecting both structural and access-related barriers to care [38]. Such disparities in hospital use emphasize how systemic underutilization of formal health services may contribute to both the progression of undiagnosed CHD and increased long-term economic burden in these regions. In addition, comparable regional gradients have been observed in China's poverty and population distribution using remote sensing–based spatial models [12,13]. These parallels highlight how geospatial approaches can uncover hidden structural inequities, reinforcing the need for province-specific strategies in Indonesia.

The LQ, by contrast, measures each province's share of the national CHD-related burden relative to its population size. Provinces such as Gorontalo, North Maluku, Papua, Southeast Sulawesi, and West Sulawesi had LQ values exceeding 2.0, suggesting that their per capita contribution to national VLW is disproportionately high. Other regions, including East Nusa Tenggara, Maluku, North Kalimantan, and North Sumatra, also fall into the "high" category. In contrast, economically stronger and densely populated provinces such as Jakarta, Yogyakarta,

XSL•FO
RenderX

Central Java, and East Java show consistently low LQ values (0.32-0.64), indicating a lower per capita burden. This may reflect underlying disparities within otherwise well-resourced provinces, where marginalized or socioeconomically disadvantaged subpopulations continue to face barriers to timely diagnosis and treatment. Previous research in high-income contexts, including the United States, has similarly demonstrated that CHD-related mortality is unequally distributed across populations, with persistent service gaps and socioeconomic deprivation contributing to avoidable deaths [32,33].

When DALY-based and YLL-based disparity indices are compared, the results show broadly similar geographic patterns but also important differences. Both measures consistently flag East Nusa Tenggara, Maluku, and West Sulawesi as high-disparity regions, while Jakarta, East Kalimantan, Riau, and Yogyakarta appear in the very low cluster across both metrics. However, DALYs, which include YLDs, tend to be higher in provinces such as West Nusa Tenggara, where survival is often accompanied by long-term morbidity. Conversely, Gorontalo and North Maluku exhibit higher YLL-based indices, suggesting early death as the dominant burden component.

Gender Disparities and Economic Impact Severity

Across all provinces and valuation models, males consistently contributed a greater share to the total VLW than females, underscoring persistent gender-based disparities in the economic impact of CHD. This pattern aligns with prevailing socioeconomic structures in Indonesia, where men dominate formal labor markets and are typically regarded as primary income earners [39]. As a result, premature death or long-term disability in males translates into greater economic loss, particularly in contexts where male productivity is central to household income and community stability [40].

In this study, the magnitude of this disparity varies considerably by province. Riau Islands exhibited the most extreme male-dominant burden, with a VLW-to-GDP gender difference of 281.25% (DALY-based) and 314.29% (YLL-based). Several other provinces, such as Aceh, Banten, North Sumatra, Lampung, and Papua, consistently fall into the high-disparity category (≥130% higher in males), spanning both western and eastern regions. In contrast, provinces such as Bali, Central Kalimantan, West Kalimantan, Maluku, and East Nusa Tenggara showed much lower disparities, with male VLW contributions below 70% higher than female, suggesting either more balanced socioeconomic structures or more equitable access to care.

While the overall pattern is consistent across DALY- and YLL-based measures, some provinces, such as Yogyakarta and North Kalimantan, demonstrated higher disparity in YLL-derived estimates, indicating that male premature mortality plays a more dominant role than long-term male disability therein. Given that CHD prevalence also remains higher in males (0.96%) than in females (0.72%) [2], targeted policy responses must consider sex-specific vulnerabilities to reduce both health and economic consequences, particularly in provinces with extreme gender disparity.

Implications and Policy Recommendations

Our dual analysis using VLW-to-GDP disparity indices and LQ reveals distinct yet overlapping geographical patterns, underscoring the need for a province-specific strategy that balances financial, systemic, and service-based interventions. In lower-resource provinces, elevated VLW_{DALY} reflects the economic consequences of survival without adequate recovery, highlighting fragmented care pathways and limited rehabilitative infrastructure. Conversely, in more affluent regions, high VLW_{YLL} underscores that income alone does not ensure early diagnosis or optimal outcomes. These findings point to persistent system inefficiencies that allow both preventable mortality and long-term disability to persist across disparate socioeconomic contexts.

Timely diagnosis is central to effective CHD management, yet screening remains inconsistently implemented nationwide. Although feasibility studies in Yogyakarta have demonstrated successful integration of pulse oximetry into newborn care [4], national scale-up has been hindered by logistical and workforce barriers. School-based screening using auscultation and electrocardiography has also shown promise [3] but remains fragmented and pilot-driven. A recent national review highlights the absence of a cohesive CHD screening strategy, contributing to diagnostic delays, often until complications such as pulmonary hypertension or irreversible cyanosis arise [41]. Screening strategies should be prioritized in light of existing evidence showing that universal neonatal pulse oximetry screening is not only effective but also highly cost-effective [42]. Beyond clinical access, the economic burden of CHD is not gender-neutral. As findings of this study suggest, male children represent a larger share of projected productivity losses due to their expected roles in the formal labor market. Provinces such as Riau Islands, Aceh, and Papua reveal extreme disparities in male-to-female VLW, suggesting that male early mortality or disability carries greater economic implications, especially in socioeconomically vulnerable areas.

To effectively reduce geographic inequities, interventions must be tailored to the burden profile of each province. Regions such as East Nusa Tenggara, Maluku, and West Sulawesi, which show both high local strain (limited resources) and moderate contribution to the national CHD-related economic burden, warrant comprehensive support. These provinces present a strategic opportunity for high-return investment: their low baseline health care capacity means that even modest improvements in screening, referral, or access to surgical services can yield substantial health gains [43,44]. As previously reported, deep learning–assisted prenatal ultrasound is highly cost-effective, generating more than 1200 additional quality-adjusted life years at a cost of just US $1720 per quality-adjusted life year [45]. Moreover, alleviating the burden in these areas reduces both localized economic strain and the national VLW [46]. Targeted interventions here not only address vulnerability but also improve overall system efficiency, making them particularly cost-effective. In contrast, provinces such as West Nusa Tenggara and Bengkulu, despite contributing less to the national burden, still experience significant local impact. These areas require strengthened local infrastructure and the

XSL•FO
RenderX

continuation of full coverage by Indonesia's Universal Health Coverage system, covering surgery, diagnostics, and long-term follow-up, to shield households from out-of-pocket costs and prevent untreated cases from progressing into costly long-term disabilities [47].

Other areas, such as Papua, North Maluku, and Gorontalo, contribute significantly to the national VLW through high premature mortality, suggesting the need for enhanced early detection, community engagement, and strengthened referral systems. However, such efforts will remain insufficient without addressing the chronic shortage and unequal distribution of pediatric cardiologists and cardiac surgeons in these regions [48]. Evidence from cost-effectiveness studies consistently supports the value of expanding surgical access in LMICs [49]. Strengthening pediatric surgical capacity in Indonesia would therefore not only reduce preventable mortality but also represent an efficient use of limited health resources.

To reduce preventable mortality and economic loss, targeted investments are needed to expand local specialist capacity, develop regional cardiac centers, and implement remote consultation systems such as telecardiology [50,51]. Task-shifting approaches, such as training nurses or midwives to perform point-of-care cardiac ultrasound, have demonstrated effectiveness in resource-limited settings by enabling earlier detection and timely referral for CHD [52]. While challenges remain, including training costs, limited internet connectivity, and unstable electricity supply, these models have been proven to address the limited specialist availability [52].

Meanwhile, well-performing provinces such as Jakarta, Central Java, and Yogyakarta can serve as national innovation hubs to accelerate progress in CHD care. These regions are well-positioned to support interprovincial partnerships and lead pilot projects for digital health integration, including the development of artificial intelligence (AI)–based models for early CHD detection and risk stratification [53-55]. Their advanced clinical infrastructure allows for the implementation of high-impact interventions, such as zero-fluoroscopy atrial septal defect closures [56], transesophageal echocardiography–guided balloon-assisted percutaneous closures in complex cases (including during pregnancy) [57], and percutaneous palliative stenting for adults with unrepaired Tetralogy of Fallot [58]. Furthermore, these provinces can spearhead trials on advanced therapies, remote robotic-assisted surgery, and AI-assisted procedural planning [59,60], while also serving as training centers for pediatric cardiologists and interventional specialists [48].

Limitations

This study is subject to several limitations, chiefly stemming from its reliance on the GBD 2019 dataset. While the GBD framework provides standardized, internationally comparable estimates of disease burden, its modeled nature may not adequately reflect the subnational heterogeneity in CHD prevalence, health care access, and mortality reporting that characterizes Indonesia's archipelagic geography. Provinces with limited health surveillance infrastructure, particularly in eastern and remote regions, may exhibit substantial discrepancies between modeled and actual disease burden, introducing uncertainty into provincial-level estimates. Furthermore, the use of age-standardized data, though essential for international comparability, may obscure local demographic nuances, such as regional fertility rates, health-seeking behaviors, and differential survival trajectories—factors particularly salient in the context of pediatric conditions.

In addition, the valuation methods used, although grounded in established economic frameworks (eg, US DOT, OECD, and wage-based models), may inadequately account for informal labor contributions, gendered economic roles, and intrahousehold productivity, all of which are significant in the Indonesian context. Nevertheless, the GBD remains among the most comprehensive sources for cross-provincial disease burden estimation and provides a rigorous foundation for quantifying the economic impact of CHD across diverse settings. The triangulation of estimates across multiple valuation models further strengthens the robustness of the findings and highlights important spatial and sociodemographic disparities.

Conclusion

Our findings reveal that CHD imposes a macroeconomically nonsignificant burden in Indonesia, accounting for up to 1.35% of GDP using the highest valuation model. Similar to patterns observed in other LMICs, this economic impact is primarily driven by premature death. Across provinces, the gap between DALY- and YLL-based estimates is typically under 5%, indicating that YLLs dominate the productivity losses from CHD. Notably, gender disparities are prominent, with provinces such as the Riau Islands showing very high male–female relative differences in both DALY- and YLL-based losses. In Yogyakarta and North Kalimantan, the disparity is more pronounced in YLL-derived estimates, suggesting that premature mortality among males is a key contributor. Geographic disparities further reveal that provinces such as East Nusa Tenggara, Maluku, and West Sulawesi—which experience both high local strain and moderate national burden—warrant comprehensive and fundamental support. Meanwhile, provinces with low VLW-to-GDP ratios, including Jakarta, Central Java, and Yogyakarta, can serve as innovation hubs, facilitating specialist training, piloting AI-assisted interventions, and supporting interprovincial knowledge exchange to reduce national inequities.

Acknowledgments

The authors thank the Postgraduate Research Committee of Universitas Muhammadiyah Aceh for facilitating author collaboration on this work. This study did not receive any grant funding.

XSL•FO
RenderX

Data Availability

All data generated or analyzed during this study are included in this study and its supplementary information files.

Authors' Contributions

Conceptualization: MI
Data curation: DDCHR
Formal Analysis: MH
Funding Acquisition: MH
Investigation: MI, DDCHR
Methodology: MI
Project Administration: IA
Resources: IA
Software: IA
Supervision: SL, SHR, RP, MH
Validation: SL, SHR, RP, MH
Visualization: IA, MH
Writing – draft preparation: MI, DDCHR
Writing – review & editing: IA, SL, SHR, RP, MH

Conflicts of Interest

None declared.

Multimedia Appendix 1
Regional DALY and YLL Burden, Population Size, and GDP per Capita.
[XLSX File (Microsoft Excel File), 38 KB - pediatrics_v8i1e80696_app1.xlsx]

Multimedia Appendix 2
Value of Lost Welfare (VLW), Gender Disparity, and Ratio Estimates Based on DALY and YLL Metrics.
[XLSX File (Microsoft Excel File), 34 KB - pediatrics_v8i1e80696_app2.xlsx]

Multimedia Appendix 3
Graphical abstract.
[PNG File , 481 KB - pediatrics_v8i1e80696_app3.png]

References

1. Xu J, Li Q, Deng L, Xiong J, Cheng Z, Ye C. Global, regional, and national epidemiology of congenital heart disease in children from 1990 to 2021. Front Cardiovasc Med 2025;12:1522644 [FREE Full text] [doi: 10.3389/fcvm.2025.1522644] [Medline: 40454242]
2. Muharram FR, Multazam CECZ, Mustofa A, Socha W, Andrianto, Martini S, et al. The 30 years of shifting in the Indonesian cardiovascular burden—analysis of the Global Burden of Disease Study. J Epidemiol Glob Health 2024;14(1):193-212 [FREE Full text] [doi: 10.1007/s44197-024-00187-8] [Medline: 38324147]
3. Dinarti LK, Hartopo AB, Kusuma AD, Satwiko MG, Hadwiono MR, Pradana AD, et al. The COngenital HeARt Disease in adult and Pulmonary Hypertension (COHARD-PH) registry: a descriptive study from single-center hospital registry of adult congenital heart disease and pulmonary hypertension in Indonesia. BMC Cardiovasc Disord 2020;20(1):163 [FREE Full text] [doi: 10.1186/s12872-020-01434-z] [Medline: 32264836]
4. Murni IK, Patmasari L, Wirawan MT, Arafuri N, Nurani N, Sativa ER, Noormanto. Outcome and factors associated with undernutrition among children with congenital heart disease. PLoS One 2023;18(2):e0281753 [FREE Full text] [doi: 10.1371/journal.pone.0281753] [Medline: 36821565]
5. Amelia P, Yosephine AG, Tobing TC, Savira M, Viandy V, Inglin M. Association between type of congenital heart disease with child growth and development status: a cross-sectional study in Medan, Indonesia. Narra J 2023;3(3):e414 [FREE Full text] [doi: 10.52225/narra.v3i3.414] [Medline: 38450335]
6. Chen-Xu J, Grad D, Mahrouseh N, Santos JV, Riva S, Gazzelloni F, et al. The role of burden of disease estimates in European Union health policymaking: a systematic analysis of EU legislation. Health Policy 2025;159:105387 [FREE Full text] [doi: 10.1016/j.healthpol.2025.105387] [Medline: 40639125]
7. Khadka A, Verguet S. The economic value of changing mortality risk in low- and middle-income countries: a systematic breakdown by cause of death. BMC Med 2021;19(1):156 [FREE Full text] [doi: 10.1186/s12916-021-02029-x] [Medline: 34266420]

XSL•FO
RenderX

8. Robinson LA, Hammitt JK, O'Keeffe L. Valuing mortality risk reductions in global benefit-cost analysis. J Benefit Cost Anal 2019;10(Suppl 1):15-50 [FREE Full text] [doi: 10.1017/bca.2018.26] [Medline: 32968616]
9. Environment Directorate. Valuing Mortality Risk Reductions in Regulatory Analysis of Environmental, Health and Transport Policies: Policy Implications.: Organisation for Economic Co-operation and Development; 2011. URL: https://www.eurosprinkler.org/wp-content/uploads/2013/06/Value-Statistical-Life-OECD.pdf [accessed 2025-07-14]
10. Wulandari L. Deriving Indonesia's Value of Statistical Life. URL: https://laidlawscholars.network/documents/deriving-indonesia-s-value-of-statistical-life-8a871e5f-65ee-40c9-9d30-65f4b0e5761f [accessed 2025-07-06]
11. Hammitt JK, Robinson LA. The income elasticity of the value per statistical life: transferring estimates between high and low income populations. J Benefit-Cost Anal 2021;2(1):1-29. [doi: 10.2202/2152-2812.1009]
12. Wang M, Wang Y, Teng F, Li S, Lin Y, Cai H. China's poverty assessment and analysis under the framework of the UN SDGs based on multisource remote sensing data. Geo-spatial Information Science 2022;27(1):111-131. [doi: 10.1080/10095020.2022.2108346]
13. Teng F, Wang Y, Wang M, Wang L. Monitoring and analysis of population distribution in China from 2000 to 2020 based on remote sensing data. Remote Sens 2022;14(23):6019. [doi: 10.3390/rs14236019]
14. Kong W, Sun Y, Qin X, Zhu G, Zhu X, Kuang Z, et al. The burden and risk factors of gastric cancer in Eastern Asia from 1990 to 2021: a longitudinal observational study of the Global Burden of Disease Study 2021. JMIR Cancer 2025;11:e75728 [FREE Full text] [doi: 10.2196/75728] [Medline: 40779780]
15. Xin Y, Shui D, Yan G, Tian W, Tang N, Liang J, et al. Dietary risk factors and associated disease burden among Chinese adults aged 25 years and older: systematic analysis of the Global Burden of Disease Study 2021. JMIR Public Health Surveill 2025;11:e72978 [FREE Full text] [doi: 10.2196/72978] [Medline: 40934441]
16. Shu T, Tang M, He B, Liu X, Han Y, Liu C, et al. Assessing global, regional, and national time trends and associated risk factors of the mortality in ischemic heart disease through Global Burden of Disease 2019 Study: population-based study. JMIR Public Health Surveill 2024;10:e46821 [FREE Full text] [doi: 10.2196/46821] [Medline: 38265846]
17. GBD 2019 Indonesia Subnational Collaborators. The state of health in Indonesia's provinces, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet Glob Health 2022;10(11):e1632-e1645 [FREE Full text] [doi: 10.1016/S2214-109X(22)00371-0] [Medline: 36240829]
18. Wang H, Lin J, Wang L, Zhang X, Zhou T, Zhang C, et al. Global, regional, and national burden of intracerebral hemorrhage in young adults from 1990 to 2021: a population-based study. J Am Heart Assoc 2024;13(21):e037286 [FREE Full text] [doi: 10.1161/JAHA.124.037286] [Medline: 39450741]
19. Graves PE. Value of statistical life, wage compensation, and property value compensation. In: Batabyal AA, Nijkamp P, editors. Research Tools in Natural Resource and Environmental Economics. Singapore: World Scientific; 2011:189-213.
20. Keadaan Angkatan Kerja di Indonesia Agustus 2019. Jakarta: Badan Pusat Statistik; 2019.
21. Pertumbuhan Agresif untuk Perlindungan Berkelanjutan. Jakarta: BPJS Ketenagakerjaan; 2019. URL: https://www.bpjsketenagakerjaan.go.id/assets/uploads/laporan_tahunan/BPJS_2020_LO17.pdf [accessed 2025-10-21]
22. Heckman JJ. Sample selection bias as a specification error. Econometrica 1979;47(1):153-161. [doi: 10.2307/1912352]
23. Wang D, Xu Y, Zhu Z, Li Y, Li X, Li Y, et al. Changes in the global, regional, and national burdens of NAFLD from 1990 to 2019: a systematic analysis of the Global Burden of Disease Study 2019. Front Nutr 2022;9:1047129 [FREE Full text] [doi: 10.3389/fnut.2022.1047129] [Medline: 36618688]
24. Molassiotis A, Kwok SWH, Leung AYM, Tyrovolas S. Associations between sociodemographic factors, health spending, disease burden, and life expectancy of older adults (70+ years old) in 22 countries in the Western Pacific Region, 1995–2019: estimates from the Global Burden of Disease (GBD) Study 2019. Geroscience 2022;44(2):925-951 [FREE Full text] [doi: 10.1007/s11357-021-00494-z] [Medline: 35000094]
25. Zhang T, Sun L, Yin X, Chen H, Yang L, Yang X. urden of drug use disorders in the United States from 1990 to 2021 and its projection until 2035: results from the Global Burden of Disease study. BMC Public Health 2024;24(1):1639 [FREE Full text] [doi: 10.1186/s12889-024-19142-0] [Medline: 38898398]
26. Arvidsson R, Nordelöf A. Towards a method for quantifying health benefits from economic value in social life cycle assessment. Int J Life Cycle Assess 2025;30(4):792-802. [doi: 10.1007/s11367-025-02433-y]
27. Uli RE, Satyana RPU, Zomer E, Magliano D, Liew D, Ademi Z. Health and productivity burden of coronary heart disease in the working Indonesian population using life-table modelling. BMJ Open 2020;10(9):e039221 [FREE Full text] [doi: 10.1136/bmjopen-2020-039221] [Medline: 32912956]
28. McGrath L, Taunton M, Levy S, Kovacs AH, Broberg C, Khan A. Barriers to care in urban and rural dwelling adults with congenital heart disease. Cardiol Young 2022;32(4):612-617. [doi: 10.1017/S1047951121002766] [Medline: 34294183]
29. Cheng SP, Heo K, Joos E, Vervoort D, Joharifard S. Barriers to accessing congenital heart surgery in low- and middle-income countries: a systematic review. World J Pediatr Congenit Heart Surg 2024;15(1):94-103. [doi: 10.1177/21501351231204328] [Medline: 37915213]
30. Fiddin D, Putra DHS, Primasakti I. Screening and etiology of congenital heart disease in developing countries: a comprehensive systematic review. Int J Med Sci Health Res 2025;9(1):42-64. [doi: 10.70070/6e8xxb74]

XSL•FO
RenderX

31. Khan AM, McGrath LB, Ramsey K, Agarwal A, Slatore CG, Broberg CS. Distance to care, rural dwelling status, and patterns of care utilization in adult congenital heart disease. Pediatr Cardiol 2022;43(3):532-540. [doi: 10.1007/s00246-021-02750-7] [Medline: 34705069]
32. Udine ML, Evans F, Burns KM, Pearson GD, Kaltman JR. Geographical variation in infant mortality due to congenital heart disease in the USA: a population-based cohort study. Lancet Child Adolesc Health 2021;5(7):483-490. [doi: 10.1016/S2352-4642(21)00105-X] [Medline: 34051889]
33. Miao Q, Dunn S, Wen SW, Lougheed J, Reszel J, Lavin Venegas C, et al. Neighbourhood maternal socioeconomic status indicators and risk of congenital heart disease. BMC Pregnancy Childbirth 2021;21(1):72 [FREE Full text] [doi: 10.1186/s12884-020-03512-8] [Medline: 33478420]
34. Murni IK, Wibowo T, Arafuri N, Oktaria V, Dinarti LK, Panditatwa D, et al. Feasibility of screening for critical congenital heart disease using pulse oximetry in Indonesia. BMC Pediatr 2022;22(1):369 [FREE Full text] [doi: 10.1186/s12887-022-03404-0] [Medline: 35761296]
35. Dinarti LK, Murni IK, Anggrahini DW, Dewanto VC, Pritazahra A, Hadwiono MR, et al. The screening of congenital heart disease by cardiac auscultation and 12-lead electrocardiogram among Indonesian elementary school students. Cardiol Young 2021;31(2):264-273. [doi: 10.1017/S1047951120003881] [Medline: 33308362]
36. Ghifari D. Indonesia's poverty rate at historic low despite uptick in inequality. Asia News Network. URL: https://asianews.network/indonesias-poverty-rate-at-historic-low-despite-uptick-in-inequality/ [accessed 2025-07-14]
37. Utomo B, Sucahya PK, Utami FR. Priorities and realities: addressing the rich-poor gaps in health status and service access in Indonesia. Int J Equity Health 2011;10:47 [FREE Full text] [doi: 10.1186/1475-9276-10-47] [Medline: 22067727]
38. Laksono AD, Wulandari RD, Rohmah N, Rukmini R, Tumaji T. Regional disparities in hospital utilisation in Indonesia: a cross-sectional analysis data from the 2018 Indonesian Basic Health Survey. BMJ Open 2023;13(1):e064532 [FREE Full text] [doi: 10.1136/bmjopen-2022-064532] [Medline: 36596635]
39. Setyonaluri D, Nasution G, Ayunisa F, Sulistya Pambudhi F, Kharistiyanti A. Social Norms and Women's Economic Participation in Indonesia. Jakarta: Investing in Women; 2021.
40. Cameron L. Gender equality and development: Indonesia in a global context. Bull Indones Econ Stud 2023;59(2):179-207. [doi: 10.1080/00074918.2023.2229476]
41. Octavius GS, Daleni VA, Sagala YDS. An insight into Indonesia's progress for newborn screening program: what is currently going on. Heliyon 2024;10(13):e33479 [FREE Full text] [doi: 10.1016/j.heliyon.2024.e33479] [Medline: 39035496]
42. Imaz-Iglesia I, Hijas-Gómez A, Rodríguez-Arbáizar J, Martínez-Portillo A, Asensio C, García Carpintero E, et al. EE308 cost-utility analysis of universal neonatal screening for critical congenital heart disease based on pulse oximetry in Spain. Value in Health 2023;26(12):S110. [doi: 10.1016/j.jval.2023.09.574]
43. Troisi G, Gafer N, Alsawahli H, Elmusharaf K, Byström M, Azar J, et al. Harnessing primary healthcare to reduce the burden of cervical cancer in the Eastern Mediterranean Region. BMJ Glob Health 2025;10(6):e017622 [FREE Full text] [doi: 10.1136/bmjgh-2024-017622] [Medline: 40484410]
44. Bloom DE, Chen S, McGovern M, Prettner K, Candeias V, Bernaert A, et al. The Economics of Non-Communicable Diseases in Indonesia. Geneva: World Economic Forum; 2015.
45. Ginsberg GM, Drukker L, Pollak U, Brezis M. Cost-utility analysis of prenatal diagnosis of congenital cardiac diseases using deep learning. Cost Eff Resour Alloc 2024;22(1):44 [FREE Full text] [doi: 10.1186/s12962-024-00550-3] [Medline: 38773527]
46. Stenberg K, Watts R, Bertram MY, Engesveen K, Maliqi B, Say L, et al. Cost-effectiveness of interventions to improve maternal, newborn and child health outcomes: a WHO-CHOICE analysis for Eastern sub-Saharan Africa and South-East Asia. Int J Health Policy Manag 2021;10(11):706-723 [FREE Full text] [doi: 10.34172/ijhpm.2021.07] [Medline: 33904699]
47. Ekawati FM, Claramita M. Indonesian general practitioners' experience of practicing in primary care under the implementation of universal health coverage scheme (JKN). J Prim Care Community Health 2021;12:21501327211023707 [FREE Full text] [doi: 10.1177/21501327211023707] [Medline: 34114507]
48. Rahmat B, Wardana PWA. Development of pediatric cardiac surgery in Indonesia-a thousand islands and a handful of centers. Indian J Thorac Cardiovasc Surg 2024;41(6):807-811. [doi: 10.1007/s12055-024-01793-8] [Medline: 40417604]
49. Mlambo V, Hyles K, Wang S, Lin Y. Cost-effectiveness analysis of valvular surgery in high- and low- to middle-income countries: a scoping review. World J Surg 2024;48(11):2571-2585. [doi: 10.1002/wjs.12381] [Medline: 39428550]
50. Gunardi F, Oktamianti P. Strengthening the marketing of pediatric cardiac surgery services to support the transformation of health services in Indonesia. J Indones Health Policy Adm 2023;8(2):6. [doi: 10.7454/ihpa.v8i2.6420]
51. Yamano T, Kotani K, Kitano N, Morimoto J, Emori H, Takahata M, et al. Telecardiology in rural practice: global trends. Int J Environ Res Public Health 2022;19(7):4335 [FREE Full text] [doi: 10.3390/ijerph19074335] [Medline: 35410012]
52. Abrokwa SK, Ruby LC, Heuvelings CC, Bélard S. Task shifting for point of care ultrasound in primary healthcare in low- and middle-income countries-a systematic review. EClinicalMedicine 2022;45:101333 [FREE Full text] [doi: 10.1016/j.eclinm.2022.101333] [Medline: 35284806]
53. Salvador M, Kong F, Peirlinck M, Parker DW, Chubb H, Dubin AM, et al. Digital twinning of cardiac electrophysiology for congenital heart disease. J R Soc Interface 2024;21(215):20230729. [doi: 10.1098/rsif.2023.0729] [Medline: 38835246]

XSL•FO
RenderX

54. Zhang Y, Lu L, Yang L, Yan W, Yu Q, Sheng J, et al. Evaluation of a new digital pediatric malnutrition risk screening tool for hospitalized children with congenital heart disease. BMC Pediatr 2023;23(1):126 [FREE Full text] [doi: 10.1186/s12887-023-03899-1] [Medline: 36934232]
55. Nashat H, Habibi H, Heng EL, Nicholson C, Gledhill JR, Obika BD, et al. Patient monitoring and education over a tailored digital application platform for congenital heart disease: a feasibility pilot study. Int J Cardiol 2022;362:68-73. [doi: 10.1016/j.ijcard.2022.05.002] [Medline: 35526658]
56. Prakoso R, Ariani R, Kurniawati Y, Siagian SN, Sembiring AA, Sakti DDA, et al. Expanding role of absolute zero fluoroscopy atrial septal defect closure: a single-center experience. Front Cardiovasc Med 2025;12:1430555 [FREE Full text] [doi: 10.3389/fcvm.2025.1430555] [Medline: 40255341]
57. Prakoso R, Ariani R, Mendel B, Lilyasari O. Transoesophageal echocardiography-guided balloon-assisted percutaneous closure of a large secundum atrial septal defect in a pregnant woman: a case report. Eur Heart J Case Rep 2024;8(1):ytae014 [FREE Full text] [doi: 10.1093/ehjcr/ytae014] [Medline: 38274706]
58. Prakoso R, Kurniawati Y, Siagian SN, Sembiring AA, Sakti DDA, Mendel B, et al. Percutaneous palliative stenting option in adults with unrepaired tetralogy of fallota. JACC Adv 2024;3(12):101073 [FREE Full text] [doi: 10.1016/j.jacadv.2024.101073] [Medline: 39817064]
59. Onan B, Onan IS. Early results of robotically assisted congenital cardiac surgery: analysis of 242 patients. Ann Thorac Surg 2021;112(6):2020-2027. [doi: 10.1016/j.athoracsur.2020.10.028] [Medline: 33232727]
60. Lo Muzio FP, Rozzi G, Rossi S, Luciani GB, Foresti R, Cabassi A, et al. Artificial intelligence supports decision making during open-chest surgery of rare congenital heart defects. J Clin Med 2021;10(22):5330 [FREE Full text] [doi: 10.3390/jcm10225330] [Medline: 34830612]

Abbreviations

AI: artificial intelligence
BPS: Badan Pusat Statistik
CHA: congenital heart anomaly
CHD: congenital heart disease
DALY: disability-adjusted life year
GBD: Global Burden of Disease
GDP: gross domestic product
LMIC: low- and middle-income country
LQ: location quotient
OECD: Organisation for Economic Co-operation and Development
OR: odds ratio
US DOT: US Department of Transportation
VLW: value of lost welfare
VLWDALY: value of lost welfare–disability-adjusted life years
VLWYLL: value of lost welfare–years of life lost
VSL: value of a statistical life
VSLY: value of a statistical life year
YLD: year lived with disability
YLL: year of life lost

Edited by S Badawy; submitted 19.07.25; peer-reviewed by Y Wang, J Nejati; comments to author 20.09.25; revised version received 02.10.25; accepted 14.10.25; published 19.11.25.

Please cite as:
Iqhrammullah M, Rampengan DDCH, Amri I, Lastri S, Rampengan SH, Prakoso R, Habiburrahman M
Monetary Valuation of Congenital Heart Disease in Indonesia: Economic Modeling Study
JMIR Pediatr Parent 2025;8:e80696
URL: https://pediatrics.jmir.org/2025/1/e80696
doi:10.2196/80696
PMID:41259090

©Muhammad Iqhrammullah, Derren DCH Rampengan, Ikhwan Amri, Surna Lastri, Starry H Rampengan, Radityo Prakoso, Muhammad Habiburrahman. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 19.11.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License

XSL•FO
RenderX

(https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Preliminary Effectiveness of a Postnatal mHealth and Virtual Social Support Intervention on Newborn and Infant Health and Feeding Practices in Punjab, India: Quasi-Experimental Pre-Post Pilot Study

Garima Singh Verma[1*], BDS, MPH; Lakshmi Gopalakrishnan[2*], PhD; Alison El Ayadi[3,4*], ScD, MPH; Nadia Diamond-Smith[2,4*], MSc, PhD; Rashmi Bagga[1*], MD; Shashi Kant Dhir[5], MD; Pushpendra Singh[6], PhD; Navneet Gill[1], PhD; Vaibhav Miglani[7], M-STAT; Naveen Mutyala[7], M-STAT; Ankita Kankaria[8], MD; Jasmeet Kaur[6], MTech; Alka Ahuja[1], PhD; Vijay Kumar[9†], MD; Mona Duggal[10*], MD

[1]Department of Obstetrics and Gynecology, Postgraduate Institute of Medical Education and Research, Chandigarh, India

[10]National Institute for Research in Digital Health and Data Science, Indian Council of Medical Research, Ansari Nagar East, New Delhi, India

[2]Institute for Global Health Sciences, University of California San Francisco, San Francisco, CA, United States

[3]Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California San Francisco, San Francisco, CA, United States

[4]Department of Epidemiology and Biostatistics, University of California San Francisco, San Francisco, CA, United States

[5]Department of Pediatrics, Guru Gobind Singh Medical College and Hospital, Faridkot, India

[6]Department of Computer Science and Engineering, Indraprastha Institute of Information Technology, Delhi, India

[7]Department of Hematology, Postgraduate Institute of Medical Education and Research, Chandigarh, India

[8]Department of Community Medicine and School of Public Health, Postgraduate Institute of Medical Education and Research, Chandigarh, India

[9]SWACH – Foundation for Survival of Women and Children, Panchkula, India

[†]deceased

[*]these authors contributed equally

Corresponding Author:
Mona Duggal, MD
National Institute for Research in Digital Health and Data Science, Indian Council of Medical Research, Ansari Nagar East, New Delhi, India

Abstract

Background: We evaluated a pilot mobile health (mHealth) intervention aimed at improving postnatal maternal and infant health. The intervention featured provider-led group sessions for education, health care communication, in-person care referrals, and virtual mHealth support for postpartum mothers through weekly calls, texts, interactive voice response (IVR), and a phone app.

Objective: We aimed to assess the preliminary effectiveness of the pilot mHealth intervention, *MeSSSSage* (*Maa Shishu Swasthya Sahayak Samooh*, which means maternal and child health support group), on infant health knowledge, behaviors, and outcomes at 6 months post partum. We focus on maternal knowledge of infant danger signs and optimal young child feeding practices at 6 months post partum and also evaluate maternal care-seeking behaviors for infants, adherence to age-appropriate immunization, and infant and young child feeding practices such as early initiation of breastfeeding and complementary feeding.

Methods: We evaluated the preliminary effectiveness of an intervention on maternal health knowledge among 135 participants in Punjab, India, who completed pre- and postintervention surveys. The intervention, led by research personnel with backgrounds similar to community health officers, aimed to empower society and support universal health coverage if successful. We assessed changes in knowledge of maternal danger signs and the appropriate age for introducing different food groups over 6 months post partum. Additionally, we examined postintervention differences in health-seeking behavior for infants, adherence to age-appropriate immunizations, and adoption of breastfeeding and complementary feeding practices among women in the synchronous (group call), asynchronous (IVR and app), and control arms.

Results: Of 12 infant risk factors, maternal knowledge of infant danger signs remained low (mean range: 1.85-2.31 preintervention and 1.81-2.22 postintervention). Participants in the synchronous arm had a statistically significant higher mean increase (mean difference: 0.87, 95% CI 0.06 - 1.69) compared to the control arm. Participants in synchronous arms had nearly 3-fold increased odds of infant health checkup by a clinical provider than asynchronous arm participants (odds ratio [OR] 2.72, 95% CI 1.02-7.23).

XSL•FO
RenderX

No significant differences were noted in age-appropriate vaccine coverage among infants between arms, though vaccination coverage was more than 80% across all arms. Early initiation of breastfeeding remained low across all arms (~47%).

Conclusions: Our pilot study on group-based mHealth education and virtual social support during the postnatal phase showed modest yet promising results. Rigorous testing is crucial to strengthening the limited evidence base for group-oriented mHealth approaches.

Trial Registration: ClinicalTrials.gov NCT04693585; https://clinicaltrials.gov/study/NCT04693585

(JMIR Pediatr Parent 2025;8:e65581) doi:10.2196/65581

KEYWORDS

digital health; mHealth; mobile health; app; postpartum; health education; social support; India; infant morbidity; care seeking; postnatal; maternal; mother; text message; virtual support; online support; pediatric; infant; baby; neonate; newborn; breastfeeding; feeding

Introduction

Background

India has made substantial improvements in child survival through a 54% reduction in neonatal mortality rate from 52 per 1000 live births in 1990 to 23.7 per 1000 live births in 2017 [1,2]. About 75% of newborn deaths occur in the first week of life, highlighting the importance of intervening in the early postnatal period [3]. Further, child undernutrition accounts for over 20% of deaths and remains a major risk factor for disease burden in children younger than 5 years in India [2,4]. The latest national survey suggests that 35.5% of children in India are stunted, 32.1% are underweight, and 19.3% are wasted with substantial variation both across and within Indian states [5].

There is a robust evidence base of interventions spanning the continuum of care from pregnancy through post partum and through the first 1000 days of life, including appropriate infant and young child feeding practices to improve newborn, and child health and nutrition outcomes [6,7]. India, backed by a two million+ female community health worker program, has adopted a comprehensive and universally available package of maternal and neonatal evidence-based interventions through its multiple national government programs, including the Integrated Child Development Services, the National Health Mission, and the National Nutrition Mission [8,9]. However, national surveys suggest that coverage of nutrition interventions, particularly in the postnatal and newborn period, remains low. Only 41.8% of children were breastfed within an hour of birth, 46% of children 6 - 8 months were initiated on complementary food, and 11% of children below 6 - 23 months received adequate diet with disparities by geographical region, socioeconomic status, and rural-urban residence [5].

Prior research from India suggests that postnatal care is associated with reduced neonatal mortality [10], and appropriate care for sick infants and children is correlated with reduced risk of severe wasting [11]. Postnatal education is an evidence-based strategy to improve newborn health and nutrition and maternal knowledge of general infant health and care [12]. While national data suggest that 79% of infants receive a postnatal checkup by skilled health personnel within 2 days of childbirth [5], a recent study of 13,000+ respondents from 3 large Indian states (including Punjab, one of our study states) highlights that 55% of mothers receive no postnatal education, with considerable knowledge gaps in appropriate newborn care practices, including skin-to-skin care, cord care, warning signs of infant illness, among other related topics [13]. Beyond postnatal education, enhancing social support for mothers through interpersonal connections is associated with reduced risk of postpartum depression [14,15], improved maternal self-efficacy [16,17], higher postnatal care attendance of mothers and infants [18], increased healthy maternal physical activity and nutritional intake [14], and better infant and young child feeding practices [19]. However, various barriers hinder postnatal care in India, including logistical challenges exacerbated by geographic distance and cultural factors [20-22]. Factors such as lower levels of women's autonomy, restricted freedom of movement, and social isolation further compound these challenges, particularly during the postnatal period when women are traditionally confined to their homes for 40 days after delivery [23]. Additional barriers include poverty, limited education, lack of male involvement, absence of health insurance, financial constraints, and perceptions of inadequate quality or lack of benefit of services [24-26].

Leveraging mobile health (mHealth)–based interventions holds promise in addressing barriers to postnatal care and improving postnatal maternal knowledge, social connectedness, and maternal and child health-related behaviors given increasing mobile phone ownership and internet access. A scoping review of 28 studies across low- and middle-income countries (LMICs) found improved immunization coverage and increased adherence to immunization schedules through mHealth-based text and voice message reminders [27], while another systematic review of 16 studies in LMICs found mHealth education interventions to increase perinatal interactions between young mothers and health care workers [28]. Individual studies reporting on mHealth interventions using text and voice messaging have improved perinatal care attendance [29], early initiation of breastfeeding and exclusive breastfeeding [30-32], protein consumption [33], general infant and young child feeding practices [34], knowledge of child immunization [35], and better adherence to child immunization schedules [36].

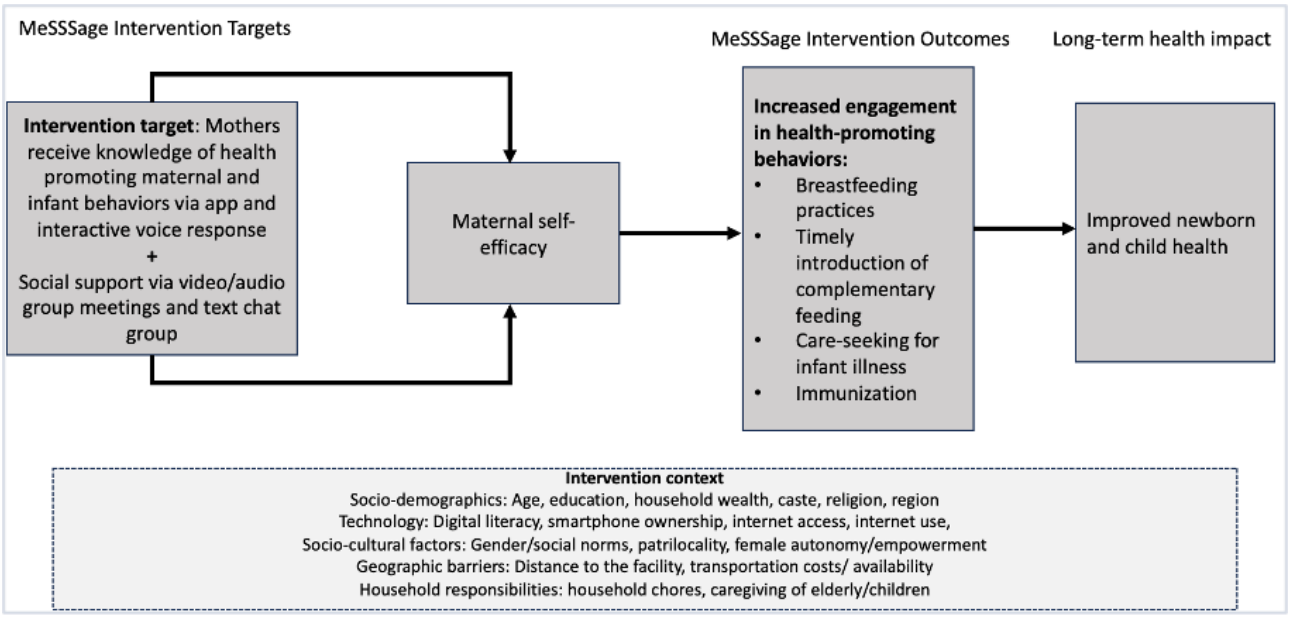
Key gaps in the evidence base on the impact of mHealth interventions on postpartum and neonatal health in India include fewer interventions focused on this topic area, with most targeting frontline health and nutrition workers to improve service delivery [37-40], limited interactions and social support provision among those targeting beneficiaries [30-32,41], and

XSL•FO
RenderX

the need for more rigorous studies [28,30,37,40]. Group-oriented mHealth interventions combining group-based learning and social support may overcome prevalent barriers given the convenience, feasibility, acceptability, and preliminary effectiveness in improving postnatal maternal and infant health outcomes [32,42-47]. However, the combined impact of interactive group-based social support delivered via mHealth modalities such as group voice calls or Zoom has been understudied in LMICs.

To address these gaps, we designed a provider-facilitated group perinatal mHealth intervention called *MeSSSSage* (*Maa Shishu Swasthya Sahayak Samooh*, which means maternal and child health support group). Informed by the capabilities and motivation constructs of the COM-B (Capability, Opportunity, and Motivation Behavior) framework [48,49], the intervention was designed to enhance maternal knowledge of health-promoting behaviors and promote maternal self-efficacy and empowerment to improve health-related knowledge, behaviors, and maternal and child outcomes (Figure 1). The intervention aimed to improve knowledge, facilitate referrals to in-person care, and foster connections with a virtual social support group for postnatal mothers with infants of similar ages through various mHealth modalities, including weekly group calls and text chat. Our development process included 2 iterative rounds of pilot testing—the first to inform the mHealth components and design factors [50] and the second to understand the feasibility and acceptability of our revised intervention [51] and explore preliminary effectiveness on health outcomes.

Figure 1. Conceptual framework of intervention context, *MeSSSSage* intervention targets and outcomes, and anticipated long-term impacts. *MeSSSSage*: *Maa Shishu Swasthya Sahayak Samooh* (which means maternal and child health support group).



Objective of This Study

In the current analysis, we aimed to assess the preliminary effectiveness of the pilot mHealth intervention, *MeSSSSage*, on infant health knowledge, behaviors, and outcomes at 6 months post partum. We focus on maternal knowledge of infant danger signs and optimal young child feeding practices at 6 months post partum and also evaluate maternal care-seeking behaviors for infants, adherence to age-appropriate immunization, and infant and young child feeding practices such as early initiation of breastfeeding and complementary feeding.

MeSSSSage Intervention

The *MeSSSSage* intervention was administered to women from late pregnancy through 6 months post partum. It included weekly audio or audio-video group calls, group text chats, and audio educational content provided via automated interactive voice response (IVR) or *MeSSSSage* app (Table 1 and Figure 2). Groups and group-based content (ie, audio-video group calls and group text chats) were facilitated by trained intervention moderators with backgrounds in public health or social work and supported by a gynecologist and neonatologist. The detailed description is published elsewhere [51].

XSL•FO
RenderX

Table . *MeSSSSage*[a] intervention modalities.

mHealth[b] modalities or arms	Description
Audio-video group sessions	Trained moderators led weekly group sessions focusing on increasing education and social support. These sessions incorporated icebreakers and group-building activities, facilitated discussions based on weekly themes (Figure 2), and allowed open questions and discussion sessions. Prenatally, a gynecologist participated in one call per month, while postnatally, both a gynecologist and a neonatologist participated in one call per month. Participants could choose to connect to their group via audio-only sessions on the TATA platform or video sessions on the Zoom platform.
WhatsApp-based group text chat	Trained moderators led weekly WhatsApp-based group chats by sharing audio and visual messages based on themes (Figure 2). Group participants were expected to engage by asking questions, and group discussion was facilitated.
MeSSSSage mobile app	Weekly educational audio messages focus on key information regarding weekly themes (Figure 2). The mobile app structured sections for these weekly audio messages, offering women the flexibility to access health education content at their convenience.
IVR[c]	IVR calls were scheduled to reach participants once a week at designated days and times. To maximize the chances of participants receiving the calls, they were sent out 3 times within a 15-minute interval. These brief audio calls, lasting between 5 and 10 minutes each, addressed essential topics concerning perinatal, neonatal, and child health. IVR calls persisted up to 6 months postdelivery.

[a]*MeSSSSage*: *Maa Shishu Swasthya Sahayak Samooh* (which means maternal and child health support group).

[b]mHealth: mobile health.

[c]IVR: interactive voice response.

Figure 2. Weekly maternal and neonatal content of *MeSSSSage* intervention. IVR: interactive voice response; *MeSSSSage*: *Maa Shishu Swasthya Sahayak Samooh* (which means maternal and child health support group).

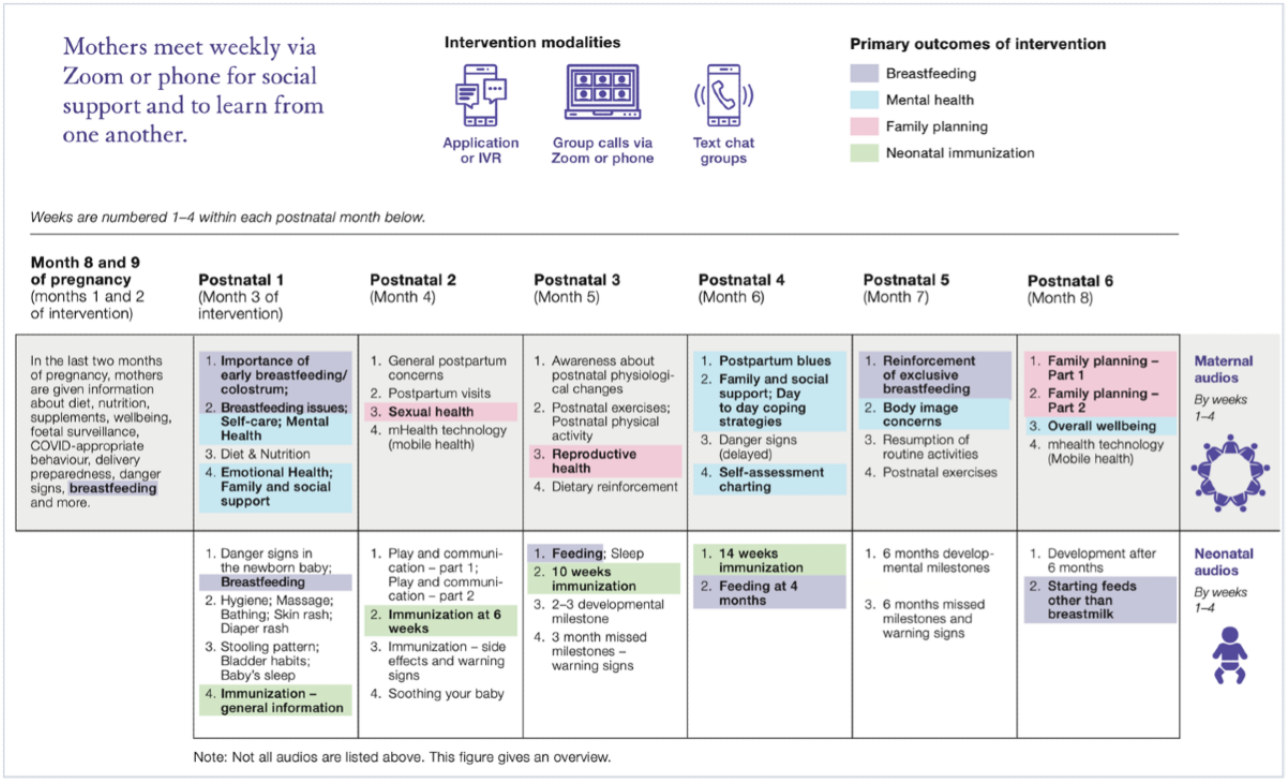


Figure 2 provides a summary of the intervention plan. While this table offers the general structure of IVR calls and audio-video group discussion topics, the audio-video group discussion topics were dynamically adjusted based on the queries and concerns shared by the new mothers, ensuring a responsive and participant-focused approach.

XSL•FO
RenderX

Methods

Study Design

This open-label pilot study on an mHealth-based perinatal health support intervention targeted women in late pregnancy through 6 months post partum in the Boothgarh block of the state of Punjab, northern India. We used a pretest-posttest nonrandomized control group design. Quantitative survey data were collected at study enrollment and intervention completion (approximately 6 months post partum).

Study Participants

Participants were eligible for inclusion in the study if they met the following criteria: (1) aged 18 years or older, (2) between 28 and 32 weeks pregnant, (3) residing in the study area, and (4) not experiencing a serious maternal complication. Participants with high-risk pregnancies and parity of more than 2 were ineligible.

Study Procedures

Our study team used antenatal clinic registry data maintained by community health workers to prescreen pregnant women in the seventh month of gestation. We then contacted these potential participants over the phone, screened them, and if found eligible, invited them to participate. We led them through an informed consent process, which included discussing study procedures, risks, and benefits. All participants provided informed consent verbally.

Out of the 397 women we tried to reach, we successfully recruited a total of 180 participants. These participants were then sequentially assigned to one of five arms: (1) app only (n=20), (2) IVR only (n=20), (3) group call+WhatsApp+app (3 separate arms, n=60), (4) group call+WhatsApp+IVR (3 separate arms, n=60), and (5) finally the control arm (n=20) at baseline. All participants, including the control arm, received the standard of care, which, in this setting, comprised community health worker–led home visits, counseling, and immunization services. Reasons for nonenrollment included being unable to reach the potential participant over the phone, as their phone was either switched off or out of service. Some women provided false information, while others were no longer pregnant due to a miscarriage or preterm birth. A few participants also described having irregular access to mobile phones since they used either their husband's or an immediate family member's phone and only had access to it in the evening when their husband or family member returned home from work. Some individuals did not respond to our calls, while others faced language challenges.

After enrollment, the 8 groups or arms were formed in a staggered fashion, leading to a study timeline from August 2021 to November 2022. Participant engagement in the intervention spanned a total of 8 months. Enrollment of participants and administration of the baseline survey occurred between August and December 2021. Intervention implementation spanned from August 2021 to July 2022, and our endline quantitative survey was conducted between May and December 2022. All data were collected through interviewer administration over the phone and directly entered into the REDCap (Research Electronic Data Capture) data collection application. For individuals who were not able to be reached for the endline survey, local ASHAs (Accredited Social Health Activists) were engaged to facilitate in-person quantitative survey administration.

Study Measures

Based on existing research on IVR and apps for maternal and child health in India, we focused on examining the supplementary impact of group calls. We anticipated that participants engaged in group calls would experience higher levels of social connectedness compared to those using the educational app or IVR, as the former allowed for direct interaction with others, fostering a sense of community and support. For analysis, we consolidated study participants into 3 intervention categories: a synchronous arm (combining arms 3 and 4 described above, comprising all group call participants), an asynchronous arm (combining arms 1 and 2 described above, comprising those in the app and IVR), and a control arm.

The primary outcomes of this analysis were the change in maternal knowledge of infant danger signs and maternal knowledge of infant and young child feeding practices between pre- and postintervention. Knowledge of infant danger signs was defined as women's ability to recall symptoms indicating infants may require medical attention within the first month of birth. We developed a cumulative score based on women's recall of various danger signs, including diarrhea, fever, cough or cold, difficulty breathing, absence of crying, chest problems, blue tongue and lips, lack of milk intake, failure to gain weight, premature birth, jaundice, coldness to touch, and others (scores ranging from 0 to 13). Women's knowledge of infant and young child feeding practices was assessed by their correct reporting of the appropriate age for introducing the following foods: water, rice, bread, legumes (dal), green leafy vegetables, pumpkin, carrot, fruits (banana, papaya, mango, and orange), meats (chicken, mutton, and fish), eggs, and different types of milk (cow, goat, powdered, etc). Women who correctly identified 6 months or older as the appropriate age for introducing all food groups except cow's/goat's milk (12 months) were coded as 1; otherwise, they were coded as 0. We developed a cumulative score based on women's correct responses.

Additional outcomes assessed postintervention included infant health status, access to health care, infant vaccination status, and infant feeding behaviors. Infant postnatal health characteristics were assessed through various questions. Postnatal care was assessed based on women's self-reports regarding whether their infants received a checkup within 6 weeks of birth, the frequency of these checkups, and the type of provider conducting the checkup (clinical or community). Infant vaccination coverage was determined by whether the infant had received all age-appropriate vaccines. Infant and young child feeding practices were evaluated through breastfeeding, early initiation of breastfeeding (defined as within 1 hour of birth), and complementary feeding (defined as whether other liquids or foods had been introduced to the infant). All variables were coded as indicator variables (yes/no).

Participant sociodemographic characteristics collected during preintervention included age, relationship status, educational attainment, religion, caste, ration card and type, parity, and mobile phone ownership.

XSL•FO
RenderX

Analysis

At baseline, 120 participants were in the synchronous arm, 40 participants in the asynchronous arm, and 20 in the control arm. At endline, we had 94 participants (78.3% retention rate) in the synchronous arm, 28 participants (70% retention rate) in the asynchronous arm, and 13 (65%) in the control arm. With our primary focus on temporal change, we restricted the analytic sample for this paper to participants with both baseline and endline data, resulting in a sample size of 135 participants.

We compared the sociodemographic characteristics of the 3 analysis arms (synchronous, asynchronous, and control arm) by identifying standardized differences [52]. Due to significant disparities across arms in the distribution of age, age at marriage, household composition, educational attainment, household income, ration card possession, mobile phone ownership, and smartphone access, we used inverse probability weighting to ensure comparability of participants across arms. This approach, similar to direct standardization, balanced preintervention discrepancies in sociodemographics between the arms [53,54].

We summarized sociodemographic characteristics using proportions and means of the matched, reweighted study population surveyed pre- and postintervention stratified by 3 arms (synchronous, asynchronous, and control). We then assessed the association of being in each intervention arm on primary outcomes (changes in maternal knowledge of infant danger signs and knowledge of infant and young child feeding practices) using mixed effects linear regression, including a random intercept for participants with robust standard errors to adjust within individual clustering due to the longitudinal structure of the data. The difference-in-difference coefficient (β) is the interaction term between a categorical variable denoting the time (before vs after the intervention was implemented) and the intervention arm (synchronous vs asynchronous modes, synchronous vs control, and asynchronous vs control). We interpreted this term as the differential change over time associated with being in each intervention arm compared to the reference group. For outcomes collected only at endline, we analyzed the differences between the arms (synchronous vs asynchronous modes, synchronous vs control, and asynchronous vs control) using logistic regression. Differences where $P<.05$ were considered statistically significant. All analyses are presented using weighted estimates. Data entry was done through REDCap, and all statistical analyses were conducted using Stata 15 (StataCorp LLC).

Ethical Considerations

This study received approval from the Indian Council of Medical Research and senior health authorities of the Government of Punjab and the Mission Director, National Health Mission, India. The study protocol was approved by the University of California San Francisco Institutional Review Board (19 - 299723), the ethics committee of the Postgraduate Institute of Medical Education and Research (IEC-03/2020 - 1567), the Collaborative Research Committee of the Postgraduate Institute of Medical Education and Research (79/30-Edu-13/1089 - 90), and the Indian Council of Medical Research (ID 2020 - 9576). All study participants were deidentified, engaged in a thorough informed consent process and provided written confirmation of informed consent at enrollment.

Results

Sociodemographic Characteristics

At study enrollment, participants had an average age of 26.8 years, and almost all (99.3%) were married (Table 2). The majority had either a high school education (44.8%) or higher education (44.3%). Nearly two-thirds of the sample belonged to the Sikh religion (65.3%), and one-third of the sample belonged to a marginalized caste (scheduled caste and scheduled tribe; 36.4%). Less than half possessed a ration card (48%), an official government document given to eligible poor families to get subsidized food grains from government fair price shops. Parity was one (53.3%) or more (46.8%). Mobile phone ownership at the household level was near-universal (99.2%), and most women owned their own phones (92.5%).

XSL•FO
RenderX

Table . Sociodemographic characteristics of the intervention participants.

	Synchronous (n=94)	Asynchronous (n=28)	Control (n=13)	Total (N=135)
Age, mean (SD)	26.7 (0.38)	26.8 (0.61)	26.7 (1.57)	26.7 (0.33)
Relationship status, n (%)				
Married or domestic partnership	94 (100)	27 (98)	13 (100)	134 (99.8)
Separated	0 (0)	1 (1.2)	0 (0)	1 (0.2)
Educational attainment, n (%)				
None	0 (0)	2 (7.2)	1 (6)	3 (1.5)
Up to secondary	9 (9.6)	1 (3.1)	3 (22.2)	13 (9.4)
Higher secondary	41 (43.6)	15 (50.1)	6 (47.1)	62 (44.8)
Diploma or higher	44 (46.8)	10 (39.6)	3 (24.7)	57 (44.3)
Religion, n (%)				
Hindu	23 (24.5)	11 (32.2)	4 (26.3)	38 (25.7)
Muslim	9 (9.6)	0 (0)	3 (21.8)	12 (9)
Sikh	62 (66)	17 (67.8)	6 (51.9)	85 (65.3)
Caste, n (%)				
General	41 (43.6)	16 (55.7)	5 (39.9)	62 (45.2)
Schedule caste or tribe	36 (38.3)	6 (21.2)	6 (48.3)	48 (36.4)
Other backward class	15 (16)	3 (9.8)	2 (11.8)	20 (14.8)
Other	2 (2.1)	3 (13.3)	0 (0)	5 (3.6)
Ration card, n (%)				
Yes	45 (47.9)	16 (45.7)	5 (35.9)	66 (48.0)
No	49 (52.1)	12 (54.3)	8 (64.1)	69 (52.0)
Parity, n (%)				
1	50 (53.2)	14 (51.6)	8 (60.2)	72 (53.4)
>1	44 (46.8)	14 (48.4)	5 (39.8)	63 (46.6)
Mobile phone ownership, n (%)				
Individual	93 (98.9)	25 (91.6)	9 (80.6)	122 (92.5)
Household	88 (93.6)	28 (100)	13 (100)	134 (99.2)

Maternal Knowledge of Infant Danger Signs

Despite increases noted across time, maternal knowledge of infant danger signs remained relatively low (Table 3). Of the 12 infant risk factors, the mean number known across arms ranged between 1.85 and 2.31 preintervention and 1.81 and 2.22 postintervention (Table 3 and Multimedia Appendix 1). Being in the synchronous arm was associated with a small but significantly greater increase in the mean number of infant danger signs known when compared to those in the control arm (mean difference 0.87, 95% CI 0.06 - 1.69; Table 3). No differences were identified between synchronous versus asynchronous arms or between asynchronous versus control arm participants.

XSL•FO
RenderX

Table . Comparisons between pre- and postintervention newborn health-related knowledge by intervention arm (n=135).[a]

	Mean (95% CI)			Arm × time parameter (95% CI)		
	Synchronous[b]	Asynchronous[c]	Control	Synchronous vs asynchronous	Synchronous vs control	Asynchronous vs control
Maternal knowledge of infant danger signs (total possible score=12)				0.56 (–0.22 to 1.35)	0.87 (0.06 to 1.69)	0.31 (–0.75 to 1.37)
Preintervention	1.85 (1.61 - 2.08)	2.06 (1.47 - 2.65)	2.31 (1.19 - 3.44)	—[d]	—	—
Postintervention	2.22 (2.00 - 2.44)	1.87 (1.32,2.43)	1.81 (1.02 - 2.60)	—	—	—
Maternal knowledge of appropriate infant and young child feeding practices (total possible score=9)				–0.75 (–1.96 to 0.45)	0.66 (–2.07 to 3.40)	1.42 (–1.55 to 4.40)
Preintervention	7.56 (7.23 - 7.89)	6.48 (5.56 - 7.40)	6.84 (5.05 - 8.65)	—	—	—
Postintervention	7.89 (7.77 - 8.01)	7.56 (6.95 - 8.18)	6.51 (4.74 - 8.28)	—	—	—

[a]Full model output for these analyses with corresponding *P* values is presented in Multimedia Appendix 1.

[b]Combining all participants assigned to weekly group calls.

[c]Combining those participants assigned to the app and interactive voice response.

[d]Not applicable.

Maternal Knowledge of Appropriate Infant and Young Child Feeding Practices

Maternal knowledge of appropriate initiation of varied food groups was high preintervention, and no increase was observed over time (Table 3). Of 9 food groups in total, the mean number of food groups that women reported the correct knowledge for ranged from 6.48 to 7.56 preintervention and 6.51 to 7.89 postintervention. No group differences were identified.

Infant Health Checkup and Infant Vaccination

Table 4 presents a postintervention comparison of outcomes. Over 50% of participants in the synchronous arm and 40% of participants in the asynchronous arm reported receiving a health checkup for their infants, compared to 28.9% in the control arm. However, no statistically significant difference was noted between arms. Regarding receipt of infant health checkups by a clinical provider, a higher proportion (53.2%) of participants in the synchronous arm reported receiving a health checkup from a clinical provider compared to the other 2 arms. Participants in the synchronous arm had 2.72 times greater odds ratio (OR 2.72, 95% CI 1.02-7.23; $P<.05$) of infant health checkup by a clinical provider compared to the asynchronous arm. There were no statistically significant differences between the synchronous arm and control arm or between the asynchronous arm and control arm. The coverage of all 4 age-appropriate vaccines—BCG (Bacillus Calmette-Guérin), polio, DPT (diphtheria, pertussis, and tetanus), and hepatitis B—was high across all arms, ranging from 89% in the synchronous arm, 84% in the asynchronous arm, and 80.3% in the control arm. No differences were noted in the postintervention between-arms comparison.

XSL•FO
RenderX

Table . Postintervention comparison of infant health care seeking, vaccination uptake, and infant and young child feeding practices at endline (n=135).

	Synchronous (n=94), n (%)	Asynchronous (n=28), n (%)	Control (n=13), n (%)	Synchronous vs asynchronous, OR[a] (95% CI)	Synchronous versus control, OR (95% CI)	Asynchronous versus control, OR (95% CI)
Infant health checkup						
Participants who had a postnatal health check for infant within the 6 weeks after giving birth	54 (57.5)	8 (40.9)	2 (28.9)	1.94 (0.71 - 5.30)	3.32 (0.64 - 17.02)	1.70 (0.25 - 11.37)
Health checkup conducted by clinical provider (Ref: no health checkup by a clinical provider)	50 (53.2)	7 (29.5)	2 (24.8)	2.72[b] (1.02 - 7.23)	3.44 (0.69 - 17.06)	1.26 (0.20 - 7.90)
Mothers whose infants fell sick in the past 3 months	36 (38.3)	7 (33.1)	5 (46.3)	1.25 (0.44 - 3.52)	0.71 (0.17 - 3.06)	0.57 (0.10 - 3.28)
Infants received BCG[c], polio, DPT[d], or hepatitis B vaccines						
BCG vaccination	87 (92.6)	23 (96.1)	11 (100)	—[e]	—	—
Polio vaccination	94 (100)	24 (96.6)	10 (93.5)	—	—	—
DPT vaccination	93 (98.9)	24 (100)	11 (100)	—	—	—
Hepatitis B vaccination	92 (97.9)	24 (100)	10 (100)	—	—	—
Received all 4 vaccines (Ref: Received fewer than 4 vaccines)[f]	84 (89)	22 (84)	10 (80.3)	1.59 (0.48 - 5.22)	2.06 (0.45 - 9.28)	1.28 (0.23 - 7.15)
Early initiation of breastfeeding their infant						
Within 1 hour of delivery (Ref: After 1 hour of delivery)	41 (47)	9 (42.1)	5 (56)	1.25 (0.47 - 3.29)	0.71 (0.18 - 2.79)	0.56 (0.11 - 2.85)
Intended length of breastfeeding						
Intend to breastfeed for >24 months (Ref:<24 months)	17 (19.8)	9 (37.6)	2 (14.9)	0.40 (0.15 - 1.13)	1.40 (0.25 - 7.86)	3.43 (0.50 - 23.4)
Mothers who have introduced complementary foods postintervention	87 (92.6)	20 (95.3)	6 (52.2)	0.61 (0.06 - 5.50)	11.37[g] (2.49 - 51.88)	18.37[b] (1.48 - 228.20)

[a]OR: odds ratio.

[b]These values were statistically significant (P<.05).

[c]BCG: Bacillus Calmette-Guérin.

[d]DPT: diphtheria, pertussis, and tetanus.

[e]Not applicable.

[f]Vaccines include BCG, polio, DPT, and hepatitis B.

[g]This value was statistically significant (P<.001).

Breastfeeding and Complementary Food Introduction

Initiation of breastfeeding within the first hour after birth was low across all arms (Table 4). The intention to breastfeed for more than 24 months was highest in the asynchronous arm at 37.6%, followed by 19.8% in the synchronous arm and 14.9% in the control arm. No differences in breastfeeding initiation or intention were noted in the postintervention between-arms

XSL•FO
RenderX

comparison. A greater proportion of participants in the synchronous arm (92.6%) and the asynchronous arm (95.3%) had introduced complementary foods by 6 months postnatal, compared to the control arm (52.2%).

Discussion

Principal Findings

Our pilot study on the preliminary effectiveness of the *MeSSSSage* mHealth education and virtual social support intervention found that synchronous arm assignment had a beneficial impact on participants' knowledge regarding infant danger signs and odds of obtaining an infant health checkup from a clinical provider when compared to control participants. We also noted no differences by arm in maternal knowledge of appropriate infant and young child feeding practices, number of infant health checkups, and early initiation of breastfeeding. Given the pilot nature of this investigation, including our study design limitations, in conjunction with our previously reported results supporting intervention feasibility and acceptability [51], these findings support continued investigation into the effectiveness of mHealth-based interventions targeting postnatal maternal and newborn health using robust research designs.

Our findings that the *MeSSSSage*'s synchronous arm that included group calls on education and social support increased maternal knowledge of infant danger signs are consistent with existing literature. Previous literature has demonstrated the effectiveness of mHealth interventions in empowering mothers to recognize infant danger signs [28], while interventions layering health education within women's self-help groups have shown promise in improving maternal knowledge across a range of outcomes [55,56]. Group-based mHealth education and social support interventions can promote health-seeking behaviors through the mechanism of "positive psychological support" among mothers [57]. On the other hand, we found less improvement in participants assigned to asynchronous modes of mHealth intervention, potentially due to unidirectional messaging and lack of social support. Our findings underscore the potential for integrating mHealth delivery into comprehensive interventions that combine both social support and health education, thereby enhancing their impact and effectiveness.

Our study findings noted no difference between pre- and postintervention on maternal knowledge of appropriate infant and young child feeding practices, though scores were high (7 out of 9) at preintervention. It is possible that high baseline levels of maternal knowledge precluded changes over time. A similar lack of effect was also noted in another Indian evaluation of an mHealth intervention for maternal knowledge of infant and child feeding practices [39] and other global studies [37]. Moreover, large-scale evaluations of mHealth interventions in India have failed to observe changes in infant and young child feeding practices [38,39]. Nonetheless, insights from another evaluation in India, including those using innovative approaches like audiovisual tools and interactive messaging, highlight the potential for future mHealth interventions to effectively impact maternal knowledge and practices concerning infant and young child feeding [58].

The synchronous arm of our mHealth intervention demonstrated the greatest impact, particularly in improving infant health checkups by clinical providers. In contrast, our asynchronous intervention arm, comprising solely audio educational messages, showed lower effectiveness. This could be attributed to various factors such as missed calls, insufficient attention to messages, or competing household obligations, resulting in null results for the intervention. Additionally, the absence of impact from the asynchronous modality may also be attributed to instances where participants' phones were with their husbands during the day, rendering it impossible for them to listen to the IVR messages. Similar challenges were encountered in a study conducted in Punjab, North India, where participants faced connectivity issues and missed messages due to household chores or not having access to their shared phone at the time [50,59]. To address these challenges, future research should identify the optimal timing for sending messages and IVR calls, and devise strategies to enhance engagement and participation in mHealth interventions, such as exploring incentives such as discounted call rates to motivate participants to carefully listen to all messages, as suggested in a study conducted in Afghanistan [60]. Given these challenges, combined effectiveness and implementation designs for mHealth research are likely to be more informative, particularly those that engage qualitative research methods.

The primary objective of our overall study was to assess the feasibility and acceptability of the intervention rather than robustly evaluating its effectiveness; thus, the preliminary effectiveness analysis reported here represents a secondary objective of the study, and the interpretation of these findings should consider the study's limitations. The sample size was determined for our feasibility and acceptability outcomes, resulting in significant differences in sociodemographic characteristics between the 3 intervention groups at baseline. While weighting techniques were used to address this imbalance, more robust experimental designs with a larger sample size will allow for a better assessment of effectiveness and potential mechanisms of impact. We also noted differential retention across the study by intervention group, which may have influenced our findings. Furthermore, our study design also limited our ability to assess whether intervention effectiveness differed by sociodemographic characteristics, and considering the important influence of social and structural factors on women of reproductive age and their influence on perinatal health, future research should focus on understanding the potential of interventions to specifically mitigate health disparities.

Conclusion

The postnatal period presents a critical opportunity to engage new mothers in enhancing their knowledge and practices concerning infant and young child feeding, infant health checkups and care-seeking behaviors, child vaccinations, and providing social support. Our pilot study on the *MeSSSSage* mHealth education and virtual social support intervention delivered mostly in the postnatal period yielded modest results and offered promising insights into its preliminary effectiveness. Such interventions, integrating mHealth-based education and communication with social support, hold significant promise but warrant further exploration to optimize their impact. With

XSL•FO
RenderX

smartphones and social media platforms like WhatsApp increasingly prevalent even in low-resource settings, there is an urgent need for more rigorous experimental research to comprehensively evaluate the impact of mHealth interventions and their underlying mechanisms. Our team is currently conducting a fully powered randomized controlled trial to examine the effectiveness and potential mechanisms of impact of an mHealth educational and social support intervention for perinatal women across multiple sites in India, with results expected in the coming years.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Model output for the analyses.
[DOCX File, 41 KB - pediatrics_v8i1e65581_app1.docx]

References

1. Sankar MJ, Neogi SB, Sharma J, et al. State of newborn health in India. J Perinatol 2016 Dec;36(Suppl 3):S3-S8. [doi: 10.1038/jp.2016.183] [Medline: 27924104]
2. Dandona R, Kumar GA, Henry NJ. Subnational mapping of under-5 and neonatal mortality trends in India: the Global Burden of Disease Study 2000-17. Lancet 2020 May 23;395(10237):1640-1658. [doi: 10.1016/S0140-6736(20)30471-2] [Medline: 32413293]
3. United Nations Inter-Agency Group for Child Mortality Estimation (UN IGME). Levels & trends in child mortality: report 2019, estimates developed by the United Nations Inter-Agency Group for Child Mortality Estimation. : United Nations Children's Fund; 2019 URL: https://childmortality.org/wp-content/uploads/2019/10/UN-IGME-Child-Mortality-Report-2019.pdf [accessed 2025-05-27]
4. Swaminathan S, Hemalatha R, Pandey A. The burden of child and maternal malnutrition and trends in its indicators in the states of India: the Global Burden of Disease Study 1990-2017. Lancet Child Adolesc Health 2019 Dec;3(12):855-870. [doi: 10.1016/S2352-4642(19)30273-1] [Medline: 31542357]
5. International Institute for Population Sciences (IIPS) and ICF. National Family Health Survey (NFHS-5), 2019-21. : International Institute for Population Sciences; 2022 Mar URL: https://dhsprogram.com/pubs/pdf/FR375/FR375.pdf [accessed 2025-05-27]
6. Bhutta ZA, Das JK, Bahl R, et al. Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost? Lancet 2014 Jul;384:347-370. [doi: 10.1016/S0140-6736(14)60792-3]
7. Bhutta ZA, Das JK, Rizvi A, et al. Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost? Lancet 2013 Aug;382:452-477. [doi: 10.1016/S0140-6736(13)60996-4]
8. NHM components. National Health Mission, Ministry of Health & Family Welfare, Government of India. 2023. URL: https://nhm.gov.in/index1.php?lang=1&level=0&linkid=353&lid=444 [accessed 2025-05-27]
9. Poshan Abhiyan. Women and Child Development Department, Haryana Government. URL: https://wcdhry.gov.in/schemes-for-children/poshan-abhiyan/ [accessed 2025-06-07]
10. Fadel SA, Ram U, Morris SK, et al. Facility delivery, postnatal care and neonatal deaths in India: nationally-representative case-control studies. PLoS One 2015;10(10):e0140448. [doi: 10.1371/journal.pone.0140448] [Medline: 26479476]
11. Choudhary TS, Srivastava A, Chowdhury R, et al. Severe wasting among Indian infants <6 months: findings from the National Family Health Survey 4. Matern Child Nutr 2019 Oct;15(4):e12866. [doi: 10.1111/mcn.12866] [Medline: 31240836]
12. Bryanton J, Beck CT, Montelpare W. Postnatal parental education for optimizing infant general health and parent-infant relationships. Cochrane Database Syst Rev 2013 Nov 28;2013(11):CD004068. [doi: 10.1002/14651858.CD004068.pub4] [Medline: 24284872]
13. Subramanian L, Murthy S, Bogam P, et al. Just-in-time postnatal education programmes to improve newborn care practices: needs and opportunities in low-resource settings. BMJ Glob Health 2020 Jul;5(7):e002660. [doi: 10.1136/bmjgh-2020-002660] [Medline: 32727842]
14. Faleschini S, Millar L, Rifas-Shiman SL, Skouteris H, Hivert MF, Oken E. Women's perceived social support: associations with postpartum weight retention, health behaviors and depressive symptoms. BMC Womens Health 2019 Nov 21;19(1):143. [doi: 10.1186/s12905-019-0839-6] [Medline: 31752823]
15. Vaezi A, Soojoodi F, Banihashemi AT, Nojomi M. The association between social support and postpartum depression in women: a cross sectional study. Women Birth 2019 Apr;32(2):e238-e242. [doi: 10.1016/j.wombi.2018.07.014] [Medline: 30274879]
16. Chen CM, Kuo SF, Chou YH, Chen HC. Postpartum Taiwanese women: their postpartum depression, social support and health-promoting lifestyle profiles. J Clin Nurs 2007 Aug;16(8):1550-1560. [doi: 10.1111/j.1365-2702.2006.01837.x] [Medline: 17655544]

XSL•FO
RenderX

17. Leahy-Warren P, McCarthy G, Corcoran P. First-time mothers: social support, maternal parental self-efficacy and postnatal depression. J Clin Nurs 2012 Feb;21(3-4):388-397. [doi: 10.1111/j.1365-2702.2011.03701.x] [Medline: 21435059]
18. Cardona Cordero NR, Ramos JP, Tavarez ZQ, et al. Relationship between perceived social support and postpartum care attendance in three Latin American countries: a cross-sectional analytic study. Glob Health Res Policy 2021 May 7;6(1):16. [doi: 10.1186/s41256-021-00196-1] [Medline: 33958000]
19. Ickes SB, Wu M, Mandel MP, Roberts AC. Associations between social support, psychological well-being, decision making, empowerment, infant and young child feeding, and nutritional status in Ugandan children ages 0 to 24 months. Matern Child Nutr 2018 Jan;14(1):e12483. [doi: 10.1111/mcn.12483] [Medline: 28782300]
20. Adams V, Craig S, Samen A, Bhatta S. It takes more than a village: building a network of safety in Nepal's mountain communities. Matern Child Health J 2016 Dec;20(12):2424-2430. [doi: 10.1007/s10995-016-1993-1] [Medline: 27048434]
21. Syed U, Khadka N, Khan A, Wall S. Care-seeking practices in South Asia: using formative research to design program interventions to save newborn lives. J Perinatol 2008 Dec;28(Suppl 2):S9-S13. [doi: 10.1038/jp.2008.165] [Medline: 19057572]
22. Lewis S, Lee A, Simkhada P. The role of husbands in maternal health and safe childbirth in rural Nepal: a qualitative study. BMC Pregnancy Childbirth 2015 Aug 4;15:162. [doi: 10.1186/s12884-015-0599-8] [Medline: 26239123]
23. Withers M, Kharazmi N, Lim E. Traditional beliefs and practices in pregnancy, childbirth and postpartum: a review of the evidence from Asian countries. Midwifery 2018 Jan;56:158-170. [doi: 10.1016/j.midw.2017.10.019]
24. Griffiths P, Stephenson R. Understanding users' perspectives of barriers to maternal health care use in Maharashtra, India. J Biosoc Sci 2001 Jul;33(3):339-359. [doi: 10.1017/s002193200100339x] [Medline: 11446398]
25. Kumar G, Choudhary TS, Srivastava A, et al. Utilisation, equity and determinants of full antenatal care in India: analysis from the National Family Health Survey 4. BMC Pregnancy Childbirth 2019 Sep 5;19(1):327. [doi: 10.1186/s12884-019-2473-6] [Medline: 31488080]
26. Vidler M, Ramadurg U, Charantimath U, et al. Utilization of maternal health care services and their determinants in Karnataka State, India. Reprod Health 2016 Jun 8;13(Suppl 1):37. [doi: 10.1186/s12978-016-0138-8] [Medline: 27356502]
27. Venkataramanan R, Subramanian SV, Alajlani M, Arvanitis TN. Effect of mobile health interventions in increasing utilization of maternal and child health care services in developing countries: a scoping review. Digit Health 2022;8. [doi: 10.1177/20552076221143236] [Medline: 36532117]
28. Dol J, Richardson B, Tomblin Murphy G, Aston M, McMillan D, Campbell-Yeo M. Impact of mobile health (mHealth) interventions during the perinatal period for mothers in low- and middle-income countries: a systematic review. JBI Database System Rev Implement Rep 2019;17(8):1634-1667. [doi: 10.11124/JBISRIR-2017-004022]
29. Adanikin AI, Awoleke JO, Adeyiolu A. Role of reminder by text message in enhancing postnatal clinic attendance. Int J Gynaecol Obstet 2014 Aug;126(2):179-180. [doi: 10.1016/j.ijgo.2014.02.009]
30. Colaci D, Chaudhri S, Vasan A. mHealth interventions in low-income countries to address maternal health: a systematic review. Ann Glob Health 2017 Mar 8;82(5):922-935. [doi: 10.1016/j.aogh.2016.09.001]
31. Lau Y, Htun TP, Tam WSW, Klainin-Yobas P. Efficacy of e-technologies in improving breastfeeding outcomes among perinatal women: a meta-analysis. Matern Child Nutr 2016 Jul;12(3):381-401. [doi: 10.1111/mcn.12202] [Medline: 26194599]
32. Patel A, Kuhite P, Puranik A, Khan SS, Borkar J, Dhande L. Effectiveness of weekly cell phone counselling calls and daily text messages to improve breastfeeding indicators. BMC Pediatr 2018 Oct 30;18(1):337. [doi: 10.1186/s12887-018-1308-3] [Medline: 30376823]
33. Downs SM, Sackey J, Kalaj J, Smith S, Fanzo J. An mHealth voice messaging intervention to improve infant and young child feeding practices in Senegal. Matern Child Nutr 2019 Oct;15(4):e12825. [doi: 10.1111/mcn.12825] [Medline: 30950190]
34. Tang S, Ghose B, Hoque MR, Hao G, Yaya S. Women using mobile phones for health communication are more likely to use prenatal and postnatal services in Bangladesh: cross-sectional study. JMIR Mhealth Uhealth 2019 Feb 28;7(2):e10645. [doi: 10.2196/10645] [Medline: 30816850]
35. Chakraborty A, Mohan D, Scott K, et al. Does exposure to health information through mobile phones increase immunisation knowledge, completeness and timeliness in rural India? BMJ Glob Health 2021 Jul;6(Suppl 5):e005489. [doi: 10.1136/bmjgh-2021-005489] [Medline: 34312153]
36. LeFevre AE, Shah N, Scott K, et al. The impact of a direct to beneficiary mobile communication program on reproductive and child health outcomes: a randomised controlled trial in India. BMJ Glob Health 2022 Jul;6(Suppl 5):e008838. [doi: 10.1136/bmjgh-2022-008838] [Medline: 35835477]
37. Chen H, Chai Y, Dong L, Niu W, Zhang P. Effectiveness and appropriateness of mHealth interventions for maternal and child health: systematic review. JMIR Mhealth Uhealth 2018 Jan 9;6(1):e7. [doi: 10.2196/mhealth.8998] [Medline: 29317380]
38. Patil SR, Nimmagadda S, Gopalakrishnan L, et al. Can digitally enabling community health and nutrition workers improve services delivery to pregnant women and mothers of infants? Quasi-experimental evidence from a national-scale nutrition programme in India. BMJ Glob Health 2022 Jul;6(Suppl 5):e007298. [doi: 10.1136/bmjgh-2021-007298]

XSL•FO
RenderX

39. Modi D, Dholakia N, Gopalan R, et al. mHealth intervention "ImTeCHO" to improve delivery of maternal, neonatal, and child care services: a cluster-randomized trial in tribal areas of Gujarat, India. PLOS Med 2019 Oct;16(10):e1002939. [doi: 10.1371/journal.pmed.1002939] [Medline: 31647821]
40. Bassi A, John O, Praveen D, Maulik PK, Panda R, Jha V. Current status and future directions of mHealth interventions for health system strengthening in India: systematic review. JMIR Mhealth Uhealth 2018 Oct 26;6(10):e11440. [doi: 10.2196/11440] [Medline: 30368435]
41. Thinking Healthy: a manual for psychosocial management of perinatal depression, WHO generic field-trial version 1.0, 2015. : World Health Organization; 2015 URL: https://apps.who.int/iris/handle/10665/152936 [accessed 2025-05-27]
42. Lok KY, Ko RW, Fan HS, et al. Feasibility and acceptability of an online WhatsApp support group on breastfeeding: protocol for a randomized controlled trial. JMIR Res Protoc 2022 Mar 9;11(3):e32338. [doi: 10.2196/32338] [Medline: 35262504]
43. Prieto JT, Zuleta C, Rodríguez JT. Modeling and testing maternal and newborn care mHealth interventions: a pilot impact evaluation and follow-up qualitative study in Guatemala. J Am Med Inform Assoc 2017 Mar 1;24(2):352-360. [doi: 10.1093/jamia/ocw102] [Medline: 27474102]
44. Yadav D, Dabas K, Malik P, Bhandari A, Singh P. "Should I visit the clinic": analyzing WhatsApp-mediated online health support for expectant and new mothers in rural India. In: CHI '22: Proceedings of the 2022 CHI Conference on Human Factors in Computing Systems: Association for Computing Machinery; 2022:1-20. [doi: 10.1145/3491102.3517575]
45. Mohamad Pilus F, Ahmad N, Mohd Zulkefli NA, Mohd Shukri NH. Effect of face-to-face and WhatsApp communication of a theory-based health education intervention on breastfeeding self-efficacy (SeBF Intervention): cluster randomized controlled field trial. JMIR Mhealth Uhealth 2022 Sep 14;10(9):e31996. [doi: 10.2196/31996]
46. Fan HSL, Ho MY, Ko RWT, et al. Feasibility and effectiveness of WhatsApp online group on breastfeeding by peer counsellors: a single-blinded, open-label pilot randomized controlled study. Int Breastfeed J 2022 Dec 22;17(1):91. [doi: 10.1186/s13006-022-00535-z] [Medline: 36544208]
47. Prabhu S, Prabhu A, Sahu KK. The use of WhatsApp social media group for nutrition counselling among parents with children of congenital heart defects. Int J Pub Health Res 2023;13(1). [doi: 10.17576/ijphr.1301.2023.04]
48. Hale N, Picklesimer AH, Billings DL, Covington-Kolb S. The impact of centering pregnancy group prenatal care on postpartum family planning. Am J Obstet Gynecol 2014 Jan;210(1):50. [doi: 10.1016/j.ajog.2013.09.001] [Medline: 24018309]
49. Shakespear K, Waite PJ, Gast J. A comparison of health behaviors of women in centering pregnancy and traditional prenatal care. Matern Child Health J 2010 Mar;14(2):202-208. [doi: 10.1007/s10995-009-0448-3] [Medline: 19184385]
50. El Ayadi AM, Duggal M, Bagga R, et al. A mobile education and social support group intervention for improving postpartum health in northern India: development and usability study. JMIR Form Res 2022 Jun 29;6(6):e34087. [doi: 10.2196/34087] [Medline: 35767348]
51. Diamond-Smith N, El Ayadi A, Bagga R, et al. Feasibility and acceptability of a multi-component mHealth group social support and education intervention for postpartum women in India. JMIR Preprints. Preprint posted online on Aug 26, 2023. [doi: 10.2196/preprints.52187]
52. Austin PC. Balance diagnostics for comparing the distribution of baseline covariates between treatment groups in propensity-score matched samples. Stat Med 2009 Nov 10;28(25):3083-3107. [doi: 10.1002/sim.3697] [Medline: 19757444]
53. Hernán MA, Hernández-Díaz S, Robins JM. A structural approach to selection bias. Epidemiology (Sunnyvale) 2004 Sep;15(5):615-625. [doi: 10.1097/01.ede.0000135174.63482.43]
54. Shade SB, Steward WT, Koester KA, Chakravarty D, Myers JJ. Health information technology interventions enhance care completion, engagement in HIV care and treatment, and viral suppression among HIV-infected patients in publicly funded settings. J Am Med Inform Assoc 2015 Apr 1;22(e1):e104-e111. [doi: 10.1136/amiajnl-2013-002623]
55. Mehta KM, Irani L, Chaudhuri I, et al. Health layering of self-help groups: impacts on reproductive, maternal, newborn and child health and nutrition in Bihar, India. J Glob Health 2020 Dec;10(2):021007. [doi: 10.7189/jogh.10.021007] [Medline: 33425331]
56. Mozumdar A, Khan ME, Mondal SK, Mohanan PS. Increasing knowledge of home based maternal and newborn care using self-help groups: evidence from rural Uttar Pradesh, India. Sex Reprod Healthc 2018 Dec;18:1-9. [doi: 10.1016/j.srhc.2018.08.003] [Medline: 30420079]
57. Kabongo EM, Mukumbang FC, Delobelle P, Nicol E. Explaining the impact of mHealth on maternal and child health care in low- and middle-income countries: a realist synthesis. BMC Pregnancy Childbirth 2021 Mar 9;21(1):196. [doi: 10.1186/s12884-021-03684-x] [Medline: 33750340]
58. Ward VC, Raheel H, Weng Y, et al. Impact of mHealth interventions for reproductive, maternal, newborn and child health and nutrition at scale: BBC Media Action and the Ananya program in Bihar, India. J Glob Health 2020 Dec;10(2):021005. [doi: 10.7189/jogh.10.0201005]
59. Pendse RS, El Ayadi AM, Sharma P, et al. Access to and use of mobile phone by postpartum, married women in Punjab, India: secondary analysis of mHealth intervention pilot data. JMIR Form Res 2022 May 12;6(5):e34852. [doi: 10.2196/34852]

XSL•FO
RenderX

60. Lebrun V, Dulli L, Alami SO, et al. Feasibility and acceptability of an adapted mobile phone message program and changes in maternal and newborn health knowledge in four provinces of Afghanistan: single-group pre-post assessment study. JMIR Mhealth Uhealth 2020 Jul 20;8(7):e17535. [doi: 10.2196/17535] [Medline: 32706690]

Abbreviations

ASHA: Accredited Social Health Activist
BCG: Bacillus Calmette-Guérin
COM-B: Capability, Opportunity, and Motivation Behavior
DPT: diphtheria, pertussis, and tetanus
IVR: interactive voice response
LMIC: low- and middle-income country
***MeSSSSage*:** *Maa Shishu Swasthya Sahayak Samooh* (which means maternal and child health support group)
mHealth: mobile health
OR: odds ratio
REDCap: Research Electronic Data Capture

Edited by S Badawy; submitted 20.08.24; peer-reviewed by T Ma, WK Hoe Mok; revised version received 20.02.25; accepted 14.04.25; published 27.06.25.

Please cite as:
Verma GS, Gopalakrishnan L, Ayadi AE, Diamond-Smith N, Bagga R, Dhir SK, Singh P, Gill N, Miglani V, Mutyala N, Kankaria A, Kaur J, Ahuja A, Kumar V, Duggal M
Preliminary Effectiveness of a Postnatal mHealth and Virtual Social Support Intervention on Newborn and Infant Health and Feeding Practices in Punjab, India: Quasi-Experimental Pre-Post Pilot Study
JMIR Pediatr Parent 2025;8:e65581
URL: https://pediatrics.jmir.org/2025/1/e65581
doi:10.2196/65581

© Garima Singh Verma, Lakshmi Gopalakrishnan, Alison El Ayadi, Nadia Diamond-Smith, Rashmi Bagga, Shashi Kant Dhir, Pushpendra Singh, Navneet Gill, Vaibhav Miglani, Naveen Mutyala, Ankita Kankaria, Jasmeet Kaur, Alka Ahuja, Vijay Kumar, Mona Duggal. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 27.6.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Impact of a 6-Week Postpartum Text Messaging Program (Essential Coaching for Every Mother) at 6 Months: Follow-Up Study to a Randomized Controlled Trial

Justine Dol[1], PhD; Marsha Campbell-Yeo[1,2], PhD; Megan Aston[2], PhD; Douglas McMillan[3], MD; Amy K Grant[4], PhD

[1]IWK Health, 5850 University Ave, Halifax, NS, Canada

[2]School of Nursing, Faculty of Health, Dalhousie University, Halifax, NS, Canada

[3]Department of Pediatrics, Faculty of Medicine, Dalhousie University, Halifax, NS, Canada

[4]Maritime SPOR SUPPORT Unit, Halifax, NS, Canada

Corresponding Author:
Justine Dol, PhD
IWK Health, 5850 University Ave, Halifax, NS, Canada

Abstract

Background: Essential Coaching for Every Mother is an SMS text messaging program that positively improved parenting self-efficacy and reduced postpartum anxiety when measured immediately after intervention at 6 weeks postpartum. However, the impact of a short-term postpartum intervention over time is unknown.

Objective: This study aims to compare parenting self-efficacy, postpartum anxiety symptoms, postpartum depression symptoms, and perceived social support at 6 months postpartum for mothers in the Essential Coaching for Every Mother trial.

Methods: Participants (n=150) were randomized to Essential Coaching for Every Mother or control (usual care). Data were collected on parenting self-efficacy (primary outcome, Karitane Parenting Confidence Scale), postpartum anxiety symptoms (Postpartum Specific Anxiety Scale), postpartum depressive symptoms (Edinburgh Postnatal Depression Scale), and perceived social support (Multidimensional Scale of Perceived Social Support) at enrollment and 6-months postpartum. Data were analyzed using analyses of covariance and chi-square analysis.

Results: A total of 139 women completed the primary outcome at 6 months and 136 completed secondary outcomes. At 6 months, there were no statistically significant differences between mothers in the intervention group and mothers in the control group on any of the outcomes. More mothers in the intervention group had higher postpartum anxiety scores (31/68, 45.6%) than mothers in the control group (16/68, 23.5%; *P*=.007).

Conclusions: At 6 months postpartum, all mothers had similar scores on parenting self-efficacy, postpartum anxiety symptoms, postpartum depression symptoms, and social support. Thus, Essential Coaching for Every Mother improved parenting self-efficacy and reduced postpartum anxiety at 6 weeks, with all mothers having similar scores at 6 months postpartum.

Trial Registration: ClincialTrials.gov NCT04730570; https://clinicaltrials.gov/study/NCT04730570

International Registered Report Identifier (IRRID): RR2-10.2196/27138

(JMIR Pediatr Parent 2025;8:e62841) doi:10.2196/62841

KEYWORDS

mHealth; mobile health; SMS text message; text messages; messaging; self-efficacy; postpartum depression; postpartum anxiety; social support; intervention; postpartum; postnatal; mental health; parenting; mother; depression; anxiety; RCT; randomized controlled trial

Introduction

Background

The growth of digital health interventions to address mental health and maternal health outcomes has grown significantly over the past decades [1,2]. Despite this growth, the extent to which preventative digital health interventions improve or maintain outcomes after the intervention has concluded is unclear. This is known as the maintenance effect, which is essential to behavior change interventions and measures the impact of the intervention on outcomes after the treatment has taken place [3]. To date, evidence is mixed as to whether the positive effects of digital health interventions are maintained over time for a variety of health areas including obesity or weight loss [4], smoking [5], and increasing physical activity

XSL•FO
RenderX

[6]. However, a meta-analysis on the maintenance effect of SMS text messaging–based interventions found that even after the intervention ends, there is a significant maintenance effect [4]. Furthermore, in the postpartum period, there have been mixed findings as to which type of interventions can maintain behavior change in maternal physical and mental health outcomes [7,8]. Thus, there is a need for reporting follow-up periods of digital health interventions to determine the effectiveness of maintenance postintervention [9] to facilitate the understanding of potential factors that lead to greater maintenance effects and whether ongoing follow-up is needed to maintain effects.

This study reports on the postimplementation outcomes of a 6-week postpartum SMS text messaging program called Essential Coaching for Every Mother. This program was designed to send daily SMS text messages to birthing people during the first 6-weeks postpartum who are living in Nova Scotia to improve parenting self-efficacy and perceived social support and to reduce postpartum anxiety and depression symptoms. Essential Coaching for Every Mother was developed through iterative testing with mothers/birthing people (eg, individuals who are physically capable of giving birth) and postpartum health care providers as an evidence-based, SMS text messaging program [10]. In the published results of this randomized controlled trial (RCT), it was found that primiparous women who received the Essential Coaching for Every Mother program had higher parenting self-efficacy at 6 weeks postbirth than those who did not receive the intervention [11]. Additionally, all mothers (regardless of parity) who received the intervention had lower postpartum anxiety symptoms than mothers who did not receive the intervention [11]. This success highlights the effectiveness of the Essential Coaching for Every Mother program to improve immediate parenting self-efficacy and reduce postpartum anxiety symptoms. However, outcomes were measured immediately after completing the intervention at 6 weeks postpartum, and thus, exploration of whether the study effects were maintained is needed to determine whether a short-term intervention has longer-term effectiveness and to determine whether ongoing follow-up is required to maintain positive outcomes.

Aim

This study aimed to compare parenting self-efficacy, postpartum anxiety symptoms, postpartum depression symptoms, and perceived social support at 6 months postpartum for mothers in the Essential Coaching for Every Mother trial.

Hypotheses

The following were our hypotheses:

1. Mothers who received Essential Coaching for Every Mother would have higher parenting self-efficacy and lower postpartum anxiety mean scores at 6 months compared with the control group.
2. Mothers who received Essential Coaching for Every Mother would be more likely to have clinically high parenting self-efficacy scores and clinically low postpartum anxiety scores at 6 months, compared with the control group.
3. Given that no significant differences were found in the original trial on postpartum depression symptoms and perceived social support, no differences at 6 months are hypothesized.

Methods

Participants

Birthing persons from Nova Scotia, Canada, were recruited remotely through SMS text messages between January 5, 2021, and August 1, 2021. Additional details are available in the study by Dol et al [11].

Ethical Considerations

This study was approved by the IWK Health Research Ethics Board (#1024984) and Nova Scotia Health Research Ethics Board (#1026534) and is registered with the ClinicalTrials.gov Protocol Registration System (NCT04730570). All participants provided informed consent and were able to opt out at any time.

Design

This is a follow-up evaluation of a 2-group, stratified, parallel arm RCT which followed a predefined protocol [12]. Participants were recruited from Nova Scotia, Canada via social media advertisements and research study posters at local hospitals and family practice clinics. Participants initiated contact by texting a study phone number to complete a preprogrammed eligibility screening process. All recruitment and onboarding occurred through standardized SMS text messages.

Upon enrollment, participants were first stratified by parity (primiparous and multiparous) and then using a 1:1 allocation, participants were randomized into the intervention or control group. Participants were not blind to their allocation, but hospital staff were. Researchers were aware of allocation but due to the nature of the randomization and remote data collection process, this did not increase any risk of bias.

Intervention

The Essential Coaching for Every Mother program includes standardized evidence-based SMS text messages that provide information related to newborn care and maternal mental health in the first 6-weeks postpartum [10]. Participants allocated to the intervention are sent messages from birth to 6 weeks postpartum based on the age of their newborn, with 2 messages sent per day in the first 2 weeks (one at 10 AM and one at 5 PM) and a daily message (at 10 AM) for weeks 3 through 6. Participants allocated to the control group did not receive any SMS text messages aside from recruitment and survey requests. No changes to regular care were implemented and no study contact occurred between the 6-week and 6-month surveys.

Outcome Measures

Participants were invited to complete a survey hosted on Research Electronic Data Capture (REDCap) [13] via SMS text message at enrollment/baseline (preintervention), 6 weeks postpartum (postintervention), and 6 months postpartum (follow-up). For the purposes of this study, only the baseline and 6-month data were used. The primary outcome was parenting self-efficacy measured using the Karitane Parenting Confidence Scale [14]. This 15-item scale assesses the perceived

XSL•FO
RenderX

self-efficacy of mothers with newborns from birth to 12 months of age. Scores can range between 0 and 45 and a score of 39 or less is considered to be clinically low perceived parenting self-efficacy [14]. Secondary outcomes included postpartum anxiety symptoms (Postpartum Specific Anxiety Scale [PSAS] [15]), postpartum depression symptoms (Edinburgh Postnatal Depression Scale [EPDS] [16]), and perceived social support (Multidimensional Scale of Perceived Social Support [17]). For the PSAS, the clinical cut-off for postpartum anxiety symptoms is 112 out of a possible 201 [15] and for the EPDS, a score of 9 or above indicates depressive symptoms in a community sample and 13 or greater indicates probable clinical depression [16,18]. Therefore, higher scores in both the PSAS and EPDS indicate higher symptomology of postpartum anxiety and depression, respectively. No clinical cut-off scores are available for the Multidimensional Scale of Perceived Social Support.

Data Analysis

Data were analyzed on a per-protocol analysis, excluding women who requested to stop receiving the messages or did not return the 6-month follow-up survey. A series of analyses of covariances were conducted to examine the effects of the intervention on the outcomes of interest at 6 months postpartum considering allocation. In all analyses of covariances, parity, maternal age, and scores on the respective outcomes at baseline were entered as co-variates (ie, when analyzing parenting self-efficacy, parity, maternal age, baseline parenting self-efficacy scores were included as co-variates).

Chi-square analysis was conducted to compare whether participants scored above or below the clinical cut-off that identifies low parenting self-efficacy or high postpartum anxiety and depression symptoms. For the chi-square analysis, all participants who completed the outcome survey at 6 months were included. A *P* value of .05 was considered significant for all outcomes. SPSS (version 29.0; IBM SPSS Statistics) was used for analysis.

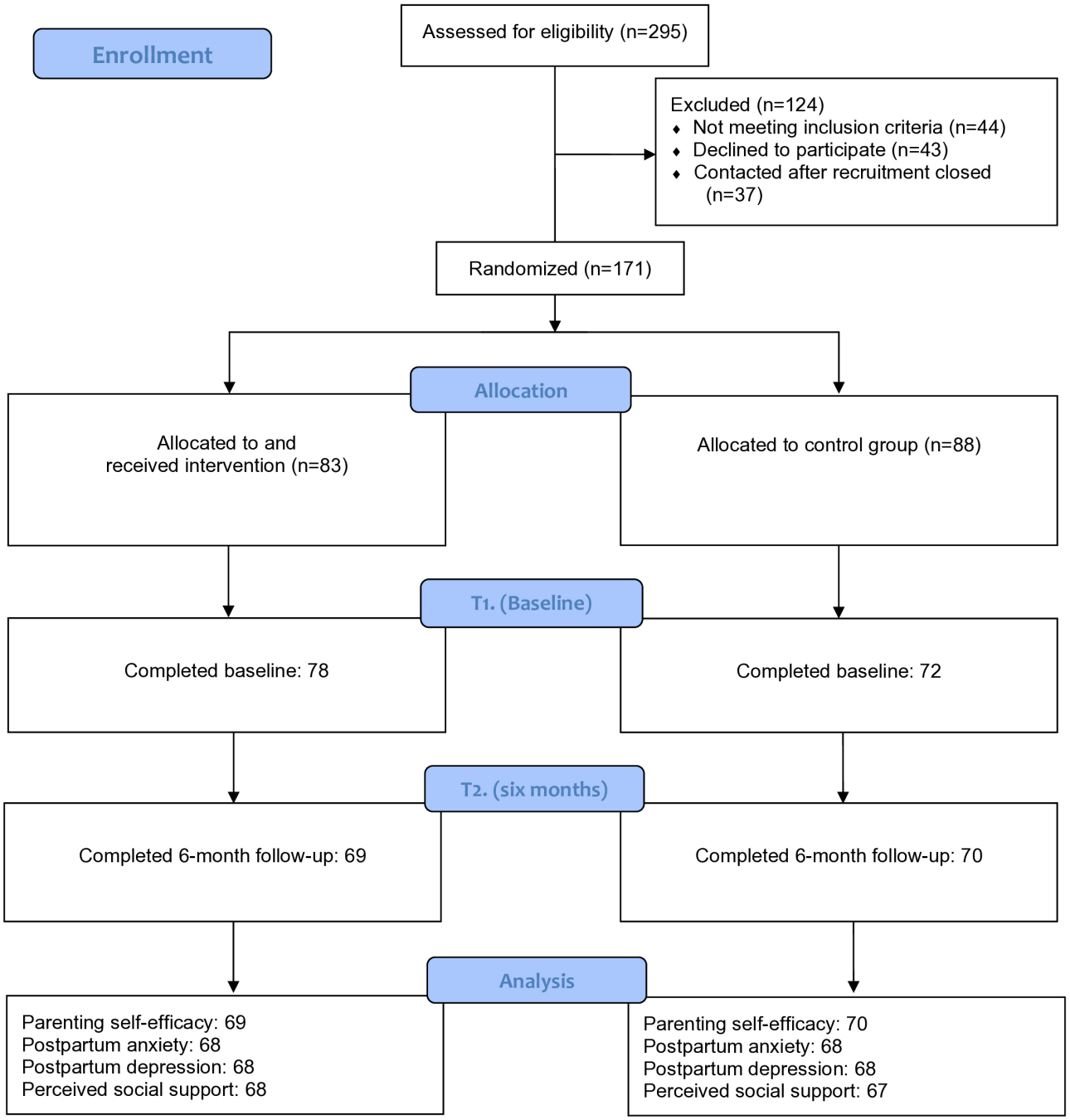
Results

Overview

Of the 171 participants randomized, 150 participants completed the baseline survey and were enrolled in the study. Of those enrolled, 139 (81.2%) participants completed the 6-month follow-up survey and were included in this analysis (Figure 1). All participants identified as cis-gendered females and as mothers; thus, the term “mother” will be used in describing the sample. Mothers were predominantly married, White, and had an undergraduate degree or higher. At 6 months, the groups were similar in all demographics, except for race, with mothers in the control group being more likely to identify as White compared with mothers in the intervention group. This differed from baseline, as there was no difference in race but mothers in the control group were significantly older than mothers in the intervention group (*P*=.053) [11]. At baseline, there were no differences between the groups on any of the primary outcomes [11]. Additional demographic details are available in Table 1 and Dol et al [11].

XSL•FO
RenderX

Figure 1. Consolidated Standards of Reporting Trails (CONSORT) flowchart.



XSL•FO
RenderX

Table . Baseline characteristics for the intervention and control groups.

Demographics	Intervention (n=69)	Control (n=70)	*P* value
Maternal age (years), mean (SD)	30.7 (4.8)	32.1 (4.1)	.07[a]
History of depression or anxiety, n (%)	24 (34.8)	18 (25.7)	.27[b]
Marital status, n (%)			.71[b]
Single or not living with partner	3 (4.3)	4 (5.7)	
Married, common-law, or living with partner	66 (95.7)	66 (94.3)	
Household income in CAD[c], n (%)			.06[b]
Less than 74,999 (US $ 52,286)	26 (37.7)	16 (22.9)	
75,000-149,999 (US $52,287-US $104,573)	31 (44.9)	34 (48.6)	
Over 150,000 (US $104,574)	8 (11.6)	17 (24.3)	
Prefer not to answer	4 (7.2)	3 (4.3)	
Education n (%)			.31[b]
High school or incomplete college or university	4 (5.8)	9 (12.9)	
College diploma	16 (23.2)	10 (14.3)	
Undergraduate degree (BA, BSc)	31 (44.9)	35 (50.0)	
Graduate degree (MSc, PhD)	17 (24.6)	16 (22.9)	
Prefer not to answer	1 (1.5)	—[d]	
Race, n (%)			.02[b]
White	58 (84.1)	67 (95.7)	
Non-White (included Black, Chinese, Filipino, Latin American, Greek, and Indigenous)	11 (15.9)	3 (4.3)	

[a]Conducted using independent *t* test.

[b]conducted using Pearson chi-square analysis.

[c]Conversion CAD to USD estimated at 1 CAD=US $0.70.

[d]Not applicable.

Parenting Self-Efficacy

Based on the 139 mothers who completed parenting self-efficacy measures at 6 months, there was no statistically significant difference in parenting self-efficacy at 6 months postpartum based on allocation ($F_{1,134}$=0.112, *P*=.74, partial η^2=0.001) (Table 2). A chi-square analysis was conducted to determine whether the proportion of mothers who had high (≥40) or low parenting self-efficacy scores (≤39) at 6 months were different based on group allocation. There were no differences in the proportion of mothers with high or low parenting self-efficacy scores based on allocation at 6 months postpartum (χ^2_1=0.091, *P*=.76) (Table 3).

Table . Adjusted means scores based on allocation at 6 months postpartum.

Outcome	Intervention, mean (SD)	Control, mean (SD)	*P* value
Parenting self-efficacy (n=139)	40.14 (3.73)	40.11 (3.94)	.74
Postpartum anxiety scores (n=136)	106.71 (20.97)	99.35 (19.13)	.30
Postpartum depression scores (n=136)	10.01 (4.66)	8.19 (4.94)	.20
Social support (n=135)	5.82 (0.95)	5.82 (1.12)	.79

XSL•FO
RenderX

Table . Comparison of high and low scores at 6 months postpartum by allocation.

Outcome	Intervention, n (%)	Control, n (%)	*P* value
Parenting self-efficacy[a]			.76
High (40 or above)	47 (68.1)	46 (65.7)	
Low (39 or below)	22 (31.9)	24 (34.3)	
Postpartum anxiety[b]			.007
High (112 or above)	31 (45.6)	16 (23.5)	
Low (111 or below)	37 (54.4)	52 (76.5)	
Postpartum depression[b]			.12
High (9 or above)	42 (61.8)	33 (48.5)	
Low (8 or below)	26 (38.2)	35 (51.5)	
Postpartum depression[b]			.08
High (13 or above)	17 (25)	9 (13.2)	
Low (12 or below)	51 (75)	59 (86.8)	

[a]Intervention (n=69) and control (n=70).

[b]Intervention (n=68) and control (n=68).

Postpartum Anxiety Symptoms

Based on 136 mothers who completed the postpartum anxiety measure at 6 months postpartum, there was no statistically significant difference in postpartum anxiety scores at 6 months postpartum ($F_{1,131}$=1.077, *P*=.30, partial η^2=0.00) (Table 2). These findings differed in the chi-square analysis, where mothers in the intervention group were more likely to have clinically high (≥112) postpartum anxiety scores (31/68, 45.6%) compared with those in the control group (16/68, 23.5%) (χ^2_1=7.315, *P*=.007) (Table 3).

Postpartum Depression Symptoms

Based on the 136 mothers who completed the postpartum depression measure at 6 months, there was no statistically significant difference in postpartum depression mean scores at 6 months postpartum based on allocation ($F_{1,131}$=1.680, *P*=.20, partial η^2=0.013) (Table 2). In the chi-square analysis comparing mothers with scores ≥9 to ≤8, there were no differences in the proportion of mothers with high or low postpartum depression symptoms at 6 months postpartum (χ^2_1=2.408, *P*=.12). Additionally, comparing participants who scored ≥13 or ≤12, there were no differences in the proportion of mothers with high or low postpartum depression symptoms (χ^2_1=3.043, *P*=.08).

Perceived Social Support

Based on the 135 mothers who completed the perceived social support measure, there was no statistically significant difference in perceived social support scores at 6 months postpartum based on allocation ($F_{1,130}$=0.071, *P*=.79, partial η^2=0.001) (Table 2).

Discussion

Principal Results

This study sought to explore mothers' parenting self-efficacy, postpartum anxiety symptoms, postpartum depression symptoms, and perceived social support at 6 months postpartum, after receiving Essential Coaching for Every Mother, a 6-week postpartum SMS text messaging intervention immediately after birth. At 6 months, all mothers, regardless of their allocation, had similar scores on all outcomes. Mothers in the intervention group were slightly more likely to have high postpartum anxiety symptoms compared with mothers in the control group. The implications of these findings are discussed below.

For the primary outcome of parenting self-efficacy, the hypotheses were not supported in the analysis. The hypotheses were that mothers who received Essential Coaching for Every Mother would have higher mean parenting self-efficacy scores compared with mothers in the control group and would be more likely to have parenting self-efficacy scores that would be considered high (≥40). While there were no significant differences in scores or differences in high scores, both the intervention and control groups had mean scores that would be considered "high" parenting self-efficacy. In the RCT measuring immediate intervention effectiveness [11], primiparous women who received the Essential Coaching for Every Mother program had a greater increase in parenting self-efficacy than those who did not receive the program. This may suggest that Essential Coaching for Every Mother was able to improve parenting self-efficacy during the earlier postpartum period, particularly for primiparous women, showing potential to improve immediate parenting self-efficacy during an early critical period. Given the relatively high parenting self-efficacy scores at 6 months postpartum, it is clear that parenting self-efficacy increases over time in the first 6 months as mothers become more comfortable and confident in their parenting role [19].

XSL•FO
RenderX

Early interventions for primiparous mothers may be helpful in bridging the gap to achieve earlier parenting self-efficacy.

In relation to postpartum anxiety symptoms, the original RCT found that postpartum anxiety symptoms decreased at 6 weeks for women who received the Essential Coaching for Every Mother program, regardless of parity, compared with the control group [11]. Thus, the hypothesis was that mothers who received Essential Coaching for Every Mother would have lower mean postpartum anxiety scores at 6 months as well as more mothers would have clinically low postpartum anxiety scores compared with the control group. Like parenting self-efficacy, there were no significant differences at 6 months between the groups on average postpartum anxiety scores. However, mothers in the intervention group were more likely to have a clinically high postpartum anxiety score compared with mothers in the control group. Postpartum anxiety symptoms have been found to be higher in mothers with an infant 4 - 6 months than mothers with an infant 0 - 3 months [20], suggesting that perhaps there may be factors that influence a later emergence of anxiety symptoms during the postpartum period. Additionally, it has been suggested that postpartum anxiety may have a u-shaped relationship, with mothers who have higher anxiety levels during pregnancy experiencing a dip when their infant is born and then continue to increase back up to pregnancy levels up to 24 months postpartum whereas mothers with low anxiety levels during pregnancy tend to stay low across the postpartum period [21]. In this study, anxiety scores at baseline were higher for the intervention group, so there may be an influence of self-referral bias whereby mothers who were more anxious were interested in enrolling in the study. Particularly since the COVID-19 pandemic, the loss of support and ability to consult with health care providers or friends has also been associated with higher levels of mental health concerns [22]. Combined with normal fluctuation that occurs in the postpartum period along with decreased social support and potentially being predisposed to higher anxiety, there may be factors other than the Essential Coaching for Every Mother program that resulted in increased anxiety symptoms for intervention mothers. Despite the higher levels in the Essential Coaching for Every Mother group, both groups had a mean below the clinical cut-off for high levels of postpartum anxiety. At the individual level, it is important to ensure that birthing people have access to ongoing mental health support throughout the postpartum period.

Last, no differences in postpartum depression symptoms and perceived social support at 6 months were hypothesized since there were no significant differences found in the original trial at 6 weeks postpartum. This was found in both analyses, with no differences in postpartum depression symptoms and social support at 6 months. Despite the lack of significant findings, mothers in the intervention group did have higher postpartum depression mean scores, and more mothers were in the >9 group than mothers in the control group. During the recruitment for the RCT, participants were not excluded if they were currently experiencing mental health concerns or had a history of mental health concerns. While randomization is expected to equalize this between groups by design, this may not have been sufficient to balance this across groups as the intervention group had higher, yet not significant, postpartum depression symptoms at baseline as well [11]. Additionally, the intervention group had a higher, although again not significant, difference in having a history of mental health concerns (24/69, 34.8% vs 18/70, 25.7%) which may have influenced their postpartum depression symptoms at 6 months postpartum.

Limitations

This follow-up analysis is limited by the small sample size and loss of follow-up, which may have impacted the ability to be sufficiently powered in the analyses. While the original study was sufficiently powered, this follow-up study lost some power as participants who did not complete the 6-month timepoint were removed. This study was carried out in Canada in English, and findings may be different in other populations. We were unable to explore other variables that influenced mothers' psychosocial and mental health scores across the postpartum period. Mothers who participated in the study may not be fully representative of the population, as they were predominately White, highly educated, and high-income earners. Additionally, our sample may have been influenced by self-referral bias, as participants were remotely recruited and signed themselves up for participation and there was a greater number of participants in the control group who dropped out before completing the baseline questionnaire [11]. Given these limitations, the findings should be interpreted in this light.

Comparison With Prior Work

Questions remain about the appropriate dose and engagement of postpartum SMS text messaging interventions to improve psychosocial and mental health outcomes. The first year after an infant is born is associated with significant changes in physical and emotional outcomes for mothers. Risk factors for postpartum depression and anxiety are wide-ranging and include, but are not limited to, having depression during pregnancy [23-25], having a history of depression [23,26], or experiencing abuse or marital conflict [24,25]. Additionally, evidence shows that postpartum anxiety varies across the first 6 months of the postpartum period, ranging from 14.8% to 17.8% [27]. In addition, well established is the comorbidity between anxiety, depression, social support, and parenting self-efficacy in the postpartum period [19,28], suggesting that postpartum adjustment is multifaceted and interdependent. More research is needed to understand whether ongoing support throughout the postpartum period may be able to alter mental health outcomes as well as other interventions that may address additional risk factors. Given that Essential Coaching for Every Mother was designed primarily to improve parenting self-efficacy, it is important that other supports are available to mothers that target mental health outcomes beyond the initial 6-weeks.

There is a challenge with designing interventions that improve mental health outcomes in the postpartum period, particularly in regard to universal support to women considered low risk [29]. In a recent scoping review analyzing 70 unique evidence-based universal interventions to support parents between conception and 12 months postpartum, only half reported evidence of effectiveness against their reported outcome measures, suggesting a need for a multifaceted approach to support parent well-being across the perinatal period [30].

XSL•FO
RenderX

Another review examining digital health interventions for postpartum anxiety and depression found that digital health interventions significantly reduced postpartum depression and postpartum anxiety symptoms [31]. It is also important to consider what might make an intervention effective beyond the treatment period. In analyzing the maintenance effectiveness of physical activity and dietary interventions for adults, Fjeldsoe et al [32] found that intervention characteristics that were associated with maintenance effects were those of longer duration (>24 weeks), face-to-face contact, the use of a variety of intervention strategies, and the use of follow-up prompts. Examining parent training more broadly, providing booster sessions or intermittent contact postintervention, have been suggested as potentially effective strategies to maintain intervention effects over time [33].

While digital health interventions are desired and accepted by postpartum mothers [34], interventions designed for implementation during the postpartum period should take into consideration how interventions can maintain positive impacts over time. In a meta-synthesis of what women want in the postpartum period, Finlayson et al [35] clearly summarize: "To cope with this period of adjustment women express the need for practical, emotional and psychological support from family members, peer groups and online sources, as well as from health providers. Women also want information and reassurance from health providers delivered in a consistent manner by authentic, familiar providers who recognise the mother's as well as baby's needs, within a well-resourced and flexible healthcare system that respects their cultural context". Given the multiple challenges that emerge for mothers during the postpartum period, both in-person and digital support from reliable sources of information that respond to mothers' needs and infant development is needed. Engaging patients in the development of perinatal digital health solutions is important to improve health outcomes but is not yet common practice [36-38].

Future Directions

Future work should explore the potential to expand the timeline of the Essential Coaching for Every Mother program beyond the immediate 6-week period, as there are clearly challenges parents experience beyond this time frame that are impacting their psychosocial and mental health. Additionally, future work should consider the population that may be in most need of such an intervention, such as primiparous mothers or those with higher postpartum anxiety and depression scores at baseline. Future work should identify at-risk groups and determine whether any differences between low-risk and high-risk groups can be improved with the Essential Coaching for Every Mother program.

Conclusions

In conclusion, mothers, regardless of whether they received Essential Coaching for Every Mother, a 6-week postpartum intervention, had similar scores on parenting self-efficacy, postpartum anxiety symptoms, postpartum depression symptoms, and social support at 6 months. This suggests that the Essential Coaching for Every Mother program was able to improve parenting self-efficacy for primiparous mothers and reduce postpartum anxiety symptoms in the immediate postpartum period. At 6 months, both groups were similar, indicating that support during the immediate 6-week postpartum period is critical to ensure early intervention.

Acknowledgments

This work was supported by an IWK Mentored Grant and an IWK Ross Fund grant held by JD and MCY.

Authors' Contributions

JD and MCY researched the literature and conceived the study with input from MA and DM. JD led protocol development, gained ethical approval, patient recruitment, and data analysis. AKG provided statistical guidance on the analysis. JD wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Checklist 1
CONSORT-eHEALTH checklist.
[PDF File, 1092 KB - pediatrics_v8i1e62841_app1.pdf]

References

1. Feldman N, Back D, Boland R, Torous J. A systematic review of mHealth application interventions for peripartum mood disorders: trends and evidence in academia and industry. Arch Womens Ment Health 2021 Dec;24(6):881-892. [doi: 10.1007/s00737-021-01138-z] [Medline: 33929636]
2. Stentzel U, Grabe HJ, Schmidt S, Tomczyk S, van den Berg N, Beyer A. Mental health-related telemedicine interventions for pregnant women and new mothers: a systematic literature review. BMC Psychiatry 2023 Apr 28;23(1):292. [doi: 10.1186/s12888-023-04790-0] [Medline: 37118689]
3. Foxx RM. The maintenance of behavioral change: the case for long-term follow-ups. Am Psychol 2013;68(8):728-736. [doi: 10.1037/a0033713]

XSL•FO
RenderX

4. Beleigoli AM, Andrade AQ, Cançado AG, Paulo MN, Diniz M, Ribeiro AL. Web-based digital health interventions for weight loss and lifestyle habit changes in overweight and obese adults: systematic review and meta-analysis. J Med Internet Res 2019 Jan 8;21(1):e298. [doi: 10.2196/jmir.9609] [Medline: 30622090]
5. Bock B, Heron K, Jennings E, et al. A text message delivered smoking cessation intervention: the initial trial of TXT-2-quit: randomized controlled trial. JMIR Mhealth Uhealth 2013 Jul 30;1(2):e17. [doi: 10.2196/mhealth.2522] [Medline: 25098502]
6. Fjeldsoe BS, Miller YD, Marshall AL. MobileMums: a randomized controlled trial of an SMS-based physical activity intervention. Ann Behav Med 2010 May;39(2):101-111. [doi: 10.1007/s12160-010-9170-z] [Medline: 20174902]
7. Su A, Buttenheim AM. Maintenance of smoking cessation in the postpartum period: which interventions work best in the long-term? Matern Child Health J 2014 Apr;18(3):714-728. [doi: 10.1007/s10995-013-1298-6] [Medline: 23812798]
8. Nylen KJ, Moran TE, Franklin CL, O'hara MW. Maternal depression: a review of relevant treatment approaches for mothers and infants. Infant Ment Health J 2006 Jul;27(4):327-343. [doi: 10.1002/imhj.20095] [Medline: 28640416]
9. Willcox JC, Dobson R, Whittaker R. Old-fashioned technology in the era of "Bling": is there a future for text messaging in health care? J Med Internet Res 2019 Dec 20;21(12):e16630. [doi: 10.2196/16630] [Medline: 31859678]
10. Dol J, Tomblin Murphy G, Aston M, McMillan D, Campbell-Yeo M. Design, development and usability testing of Essential Coaching for Every Mother: a postnatal text message educational intervention. Women Birth 2021 May;34(3):e228-e236. [doi: 10.1016/j.wombi.2020.05.004] [Medline: 32475782]
11. Dol J, Aston M, Grant A, McMillan D, Tomblin Murphy G, Campbell-Yeo M. Effectiveness of the "Essential Coaching for Every Mother" postpartum text message program on maternal psychosocial outcomes: a randomized controlled trial. Digit HEALTH 2022;8:20552076221107886. [doi: 10.1177/20552076221107886] [Medline: 35720618]
12. Dol J, Aston M, McMillan D, Tomblin Murphy G, Campbell-Yeo M. Effectiveness of a postpartum text message program (Essential Coaching for Every Mother) on maternal psychosocial outcomes: protocol for a randomized controlled trial. JMIR Res Protoc 2021 Mar 25;10(3):e27138. [doi: 10.2196/27138] [Medline: 33764309]
13. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381. [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
14. Crncec R, Barnett B, Matthey S. Development of an instrument to assess perceived self-efficacy in the parents of infants. Res Nurs Health 2008 Oct;31(5):442-453. [doi: 10.1002/nur.20271] [Medline: 18297638]
15. Fallon V, Halford JCG, Bennett KM, Harrold JA. The postpartum specific anxiety scale: development and preliminary validation. Arch Womens Ment Health 2016 Dec;19(6):1079-1090. [doi: 10.1007/s00737-016-0658-9] [Medline: 27571782]
16. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. development of the 10-item Edinburgh postnatal depression scale. Br J Psychiatry 1987 Jun;150(782–786):782-786. [doi: 10.1192/bjp.150.6.782] [Medline: 3651732]
17. Zimet GD, Dahlem NW, Zimet SG, Farley GK. The multidimensional scale of perceived social support. J Pers Assess 1988 Mar;52(1):30-41. [doi: 10.1207/s15327752jpa5201_2]
18. Dennis CL. Can we identify mothers at risk for postpartum depression in the immediate postpartum period using the Edinburgh postnatal depression scale? J Affect Disord 2004 Feb;78(2):163-169. [doi: 10.1016/s0165-0327(02)00299-9] [Medline: 14706728]
19. Leahy-Warren P, McCarthy G. Maternal parental self-efficacy in the postpartum period. Midwifery 2011 Dec;27(6):802-810. [doi: 10.1016/j.midw.2010.07.008] [Medline: 20888092]
20. Dol J, Richardson B, Grant A, et al. Influence of parity and infant age on maternal self-efficacy, social support, postpartum anxiety, and postpartum depression in the first six months in the Maritime Provinces, Canada. Birth 2021 Sep;48(3):438-447. [doi: 10.1111/birt.12553] [Medline: 34008241]
21. Agrati D, Browne D, Jonas W, et al. Maternal anxiety from pregnancy to 2 years postpartum: transactional patterns of maternal early adversity and child temperament. Arch Womens Ment Health 2015 Oct;18(5):693-705. [doi: 10.1007/s00737-014-0491-y] [Medline: 25627018]
22. Tsuno K, Okawa S, Matsushima M, Nishi D, Arakawa Y, Tabuchi T. The effect of social restrictions, loss of social support, and loss of maternal autonomy on postpartum depression in 1 to 12-months postpartum women during the COVID-19 pandemic. J Affect Disord 2022 Jun 15;307:206-214. [doi: 10.1016/j.jad.2022.03.056] [Medline: 35341813]
23. Liu X, Wang S, Wang G. Prevalence and risk factors of postpartum depression in women: a systematic review and meta-analysis. J Clin Nurs 2022 Oct;31(19-20):2665-2677. [doi: 10.1111/jocn.16121] [Medline: 34750904]
24. Hutchens BF, Kearney J. Risk factors for postpartum depression: an umbrella review. J Midwife Womens Health 2020 Jan;65(1):96-108. [doi: 10.1111/jmwh.13067]
25. Field T. Postpartum anxiety prevalence, predictors and effects on child development: a review. J Psychiatry Psychiatric Disord 2017;01(2):86-102. [doi: 10.26502/jppd.2572-519X0010]
26. Goodman JH, Watson GR, Stubbs B. Anxiety disorders in postpartum women: a systematic review and meta-analysis. J Affect Disord 2016 Oct;203(292–331):292-331. [doi: 10.1016/j.jad.2016.05.033] [Medline: 27317922]
27. Dennis CL, Falah-Hassani K, Shiri R. Prevalence of antenatal and postnatal anxiety: systematic review and meta-analysis. Br J Psychiatry 2017 May;210(5):315-323. [doi: 10.1192/bjp.bp.116.187179] [Medline: 28302701]
28. Leahy-Warren P, McCarthy G, Corcoran P. First-time mothers: social support, maternal parental self-efficacy and postnatal depression. J Clin Nurs 2012 Feb;21(3-4):388-397. [doi: 10.1111/j.1365-2702.2011.03701.x] [Medline: 21435059]

XSL•FO
RenderX

29. Shaw E, Levitt C, Wong S, Kaczorowski J, McMaster University Postpartum Research Group. Systematic review of the literature on postpartum care: effectiveness of postpartum support to improve maternal parenting, mental health, quality of life, and physical health. Birth 2006 Sep;33(3):210-220. [doi: 10.1111/j.1523-536X.2006.00106.x] [Medline: 16948721]
30. Middleton G, Matvienko-Sikar K, Briley A, et al. Supporting parents in the transition to parenthood through wellbeing interventions; an international scoping review. Midwifery 2025 Mar;142:104296. [doi: 10.1016/j.midw.2025.104296] [Medline: 39862591]
31. Lewkowitz AK, Whelan AR, Ayala NK, et al. The effect of digital health interventions on postpartum depression or anxiety: a systematic review and meta-analysis of randomized controlled trials. Am J Obstet Gynecol 2024 Jan;230(1):12-43. [doi: 10.1016/j.ajog.2023.06.028] [Medline: 37330123]
32. Fjeldsoe B, Neuhaus M, Winkler E, Eakin E. Systematic review of maintenance of behavior change following physical activity and dietary interventions. Health Psychol 2011 Jan;30(1):99-109. [doi: 10.1037/a0021974] [Medline: 21299298]
33. Eyberg SM, Edwards D, Boggs SR, Foote R. Maintaining the treatment effects of parent training: the role of booster sessions and other maintenance strategies. Clin Psychol 1998;5(4):544-554. [doi: 10.1111/j.1468-2850.1998.tb00173.x]
34. Lim S, Tan A, Madden S, Hill B. Health professionals' and postpartum women's perspectives on digital health interventions for lifestyle management in the postpartum period: a systematic review of qualitative studies. Front Endocrinol (Lausanne) 2019;10:767. [doi: 10.3389/fendo.2019.00767] [Medline: 31787932]
35. Finlayson K, Crossland N, Bonet M, Downe S. What matters to women in the postnatal period: a meta-synthesis of qualitative studies. PLoS ONE 2020;15(4):e0231415. [doi: 10.1371/journal.pone.0231415] [Medline: 32320424]
36. Ke JXC, George RB, Wozney L, Chorney JL. Patient-centred perioperative mobile application in cesarean delivery: needs assessment and development. Can J Anesth/J Can Anesth 2019 Oct 15;66(10):1194-1201. [doi: 10.1007/s12630-019-01392-x]
37. Auxier JN, Bender M, Hakojärvi HR, Axelin AM. Patient engagement practice within perinatal eHealth: a scoping review. Nurs Open 2023 Aug;10(8):4971-4984. [doi: 10.1002/nop2.1822] [Medline: 37211718]
38. Marzban S, Najafi M, Agolli A, Ashrafi E. Impact of patient engagement on healthcare quality: a scoping review. J Patient Exp 2022;9:23743735221125439. [doi: 10.1177/23743735221125439] [Medline: 36134145]

Abbreviations

EPDS: Edinburgh Postnatal Depression Scale
PSAS: Postpartum Specific Anxiety Scale
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture

Edited by S Badawy; submitted 02.06.24; peer-reviewed by N Hussain-Shamsy, U Stentzel; revised version received 05.02.25; accepted 28.02.25; published 02.04.25.

Please cite as:
Dol J, Campbell-Yeo M, Aston M, McMillan D, Grant AK
Impact of a 6-Week Postpartum Text Messaging Program (Essential Coaching for Every Mother) at 6 Months: Follow-Up Study to a Randomized Controlled Trial
JMIR Pediatr Parent 2025;8:e62841
URL: https://pediatrics.jmir.org/2025/1/e62841
doi:10.2196/62841

© Justine Dol, Marsha Campbell-Yeo, Megan Aston, Douglas McMillan, Amy K Grant. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 2.4.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Fetal Birth Weight Prediction in the Third Trimester: Retrospective Cohort Study and Development of an Ensemble Model

Jing Gao[1*], MD; Xu Jie[2*], DHM; Yujun Yao[2*], MM; Jingdong Xue[3*], MD; Lei Chen[1], MS; Ruiyao Chen[2], MD; Jiayuan Chen[2], MD; Weiwei Cheng[1], PHD

[1]International Peace Maternity and Child Health Hospital, School of Medicine, Hengshan road NO.910, Shanghai, China

[2]Shanghai Artificial Intelligence Laboratory, Shanghai, China

[3]Shanghai Tongji Hospital, Shanghai, China

[*]these authors contributed equally

Corresponding Author:
Weiwei Cheng, PHD
International Peace Maternity and Child Health Hospital, School of Medicine, Hengshan road NO.910, Shanghai, China

Abstract

Background: Accurate third-trimester birth weight prediction is vital for reducing adverse outcomes, and machine learning (ML) offers superior precision over traditional ultrasound methods.

Objective: This study aims to develop an ML model on the basis of clinical big data for accurate prediction of birth weight in the third trimester of pregnancy, which can help reduce adverse maternal and fetal outcomes.

Methods: From January 1, 2018 to December 31, 2019, a retrospective cohort study involving 16,655 singleton live births without congenital anomalies (>28 weeks of gestation) was conducted in a tertiary first-class hospital in Shanghai. The initial set of data was divided into a train set for algorithm development and a test set on which the algorithm was divided in a ratio of 4:1. We extracted maternal and neonatal delivery outcomes, as well as parental demographics, obstetric clinical data, and sonographic fetal biometry, from electronic medical records. A total of 5 basic ML algorithms, including Ridge, SVM, Random Forest, extreme gradient boosting (XGBoost), and Multi-Layer Perceptron, were used to develop the prediction model, which was then averaged into an ensemble learning model. The models were compared using accuracy, mean squared error, root mean squared error, and mean absolute error. International Peace Maternity and Child Health Hospital's Research Ethics Committee granted ethical approval for the usage of patient information (GKLW2021-20).

Results: Train and test sets contained a total of 13,324 and 3331 cases, respectively. From a total of 59 variables, we selected 17 variables that were readily available for the “few feature model,” which achieved high predictive power with an accuracy of 81% and significantly exceeded ultrasound formula methods. In addition, our model maintained superior performance for low birth weight and macrosomic fetal populations.

Conclusions: Our research investigated an innovative artificial intelligence model for predicting fetal birth weight and maximizing health care resource use. In the era of big data, our model improves maternal and fetal outcomes and promotes precision medicine.

(JMIR Pediatr Parent 2025;8:e59377) doi:10.2196/59377

KEYWORDS

fetal birthweight; ensemble learning model; machine learning; prediction model; ultrasonography; macrosomia; low birth weight; birth weight; fetal; AI; artificial intelligence; prenatal; prenatal care; Shanghai; neonatal; maternal; parental

Introduction

The assessment of fetal birth weight for the purpose of fetal growth monitoring is essential in contemporary prenatal care, as anomalies in growth are linked with negative consequences for both the mother and the fetus [1,2]. For instance, the birth of a macrosomic fetus is associated to unfavorable delivery outcomes (operative vaginal, caesarean delivery, or shoulder dystocia), trauma (maternal severe birth canal laceration and postpartum hemorrhage, fetal clavicular fracture, brachial plexus injury, neonatal hypoglycemia, and birth asphyxia) [3]. Infants with low birth weight may present a greater risk of acute or chronic hypoxia, acidemia, fetal demise, neonatal death, neonatal morbidity, and abnormal neurodevelopmental outcome, which are more likely to be admitted to a neonatal intensive care unit (NICU) and to have lifelong illnesses [4]. Consequently, precise fetal birthweight prediction helps clinical decision-making, such as appropriate prenatal treatments and acceptable mode of delivery selection, which might assist to enhance pregnancy outcomes [5].

Ultrasonographic evaluation based on biometric measurements and regression equations is the method of choice in obstetrics

XSL•FO
RenderX

due to its objectivity and convenience. However, the majority of ultrasonic formulae are based on western populations, and there are biases when applied to Chinese as fetal birth weight after 20 weeks varies significantly by race [6]. Predictions of macrosomia and low birth weight infants based on estimated fetal weight are significantly less accurate [7,8]. A meta-analysis of 29 studies reveals that the pooled sensitivity of the Hadlock formula for fetal weight estimation was only 0.56. (95% CI 0.49 - 0.62) [9]. Inaccurate estimations may result in inappropriate interventions, so alternative approaches to precision estimation are urgently required.

With more ability than traditional statistical methods of handling complex, nonlinear, and multidimensional clinical data, machine learning (ML) has been explored successfully in several obstetrics domains, including gestational diabetes mellitus (GDM) [10], preterm birth [11], and postpartum hemorrhage [12]. Currently, there are only a few of published models using ML to estimate fetal birth weight before delivery, such as Wang et al [13]. used a Random Forest Algorithm to predict macrosomia and Gao et al [14] proposed a fetal weight prediction model based on genetic algorithm to improve back propagation (GA-BP) neural network. However, their simple size was too small and the feature parameters were insufficient; consequently, the performance of published models was unreliable and differentially robust.

In this study, we aimed to analyze the vast clinical data of a large cohort of pregnant women and create predictive models for the prediction of fetal birth weight using a variety of ML algorithms. Compared to the preexisting ultrasound formula, our novel ML models are anticipated to achieve an advanced result with a high degree of accuracy and offer convenient service to both medical staff and families of pregnant women in the future.

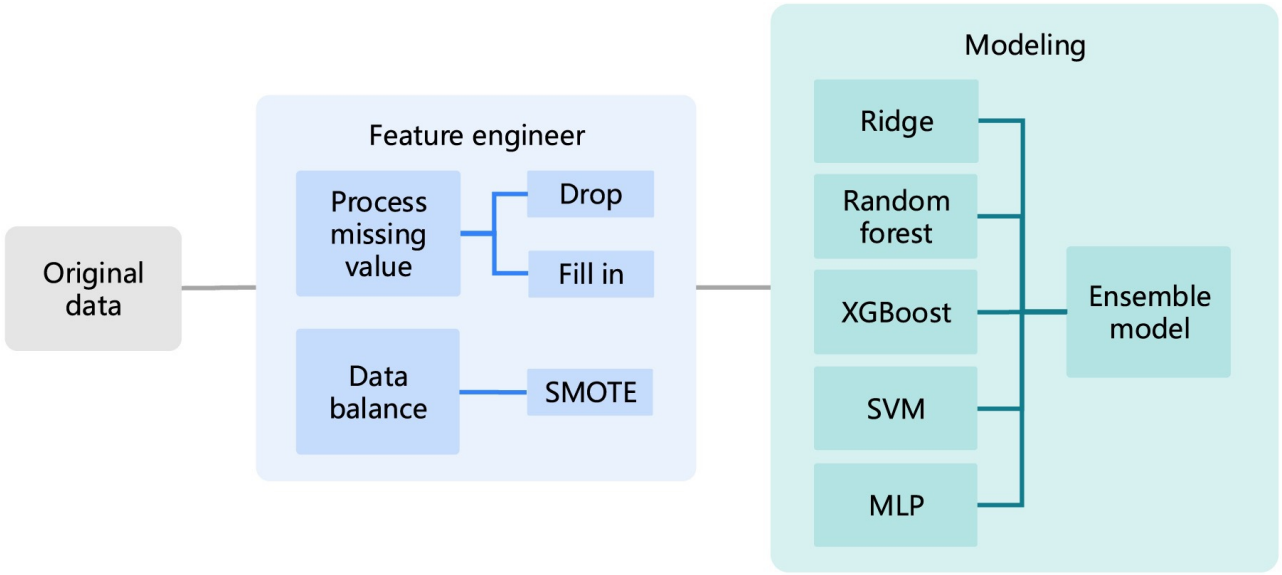
Methods

Study Design

This is a retrospective observational study using ML algorithms to increase the accuracy of fetal birth weight prediction based on real-world data. The process included feature engineering and modeling, as depicted in Figure 1 and described in detail in this section. This project established a simplified model suitable for maternal self-testing or clinical staff rapid prediction and transformed this model into a mobile application for use in clinical practice. Previously, there existed a model suitable for medical electronic record system with more detailed features, and the results will be improved.

This research was reported in accordance with the Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD) statement. The official TRIPOD checklist is shown in Table S1 (Multimedia Appendix 1).

Figure 1. The whole process of fetal birth weight prediction. SMOTE: Synthetic Minority Over-sampling Technique; SVM: support vector machine; MLP: multilayer perceptron.



Study Population and Data Source

International Peace Maternity and Child Health Hospital (IPMCH), a tertiary first-class hospital in China, is the source of the data. The following were the criteria for inclusion: (1) gestational weeks of less than 28, (2) a singleton pregnancy, and (3) a normal pregnancy outcome (no or severe fetal malformations, stillbirths, or neonatal deaths). We searched for predictors of fetal birth weight that were repeatedly reported in studies or systematic reviews, can be easily ascertained in different settings with various clinical experiences, and are part of the routine examination during pregnancy. It includes samples of 18,837 pregnant women who gave birth between January 1, 2018 and December 31, 2019, including parental demographics, clinical characteristics, ultrasound information, and laboratory tests. Concerning the height and weight of the husband were oral reported by pregnant women, both the reliability and filling rate were extremely low, so we only included the age and education level information of the husband. A total of 59 characteristics, was shown in Table S2 in Multimedia Appendix

XSL•FO
RenderX

1. The measurement data's extreme and error values were eliminated, and the categorical data were standardized and coded.

At the first prenatal visit, between 9 and 13 weeks of gestation, we gathered parental data on the demographics, reproductive history, and medical history. Parental age was calculated through the date of birth and double checked by interviews. Face-to-face interviews were used to record maternal weight, height, parity, gravity, parental educational level, and baseline blood pressure (diastolic blood pressure [DBP] and systolic blood pressure [SBP]). Gestational weight gain (GWG) throughout pregnancy was measured by subtracting prepregnancy weight from the woman's weight at her final prenatal checkup. Gestational age was derived from sonographic measurement of the fetal crown-rump length or biparietal diameter. In the first trimester, between 9 and 14 weeks of pregnancy, samples of the mother's fasting lipid serum were collected in vacutainer tubes of 10 mL and centrifuged. Triglycerides (TG), high-density lipoprotein (HDL), low-density lipoprotein (LDL), and total cholesterol (TC), were among the laboratory indices. The glucose index was derived from a 75-g oral glucose tolerance test (OGTT) between pregnancy weeks 24 and 28—including fasting plasma glucose (FPG), 1-hour glucose (GLU-1H), 2-hour glucose (GLU-2H), and hemoglobin (HGB). Attending physicians with more than 5 years of obstetric ultrasound experience performed routine sonographic evaluations of the fetal abdominal circumference (AC), head circumference (HC), biparietal diameter (BPD), humerus length (HL), transverse trunk diameter (TTD), femur length (FL), amniotic fluid index (AFI), and anteroposterior trunk diameter (APTD). Only ultrasound data within 2 weeks before delivery were collected. Each neonate's birthweight (in gram) was measured routinely by registered midwives using an electronic weighing scale within half an hour of delivery. Those newborns with birth weights <2500 g or ≥4000 g were defined as low birth weight or macrosomia, separately. Shinozuka's formula [15] was used to estimate fetal weight since it has been shown to be most suitable for weighing Asian fetuses.

$$(1) y=1.07*BPD3+3.42*APTD*TTD*FL$$

During the modeling process, four-fifths of the sample is picked at random as train data, and one-fifth is used as test data. Each model is trained on the same dataset partition.

Model Training and Validation

The Model Training and Validation process involved feature engineering steps, including handling missing values, filtering outliers, creating new features, selecting important features, and balancing the dataset. Pearson correlation coefficient, Ridge, and XGBoost methods were used for feature selection. The dataset imbalance was addressed by dividing the samples into categories and performing up-sampling using the SMOTE algorithm. Ensemble learning with bagging was used, averaging results from benchmark models, which included Ridge, Random Forest, support vector machine (SVM), k-nearest neighbor (KNN), and Multilayer Perceptron (MLP). Evaluation metrics such as relative error (RE), absolute error (AE), mean squared error (MSE), root mean squared error (RMSE), and mean absolute error (MAE) were used. The process aimed to optimize the model's accuracy in predicting fetal birth weight.

Statistical Analyses

The classification index expressed in numbers and percentages (%). The continuous data were shown as mean (SD). Kolmogorov-Smirnov (KS) divergence were used to measure whether there is a significant difference between 2 sets of data distributions, a *P* value less than .05 was deemed significant.

Ethical Considerations

International Peace Maternity and Child Health Hospital's Research Ethics Committee granted ethical approval for the usage of patient information (GKLW2021-20). We ascertained that the International Peace Maternity and Child Health Hospital's Ethics Committee waived informed consent since the research was reviewed.

Results

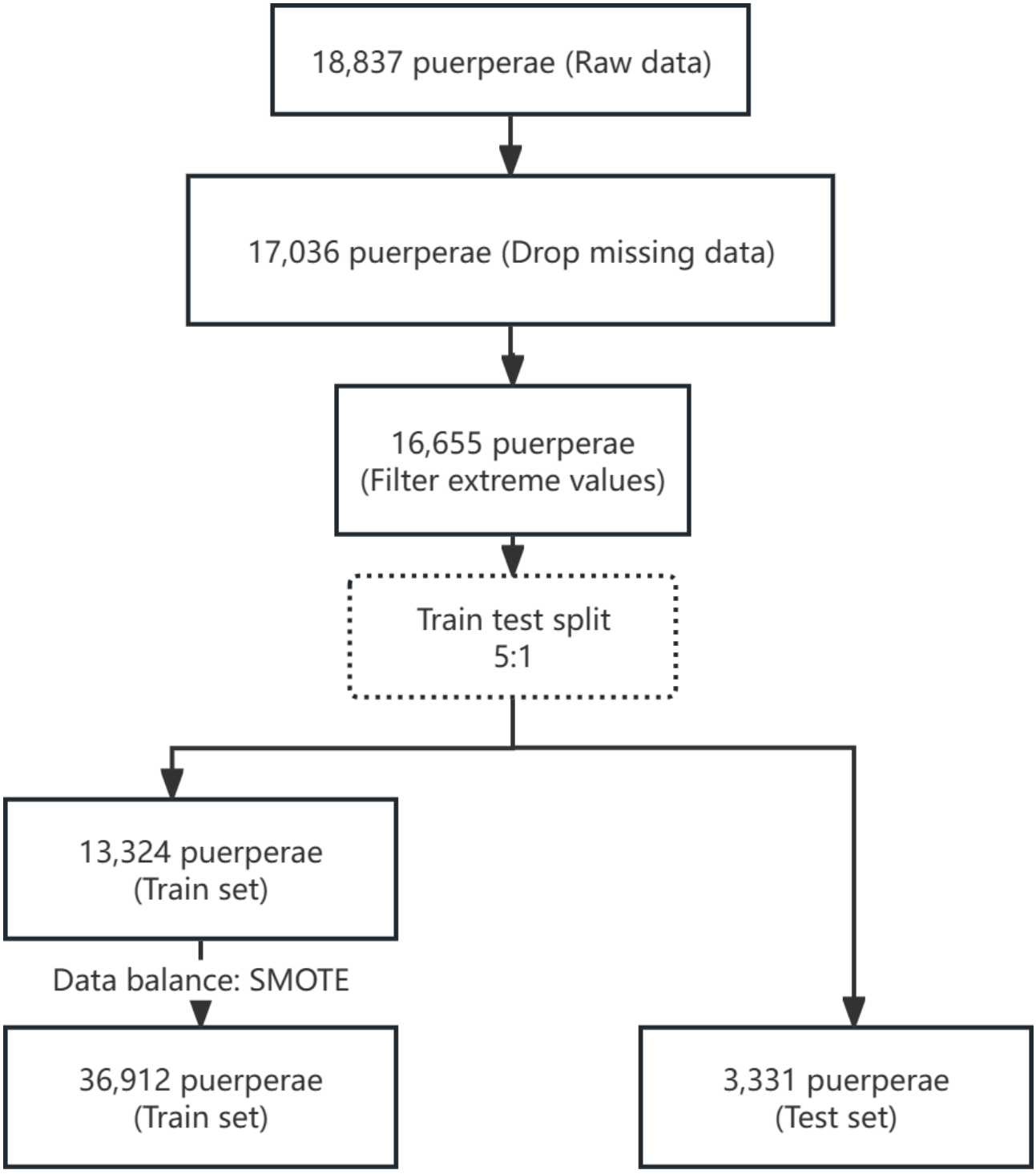
Sample Size and Clinical Features

A total of 16,655 individuals were enrolled in our study after application of inclusion criteria and data cleaning; 13,324 cases were included in the train dataset, and 3331 cases were included in the test dataset (Figure 2).

Table 1 provides an outline of clinical characteristics. The incidence of low birth weight and macrosomia did not differ statistically between the train dataset and the test dataset (low birth weight 1.79% vs 1.92%; *P*=.24; macrosomia 5.87% vs 5.88%; *P*=.98). There is generally good data consistency between the training dataset and the testing dataset (Table 1).

XSL•FO
RenderX

Figure 2. Chart illustrating patient flow in this study. SMOTE:Synthetic Minority Over-sampling Technique .



XSL•FO
RenderX

Table . Clinical characteristics of the train group and test group.

Characteristics		Train set (N=13,324)	Test set (N=3331)	*P* value
Fetal birth weight categories, n (%)				
	Low birth weight	238 (1.79)	64 (1.92)	.24
	Normal weight	12304 (92.34)	3071 (92.2)	.24
	Macrosomia	782 (5.87)	196 (5.88)	.98
Sociodemographic characteristics, mean (SD)				
	Preg_Days[a]	274.5 (8.1）	274.7 (8）	.82
	Gravida	1.9 (1.1）	1.9 (1.1）	.98
	Parity	1.3 (0.5）	1.3 (0.5）	≥.99
	pre_weight[b]	55.8 (7.9）	55.9 (8.2）	.98
	maternal_weight_last[c]	70.5 (9）	70.6 (9.1）	.99
	GA_last[d]	269.8 (8.9）	270 (9）	.68
	GWG[e]	14.7 (4.5）	14.7 (4.5）	.72
	height	161.9 (5）	161.9 (5）	.91
	pre_BMI[f]	21.3 (2.8）	21.3 (2.8）	.75
	SBP_first	111.3 (12.5）	111.2 (12.5）	.84
	DBP_first	69.4 (9.8）	69.4 (9.6）	.85
	GDM[g]	0.1 (0.3）	0.2 (0.4）	.7
	HDP[h]	0.1 (0.2）	0.1 (0.2）	≥.99
Ultrasound measurements, mean (SD)				
	BPD[i]	92.9 (4.1）	93 (4.1）	.47
	HC[j]	317.9 (13.2）	318.3 (13.4）	.34
	FL[k]	68.2 (3.3）	68.3 (3.3）	.36
	HL[l]	59.8 (3.2）	59.9 (3.3）	.07
	AC[m]	315.9 (20.2）	316.8 (19.8）	.16
	TTD[n]	99.8 (7.2）	100.2 (7.1）	.06
	APTD[o]	101.7 (7.4）	101.9 (7.5）	.42
	days_last_ul_to_delivery[p]	11.4 (8.8）	11.1 (8.6）	.22
	AFI[q]	126.3 (31.5）	125.6 (30.9）	.2
Laboratory indices, mean (SD)				
	FPG[r]	4.2 (0.4）	4.2 (0.4）	.87
	GLU-1H[s]	7.8 (1.5）	7.8 (1.6）	.32
	GLU-2H[t]	6.6 (1.4）	6.6 (1.4）	.73
	HBA_{1C}	5 (0.3）	5 (0.3）	.98
	HDL[u]	2 (0.4）	1.9 (0.4）	.29
	LDL[v]	2.5 (0.7）	2.6 (0.7）	.61
	TG[w]	1.4 (0.5）	1.4 (0.5）	.51
	TC[x]	4.5 (0.7）	4.5 (0.7）	.67

XSL•FO
RenderX

Characteristics	Train set (N=13,324)	Test set (N=3331)	*P* value
HGB[y]	118.7 (11.4)	118.8 (11.6)	.67

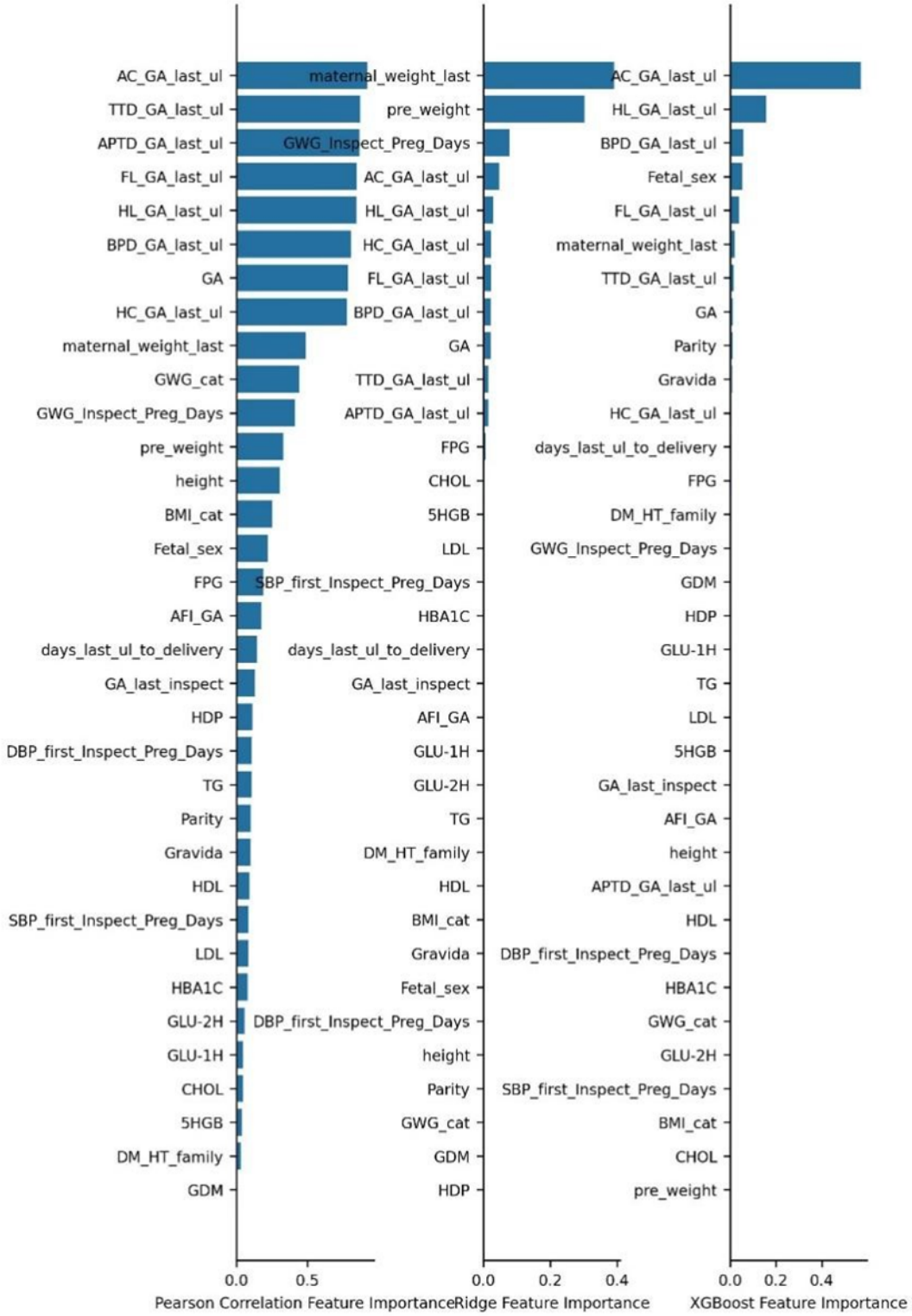
[a]Gestational age.
[b]Prepregnancy weight.
[c]Maternal weight at the last antenatal examination.
[d]Gestational age at the last antenatal examination.
[e]GWG: gestational weight gain.
[f]Prepregnancy body mass index.
[g]GDM: gestational diabetes mellitus.
[h]HDP: hypertensive disorders of pregnancy.
[i]BPD: biparietal diameter.
[j]HC:head circumference.
[k]FL: femur length.
[l]HL: humerus length.
[m]AC: abdominal circumference.
[n]TTD: transverse trunk diameter.
[o]ATD: anteroposterior trunk diameter.
[p]The number of days from the last antenatal ultrasound measurement to delivery.
[q]Sum of Amniotic Fluid Indices.
[r]Fasting plasma glucose.
[s]1-hour glucose.
[t]2-hour glucose.
[u]HDL: high-density lipoprotein.
[v]LDL: low-density lipoprotein.
[w]TG: triglycerides.
[x]TC: total cholesterol.
[y]HGB: hemoglobin

Variable Setting

Table S2 (Multimedia Appendix 1) displays 59 alternative variables, including sociodemographic characteristics, ultrasound measurements, and laboratory indices. In order to facilitate fetal birthweight prediction in the real world, a number of feature selection models were used to evaluate feature significance, as depicted in Figure 3. Due to the significance of features and the difficulty of obtaining them in the real world, few variables were eliminated before engineering implementation. A total of 17 variables were selected into our "few feather model," including "Parity," "pre_weight," "maternal_weight_last," "days_last_ul_to_delivery," "BMI," "GWG," "GA," "GWG_Inspect_Preg_Days," "GDM," "BPD," "HC," "FL," "HL," "AC," "TTD," "APTD," and "AFI" (Table 2). Those variables can be verbally responded to by pregnant women or extracted through an ultrasound report, instead of the blood test report requiring careful checking, which is convenient for clinical use and saves time.

XSL•FO
RenderX

Figure 3. Feature importance on different models.



XSL•FO
RenderX

Table . Meaning and value range of 17 features.

Variable	Variable meaning	Minimum	Maximum	Unit
Preg_Days	Gestational age	239	295	days
Parity	Parity	1	4	__[a]
pre_weight	Prepregnancy weight	40	125	kg
maternal_weight_last	Maternal weight at the last antenatal examination	43.6	129.3	kg
GA_last	Gestational age at the last antenatal examination	86	290	days
GWG	Gestational weight gain	−45.4	45.2	kg
pre_BMI	Prepregnancy body mass index	14.5	39.6	kg/m^2
GDM	Gestational diabetes mellitus	0	1	—
BPD	Biparietal diameter	53	109	mm
HC	Head circumference	197	367	mm
FL	Femur length	37	78	mm
HL	Humerus length	4	71	mm
AC	Abdominal circumference	158	381	mm
TTD	Transverse trunk diameter	45	130	mm
APTD	Anteroposterior trunk diameter	55	128	mm
days_last_ul_to_delivery	The number of days from the last antenatal ultrasound measurement to delivery	0	113	days
AFI	Sum of Amniotic Fluid Indices	12	333	mm

[a]Not available.

The Development and Performance of Prediction Model

The basic models, with the exception of KNN, were substantially superior to the ultrasound formula. Therefore, KNN was omitted from the ensemble model, which was a bagging ensemble model based on the results of the remaining 5 models. Using a variety of models, including basic models and an ensemble model, to predict fetal birthweight, and comparing the results of these models to those calculated by the original ultrasound formula, while keeping only a few essential and easily-obtained variables. The ensemble model with 17 variables predicted fantasy performance displayed in Table 3 with an accuracy of 81.84% (RE≤10%） and 66.98% (AE≤250 g) , and the MSE, RMSE, and MAE were the lowest when compared with other methods. (Table S3 in Multimedia Appendix 1, and Figures 4 and 5). The results demonstrated that the effect of the final ensemble learning is greater than that of the ultrasound formula and other single models.

XSL•FO
RenderX

Table . Evaluation on different models based on 17 features.

Model	Accuracy		MSE[c]	RMSE[d]	MAE[e] (g)
	RE[a] (≤10%)	AE[b] (≤250 g)			
Ultrasound formula methods					
Shinozuka's formula	0.71	0.59	125,65	354	266
Machine learning methods					
Ridge	0.79	0.64	76,14	276	220
XGBoost[f]	0.79	0.65	75,97	276	218
Random Forest	0.81	0.66	72,05	268	212
SVM[g]	0.79	0.64	75,99	276	220
KNN[h]	0.73	0.57	10,53	325	257
MLP[i]	0.80	0.67	77,08	278	212
Ensemble model	0.82	0.67	68,47	262	208

[a]RE: relative error.

[b]AE: absolute error.

[c]MSE: mean squared error.

[d]RMSE: root mean squared error.

[e]MAE: mean absolute error.

[f]XGBoost: extreme gradient boosting.

[g]SVM: support vector machine.

[h]KNN: k-nearest neighbor.

[i]MLP: Multilayer Perceptron.

XSL•FO
RenderX

Figure 4. Prediction scatter diagram based on 17 features (RE≤10%). SVM: support vector machine; KNN: k-nearest neighbor.

XSL•FO
RenderX

Figure 5. Prediction scatter diagram based on 17 features (AE≤250 g). SVM: support vector machine; KNN: k-nearest neighbor.

XSL•FO
RenderX

In addition, a segmented evaluation of the final prediction results was conducted, with division values of 2500 g and 4000 g for the 3 segments. Displaying the range of 10 percent metrics was selected. It demonstrates that the prediction effects of various models in various weight intervals were quite distinct. Some models performed better in the low weight interval, such as XGBoost and Random Forest, while others performed better in the high weight interval, such as Ridge and SVM. In addition, the MLP performed better in the normal weight range. The Ensemble Model combines the benefits and drawbacks of these distinct algorithm models, which has no serious shortcomings. The predictive effect of our established ensemble learning method significantly outweighs that of ultrasound. The accuracy for low birth weight can reach 70.30% (RE≤10%) and 73.44% (AE≤250 g). With 81.12% (RE≤10%) and 61.22% (AE≤250 g), the accuracy of macrosomia has also increased significantly (Figures 4 and 5). Besides, during the training process, trying to use more features (31 features) did not bring much improvement to the results with an accuracy of 83.49% (RE 10%) and 69.71% (AE≤250 g; Table S2, and Figure S1a and S1b in Multimedia Appendix 1). This group of controlled experiments shows that the 17 features are considered to be able to maintain good results, and to select easy obtain variables is of great significance for practical use.

Discussion

Principal Findings

As a key parameter for monitoring fetal development in utero, fetal birth weight can be used to evaluate fetal growth trends and screen for abnormal growth. Predicting the fetal birth weight in late gestation can effectively guide clinical decisions and reduce adverse pregnancy outcomes, such as increasing the survival of infants with intrauterine growth restriction and decreasing maternal-fetal complications in macrosomia delivery. Consequently, an accurate estimation of the fetal birth weight is crucial. Unfortunately, it is not possible to measure the fetal birth weight directly. Clinicians lack confidence in the estimation of the formula fetal birth weight at present due to the large variation in the accuracy of estimation results obtained through abdominal palpation or ultrasound measurement.

ML is based on clinical data, and the ML method is used to optimize health care resource use. The established ML algorithm model has high accuracy and is straightforward to implement; it is a win-win project that benefits patients, hospitals, and society; and it will have a major impact on the future of reproductive health.

In this study, data on pregnant women, including outpatient prenatal visits and hospital deliveries, was subjected to necessary feature processing and imbalanced data handling. A total of 5 ML methods were used as basic models for modeling through ensemble learning, which effectively balances the prediction effects of all models on fetuses in different weight ranges, achieving promising performance in predicting the different birth weights of newborns (low weight infants, normal weight infants, and macrosomia infants). The defining characteristic of ensemble learning is “Learn from the best.” First, it prevents underfitting by combining all the weaker learners and obtaining superior models through collective intelligence (in this case, like expert consultation, more complex learning models are obtained from advice from experts in different fields). Second, the integrated model prevents over-fitting: by combining all the results, it is simple to develop a more moderate model, thus avoiding some extreme case. Although it is not the best in all weight estimation ranges, the overall effect is the best, reducing the likelihood of large errors in a particular weight range.

In this study, the maternal sociodemographic characteristics and sonomicrometry data were inputs, and the predicted fetal birthweights were outputs of machine learning algorithms. Age, parity, mode of conception, education, prepregnancy weight and BMI, weight gain during pregnancy, gestational age, and GDM were the sociodemographic variables of the mothers. These variables are readily accessible in clinical practice and do not involve specific, difficult-to-obtain clinical indicators such as blood glucose, lipids, and protein levels, etc. In published prediction models, the input indicators usually include data such as uterine height [16] and pelvic measurements [13], which are subjective and prone to risk of bias.

Ultrasound as a direct method for measuring fetal size contributes significantly to the estimated fetal weight. Sonography is a time-saving, non-painful, and radiation-free tool that is widely used in obstetrics. In the third trimester, term-pregnant women in Shanghai undergo more than 2 or 3 ultrasound examinations. In our model, all ultrasonographic input data come from a reliable and accurate ultrasound report. In our model, we accounted for the time between the acquisition of ultrasound data and maternal delivery outcomes, which may have contributed to the model’s accuracy. However, Lu et al [16] and Shigemi et al [17] abandoned ultrasound data to benefit pregnant women in clinical practice, considering limited medical resources, whereas, at the expense of lower accuracy (the accuracy of Lu’s model is only 64.3%). Ultrasonography has become the most common auxiliary examination in obstetrics because of its security. In the vast majority of patient populations, ultrasound data need not be discarded. Our predictive model maximizes the clinical use of ultrasound and has significant implications for antenatal monitoring, antenatal assessment, intrapartum decision-making, and postpartum care. On the contrary, Ye et al [18] established an ensemble model, only used ultrasonographic measurements based on 26 different empirical ultrasonographic formulas. The risk factors associated with macrosomia were not collected thoroughly; therefore, the model did not provide the greatest benefits.

Compared with previously published predicted models, our model predicts fetal birth weight ranges with greater precision. Gao et al [14] adopted back propagation neural network model with the accuracy rate of 76.3%. Another previously published model reveals that the genetic algorithm-optimized neural network model’s accuracy is 74.9% [19]. In addition, 1 study found that the accuracy of prediction was only around 80% among GDM pregnant women [20]. Both low birth weight (2500 grams) and macrosomia (≥4000grams) are major public health concerns. In contrast to ultrasound’s poor performance in estimating extreme fetal weight, our model not only has excellent predictive performance in normal weight, but also in estimating extreme fetal weight. Although numerous studies

XSL•FO
RenderX

have been conducted in the field of predicting extreme body weight, many prediction models consist only of simple binary variables ("Yes or No") and do not provide quantitative results [13,21-23]. In our model, the evaluation metrics for accuracy were based on predicting birth weight within ±10% or ±250g, which are two of the most commonly used metrics in the existing literature. For larger birth weights, the ±250g metric may better reflect the accuracy of the model, while for smaller birth weights, the ±10% metric is more appropriate for assessing the model's precision. In our study results, the ensemble learning model demonstrated satisfactory predictive performance in both the <250 g and >4000 g subgroups. In contrast, other models exhibited better predictive ability in only one of the extreme weight categories. Our model's accurate estimation of fetal birth weight values will improve clinical decision-making and have significant clinical application value.

In order to turning our ML model into practice, we transformed the simple optimization model into a mobile application with a visual page to provide pregnant women, obstetricians, and midwives with a real-time, efficient method for fetal birthweight estimation (Figure S2 in Multimedia Appendix 1). In the future, with the purpose of improving the accuracy of fetal weight estimation, we will embed the original model into the doctor's medical record workstation so that it can cover more variables and retrieve the relevant data automatically.

Limitations

This model is primarily designed for monitoring the fetal growth trend in the third trimester, not the second. The subsequent research can further expand the data set (including the first and second trimesters) in order to optimize the ML algorithm for estimating the fetal weight at various gestational ages.

Fetal birthweight is also closely associated with genetic predisposition. In our study, we lack the husband or partner's more relevant information, such as weight, height, and weight gain during pregnancy. Provided it is possible, we can also obtain the parental birth weight. For further study, we can invite the husband or partner to join our first interview for more details.

Conclusions

Assessment of the fetal birth weight in late-pregnant women before delivery presents numerous challenges, but also presents an opportunity for the advancement of ML in the obstetric field. In our study, 5 fundamental algorithms (Ridge, SVM, Random Forest, XGBoost, and Multi-Layer Perceptron) and an ensemble learning model were investigated to determine the algorithm with the best performance in fetal birth weight prediction. As anticipated, ensemble learning performed the best and was chosen to create a mobile application for pregnant women and obstetric staff. We believe our model will promote precision medicine and improve the quality and efficiency of maternal and fetal health care, despite the need for additional experiments.

Acknowledgments

This work was supported by Shanghai Municipal Health Commission (Project 202140091). We would like to thank our study participants. Shanghai Municipal Health Commission (Project 202140091).

Data Availability

The data sets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

WC, XJ, JG, and JX designed the study. JG and RC were responsible for writing the manuscript. LC and JC collected and sorted out the data. YY and JX performed the statistical analysis. WC and XJ reviewed and edited the manuscripts. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary material.
[DOCX File, 722 KB - pediatrics_v8i1e59377_app1.docx]

References

1. Mayer C, Joseph KS. Fetal growth: a review of terms, concepts and issues relevant to obstetrics. Ultrasound Obstet Gynecol 2013 Feb;41(2):136-145. [doi: 10.1002/uog.11204] [Medline: 22648955]
2. Kadji C, Cannie MM, Resta S, et al. Magnetic resonance imaging for prenatal estimation of birthweight in pregnancy: review of available data, techniques, and future perspectives. Am J Obstet Gynecol 2019 May;220(5):428-439. [doi: 10.1016/j.ajog.2018.12.031] [Medline: 30582928]
3. Beta J, Khan N, Khalil A, Fiolna M, Ramadan G, Akolekar R. Maternal and neonatal complications of fetal macrosomia: systematic review and meta-analysis. Ultrasound Obstet Gynecol 2019 Sep;54(3):308-318. [doi: 10.1002/uog.20279] [Medline: 30938004]

XSL•FO
RenderX

4. Jin J. Babies with low birth weight. JAMA 2015 Jan 27;313(4):432. [doi: 10.1001/jama.2014.3698]
5. Chiossi G, Pedroza C, Costantine MM, Truong VTT, Gargano G, Saade GR. Customized vs population-based growth charts to identify neonates at risk of adverse outcome: systematic review and Bayesian meta-analysis of observational studies. Ultrasound Obstet Gynecol 2017 Aug;50(2):156-166. [doi: 10.1002/uog.17381] [Medline: 27935148]
6. Buck Louis GM, Grewal J, Albert PS, et al. Racial/ethnic standards for fetal growth: the NICHD Fetal Growth Studies. Am J Obstet Gynecol 2015 Oct;213(4):449. [doi: 10.1016/j.ajog.2015.08.032] [Medline: 26410205]
7. Dimassi K, Douik F, Ajroudi M, Triki A, Gara MF. Ultrasound fetal weight estimation: how accurate are we now under emergency conditions? Ultrasound Med Biol 2015 Oct;41(10):2562-2566. [doi: 10.1016/j.ultrasmedbio.2015.05.020] [Medline: 26164286]
8. Dittkrist L, Vetterlein J, Henrich W, et al. Percent error of ultrasound examination to estimate fetal weight at term in different categories of birth weight with focus on maternal diabetes and obesity. BMC Pregnancy Childbirth 2022 Mar 23;22(1):241. [doi: 10.1186/s12884-022-04519-z] [Medline: 35321691]
9. Malin GL, Bugg GJ, Takwoingi Y, Thornton JG, Jones NW. Antenatal magnetic resonance imaging versus ultrasound for predicting neonatal macrosomia: a systematic review and meta-analysis. BJOG 2016 Jan;123(1):77-88. [doi: 10.1111/1471-0528.13517] [Medline: 26224221]
10. Wu YT, Zhang CJ, Mol BW, et al. Early prediction of gestational diabetes mellitus in the Chinese population via advanced machine learning. J Clin Endocrinol Metab 2021 Mar 8;106(3):e1191-e1205. [doi: 10.1210/clinem/dgaa899] [Medline: 33351102]
11. Ren Y, Wu D, Tong Y, López-DeFede A, Gareau S. Issue of data imbalance on low birthweight baby outcomes prediction and associated risk factors identification: establishment of benchmarking key machine learning models with data rebalancing strategies. J Med Internet Res 2023 May 31;25:e44081. [doi: 10.2196/44081] [Medline: 37256674]
12. Venkatesh KK, Strauss RA, Grotegut CA, et al. Machine learning and statistical models to predict postpartum hemorrhage. Obstet Gynecol 2020 Apr;135(4):935-944. [doi: 10.1097/AOG.0000000000003759] [Medline: 32168227]
13. Wang F, Wang Y, Ji X, Wang Z. Effective macrosomia prediction using random forest algorithm. Int J Environ Res Public Health 2022 Mar 10;19(6):3245. [doi: 10.3390/ijerph19063245] [Medline: 35328934]
14. Gao H, Wu C, Huang D, Zha D, Zhou C. Prediction of fetal weight based on back propagation neural network optimized by genetic algorithm. Math Biosci Eng 2021 May 20;18(4):4402-4410. [doi: 10.3934/mbe.2021222] [Medline: 34198444]
15. Shinozuka N, Okai T, Kohzuma S, et al. Formulas for fetal weight estimation by ultrasound measurements based on neonatal specific gravities and volumes. Am J Obstet Gynecol 1987 Nov;157(5):1140-1145. [doi: 10.1016/s0002-9378(87)80278-8] [Medline: 3318464]
16. Lu Y, Fu X, Chen F, Wong KKL. Prediction of fetal weight at varying gestational age in the absence of ultrasound examination using ensemble learning. Artif Intell Med 2020 Jan;102:101748. [doi: 10.1016/j.artmed.2019.101748] [Medline: 31980089]
17. Shigemi D, Yamaguchi S, Aso S, Yasunaga H. Predictive model for macrosomia using maternal parameters without sonography information. J Matern Fetal Neonatal Med 2019 Nov;32(22):3859-3863. [doi: 10.1080/14767058.2018.1484090] [Medline: 29852791]
18. Ye S, Zhang H, Shi F, Guo J, Wang S, Zhang B. Ensemble learning to improve the prediction of fetal macrosomia and large-for-gestational age. J Clin Med 2020 Jan 31;9(2):380. [doi: 10.3390/jcm9020380] [Medline: 32023935]
19. Hailong Z, Jing T, Kai Y, Xuhong Z, Zhenming Y. Fetal weight prediction analysis based on GA-BP neural networks. Computer Systems & Applications 2018;27:162-167.
20. Zhou M, Ji J, Xie N, Chen D. Prediction of birth weight in pregnancy with gestational diabetes mellitus using an artificial neural network. J Zhejiang Univ Sci B 2022 May 15;23(5):432-436. [doi: 10.1631/jzus.B2100753] [Medline: 35557043]
21. Kuhle S, Maguire B, Zhang H, et al. Comparison of logistic regression with machine learning methods for the prediction of fetal growth abnormalities: a retrospective cohort study. BMC Pregnancy Childbirth 2018 Aug 15;18(1):333. [doi: 10.1186/s12884-018-1971-2] [Medline: 30111303]
22. Zou Y, Zhang Y, Yin Z, Wei L, Lv B, Wu Y. Establishment of a nomogram model to predict macrosomia in pregnant women with gestational diabetes mellitus. BMC Pregnancy Childbirth 2021 Aug 22;21(1):581. [doi: 10.1186/s12884-021-04049-0] [Medline: 34420518]
23. Sun M, Zhao B, He S, et al. The alteration of carnitine metabolism in second trimester in GDM and a nomogram for predicting macrosomia. J Diabetes Res 2020;2020:4085757. [doi: 10.1155/2020/4085757] [Medline: 32851095]

Abbreviations

AC: abdominal circumference
AE: absolute error
AFI: amniotic fluid index
APTD: anteroposterior trunk diameter
BMI: body mass index
BPD: biparietal diameter

XSL•FO
RenderX

DBP: diastolic blood pressure
FL: femur length
FPG: fasting plasma glucose
GA-BP: genetic algorithm to improve back propagation
GDM: gestational diabetes mellitus
GLU-1H: 1-hour glucose
GLU-2H: 2-hour glucose
GWG: gestational weight gain
HBG: hemoglobin
HC: head circumference
HDL: high-density lipoprotein
HL: humerus length
IMPCH: International Peace Maternity and Child Health Hospital
KNN: k-nearest neighbor
KS: Kolmogorov-Smirnov
LDL: low-density lipoprotein
MAE: mean absolute error
ML: machine learning
MLP: Multilayer Perceptron
MSE: mean squared error
NICU: neonatal intensive care unit
OGTT: oral glucose tolerance test
PCC: Pearson correlation coefficient
RE: relative error
RMSE: root mean squared error
SBP: systolic blood pressure
SVM: support vector machine
TC: total cholesterol
TG: triglycerides
TRIPOD: Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis
TTD: transverse trunk diameter
XGBoost: extreme gradient boosting

Edited by S Badawy; submitted 10.04.24; peer-reviewed by S Casciaro; revised version received 19.12.24; accepted 13.01.25; published 10.03.25.

Please cite as:
Gao J, Jie X, Yao Y, Xue J, Chen L, Chen R, Chen J, Cheng W
Fetal Birth Weight Prediction in the Third Trimester: Retrospective Cohort Study and Development of an Ensemble Model
JMIR Pediatr Parent 2025;8:e59377
URL: https://pediatrics.jmir.org/2025/1/e59377
doi:10.2196/59377

©Jing Gao, Yujun Yao, Jingdong Xue, Lei Chen, Ruiyao Chen, Jiayuan Chen, Jie Xu, Weiwei Cheng. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 10.3.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

An Online Family Literacy and Wellness Program for Latino Dual Language Learners: Pilot Randomized Waitlist Controlled Trial

Kevin D Guerrero[1], MS; Lucia Lakata[1], EdD; Daniel Lima[2], MSW; Caroline Mendoza[2], BA; Nila Uthirasamy[2], BA; Lesley M Morrow[3], PhD; Silvia Perez-Cortes[4], PhD; Maria Pellerano[5], MA, MBA, MPH; Alicja Bator[5], MPH; Pamela Ohman Strickland[6], PhD; Benjamin F Crabtree[5], PhD; Manuel E Jimenez[2], MS, MD

[1]Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ, United States

[2]The Boggs Center on Disability and Human Development, Department of Pediatrics, Rutgers Robert Wood Johnson Medical School, Liberty Plaza – 335 George Street, 3rd Floor, New Brunswick, NJ, United States

[3]Graduate School of Education, Rutgers University, New Brunswick, NJ, United States

[4]Camden College of Arts and Sciences, Rutgers University, Camden, NJ, United States

[5]Department of Family Medicine and Community Health, Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ, United States

[6]Rutgers School of Public Health, Piscataway, NJ, United States

Corresponding Author:
Manuel E Jimenez, MS, MD
The Boggs Center on Disability and Human Development, Department of Pediatrics, Rutgers Robert Wood Johnson Medical School, Liberty Plaza – 335 George Street, 3rd Floor, New Brunswick, NJ, United States

Abstract

Background: Early childhood interventions can simultaneously promote positive health and early language experiences, but implementation and health equity often receive insufficient attention during the development process.

Objective: We apply a health equity lens to refine and pilot-test a family literacy and wellness program designed for Latino dual language learners (DLLs) entering kindergarten and their caregivers.

Methods: In collaboration with a parent and community advisory board, we refined an 8-week family literacy and wellness program and conducted a pilot randomized controlled trial (RCT) with a waitlist control. The program, specifically designed by our interprofessional team for Latino DLLs, uses health topics (ie, nutrition, physical activity, sleep, and social-emotional development) to (1) introduce foundational language and literacy skills to children; (2) empower families to engage in health and home literacy activities using a strengths-based approach; and (3) encourage maintenance of families' home language. We assessed reach by collecting sociodemographic information; attendance and acceptability using a parent survey; and preliminary effects on home literacy activities through a validated parent-report instrument ($StimQ_2$ quantity, quality, content, and concepts subdomains) and on child literacy skills using investigator-developed assessments. We analyzed quantitative data using descriptive statistics and regression analyses.

Results: Parents and community advisors informed the program content. A total of 32 parent-child dyads were enrolled in the pilot RCT. All parents identified as Latino, and half had not completed high school, indicating that we reached the intended audience. Parents rated the program as highly acceptable, and 23 (72%) participants attended at least half of the sessions. After participation, group 1 had higher $StimQ_2$ quality scores (effect size 0.99, P=.02) and higher quantity scores (effect size 1.01, P=.04) compared with group 2.

Conclusions: Similar interprofessional collaborations may be a promising strategy to promote equity in early language experiences for Latino DLLs and their families.

Trial Registration: ClinicalTrials.gov NCT05339464; https://clinicaltrials.gov/ct2/show/NCT05339464

(JMIR Pediatr Parent 2025;8:e60764) doi:10.2196/60764

KEYWORDS

pediatrics; children; family; English as a second language; ESL; child development; development; wellness; health equity; dual language learner; literacy; language; Latinos; Spanish; Hispanic; randomized; controlled trials

XSL•FO
RenderX

Introduction

Education is critically important for health and well-being, yet this social driver of health has received insufficient attention in health care settings [1]. Kindergarten performance is a strong predictor of health risk behaviors and indicators of well-being, such as college education [2-4]. As a result, existing inequities in kindergarten readiness [5,6] pose a threat to long-term health and well-being at both individual and population levels.

The US Department of Health and Human Services and the US Department of Education define dual language learners (DLLs) as children with a home language other than English who are learning 2 or more languages simultaneously or learning a second language while still developing their first language [7]. Latino DLLs are a rapidly growing segment of the population who face discrimination and unequal opportunities, predisposing them to poor educational, occupational, and health outcomes [8,9]. Sustainable interventions to support this population are therefore urgently needed.

Pediatric clinicians are in a unique position to implement early childhood interventions that promote optimal school readiness, given their near-universal access to young children, frequent contact with families, and opportunities to build and leverage strong parent-clinician relationships [10-12]. Several programs are designed to be embedded within early childhood settings to promote early language development among DLLs [13,14]. However, early childhood interventions can simultaneously promote both physical and academic school readiness. Interventions focused on family literacy offer a clear example. Family literacy can be defined as the way families use literacy in their homes and communities, including during typical routines [15-17]. Families already engage in a wide range of literacy activities that are present in many health-related routines (eg, reading food labels). Embedding these practices into family literacy programs may provide a more ecologically valid intervention—one rooted in existing rather than entirely new practices and one that embraces cultural diversity. Few early childhood interventions take advantage of these opportunities. One example is a program that uses culturally sensitive, typical family food routines to support children's language and literacy skills, such as vocabulary, decoding, and writing [18]. Programs can adopt this approach to engage families and build cross-sector partnerships between pediatric professionals and educators—partnerships that find synergy in their complementary expertise. Despite their potential to promote equity through family engagement, such cross-sector partnerships remain rare.

Implementation often receives insufficient attention early in the development of health promotion interventions. This is critical, as a limited understanding of community context and partner priorities can potentially diminish—or even eliminate—an intervention's impact [19]. Baumann and Cabassa [19] identified key elements that can support the integration of an equity lens early in implementation research, including a focus on reach from the outset and the intentional design of interventions with historically marginalized populations in mind. Partnered approaches from the earliest stages of intervention design and refinement can help promote health equity, yet they remain rare. To our knowledge, few early childhood interventions have leveraged this strategy.

To address these gaps, we applied implementation science with a health equity lens to refine and pilot-test an online family literacy and wellness program designed for Latino DLLs entering kindergarten and their families. Using community-engaged research strategies, we partnered with parents to refine the program and subsequently conducted a pilot randomized controlled trial (RCT). Consistent with the approach proposed by Baumann and Cabassa [19], we intentionally focused on intervention reach, design, and equity-relevant implementation outcomes. These insights can inform similar cross-sector education-health care partnerships that aim to promote equity for Latino DLLs and their families.

Methods

Study Design and Registration

We conducted a pilot study using an RCT with a waitlist control design.

Ethical Considerations

The Rutgers Health Institutional Review Board approved this study (approval number Pro2021001575). All participants provided informed consent. Data were deidentified. Participants received a US $25 retail gift card for each study visit completed. The study was registered before enrollment of the first participant at ClinicalTrials.gov (NCT05339464). We followed CONSORT (Consolidated Standards of Reporting Trials) guidelines for reporting clinical trials [20].

Study Population and Setting

We recruited Latino DLLs (aged 4 - 6 years) and their parents from Eric B. Chandler Health Center, a local Federally Qualified Health Center, and the surrounding greater New Brunswick area. Eric B. Chandler Health Center primarily serves Latino individuals from underresourced communities. Clinicians at the center referred potentially eligible participants to the study team. We also advertised the study with our local community partners using recruitment flyers and word of mouth. Eligibility criteria included primary caregivers aged ≥18 years (referred to as parents for the remainder of this article) of children entering kindergarten who identified as Latino, used Spanish at home, owned a cellphone, and were willing to receive SMS text messages and be randomized. We excluded children with multiple anomalies or genetic disorders, as well as those with previously identified developmental delays.

Program Refinement

We partnered with our parent advisory board through a series of community engagement studios that helped refine the program throughout the project [21]. The parent advisory board consists of parents who participated in past iterations of the family literacy and wellness program. All parents identify as Latino and prefer Spanish as their primary language for communication. Their children are in kindergarten, first grade, or second grade, providing a range of scholastic experiences and perspectives on their children's needs. We conducted 7

XSL•FO
RenderX

community engagement studios with our parent advisory board from January 6, 2021, to January 30, 2023. We adapted the community engagement studio concept from the approach developed by the Meharry-Vanderbilt Community Engaged Research Core [21] to facilitate meaningful participation and engagement. Each studio focused on a specific aspect of the program. Bilingual team members presented relevant information about the program, and a bilingual research coordinator then facilitated dialogue to elicit parents' feedback on the content and procedures. Through this process, parent advisors provided substantive input on the program's mission, intervention content, and logistics. The project also includes a community advisory board composed of local community leaders, including educators, a pediatrician, a librarian, and a community health expert, that meets regularly to advise the team on outreach and engagement strategies, as well as program content.

Study Conditions

All parent-child dyads participated in the family literacy and wellness program, Ready and Healthy for Kindergarten. Parent-child dyads were enrolled and randomized 1:1 to either the first group (June-July) or the second group (July-August). The randomization schedule was computer generated by the study biostatistician (POS). Allocation concealment was maintained using the REDCap (Research Electronic Data Capture; Vanderbilt University) randomization module. Participants in both groups received a book bag with school supplies, an activity kit, and program books at enrollment. The program was specifically designed by our interdisciplinary team (ie, education, linguistics, and pediatrics) for Latino DLLs, using health topics (ie, nutrition, physical activity, sleep, and social-emotional development) to (1) introduce and reinforce foundational language and literacy skills to children, (2) empower families to engage in health and home literacy activities using a strengths-based approach, and (3) encourage the maintenance of families' home language and cultural traditions [22,23]. The program is designed to be strengths-based by building on families existing routines and inviting caregivers to incorporate new ones that support their goals and the objectives listed above. For example, during the nutrition topic, teachers may highlight how following a family recipe during meal preparation, whether written or recalled from memory, offers embedded opportunities for sequencing tasks, storytelling, and interaction. During the physical activity topic, teachers may point out how everyday simple family activities, such as walking to the bus stop, can include literacy-rich moments like reading street signs. Each session follows a predictable structure that draws out families' existing routines. Teachers use language flexibly and authentically, in alignment with the families' preferences, to tacitly normalize bilingualism and position home language maintenance as the standard, thereby empowering participation. In addition, the social-emotional unit includes a dedicated session focused on cultural pride, honoring one's heritage, and highlighting the advantages of multilingualism, explicitly encouraging the maintenance of the home language.

We first offered the program in person at Eric B. Chandler Health Center in 2019 [22]. This initial iteration established the program structure, which included (1) 8 parent-child workshops; (2) take-home kits, including a book bag with school supplies, activity kit, and program books, to support at-home extension activities that reinforced session content; and (3) reminder SMS text messages that reinforced in-class content [22]. In 2020, in response to the COVID-19 pandemic, the workshops shifted to an online format using videoconferencing software [23]. We retained the virtual format for the 8 parent-child workshops, which we then refined and pilot-tested in this study.

Data Collection

Trained bilingual research assistants collected data online via secure videoconference software at 3 time points: enrollment (study visit 1); approximately 2 months after enrollment, after group 1 completed the program and before group 2 began (study visit 2); and approximately 4 months after enrollment, after group 2 completed the program (study visit 3). Recruitment began in March 2024, the first study visit occurred on May 9, 2022, and the last study visit took place on September 25, 2022. In this paper, we focus on between-group differences in parent literacy and language activities and child outcomes at study visit 2, which captures the period after group 1 completed the program and before group 2 began.

Implementation Outcomes

Reach

As noted by Baumann and Cabassa [19], equity research requires attention to reach, that is, who is included in and participating in research. To assess whether the program reached its intended audience, we examined demographic characteristics of parent-child dyads, including ethnicity, parent education, and self-reported English proficiency.

Attendance

To understand the extent to which parents and children would use the program, we examined session attendance. A study team member documented attendance at each session.

Acceptability

Acceptability can be defined as users' perception of the extent to which a treatment or service is satisfactory [24]. In this study, we assessed acceptability using the Acceptability of Intervention Measure (AIM) [25], a validated 4-item survey that evaluates participants' perceptions of program acceptability.

Parenting and Child Outcomes

Parenting Outcomes

The $StimQ_2$ is a validated parent-report measure of the home cognitive environment, available in both English and Spanish [26]. In the validation sample, 93% of caregivers identified as Latino, 76% completed the surveys in Spanish, and 91% were classified as having low socioeconomic status based on the Hollingshead Four Factor Index. We used the $StimQ_2$ READ scale to explore the program's effects on parent-home literacy activities, focusing on subdomains that assess quantity, quality, content, and concepts. We used the $StimQ_2$ Parent Verbal Responsivity (PVR) scale to examine verbal responsivity during parent-child interactions. Both the READ and PVR subscales demonstrate good reliability (Cronbach α=0.753 and 0.790,

XSL•FO
RenderX

respectively) and strong validity, as indicated by correlations with assessments of child language, cognitive ability, and social-emotional skills.

Child Outcomes

We used investigator-developed assessments to explore the program's effect on child outcomes. These assessments were administered by a bilingual research assistant in the child's preferred language. Here, we focus on tests of children's development in letter identification, letter sound identification, thematic vocabulary identification, and book awareness. To assess book awareness, children were asked to identify different print concepts (ie, front and back cover, title page) using a book of their choice. The examination of letter and sound identification involved an untimed task in which children were asked to identify 10 different letters (presented in upper and lower case) and to produce their corresponding sounds. Vocabulary identification, focusing on words discussed during the workshops, such as healthy habits, foods, and family routines, was assessed using a picture-based vocabulary recognition task.

Sample Size

In determining our sample size, we considered the main objective of this pilot study, to examine equity-relevant implementation outcomes such as reach, engagement, and acceptability, and to explore the program's preliminary effects on parenting and child outcomes in an exploratory manner. We also followed best practice recommendations [27,28]. Based on these factors, our goal was to randomize at least 24 participants (12 per arm). The recruitment response exceeded our expectations, and we enrolled more participants to avoid turning interested families away.

Data Analysis

We first calculated means and SDs or percentages for continuous or categorical variables to examine reach using sociodemographic data, engagement using attendance logs, and acceptability using AIM survey responses. Participants were analyzed according to the group to which they were originally randomized. Participants who discontinued or were lost to follow-up were excluded from analyses. We used regression models to explore between-group differences in home literacy activities measured by the $StimQ_2$ READ scale total score and its subdomains, quantity, quality, diversity of concepts, and diversity of content, as well as responsive verbal interactions assessed by the $StimQ_2$ PVR. In addition, child literacy skills were evaluated using investigator-developed assessments focused on letter identification, letter-sound knowledge, vocabulary, and book awareness. We adjusted for the following important a priori–identified covariates: baseline scores, child age, child language, and parent education. To enable comparison across outcomes, we calculated effect size estimates by dividing the treatment coefficient from the regression models by the residual SD of each outcome.

Results

Program Refinement

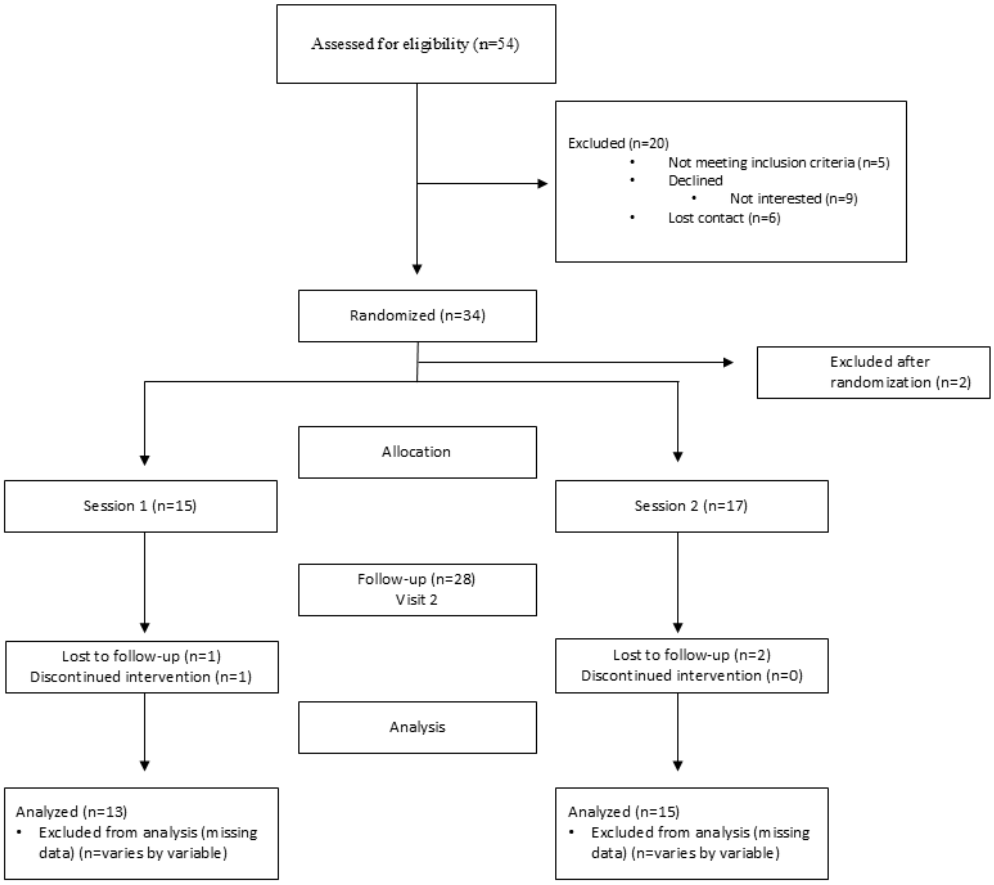
The parent advisory board helped shape the program's logistics and content. Drawing on their experience with the program, parents provided specific feedback that guided decisions about session length, program duration, and optimal dates and times for the online sessions. Synthesizing this feedback, we kept sessions under 1 hour, offered multiple evening options on weekdays, and scheduled Saturday sessions in the late morning or around noon. Parents also provided guidance and feedback on recruitment strategies and materials, which helped enhance reach. During meetings, they also offered input that informed adjustments to instructional pace, use of materials, and routines for parent-child interactions. Key considerations were whether the materials were easy to read and use at home. For example, children enjoyed opportunities to draw pictures starting with the session's focus letter, and parents shared that their children liked cutting out cards to practice letter sounds. As a result, we adapted the session content and at-home activity kits to include more opportunities for these activities. Families found the at-home extension activities enjoyable and identified them as a strength. Parents also reported that the school supplies sent home in the backpack were useful for their home learning environment.

Pilot Study

A total of 54 parent-child dyads initially expressed interest in participating; however, 5 of these dyads did not meet the inclusion criteria, 6 were lost to contact, and 9 declined participation. The most common reason for declining was lack of interest. Ultimately, we randomized 34 parent-child dyads (Figure 1). Two parent-child dyads were later excluded for not meeting eligibility criteria, resulting in a final enrolled sample of 32 dyads. Among these, 3 parent-child dyad groups were lost to follow-up, and 1 dyad discontinued participation, leaving 13 dyads in group 1, and 15 dyads in group 2.

XSL•FO
RenderX

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flowchart.



Reach

Demographic characteristics are summarized in Table 1. All participants identified as Latino (N=32), with 16 of 32 (50%) reporting Mexican origin; 29 out of 32 (91%) reported speaking English less than very well, and 17 (53%) had not completed high school. At enrollment, children were on average 4.5 years old, and 20 (63%) were identified as native-like Spanish speakers. These characteristics suggest that the program reached the intended audience.

XSL•FO
RenderX

Table . Demographic information of study participants at enrollment.

	Total (n=32)	Group 1 (n=15)	Group 2 (n=17)
Child age (years), mean (SD)	4.5 (0.5)	4.6 (0.5)	4.5 (0.5)
Child sex, n (%)			
Male	17 (53)	7 (47)	10 (59)
Female	15 (47)	8 (53)	7 (41)
Child's ability to speak Spanish, n (%)			
Speaks like a native speaker	20 (63)	7 (47)	13 (76)
Almost like a native speaker	6 (19)	4 (27)	2 (12)
Difficulty speaking it	5 (16)	3 (20)	2 (12)
Barely speaks it	1 (3)	1 (7)	0 (0)
Child's ability to understand Spanish, n (%)			
Understands it like a native speaker	22 (69)	9 (60)	13 (76)
Understands it for the most part	5 (16)	3 (20)	2 (12)
Difficulty understanding it	3 (9)	2 (13)	1 (6)
Barely understands it	2 (6)	1 (7)	1 (6)
Preschool attendance, n (%)			
Beginning at age 3	19 (59)	10 (67)	9 (53)
Beginning at age 4	9 (28)	4 (27)	5 (29)
Never attended	4 (13)	1 (7)	3 (18)
Parent's age (years), n (%)			
21-25	5 (16)	3 (20)	2 (12)
26-30	5 (16)	2 (13)	3 (18)
31-40	22 (69)	10 (67)	12 (71)
Parent's country of birth, n (%)			
Mexico	16 (50)	7 (47)	9 (53)
Honduras	5 (16)	3 (20)	2 (12)
Other	9 (28)	3 (20)	6 (35)
United States	2 (6)	2 (13)	0 (0)
Parent-reported English proficiency[a], n (%)			
Very well	3 (9)	2 (13)	1 (6)
Well	5 (16)	2 (13)	3 (18)
Not well	12 (38)	7 (47)	5 (29)
Not at all	12 (38)	4 (27)	8 (47)
Parent's highest level of education, n (%)			
Less than eighth grade	7 (22)	3 (20)	4 (24)
Ninth to twelfth grade (no diploma)	10 (31)	2 (13)	8 (47)
High school diploma or greater	15 (47)	10 (67)	5 (29)

[a]Parents' response to "How well do you speak English?"

Attendance

Program attendance is summarized in Table 2. Seventy-two percent of parents (23/32) attended at least half of the sessions. Timing appeared to influence attendance, with lower participation observed in the second half of the summer. Some families reported traveling internationally or taking on additional

XSL•FO
RenderX

seasonal work during this period, which may have impacted their ability to attend.

Table . Number of workshops attended by participants during the family literacy and wellness program (n=32).

Number of sessions attended	Number of participants
0	4
1	1
2	2
3	2
4	3
5	2
6	5
7	5
8	8

Acceptability

On average, parents agreed that the program met their approval, it was appealing, they liked the program, and they welcomed what they learned (Table 3).

Table . Acceptability of intervention survey among the study population (n=25 parents).

AIM[a] question	AIM score, mean (SD); range[b]
The program met my approval.	3.5 (0.5); 3-4
The program was appealing to me.	3.5 (0.5); 3-4
I liked the program.	3.5 (0.5); 3-4
I welcome what I learned in the program.	3.5 (0.5); 3-4

[a]AIM: Acceptability of Intervention Measure.

[b]0=completely disagree, 1=disagree, 2=neither agree nor disagree, 3=agree, and 4=completely agree.

Parenting Outcomes

Results of the $StimQ_2$ READ and PVR scales are presented in Table 4. Although not statistically significant, there was a moderate difference on the total $StimQ_2$ READ scale between group 1 (ie, those who completed the program) and group 2 (ie, those who had not yet begun; Cohen *d*=0.55; *P*=.23). However, there were large and statistically significant differences between the groups on the quantity and quality subdomains (Cohen *d*=1.01; *P*=.04 and Cohen *d*=0.99; *P*=.02). By contrast, the between-group difference on the PVR scale was small and not statistically significant (*P*=.75).

Table . Effects of Ready and Healthy for Kindergarten participation (group 1) compared with waitlist control (group 2) on the Home Literacy Environment and Parent Verbal Responsivity scale scores.[a]

Measures	Group 1, effect size estimate (95% CI)	*P* value
$StimQ_2$ READ scale[b]		
Total score	0.55 (−0.44 to 1.10)	.23
Subdimensions		
Book reading quantity	1.01 (0.05 to 1.52)	.04
Book reading concepts	−0.20 (−1.41 to 0.52)	.66
Book reading content	0.02 (−1.09 to 0.68)	.95
Book reading quality	0.99 (0.18 to 1.41)	.02
$StimQ_2$ Parent Verbal Responsivity Scale[b]	0.14 (−0.92 to 0.76)	.75

[a]Linear regression analyses were conducted, adjusting for baseline scores, child age, child language, and parent education. Effect size estimates were calculated by dividing the treatment coefficient from the regression models by the residual SD of each outcome.

[b]Subscale of the $StimQ_2$-Preschool, a parent-report questionnaire that assesses the cognitive home environment for children aged 36-72 months.

XSL•FO
RenderX

Child Outcomes

Child outcomes are summarized in Table 5. Between-group differences in letter identification, letter-sound knowledge, and vocabulary were either minimal or in an unexpected direction. However, a moderate-to-large effect, though not statistically significant, was observed for book awareness (Cohen *d*=0.82; *P*=.11).

Table . Effects of Ready and Healthy for Kindergarten participation (group 1) compared with waitlist control (group 2) on child skills.[a]

	Group 1, effect size estimate (95% CI)	*P* value
Letters identified	0.07 (−1.07 to 0.71)	.88
Letters sounds identified	−0.03 (−1.18 to 0.64)	.95
Vocabulary words identified	−1.68 (−5.84 to 0.21)	.10
Book awareness	0.82 (−0.23 to 1.35)	.11

[a]Linear regression analyses were conducted, adjusting for baseline scores, child age, child language, and parent education. Effect size estimates were calculated by dividing the treatment coefficient from the regression models by the residual SD of each outcome.

Discussion

Principal Findings

In this study, we refined an online family literacy and wellness program using parent feedback. During pilot testing, we found that the program effectively reached and engaged Latino DLLs and their families. We also observed promising improvements in parent home literacy activities after participation. The intentional involvement of families and community partners throughout the research process, along with a deliberate focus on reach and other early implementation outcomes, provided valuable insights into applying a health equity lens to early childhood interventions. These findings offer guidance for interdisciplinary teams aiming to build cross-sector collaborations and move beyond siloed efforts in the pursuit of equity.

The US Centers for Disease Control and Prevention defines health equity as “the state in which everyone has a fair and just opportunity to attain their highest level of health” [29]. The Robert Wood Johnson Foundation elaborates that achieving health equity “requires removing obstacles to health such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and health care” [30]. Such obstacles drive health inequities, and health care organizations have developed programs in response to growing evidence that social needs impact health [31]. However, health care interventions have largely missed the opportunity to address educational achievement, an important social driver of health that underlies both social and health outcomes [32]. As a cross-sector partnership between health and education, Ready and Healthy for Kindergarten aims to promote health equity by coaching families on how to implement healthy routines early, while supporting children’s development of literacy and numeracy skills that foster health literacy and wellness throughout their life course.

All caregivers in our sample identified as Latino, and half had not completed high school, indicating that the program successfully reached the intended audience. The family literacy and wellness program was designed to address the specific needs of this population, with careful consideration of their linguistic and ethnic backgrounds. Central to this approach, our program is bilingual, supporting children’s language development while honoring and accommodating parents’ linguistic preferences. The focus on families from Latino backgrounds encompassed not only the language of implementation but also the cultural aspects embedded in the program. Meta-analyses support that family literacy programs increase parent literacy activities and improve child emergent literacy [33,34]. However, low participation and engagement among Latino parents from underresourced communities have been major weaknesses of these programs [35]. There are important modifiable program design weaknesses [18]. First, similar programs have been criticized for taking a deficit approach and imposing dominant cultural activities on families without building on their unique strengths [35,36]. Such approaches do not take into account parents’ experiences with activities such as reading, which may be negative [37]. Second, while bilingual programs are emerging, most do not build on families’ heritage language, which is a major issue [38-41]. Third, there is a paucity of studies focused on engagement with Latino families from underresourced communities [18]. By engaging parents as partners throughout the research process and refining the program based on their feedback, we were able to overcome many of these barriers and reach the intended audience with high attendance levels.

Consistent with previous work, we found that the online family literacy and wellness program was well attended and highly acceptable to families [22,23]. This study extends our prior work by demonstrating promising patterns in both the quantity and quality of home literacy activities. Although we did not identify differences in letter identification, letter-sound knowledge, and vocabulary, it is possible that 8 weeks is not sufficient time to detect these differences. Although not statistically significant, the moderate to large effect on book awareness aligns with the enhanced quantity and quality of home literacy activities. One possibility is that by increasing parent literacy activities during the summer before kindergarten, improvements in child outcomes may be observed later. Future studies will need to follow children for a longer period to test this hypothesis—an issue we are currently addressing in our ongoing work.

This work is subject to certain limitations. First, while pervasive inequities in school readiness and wellness provide a strong rationale for focusing on Latino DLLs and their families, our

XSL•FO
RenderX

findings may not generalize to all settings or other populations. Future work is needed to tailor program content for participants from different racial and ethnic backgrounds. Second, as this was a pilot study, the primary focus was on examining equity-focused implementation outcomes including reach, attendance, and acceptability. While a sample size of 32 aligns with recommendations for pilot studies [27,28], it is possible that the statistical analyses did not have adequate power to detect differences in parent and child outcomes that may be meaningful. Further, we were unable to examine a threshold for the dose of the intervention necessary to affect outcomes; we are addressing this limitation in our ongoing work. Third, we relied on parent-report measures for home literacy activities and health routines, which may be subject to recall bias and social desirability. Future work should incorporate observational measures to help address this limitation. Fourth, engagement with an intervention goes beyond usage and must capture the relationship between the program and the intended goal of the intervention [42], in this case empowering caregivers to build on their existing strengths and support their children's physical health and school readiness. While this was beyond the scope of this pilot study, we plan to address it in future work.

Conclusion

We found that a family literacy and wellness program designed for Latino DLLs reached the intended audience, achieved strong attendance, and showed promising patterns in home literacy activities. While additional work is needed to definitively test the program's effects and identify optimal implementation strategies, these findings suggest that such interdisciplinary collaborations could be a promising approach to promote equity in children's early language experiences.

Acknowledgments

This project was funded under grant number R18HS028574 from the Agency for Healthcare Research and Quality (AHRQ), US Department of Health and Human Services (HHS). The authors are solely responsible for this document's contents, findings, and conclusions, which do not necessarily represent the views of AHRQ. Readers should not interpret any statement in this report as an official position of AHRQ or HHS. None of the authors have any affiliation or financial involvement that conflicts with the material presented in this report. We thank our partners who contributed to the development and delivery of this program. The parents on the Parent Advisory Board generously contributed their time and ideas to refine the program and set its priorities. The board included the following parents: Morena Castillo, Nely Chanes, Sofia Gonzalez, Aleyda Elias, Gabriela Zepeda, Glennys Cruz, and Romina Jimenez. The sessions were facilitated by two dedicated teachers, Lirizell Johnson and Diana Galindo. They contributed to the refinement of the sessions, built positive relationships with the children and their families, and brought enthusiasm to each session. We also acknowledge the support from the staff at Greater Brunswick Charter School, especially Lilia Fabila-Guilbot and Hector Alvarez, for their contributions to this program and their commitment to promoting child and family well-being. Additionally, we thank pediatricians Drs. Usha Ramachandran and Shilpa Pai for their support.

Conflicts of Interest

None declared.

Checklist 1
CONSORT-EHEALTH checklist.
[PDF File, 453 KB - pediatrics_v8i1e60764_app1.pdf]

References

1. Peterson JW, Loeb S, Chamberlain LJ. The intersection of health and education to address school readiness of all children. Pediatrics 2018 Nov;142(5):e20181126. [doi: 10.1542/peds.2018-1126] [Medline: 30366953]
2. Chetty R, Friedman JN. School quality and income inequality: the long-term effects of early childhood education. : Federal Reserve Bank of Boston; 2011.
3. Chetty R, Friedman JN, Hilger N, Saez E, Schanzenbach DW, Yagan D. How does your kindergarten classroom affect your earnings? Evidence from Project Star. Q J Econ 2011;126(4):1593-1660. [doi: 10.1093/qje/qjr041] [Medline: 22256342]
4. Chetty R, Cutler D, Stepner M. Effects of local health interventions on inequality in life expectancy: new publicly available data. Am J Public Health 2016 Dec;106(12):2154-2155. [doi: 10.2105/AJPH.2016.303492] [Medline: 27736211]
5. Reardon SF, Portilla XA. Recent trends in income, racial, and ethnic school readiness gaps at kindergarten entry. AERA Open 2016 Jul;2(3):1-18. [doi: 10.1177/2332858416657343]
6. Ricciardi C, Manfra L, Hartman S, Bleiker C, Dineheart L, Winsler A. School readiness skills at age four predict academic achievement through 5th grade. Early Child Res Q 2021;57:110-120. [doi: 10.1016/j.ecresq.2021.05.006]
7. US Department of Health and Human Services, US Department of Education. Policy statement on supporting the development of children who are dual language learners in early childhood programs. Education Resources Information Center. 2016. URL: https://eric.ed.gov/?id=ED566723 [accessed 2025-06-11]
8. Romo HD, Thomas KJA, García EE. Changing demographics of dual language learners and English learners: implications for school success. Soc Policy Rep 2018 Jun;31(2):1-35. [doi: 10.1002/j.2379-3988.2018.tb00028.x]

XSL•FO
RenderX

9. National Research Council (US) and Institute of Medicine (US) Committee on Integrating the Science of Early Childhood Development. In: Shonkoff JP, Phillips DA, editors. From Neurons to Neighborhoods: The Science of Early Childhood Development: National Academies Press; 2000. [doi: 10.17226/9824] [Medline: 25077268]
10. Jimenez ME, Crabtree BF, Hudson SV, et al. Enhancing reach out and read with a video and text messages: a randomized trial in a low-income predominantly Latino sample. Acad Pediatr 2021 Aug;21(6):968-976. [doi: 10.1016/j.acap.2021.02.011] [Medline: 33618060]
11. Cates CB, Weisleder A, Mendelsohn AL. Mitigating the effects of family poverty on early child development through parenting interventions in primary care. Acad Pediatr 2016 Apr;16(3 Suppl):S112-S120. [doi: 10.1016/j.acap.2015.12.015] [Medline: 27044688]
12. Jimenez ME, Crabtree BF, Veras J, et al. Latino parents' experiences with literacy promotion in primary care: facilitators and barriers. Acad Pediatr 2020;20(8):1177-1183. [doi: 10.1016/j.acap.2020.08.003] [Medline: 32795690]
13. Hur JH, Snyder P, Reichow B. Systematic review of English early literacy interventions for children who are dual language learners. Topics Early Child Spec Educ 2020 May;40(1):6-23. [doi: 10.1177/0271121419894623]
14. Wilson SJ, Dickinson DK, Rowe DW. Impact of an early reading first program on the language and literacy achievement of children from diverse language backgrounds. Early Child Res Q 2013;28(3):578-592. [doi: 10.1016/j.ecresq.2013.03.006]
15. Taylor D. Family Literacy: Young Children Learning to Read and Write: Heinemann Ed Books; 1983.
16. Morrow LM, Neuman SB. Introduction: family literacy. Read Teach 1995;48(7):550-551.
17. Morrow LM, Paratore J, Gaber D, et al. Family literacy - perspective and practices. Read Teach 1993;47(3):194-200.
18. Leyva D, Skorb L. Food for thought: family food routines and literacy in Latino kindergarteners. J Appl Dev Psychol 2017 Sep;52:80-90. [doi: 10.1016/j.appdev.2017.07.001]
19. Baumann AA, Cabassa LJ. Reframing implementation science to address inequities in healthcare delivery. BMC Health Serv Res 2020 Mar 12;20(1):190. [doi: 10.1186/s12913-020-4975-3] [Medline: 32164706]
20. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Med 2010 Mar 24;8:18. [doi: 10.1186/1741-7015-8-18] [Medline: 20334633]
21. Joosten YA, Israel TL, Williams NA, et al. Community engagement studios: a structured approach to obtaining meaningful input from stakeholders to inform research. Acad Med 2015 Dec;90(12):1646-1650. [doi: 10.1097/ACM.0000000000000794] [Medline: 26107879]
22. Shelton PA, Morrow LM, Lima D, et al. Ready and healthy for kindergarten: a bilingual family literacy program in primary care. Matern Child Health J 2021 Apr;25(4):521-527. [doi: 10.1007/s10995-020-03115-x] [Medline: 33449273]
23. Choi Y, Uthirasamy N, Córdoba D, et al. Feasibility and acceptability of an online family literacy program in an under-resourced community during the COVID-19 pandemic. J Dev Behav Pediatr 2023;44(2):e104-e110. [doi: 10.1097/DBP.0000000000001155] [Medline: 36750983]
24. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health 2011 Mar;38(2):65-76. [doi: 10.1007/s10488-010-0319-7] [Medline: 20957426]
25. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci 2017 Aug 29;12(1):108. [doi: 10.1186/s13012-017-0635-3] [Medline: 28851459]
26. Cates CB, Roby E, Canfield CF, et al. Validation of the StimQ2: a parent-report measure of cognitive stimulation in the home. PLoS One 2023;18(7):e0286708. [doi: 10.1371/journal.pone.0286708] [Medline: 37486914]
27. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. Am J Prev Med 2009 May;36(5):452-457. [doi: 10.1016/j.amepre.2009.02.002] [Medline: 19362699]
28. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharm Stat 2005 Oct;4(4):287-291. [doi: 10.1002/pst.185]
29. Health equity. Centers for Disease Control and Prevention (CDC). URL: https://www.cdc.gov/health-equity/what-is/index.html [accessed 2024-12-16]
30. Braveman P, Arkin E, Orleans T, Proctor D, Plough A. What Is Health Equity? And What Difference Does a Definition Make: Robert Wood Johnson Foundation; 2017. URL: https://nccdh.ca/resources/entry/what-is-health-equity-and-what-difference-does-a-definition-make [accessed 2025-06-13]
31. Gottlieb LM, DeSalvo K, Adler NE. Healthcare sector activities to identify and intervene on social risk: an introduction to the American Journal of Preventive Medicine supplement. Am J Prev Med 2019 Dec;57(6 Suppl 1):S1-S5. [doi: 10.1016/j.amepre.2019.07.009] [Medline: 31753275]
32. Fiscella K, Kitzman H. Disparities in academic achievement and health: the intersection of child education and health policy. Pediatrics 2009 Mar;123(3):1073-1080. [doi: 10.1542/peds.2008-0533] [Medline: 19255042]
33. Sénéchal M, Young L. The effect of family literacy interventions on children's acquisition of reading from kindergarten to grade 3: a meta-analytic review. Rev Educ Res 2008 Dec;78(4):880-907. [doi: 10.3102/0034654308320319]
34. Steensel R, McElvany N, Kurvers J, et al. How effective are family literacy programs?: Results of a meta-analysis. Rev Educ Res 2011 Mar;81(1):69-96. [doi: 10.3102/0034654310388819]
35. Anderson A, Anderson J, Gear A. Family literacy programs as intersubjective spaces: insights from three decades of working in culturally, linguistically and socially diverse communities. Lang Lit 2015 Jun;17(2):41. [doi: 10.20360/G2N30D]

XSL•FO
RenderX

36. Auerbach ER. Toward a social-contextual approach to family literacy. Harv Educ Rev 1989 Jul 1;59(2):165-182. [doi: 10.17763/haer.59.2.h237131364l283156]
37. Janes H, Kermani H. Caregivers' story reading to young children in family literacy programs: pleasure or punishment. J Adolescent Adult Lit 2001 Feb;44(5):458-466.
38. Anderson J, Anderson A, Friedrich N, Teichert L. "You Guys Should Offer the Program more Often!": some perspectives from working alongside immigrant and refugee families in a bilingual family literacy program. In: McLachlan C, Arrow A, editors. Literacy in the Early Years: Springer; 2017. [doi: 10.1007/978-981-10-2075-9_4]
39. Hirst K, Hannon P, Nutbrown C. Effects of a preschool bilingual family literacy programme. J Early Child Lit 2010 Jun;10(2):183-208. [doi: 10.1177/1468798410363838]
40. Rodriguez-Brown FV. Latino culture and schooling: reflections on family literacy with a culturally and linguistically different community. In: Dunsmore K, Fisher D, editors. Bringing Literacy Home: International Reading Association:2010.
41. Reyes LV, Torres MN. Decolonizing family literacy in a culture circle: reinventing the family literacy educator's role. J Early Child Lit 2007 Apr;7(1):73-94. [doi: 10.1177/1468798407074837]
42. Yardley L, Spring BJ, Riper H, et al. Understanding and promoting effective engagement with digital behavior change interventions. Am J Prev Med 2016 Nov;51(5):833-842. [doi: 10.1016/j.amepre.2016.06.015] [Medline: 27745683]

Abbreviations

AIM: Acceptability of Intervention Measure
CONSORT: Consolidated Standards of Reporting Trials
DLL: dual language learner
PVR: Parent Verbal Responsivity
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture

Edited by A Nguyen; submitted 20.05.24; peer-reviewed by D Walker, GD Lara; revised version received 19.12.24; accepted 16.01.25; published 19.06.25.

Please cite as:
Guerrero KD, Lakata L, Lima D, Mendoza C, Uthirasamy N, Morrow LM, Perez-Cortes S, Pellerano M, Bator A, Ohman Strickland P, Crabtree BF, Jimenez ME
An Online Family Literacy and Wellness Program for Latino Dual Language Learners: Pilot Randomized Waitlist Controlled Trial
JMIR Pediatr Parent 2025;8:e60764
URL: https://pediatrics.jmir.org/2025/1/e60764
doi:10.2196/60764

© Kevin D Guerrero, Lucia Lakata, Daniel Lima, Caroline Mendoza, Nila Uthirasamy, Lesley M Morrow, Silvia Perez-Cortes, Maria Pellerano, Alicja Bator, Pamela Ohman Strickland, Benjamin F Crabtree, Manuel E Jimenez. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 19.6.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Review

Effect of Digital Safety Interventions on Parental Practices in Safeguarding Children's Digital Activities: Systematic Review and Meta-Analysis

Maggie Zgambo[1,2], BSc, MSc, PhD; Edah Anyango[1], BSc, PhD; Diana H Arabiat[1,2,3,4*], BSc, PhD, MSc; Irene Ngune[1*], BSc, MPH, MSc, PhD; Evalotte Mörelius[1,2,3,5*], BSc, MSc, PhD; Min Zhang[1], BMed, MSc; Lisa Claire Whitehead[1,2,3,6*], BSc, MA, PhD

[1]School of Nursing and Midwifery, Edith Cowan University, Perth, Australia

[2]ARC Centre of Excellence for the Digital Child, Brisbane, Australia

[3]Maternal and Child Nursing Department, School of Nursing, The University of Jordan, Amman, Jordan

[4]JBI The University of Jordan Health Research Centre, University of Jordan, Amman, Jordan

[5]Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden

[6]The Centre for Evidence Informed Nursing, Midwifery and Healthcare Practice:, A JBI Affiliated Group, Adelaide, Australia

[*]these authors contributed equally

Corresponding Author:
Maggie Zgambo, BSc, MSc, PhD
School of Nursing and Midwifery
Edith Cowan University
270 Joondalup Dr
Joondalup
Perth, 6027
Australia
Phone: 61 863047178
Email: m.zgambo@ecu.edu.au

Abstract

Background: The prevalence of and growth in digital technology present opportunities for educational and social enrichment; however, there are also many health and digital safety risks for children engaging with digital technology. While there is a growing body of research on digital safety programs to enhance children's digital safety through parental support, evidence regarding the effectiveness of such interventions remains limited.

Objective: This study aimed to evaluate the effectiveness of digital safety interventions on parental practices related to safeguarding children's digital activities.

Methods: The review was conducted following the Joanna Briggs Institute methodology for systematic reviews and has been reported in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. A comprehensive search was performed in May 2024 in MEDLINE, CINAHL Ultimate, PsycINFO, Web of Science, The Allied and Complementary Medicine Database, ProQuest Central, and IEEE Xplore databases to identify peer reviewed articles that were (1) published in English, (2) included parents as participants, and (3) reported on programs or interventions designed to enhance parents' knowledge and skills to safeguard children's digital safety.

Results: A total of 11 published studies between 2012 and 2024 were included in the review. Data from 8 studies were included in the meta-analysis. A significant effect (Hedges g=–0.47; 95% CI –0.85 to –0.08; P<.001) was observed in children's screen time in the 5 randomized controlled studies, while a large effect size was observed in 3 quasi-experimental studies (Hedges g=1.90; 95% CI –4.36 to 8.16; P<.001). A substantial level of heterogeneity was evident in the randomized studies (I^2=87.95%). The quasi-experimental studies exhibited no heterogeneity (I^2=0%). Overall, parents' digital safety knowledge and skills improved as a result of the digital safety interventions. Notably, children's screen time (P=.04) and parents' own screen time (P=.001) decreased following the digital safety intervention.

Conclusions: Parents who participate in digital safety interventions report higher levels of knowledge and skills related to digital safety, as well as a shift in attitudes, including the intention to implement strategies to safeguard their children engaging with

XSL•FO
RenderX

technology. The enhanced knowledge and skills reported in these studies led to measurable reductions in both parents' and children's screen time. Future research should identify strategies that address community norms and other digital safety risks beyond screen time and bullying, which were predominant outcomes in these studies.

(JMIR Pediatr Parent 2025;8:e70745) doi:10.2196/70745

KEYWORDS

child; parental mediation; digital safety; parental education; meta-analysis; intervention effectiveness; screen time; digital technology; digital literacy

Introduction

Technology has transformed the way children learn, socialize, and interact with the world. Internet and digital technology have made access to new information from afar more accessible and immediate [1,2]. Digital technology is embedded in the school system [3] and this means that children spend a significant portion of their time engaging with and using digital technologies to perform daily tasks such as homework, to form and nurture friendships, and for entertainment [1]. These digital advancements offer a wealth of opportunities for educational and social growth, with evidence indicating that moderate use of digital technology can positively impact children's learning, development, and mental well-being [4,5], mainly through enhancing children's literacy and numeracy skills, manual dexterity, and visuo-spatial working memory [6]. The rapid integration of digital technologies into daily life has increased the use of digital technology in schools and at home, with parents admitting being obligated to embrace the digital world that is often new to them, as their children now access web-based school learning resources, such as homework and timetables [7]. Digital technology use has impacted children of all ages, including children less than a year old, who spend time on digital media privately or independently [5]. However, in Australia, digital technology use and access to digital platforms increase with age, with adolescents (13-17 years) having access to various social media platforms, such as YouTube (86%), Facebook (75%), Snapchat (67%), and Instagram (70%) [8].

Healthy digital use among children has been debated, with Suresh and Tiwari [5] recommending minimal technology use of 1 to 2 hours a day for children aged 3 to 8 years. The American Academy of Pediatrics reinforces this stance, and they further recommend that children younger than 2 years should not engage in screen time [9]. In 2016, the Canadian Society of Exercise Physiology released the 24-hour movement guidelines tailored for children and young people aged 5 to 17 years, which are intended to assist parents and educators to promote appropriate daily levels of physical activity, manage screen time, and ensure adequate sleep duration [10]. Various countries, including Australia [11], South Africa [12], and New Zealand [13], along with international bodies such as the World Health Organization [14], have adopted these guidelines. However, experts from the Australian Research Council Centre of Excellence for the Digital Child have contended that while limiting screen time is often recommended in these guidelines, such restrictions may overlook potential developmental benefits [15].

Recent evidence indicates that children report spending up to 4 hours or more (outside their digital classes) of screen time on their technological devices, such as computers, television, smartphones, video games, and other mobile devices such as iPads [1]. Alongside its countless benefits, the digital space can pose several risks, particularly for children who lack the experience and understanding to navigate it safely. Scholars argue that the increasing use of digital technology among children has amplified their exposure to a broad spectrum of web-based risks, including cyberbullying, exposure to inappropriate content, privacy violations, digital addiction, and online sexual exploitation [16,17]. These threats can impact children's mental well-being and lead to mental disorders, such as depression or anxiety [18,19]. Parents are tasked with the primary role of protecting their children's well-being, and this now needs to encompass digital safety: defined in this review as safeguarding children from web-based risks such as cyberbullying, exposure to inappropriate content, privacy violations, online sexual exploitation and the inappropriate use of digital technologies including excessive screen time that can lead to digital addiction and negative mental health outcomes [20,21]. However, the digital landscape offers a high level of anonymity and accessibility that complicates direct oversight, making parents feel unequipped to navigate the vast and rapidly evolving digital space [22].

Therefore, it is essential to position parents as active participants in mitigating potential harm by developing effective digital safeguarding practices that facilitate children's safety [23,24], giving parents a primary role in moderating the use of technology by monitoring, guiding, and supervising their children [5,24]. Banić and Orehovački [23] emphasize that parents must participate in their children's digital technology usage. This means parents need to be equipped with the knowledge, skills, and values necessary to foster safe and responsible navigation of the digital landscape by children while safeguarding their well-being [1]. However, despite the wide embrace of digital platforms, the capacity of parents to effectively safeguard their children's digital activities remains inconsistent, often constrained by varying levels of digital literacy, awareness of web-based risks, and access to appropriate resources.

Various digital safety interventions have been developed to equip parents with the knowledge and tools to protect their children in the digital space. Despite this growing number of digital safety interventions available to parents, there remains a lack of comprehensive evidence regarding their effectiveness in improving parental knowledge, skills, and practices and, ultimately, enhancing child safety on the web. Recent reviews

XSL•FO
RenderX

have highlighted the significance of parental mediation through strategies such as educational programs, digital monitoring tools, parental controls, and strategies for fostering open communication between parents and children about web-based risks [23,25-27].

Existing reviews on the topic predominantly focused on the effects of digital literacy practices on children's learning, identifying parental mediating strategies, and factors affecting parental mediation strategies [23,25-29]. None of the existing reviews has evaluated evidence on the effectiveness of the approaches in increasing the knowledge and skills of the parents, as well as enhancing the safe practices of using digital technology by their children. Aggregating evidence through a systematic review and meta-analysis has the potential to inform decision-makers by providing a comprehensive and critically evaluated synthesis of evidence while also uncovering research gaps. The rigorous statistical analysis involved in measuring the size of effect, examining the heterogeneity, and identifying possible sources of bias enhances the reliability of the synthesis. Therefore, this systematic review and meta-analysis evaluated the effectiveness of digital safety interventions in improving parental practices related to safeguarding children's digital activities. The primary research question for this review was "What is the effectiveness of digital safety interventions on parental literacy and practices in increasing parental knowledge and skills on digital safety?"; the secondary review question was "What is the effectiveness of parental digital safety interventions on children's digital safety?"

Methods

Design

The systematic review was conducted following the Joanna Briggs Institute (JBI) methodology for systematic reviews [30]. The review involved developing a clear and focused review question, establishing explicit inclusion and exclusion criteria, a systematic search of relevant databases, a critical appraisal of included studies, and a synthesis of findings. These steps adhered to the a priori protocol that was developed before commencing the study. The protocol was discussed by the members of the research team before being registered in the Open Science Framework [31].

Eligibility Criteria

To be included in this review, peer reviewed articles published from database inception to 2024, were required to meet the following criteria: (1) population included parents or primary caregivers responsible for children aged 0-17 years; (2) irrespective of the delivery methods, interventions included resources, programs or interventions designed to enhance parents' knowledge, and skills to safeguard children's activities when interacting with digital technologies; (3) control groups received no intervention or were waitlisted for the intervention following the conclusion of the study; (4) primary or secondary outcomes on effectiveness of the intervention on parental practices and children's digital safety were explicitly reported; and (5) interventional studies including randomized controlled trials (RCTs), non-RCTs, and quasi experiment. Articles were excluded if they were published in a language other than English and if they did not meet the inclusion criteria outlined above.

Search Strategy

A 3-step search strategy was used in this review. The first phase of the search involved a limited exploratory search in 2 databases: MEDLINE (PubMed) and CINAHL (EBSCO). This preliminary search aimed to identify key articles that would inform subsequent search stages. The text words contained in the titles and abstracts of relevant articles and the index terms used to describe the articles were used to develop a comprehensive search strategy. The full search strategy was applied to the following databases: MEDLINE, CINAHL Ultimate, PsycINFO, Web of Science, The Allied and Complementary Medicine Database, ProQuest Central, and IEEE Xplore (Table 1).

XSL•FO
RenderX

Table 1. Search strategy.

Search 1	(Parent* OR famil*)
Search 2	((cybersafe* OR “cyber safe*” OR “digital* safe*” OR “digital security” OR “digital risk” OR “e safety” OR esafety OR “internet safe*” OR “internet security” OR “internet risk*” OR “online safe*” OR “online risk*” OR “online security” OR “safe technolog*”))
Search 3	(((MH “Child”) OR (MH “Child, Preschool”)) OR ((MH “Minors”)) OR ((MH “Adolescent”)) OR (child* OR minor* OR adolescen*))
Search 4	((“Parent* education” OR “Parent* knowledge” OR “Parent* support” OR “Parent* mediation” OR “famil* education” OR “famil* knowledge” OR “famil* support” OR “famil* mediation”))
Search 5	S1 AND S2 AND S3 (Parent* OR famil*)AND (cybersafe* OR “cyber safe*” OR “digital* safe*” OR “digital security” OR “digital risk” OR “e safety” OR esafety OR “internet safe*” OR “internet security” OR “internet risk*” OR “online safe*” OR “online risk*” OR “online security” OR “safe technolog*”) AND (((MH “Child”) OR (MH “Child, Preschool”)) OR ((MH “Minors”)) OR ((MH “Adolescent”)) OR (child* OR minor* OR adolescen*))
Search 6	S2 AND S3 AND S4 (cybersafe* OR “cyber safe*” OR “digital* safe*” OR “digital security” OR “digital risk” OR “e safety” OR esafety OR “internet safe*” OR “internet security” OR “internet risk*” OR “online safe*” OR “online risk*” OR “online security” OR “safe technolog*”) AND ((MH “Child”) OR (MH “Child, Preschool”)) OR ((MH “Minors”)) OR ((MH “Adolescent”)) OR (child* OR minor* OR adolescen*) AND ((“Parent* education” OR “Parent* knowledge” OR “Parent* support” OR “Parent* mediation” OR “famil* education” OR “famil* knowledge” OR “famil* support” OR “famil* mediation”))

The databases were searched systematically using the identified keywords and MeSH (Medical Subject Headings) terms. No date or language limitations were applied. The Boolean operator “OR” was used to combine similar search terms, while “AND” was applied when combining different search terms. Two reviewers searched each database independently and then compared findings for similarities or any divergences. Last, a hand search of the reference lists of included studies, along with the use of the Scite artificial-powered research tool, was conducted to identify additional articles. The database search was conducted between May and August 2024.

Study Selection

Identified citations were uploaded into EndNote (version X9; Clarivate) Reference Management System and duplicates removed [32]. The remaining titles were imported into the JBI System for the Unified Management, Assessment, and Review of Information (JBI SUMARI) [33]. Titles were then screened independently by 2 reviewers. Titles and abstracts deemed eligible were retained for level 2 screening, where full texts were retrieved and assessed independently by 2 reviewers. Disagreements occurring between the 2 reviewers at both screening levels were resolved with a discussion in the presence of team members to reach a consensus.

Assessment of Methodological Quality

In this review, eligible studies underwent a rigorous critical appraisal conducted by 2 independent reviewers. The evaluation of the RCTs was performed using the JBI checklist for randomized controlled studies, which has 13 appraisal questions to assess bias related to selection and allocation of participants, administration of the intervention, assessment / detection / measurement of the outcome, participant retention, and data analysis [34]. Nonrandomized studies were assessed by 7 questions in the checklist (Multimedia Appendix 1) for quasi-experimental studies, and these questions assess bias in the domains of temporal precedence, selection and allocation of participants, confounding factors, administration of intervention, assessment/detection/measurement of the outcome, retention, and statistical validity [35]. The response options to each question are “Yes” (scores 1), “No” (scores 0), or “Unclear” (scores 0). The total score was converted into a percentage, and based on previous research [36], each study was ranked according to 3 levels of bias: high (for scores between 0% and 49%), moderate (for scores between 50% and 79%), and low (for scores between 80% and 100%). The specific questions used to assess the methodological quality of the included studies are detailed in Tables 2 and 3, which highlight the criteria followed during the appraisal process. In instances where discrepancies arose between the 2 reviewers, resolutions were achieved through collaborative discussion or a third reviewer to reach a consensus.

XSL•FO
RenderX

Table 2. Critical appraisal of eligible randomized controlled trials.

	Roberto et al [37]	Sanders et al [38]	Adams et al [39]	Birken et al [40]	Lin et al [41]	Raj et al [42]	Percentage
Appraisal questions							
Was true randomization used for the assignment of participants to treatment groups?	Yes	Yes	Yes	Yes	Yes	Yes	100
Was allocation to treatment groups concealed?	No	Unclear	Unclear	No	Yes	Yes	33.3
Were the treatment groups similar at the baseline?	Yes	Yes	Yes	Yes	Yes	Yes	100
Were participants blind to treatment assignment?	Unclear	Unclear	Unclear	Unclear	Yes	Yes	33.3
Were those delivering the treatment blind to treatment assignment?	No	No	Unclear	Yes	Yes	No	33.3
Were outcome assessors blind to treatment assignment?	No	No	Unclear	Yes	Yes	Unclear	33.3
Were treatment groups treated identically, other than the intervention of interest?	Yes	Yes	Yes	Yes	Yes	Yes	100
Was follow-up complete and, if not, were differences between groups in terms of their follow-up adequately described and analyzed	Yes	Yes	Yes	Yes	Yes	Yes	100
Were participants analyzed in the groups to which they were randomized?	Yes	Yes	Yes	Yes	Yes	Yes	100
Were outcomes measured in the same way for treatment groups?	Yes	Yes	Yes	Yes	Yes	Yes	100
Were outcomes measured in a reliable way?	Yes	Yes	Yes	Yes	Yes	Yes	100
Was appropriate statistical analysis used?	Yes	Yes	Yes	Yes	Yes	Yes	100
Was the trial design appropriate and any deviations from the standard randomized controlled trial design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	Yes	Yes	Yes	Yes	Yes	Yes	100
Percentage score per article	69	69	69	85	100	85	__[a]

[a]Not applicable.

XSL•FO
RenderX

Table 3. Critical appraisal of eligible quasi experiment.

	Uludaşdemir and Küçük [43]	Boonmun et al [44]	De Lepeleere et al [45]	Sadeghi et al [46]	Canpolat and Karadaş [47]	Percentage score per question
Appraisal questions						
Is it clear in the study what is the "cause" and what is the "effect" (ie, there is no confusion about which variable comes first)?	Yes	Yes	Yes	Yes	Yes	100
Were the participants included in any comparisons similar?	Yes	Yes	Yes	Yes	Yes	100
Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest?	Yes	Yes	Yes	Yes	Yes	100
Was there a control group?	Yes	Yes	Yes	N	Yes	80
Were there multiple measurements of the outcome both pre and post the intervention/exposure?	Yes	Yes	Yes	Yes	Yes	100
Was follow up complete and if not, were differences between groups in terms of their follow-up adequately described and analyzed?	Yes	Yes	Yes	Yes	Yes	100
Were the outcomes of participants included in any comparisons measured in the same way?	Unclear	Unclear	Unclear	Yes	Yes	100
Percentage score per article	100	100	100	85.7	100	__[a]

[a]Not applicable.

Data Extraction

Data were independently extracted using the standardized JBI RCT data extraction forms by 2 independent reviewers and then crosschecked by a third reviewer. The extracted information included (1) attributes of the study: author, geographical location, year of publication, economic background, setting, study aims; (2) methodological qualities: study design, sample size/ population, characteristics of intervention, statistical analyses; and (3) findings and conclusions (Multimedia Appendix 2 [37-49]).

Data Synthesis

Data synthesis was conducted through meta-analysis and narrative synthesis. Meta-analysis was conducted when studies demonstrated a sufficient degree of homogeneity in terms of participants, interventions, and outcomes. Based on these criteria, a meta-analysis was conducted specifically for the outcome of children's screen time. Forest plots were generated to show mean differences with 95% CIs and funnel plots. Random-effects meta-analyses using the restricted maximum likelihood method were used to pool the data. Heterogeneity was assessed using an I^2 test, with values <50% considered nonsubstantial. The outcome was deemed statistically significant if the P value was less than .05. Effect sizes were interpreted according to GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) recommendations: small (<0.5), moderate (0.5-0.8), and large (> 0.8) effects [50]. Sensitivity analyses using the leave-one-out approach were performed to explore sources of heterogeneity. Subgroup analyses and meta-regression were not conducted due to the insufficient number of studies in both RCT and quasi-experimental meta-analyses. For other outcomes (eg, parental awareness, attitudes) with substantial conceptual heterogeneity measured by different instruments, a narrative synthesis was undertaken with supporting tables due to the inappropriateness of statistical pooling. Publication bias was evaluated through funnel plot visualization, Egger regression test, and trim-and-fill analysis. All analyses were conducted using Stata (version 17.0; StataCorp LLC).

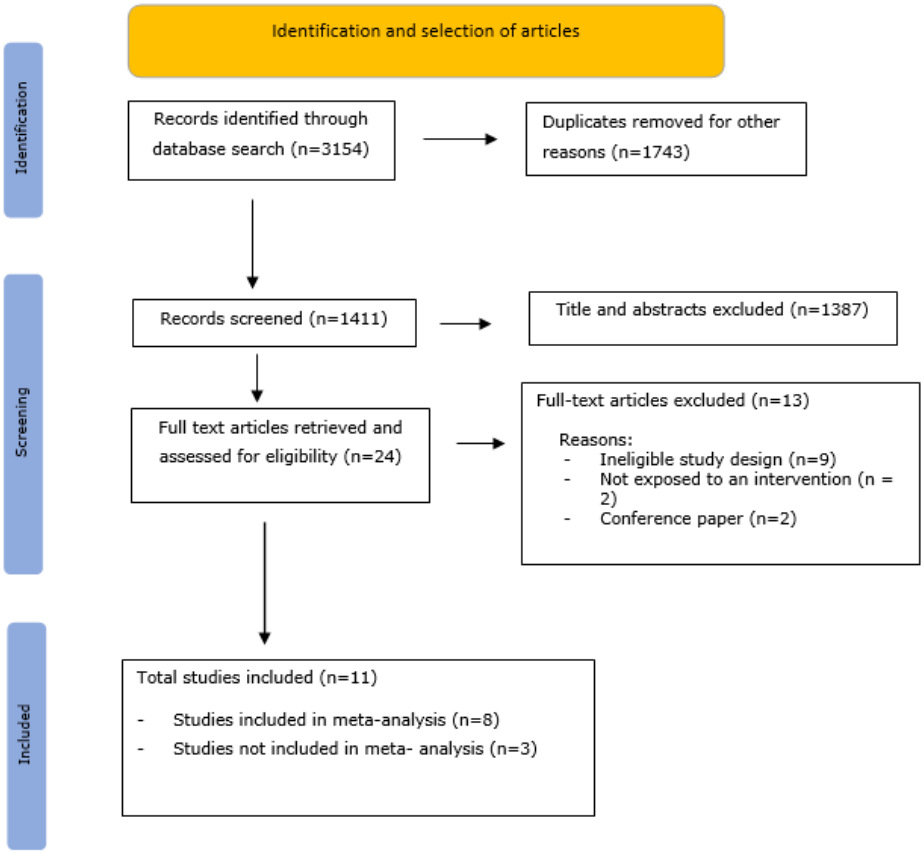
Results

Study Selection

After removing duplicates from a total hit of 3154, a total of 24 potentially eligible titles and abstracts were retained from 1411 records. Following a full-text assessment of 24 articles, 13 were excluded based on the following exclusion criteria: ineligible study design (n=9), lack of intervention exposure (n=2), incompatible participant characteristics (n=1), ineligible outcomes (1), conference proceedings (n=2). Eleven studies were included in this systematic review and meta-analysis, and details are provided in Figure 1.

XSL•FO
RenderX

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



Methodological Quality

Overall, the risk of bias score for RCTs was low to moderate (average score of 82%; range 69% to 100%; Table 2). Three articles scored moderate risk [37-39], and another 3 articles scored low risk [40-42]. Studies that had a moderate risk were either unclear in their description or did not (1) conceal allocation of intervention groups, (2) blind participants to intervention groups, (3) blind those delivering interventions, and (4) outcome assessors were not blind to intervention assignment [37-39]. All quasi-experimental studies scored 100% except one article, which scored 85% [46], representing the lowest risk of bias (Table 3).

Characteristics of Included Studies

The review included 11 studies published between 2012 and 2024. Study designs consisted of RCTs (6/11, 54.5%) and quasi-experimental studies (5/11, 45.5%). Studies were conducted across 8 countries: Turkey (2/11, 18.2%), Iran (2/11, 18.2%), the United States (2/11, 18.2%), and one study each from Thailand, Belgium, Canada, Malaysia, and Taiwan (1/11 each, 9.1%). Sample sizes ranged from 28 to 360 parent-child dyads. Regarding intervention delivery formats, studies used face-to-face sessions (5/11, 45.5%), online/web-based delivery (4/11, 36.4%), and combined web-based and face-to-face delivery (2/11, 18.2%). Participants were primarily parents (with mothers comprising >80% in most studies) and children ranging from toddlers (18 months) to adolescents. The duration of interventions varied from a single session to 9 weeks. The follow-up periods ranged from immediate postintervention to 4 months. The contents of interventions mainly focused on 3 domains: cyberbullying prevention (3/11, 27.3%), screen time management (5/11, 45.4%), and gaming-related parenting practices (3/11, 27.3%). Detailed characteristics of the included studies are presented in Multimedia Appendix 2 [37-49].

Summary of Effects of Digital Safety Interventions on Parental Outcomes

Parental Digital Safety Knowledge, Attitudes, and Skills

Six studies reported the effectiveness of digital safety interventions in improving parents' digital safety knowledge and skills (Table 4) [37,42-45,47]. For cyberbullying-related outcomes, significant improvements were observed in both parental awareness [43] and various communication intentions [37] (all $P<.05$). Screen time management interventions showed mixed results: while parental attitudes demonstrated significant improvements ($P<.05$), changes in intentions and subjective norms remained nonsignificant [44]. Raj et al [42] in their larger study (n=360) found significant enhancements in parental knowledge and self-efficacy for screen time reduction ($P<.001$). However, De Lepeleere et al [45] found no significant improvements in parental self-efficacy for either modeling or permission concerning gaming ($P>.05$), suggesting limited intervention effectiveness in this domain. Overall, the interventions appeared most effective in enhancing cyberbullying-related competencies, moderately effective for screen time management, but showed minimal impact on gaming-related outcomes.

XSL•FO
RenderX

Table 4. Effects of digital safety interventions on parental digital safety knowledge and skills. Effect sizes and statistical tests are presented as reported in the original studies. For repeated measures, only postintervention and final time point results are shown.

Reference	Sample size (n/N)[a]	Outcome measure	Intervention results					Timing of measurement
			Effect estimate				*P* value	
			Z test[b]	*F* test (*df*)	*t* test (*df*)	Mean difference (95% CI)		
Uludaşdemir and Küçük [43]	33/31	Parent cyberbullying awareness form	−2.035	__[c]	—	—	.04	Postintervention (5-week)
Boonmun et al [44]	35/35							
		Parents' attitudes (children's screen time reduction)						
			—	—	—	2.37 (0.45 to 4.29)	.015	Postintervention (2-week)
			—	—	—	2.06 (–0.79 to 4.91)	.16	2-month follow-up
		Parents' perceived behavioral control						
			—	—	—	1.29 (–1.05 to 3.62)	.28	Postintervention (2-week)
			—	—	—	2.63 (0.19 to 5.07)	.04	2-month follow-up
		Parents' intentions (children's screen time reduction)						
			—	—	—	0.11 (–0.92 to 1.14)	.83	Postintervention (2-week)
			—	—	—	0.25 (–0.89 to 1.39)	.67	2-month follow-up
		Parents' subjective norms (children's screen time reduction)						
			—	—	—	–0.91 (–3.49 to 1.66)	.49	Postintervention (2-week)
			—	—	—	–0.55 (–3.24 to 2.15)	.69	2-month follow-up
Canpolat and Karadaş [47]	14/14	Digital parental awareness scale (risk protection)						
			—	31.709 (1,26)[d]	—	—	<.001	Postintervention
			—	—	—	—	<.001	3-month follow-up
Raj et al [42]	180/180							
		Parental knowledge	—	—	—	6.88 (6.11 to 7.65)	<.001	3-month follow-up
		Parental perception	—	—	—	–0.86 (– 0.98 to −0.73)	<.001	3-month follow-up
		Parental self-efficacy (screen time reduction)	—	—	—	1.59 (1.48 to 1.70)	<.001	3-month follow-up
De Lepeleere et al [45]								
	44/70	Parental self-efficacy (gaming-modeling)	—	1.11 (1, 112)[d]	—	—	.29	1-month follow-up
	50/65	Parental self-efficacy (gaming-permission)	—	0.78 (1, 112)[d]	—	—	.38	4-month follow-up

XSL•FO
RenderX

Reference	Sample size (n/N)[a]	Outcome measure	Intervention results					Timing of measurement
			Effect estimate				*P* value	
			Z test[b]	*F* test (*df*)	*t* test (*df*)	Mean difference (95% CI)		
Roberto et al [37]	26/25							
		Parents' perceived susceptibility (child cyberbullying risk)	—	—	2.76 (49)	—	.01	Postintervention (one session)
		Parents' intentions to talk to their child about saving evidence if cyberbullied	—	—	2.19 (49)	—	.03	Postintervention (one session)
		Parents' intentions to talk to their child about not retaliating if cyberbullied	—	—	2.66 (49)	—	.01	Postintervention (one session)
		Parents' intentions to talk to their child about telling an adult if cyberbullied	—	—	2.24 (49)	—	.03	Postintervention (one session)

[a]n/N: Sample size of treatment group/control group or pretest/posttest.

[b]Mann-Whitney U test.

[c]Not applicable.

[d]Degrees of freedom for *F* tests were calculated based on sample sizes (df_1=1, df_2=total sample size of 2).

Parents' Behavioral Outcomes

Based on data from 6 studies [37,42-45,47], including 827 participants, collectively examining behavioral outcomes, digital safety interventions showed mixed results in changing parents' behaviors (Table 5). Only 2 outcomes demonstrated significant improvements: parents' immediate screen time reduction (for child) behaviors (*P*=.05) and parents' own screen time at 3-month follow-up (*P*=.001) [42,44]. However, interventions showed no significant effects on cyberbullying incidents and victimization, television and gaming-related parenting practices (rules, modeling, monitoring, and explanations), or technology-specific parenting (all *P*>.05), suggesting limited effectiveness in achieving sustained behavioral changes (Table 5).

XSL•FO
RenderX

Table 5. Effects of digital safety interventions on parents' behavioral outcomes.

First author	Sample Size (T/C)[a]	Outcome measure	Intervention results				Timing of measurement
			Effect estimate			*P* value	
			Z test[b]	Mean difference (95% CI)	*F* test (*df*)		
Uludaşdemir and Küçük [43]	33/31						
		Cyberbullying incidents - The adolescents' RCBI-II[c]	0.096	—[d]	—	.92	Postintervention (5-week)
		Cyber Victimization - The adolescents' RCBI-II	−1.124	—	—	.26	Postintervention (5-week)
Boonmun et al [44]	35/35	Parents' behaviors concerning children's screen time reduction questionnaire					
			—	3.46 (0.03 to 6.88)	—	.05	Postintervention (2-week)
			—	1.64 (–1.65 to 4.92)	—	.33	2-month follow-up
Raj et al [42]	180/180	Parents' screen time	—	–70.43 (–91.51 to 49.35)	—	.001	3-month follow-up
De Lepeleere et al [45]							
	41/66	Rules concerning television	—	—	0.00 (1, 105)[e]	.97	1-month follow-up
	45/69	Modeling concerning television	—	—	1.79 (1, 112)[e]	.18	1-month follow-up
	50/63	Modeling concerning television	—	—	1.57 (1, 111)[e]	.21	4-month follow-up
	37/61	Rules concerning gaming	—	—	1.16 (1, 96)[e]	.28	1-month follow-up
	45/69	Modeling concerning gaming	—	—	2.42 (1, 112)[e]	.12	1-month follow-up
	37/45	Giving an explanation concerning television	—	—	0.1 (1, 80)[e]	.75	4-month follow-up
	28/40	Giving an explanation concerning gaming	—	—	0.29 (1, 66)[e]	.59	4-month follow-up
	40/54	Monitoring gaming	—	—	1.84 (1, 92)[e]	.17	4-month follow-up
Sanders et al [38]	17/15	Technology-specific parenting	N/A[f]	N/A	N/A	.48	Postintervention (one session)

[a]T/C: treatment/ control.

[b]Mann-Whitney *U* test.

[c]RCBI-II: Revised Cyber Bullying Inventory.

[d]Not applicable.

[e]Degrees of freedom for *F* tests were calculated based on sample sizes (df_1=1, df_2=total sample size of 2).

[f]N/A: Not available.

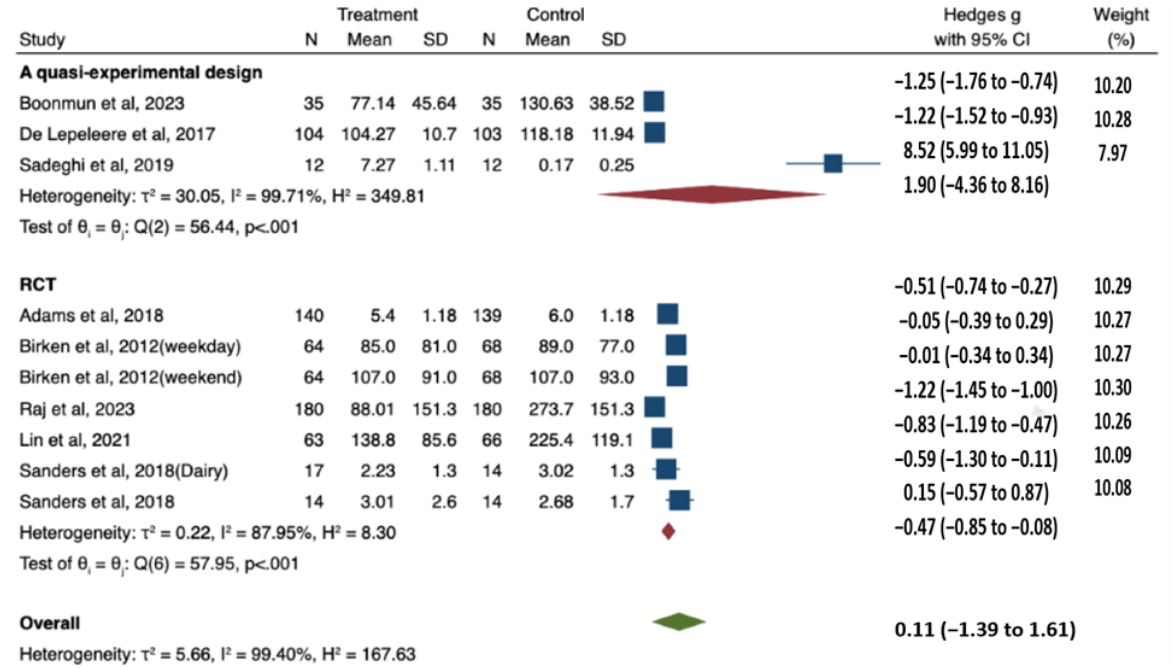
XSL•FO
RenderX

Meta-Analysis Results

Effects of Digital Safety Interventions on Children's Screen Time

Figure 2 [38-42,44-46] presents a forest plot from a meta-analysis comparing treatment and control groups across 2 study types: quasi-experimental designs and RCTs. The quasi-experimental studies, comprising 3 studies and 151 participants, demonstrated a large effect (Hedges g=1.90; 95% CI –4.36 to 8.16; P<.001) with substantial heterogeneity (I^2=99.71%). Conversely, the RCTs, comprising 5 studies (7 datasets) and 1091 participants, revealed a smaller yet significant effect (Hedges g=–0.47; 95% CI –0.85 to –0.08; P<.001) with substantial heterogeneity (I^2=87.95%). The statistical analysis of group differences (Q=0.55, P=.46) indicates no significant disparities between the quasi-experimental and RCT designs.

Figure 2. Meta-analysis of randomized controlled trials and quasi-experimental studies on the effects of digital safety interventions on children's screen time [38,40-44,46,47]. REML: restricted maximum likelihood.



Descriptive Comparison by Control Group Type and Delivery Mode

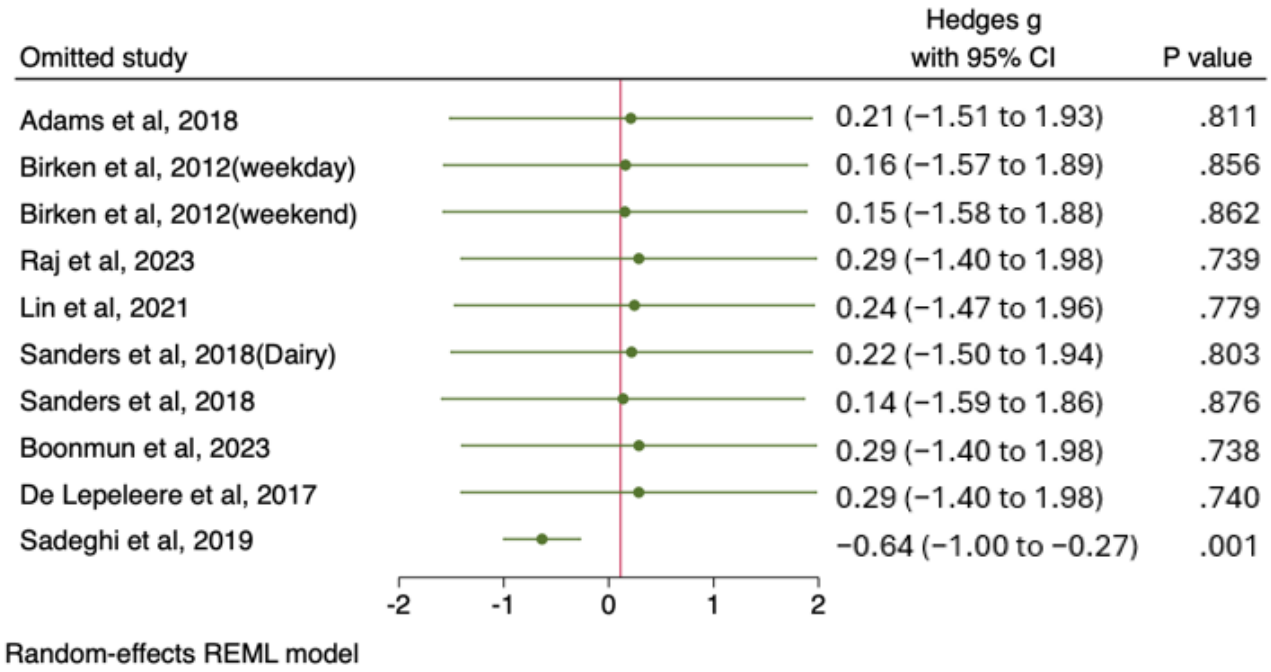
Among the 5 RCTs (7 datasets) included in the meta-analysis, formal subgroup analyses could not be conducted due to most subgroups having fewer than 2 studies. Therefore, effect size was compared descriptively by intervention delivery modes and control group types, with results interpreted cautiously given these limitations. Studies using waitlist controls [38,41,42] showed effect sizes ranging from –0.59 to –1.22, whereas studies with an active control [39] and standard care control [40] yielded effect sizes of –0.51 and –0.05, respectively. Regarding the mode of delivery, face-to-face interventions [38-41] showed variable effects (–0.05 to –0.83), while a single web-based intervention [42] demonstrated an effect size of –1.22 (Figure 2 [38-42,44-46]).

Sensitivity Analysis

The leave-one-out sensitivity analysis demonstrated the robustness of the meta-analysis findings for children's screen time, with Hedges g values ranging from 0.14 to 0.29 and all 95% CIs crossing zero (P>.05), except when Sadeghi et al [46] was excluded (Hedges g=–0.64, P=.001) (Figure 3 [38-42,44-46]). The most pronounced effect was observed when the studies by Raj et al [42], Boonmun et al [44], Birken et al [40], or De Lepeleere et al [45] were excluded (Hedges g=0.29), while the smallest effect was noted when the study by Sander et al [38] or were omitted (Hedges g=0.14). These results indicate that the overall findings are not disproportionately influenced by most studies, except for Sadeghi et al [46], which appears to have a significant impact on the pooled effect estimate.

XSL•FO
RenderX

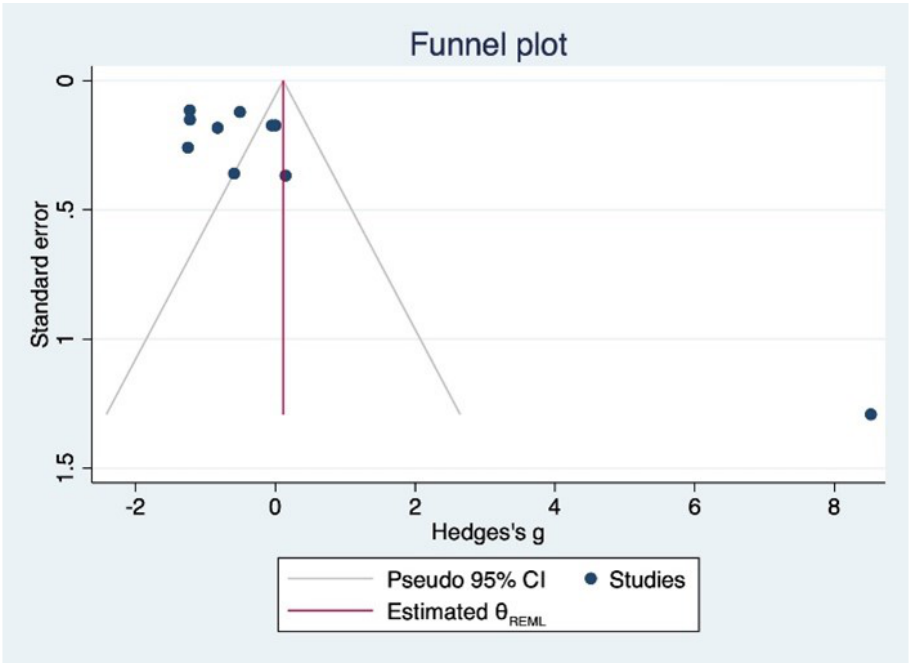
Figure 3. Leave-one-out sensitivity analysis on children's screen time [38,40-44,46,47]. REML: restricted maximum likelihood.



Publication Bias

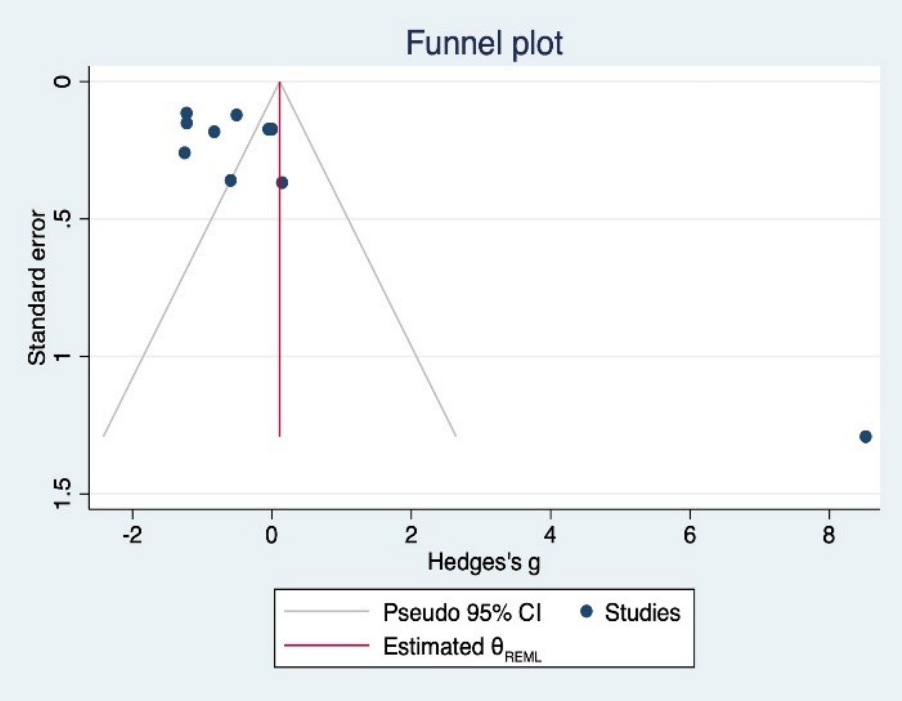
Visual inspection of the funnel plot from the random-effects restricted maximum likelihood model (Figure 4) showed relative symmetry, and the Egger test indicated no significant publication bias (t=2.04, P=.08). The trim-and-fill analysis yielded an identical funnel plot (Figure 5) with zero missing studies, further confirming the absence of publication bias. The test of residual heterogeneity was significant (Q-res=83.64, P<.001). This suggests that while there is substantial heterogeneity in the included studies, there is no significant indication of publication bias in our meta-analysis.

Figure 4. Funnel plot of the random-effects REML model. REML: restricted maximum likelihood.



XSL•FO
RenderX

Figure 5. Funnel plot after trim-and-fill analysis. REML: restricted maximum likelihood.



Discussion

Principal Results

To the best of our knowledge, this is the first meta-analysis to assess the effectiveness of digital safety interventions on parental practices related to safeguarding children's digital activities. This systematic review and meta-analysis identified 6 RCTs and 5 quasi-experimental studies to evaluate the impact of digital safety interventions on parental practices. Based on the comprehensive search of available studies, this area of research has been given limited attention. Nonetheless, the results provide evidence that parents who participate in digital safety interventions have a higher chance of increasing digital safety knowledge and skills, with a positive change in attitudes, including intentions to use strategies to safeguard their children engaging with technology.

Findings demonstrate that interventions targeting parents' knowledge related to digital safety were more effective in intervention groups compared with control groups. While increased knowledge is associated with a behavior change [51,52], knowledge alone does not necessarily translate to a change in behavior [53,54]. Theories of Behavior Change [55] such as the Theory of Planned Behavior, emphasize that an individual's likelihood of changing their behavior depends on their attitudes, social norms (which refer to beliefs about what others think regarding certain behaviors), and behavioral control (the individual's ability to act) [56]. Similarly, the Social Cognitive Theory by Albert Bandura highlights personal (individual's self-efficacy towards behavior), environmental (situational influences), and behavioral (having the ability to perform the behavior) factors as important elements in changing one's behaviors [57]. Therefore, the effectiveness of an intervention such as those aimed at promoting parental support in safeguarding children engaging in digital technology relies not only on knowledge but also on enabling a shift in social norms and addressing contextual factors that influence behavioral control. While it is commendable that 7 of the 11 articles used either a model, a theory, or a framework to underpin their interventions, the inclusion of social norms or environmental influences in the targeting interventions remains insufficient. Future studies and interventions should consider strategies that can address community norms around the digital safety of children.

In this review, some included studies evaluated either knowledge or behavioral outcomes independently, and all studies used educational sessions as an intervention (or part of the interventions). These educational sessions were delivered through different approaches, including videos, infographics, presentations face to face, role play, in groups, or via web. It is, therefore, limiting to isolate the effect of an individual approach to parent education to influence their knowledge or behavior. Regarding the behavior outcomes, while the desired direction of effect is noted in most of the reported effect estimates, the majority were not statistically significant, except for 2 outcomes: parents' own screen time [42] and children's screen time [44], which reduced after exposure to digital interventions. Similar findings were reported in a previous meta-analysis, where the behaviors of youths did not change after exposure to anti-bullying interventions [58]. To further the understanding of the effectiveness of digital interventions, future research should consider evaluating the individual effects of components of the intervention. In addition, interventions predominantly targeted cyberbullying and screen time. Considering that digital safety encompasses broader outcomes beyond cyberbullying and screen time, we recommend that interventions targeting digital safety should adopt a holistic framework rather than addressing isolated components where applicable. There is a need for additional research that can measure digital safety outcomes that have not been included in

XSL•FO
RenderX

these studies, albeit important, such as exposure to inappropriate content, web-based grooming or sexual exploitation, and digital citizenship.

Small effect sizes were also observed on giving an explanation concerning TV ($F_{1,80}$=0.10; P=.75) or gaming ($F_{1,66}$=0.29; P=.59), cyberbullying incidents (t/z=−1.124; P=.26), and rules concerning TV ($F_{1,105}$=0.00; P=.97). The findings suggest an influence of the study design on the observed effect sizes as indicated in the significant difference between quasi-experimental studies and RCTs (Q=10.72, P<.001). The larger effect observed in the quasi-experiment could be because of the lack of randomization in these studies [59]. This potential bias, along with the detected substantial heterogeneity observed in RCTs, limits the reviewers' ability to draw conclusions based on this finding. Therefore, further investigations, with an improved study design that involves implementors and outcome assessors, are required to understand the effect of digital interventions on children's screen time and other studied outcomes.

Overall, the outcome of the analysis indicates that articles included in this review and meta-analysis were of high quality, with the majority (n=8/11) considered to have a low risk of bias. Another strength of the study lies in the systematic and robust search strategies used to identify the included studies. Just like other systematic reviews and meta-analyses, our study has some limitations. The search for articles did not extend to gray literature databases, which may have missed relevant studies conducted by reputable organizations and government agencies [60]. Results from the sensitivity analysis demonstrate a significant influence of one article [46] on children's screen time despite a small sample size of 12; therefore, its validity should be interpreted with caution. Last, studies published in languages other than English were excluded due to time and financial constraints associated with translation, which may limit generalization of the outcomes.

Conclusions

To the best of the reviewers' knowledge, this is the first review to evaluate the effectiveness of digital safety interventions on parental practices related to safeguarding children's digital activities. Several interventions were identified, with educational sessions being the most common intervention across the studies. The analysis for this study indicates that the identified interventions effectively increased parents' knowledge and skills to safeguard their children while engaging with technology. Future research should use more robust designs that include blinding of outcome assessors and consider environmental factors. There is a need to focus on examining the effect of individual approaches to educational sessions on parents' practices.

Acknowledgments

This project is supported through an Edith Cowan University Early Career Researcher Grant Scheme and Financial support, including salaries from the Australian Research Council Centre of Excellence for the Digital Child.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA 2020 checklist.
[PDF File (Adobe PDF File), 75 KB - pediatrics_v8i1e70745_app1.pdf]

Multimedia Appendix 2
Characteristics of included studies.
[DOCX File , 37 KB - pediatrics_v8i1e70745_app2.docx]

References

1. Shatri ZG. Advantages and disadvantages of using information technology in learning process of students. J Turk Sci Educ 2020;17(3):420-428. [doi: 10.36681/tused.2020.36]
2. Plaza-de-la-hoz J. Advantages and downsides of children ICT use in Spain: the parent's perspective. Int J Lifelong Educ Leadersh 2017;3(2):22-31 [FREE Full text]
3. Tour E. Supporting primary school children's learning in digital spaces at home: migrant parents' perspectives and practices. Child Soc 2019;33(6):587-601. [doi: 10.1111/chso.12347]
4. Karim F, Oyewande A, Abdalla L, Chaudhry Ehsanullah R, Khan S. Social media use and its connection to mental health: a systematic review. Cureus 2020;12(6):e8627 [FREE Full text] [doi: 10.7759/cureus.8627] [Medline: 32685296]
5. Suresh A, Tiwari S. Parental knowledge, attitudes and concerns towards media technology and screen time use in children with ASD and typically developing children. Tech Disabil 2023;35(1):21-42. [doi: 10.3233/tad-220389]
6. Arabiat D, Al Jabery M, Robinson S, Whitehead L, Mörelius E. Interactive technology use and child development: a systematic review. Child Care Health Dev 2023;49(4):679-715 [FREE Full text] [doi: 10.1111/cch.13082] [Medline: 36399381]

XSL•FO
RenderX

7. Hatzigianni M, Stephenson T, Harrison LJ, Waniganayake M, Li P, Barblett L, et al. The role of digital technologies in supporting quality improvement in Australian early childhood education and care settings. Int J Child Care Educ Policy 2023;17(1):5 [FREE Full text] [doi: 10.1186/s40723-023-00107-6] [Medline: 36778763]
8. Young people and social media usage. eSafety Commissioner. 2021. URL: https://www.esafety.gov.au/research/youth-digital-dangers/social-media-usage [accessed 2025-09-10]
9. American Academy of Pediatrics. Where we stand: screen time. Healthy Children. USA: American Academy of Pediatrics URL: https://www.healthychildren.org/English/family-life/Media/Pages/Where-We-Stand-TV-Viewing-Time.aspx [accessed 2023-12-13]
10. Tremblay MS, Carson V, Chaput J, Connor Gorber S, Dinh T, Duggan M, et al. Canadian 24-hour movement guidelines for children and youth: an integration of physical activity, sedentary behaviour, and sleep. Appl Physiol Nutr Metab 2016;41(6 Suppl 3):S311-S327 [FREE Full text] [doi: 10.1139/apnm-2016-0151] [Medline: 27306437]
11. Physical activity and exercise guidelines for all Australians: for children and young people (5 to 17 years). Australian Government Department of Health. 2021. URL: https://www.health.gov.au/topics/physical-activity-and-exercise/physical-activity-and-exercise-guidelines-for-all-australians/for-children-and-young-people-5-to-17-years [accessed 2021-05-06]
12. Draper CE, Tomaz SA, Biersteker L, Cook CJ, Couper J, de Milander M, et al. The South African 24-hour movement guidelines for birth to 5 years: an integration of physical activity, sitting behavior, screen time, and sleep. J Phys Act Health 2020;17(1):109-119 [FREE Full text] [doi: 10.1123/jpah.2019-0187] [Medline: 31877557]
13. Sit less, move more, sleep well: active play guidelines for under-fives. Ministry of Health. Wellington, New Zealand: Ministry of Health; 2017. URL: https://www.health.govt.nz/publications/sit-less-move-more-sleep-well-active-play-guidelines-for-under-fives [accessed 2017-05-31]
14. WHO guidelines on physical activity and sedentary behaviour. World Health Organization. Geneva, Switzerland: World Health Organization; 2020. URL: https://www.who.int/publications/i/item/9789240015128 [accessed 2025-09-10]
15. Straker L, Edwards S, Kervin L, Burley J, Hendry D, Cliff D. Moving screen use guidelines: nine reasons why screen use guidelines should be separated from public health 24-hour movement guidelines in Australia and internationally. Digital Child. 2023. URL: https://tinyurl.com/7bdzyf28 [accessed 2025-09-10]
16. Fardouly J, Magson NR, Rapee RM, Johnco CJ, Oar EL. The use of social media by Australian preadolescents and its links with mental health. J Clin Psychol 2020;76(7):1304-1326. [doi: 10.1002/jclp.22936] [Medline: 32003901]
17. Ray A, Henry N. Sextortion: a scoping review. Trauma Violence Abuse 2025;26(1):138-155 [FREE Full text] [doi: 10.1177/15248380241277271] [Medline: 39323232]
18. Schmidt-Persson J, Rasmussen MGB, Sørensen SO, Mortensen SR, Olesen LG, Brage S, et al. Screen media use and mental health of children and adolescents: a secondary analysis of a randomized clinical trial. JAMA Netw Open 2024;7(7):e2419881 [FREE Full text] [doi: 10.1001/jamanetworkopen.2024.19881] [Medline: 38995646]
19. Twenge JM, Campbell WK. Associations between screen time and lower psychological well-being among children and adolescents: evidence from a population-based study. Prev Med Rep 2018;12:271-283 [FREE Full text] [doi: 10.1016/j.pmedr.2018.10.003] [Medline: 30406005]
20. Ma CMS, Shek DTL, Fan IYH, Zhu X, Hu X. The impact of digital safety competence on cognitive competence, AI self-efficacy, and character. Appl Sci 2025;15(10):5440. [doi: 10.3390/app15105440]
21. Screen time | how much is too much? eSafety Commissioner. 2025. URL: https://www.esafety.gov.au/parents/issues-and-advice/screen-time [accessed 2025-09-10]
22. Livingstone S, Blum-Ross A. Parenting for a Digital Future: How Hopes and Fears about Technology Shape Children's Lives. USA: Oxford University Press; 2020.
23. Banić L, Orehovački T. A comparison of parenting strategies in a digital environment: a systematic literature review. Multimodal Technol Interact 2024;8(4):32. [doi: 10.3390/mti8040032]
24. Ramachar A, Arenas A, Valogianni K. Navigating Digital Waters: The Role of Parental Behaviours and Parent-Child Relationships in Shaping Adolescents' Digital Maturity. 2024 Presented at: The 16th Mediterranean Conference on Information Systems (MCIS) and the 24th Conference of the Portuguese Association for Information Systems (CAPSI); 2024 May 20; Porto.
25. Wahyuningrum E, Suryanto S, Suminar D. Parenting in digital era: a systematic literature review. J Educ Health Community Psychol 2020:226-258. [doi: 10.12928/jehcp.v9i3.16984]
26. Rega V, Gioia F, Boursier V. Parental mediation and cyberbullying: a narrative literature review. Marriage Fam Rev 2022;58(6):495-530. [doi: 10.1080/01494929.2022.2069199]
27. Nichols S, Selim N. Digitally mediated parenting: a review of the literature. Societies 2022 Mar 31;12(2):60-174 [FREE Full text] [doi: 10.3390/soc12020060]
28. Alkan R, Aslan A, Turgut Y, Kurşun E. Factors affecting parental mediation strategies in children's technology use: a systematic review. J Comp Educ Res 2021;9(18):702-723. [doi: 10.18009/jcer.925859]
29. Soyoof A, Reynolds BL, Neumann M, Scull J, Tour E, McLay K. The impact of parent mediation on young children's home digital literacy practices and learning: a narrative review. J Comput Assist Learn 2023;40(1):65-88. [doi: 10.1111/jcal.12866]

XSL•FO
RenderX

30. Aromataris E, Fernandez R, Godfrey C, Holly C, Khalil H, Tungpunkom P. Summarizing systematic reviews: methodological development, conduct and reporting of an umbrella review approach. Int J Evid Based Healthcare 2015;13(3):132-140. [doi: 10.1097/XEB.0000000000000055] [Medline: 26360830]
31. Zgambo M, Anyango E, Ngune I, Arabiat D, Morelius E, Whitehead L. Evaluating the effectiveness of digital safety interventions on parental practices in safeguarding children's digital activities: a systematic review and meta analysis. Open Sci Framework 2024 [FREE Full text] [doi: 10.17605/OSF.IO/SD356]
32. The Endnote Team. EndNote 20.1. Philadelphia, PA: Clarivate; 2021.
33. Munn Z, Aromataris E, Tufanaru C, Stern C, Porritt K, Farrow J, et al. The development of software to support multiple systematic review types: the Joanna Briggs Institute system for the unified management, assessment and review of information (JBI SUMARI). Int J Evid Based Healthcare 2019;17(1):36-43. [doi: 10.1097/XEB.0000000000000152] [Medline: 30239357]
34. Barker TH, Stone JC, Sears K, Klugar M, Tufanaru C, Leonardi-Bee J, et al. The revised JBI critical appraisal tool for the assessment of risk of bias for randomized controlled trials. JBI Evid Synth 2023;21(3):494-506. [doi: 10.11124/JBIES-22-00430] [Medline: 36727247]
35. Barker TH, Habibi N, Aromataris E, Stone JC, Leonardi-Bee J, Sears K, et al. The revised JBI critical appraisal tool for the assessment of risk of bias for quasi-experimental studies. JBI Evid Synth 2024;22(3):378-388. [doi: 10.11124/JBIES-23-00268] [Medline: 38287725]
36. Siddiqui AA, Alshammary F, Mulla M, Al-Zubaidi SM, Afroze E, Amin J, et al. Prevalence of dental caries in Pakistan: a systematic review and meta-analysis. BMC Oral Health 2021;21(1):450 [FREE Full text] [doi: 10.1186/s12903-021-01802-x] [Medline: 34530810]
37. Roberto AJ, Eden J, Deiss DM, Savage MW, Ramos-Salazar L. The short-term effects of a cyberbullying prevention intervention for parents of middle school students. Int J Environ Res Public Health 2017;14(9):24 [FREE Full text] [doi: 10.3390/ijerph14091038] [Medline: 28891936]
38. Sanders W, Parent J, Forehand R. Parenting to reduce child screen time: a feasibility pilot study. J Dev Behav Pediatr 2018;39(1):46-54 [FREE Full text] [doi: 10.1097/DBP.0000000000000501] [Medline: 28937450]
39. Adams EL, Marini ME, Stokes J, Birch LL, Paul IM, Savage JS. INSIGHT responsive parenting intervention reduces infant's screen time and television exposure. Int J Behav Nutr Phys Act 2018;15(1):24 [FREE Full text] [doi: 10.1186/s12966-018-0657-5] [Medline: 29544506]
40. Birken CS, Maguire J, Mekky M, Manlhiot C, Beck CE, Degroot J, et al. Office-based randomized controlled trial to reduce screen time in preschool children. Pediatrics 2012;130(6):1110-1115. [doi: 10.1542/peds.2011-3088] [Medline: 23129085]
41. Lin Y, Kuo S, Chang Y, Lin P, Lin Y, Lee P, et al. Effects of parental education on screen time, sleep disturbances, and psychosocial adaptation among Asian preschoolers: a randomized controlled study. J Pediatr Nurs 2021;56:e27-e34. [doi: 10.1016/j.pedn.2020.07.003] [Medline: 32703680]
42. Raj D, Ahmad N, Mohd Zulkefli NA, Lim PY. Stop and play digital health education intervention for reducing excessive screen time among preschoolers from low socioeconomic families: cluster randomized controlled trial. J Med Internet Res 2023;25:e40955 [FREE Full text] [doi: 10.2196/40955] [Medline: 37140970]
43. Uludaşdemir D, Küçük S. Raising awareness among adolescent cyberbullies and their parents in Türkiye through a web-based cyberbullying education program based on Pender's health promotion model. J Pediatr Nurs 2024;77:152-161. [doi: 10.1016/j.pedn.2024.03.027] [Medline: 38520839]
44. Boonmun W, Rutja P, Sirichai H, Apawan N, Natkamol C. A program for parents' screen time reduction for preschool children: a quasi-experimental study. Pac Rim Int J Nurs Res 2023;27(2):368-380. [doi: 10.60099/prijnr.2023.260440]
45. De Lepeleere S, De Bourdeaudhuij I, Cardon G, Verloigne M. The effect of an online video intervention 'Movie Models' on specific parenting practices and parental self-efficacy related to children's physical activity, screen-time and healthy diet: a quasi experimental study. BMC Public Health 2017;17(1):366 [FREE Full text] [doi: 10.1186/s12889-017-4264-1] [Medline: 28449658]
46. Sadeghi S, Pouretemad H, Khosrowabadi R, Fathabadi J, Nikbakht S. Behavioral and electrophysiological evidence for parent training in young children with autism symptoms and excessive screen-time. Asian J Psychiatr 2019;45:7-12. [doi: 10.1016/j.ajp.2019.08.003] [Medline: 31430692]
47. Canpolat M, Karadaş C. A mixed method research on increasing digital parenting awareness of parents. Educ Inf Technol 2023;29(6):6683-6704. [doi: 10.1007/s10639-023-12094-9]
48. Ajzen I. Understanding Attitudes and Predictiing Social Behavior. Englewood cliffs: Psychology Press; 1980.
49. Witte K, Cameron KA, McKeon JK, Berkowitz JM. Predicting risk behaviors: development and validation of a diagnostic scale. J Health Commun 1996;1(4):317-341. [doi: 10.1080/108107396127988] [Medline: 10947367]
50. Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336(7650):924-926 [FREE Full text] [doi: 10.1136/bmj.39489.470347.AD] [Medline: 18436948]
51. Kite J, Gale J, Grunseit A, Li V, Bellew W, Bauman A. From awareness to behaviour: testing a hierarchy of effects model on the Australian make healthy normal campaign using mediation analysis. Prev Med Rep 2018;12:140-147 [FREE Full text] [doi: 10.1016/j.pmedr.2018.09.003] [Medline: 30258762]

XSL•FO
RenderX

52. An Q, Hong W, Xu X, Zhang Y, Kolletar-Zhu K. How education level influences internet security knowledge, behaviour, and attitude: a comparison among undergraduates, postgraduates and working graduates. Int J Inf Secur 2023;22(2):305-317. [doi: 10.1007/s10207-022-00637-z] [Medline: 36466362]
53. Arlinghaus KR, Johnston CA. Advocating for behavior change with education. Am J Lifestyle Med 2018;12(2):113-116 [FREE Full text] [doi: 10.1177/1559827617745479] [Medline: 30283247]
54. Vallis M, Shepherd T. Awareness is not enough: developing competencies in behaviour change counselling for obesity management. Obes Pillars 2024;11:100124 [FREE Full text] [doi: 10.1016/j.obpill.2024.100124] [Medline: 39252794]
55. El Kirat H, van Belle S, Khattabi A, Belrhiti Z. Behavioral change interventions, theories, and techniques to reduce physical inactivity and sedentary behavior in the general population: a scoping review. BMC Public Health 2024;24(1):2099 [FREE Full text] [doi: 10.1186/s12889-024-19600-9] [Medline: 39097741]
56. Ajzen I. The theory of planned behavior. Organ Behav Hum Decis Process 1991;50(2):179-211. [doi: 10.1016/0749-5978(91)90020-T]
57. Bandura A. Social Learning Theory. Englewood Cliffs: Prentice Hall; 1977.
58. Mishna F, Cook C, Saini M, Wu M, MacFadden R. Interventions for children, youth, and parents to prevent and reduce cyber abuse. Campbell Syst Rev 2009;5(1):132-151. [doi: 10.4073/csr.2009.2]
59. Miller CJ, Smith SN, Pugatch M. Experimental and quasi-experimental designs in implementation research. Psychiatry Res 2020;283:112452 [FREE Full text] [doi: 10.1016/j.psychres.2019.06.027] [Medline: 31255320]
60. D'Amore C, Reid JC, Chan M, Fan S, Huang A, Louie J, et al. Interventions including smart technology compared with face-to-face physical activity interventions in older adults: systematic review and meta-analysis. J Med Internet Res 2022;24(10):e36134 [FREE Full text] [doi: 10.2196/36134] [Medline: 36315229]

Abbreviations

GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
JBI: Joanna Briggs Institute
MeSH: Medical Subject Headings
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial

Edited by A Nguyen; submitted 31.12.24; peer-reviewed by NH Mohamad Zainal, P Wu, S Mallawaarachchi; comments to author 06.06.25; revised version received 21.08.25; accepted 06.09.25; published 10.10.25.

Please cite as:
Zgambo M, Anyango E, Arabiat DH, Ngune I, Mörelius E, Zhang M, Whitehead LC
Effect of Digital Safety Interventions on Parental Practices in Safeguarding Children's Digital Activities: Systematic Review and Meta-Analysis
JMIR Pediatr Parent 2025;8:e70745
URL: https://pediatrics.jmir.org/2025/1/e70745
doi:10.2196/70745
PMID:

©Maggie Zgambo, Edah Anyango, Diana H Arabiat, Irene Ngune, Evalotte Mörelius, Min Zhang, Lisa Claire Whitehead. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 10.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Parental Use of Social Media and the Internet in the Context of Their Child's Genetic Neurodevelopmental Disorder: Mixed Methods Study Nested in the GenROC Cohort Study

Karen Jaqueline Low[1,2], MBChB, MRCPH, BSc; Georgia Treneman-Evans[1], MSc; Sarah L Wynn[3], PhD; Jenny Ingram[1], PhD; John Powell[4], PhD

[1]Centre for Academic Child Health, Bristol Medical School, University of Bristol, Canynge Hall, Whatley Road, Bristol, United Kingdom

[2]Department of Clinical Genetics and Genomics, University Hospitals Bristol and Weston NHS Trust, Bristol, United Kingdom

[3]Unique, Oxted, United Kingdom

[4]Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, United Kingdom

Corresponding Author:
Karen Jaqueline Low, MBChB, MRCPH, BSc
Centre for Academic Child Health, Bristol Medical School, University of Bristol, Canynge Hall, Whatley Road, Bristol, United Kingdom

Abstract

Background: Social media groups (SMGs) enable individuals with rare diseases to connect with one another and access instant support and advice. Accelerated diagnoses of genetic neurodevelopmental disorders (NDDs) over the last decade have driven rapid expansion of gene-specific SMG membership. Limited literature regarding parental use of SMGs in the context of managing their child's NDD exists.

Objective: The objective of our study was to determine and describe how parents use social media and the internet in the context of their child's NDD.

Methods: We undertook a mixed methods study of 477 parents within a cohort of children with NDDs (Genetic Rare Disease: Observational Cohort Study; GenROC). A total of 359 parents provided quantifiable survey responses regarding their use of social media. We also interviewed 17 parents to understand how they use SMGs and their views on the data held within these groups.

Results: Our survey found 359/475 (75.7%) of parents use SMGs related to their child's genetic disorder, and of these, 98.5% (354/359) are on Facebook. Most SMGs are closed, international, have more than 200 members, are specific to the NDD, and are associated with a corresponding charity or foundation. In total, 191/312 (61.2%) parents could not recall what they had consented to when joining the group with respect to the use of their posted data. Most parents trust the data (Likert scale 1 - 10; mean 7.03, SD 1.98) that are shared but acknowledged the anecdotal nature of them. Parents found the most valuable element of the SMG to be shared lived experience with other families. Interview data from 17 parents were coded and analyzed thematically. A total of 4 main themes were identified: (1) SMGs for support and shared lived experience; (2) possible harms from participation in SMGs; (3) SMG composition, demographics, and dynamics; and (4) usefulness and use of data shared within the groups.

Conclusions: This mixed methods study shows the evolving landscape of SMG use in neurodevelopmental disorders, highlights its benefits and downsides, and is widely applicable to all parent SMGs for specific niche medical conditions. Using the strength of these groups in a more collaborative approach in the future could prove useful to clinicians, families, and researchers alike.

International Registered Report Identifier (IRRID): RR2-10.1136/bmjopen-2024-085237

(JMIR Pediatr Parent 2025;8:e76526) doi:10.2196/76526

KEYWORDS

genetics; rare disease; social media; genetic neurodevelopmental disorders; parental support; mixed methods research; online health communities

Introduction

Social media groups (SMGs) have dramatically changed the way individuals seek and share information online, particularly in the context of health care and are used by parents both as a support mechanism but also as a way of finding out information to help them look after their child [1,2]. Genetic neurodevelopmental disorders (NDDs) are rare with wide geographic spread, heightening the need for connection and increasing the information drought. Our recent literature review

XSL•FO
RenderX

(Bogaert et al, unpublished data,December 2024) showed that SMGs empower parents by providing key information and a support role. Most parents use social media to help them manage their child's NDD, and the majority use Facebook groups that are gene- or NDD-specific and are "closed" requiring authorized access by a group "admin" based on group-specific set criteria [3].

Regardless of the underlying disorder, parents use social media to acquire health-related information about specific medical concerns both before and after their child receives a medical diagnosis, and to seek out information based on other parents' lived experience. This also provides a sense of support and community. Parents increasingly use this acquired information to discuss and sometimes challenge health care providers regarding the treatment options that are being offered for their child [4].

Medical health care was named as one of the key information needs identified in a study of parents of individuals with rare genetic disorders in a Facebook community group [5,6]. Tozzi et al [7] undertook a survey of 516 Italian families with rare genetic disorders to describe their internet use and found that 99% searched on disease characteristics, with 93% looking for therapies and 63% for alternative therapies, indicating high levels of need around treatments and therapy [7].

The number of diagnosed individuals with NDDs has changed substantially over the last decade largely due to changes in technology and access to genomic testing [8]. This means that the number of SMGs and number of individual members within each SMG have rapidly increased since 2010 and continue to climb [3,9].

However, the data about how SMGs help parents is limited, and with increasing numbers of diagnoses, the landscape of social media use is shifting. Our study aimed to answer the research question, "How do parents of children with NDDs use SMGs for support, and what is the perceived impact of these groups on their emotional well-being and access to clinical information?"

We aimed to describe this landscape and lived experience shared in SMGs by parents of children with NDDs in order to inform improved digital collaboration for the benefit of patients and families, clinical care, and scientific advancement.

Methods

Overview

We used a convergent mixed methods design for the surveys of parents and for the interviews with parents. This approach allowed for the simultaneous collection and analysis of qualitative and quantitative data, which were integrated during interpretation to provide a comprehensive understanding.

Parent Surveys

This study is nested within the Genetic Rare Disease: Observational Cohort Study (GenROC) study, a UK-based cohort study of children aged 6 months to 16 years old with rare monogenic neurodevelopmental conditions (GenROC REC22/EM/0274) [10]. Parents were asked to complete 2 online separate patient questionnaires (PQs), PQ1 and PQ2 (completed between 2023 and 2025). Study data were collected and managed using REDCap (Research Electronic Data Capture; Vanderbilt University) electronic data capture tools hosted at the University of Bristol. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing (1) an intuitive interface for validated data capture, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for data integration and interoperability with external sources [11,12]. The parent questionnaires were developed with stakeholders (3 genetics researchers, 2 genetics charity representatives, 2 neurodisability pediatricians, 2 digital health academics, and 1 qualitative researcher) and patient participant involvement (PPI) input (6 parents of children with genetic NDDs and 1 adult with genetic NDD) and tested with 3 parents of children with NDDs using a think-aloud approach [13].

PQ1 and PQ2 both included social media questions (see Sections S5 and S6 in Multimedia Appendix 1) for the relevant sections of each survey, respectively, and development of PQ2 was informed by the results of the qualitative study described below.

Survey results were analyzed using descriptive statistics (in REDCap) for proportions and frequencies related to SMG use and parent attitudes.

Parent Interviews

A total of 17 parents (5 fathers and 12 mothers) of 13 children were purposively sampled (Low et al [10], submitted) and interviewed using a topic guide which was informed by the literature, clinical expertise, and PPI input. Most parents were interviewed one-to-one but 4 couples chose to be interviewed together. In one case, a mother was interviewed with her child present throughout. Interviews took place between October 2023 and March 2024.

Interviews took place on Zoom (Zoom Communications) and were recorded, transcribed, and anonymized, then imported into NVIVO qualitative data management software (release 1.71; Lumivero) for coding and data management. All interviews were undertaken by the first author.

Data were analyzed following the principles of inductive thematic analysis [14-16]. An iterative approach was used to develop an initial codebook (deductive component) [17]. After 8 parents were interviewed, the process was paused to review the data and to develop and refine the coding matrix. This was then used for the remaining transcripts. We determined that we would continue with interviews until no new code categories were being generated and no new themes were created [15,16]. No repeat interviews were undertaken. The first 8 transcripts were coded by the first author, and additional codes that were not covered by the initial codebook were then added (inductive component). In addition, 20% of the transcripts were double coded by an experienced qualitative researcher who was not a clinician and had no previous experience of pediatric genetic disorders. All discrepancies were reconciled through consensus. Data are reported according to the Consolidated criteria for Reporting Qualitative studies (COREQ) guidelines [18].

XSL•FO
RenderX

Data Integration

We integrated qualitative and quantitative findings during the interpretation phase using a side-by-side comparison approach [19].

Ethical Considerations

The GenROC study received Research Ethics Committee approval on December 15, 2022, and Health Research Authority approval on February 9, 2023. All participants provided informed consent for the interview as per the GenROC study protocol. All information is deidentified to protect confidentiality and anonymity.

Results

Parent Surveys

A total of 474 parents completed the GenROC parent questionnaire. Of these, 97 (20.5%) said that they were not a member of an SMG for whom no further responses were collated. In addition, 359/474 parents (75.7%) stated that they were a member of an SMG. Multimedia Appendix 2 shows that 352/359 (98.5%) of the SMGs were on Facebook. Multimedia Appendix 2 shows the categories of genetic group, geographical distribution, numbers of SMGs used, and size of groups, respectively. The 4/359 (1.1%) participants who stated that the SMG was not on Facebook did not provide information regarding the location of the group. Only 1 parent answered that their child was a member of an SMG. Those who participated in more than 1 SMG did not consider the information to be conflicting.

Almost half (n=126, 44.8%) remembered being asked when joining to keep information within the SMG confidential, but almost as many parents (n=113, 40.2%) weren't sure. Most parents (n=191, 61.2%) did not recall providing consent for their data from the SMG to be used elsewhere, with 30% (n=84) not being able to remember whether they had been asked. Of the 29 parents (10.3%) that recalled giving consent, 3 quarters remember giving consent to information being shared outside the SMG; 7 (24.1%) for any purpose; 15 (51.7%) to be shared with doctors and researchers working on the condition; and 7 (24.1%) could remember giving consent but could not remember any further details. A total of 65 (18%) respondents did not take part in any SMG with respect to their child's NDD.

The results of the statements about attitudes toward the information held in the SMG are summarized in Table 1 (1 representing the lowest agreement and 10 the highest) with the distribution depicted in Figure 1.

XSL•FO
RenderX

Table . Responses by Likert scale to attitudinal statements.

Statement	Response rate[a] (N=359), n (%)	Mean (SD)	Minimum[b]	Median (IQR)	Maximum[c]
Item 1: "I completely trust the information provided in the group."	271 (74)	7.03 (1.98)	1	7 (5-8)	10
Item 2: "To what extent do you agree with the statement 'the information provided in the group is completely biased (for example a feature might look more common because people only respond to a poll if their child has the feature)."	263 (72)	5.77 (2.02)	1	5 (5-7)	10
Item 3: "To what extent do you believe that doctors or healthcare professions should be using the information from these groups when making clinical decisions?"	272 (75)	6.79 (2.03)	1	7 (5-8)	10
Item 4: "To what extent do you agree with the statement: The social media group helps by giving me contact with other people who have similar experiences."	277 (77)	8.52 (1.85)	1	9 (8-10)	10
Item 5: "To what extent do you agree with the statement: I find that the information from the group can make me worried or anxious."	269 (75)	4.69 (2.11)	1	5 (3-6)	10
Item 6: "I find that there is conflicting information in the different groups."	145 (92)[d]	3.51 (2.2)	1	3 (2-5)	10

[a]Response rates were calculated as a percentage of parents who responded to the question out of a total count of 361, the number of parents who replied "yes" to being a member of a social media group (SMG) in the question already discussed.

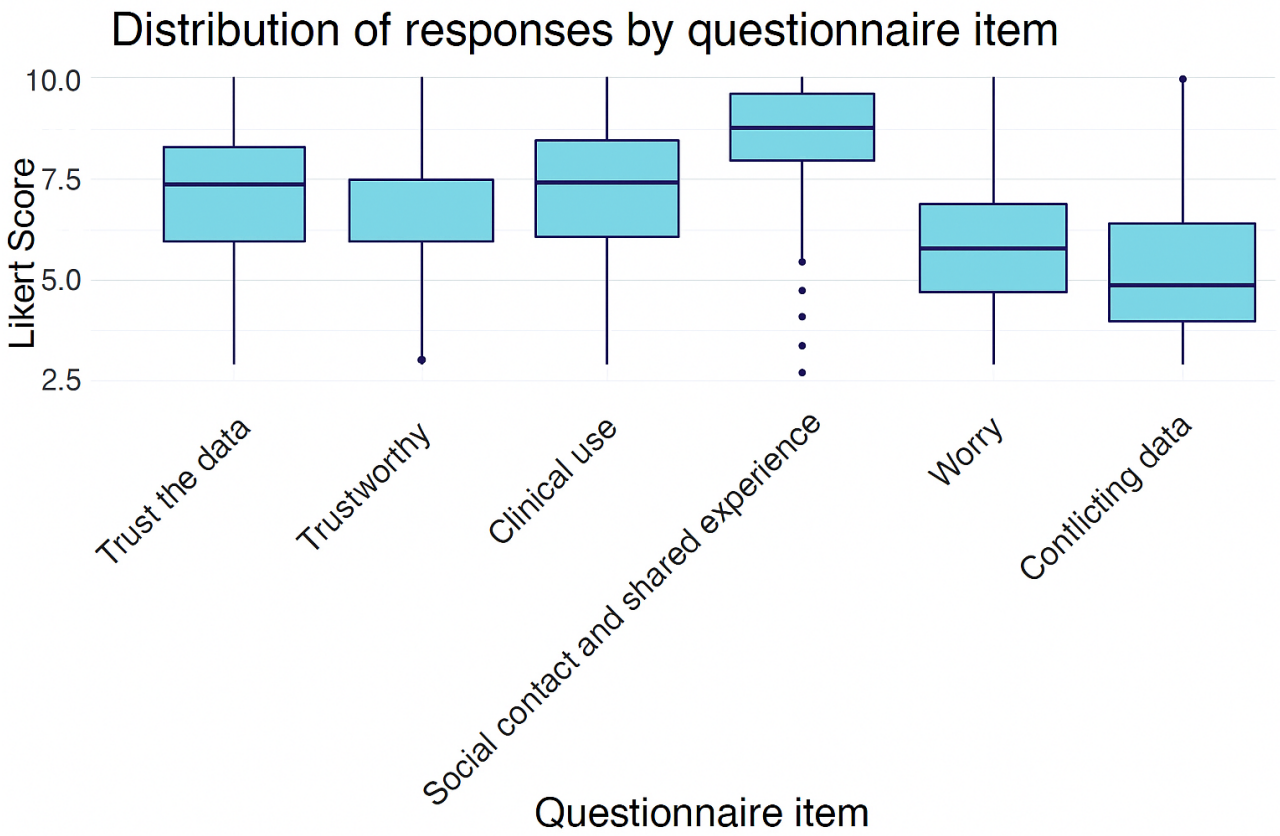
[b]Lowest agreement.

[c]Highest agreement.

[d]n=158, as this question was only asked of people who had responded that they were part of more than one SMG with respect to their child's genetic condition.

XSL•FO
RenderX

Figure 1. Distribution of responses by questionnaire item.



Most activity occurs in Facebook; 18 (8.3%) reported using a gene-specific WhatsApp group, with 5 (2.3%) using LinkedIn and 14 (6.4%) using Instagram. In addition, 10 (4.6%) follow an influencer on social media relevant to their child's diagnosis: 8 followed a parent of a child with the same condition, 4 followed a parent of a child with another genetic condition, and 1 was a person with a genetic condition. Only 7 (3.2%) reported listening to relevant podcasts.

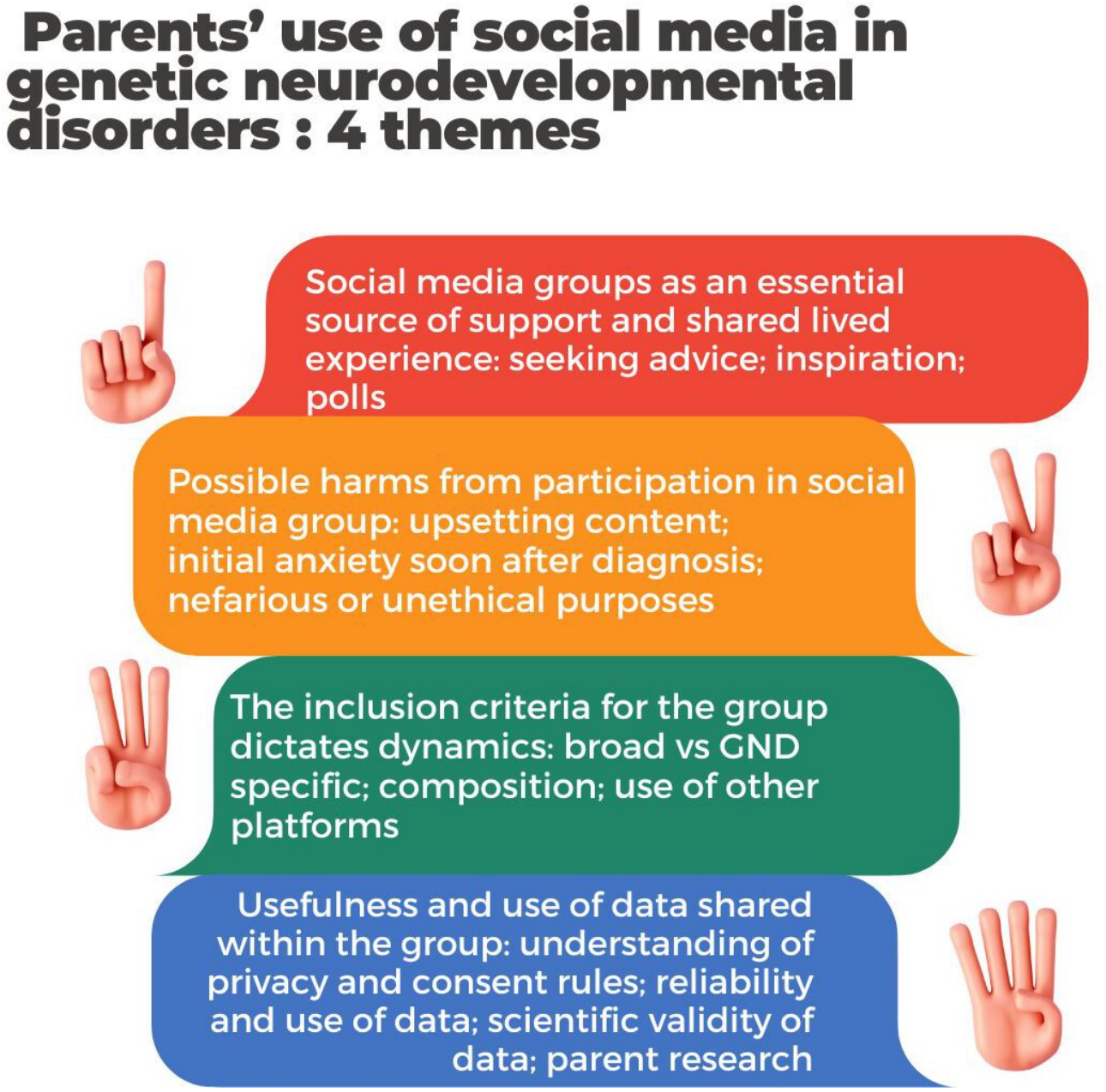
Parent Interviews

A total of 4 main themes (see Figure 2) were created from the parent interviews.

Quotes and participants are numbered in the tables and identified as mother or father.

XSL•FO
RenderX

Figure 2. Summary of themes from parent interviews regarding parent use of social media groups (SMGs) with respect to their child's neurodevelopmental disorder (NDD). GND: genetic neurodevelopmental disorder.



Social Media Groups (SMGs) for Support and Shared Lived Experience

Table S1 in Multimedia Appendix 1 shows that some parents reported that clinicians signposted them to the gene-specific Facebook group after diagnosis as a possible avenue of support (Quote 1).

All parents described the SMG as providing them with a feeling of shared lived experience, which is vital for them as a coping mechanism (Quote 2).

The lack of natural history data in NDDs makes it hard for parents to know what the future might look like for their family, which they find very difficult. SMGs allow them to get more insight (Quote 3) and show how parents rely on the SMG as an easy way of accessing information about their child's NDD and as a way of staying up to date and well informed (Quote 4).

Parents described some of the reasons for searching or posting. These included:

1. To help find information before attending an appointment with a health care professional for their child (Quote 5).
2. To get ideas for specific aids, interventions, days out, or toys that might be particularly appropriate or enjoyable for their child (Quote 6).
3. For medical advice about their child from other parents in the group (Quote 7).
4. For polls to find out about the prevalence of symptoms, features, and interventions, as well as to help researchers (Quote 8).

Potential Harms From Participation in SMGs

Table S2 in Multimedia Appendix 1 shows that parents described 3 subthemes of potential harms through participation in SMGs.

XSL•FO
RenderX

First, parents become upset by the content that they read or see in the groups.

Reading the posts in the SMGs can cause anxiety, and this can lead to reduced use (Quote 9) or have an impact on mental health (Quote 10).

Parents talked about how they are particularly distressed when they read posts about children in the group dying. A parent explained that it is not simply the subject matter itself but also the reflex anxiety it generates about one's own child and a tendency to heightened anxiety and emotion within the group that can be difficult to deal with (Quote 11).

For some, the distressing content was about their own child. A parent explained that another member of the SMG was the first person to suggest the diagnosis for her child (Quote 12).

Second, joining a SMG soon after a child's diagnosis can result in a spike in anxiety.

Participation in the SMGs can cause considerable anxiety in parents when joining soon after their child's diagnosis (Quote 13). This was highlighted by a foster carer with her viewpoint on this initial spike of anxiety in biological parents (Quote 14).

The process of participating in the SMG, experiencing anxiety, and learning to manage that may be helpful in enabling parents to come to terms with their child's NDD (Quote 15). Another parent described this phenomenon of initial anxiety and tried to highlight positive stories for newly joined families but recognizes that even she can get anxious in the groups (Quote 16).

Third, SMGs can be used for harmful purposes, but this is infrequent.

Parents described use of data in SMGs for unintended or unacceptable purposes, including a description of members of the group whose children had variants of uncertain significance that "didn't look likely" and how they were trying to use information acquired in the group to try and obtain a diagnosis or "proof" for their child. A more extreme example of this misuse of data is where a parent describes a safeguarding case arising from a feeding tube Facebook group (Quote 17).

Parents reported that occasionally groups can be targeted for commercial purposes such as unsolicited marketing of equipment. While unwelcome, most of these instances are genuine; however, occasionally they can be preying on vulnerable families as part of a scam (Quote 18).

The Inclusion Criteria for the Group Dictates Dynamics

Table S3 in Multimedia Appendix 1 shows the inclusion criteria.

First, parent experience differs in groups that have broad inclusion versus specific criteria.

While most parents were members of NDD SMGs, some were members of broader SMGs as well. A foster parent reported preferring a broader fostering SMG to the NDD SMG as members were less likely to be offended by posts (Quote 19). In contrast, another parent explained that the mixed SMGs can result in a competitive dynamic between members who wish to be seen as the one having the most difficult time (Quote 20).

Second, group dynamics are impacted by geographical spread, size, and composition.

For some NDDs, the number of children being diagnosed has increased significantly, which has resulted in a much bigger SMG. This has resulted in some SMGs being split by composition (parents, grandparents, and researchers) and has impacted the content within the SMG (Quote 21). Some NDDs will have an international SMG as well as country-specific SMGs (such as UK families only). Parents explained the pros and cons of being part of one of the big international SMGs (Quote 22). Another problem with the international SMGs is that non-English speakers tend to receive fewer responses to their posts (Quote 23). As the SMGs get bigger and more children are diagnosed, more specific charities are set up, which can result in competition between charities within the groups. The same mother, who has set up an NDD charity, described some of the competing politics arising in a big SMG (Quote 24).

Third, group composition and dynamic may prompt the use of other platforms.

A parent explained that for the NDD, there is a UK-only Facebook group and then a bigger international one, hosted by a US charity. She reported that the UK SMG is very "quiet" and suspects that people think they have a higher chance of getting relevant information in the bigger SMG. However, there is still a desire for local or UK-specific support. For this reason, the UK-based charity is trialing a WhatsApp group just for UK families (Quote 25).

Another parent advocate who had set up a UK charity explained that she also uses LinkedIn for her charity work but in a professional capacity and in a different way from how she would use the Facebook group (Quote 26).

Usefulness and Use of Data Shared Within Groups

Table S4 in Multimedia Appendix 1 shows the usefulness and use of data shared within groups.

First, parent understanding about their data in the groups, privacy, and consent:

Parents varied in their recall of what they had been asked or what rules they agreed to when they signed up for the SMG (Quote 27). However, a parent was certain the only question they had been asked was whether their child had the specific genetic diagnosis.

Some parents considered the need to decide about sharing information in terms of their child's best interests (Quote 28). Parents reported they have noticed that many parents in the SMGs appear to trust it implicitly and will share highly confidential data (Quote 29). However, some parents stated that they had little confidence in anything they shared being kept private (Quote 30) and that there are no guarantees that the people who join are genuine (Quote 31).

Foster carers described a nuanced aspect regarding the privacy of data and the need to protect a looked-after child's identity, particularly within a small SMG in which a birth parent may be a member if they have the same genetic condition as the child

XSL•FO
RenderX

(Quote 32). This need for heightened privacy limits their ability to access the same amount of support from the SMG as others.

Second, parent views on the reliability and use for the data in the groups:

Parents discussed how they assess digital content for scientific validity. All report using search engines, mostly Google, as a starting point. Many reported that they would trust information that was in a scientific journal or if it was affiliated with a university in some way (Quote 33).

Third, parent views on the trustworthiness of the data in the groups:

Parents perceived a bias in the frequency of posters, but there were differing views. A parent commented that "you do tend to hear more from the people that are having the worst time"(#15, father), whereas another parent reported that the parents who post most have the "mildest" children (Quote 34).

Nonetheless, parents feel they are objective about the information being presented and consider it useful but anecdotal (Quote 35). Another parent talked about the need to verify and fact-check information from within the SMGs (Quote 36).

Fourth, parent-independent research and participation in research:

Although a lot of data are being collected in SMGs, most parents doubted that useful information could be extracted, or that it would be legal to do so, but felt that it was helpful to be able to search old threads such as regarding treatment options (Quote 37). Parents suggested that the data could be used to identify themes that could guide researchers toward avenues for future studies (Quote 38).

A parent reported that a large language model application is being used within their group that she found out about recently at the family conference (Quote 39).

Most parents described researching their child's specific genetic variant themselves. For some, this would be through the SMG, and some parents would develop expertise and answer other members' questions about the variants within the group. To gain understanding and expertise, they use online data sources with a search engine as a starting point (Quote 40).

Many parents reported taking part in online registries and in rare disease portals where they are asked to complete questionnaires at intervals. Parents considered this as being very different from their posting in Facebook groups, thinking of the former as scientific research and the latter as anecdotal and social.

Integration

Table 2 shows the side-by-side comparison approach of the qualitative and quantitative results. Mapping of the themes to the survey findings confirmed that parents highly valued SMGs for emotional support and shared experiences, though some reported moderate concerns about anxiety. Group composition influenced perceived support. While parents generally trusted SMG data, they acknowledged potential bias and privacy concerns.

Table . Joint display table mapping qualitative themes to quantitative results.

Qualitative theme	Subthemes	Mapped quantitative findings	Interpretation
Support and shared experience	Signposting by professionals, emotional connection, and practical advice.	High agreement (8.52/10) on SMGs[a] providing contact with similar experiences.	SMGs are a vital support system for parents.
Potential harms	Anxiety, distressing content, and misuse of data.	Moderate agreement (4.69/10) on SMGs causing anxiety.	Harms are present but not dominant; qualitative data adds nuance.
Group composition and dynamics	Inclusion criteria, international versus local, and platform choice.	A total of 98% (354/359) of SMGs on Facebook; some use WhatsApp or LinkedIn.	Group structure affects experience; larger groups may dilute support.
Usefulness and data trust	Privacy concerns, trust, bias, and research use.	Mixed scores: trust (7.03), bias (5.77), and doctor use (6.79).	Parents value SMG data but recognize limitations and risks.
Independent research and advocacy	Self-directed learning, registry participation, and data mining.	Not directly surveyed.	Parents are proactive in research; SMGs serve as informal knowledge hubs.

[a]SMG: social media group.

Discussion

Principal Findings

Use of SMGs is highly prevalent in this cohort and provides support and information to fill an existing gap. However, the information in these SMGs is largely anecdotal, requires a degree of critical assessment, and can cause anxiety. Understanding SMG use and activity is important to ensure optimal support for parents, to address information needs adequately, and to improve collaboration between parents, clinicians, and researchers.

Some parents told us in interviews that they were directed to the SMG by their child's health care professional who suggested it to them as an avenue of support and information. Unfortunately, this was not specifically quantified within our parent survey but is consistent with a previous study in which a quarter of parents were directed to the group by their child's health care professional [4].

XSL•FO
RenderX

Parents value these SMGs very highly as shown by their high Likert response and qualitative analysis that is consistent with the literature [5-7,9,20,21]. Most parents view the SMGs as an opportunity to connect with other families who are in the same situation and develop real connections with them and friendships. Parents particularly valued the chance to understand the spectrum of the NDD by looking at other members' posts about their children. Having members with older or adult children allowed them to get some understanding about the long-term outlook for their child, which is consistent with previous literature [5,21-23].

Some parents also use the SMG to obtain quasi-medical advice from other members and would trust it implicitly. We cited an example where a parent chose not to be present for an acute review of her child based on medical advice provided within the group. An important factor here may be responsiveness—Facebook groups provide rapid responses and ongoing support and feedback [24], which may empower a parent to make a decision to "watch and wait." However, some parents in our study reported concerns about using the group in this way and expressed concerns that the level of trust placed in the reliability of such advice might be unfounded or too high. This is echoed in a previous analysis of Hirschsprung disease in which the Facebook group was shown to have reach and responsiveness but lacked consistent evidence-based guidance in the posts [24]. A particular use detected in our study was to prepare a parent before a child's health appointment to ensure they knew what to discuss and request from the provider. While this behavior is cited as common among parents of all children [1], it is more nuanced in NDDs where parents may feel that they need to undertake this preparatory research to negate their clinician's lack of expertise. If clinicians recognize this phenomenon is occurring, they can use this as a route to provide better collaborative support for parents. An example of this might be suggesting to parents that they may read information in SMGs that they might want to note down and come prepared with some questions or even inviting parents to send questions in advance, which might allow the clinician adequate time to do their own research. A real-world scenario could involve a clinician opening with the question, "Have you read anything on the Facebook group that you want to discuss with me today?"

Most parents indicated high levels of trust in the SMG (by the Likert scale responses) and are not worried about their data or put off posting for this reason, although a small proportion did discuss their concerns around this. A study in 2022 of 231 parents indicated that parents do express concern about privacy issues and that the SMG's privacy setting can be a critical factor influencing active support group participation [4]. However, almost half of our respondents could not recall whether they had been asked to agree to any statements regarding consent or privacy when joining, but continued to participate in the SMGs. The analysis of parent interviews suggests that parents with the highest levels of concerns around privacy would be most cautious about what they post in the SMGs. It is also noteworthy that an SMG appears to be using some form of natural language processing model to mine the data for themes. This raises questions regarding consent within the groups and use of data.

Looked-after children represent a particularly vulnerable group within social media, and foster or adoptive parents are required to hide their identities to protect them. This can be difficult with a rare NDD where patient numbers may be very small. Genetic variants can be unique to a family or individual and could theoretically be identifiable, and so this may limit the foster or adoptive parents' options for interactions and questions within an SMG, limiting their support opportunities compared to other families.

SMG participation is not without its downsides. A spike in anxiety can occur initially after joining, particularly when this occurs soon after receiving a diagnosis (which is the most common time that parents join). Nonetheless, most of the survey respondents did not agree that the SMG made them worry more. The potential negative impact is sparsely discussed in the literature to date [6].

There was recognition of posting bias within the SMGs, but some of the parents who talked about this felt that they were able to assess the posts and come to conclusions about bias themselves. However, parents trust the data that are shared, as evidenced by the high levels of trust reported by the Likert scale, and parents report making health care decisions about a child presenting with new symptoms based on the SMG responses.

Our results show that there are many NDDs that have more than 1 SMG, which families can join, consistent with a previous estimate that 33% of monogenic disorders had more than 1 SMG [9]. It is likely that this percentage will have increased based on the rapid acceleration of diagnosis in these conditions. The same study found that SMGs with large numbers of members were more likely to be active and have the most posts [4]. This is in keeping with our findings that parents are likely to go to larger SMGs where they feel they have the highest chance of getting data that they seek. However, these larger SMGs appear to have downsides, as does the presence of more than 1 group per NDD. Our results suggest that there are increasing politics and tensions within groups, particularly where there is a suggestion of increasing competition for members within NDD charities and foundations, and that the SMGs may be being used to steer members toward particular organizations. These changing dynamics are scarcely explored in the literature to date, which may be because this is a newly evolving phenomenon with time and rapidly increasing numbers of diagnosed conditions.

The changing dynamics within groups have resulted in some groups trying options that are not Facebook. This has included WhatsApp as an option for 1 UK-based group who has fewer than 50 families. The decision was made to try and create a more UK-specific option for families. However, functionality may become a barrier as the group increases in size, as might its lack of interactive options and easy search tools. Our results otherwise suggest that parents are not using other platforms very much for this specific purpose. A smaller number of parents use LinkedIn, but particularly for professional advocacy purposes.

Facebook groups are closed, and it appears this is vital for ensuring families feel able to participate in a way that protects their privacy needs [8]. Nonetheless, our findings suggest that

XSL•FO
RenderX

SMGs could increasingly be used by researchers to engage with patient groups better. In addition, we report several examples within groups to determine appetite for a topic of research or assess the availability of data before embarking on a research proposal. Using poll results could also identify important topics that matter to families. Researchers need to establish positive connections with group administrators to do this successfully. Very little exists in the literature to date on this theme, again reflecting this rapidly advancing field and area.

Strengths and Limitations

This study uses a large cohort of parents of children with a mix of genetic conditions from across the United Kingdom. The majority of survey respondents and interviewees were mothers, but some fathers were included. Our methods were able to capture responses from parents who do not use SMGs or who have stopped doing so, as well as regular users. The lead investigator is a clinical geneticist, but the second coder for the interviews is a nonclinical experienced behavioral and psychological qualitative researcher. Parents described negative experiences with health care professionals suggesting that they felt able to express their views despite the researcher's clinical background. The PQ2 survey had questions that had hoped to capture parental behavior change regarding SMG with time but were limited in the short interval between survey administrations for some families who were recruited later.

Conclusions and Implications for Practice

Data poverty in rare diseases drives parents to do their own research and propels them into SMGs for connection. Parent-reported data in groups reflect lived experience data. SMGs are essential for parents as a space to connect and compare experiences and may represent an opportunity as an avenue to drive forward research connections and priorities and allow for opportunities for advocates and peer mentoring to flourish. Parents use SMGs as a quasi-clinical advisor in some situations and for preparation before attending health care appointments—this could represent a way in for enhanced collaboration with parents in the clinic. The rapidly changing landscape of NDDs may shift the dynamics within groups that could result in an evolution in the number of groups and platforms used. Limited reports exist on the negative aspects, and these appear to be a minority, but some parents reported reducing or stopping their use of the group altogether, which may be associated with these problems. Further research should ascertain if this is an increasing trend, as this could result in a support gap for parents in the future. Changing behavior over time and evolving information needs represent an avenue for future research.

Acknowledgments

We thank all the parents in the Genetic Rare Disease: Observational Cohort (GenROC) study for contributing their views and the GenROC study patient participant involvement (PPI) panel for their invaluable thoughts and guidance. The GenROC consortium comprises multiple contributors from National Health Service (NHS) sites across the United Kingdom, including individuals who have either acted as a local site principal investigator (PI) or associate PI, completed clinical proformas for GenROC, or contributed in other ways. The full list is shown in Section S7 in Multimedia Appendix 1. Tables S1-S4 in Multimedia Appendix 1 show quotes from parents for themes 1-4, and Section S5 shows the list of GenROC consortium members. For the purpose of open access, the author has applied a CC-BY public copyright license to any author-accepted manuscript version arising from this submission. KL and GenROC are supported by the National Institute for Health and Care Research Doctoral Research Fellowship 302303. The views expressed are those of the authors and not necessarily those of the National Institute for Health and Care Research (NIHR) or the Department of Health and Social Care. JP receives funding from the NIHR Applied Research Collaboration Oxford and Thames Valley at Oxford Health NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

Authors' Contributions

Conceptualization: KJL
Data curation: KJL
Formal analysis: KJL, GT-E
Investigation: KJL
Methodology: KJL, GT-E, JI, JP
Project administration: KJL
Visualization: KJL
Writing – original draft: KJL
Writing – review & editing: KJL, GT-E, SLW, JP, JI
Resources: SLW

Conflicts of Interest

None declared.

Multimedia Appendix 1

XSL•FO
RenderX

Quotes from parents for themes 1-4 and the list of Genetic Rare Disease: Observational Cohort Study (GenROC) consortium members.
[PDF File, 369 KB - pediatrics_v8i1e76526_app1.pdf]

Multimedia Appendix 2
Demographics of social media group (SMG) use.
[PNG File, 141 KB - pediatrics_v8i1e76526_app2.png]

References

1. Frey E, Bonfiglioli C, Frawley J. Parents' use of social media for health information before and after a consultation with health care professionals: Australian cross-sectional study. JMIR Pediatr Parent 2023 Oct 20;6:e48012. [doi: 10.2196/48012] [Medline: 37933198]
2. Frey J, Black KJ, Malaty IA. TikTok tourette's: are we witnessing a rise in functional tic-like behavior driven by adolescent social media use? Psychol Res Behav Manag 2022;15:3575-3585. [doi: 10.2147/PRBM.S359977] [Medline: 36505669]
3. Titgemeyer SC, Schaaf CP. Facebook support groups for pediatric rare diseases: cross-sectional study to investigate opportunities, limitations, and privacy concerns. JMIR Pediatr Parent 2022 Jan 6;5(1):e31411. [doi: 10.2196/31411] [Medline: 34989690]
4. Breivold J, Rø KI, Hjörleifsson S. Conditions for gatekeeping when GPs consider patient requests unreasonable: a focus group study. Fam Pract 2022 Jan 19;39(1):125-129. [doi: 10.1093/fampra/cmab072] [Medline: 34173654]
5. Cacioppo CN, Conway LJ, Mehta D, Krantz ID, Noon SE. Attitudes about the use of internet support groups and the impact among parents of children with Cornelia de Lange syndrome. Am J Med Genet C Semin Med Genet 2016 Jun;172(2):229-236. [doi: 10.1002/ajmg.c.31504] [Medline: 27163126]
6. Wang T, Lund B. Categories of information need expressed by parents of individuals with rare genetic disorders in a Facebook community group. J Consumer Health Internet 2020;24(1):20-34. [doi: 10.1080/15398285.2020.1717550]
7. Tozzi AE, Mingarelli R, Agricola E, et al. The internet user profile of Italian families of patients with rare diseases: a web survey. Orphanet J Rare Dis 2013 May 16;8(76):23680080. [doi: 10.1186/1750-1172-8-76] [Medline: 23680013]
8. Wright CF, Campbell P, Eberhardt RY, et al. Genomic diagnosis of rare pediatric disease in the United Kingdom and Ireland. N Engl J Med 2023 Apr 27;388(17):1559-1571. [doi: 10.1056/NEJMoa2209046] [Medline: 37043637]
9. Titgemeyer SC, Schaaf CP. Facebook support groups for rare pediatric diseases: quantitative analysis. JMIR Pediatr Parent 2020 Nov 19;3(2):e21694. [doi: 10.2196/21694] [Medline: 33211019]
10. Low KJ, Watford A, Blair P, et al. Improving the care of children with GENetic Rare disease: Observational Cohort study (GenROC)-a study protocol. BMJ Open 2024 May 16;14(5):e085237. [doi: 10.1136/bmjopen-2024-085237] [Medline: 38760043]
11. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. J Biomed Inform 2019 Jul;95:103208. [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]
12. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381. [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
13. Bradbury K, Morton K, Band R, et al. Using the person-based approach to optimise a digital intervention for the management of hypertension. PLoS ONE 2018;13(5):e0196868. [doi: 10.1371/journal.pone.0196868] [Medline: 29723262]
14. Burns M, Bally J, Burles M, Holtslander L, Peacock S. Constructivist grounded theory or interpretive phenomenology? Methodological choices within specific study contexts. Int J Qual Methods 2022 Apr;21:16094069221077758. [doi: 10.1177/16094069221077758]
15. Braun V, Clarke V. Toward good practice in thematic analysis: avoiding common problems and be(com)ing a knowing researcher. Int J Transgend Health 2023;24(1):1-6. [doi: 10.1080/26895269.2022.2129597] [Medline: 36713144]
16. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
17. Roberts K, Dowell A, Nie JB. Attempting rigour and replicability in thematic analysis of qualitative research data; a case study of codebook development. BMC Med Res Methodol 2019 Mar 28;19(1):66. [doi: 10.1186/s12874-019-0707-y] [Medline: 30922220]
18. Booth A, Hannes K, Harden A, Noyes J, Harris J, Tong A. COREQ (Consolidated Criteria for Reporting Qualitative Studies). In: Moher D, Altman DG, Schulz KF, Simera I, Wager E, editors. Guidelines for Reporting Health Research: A User's Manual: Wiley; 2014:214-226. [doi: 10.1002/9781118715598.ch21]
19. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. Health Serv Res 2013 Dec;48(6 Pt 2):2134-2156. [doi: 10.1111/1475-6773.12117] [Medline: 24279835]
20. Barton KS, Wingerson A, Barzilay JR, Tabor HK. "Before Facebook and before social media…we did not know anybody else that had this": parent perspectives on internet and social media use during the pediatric clinical genetic testing process. J Community Genet 2019 Jul;10(3):375-383. [doi: 10.1007/s12687-018-0400-6] [Medline: 30569339]

XSL•FO
RenderX

21. Deuitch NT, Beckman E, Halley MC, et al. “Doctors can read about it, they can know about it, but they’ve never lived with it”: How parents use social media throughout the diagnostic odyssey. J Genet Couns 2021 Dec;30(6):1707-1718. [doi: 10.1002/jgc4.1438] [Medline: 34096130]
22. Nicholl H, Tracey C, Begley T, King C, Lynch AM. Internet use by parents of children with rare conditions: findings from a study on parents’ web information needs. J Med Internet Res 2017 Feb 28;19(2):e51. [doi: 10.2196/jmir.5834] [Medline: 28246072]
23. Demarest S, Marsh R, Treat L, et al. The lived experience of parents’ receiving the diagnosis of CDKL5 deficiency disorder for their child. J Child Neurol 2022 May;37(6):451-460. [doi: 10.1177/08830738221076285] [Medline: 35196159]
24. Wittmeier K, Holland C, Hobbs-Murison K, et al. Analysis of a parent-initiated social media campaign for Hirschsprung’s disease. J Med Internet Res 2014 Dec 11;16(12):e288. [doi: 10.2196/jmir.3200] [Medline: 25499427]

Abbreviations

NDD: neurodevelopmental disorder
PPI: patient participant involvement
PQ: Parent Questionnaire
REDCap: Research Electronic Data Capture
SMG: social media group

Edited by S Badawy; submitted 25.04.25; peer-reviewed by CS Ginn, T Wang; revised version received 02.09.25; accepted 10.09.25; published 14.10.25.

Please cite as:
Low KJ, Treneman-Evans G, Wynn SL, Ingram J, Powell J
Parental Use of Social Media and the Internet in the Context of Their Child’s Genetic Neurodevelopmental Disorder: Mixed Methods Study Nested in the GenROC Cohort Study
JMIR Pediatr Parent 2025;8:e76526
URL: https://pediatrics.jmir.org/2025/1/e76526
doi:10.2196/76526

© Karen Jaqueline Low, Georgia Treneman-Evans, Sarah L Wynn, Jenny Ingram, John Powell. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 14.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

A Low-Cost, Social Media–Supported Intervention for Caregivers to Enhance Toddlers' Language Learning: Mixed Methods Feasibility and Acceptability Study

Mollie Romano[1], PhD; Diana Abarca[1], MS; Frances Baehman[1], MS

School of Communication Science and Disorders, Communication and Early Childhood Research and Practice Center, Florida State University, Tallahassee, FL, United States

Corresponding Author:
Mollie Romano, PhD
School of Communication Science and Disorders
Communication and Early Childhood Research and Practice Center
Florida State University
201 W Bloxham Street
Tallahassee, FL, 32306-1200
United States
Phone: 1 850 322 0152
Email: mollie.romano@cci.fsu.edu

Abstract

Background: Widely accessible, cost-effective early language development interventions for caregivers of young children are needed to promote optimal outcomes in children in the United States. Social media short-form videos, such as those on TikTok, may be a natural fit for delivering this type of intervention.

Objective: This study aims to examine the feasibility and acceptability of a low-intensity, short-term social media intervention for caregivers of young toddlers.

Methods: In total, 25 caregivers of children aged between 12 and 18 months participated in this study. We shared 32 short-form videos via TikTok over an 8-week period to help increase caregivers' knowledge about early childhood communication. We examined metrics to characterize participant engagement, explored measures of changes in caregivers' knowledge, and conducted a qualitative analysis of caregiver interviews after the intervention.

Results: Results indicated that most caregivers were able to consistently view the videos, with approximately 75% (16/21) viewership per video (mean 15.75 likes out of 21 possible likes), and caregivers reported positive effects of the intervention on their knowledge of how to support their child's communication. The results of the exploratory measure of change in caregiver knowledge were positive but not statistically significant (t_{21}=–1.357; P=.09). Caregivers offered suggestions for content and enhancements to videos for future investigations.

Conclusions: Low-cost, short-term social media interventions could be an effective means to equip caregivers with the information they need to advance their children's language abilities, particularly for families from lower-income backgrounds whose access to health information about their young children may be limited.

(JMIR Pediatr Parent 2025;8:e66175) doi:10.2196/66175

KEYWORDS

social media; language development; toddler; infant; infancy; pediatric; language learning; feasibility; acceptability; caregiver; TikTok; mixed methods; short video; qualitative analysis; child support; health information

Introduction

Background

Infants undergo multiple developmental transitions that change the way they engage with the world around twelve months of age. Most infants take their first steps to become new walkers, become more consistent and advanced gesture users, and make the transition to symbolic language as they say their first words [1]. In the months that follow, variability in children's expressive vocabulary appears as some children learn words quickly, while others learn words more slowly [2]. Because children's language

XSL•FO
RenderX

outcomes are directly linked to their academic, social-emotional success, and mental health, promoting optimal language learning is a critical public health issue [3]. Efforts to bolster early language learning by supporting caregiver-child interactions, especially in lower-income communities, are key to promoting school readiness, social and emotional learning, and optimal language outcomes in all children [4].

However, more research is needed on effective interventions for caregivers and children at the population level to promote optimal child language outcomes while providing targeted support for children in greater need of intervention [3]. Investments in population-wide, universal interventions may bolster child outcomes by increasing caregiver knowledge and confidence in supporting their infant's early learning. Unlike more intensive coaching approaches that are often geared toward lower-income families, widely accessible interventions may also avoid stigmatizing families who are often the recipients of preventive interventions [5]. In this feasibility and acceptability study, we describe the development and the use of a cost-effective, media-supported approach to sharing information and strategies with caregivers to support language learning in toddlers aged between 12 and 18 months, a critical developmental inflection point. The BabyTok Project is designed as a light touch social media–supported intervention to increase caregivers' knowledge about early language learning and how they may promote it with the use of specific strategies.

Factors That Support Early Language Development

Caregiver-child interactions in the first few years of life are influenced by a family's culture [6] and what caregivers know and believe about children's language and cognitive development [7]. Caregivers who believe that children's language learning begins early and is dependent on the input from adults around them are more likely to engage their children in back-and-forth exchanges [7]. For their part, children also influence caregiver-child interactions through their own initiations and contributions during exchanges through vocalizations, gestures, gaze, and early word use [8].

While it is well established that sufficient language input is related to infants' early language learning [9], other characteristics of caregiver-child interactions contribute to meaningful moments of early word learning. For instance, the degree to which caregivers and children engage as conversational partners during back-and-forth turn-taking exchanges relates to children's later language outcomes as well as their neuroanatomy and physiology [10,11]. Caregiver input that is timely, contingent, and functional within the immediate contexts of everyday life also helps to facilitate early language learning [12]. During infancy and the early toddler years, linguistic features such as caregivers' use of parentese (marked by more exaggerated intonational patterns and repetition of words and phrases), gestural input [13], and touch cues also support early language learning in the first 2 years of life [14]. While some caregivers may know that these strategies support their child's ability to talk, others may not, particularly if they are first-time caregivers who do not have extensive experience interacting with infants and toddlers or if they do not have access to information about how children learn [7,15].

Interventions to Increase Caregivers' Knowledge About Early Language Learning

Several interventions that center on infants, toddlers, and caregivers demonstrate promise in supporting child language learning, particularly in communities experiencing poverty. For example, the "3Ts" home visiting curriculum [7] and another model named Duet [16] use home visiting models to enhance caregivers' knowledge and responsive interactions with toddlers. However, limitations of such approaches relate to scalability and cost. Training and employing home visitors for more time-intensive models limit the ability of programs to offer support for every child and family who qualifies. This does not mean that more intensive programs are not worth the investments they require; rather, additional approaches are needed at the population level to support widespread access to developmental information that may influence caregiver-child interactions.

Several mobile health interventions aimed at caregivers of very young children have shown evidence of effectiveness in increasing caregiver knowledge [17,18]. For example, an intervention called Sharing Stories used WhatsApp as a platform to promote responsive caregiving and parent well-being within a 6-week intervention in Tanzania. Caregivers in the intervention condition, which consisted of 6 content webinars on early learning, reported higher developmental outcomes for their children than the control group [19]. Fully asynchronous app-based interventions such as Háblame Bebé are also being tested in the United States to examine whether low-intensity interventions have a direct impact on caregiver-child interactions by sharing information about "language nutrition" in the early years of life [20]. While data from a randomized controlled trial are mixed related to the ability of Háblame Bebé alone to impact caregiver-child interactions, caregivers report positive outcomes related to increased knowledge about children's language learning and cultural pride regarding their use of Spanish with their child [21]. Compared to other areas, such as maternal and child health, developmental interventions that focus on early language development using social media are rare [17].

Although research evaluations to support early language development on social media are scarce, they could be a natural fit for mobile health interventions because many caregivers in the United States use social media to seek information and connections with others as they transition to parenthood [22,23]. Approximately 89% of new caregivers report using social media apps to search for information and social support about caregiving-related topics, such as infant sleep, feeding, growth, and development [24]. Low-income communities in the United States report the use of social media and the internet to access parenting information and social support at high rates, making it a logical platform to share information that could be accessible for all caregivers [23,25]. Mothers with low incomes in the United States have described using their mobile phones as a primary source of access to the internet, and they report using search features to quickly gain access to information while multitasking with other responsibilities [25]. Creators on social media already generate publicly available content specific to supporting language learning in young children and have large followings of caregivers. However, few investigations explore

XSL•FO
RenderX

whether caregivers can consistently access and retain information and use strategies from social media to support language-rich interactions with their children.

BabyTok Project

We first developed and tested the BabyTok Project as a means to connect with teachers of infants and toddlers during the COVID-19 pandemic because it made use of mobile technology while social distancing [26]. In our initial study, we conducted an 8-week intervention with teachers serving infants and toddlers in low-income communities by giving an overview of early communication development in the first year of life, responsive strategies to support child communication in the classroom, and affirmations for teachers about their critical role as early educators during the pandemic. The BabyTok Project reinforced the infant toddler teachers' positive interactions with children as described by the teachers, encouraged them to implement new communication strategies with children in their classroom in some cases, and increased or reinforced feelings of pride in their role in children's learning. Results also indicated positive, though not statistically significant, gains in knowledge scores related to early language learning on a standardized measure. Most participants endorsed the use of social media as a platform for the BabyTok Project because of its convenience, engaging style, and short-form nature [26].

Purpose of This Study

The purpose of this investigation is to examine the feasibility and acceptability of the BabyTok Project as a means to support home-based caregivers' knowledge about early language development and intervention. Feasibility is characterized by caregiver retention and caregiver engagement with the project videos and procedures, and acceptability will be described through qualitative analysis of caregiver interviews after the intervention. We also use an exploratory measure to determine the potential of the tools to capture change from a light-touch intervention such as the BabyTok Project for future effectiveness studies.

Methods

Participants

Study recruitment occurred in the summer of 2022 through an informational video that was posted on TikTok (ByteDance) and the study flyer posted on relevant Facebook (Meta Platforms, Inc) groups. To be eligible, caregivers had to (1) have at least 1 child aged between 12 and 18 months and (2) receive at least 1 public benefit (Women Infants and Children, Medicaid, Temporary Assistance for Needy Families, and housing assistance), which served as a proxy for income. Interested individuals were directed to a survey link that included 2 screening questions to verify their eligibility status (ie, "How old is your child?" "Does your family receive any of the following assistance: commodities, food stamps, housing assistance, Medicaid, supplemental security income, and/or WIC?"). While the intervention was intended to be universal, we focused recruitment on caregivers who used social services to ensure that the intervention was accessible and acceptable to caregivers with fewer financial resources.

After duplicates and incomplete responses from the initial interest survey were removed, 42 eligible caregivers across the United States expressed interest and shared their information to join the study within the 7-day recruitment period. Of them, 27 (64%) caregivers completed pretest measures and began participation in the study, while the remaining 15 (36%) did not respond to pretest measures. We held an initial Zoom (Zoom Communications, Inc) meeting with each of the 27 participants, which ensured the participants were real and not bots. Moreover, 2 (7%) participants did not complete any posttest data and were considered lost to attrition, so demographic data for 25 participants were reported. The study participants included 24 (96%) mothers and 1 (4%) grandmother. In total, 11 (44%) participants were White, 8 (32%) were Black, 2 (8%) were multiracial (Black and White: n=1, 4%; Black, White, and Hispanic: n=1, 4%), 1 (4%) was Asian, and 1 (4%) was Hispanic. In addition, 1 (4%) participant did not self-report her race or ethnicity. All (n=25, 100%) participants spoke English, and 4 (16%) spoke an additional language (ie, Spanish or Vietnamese), and they were aged between 23 and 49 years. In total, 15 (60%) participants reported having a male child, 10 (40%) reported having a female child, and none (n=0, 0%) were identified with a developmental condition (Table 1 presents more demographic information about the participants).

XSL•FO
RenderX

Table 1. Caregivers' demographic information (N=25).

Characteristic	Participants, n (%)
Relation to the child	
Mother	24 (96)
Grandmother	1 (4)
Age (y)	
20-29	8 (32)
30-39	15 (60)
40-49	2 (8)
Race or ethnicity	
Asian	1 (4)
Black	8 (32)
Black and White	1 (4)
Black, White, and Hispanic or Latino	1 (4)
Hispanic and Latino White	1 (4)
Hispanic and Latino non-White	1 (4)
White	11 (44)
Did not report	1 (4)
Languages spoken	
English	25 (100)
Spanish	3 (12)
Vietnamese	1 (4)
Educational level	
High school diploma	4 (16)
GED[a] or an alternative credential	1 (4)
Trade and vocational school	2 (8)
Some college	5 (20)
Associate's degree (associate of arts and associate of sciences)	3 (12)
Bachelor's degree (BA and BS)	9 (36)
Doctorate (PhD)	9 (36)
Estimated household income (US $)	
<10,000	3 (12)
10,000-19,999	1 (4)
20,000-29,999	3 (12)
30,000-39,999	7 (28)
40,000-49,999	2 (8)
50,000-59,999	3 (12)
60,000-69,999	1 (4)
70,000-79,999	2 (8)
90,000-99,999	1 (4)
≥100,000	1 (4)
Prefer not to answer	1 (4)
Child's sex	
Male	15 (60)

XSL•FO
RenderX

Characteristic	Participants, n (%)
Female	10 (40)
Child's daytime setting	
Childcare program	5 (20)
Parent's home	19 (76)
Another family member's home	1 (4)

[a]GED: General Educational Development.

BabyTok Project Videos

The BabyTok Project videos were developed by the research team using the video production capabilities within the TikTok platform. Most videos featured the first author as a narrator in a conversational style that is common on the platform. All videos were recorded by the first author on her handheld iPhone (Apple Inc). The first video was an introduction by the first author explaining her credentials as a speech therapist and researcher and providing more details about the project. She served as the "narrator" for the videos and is a White female researcher who is also a parent. As 56% (14/25) of our sample was not White, we asked for feedback on her narration and relatability to gain participant input to guide future investigations. While we did not use caregiver feedback to guide the development of this set of videos, we built in feedback opportunities in the postintervention interviews to gather caregivers' ideas and preferences for content. A total of 33 videos (1 introduction video and 32 content videos) were shared with participants across 4 overarching topics: *using words*, *shared book reading*, *learning in everyday routines*, and *affirmations*. Videos were developed using the best available research on strategies to support early caregiver-child interactions and early development as described in the study by Romano et al [26].

At the midpoint, the first author also offered participants an opportunity to choose between topics to give them a role in content development, and most participants chose to gain more information about routines (Table 2 presents more detailed descriptions of the videos).

Table 2. BabyTok content video descriptions (n=32).

Topic	Videos, n (%)	Purpose
Using words	9 (28)	Children learn so much in their first few years of life, and their caregivers have a lasting impact on their development. These videos introduced expectations of milestones at various ages and strategies for supporting children's language development, such as expanding on their words and providing choices.
Shared book reading	6 (19)	Shared book reading with toddlers is shown to support their language learning and academic success. These videos shared information about the benefits of reading to toddlers, strategies to use during book reading, and choosing appropriate books for toddlers.
Learning in everyday routines	12 (38)	Learning opportunities are plentiful throughout daily routines. These videos shared foundational information about routines and examples of strategies to use during common daily activities, such as getting dressed or mealtime, to facilitate language development.
Affirmations	4 (12)	These videos were shared throughout the intervention as messages of encouragement for caregivers about their role as parents.
Participant Input	1 (3)	In this video the narrator asked participants for input about which topics they would like to learn more about in future videos.

Study Design

We used a convergent parallel design with an intervention mixed methods framework with a primary focus on qualitative data [27] to investigate the feasibility, usability, and acceptance of the BabyTok intervention for caregivers of young children. We collected qualitative data to support the continued development of the BabyTok intervention and quantitative data to investigate engagement and use of the intervention and its short-term effects and explore the utility of the measures used to describe intervention effects. The data were merged after individual analysis to present results on the holistic effects of the BabyTok intervention.

Measures

TikTok Engagement Metrics

TikTok engagement metrics were gathered to examine the feasibility of the intervention to shed light on how many videos participants viewed and how often they liked and commented on the videos. Public TikTok account owners have access to TikTok Analytics, which tracks metrics, including the number of likes, the number of shares, the number of views, and the average time viewers spent watching videos. However, to maintain a level of confidentiality for participants, we used a private TikTok account, and this precluded us from having access to all TikTok Analytics data. However, we were able to manually see total views for each video, the number of likes, and comments by each participant. To collect data regarding the participants' use of the BabyTok video series, participants

XSL•FO
RenderX

were asked to "like" the videos posted to indicate that they viewed them. To collect additional data about participants' engagement with videos, caregivers were invited to comment on the videos. Individual responses were tracked for each video by clicking each post and reviewing who liked or commented. After the study was completed, the TikTok metrics were analyzed by recording the total sums of likes and comments per video and the total sum of likes and comments per participant across the 8 weeks of the intervention and calculating the mean, SD, and range for each. The feedback was analyzed by reviewing individual comments made for each video.

Caregiver Interviews

Postintervention interviews were used to evaluate the feasibility and acceptability of the intervention from the vantage point of the caregivers. Participants were interviewed in English by a trained graduate research assistant or second author through web-based meetings on Zoom using a semistructured interview protocol. The semistructured interview protocol was adapted from a previous study that investigated a similar intervention with childcare providers [26]. The protocol contained 7 questions about what participants recalled from the BabyTok videos, their feelings about their role as caregivers because of the BabyTok intervention, and the impact of the BabyTok intervention on their interactions with their child. Questions also focused on the suggestions and feedback participants had about the BabyTok videos and if they would like to see content about different topics (Multimedia Appendix 1). Each interview lasted approximately 10 to 15 minutes, was screen recorded, and was transcribed using the Otter.ai platform. Two graduate research assistants reviewed the transcriptions and corrected any errors.

Exploratory Measure (Survey of Parent/Provider Expectations and Knowledge-Research)

For this study's purposes, the Survey of Parent/Provider Expectations and Knowledge-Research (SPEAK-R) was used as an exploratory tool to quantify changes in parents' perceptions of their understanding of the early childhood cognitive and language learning. The SPEAK-R is a 22-item, self-administered questionnaire designed to assess knowledge of and beliefs about early childhood cognitive and language development [28]. The questionnaire consists of 4 multiple-choice items, 14 Likert scale items scored as *definitely true (0)* to *definitely not true (4)*, and 4 Likert scale items reverse scored as *definitely not true (0)* to *definitely true (4)*. The questions focused on six topics: (1) bilingualism, (2) early exposure, (3) media use for child learning, (4) nature versus nurture, (5) sensitivity and responsiveness, and (6) talking and reading [28]. The SPEAK-R survey was developed and tested on multiple population samples that included caregivers with low incomes [15]. The second version (SPEAK-2) showed significant, positive correlations between scores and level of education, receptive language skills, and the quality of language in the home environment. The mean SPEAK-R score reported by its developers was 47.27 in a sample with low-income caregivers [15]. The SPEAK-R indices were proven reliable during field testing with Cronbach α scores of 0.92 [28]. The SPEAK-R was conducted at entry and after the 8-week intervention. The measure was gathered and scored using REDCap (Research Electronic Data Capture; Vanderbilt University), and the data were imported into SPSS (IBM Corp) for analysis.

Procedures

After the consent process was completed, the research team sent out a step-by-step handout via email and SMS text message with information for completing the pretest measures and accessing the BabyTok study channel. Participants completed a demographic survey and the SPEAK-R online. They also scheduled an observation with a member of the research team, hosted via a teleconferencing platform, to verify that they were not bots and to use it to pilot other potential observational measures. Caregivers were asked to interact with their child as they normally would during a typical routine or activity they would be engaging in during that time, such as playing with toys, book sharing, or caregiving activities, such as snacks and diaper changes.

After all participants completed the pretest measures, the research team began sharing videos with all participants on the social media platform 3 to 5 times per week. The videos were posted on the channel, and they were sent to the participants via direct messages. Participants were encouraged to watch each video, like, and comment to verify that they viewed the videos. At the end of this 8-week period, participants completed the posttest measures, which included the SPEAK-R and another recorded caregiver-child observation as well as an independent web-based interview regarding participants' perceptions of the BabyTok intervention.

Data Analysis

TikTok Engagement Metrics

We used a descriptive quantitative analysis to show means and ranges of the TikTok engagement metrics. We obtained simple counts of likes and comments per video and the number of likes and comments per participant.

Caregiver Interviews

The transcripts were analyzed based on the template analysis method as described in the study by Brooks et al [29]. The qualitative coding team included a doctoral student, a graduate-level research assistant, and an undergraduate research assistant. To become familiar with the data, each team member read and reread the transcripts and took general notes on thoughts about overall themes in the data. Next, the team met, discussed the data, took more notes, and began developing preliminary codes based on the interview questions, responses to the questions, and themes from a previous BabyTok Project [26]. The 3 main codes developed at this meeting were *takeaways from BabyTok*, *effects of BabyTok*, and *attitudes or perspectives or feelings about BabyTok*, and each code was assigned a different color. Next, the team split the transcripts among individuals and separately coded quotes within the transcripts by highlighting them in the color assigned to the corresponding code. The team met several more times to ensure the codes effectively described the data the data. Codes that were no longer applicable were removed, codes were reorganized and redefined, and a more accurate template was

XSL•FO
RenderX

developed. Specifically, we recognized that the code *takeaways from BabyTok* overlapped with the code *effects of BabyTok.* Because of this overlap, the codes were reclassified, with the code *takeaways from BabyTok* becoming a subcode of the code *effects of BabyTok.* In addition, the code *attitudes or perspectives or feelings about BabyTok* was split into the subcodes *supportive feedback* and *recommendations*. The team also identified several pieces of data that did not fit into the codebook framework but were important because they described the usefulness of the BabyTok content for different caregivers and in different contexts. Thus, the new subcode of *supportive feedback: content is useful for all caregivers* was established. Next, the team looked for disconfirming evidence or null effects. Because very few examples were discovered, instead of a separate code, we decided to include *negative or null effects* as a subcode of *takeaways from BabyTok*. Finally, the team cross-checked each other's coding by pulling a sample of 50 significant quotes from the transcripts and independently coding each quote to ensure consistency of coding. The final coding template included codes, subcodes, definitions of subcodes, and an example of a quote for each subcode (Table 3 presents the codebook).

To ensure the trustworthiness of the data, the data analysis team took several steps, such as those described by Nowell et al [30]. Our approach included data familiarization, debriefing with the first author, checking for coding reliability to support the credibility of our findings, providing thick descriptions coupled with several examples of direct quotes to increase transferability, and keeping an audit trail of our decision-making process to achieve dependability. By taking these steps, the confirmability of the data was established [30,31].

XSL•FO
RenderX

Table 3. Codebook for posttest caregiver interviews.

Theme	Definition	Sample quote
Effects of BabyTok		
Changes in how they interacted with their child	Differences in how the caregiver approached communicating, engaging, playing, and building a relationship with their child or children after participating in the BabyTok intervention	"I feel like I'm a lot more mindful of what I'm doing when I'm interacting with her...I try to repeat phrases more often and kind of pause and let her try to do it as well."
Changes in how they viewed their role as parents	Differences in how caregivers viewed and felt about their impact on their children (eg, how they develop, communicate, and learn) and/or differences in how they felt about their own parenting style or skills	"I was very critical about her not speaking yet and...really worried about it. But then she just...made me feel better...it's okay if they're not as far with their language as they're supposed to be...it helps me,...feel more grounded and not,...stressed out about it as much."
Changes they noticed in their child	Differences in the child's behavior and communication after trying BabyTok techniques, strategies, and tools.	"We're introducing 'POW'...the point, wait, and the wait for them to repeat type thing,...I noticed that my daughter was catching on to things a lot quicker when I was using like some of those resources."
Takeaways from BabyTok[a]	Information that caregivers described as remembering, learning, trying, or as being useful after participating in the BabyTok intervention	"...what I remember most is just labeling everything for them to help them build their vocabulary. So just labeling and giving them wait time to just kind of let it sink in and process."
Supportive feedback		
Use of social media platforms	Comments about the convenience and accessibility of hosting the videos on TikTok (eg, did not take a lot of time, could do from anywhere, and familiarity with TikTok)	"...I enjoyed all the content, it was super accessible to have it on TikTok, because it was there, and I could watch it once it was posted when it was convenient to me."
Engagement with other caregivers	Comments about interacting with and relating to other caregivers through the BabyTok platform to feel affirmed and build camaraderie	"...just to hear other people's opinions,...I'm dealing with the same thing as a mom' and it was just very enlightening. Sometimes you think like you're the only one in this situation, but come to find out you're not..."
Content delivery expert	Comments about the narrator in the videos and as the facilitator	"She is very enjoyable to watch. She's really cute. And she's really engaging....I enjoyed watching her videos...if you're wondering whether she's an appropriate candidate to continue doing videos, she's great. I loved her."
Trustworthiness	Comments about the credibility of the information shared and/or the participants' confidence in the source	"...I get a lot of parenting videos...but I don't know, for a research project,...I definitely felt like I was getting the right information versus you never know exactly what you're getting..."
Content is useful for all caregivers	Comments that the content was useful for new and experienced parents as well as other caregivers like grandparents.	"I think it's a great resource for all parents,...new and parents that are already experienced in parenthood just to open your mind and broaden your horizon and other ways to help implement teaching resources for your child."
Recommendations		
Content suggestions	Suggestions regarding the topics covered throughout the BabyTok project (eg, behavior management, potty training, routines, sign language, and bedtime)	"I guess one thing that I wish was covered a little bit more was routines...Routines and...how we can build in little learning...incorporate learning opportunities into our daily routines..."
Delivery suggestions	Suggestions regarding how the BabyTok project is shared, including what social media platforms are used, the format of the video, and how the participants were notified	"If maybe, throughout the project, there was like a email that went out at the end of the week, like, 'Hey, make sure you watch these five videos.' So, I knew if I missed one, to go back and find that rather than having to scroll through the whole account,..."
Suggestions for the engagement of users	Suggestions regarding how to increase interactions with BabyTok users, including how to facilitate discussion among users and how users could share videos of their children	"If it was more interactive with those that were participating...maybe if there was some type of participation through the process, outside of maybe commenting."

[a]Null and negative effects are included here and not as a separate subcode because they were uncommon but still relevant.

Ethical Considerations

All participants provided implied consent for the institutional review board–approved study (Florida State University 10003010) through an online interest form with a waiver of documentation of consent. Participants received up to US $100 in gift cards for compensation. Compensation was distributed via mail after pretest data collection (US $50) and the social

XSL•FO
RenderX

media intervention and posttest data collection (US $50). All participants were issued an alphanumeric code for all data files. One single excel file linked personal information to the code. The linking file and deidentified files are kept on an encrypted Microsoft Teams folder hosted by the university.

Results

TikTok Engagement Metrics

In total, 32 videos were shared across the 8-week intervention period. The data were gathered on 21 participants. We excluded 4% (1/25) of the participants who were lost to attrition (ie, did not complete any follow-up data) and 12% (3/25) of the participants who unfollowed the BabyTok page after the project ended. We were unable to gather their data from TikTok after they exited the group. Participants were asked to like a video as confirmation that they viewed it; 24% (5/21) of the participants liked all 32 videos, and most (16/21, 76%) of the participants liked more than half of the videos (mean 23.95, SD 8.99; range 3-32).

To understand which videos garnered the most engagement and discussion from caregivers, we examined the number of likes per video and the number of comments per video. The videos with the most likes (n=18) were videos about milestones for children aged 1 year and those aged 18 months and a video about modeling and waiting when labeling objects. In total, 2 (6%) of the 32 videos received the least number of likes (n=13); one was a video that asked participants' opinions about which video topics they would like to see posted during the week, and the other was about activities to engage in during a morning routine. Overall, viewership of each video was 76% (16/21); the mean was 15.75 (SD 1.39; range 13-18) likes per video. The number of comments per video ranged from 2 to 14 (mean 6.44, SD 2.68). The video with the greatest number of comments (n=14) was posted on the first day of the intervention and asked caregivers to share the words their babies understand. The video with the second-highest number of comments (n=12) asked caregivers to answer the question, "What's your baby up to?" The videos with the least number of comments, 2 each, were about coviewing with screens and constructive play.

We also gathered the number of comments per participant to understand more about engagement per participant. The number of comments was unevenly spread among the participants, with 4 (19%) of the 21 participants commenting >20 times and 13 (62%) participants commenting ≤5 times (mean 8.81, SD 8.9; range 1-28). When commenting on videos, participants typically shared their positive feelings toward the strategies suggested. Participants shared their excitement to try the strategies. For instance, about a video called *Three Tips for Book Time*, a participant stated, "I'll have to try this! Especially the waiting strategy." About a video describing a strategy of pointing, using 1 word, and then waiting a few seconds for a response, a participant shared, "I'm going to try it tonight when I read to him." Participants also shared how they were trying the strategies and how their children were responding. When commenting on a video about modeling words instead of pressuring children to say words with several prompts, a participant shared, "I did this with [my] son with 'banana' [his favorite food], and he tried to say it!" One participant shared how a motivational video helped her after a challenging time with her child. After viewing the video, *They Come to You*, she commented the following:

> *I needed to hear this today. After a long night with the babe, sometimes it's so easy to question my motherhood journey.*

Other common responses in the comments included sharing about their babies' milestones and how they felt affirmed and emoticons of smiles, laughs, and hearts.

Caregiver Interviews

Participants' perspectives of the BabyTok intervention were organized into 3 main themes: effects of BabyTok, supportive feedback of BabyTok, and recommendations for BabyTok. Each theme included 3 to 5 subthemes, as displayed in Table 3. In total, 23 (92%) of the 25 participants completed individual interviews following the 8-week BabyTok intervention.

Effects of BabyTok

Changes in How They Interacted With Their Child

In response to how the BabyTok videos impacted their interactions with their children, many (21/23, 91%) participants reported becoming more purposeful, more mindful, more positive, paying closer attention to their child, having more face-to-face interactions, and using strategies to promote communication more often. One participant stated the following:

> *I feel like I'm a lot more mindful of what I'm doing when I'm interacting with her on trying to do things that she might copy so that she can implement that and understand what I'm doing. I try to repeat phrases more often and kind of pause and let her try to do it as well.*

Another participant discussed the change in her phone use when interacting with her child:

> *I think it made me sit down and do more face to face with her. Get off the phone a little bit...and make sure that we are doing things to help promote her speech and just spend more time with them.*

Changes in How They Viewed Their Role as Parents

Participants reported changes in how they viewed and felt about their impact on their children's language development. They also expressed how they felt about their own parenting style or skills. For example, one participant described a change in her confidence and in the importance of her role:

> *I feel a lot more confident in my role and helping to develop her language development. And her development in general, like, the videos and description of the one-on-one time and the eye-to-eye contact, all of that being kind of brain food or setting them up for success...It made me feel like I had a more important role than I was giving myself previously.*

Another participant described how her understanding of the parent's role in a child's language development changed:

XSL•FO
RenderX

> *It kind of...put that into perspective and how I actually need to do that [consistently label] to help him develop, like how critical parents are to developing the language. It doesn't just come naturally to them from listening.*

Other (9/23, 39%) participants expressed their thoughts on their role with statements such as, "What I learned is that basically, we play a huge part in, you know, teaching our kids," and "...it made me feel more confident in things that I was doing," and "I feel like I have to remember to do a little bit more teaching than I did, than I have in the past."

Changes Noticed in Their Child

Participants described noticing that their children paid more attention, learned more quickly, and began to copy words. For example, after using a specific strategy from the videos, a participant stated the following:

> *It seems like still, he pays attention more when I do it. And it's nice, because it shows that he's trying to listen, and figure out what I'm saying.*

Another caregiver noticed that her child was beginning to say words because of trying a strategy suggested in a BabyTok video. She stated the following:

> *But she is picking things up like—she did say "cat" while we were doing that after I pointed out cat several times on several pages to her. I wasn't getting that kind of a reaction or that kind of an interest or response before I did that, because I wasn't waiting for any kind of a response from her.*

Another caregiver described a similar change in her child:

> *We're introducing "POW," I believe it was. Like the point, wait, and the wait for them to repeat type thing, which I thought was really cool, because I noticed that my daughter was catching on to things a lot quicker when I was using like some of those resources.*

Participant Takeaways

When asked what they remembered most about the BabyTok videos, participants described what they remembered, what they learned, or strategies they tried. Many (19/23, 83%) caregivers listed specific strategies that were shared in the videos. One participant said the following:

> *What I remember most is just labeling everything for them to help them build their vocabulary. So just labeling and giving them wait time to just kind of let it sink in and process.*

Another described learning from the demonstrations of implementing strategies:

> *I think what I remember the most about the BabyTok videos, were just some of the demonstrations, or I guess...suggestions on what you could do with the baby. So, I've blown bubbles, but I thought it was really intimate and kind of cool just to blow the bubbles while the kid was sitting. So, we tried that.*

A few (5/23, 22%) caregivers also described retaining content related to the emphasis on daily routines. One caregiver recalled how to talk to her baby during daily activities. She stated the following:

> *So, I think I definitely learned a lot of routines and when to talk and how to during throughout the day. That was really important for me to try to remember I could fit in throughout the day.*

Another remembered learning that routines were specific to each child and their family. She stated the following:

> *I think probably about setting a routine and how it doesn't have to be like a normal routine. It just has to be, because most people, they brush their teeth immediately before going to bed. But we have to kind of settle her down after that, because it's always a fight. And that's okay. It doesn't have to be [a] normal routine, it just has to be, this is what you do from day to day.*

Disconfirming and Null Effects

When asked what they remembered most about BabyTok videos, two participants described some of the strategies in the videos as not being useful. For example, one participant recounted the following about the point, one word, and wait strategy:

> *The one about the POW, the point, and then, say the word and then wait, I found that I like that a lot. It didn't really work for me. But I think I'm gonna keep trying.*

The other participant stated the following about trying the book reading and screen time strategies:

> *He doesn't really like books that much or TV. He just doesn't, you know, so I guess it's individualized for child. So, a lot of the book things, like I read him books, but usually he doesn't pay attention to them. So and then, like the screen time things, again, he doesn't pay attention to the screen at all.*

One caregiver was unable to try the strategies or implement new routines with her child because of her busy work schedule. She said the following:

> *My schedule has been off. So, most of the days he's at daycare or he's been with his dad the past three weeks...So I haven't really got a chance to spend time with him as much.*

Supportive Feedback

Use of Social Media Platform

Participants discussed the convenience and accessibility of being able to watch and learn while scrolling on TikTok. One participant described the following:

> *You're on TikTok anyway. So, if you follow them, and they'll come up on your following page, and, you know, it makes it like, not so stressful, like, you're not researching it, you know, intently, you're just scrolling, and I learned a million things. Since I've started watching videos, I cooked a meal off it last night. And so like, at the same time, when I'm*

XSL•FO
RenderX

> *scrolling, I'm like, "Oh, I just learned something I can do with my baby."*

Others liked the ease of use and the short length of the videos. One participant stated the following:

> *It's user friendly. You don't have to worry about, I don't know, she would just message us videos, and I just click on them, and it pops right up so fast.*

Another stated, "I liked that they were smaller, bite sized pieces, bite sized segments." However, one caregiver requested longer videos to be interspersed with the shorter videos.

Engagement With Other Caregivers

Another element of the social media intervention that participants enjoyed was engaging with other caregivers. For example, a participant stated the following:

> *So just to hear other people's opinions, like, "Hey, I'm dealing with the same thing as a mom," and it was just very enlightening. Sometimes you think like you're the only one in this situation but come to find out you're not and plenty of other parents are dealing with the same thing.*

Content Delivery Expert

Participants also shared their approval of the host and speaker in the videos with comments such as the following:

> *It's Mollie, right, that was doing the videos? She is very enjoyable to watch. She's really cute, and she's really engaging.*
>
> *She was very interactive and very responsive, like when we would make comments or have questions. So yes, I really enjoyed that part.*

Trustworthiness

Participants viewed the content of BabyTok as more trustworthy than information they received from other sources, such as family, friends, and content creators on TikTok. One caregiver commented the following:

> *I get a lot of parenting videos, but I don't know, this was specifically for a research project, so I definitely felt like I was getting the right information versus you never know exactly what you're getting on TikTok.*

Another described getting a "better perspective" from the content on BabyTok. She said the following:

> *Basically I really get my advice from like, parents and people, you know, who already have kids. Um, so it was just different to like, you know, actually, like, get a better perspective and learn more about how to teach babies and toddlers, you know how to speak.*

Content Is Useful for All Caregivers

Participants described the content as useful for a wide range of caregivers in multiple contexts. One participant commented that BabyTok would help introduce strategies for language development to the other caregivers in her child's life:

> *But then watching the videos gave me more ideas and how to help other people in our life, introduce things to her as well. So it's not just my responsibility, Dad can help and grandma can help and things like that.*

Some (9/23, 39%) caregivers described BabyTok as useful for all parents. One caregiver commented the following:

> *I think it's a great resource for all parents, like new and parents that are already experienced in parenthood just to open your mind and broaden your horizon and other ways to help implement teaching resources for your child.*

Another said the following:

> *So I think different generational gaps have different styles of parenting. So I think it's very beneficial for different generations. So, for example, a lot of the things that she was teaching I wasn't familiar with only because I'm not used to doing it that way. So I think different generations would find this beneficial to view those videos as well.*

Recommendations

Content Suggestions

To close out the interviews, the interviewers asked the participants if there was anything they wished was improved or included in the video. Many (16/23, 70%) participants responded with varying ideas for content additions, including more content about routines, baby signing, speech delays, help with bedtime, how to handle challenging toddler behaviors, and pretend play with toddlers. For example, a participant stated the following:

> *I guess one thing that I wish was covered a little bit more was routines...Routines and how you can build more—how we can build in little learning, like, incorporate learning opportunities into our daily routines is what I'm trying to say.*

Delivery Suggestions

In addition to recommending changes to content, some (10/23, 43%) participants recommended changes to video formats, how participants were notified of videos to view, and using other social media platforms, such as Instagram. Other suggestions included adding more to the videos to make them grab and hold attention. For instance, one caregiver said, "I think it would have been more interesting if there was more captions, or pictures and stuff on there," and another said, "Eye-catching, so instead just like someone talking, there were different varieties." One participant discussed the use of actual babies in videos to see the activities and strategies demonstrated. Finally, there were recommendations for how participants were notified of videos to view. A participant suggested a method of notification via email. She stated the following:

> *I think there were a few times where like, I missed a notification...If maybe, throughout the project, there was like an email that went out at the end of the week, like, "Hey, make sure you watch these five videos." So, I knew if I missed one, to go back and find that*

XSL•FO
RenderX

> *rather than having to scroll through the whole account to see if there was one I hadn't reacted to or liked or whatever.*

Suggestions for the Engagement of Users

Two (9%) participants wanted more interaction with other caregivers. The following quote from a participant demonstrated this:

> *I think, yeah, if it was more interactive with those that were participating. It is nice to watch the videos, you can do it on your own time, but maybe if there was some type of participation through the process, outside of maybe commenting.*

Another participant suggested the use of Facebook groups for added interaction among participants:

> *Facebook has groups, so y'all could make a BabyTok group. And then when y'all have videos, maybe you could put like a post that's like a discussion post about the video from October 11. And then maybe people could comment.*

Exploratory Measure (SPEAK-R)

We used a pre-post, paired samples 1-tailed *t* test to assess whether there were changes in caregiver knowledge on the SPEAK-R. A total of 22 caregivers completed the SPEAK-R at posttest measurement. Pretest data on the SPEAK-R had a mean of 48.62 (SD 7.70; range 30-63), and posttest data had a mean of 51.52 (SD 12.94; range 30-69). The 1-tailed *t* test was not statistically significant (t_{21}=–1.357; *P*=.09). Some SPEAK-R data were missing at posttest measurement (n=4), indicating a need for additional support for participants to complete it after the intervention. One participant had a notably low posttest score that might have indicated that they completed the measure without responding to all the items.

Integrated Results

We merged results across the qualitative and quantitative data to understand the feasibility and acceptability of the BabyTok intervention. As was expected with a distal measure there was incomplete alignment between the SPEAK-R items and the content of the BabyTok intervention. Some items on the SPEAK-R (ie, supporting dual language learning, when children begin learning Science, Technology Engineering and Mathskills) were not covered within the project videos, so we would not expect to see participant comments or gains in these areas. However, there was some overlap, specifically across 3 content areas: screen time, caregiver responsiveness, and shared book reading. Our integrated analysis focused on SPEAK-R items, TikTok metrics, and qualitative themes that were related to those 3 content areas (Multimedia Appendix 2 provides a joint display of merged results).

Overall, we found evidence of positive changes related to participants' knowledge about caregiver responsiveness and shared book reading across all 3 sources of data. Changes in pretest to posttest raw scores on the SPEAK-R items related to caregiver responsiveness (ie, items 26, 34, and 36) indicated that participants gained new knowledge within this content area, as evidenced by increases in the raw scores. A total of 3 (9%) of the 32 BabyTok videos included content related to caregiver responsiveness, and 5 (16%) videos included content related to book reading. Each of these videos, except one (ie, "Myths about Reading"), received at least 17 likes, which was more than the average number of likes across all videos. These videos also received various comments from participants, ranging from 3 to 9 comments. We collected various quotes from participants related to responding to their children and reading with their children across 4 subthemes, indicating that participants learned new strategies, saw changes in their child, and viewed their roles as parents differently in relation to book reading and caregiver responsiveness.

However, changes on the SPEAK-R items related to screen time for young children (ie, 14, 56, 57, and 58) were mixed from before the test to after the test. A total of 2 of the 32 BabyTok videos included content related to screen time; 1 (3%) had 16 likes and 2 comments; 1 (3%) received 17 likes and 9 comments. No (0/21, 0%) participants discussed this content in their interview, indicating that this content may not have been as important to their experience in the BabyTok intervention.

Discussion

Principal Findings

This study examined the feasibility and acceptability of the BabyTok Project with caregivers of toddlers while exploring potential outcome measures for future investigations. We wanted to understand how and to what degree caregivers engaged with the BabyTok Project, what they retained from the content, and what caregivers liked or did not like about their experiences with the videos and the platform. Overall, participants expressed positive feedback about the BabyTok content and the short-form, video-based nature of the intervention. Although the distal knowledge measure (SPEAK-R) showed raw score gains but not statistical significance, most (22/23, 96%) participants listed specific strategies that they recalled from the videos and gave examples of using the strategies with their child.

Caregiver Engagement With the BabyTok Content

In general, we found consistent engagement through likes from most caregivers throughout the project (mean 15.75, SD 1.39 likes/video; viewership: 16/21, 75%). This could suggest that the intervention is well aligned with caregivers who use their mobile devices to access content on social media with regularity and that the content might fit in easily with their use patterns [25]. Two caregivers reported watching the videos when they were sent a direct message, two other caregivers watched them in a batch and "caught up" on the videos when prompted. Still more caregivers viewed the videos from their "For You" screen on the app, suggesting that the multiple points of contact may have helped increase the ability of caregivers to access the videos. The overall viewership and engagement data among caregivers were similar to that of the infant toddler teachers in our earlier investigation (16/21, 75% and 73%, respectively). While it is not possible to directly compare to other app-based studies such as Háblame Bebé that can track time in the app [21], we note similar patterns of engagement in that most (16/21, 76%) caregivers participated at intended levels, with a few low responders, indicating the need for individualized support. One

XSL•FO
RenderX

caregiver in our investigation had notably low viewership, suggesting the need for additional strategies to increase engagement for some caregivers. Such individualization could include tailoring when the direct messages are sent (to align with their time on social media or their off time from work) and when, how, and how often reminders are sent.

Caregivers Gave Specific Details From the Content

Caregivers described the convenience of the short, "bite-sized" content units, that they were on the app anyway for other purposes, such as looking for dinner recipes or entertainment, and that they were able to learn useful information to support their child's learning. Caregivers noted they may not have had time to watch long videos, but the short content units kept them in touch with the ideas presented in the videos more often and made it enjoyable. This feedback was also consistent with that of the infant toddler teachers in the earlier investigation. Although this study did not experimentally evaluate whether caregivers made changes in their interactions, caregivers did indicate that they believed the approach supported them in engaging their child in language-rich interactions and equipped them with strategies to use every day. Among the strategies, caregivers found the content related to the point, one word, and wait strategy to be salient, along with expansions and book-sharing strategies for their toddlers. The specificity of caregivers' responses around these strategies was encouraging because it reflected ideas shared in the videos that caregivers were not likely to have learned elsewhere.

Caregivers Described the Trustworthiness of the Content

The first author, who is also the main video narrator, provided her credentials in an introductory video at the beginning of this study. This may be one reason that caregivers described the content viewed on the BabyTok page as "the right information" and that it gave them a "better perspective" about toddler language development than information they received from family, friends, and other TikTok creators. These statements relating to trustworthiness are encouraging and may indicate caregiver acceptability of the content and overall intervention.

Suggestions for Additional Content

Caregivers gave suggestions for future videos, which can be implemented into future studies, such as including the use of different methods of delivery (ie, Instagram or Facebook groups); use of text on screen, including more eye-catching images; and videos with real babies and caregivers to show examples of the strategies. They also suggested content that extends from communication content directly into everyday concerns, such as sleep and challenging toddler behavior. This is important because caregivers seem to not only want information about how to help their children talk but also ways to navigate everyday challenges that caregivers of children in this age range face, which may then impact their interactions with their child. Tackling these parenting issues may also give caregivers a means to engage with one another as they share what has worked and what has not for their child, which could serve to build their own confidence in sharing their experience with one another.

Implications for Media-Based Universal Interventions

While we cannot extend these findings to other types of interventions, there are potential implications for video-based interventions with caregivers of young children. Similar to our experience with teachers [26], home-based caregivers did not have a 100% watch rate, but they did view most videos, on average. Because few caregivers will be able to watch every video, it is important to build in redundancy by reinforcing similar messages and delivering the same message more than once. Furthermore, our attempts at reaching caregivers through multiple modes, such as sending videos via direct messaging, SMS text message reminders, and the "For You" page. seemed to help increase the number of videos viewed by each caregiver. While publicly available content may have similar messages as the BabyTok videos, there are no mechanisms yet to support caregivers to consistently engage with the content beyond what appears based on the algorithm or to ensure that enough video content reaches users to create changes in knowledge and caregiver-child interactions.

Limitations and Future Directions

While the findings in this investigation suggest the promise of social media–based interventions to support caregiver knowledge about early language learning, the study does face several limitations. First, the small sample size of participants may be a limiting factor in evaluating and drawing conclusions from the data. Next, because of the nature of the TikTok platform, we had limited metrics available to us as a private TikTok page. With this lack of metrics, we were not able to gather data on the watch time of each video by the participants. It is possible that participants may have pressed "like" on the video without fully viewing it, and it is also possible that participants did view the video but neglected to press "like," leading to an underrepresentation of their viewing. We also did not collect data to understand how our participants typically engaged with and used social media to compare with how they engaged with and used the BabyTok content relative to other social media content. We made assumptions that participants engaged with content if they liked and commented on the videos, but they may have engaged in other ways, such as showing the video to a friend or partner.

In future studies, we could ask caregivers to report on their overall social media use patterns to compare their engagement with the content relative to their overall social media use. Although our sample of participants was similar in age and gender to the average US TikTok user, there were some differences in parenting status, education level, income level, and race or ethnicity [32,33]. These differences may have made it more difficult to evaluate engagement data of some participants, as they may not have been typical TikTok users. Our participants were more educated (bachelor's degree: 9/25, 36%) compared to the average US adult aged >25 years (23.5% with a bachelor's degree) [34], and fewer of our participants had their toddlers in childcare outside the home (6/25, 24%) than the average US family (55%) [35]. This may indicate that caregivers who are in the home and more educated may be more likely to access and engage in this type of social media intervention.

XSL•FO
RenderX

Although some caregivers reported gains in their child's communication, we did not directly measure child language skills as an outcome in this feasibility and acceptability study. It is important to note that children should acquire new words during this developmental period, so randomized controlled trials are needed to determine whether there are child-level effects above and beyond the communication gains that would take place through the child's maturation alone.

The SPEAK-R provided a related outcome representing caregiver knowledge, although there were items on the measure that did not align with the video content (ie, early mathematics and cognitive concepts). Those domains would not have been likely to change because of the BabyTok intervention. SPEAK-R has been used as an outcome in a few studies that offer video-based educational content [36], but it is difficult to compare relative changes between studies because our intervention focuses only on communication rather than communication and cognition. In addition to measuring caregiver knowledge, it would also be useful to measure long-term impacts on children's vocabulary development by using caregiver-reported tools about their child's communication in a larger, randomized study. Additional future directions also include creating and testing Spanish-language videos for caregivers in the United States who speak Spanish as a primary language, with a focus on supporting children in both languages.

Conclusions

The findings of this study add evidence to the feasibility and acceptability of the BabyTok Project as a means to increase caregiver knowledge of how to support children's language learning. This research is important because, to date, there have been few social media–based interventions targeting children's early communication. While there is a sizeable body of evidence related to intensive coaching models to help caregivers engage with their children, low-cost, light-touch interventions could be a scalable and accessible means to equip caregivers with information they need to advance their children's language abilities [21], with downstream effects on academic and social outcomes if future efficacy testing indicates positive effects. This approach to intervention may be particularly important for families from low-income backgrounds whose access to health information about their young children may be limited.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Semistructured interview protocol.
[DOCX File , 14 KB - pediatrics_v8i1e66175_app1.docx]

Multimedia Appendix 2
Joint display of merged results.
[DOCX File , 22 KB - pediatrics_v8i1e66175_app2.docx]

References

1. Parladé MV, Iverson JM. The interplay between language, gesture, and affect during communicative transition: a dynamic systems approach. Dev Psychol 2011 May;47(3):820-833 [FREE Full text] [doi: 10.1037/a0021811] [Medline: 21219063]
2. Määttä S, Laakso ML, Ahonen T, Tolvanen A, Westerholm J, Aro T. Continuity from prelinguistic communication to later language ability: a follow-up study from infancy to early school age. J Speech Lang Hear Res 2016 Dec 01;59(6):1357-1372. [doi: 10.1044/2016_JSLHR-L-15-0209] [Medline: 27788278]
3. Greenwood CR, Schnitz AG, Carta JJ, Wallisch A, Irvin DW. A systematic review of language intervention research with low-income families: a word gap prevention perspective. Early Child Res Q 2020;50:230-245. [doi: 10.1016/j.ecresq.2019.04.001]
4. Heidlage JK, Cunningham JE, Kaiser AP, Trivette CM, Barton EE, Frey JR, et al. The effects of parent-implemented language interventions on child linguistic outcomes: a meta-analysis. Early Child Res Q 2020;50:6-23. [doi: 10.1016/j.ecresq.2018.12.006]
5. Raz M, Beatty BR. Replacing the "word gap" with nonstigmatizing approaches to early literacy and language building. Pediatrics 2018 Dec;142(6):e20181992. [doi: 10.1542/peds.2018-1992] [Medline: 30389714]
6. Kuchirko YA, Tamis-LeMonda CS. The cultural context of infant development: variability, specificity, and universality. Adv Child Dev Behav 2019;57:27-63. [doi: 10.1016/bs.acdb.2019.04.004] [Medline: 31296318]
7. Leung CY, Hernandez MW, Suskind DL. Enriching home language environment among families from low-SES backgrounds: a randomized controlled trial of a home visiting curriculum. Early Child Res Q 2020;50:24-35. [doi: 10.1016/j.ecresq.2018.12.005]
8. Choi B, Nelson CA, Rowe ML, Tager-Flusberg H. Reciprocal influences between parent input and child language skills in dyads involving high- and low-risk infants for autism spectrum disorder. Autism Res 2020 Jul;13(7):1168-1183. [doi: 10.1002/aur.2270] [Medline: 32003131]

XSL•FO
RenderX

9. Huttenlocher J, Waterfall H, Vasilyeva M, Vevea J, Hedges LV. Sources of variability in children's language growth. Cogn Psychol 2010 Dec;61(4):343-365 [FREE Full text] [doi: 10.1016/j.cogpsych.2010.08.002] [Medline: 20832781]
10. Romeo RR, Leonard JA, Robinson ST, West MR, Mackey AP, Rowe ML, et al. Beyond the 30-million-word gap: children's conversational exposure is associated with language-related brain function. Psychol Sci 2018 May;29(5):700-710 [FREE Full text] [doi: 10.1177/0956797617742725] [Medline: 29442613]
11. Romeo RR, Segaran J, Leonard JA, Robinson ST, West MR, Mackey AP, et al. Language exposure relates to structural neural connectivity in childhood. J Neurosci 2018 Sep 05;38(36):7870-7877 [FREE Full text] [doi: 10.1523/JNEUROSCI.0484-18.2018] [Medline: 30104336]
12. Masek LR, Paterson SJ, Golinkoff RM, Bakeman R, Adamson LB, Owen MT, et al. Beyond talk: contributions of quantity and quality of communication to language success across socioeconomic strata. Infancy 2021 Jan;26(1):123-147. [doi: 10.1111/infa.12378] [Medline: 33306866]
13. Rowe ML, Ozçalişkan S, Goldin-Meadow S. Learning words by hand: gesture's role in predicting vocabulary development. First Lang 2008 Jan 01;28(2):182-199 [FREE Full text] [doi: 10.1177/0142723707088310] [Medline: 19763249]
14. Abu-Zhaya R, Seidl A, Cristia A. Multimodal infant-directed communication: how caregivers combine tactile and linguistic cues. J Child Lang 2017 Sep;44(5):1088-1116. [doi: 10.1017/S0305000916000416] [Medline: 27573414]
15. Suskind DL, Leung CY, Webber RJ, Hundertmark AC, Leffel KR, Suskind E, et al. Development of the Survey of Parent/Provider Expectations and Knowledge (SPEAK). First Lang 2017 Nov 02;38(3):312-331. [doi: 10.1177/0142723717737691]
16. Alper R, Luo R, Mogul M, Bakeman R, Masek L, Paterson S, et al. Duet: an exploratory language intervention for toddlers in low-income households. Infants Young Child 2023 Dec;36(4):296-313. [doi: 10.1097/IYC.0000000000000248]
17. Mertens E, Ye G, Beuckels E, Hudders L. Parenting information on social media: systematic literature review. JMIR Pediatr Parent 2024 Oct 23;7:e55372 [FREE Full text] [doi: 10.2196/55372] [Medline: 39442173]
18. Frey E, Bonfiglioli C, Brunner M, Frawley J. Parents' use of social media as a health information source for their children: a scoping review. Acad Pediatr 2022;22(4):526-539 [FREE Full text] [doi: 10.1016/j.acap.2021.12.006] [Medline: 34906742]
19. Skeen S, Marlow M, du Toit S, Melendez-Torres GJ, Mudekunye L, Mapalala E, et al. Using WhatsApp support groups to promote responsive caregiving, caregiver mental health and child development in the COVID-19 era: a randomised controlled trial of a fully digital parenting intervention. Digit Health 2023;9:20552076231203893 [FREE Full text] [doi: 10.1177/20552076231203893] [Medline: 37928327]
20. Baralt M, Mahoney AD, Brito N. Háblame Bebé: a phone application intervention to support Hispanic children's early language environments and bilingualism. Child Lang Teach Ther 2020 Mar;36(1):33-57 [FREE Full text] [doi: 10.1177/0265659020903779] [Medline: 35875512]
21. Larson AL, Baralt M, Hokenson J, Hammer CS, Barrett T, DeVilbiss N. A randomized controlled trial assessing the effectiveness of the Háblame Bebé mobile application with Spanish-speaking mothers experiencing economic hardship. Am J Speech Lang Pathol 2022 Mar 10;31(2):722-738. [doi: 10.1044/2021_AJSLP-21-00094] [Medline: 35077657]
22. Moon RY, Mathews A, Oden R, Carlin R. Mothers' perceptions of the internet and social media as sources of parenting and health information: qualitative study. J Med Internet Res 2019 Jul 09;21(7):e14289 [FREE Full text] [doi: 10.2196/14289] [Medline: 31290403]
23. Pretorius K, Johnson KE, Rew L. An integrative review: understanding parental use of social media to influence infant and child health. Matern Child Health J 2019 Oct;23(10):1360-1370. [doi: 10.1007/s10995-019-02781-w] [Medline: 31222601]
24. Baker B, Yang I. Social media as social support in pregnancy and the postpartum. Sex Reprod Healthc 2018 Oct;17:31-34. [doi: 10.1016/j.srhc.2018.05.003] [Medline: 30193717]
25. Guerra-Reyes L, Christie VM, Prabhakar A, Harris AL, Siek KA. Postpartum health information seeking using mobile phones: experiences of low-income mothers. Matern Child Health J 2016 Nov;20(Suppl 1):13-21 [FREE Full text] [doi: 10.1007/s10995-016-2185-8] [Medline: 27639571]
26. Romano M, Perez K, Abarca D. The BabyTok Project: examining the feasibility and acceptability of a light-touch social media project for infant-toddler teachers. Early Child Educ J 2022 Nov 19:1-16 [FREE Full text] [doi: 10.1007/s10643-022-01426-y] [Medline: 36439905]
27. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. Health Serv Res 2013 Dec;48(6 Pt 2):2134-2156 [FREE Full text] [doi: 10.1111/1475-6773.12117] [Medline: 24279835]
28. Suskind D, Leung C, Hundertmark A, Ladner PH, Leffel KR, Miller K. Impacting low-SES caregiver knowledge, language behaviors, and infant vocabulary skills through a web-based pediatric primary care intervention: a randomized controlled trial. Pediatrics 2019 Aug;144(2):71. [doi: 10.1542/peds.144.2ma1.71]
29. Brooks J, McCluskey S, Turley E, King N. The utility of template analysis in qualitative psychology research. Qual Res Psychol 2015 Apr 03;12(2):202-222 [FREE Full text] [doi: 10.1080/14780887.2014.955224] [Medline: 27499705]
30. Nowell LS, Norris JM, White DE, Moules NJ. Thematic analysis: striving to meet the trustworthiness criteria. Int J Qual Methods 2017 Oct 02;16(1). [doi: 10.1177/1609406917733847]
31. Guba EG, Lincoln YS. Fourth Generation Evaluation. Thousand Oaks, CA: SAGE Publications; 1989.
32. Gottfried J. Americans' social media use. Pew Research Center. 2024 Jan 31. URL: https://www.pewresearch.org/internet/2024/01/31/americans-social-media-use/ [accessed 2025-03-15]

XSL•FO
RenderX

33. Rau S, Varghese J, Al-iriani S. Social media: TikTok users in the United States. Statista. URL: https://www.statista.com/study/72735/social-media-tiktok-users-in-the-united-states/ [accessed 2025-03-15]
34. Census Bureau releases new educational attainment data. United States Census Bureau. 2022 Feb 24. URL: https://www.census.gov/newsroom/press-releases/2022/educational-attainment.html [accessed 2025-03-22]
35. Fast facts. National Center for Education Statistics. URL: https://nces.ed.gov/fastfacts/display.asp?id=4# [accessed 2025-03-22]
36. Leung CY, Trinidad JE, Suskind DL. Video-based anticipatory guidance on early cognitive and language development in the first 6 months: a randomized controlled trial. J Pediatr 2022 Jun;245:227-9.e1 [FREE Full text] [doi: 10.1016/j.jpeds.2022.03.008] [Medline: 35301018]

Abbreviations

REDCap: Research Electronic Data Capture
SPEAK-R: Survey of Parent/Provider Expectations and Knowledge-Research

Edited by S Badawy; submitted 05.09.24; peer-reviewed by K Pretorius, F Bulgarelli; comments to author 28.01.25; revised version received 25.03.25; accepted 20.05.25; published 23.06.25.

Please cite as:
Romano M, Abarca D, Baehman F
A Low-Cost, Social Media–Supported Intervention for Caregivers to Enhance Toddlers' Language Learning: Mixed Methods Feasibility and Acceptability Study
JMIR Pediatr Parent 2025;8:e66175
URL: https://pediatrics.jmir.org/2025/1/e66175
doi:10.2196/66175
PMID:40550118

©Mollie Romano, Diana Abarca, Frances Baehman. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 23.06.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

A Noninvasive Approach to Assess the Prevalence of and Factors Associated With Anemia Risk in Malaysian Children Under Three Years of Age: Cross-Sectional Study

Muhammad Yazid Jalaludin[1], MBBS, MMed (Paeds); Ho Bee Kiau[2], MBBS, MMed; Suriati Hasim[3], MBBS, MMed; Wai Khew Lee[4], MBBS, MMed; Angie Low[5], MSc; Nik Harlina Nik Kazim[6], MBBCh, BAO, MMed; Jia Tse Hoi[7], MSc; Sri Wahyu Taher[8], BSc Med Science, MBChB, MMed

[1]Faculty of Medicine, University Malaya, Lembah Pantai, Kuala Lumpur, Malaysia

[2]Klinik Kesihatan Bandar Botanik, Selangor, Malaysia

[3]Klinik Kesihatan Endau, Johor, Malaysia

[4]Klink Kesihatan Luyang, Sabah, Malaysia

[5]Danone Specialized Nutrition (Malaysia), Kuala Lumpur, Malaysia

[6]Klinik Kesihatan Wakaf Bahru, Kelantan, Malaysia

[7]Danone Research & Innovation, Singapore, Singapore

[8]Klinik Kesihatan Simpang Kuala Kedah, Kedah, Malaysia

Corresponding Author:
Muhammad Yazid Jalaludin, MBBS, MMed (Paeds)
Faculty of Medicine, University Malaya, Lembah Pantai, Kuala Lumpur, Malaysia

Abstract

Background: Anemia remains a significant public health concern with adverse effects among children. Noninvasive screening assessments enable the early detection and prompt treatment of anemia. However, there is limited literature on the use of such screening assessments.

Objective: The study aimed to assess the prevalence of and factors associated with being at risk of anemia among Malaysian children aged ≥6 months to ≤36 months by using a noninvasive hemoglobin assessment.

Methods: This was a cross-sectional study (from July to December 2022) of outpatient Malaysian children, aged ≥6 months to ≤36 months, who were selected from five maternal-and-child health clinics by convenience sampling. At risk of anemia was defined as a total hemoglobin level of <12 g/dL, measured using the Masimo Rad-67, a noninvasive screening device for total hemoglobin levels. The χ^2 and multiple logistic regression analyses were used to assess the prevalence and factors associated with being at risk of anemia, using R-Studio (version 4.0.0).

Results: The study included 1201 participants, of whom 30% (95% CI 28 - 33) were at risk of anemia. Children aged 6 - 12 months (210/364, 57.7%, *P*<.001), those of Asian Malay race (238/364, 65.4%, *P*<.05), those residing in the Klang district (123/371, 33.9%, *P*<.05), those born via a normal vaginal delivery (275/364, 75.5%, *P*<.05), those without a family history of thalassemia (284/364, 78.0%, *P*<.05), and those with lower weight-for-age Z scores (*P*<.05) were associated with being at risk of anemia. Children aged 6 - 12 months (adjusted odds ratio=1.73; 95% CI 1.34 - 2.24) had higher odds of being at risk of anemia compared to children aged >12 - 36 months. However, weight-for-age (adjusted odds ratio=0.88; 95% CI 0.80 - 0.98) was associated with lower odds of being at risk of anemia.

Conclusions: The current study revealed a substantial prevalence of Malaysian children being at risk of developing anemia. The study results therefore imply a need for more community education and awareness on anemia, including nutrition education, as well as targeted community screening to enable the early detection and prompt treatment of anemia cases. Anemia reduction strategies in Malaysia should consider the highlighted factors indicative of higher risk of anemia.

Trial Registration: Clinicaltrials.gov NCT05181436, https://clinicaltrials.gov/study/NCT05181436

(JMIR Pediatr Parent 2025;8:e58586) doi:10.2196/58586

KEYWORDS

anemia; iron deficiency; children; Masimo Rad-67; noninvasive assessment; Malaysia

XSL•FO
RenderX

Introduction

Anemia is a specific condition where the body does not have enough normal or healthy red blood cells or hemoglobin (Hb) to provide adequate oxygen to the body tissues. It is usually caused by iron deficiency, which is the most common micronutrient deficiency in both low-income and high-income countries [1,2]. Generally, it takes at least several weeks after the depletion of iron stores before anemia develops. When iron deficiency occurs, Hb concentrations are reduced to below-optimal levels, a condition known as iron deficiency anemia (IDA) [2], which is the most common type of anemia found in children. Among children, the most common causes of IDA include insufficient iron intake along with rapid growth, low birth weight, and gastrointestinal losses, among others [3,4].

Generally, the prevalence of anemia and IDA in low-income countries is three to four times higher than that in high-income countries [1]. The global prevalence of anemia in 2019 was 39.8% in children aged 6 - 59 months, with 269 million children having anemia, while in Malaysia, the prevalence of anemia was 24.6% in children of the same age [5]. In Malaysia, the current prevalence of anemia is approximately 46.5% among children, and 1 in 3 children (<5 years of age) has iron deficiency [6,7].

Iron deficiency can occur without anemia; this occurs when the iron store is depleted while the individual is still having normal Hb levels. IDA is a situation where the iron store and Hb levels are both below normal levels. Iron deficiency and IDA are typically diagnosed through an invasive blood test, with one of the diagnostic criteria for anemia being a Hb level below 11 g/dL [2]. The American Academy of Pediatrics recommends that all infants be tested for anemia starting between ages 9 months and 12 months [8], and that for those who have risk factors for iron deficiency, additional screenings will be required at later ages between 1 and 5 years [9].

Iron deficiency in childhood is associated with adverse outcomes such as impaired neurocognitive function and brain development, as well as compromised immune function [10,11]. In Malaysia, recent evidence shows that anemia is associated with cognitive and motor delays among infants aged 6 - 12 months [12]. This implies that prompt diagnosis and anemia prevention are essential through early screening during infancy and early childhood.

The conventional diagnosis of anemia and IDA in infants is difficult, as blood sampling and obtaining sufficient blood volume are often difficult for typical laboratory detection. Moreover, these tests can be painful for the participant, expose the staff to human blood, and require training and quality control to ensure appropriate utilization and adherence to standards [3,11]. In this regard, an alternative device can be preferable, such as noninvasive Hb screening using a sensor that shines multiwavelengths of light through the finger of the patient [13]. Such noninvasive device options include the Masimo Pronto (Masimo Corporation) and Masimo Rad-67™ Pulse CO-Oximeters (Masimo Corporation). These devices were cleared by the US Food and Drug Authority for use in clinical and nonclinical settings to measure oxygen saturation [14] and have been used as a noninvasive measurement method for determining the Hb levels in children [15]. The Masimo Pronto and Masimo Rad-67™ Pulse CO-Oximeters have good accuracy and validity compared to Hemocue (HemoCue); however, the Hb levels were underreported for the devices compared to the levels determined in venous blood samples [16-18]. This study used the Masimo Rad-67™ Pulse CO-Oximeter for anemia screening.

This study aimed to assess the prevalence and factors associated with being at risk of anemia (defined as total Hb levels <12 g/dL) among Malaysian children aged ≥6 to ≤36 months by using noninvasive Hb assessment (the Masimo Rad-67 Pulse CO-Oximeter). We used a noninvasive approach for anemia screening and compared the prevalence rates with those obtained in previous studies. Using a noninvasive screening approach offers the potential for the early detection and prompt treatment before worsening of the child's condition to severe anemia-related complications.

Materials and Methods

Study Design

This was a cross-sectional study among children aged ≥6 months to ≤36 months conducted in five maternal-and-child health clinics and Ministry of Health primary care clinic settings in urban and rural areas of Malaysia from July to December 2022. The clinics were chosen and the study participants were enrolled based on the need to include major ethnic groups in Malaysia in the study via convenience sampling.

Participants and Sample Size Planning

The study participants were outpatient children aged ≥6 months to ≤36 months at maternal-and-child health clinics accompanied by their primary caretakers (ie, parents, grandparents, or relatives) who were aged ≥18 years and could speak English, Bahasa Malaysia, or Chinese (Mandarin). Children who came to the clinics for routine vaccinations or routine health examinations were enrolled if the study requirements were met. The plan was to have 50% of participants aged 6 - 12 months and 50% aged >12 - 36 months, with the following ethnicity distribution: 69.8% Malay and Bumiputera, 22.4% Chinese, 6.8% Indian, and 1% others to ensure good representation of data from each site.

The study excluded children with any medical conditions for which interventions to increase nutritional intake might not be effective, per the investigator, in improving weight gain and the nutritional status. In addition, children participating in other studies involving iron-fortified foods or supplementation and those whose caretakers were not able to communicate effectively with the interviewers were excluded. The enrolment at the clinic was stopped when the participant number for specific sexes, age groups, and ethnicities, determined at the start of the study, was achieved. The World Health Organization and World Bank estimated the prevalence of anemia (ie, Hb level <11 g/dL) at 25% in 2019 among Malaysian children under 5 years of age [19]. In this study, we estimated that 30% of children aged ≥6 to ≤36 months will be at risk of anemia (ie, Hb level <12 g/dL), and considering a precision of ±3% and 95% confidence level,

XSL•FO
RenderX

a sample size of 1200 subjects was required after accounting for 10% each of screen failures and dropouts. Any withdrawn subjects and screen failures were replaced until the sample size was obtained.

Data Collection

The study was conducted in five maternal-and-child health clinics that were conveniently selected based on the research need: three from urban areas and two from rural areas of Malaysia. From each of the clinics, approximately 240 participants were selected. Interviewers were trained on the protocol. The trained interviewers identified and approached potential participants and asked the parents or guardians to participate in the survey. Those who were willing to participate were screened for eligibility, and written consent was obtained after they were briefed about the study objectives, procedures, and other details. Respondents were reminded of their right to quit the study at any time without any consequences, and anonymity was guaranteed.

During the assessment, a clip with a sensor attached to the Masimo Rad-67 Pulse CO-Oximeter was placed on the child's finger or toe, and the reading took approximately 30 seconds. Children found to be at risk of anemia were referred to healthcare professionals for further clinical assessment. In addition, the child's weight (kg) and length or height (cm) were measured and input into the Iron Strong app (Groupe Danone).

Data were collected via the Iron Strong app device, a data collection tool with an optical character recognition model that allows the user (by taking a picture) to accurately predict all units and digits on the Masimo Rad-67 Pulse CO-Oximeter and stores the data within the app or server during face-to-face interviews in English, Bahasa Malaysia, or Chinese (Mandarin). The interview and data collection took about 30 - 40 minutes to complete.

Measurements

Development of the Questionnaire

The questionnaire was developed by a panel of three public health researchers. Bilingual researchers translated the English version of the questionnaire into Bahasa Malaysia and Chinese (Mandarin). The agreed versions were back-translated into English by independent bilingual researchers to ensure linguistic equivalence. The questionnaire was not pretested because it mainly asked about respondents' sociodemographic characteristics, anthropometric measurements, and 24-hour dietary recall.

Sociodemographic Characteristics

Participants reported their sociodemographic characteristics, such as the child's sex, age, race, residence location, physical activity, as well as caregiver's education level and household income. Birth history key indicators were asked, including mode of delivery, gestational age at birth, birth order, and the number of siblings. In addition, key indicators of family history such as thalassemia diagnosis and family history of anemia were asked.

Hb Level and Other Rad-67 Measurements

Anemia was assessed on the basis of the continuous total Hb level, with a cutoff value determined at <12 g/dL; this value was indicative of at risk of anemia, after considering the underestimation of the Hb concentration reported for Masimo devices [16-18]. This was measured using the Masimo Rad-67 Pulse CO-Oximeter, which is a noninvasive device for screening the total Hb levels. The reliability of the Masimo Rad-67 Pulse CO-Oximeter was reported to be ±1 g/dL versus the laboratory reference device in adults who had no motion, children, and infants. These findings have been validated by a group of researchers from Thailand [20].

Growth Parameters

Growth parameters were taken from the documentation available in the infant and child health record book. These parameters were taken by trained clinic nurses using standard methods.

Statistical Analysis

Categorical variables were summarized as the frequency and percentages, while continuous variables were summarized as the mean and standard deviation. Being at risk of anemia was the dependent variable. The χ^2 test was used to test for the differences in background and predictor variables between children at risk of anemia and those not at risk. Bivariable and multivariable logistic regression models were fitted to explore the association between independent variables and the dependent variable (at risk of anemia). The multivariable regression models included significant factors on bivariable analysis as well as other factors known to be associated with being at risk of anemia from previous studies, regardless of their significance on bivariable analysis. We presented the respective crude odds ratios, adjusted odds ratios, 95% CI, and *P* values. All the analyses were performed using R-Studio (Posit, PBC), version 4.0.0, with a *P* value <.05 being the level of statistical significance.

Ethical Considerations

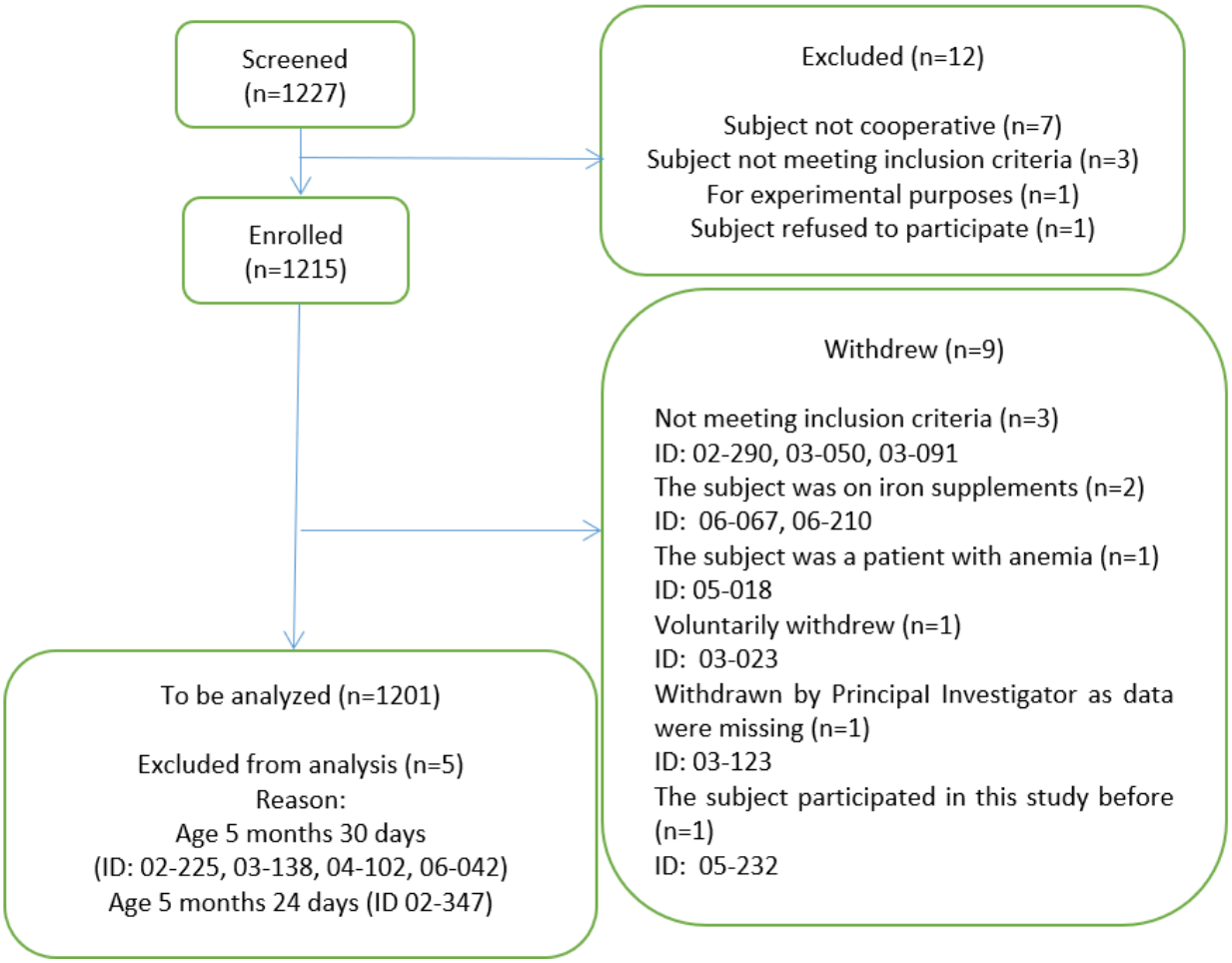
The study was approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia (Ref: 21 - 02114-PV7(2)) and the Medical Research Ethics Committee, University of Malaya Medical Centre (Ref: 20211014 - 10694). Study data were anonymized to ensure the privacy of all participants and were accessed only by authorized personnel. Informed consent was obtained from all participants prior to their involvement in the study. Participants were provided with detailed information about the study and were informed that participation was voluntary and that they could withdraw at any time without penalty. For secondary analyses of previously collected data, the original informed consent covered subsequent research uses, as confirmed by the ethics committee. Participants in the study received RM 20 (US $4.50) as monetary payment that was approved by the ethics board for their time and effort involved in participation.

XSL•FO
RenderX

Results

A total of 1227 potential respondents were reached, of whom 27 declined to participate due to various reasons, yielding a response rate of 97.9% (Figure 1).

Figure 1. Flowchart depicting the selection of study participants for a cross-sectional study on the prevalence and risk factors of anemia among Malaysian children aged 6 - 36 months. The study was conducted across five maternal-and-child health clinics in Malaysia between July and December 2022.



Characteristics of Participants

A total of 1,201 participants were included in this study (Table 1). Slightly more than half were male (631/1201, 52.5%) and aged >12 - 36 months (610/1201, 51%); the majority were Asian Malay (727/1201, 60.5%) and from urban areas (687/1201, 57.2%). The majority had mothers with no university degree (898/1201, 74.8%), were born full-term (916/1201, 76%), via normal vaginal delivery (860/1201, 72%), and were of second or higher birth order (767/1201, 63.9%). Moreover, a very small number reported a family history of thalassemia (6/1201, 0.5%) with a quarter not knowing their thalassemia status (316/1201, 26.3%), while a majority had no family history of anemia (1078/1201, 89.8%) and reported moderate or vigorous physical activity (862/1201, 71.8%).

XSL•FO
RenderX

Table . Baseline characteristics of the study participants (N=1201).

Characteristics	Frequency, n (%)
Sex	
Female	570 (47.5)
Male	631 (52.5)
Age	
>12 - 36 months	610 (51)
6 - 12 months	591 (49)
Race	
Asian, Chinese	270 (22.5)
Asian, Bumiputera	119 (9.9)
Asian, Indian	85 (7.1)
Asian, Malay	727 (60.5)
Town or District	
Alor Setar	205 (17.1)
Klang	369 (30.8)
Endau	240 (20.0)
Kota Kinabalu	133 (11.1)
Tumpat	253 (21.1)
Residence location	
Rural	514 (42.8)
Urban	687 (57.2)
Mother’s education	
Bachelor’s degree or higher	303 (25.2)
Secondary education and below	898 (74.8)
Household income	
Low	585 (48.7)
Middle or high	616 (51.3)
Physical activity level	
Sedentary or lightly active	177 (14.7)
Moderately active or vigorously active	862 (71.8)
No activity recorded	162 (13.5)
Gestational age at birth	
Term	916 (76)
Preterm	285 (24)
Mode of delivery	
Vaginal	860 (72)
Cesarean	341 (28)
Birth order	
First	434 (36.1)
Second or more	767 (63.9)
Family history of thalassemia	
Yes	6 (0.5)
No	879 (73.2)

XSL•FO
RenderX

Characteristics	Frequency, n (%)
Not known	316 (26.3)
Family history of anemia	
Yes	123 (10.2)
Not known	1078 (89.8)

Population at Risk of Anemia and Other Masimo Rad-67 Pulse CO-OximeterParameters

Of the 1,201 participants, 364 (30%, 95% CI 28 - 33) were identified as being at risk of anemia on the Masimo Rad-67 Pulse CO-Oximeter (Table 2). Additionally, participants had a mean (SD) weight-for-age Z score of −0.67 (1.29), length-for-age Z score of −0.65 (1.72), and weight-for-length Z score of −0.41 (1.29).

Table . Population at risk of anemia and other Rad-67 measurements (N=1201).

Study site	Frequency of subjects at risk of anemia, n/N (%)
Alor Setar	39/205 (10.7)
Klang	123/371 (33.9)
Endau	60/240 (16.5)
Kota Kinabalu	43/133 (11.8)
Tumpat	98/252 (27.0)

Distribution of Being at Risk of Anemia by Study Variables

The distribution of being at risk of anemia across the study variables is shown in Table 3. Children aged 6 - 12 months (n= 210, 57.7%), those of Asian Malay race (n=238, 65.4%), those from Klang district (n=123, 33.9%), those birthed via normal vaginal delivery (n=275, 75.5%), and those without a history of thalassemia (n=284, 78.0%) were associated with being at risk of anemia. Additionally, children at risk of anemia had significantly lower weight-for-age Z scores (ie, a greater negative deviation from the normal weight) than those at no risk.

XSL•FO
RenderX

Table . Distribution of being at risk of anemia across study variables among Malaysian children aged ≥6 months to ≤36 months.

Variable	Not at risk of anemia, N=837	At risk of anemia, N=364	*P* value
Sex, n (%)			.87
Female	396 (47.3)	174 (47.8)	
Male	441 (52.7)	190 (52.2)	
Age, n (%)			<.001
>12 - 36 months	456 (54.5)	154 (42.3)	
6 - 12 months	381 (45.5)	210 (57.7)	
Race, n (%)			.02
Asian, Chinese	201 (24.0)	69 (19.0)	
Asian, Bumiputera	79 (9.4)	40 (11.0)	
Asian, Indian	68 (8.1)	17 (4.7)	
Asian, Malay	489 (58.4)	238 (65.4)	
Residence location, n (%)			.19
Rural	348 (41.6)	166 (45.6)	
Urban	489 (58.4)	198 (54.4)	
Education, n (%)			.75
Bachelor's degree or higher	209 (25.0)	94 (25.8)	
Secondary education and below	628 (75.0)	270 (74.2)	
Household income, n (%)			.08
Low	394 (47.1)	191 (52.5)	
Middle or high	443 (52.9)	173 (47.5)	
Gestational age at birth, n (%)			.83
Term	637 (76.1)	279 (76.6)	
Preterm	200 (23.9)	85 (23.4)	
Mode of delivery, n (%)			.046
Vaginal	585 (69.9)	275 (75.5)	
Cesarean	252 (30.1)	89 (24.5)	
Birth order, n (%)			.17
First	313 (37.4)	121 (33.2)	
Second or more	524 (62.6)	243 (66.8)	
Siblings, n (%)			.37
No	289 (34.5)	116 (31.9)	
Yes	548 (65.5)	248 (68.1)	
Family history of thalassemia, n (%)			.03
Yes	4 (0.5)	2 (0.5)	
No	595 (71.1)	284 (78.0)	
Not known	238 (28.4)	78 (21.4)	
Family history of anemia, n (%)			.57
Yes	83 (9.9)	40 (11.0)	
Not known	754 (90.1)	324 (89.0)	
Weight-for-age Z score, mean (SD)	−0.62 (1.35)	−0.78 (1.15)	.03
Length-for-age Z score, mean (SD)	−0.60 (1.77)	−0.77 (1.57)	.10

XSL•FO
RenderX

Variable	Not at risk of anemia, N=837	At risk of anemia, N=364	*P* value
Weight-for-length Z score, mean (SD)	−0.38 (1.36)	−0.47 (1.09)	.20

Factors Associated With Being at Risk of Anemia Among Malaysian Children Aged ≥6 Months to ≤36 Months

The results of bivariable and multivariable logistic regression are detailed in Table 4. In our logistic regression analysis examining being at risk of anemia in children, the primary independent variable, weight-for-age Z score, showed a statistically significant inverse association with being at risk of anemia both in univariable (crude odds ratio=0.91, 95% CI 0.82 - 1.00; *P*=.046) and multivariable models (adjusted odds ratio=0.88, 95% CI 0.80 - 0.98; *P*=.020), indicating that higher Z scores were associated with reduced odds of being at risk of anemia. Among the covariates, only age showed a significant association; specifically, children aged 6 - 12 months had 1.73 times higher odds of being at risk of anemia compared to those aged 12 - 36 months (adjusted odds ratio=1.73, 95% CI 1.34 - 2.24; *P*<.001). Other demographic and medical factors, such as sex, race, residence location, and socioeconomic status, did not significantly impact being at risk of anemia (Table 4). This study underscores the importance of weight monitoring and age-specific interventions in mitigating anemia risk in children.

XSL•FO
RenderX

Table . Results from bivariable and multivariable logistic regression models examining predictors of being at risk of anemia among Malaysian children aged ≥6 months to ≤36 months.

Variable	Crude odds ratio (95% CI)	*P* value	Adjusted odds ratio (95% CI)	*P* value
Sex				
Female	1		1	
Male	0.98 (0.77 - 1.25)	.876	0.96 (0.75 - 1.23)	.74
Age				
>12 - 36 months	1		1	
6 - 12 months	1.63 (1.27 - 2.09)	<.001	1.73 (1.34 - 2.24)	<.001
Race				
Asian, Chinese	1		1	
Asian, Bumiputera	1.47 (0.92 - 2.35)	.104	1.34 (0.80 - 2.24)	.25
Asian, Indian	0.73 (0.39 - 1.30)	.298	0.72 (0.38 - 1.31)	.29
Asian, Malay	1.42 (1.04 - 1.95)	.029	1.23 (0.88 - 1.73)	.22
Residence location				
Rural	1		1	
Urban	0.85 (0.66 - 1.09)	.195	0.96 (0.72 - 1.27)	.76
Education				
Bachelor's degree or higher	1		1	
Secondary education and below	0.96 (0.72 - 1.27)	.754	0.84 (0.62 - 1.14)	.25
Household income				
Low	1		1	
Middle or high	0.81 (0.63 - 1.03)	.086	0.78 (0.59 - 1.02)	.07
Physical activity level				
Sedentary or lightly active	1		1	
Moderately active or vigorously active	1.04 (0.74 - 1.50)	.812	1.19 (0.80 - 1.79)	.39
Gestational age at birth				
Term	1		1	
Preterm	0.97 (0.72 - 1.29)	.839	0.98 (0.73 - 1.32)	.91
Mode of delivery				
Vaginal	1		1	
Cesarean	0.75 (0.57 - 0.99)	.046	0.78 (0.58 - 1.04)	.09
Birth order				
First	1		1	
Second or more	1.23 (0.93 - 1.63)	.144	1.11 (0.83 - 1.49)	.49
Family history of thalassemia				
No	1		1	
Yes	1.15 (0.16 - 5.92)	.872	1.26 (0.17 - 6.90)	.79
Family history of anemia				
Yes	1		1	
Not known	0.89 (0.60 - 1.34)	.573	0.95 (0.62 - 1.49)	.83

XSL•FO
RenderX

Variable	Crude odds ratio (95% CI)	*P* value	Adjusted odds ratio (95% CI)	*P* value
Weight-for-age Z score	0.91 (0.82 - 1.00)	.046	0.88 (0.80 - 0.98)	.02
Length-for-age Z score	0.95 (0.88 - 1.03)	.206	0.74 (0.41 - 1.31)	.31
Weight-for-length Z score	0.95 (0.85 - 1.05)	.313	0.65 (0.28 - 1.47)	.30

Discussion

Principal Findings and Comparison with Previous Works

The study assessed the prevalence and profiles of Malaysian children aged ≥6 to ≤36 months being at risk of anemia using a noninvasive Hb approach (the Masimo Rad-67 Pulse CO-Oximeter). Unlike the conventional methods of assessing anemia, this noninvasive screening approach offers rapid, accurate, and reproducible results, favoring the implementation in maternal child health clinics for early detection and prompt treatment before the condition worsens to severe anemia-related complications. This study had a response rate of 97.9% and only 7 out of 1227 patients were not cooperative to be included in the study. A high response rate among participants to be part of the study indicates their receptiveness to a noninvasive approach. The lack of parental consent due to invasive approaches has been observed and highlighted as a limitation in a similar study [21]. Caregivers of children highly favor noninvasive disease screening methods that lead to better testing compliance compared to invasive techniques that can cause discomfort and pain [22]. Noninvasive methods also reduce the risk of infection and could potentially be more cost-effective due to less usage of consumables and reagents [23].

This study found that 30% of Malaysian children aged ≥6 to ≤36 months were at risk of anemia. The observed prevalence was slightly higher than the 25% national prevalence of anemia among children below 5 years [19]. Moreover, the observation was also higher than that observed in two previous studies, which reported prevalence rates of 21.2% [23] and 22.3% [24], respectively. However, the observed prevalence was lower than the prevalence rate of 42.4% reported by Sabri et al [12] and 46.5% reported by the 2022 National Health and Morbidity survey [7]. As a screening tool for anemia, the Masimo Rad-67 Pulse CO-Oximeter is less stringent, which may account for the slightly higher prevalence observed in this sample population. As this is as a screening tool, confirmatory laboratory tests will be required for a diagnosis after screening.

This study focused on looking at contributing factors of anemia, although it did not measure iron content to evaluate the prevalence of IDA. A retrospective study in Pulau Pinang showed that the rate of IDA was 24% among children [24]. However, the 24-hour dietary recall that was performed may give an idea of the children's iron intake. It will be interesting to see if the children's intake of iron and other nutrients has any association with anemia development in this study. In this study, parental interpretation was used to measure physical activity. No specific children's physical activity measurement tool was used.

Although several measures have been undertaken, the observed prevalence of being at risk of anemia in Malaysia is substantially high, implying a need for more focused interventions aimed at prevention, early screening, and detection as well as treatment. In this regard, the extensive use and adoption of noninvasive screening tools at maternal and health clinics, which are points of child vaccination and regular health checks, would be essential for the early detection and providing prompt treatment, thus curbing the adverse complications of anemia in children [25-27].

The study explored factors associated with anemia among Malaysian children, of which age and weight-for-age were significant. The study results indicate that a higher risk of anemia is more common among children aged 6 - 12 months and lower weight-for-age. As expected, our results partly agree with the existing literature that has also reported children 6 - 12 months to have a higher risk of anemia compared to older children, due to increased iron needs that, if not provided by weaning foods, put this age group at a higher risk of serious anemia [3,4,28]. This aligns with previous studies that have reported a similar trend in India [29], Ethiopia [30], Brazil [31], and Peru [32].

Notably, although nonsignificant on adjusted regression analysis, children of the Asian-Malay race showed higher proportions of being at risk of anemia (65%) than other races, a finding that aligns with previous studies that have reported racial disparities in the risk of anemia [33,34]. Khalil et al showed a vast difference in the prevalence of anemia between the Orang Asli tribes in Malaysia, which was attributed to differences in socioeconomic background and other risk factors of anemia [35]. Similar to another study, anemia prevalence differences observed among racial and ethnic groups in this study can also be due to different food practices and low dietary intake of iron [21].

We expected thalassemia, a genetic predisposing factor affecting one's Hb concentration, to be positively associated with the risk of anemia, which is in contrast to this study's finding. In our study, Thalassemia status is based on parental and carer's reporting and could be subjected to reporting error, since as high as 26.3% of the subjects were unaware of their thalassemia status. Similarly, cesarean section as a mode of delivery is reported to have a negative impact on child feeding practices compared to normal vaginal delivery [21]; thus, we expected a positive association with anemia risk, which also deviates from our finding. Nonetheless, the difference in sample size and composition in our study could explain the observed mismatch. Additionally, mothers with children born of cesarean section and with thalassemia may be more aware of the increased risk of anemia from clinical counseling and education [36]. Therefore, they may be more likely to take extra measures to

XSL•FO
RenderX

prevent anemia in their children, unlike mothers with no such known risk, which may explain our finding of surprisingly increased risk of anemia among children born via normal vaginal delivery and with no family history of thalassemia.

Malnutrition has been previously recognized as a factor for anemia among underweight children [28,37]. Additionally, micronutrient deficiency, food insecurity, and poverty have been established as factors leading to underweight children [28,38]. A study in China found that malnutrition resulted from the caregiver's lack of knowledge of child feeding practices [37], which may also be a contributing factor to anemia among children in this study. In addition, although the current data revealed that children from lower-income families had a higher proportion of being at risk of anemia, the household income surprisingly showed no statistically significant association with being at risk of anemia in the previous study [37].

It is worth noting that the observed high prevalence of anemia risk among children, including Malaysian children, is driven by complex interlinked factors including socioeconomic status, access to healthcare, dietary patterns, and cultural practices, amongst others [21,28,37,38]. A few such factors have been re-echoed in this study. The socioeconomic status, for example, affects food access and dietary quality, which are primary causes of anemia [28,38]. The socioeconomic status also affects healthcare access, without which the impact of anemia among children may be worsened. This calls for a comprehensive and inclusive approach to designing anemia prevention programs, considering the interaction of various key drivers.

Implications of Study Findings

Our study findings have some practical implications for addressing the observed high risk of anemia among Malaysian children. There is a need for more efforts in strengthening prompt community screening of anemia nationwide to enable the early detection and, thus, appropriate intervention or treatment, and this could be achieved by the adoption and use of noninvasive screening tools like the Masimo Rad-67 Pulse CO-Oximeter. The study results also imply that the Masimo Rad-67 Pulse CO-Oximeter could be a useful tool in the clinical assessment of Malaysian children for anemia, which could be incorporated into regular child immunization and monitoring visits. These efforts and other anemia prevention strategies should focus on children aged 6 - 12 months of Asian Malay heritage or race, and underweight children because they have a higher risk of anemia. Moreover, more efforts are needed in community education and sensitization about anemia risk, its consequences and prevention, and this should focus on the mothers and caregivers of children under 5 years. Additionally, nutritional education should be incorporated in the discussions with parents and caregivers after the examination of infants and young children to reduce the incidence of being underweight among children and to ensure anemia prevention and reduction.

Limitations

The study has some limitations. Some of the data, especially background predictor variables, were based on self-reporting, risk recall, and misclassification biases. Moreover, given the cross-sectional design of the study, no causal inference can be drawn between anemia and the other factors considered, beyond mere associations. Despite the limitations, the study provides valuable information on the prevalence of the risk of anemia and associated factors among Malaysian children using a noninvasive assessment tool.

Conclusions

Using a noninvasive screening tool, the study found that 30% of Malaysian children aged ≥6 to ≤36 months are at risk of anemia. Moreover, children aged 6 - 12 months and of Asian-Malay heritage or race had high odds of anemia. Weight-for-age was also negatively associated with the risk of anemia. Therefore, there is a need for more efforts in targeted community screening to enable the early detection and prompt treatment of anemia. More community education and awareness about anemia, including nutrition education, is also needed to address the high levels of anemia in the country.

Acknowledgments

We would like to acknowledge all health clinics staffs for the support given to undertake this study. We also would like to thank Dr Nouran Hamza for her contribution in the study's statistical analysis. Our special thanks and appreciation also goes to all children and their mothers who voluntarily participated. This project was funded by Danone Specialized Nutrition (Malaysia) Sdn Bhd.

Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

References

1. World Health Organisation. Worldwide prevalence of anaemia 1993–2005. In: de Benoist B, McLean E, Egli I, Cogswell M, editors. WHO Global Database on Anaemia: World Health Organization; 2008.

XSL•FO
RenderX

2. World Health Organisation. Iron deficiency anaemia assessment, prevention, and control A guide for programme managers. : World Health Organization; 2001 URL: https://www.who.int/publications/m/item/iron-children-6to23--archived-iron-deficiency-anaemia-assessment-prevention-and-control [accessed 2023-04-07]
3. Özdemir N. Iron deficiency anemia from diagnosis to treatment in children. Turk Pediatri Ars 2015 Mar;50(1):11-19. [doi: 10.5152/tpa.2015.2337] [Medline: 26078692]
4. Subramaniam G, Girish M. Iron deficiency anemia in children. Indian J Pediatr 2015 Jun;82(6):558-564. [doi: 10.1007/s12098-014-1643-9] [Medline: 25636824]
5. World Health Organization. Anaemia in women and children. 2021. URL: https://www.who.int/data/gho/data/themes/topics/anaemia_in_women_and_children?utm_content=buffer 85683&utm [accessed 2025-02-24]
6. National health and morbidity survey. 2019 URL: https://www.iku.gov.my/images/IKU/Document/REPORT/NHMS2019/Report_NHMS2019-NCD_v2.pdf [accessed 2023-04-05]
7. Institute for Public Health (IPH). National health and morbidity survey (NHMS) 2022: maternal and child health – key findings. 2023 URL: https://iku.gov.my/images/nhms-2022/4a.-infographic_nhms-mch_english_19.05.2023.pdf?_t=1684481335 [accessed 2023-04-05]
8. Baker RD, Greer FR, Committee on Nutrition American Academy of Pediatrics. Diagnosis and prevention of iron deficiency and iron-deficiency anemia in infants and young children (0-3 years of age). Pediatrics 2010 Nov;126(5):1040-1050. [doi: 10.1542/peds.2010-2576] [Medline: 20923825]
9. Kohli-Kumar M. Screening for anemia in children: AAP recommendations--a critique. Pediatrics 2001 Sep;108(3):e56-e56. [doi: 10.1542/peds.108.3.e56] [Medline: 11533374]
10. Khedr E, Hamed SA, Elbeih E, El-Shereef H, Ahmad Y, Ahmed S. Iron states and cognitive abilities in young adults: neuropsychological and neurophysiological assessment. Eur Arch Psychiatry Clin Neurosci 2008 Dec;258(8):489-496. [doi: 10.1007/s00406-008-0822-y] [Medline: 18574611]
11. Hassan TH, Badr MA, Karam NA, et al. Impact of iron deficiency anemia on the function of the immune system in children. Medicine (Baltimore) 2016 Nov;95(47):e5395. [doi: 10.1097/MD.0000000000005395] [Medline: 27893677]
12. Sabri N‘‘, Gan WY, Law LS, Chin YS, Mohd Shariff Z. Factors associated with cognitive and motor delays in Malaysian infants aged 6–12 months. Early Child Dev Care 2022 Apr 4;192(5):781-794. [doi: 10.1080/03004430.2020.1801666]
13. Joo EY, Kim KY, Kim DH, Lee JE, Kim SK. Iron deficiency anemia in infants and toddlers. Blood Res 2016 Dec;51(4):268-273. [doi: 10.5045/br.2016.51.4.268] [Medline: 28090490]
14. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Masimo Rad-67 Pulse CO-Oximeter and Accessories/ K182887 approval letter. 2019 Mar 22. URL: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K182887 [accessed 2021-12-09]
15. Zhao QM, Ma XJ, Ge XL, et al. Pulse oximetry with clinical assessment to screen for congenital heart disease in neonates in China: a prospective study. Lancet 2014 Aug 30;384(9945):747-754. [doi: 10.1016/S0140-6736(14)60198-7] [Medline: 24768155]
16. Hiscock R, Kumar D, Simmons SW. Systematic review and meta-analysis of method comparison studies of Masimo pulse co-oximeters (Radical-7 or Pronto-7™) and HemoCue® absorption spectrometers (B-Hemoglobin or 201+) with laboratory haemoglobin estimation. Anaesth Intensive Care 2015 May;43(3):341-350. [doi: 10.1177/0310057X1504300310] [Medline: 25943608]
17. Shamah Levy T, Méndez-Gómez-Humarán I, Morales Ruán MDC, Martinez Tapia B, Villalpando Hernández S, Hernández Ávila M. Validation of Masimo Pronto 7 and HemoCue 201 for hemoglobin determination in children from 1 to 5 years of age. PLoS ONE 2017;12(2):e0170990. [doi: 10.1371/journal.pone.0170990] [Medline: 28170445]
18. De Rosa RC, Romanelli A. Accuracy and precision of non-invasive continuous haemoglobin concentration monitoring in diabetic patients. Ain-Shams J Anesthesiol 2022 Dec;14(1):1-8. [doi: 10.1186/s42077-021-00201-2]
19. The World Bank Data Prevalence of anemia among children (% of children ages 6-59 months) - Malaysia. URL: https://data.worldbank.org/indicator/SH.ANM.CHLD.ZS?locations=MY [accessed 2023-03-24]
20. Saengnipanthkul S, Tawiangnan C, Sirikarn P, et al. Accuracy of noninvasive total haemoglobin measurement for detecting anaemia in infants: a cross-sectional study in a well-child care clinic, Khon Kaen, Thailand. BMJ Open 2024 Dec 30;14(12):e083356. [doi: 10.1136/bmjopen-2023-083356] [Medline: 39806708]
21. Nik Shanita S, Siti Hanisa A, Noor Afifah AR, et al. Prevalence of anaemia and iron deficiency among primary schoolchildren in Malaysia. Int J Environ Res Public Health 2018 Oct 23;15(11):2332. [doi: 10.3390/ijerph15112332] [Medline: 30360488]
22. Maxim LD, Niebo R, Utell MJ. Screening tests: a review with examples. Inhal Toxicol 2014 Nov;26(13):811-828. [doi: 10.3109/08958378.2014.955932] [Medline: 25264934]
23. Murtaza SF, Lee LJ, Usaini NN, Gan WY, Sulaiman N. Factors associated with anemia among Orang Asli children aged two to six years in Negeri Sembilan, Malaysia. Cureus 2023 Feb;15(2):e35511. [doi: 10.7759/cureus.35511] [Medline: 37007386]
24. Othman Tan SES, Ishak NN, Mohd Yusoff N. Prevalence of anaemia in children treated in Kepala Batas, Penang. MJPCH 2020 Nov 18;26(2):35-50. [doi: 10.51407/mjpch.v26i2.110]

XSL•FO
RenderX

25. Smyth R, Dibaba A, Thomas A, Malimbwi M, Mtimbwa F, Bukuru N. Acceptability and perceived usability of a non-invasive haemoglobin monitor among community members and health workers in Tanzania. URL: https://www.ennonline.net/fex/61/haemoglobinmonitortanzania [accessed 2025-02-24]
26. Ramaswamy G, Vohra K, Yadav K, et al. Point-of-care testing using invasive and non-invasive hemoglobinometers: reliable and valid method for estimation of hemoglobin among children 6-59 months. J Trop Pediatr 2021 Jan 29;67(1):fmaa111. [doi: 10.1093/tropej/fmaa111] [Medline: 33367788]
27. Arai Y, Shoji H, Awata K, Inage E, Ikuse T, Shimizu T. Evaluation of the use of non-invasive hemoglobin measurement in early childhood. Pediatr Res 2023 Mar;93(4):1036-1040. [doi: 10.1038/s41390-022-02204-7] [Medline: 35906313]
28. Keokenchanh S, Kounnavong S, Midorikawa K, et al. Prevalence of anemia and its associated factors among children aged 6-59 months in the Lao People's Democratic Republic: A multilevel analysis. PLoS ONE 2021;16(3):e0248969. [doi: 10.1371/journal.pone.0248969] [Medline: 33765048]
29. Kalaiselvam P, Chelliah S, Pachamuthu M. Prevalence of nutritional anemia in children of high socioeconomic status in a tertiary care center. Indian J Child Health 2021 Oct 26;8(10):359-361. [doi: 10.32677/ijch.v8i10.3060]
30. Woldie H, Kebede Y, Tariku A. Factors associated with anemia among children aged 6-23 months attending growth monitoring at Tsitsika Health Center, Wag-Himra Zone, Northeast Ethiopia. J Nutr Metab 2015;2015:928632. [doi: 10.1155/2015/928632] [Medline: 26106486]
31. Zuffo CRK, Osório MM, Taconeli CA, Schmidt ST, da Silva BHC, Almeida CCB. Prevalence and risk factors of anemia in children. J Pediatr (Rio J) 2016;92(4):353-360. [doi: 10.1016/j.jped.2015.09.007] [Medline: 26893206]
32. Velásquez-Hurtado JE, Rodríguez Y, Gonzáles M, et al. Factors associated with anemia in children under three years of age in Perú: analysis of the Encuesta Demográfica y de Salud Familiar, ENDES, 2007-2013. Biomedica 2016 Jun 3;36(2):220-229. [doi: 10.7705/biomedica.v36i2.2896] [Medline: 27622483]
33. Brotanek JM, Gosz J, Weitzman M, Flores G. Iron deficiency in early childhood in the United States: risk factors and racial/ethnic disparities. Pediatrics 2007 Sep;120(3):568-575. [doi: 10.1542/peds.2007-0572] [Medline: 17766530]
34. Atkinson MA, Melamed ML, Kumar J, et al. Vitamin D, race, and risk for anemia in children. J Pediatr 2014 Jan;164(1):153-158. [doi: 10.1016/j.jpeds.2013.08.060] [Medline: 24112861]
35. Khalil MKN, Abd Razak MA, Tahir FA, et al. Prevalence and risk factors of anaemia among Orang Asli children in Malaysia: a scoping review. Nutrients 2023 Mar 20;15(6):1493. [doi: 10.3390/nu15061493] [Medline: 36986223]
36. Saaka M, Hammond AY. Caesarean section delivery and risk of poor childhood growth. J Nutr Metab 2020;2020:6432754. [doi: 10.1155/2020/6432754] [Medline: 32399289]
37. Yao S, Wang J, Xiao S, et al. Inadequate nutrition and associated factors in children aged 6 to 24 months - 4 counties, Liangshan Yi Autonomous Prefecture, China, 2018. China CDC Wkly 2020 Nov 6;2(45):873-877. [doi: 10.46234/ccdcw2020.155] [Medline: 34594783]
38. Chowdhury MRK, Khan MMH, Khan HTA, et al. Prevalence and risk factors of childhood anemia in Nepal: a multilevel analysis. PLoS ONE 2020;15(10):e0239409. [doi: 10.1371/journal.pone.0239409] [Medline: 33021981]

Abbreviations

Hb: hemoglobin
IDA: iron deficiency anemia

Edited by S Badawy; submitted 20.03.24; peer-reviewed by EA Ashaat, SM Awaluddin, Y Essar; revised version received 21.01.25; accepted 28.01.25; published 24.03.25.

Please cite as:
Jalaludin MY, Kiau HB, Hasim S, Lee WK, Low A, Kazim NHN, Hoi JT, Taher SW
A Noninvasive Approach to Assess the Prevalence of and Factors Associated With Anemia Risk in Malaysian Children Under Three Years of Age: Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e58586
URL: https://pediatrics.jmir.org/2025/1/e58586
doi:10.2196/58586

© Muhammad Yazid Jalaludin, Ho Bee Kiau, Suriati Hasim, Wai Khew Lee, Angie Low, Nik Harlina Nik Kazim, Jia Tse Hoi, Sri Wahyu Taher. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 24.3.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic

XSL•FO
RenderX

information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Preoperative Anxiety Management Practices in Pediatric Anesthesia: Comparative Analysis of an Online Survey Presented to Experts and Social Media Users

Armin Sablewski[1], MD; Christine Eimer[1], MD; Marcus Nemeth[2], MD; Clemens Miller[2,3], MD

[1]Department of Anesthesiology and Intensive Care Medicine, University Medical Center Schleswig-Holstein, Campus Kiel, Arnold-Heller-Straße 3, Haus R3, Kiel, Germany

[2]Department of Anesthesiology, University Medical Center Goettingen, Goettingen, Germany

[3]Department of Anesthesiology, Children's Orthopedic Hospital Aschau im Chiemgau, Aschau im Chiemgau, Germany

Corresponding Author:
Armin Sablewski, MD
Department of Anesthesiology and Intensive Care Medicine, University Medical Center Schleswig-Holstein, Campus Kiel, Arnold-Heller-Straße 3, Haus R3, Kiel, Germany

Abstract

Background: Managing preoperative anxiety in pediatric anesthesia is challenging, as it impacts patient cooperation and postoperative outcomes. Both pharmacological and nonpharmacological interventions are used to reduce children's anxiety levels. However, the optimal approach remains debated, with evidence-based guidelines still lacking. Health care professionals using social media as a source of medical expertise may offer insights into their management approaches.

Objective: A public survey targeting health care professionals was disseminated via social media platforms to evaluate current practices in anxiety management in children. The same questions were posed during an annual meeting of pediatric anesthesiologists with their responses serving as reference. The primary objective was to compare pediatric anesthesia expertise between the groups, while secondary objectives focused on identifying similarities and differences in preoperative anxiety management strategies hypothesizing expertise differences between the groups.

Methods: Two surveys were conducted. The first survey targeted 100 attendees of the German Scientific Working Group on Pediatric Anesthesia in June 2023 forming the "Expert Group" (EG). The second open survey was disseminated on social media using a snowball sampling approach, targeting followers of a pediatric anesthesia platform to form the "Social Media Group" (SG). The answers to the 24 questions were compared and statistically analyzed. Questions were grouped into 5 categories (pediatric anesthesia expertise, representativity, structural conditions, practices of pharmacological management, and practices in nonpharmacological management).

Results: A total of 194 responses were analyzed (82 in EG and 112 in SG). The EG cohort exhibited significantly greater professional experience in pediatric anesthesia than the SG cohort (median 19 vs 10 y, $P<.001$), higher specialist status (97.6% vs 64.6%, $P<.001$), and a greater pediatric anesthesia volume (43.9% vs 12% with more than 500 cases per year, $P<.001$). Regarding the representativity, 2 items out of 4 were statistically significant (level of care of institution, annual caseload of institution). Regarding the overall anxiety management practices used, there is a heterogeneous response pattern within both groups.

Conclusions: Despite heterogeneous approaches, health care professionals using social media demonstrated less expertise in pediatric anesthesia but showed minimal differences in the daily management of preoperative anxiety compared with pediatric anesthesia experts. Our study highlights the potential for meaningful use of social media but future studies should explore the impact of social media health care professionals' knowledge in other specific topics. Additionally, regarding preoperative anxiety, further recommendations are needed that could help to standardize and improve anxiety levels in children.

(JMIR Pediatr Parent 2025;8:e64561) doi:10.2196/64561

KEYWORDS

pediatric anesthesia; pharmacological interventions; nonpharmacological interventions; preoperative; anxiety; anxiety management; practices; anesthesia; comparative analysis; online survey; preoperative anxiety; challenges; postoperative outcome; pediatric; infant; baby; neonatal; toddler; child; social media; survey; anesthesia provider

XSL•FO
RenderX

Introduction

Although “no fear” is the first of the “10-N quality criteria” in pediatric anesthesia, preoperative anxiety remains prevalent [1,2]. It is evident that high levels of anxiety are associated with decreased cooperativeness during induction of anesthesia, increased postoperative analgesic requirements, increased rates of postoperative delirium, and maladaptive behavioral problems [3,4]. Therefore, it is crucial to keep anxiety levels low.

Established options for preoperative anxiolysis in children include pharmacological and nonpharmacological interventions. Midazolam, clonidine, and dexmedetomidine as well as (s-)ketamine are frequently used for pharmacological premedication [5,6]. However, the general use of these drugs is subject to controversial debate [6,7]. Nonpharmacological interventions include parental presence at induction of anesthesia, educational approaches (eg, informational mediation and prior inspection of the operating room), complementary medical procedures (such as acupuncture, music therapy, hypnosis), and cognitive-behavioral therapeutic measures (such as strengthening coping strategies, distraction, breathing exercises, model learning) [8-14]. Nonpharmacological interventions have been shown to be at least as effective as the administration of midazolam [15]. Although many different options are available, there are currently no evidence-based recommendations and guidelines on which intervention is best for which situation. Recently, we conducted a survey on the current practice of preoperative anxiety management in pediatric anesthesia among German-speaking participants [16]. It was conducted during an expert meeting of the Scientific Working Group for Pediatric Anesthesia of the German Society of Anesthesiology and Intensive Care Medicine and revealed relevant differences in the structural conditions, management of pharmacologic premedication, and the use of nonpharmacologic measures [16].

However, participants in expert meetings may not accurately reflect the realities of daily anxiety management practices. Social media, defined as “any form of electronic communication [...] to share information” [17], offers the potential to enhance these insights by leveraging swarm intelligence and engaging a broader and more diverse group of health care professionals involved in preoperative anxiety management. Web-based surveys disseminated through social media targeting pediatric anesthesia health care professionals could thus capture a larger, geographically diverse sample, enhancing overall insight. While web-based surveys are efficient and cost-effective, they have limitations, such as open participation, low response rates (≈10%), and uncertain respondent identity [18]. In contrast, closed-group surveys, such as those conducted among expert meeting participants, provide more defined and reliable profiles, potentially serving as a reference for comparison.

Thus, a web-based survey on preoperative anxiety was sent to social media users involved in pediatric anesthesia, and their responses were compared with those from a pediatric anesthesia Expert Group (EG). The study aimed to test the hypothesis that expertise and preoperative anxiety management practice differ between a broad, randomly selected social media population and a dedicated EG.

Methods

Overview

The web-based survey was aimed at anesthesiologists who are active on social media. Currently, there are approximately 27,000 anesthesiologists in Germany, around 3300 in Austria, and 1600 in Switzerland [19-21]. It is estimated that approximately 70% - 90% of all physicians actively use social media, meaning that around 25,000 anesthesiologists were eligible to participate in the web-based questionnaire [22,23]. As this was an open survey, the participation of nonanesthesiologists could not be excluded. The survey related to the scientific conference was directed at the scientific working group on pediatric anesthesia in German-speaking countries. It consists of physicians with predominantly high expertise in the field of pediatric anesthesia, with approximately 100 participants attending the conference each year.

Ethical Considerations

This analysis did not require approval by an institutional review board or entry into a clinical trial register since it did not include data from patients or medical records according to the Helsinki Declaration. Participation was voluntary, and privacy was ensured through the anonymous collection of study data. No personal information, cookies, or IP addresses that could enable identification were stored. Participants did not receive any compensation.

Survey Development

We adhered to the items of the “Good practice in the conduct and reporting of survey research” and the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [24,25]. Technical tests were carried out before the surveys were conducted to enhance comprehensibility and rule out possible errors. The completion rate (ratio of users who finished the survey/users who answered the first question) was calculated for both groups and the participant rate (ratio of unique visitors who agreed to participate/unique first survey page visitors) for EG. For completeness checking, incomplete data were marked as “not applicable” to indicate the extent of survey completion. The processed data consisted of 2 surveys, each conducted independently. There were no follow-up validation attempts to verify if the respondents were truly qualified.

Data Sources

The first survey was conducted among participants of the annual meeting of the Scientific Working Group on Pediatric Anesthesia of the German Society for Anesthesiology and Intensive Care medicine (DGAI), which took place in Hamburg, Germany, on June 16 - 17, 2023. During the event, access to a web-based survey, using Microsoft Forms (Office 365), was given via a QR code. The survey contained 25 questions targeting the daily practice of preoperative anxiety management in children (Multimedia Appendix 1). Those respondents formed the EG, serving as a reference to the second survey. The results of this survey were formerly published [16].

XSL•FO
RenderX

The second open survey was announced among followers of a German-language podcast on pediatric anesthesia [26]. This podcast is broadcast on platforms such as Spotify and Apple Podcast (in total 44 platforms) and has achieved approximately 130k downloads and streams with its 34 episodes (data retrieved on July 01, 2024). Users were given access to this survey from October 01 to 31, 2023. The first call for participation was made on October 01, 2023, via short posts on the social media platforms X, Bluesky, and Instagram, as well as posts on the corresponding social media accounts in the field of anesthesiology following the random snowball sampling method. The invitation included an image with a QR code and a link to the web-based survey (Multimedia Appendix 2) along with a request for reposts. Several reposts were made and a short podcast episode on October 19, 2023, was broadcast to recall for participation (1117 downloads in the survey period). The episode was available on major podcast platforms, including Podigee, Spotify, Apple Podcasts, Amazon Podcasts, and Google Podcasts [27]. In comparison to the first survey, this one was expanded to cover the broad spectrum of social media users with 4 more questions (marked with asterisk (*) in Multimedia Appendix 1). Respondents formed the "Social Media Group" (SG).

All items were displayed on a website and were only interrupted by adaptive questions. Completeness checks before submission were not integrated, and respondents were able to modify their answers before submission. For both surveys, multiple participation could not be technically excluded but respondents of the second survey were asked to refuse participation in case of prior participation to the first survey. Multiple selections were possible for some questions.

Data Processing

Both survey data were checked for incomplete data and then matched using Microsoft Excel (Office 2019, Microsoft). The questions were clustered into five categories: (1) pediatric anesthesia expertise (3 items), (2) representativity (5 items for both surveys and 4 additional items in SG), (3) structural conditions (9 items), (4) practices of pharmacological routine (6 items), and (5) practices of nonpharmacological routine (2 items). The item "zip codes" and the 4 additional questions were excluded from the comparison between the 2 groups, resulting in a total of 24 items being compared.

Objectives

The primary objective was to assess the pediatric anesthesia expertise of the SG compared with the EG, given by significant differences in professional expertise (defined by years of professional experience), expert status (defined as being a board-certified anesthesiologist with passed professional examination), and a number of personal annual pediatric anesthesia case volume. The secondary objectives were the differences in the clustered categories of general characteristics and practices in managing preoperative anxiety, capturing structural conditions and practices in both pharmacological and nonpharmacological interventions.

Statistical Analysis

In the descriptive analysis, we presented the absolute and relative frequencies for the respective groups for categorical variables and the medians, IQRs, and total ranges for the respective groups for continuous variables. We applied a significance level of 0.05 for all statistical tests. The Kolmogorov-Smirnov test was used to assess the normality of the distribution. *P* values for the comparison of both groups were calculated using Fisher exact test or chi-square test for categorical variables, and the Wilcoxon rank sum test for continuous variables. Analysis and illustrations were performed using GraphPad Prism (GraphPad Software) and Microsoft Excel (Office 2019, Microsoft).

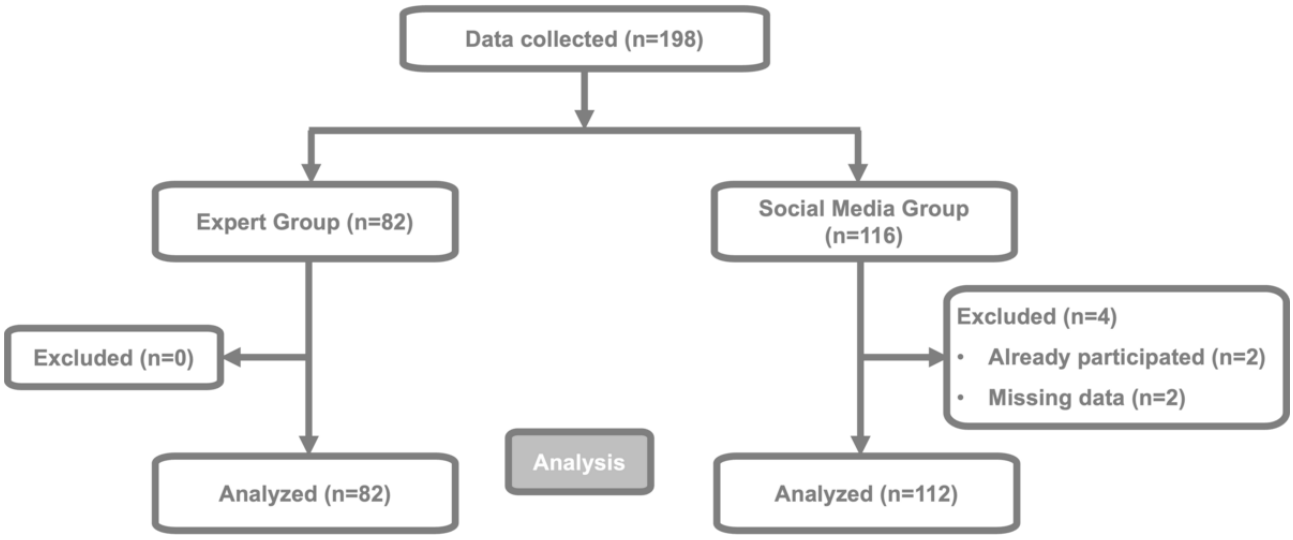
Results

Overview

A total of 198 respondents participated in both surveys, 82 respondents in the EG and 116 respondents in the SG, respectively. Two responses from the SG were excluded due to prior participation in the EG survey, and another 2 responses were excluded due to missing data, leaving 194 responses for the final analysis in both groups (Figure 1). Unless stated otherwise, the full analysis set consisted of 82 respondents in the EG and 112 in the SG, with nonrespondents excluded from all calculations.

XSL•FO
RenderX

Figure 1. Flow chart of data collection and analysis.



The participation rate in EG was 82% as 82 participants out of 100 joined the survey during the annual meeting. Since no IP addresses were recorded, the participation rate for the SG could not be calculated. The completion rate of analyzed data was 100% in both groups.

In the 5 clustered categories, we found 10 out of 24 items to be significantly different in the response behavior between the 2 groups (see Table 1, corresponding questions in Multimedia Appendix 1).

XSL•FO
RenderX

Table . Survey items in clustered categories with differences between the Expert Group (EG) and the Social Media Group (SG). Detailed evaluation in the text.

Category and item		*P* value
Pediatric anesthesia expertise		
	Years of professional experience	<.001
	Specialist (board-certified anesthesiologist)	<.001
	Personal pediatric anesthesia case volume annually	<.001
Representativity		
	Gender	.51
	Country of respondents' institution	.65
	Level of care of the institution	<.001
	Institutional pediatric anesthesia case volume annually	<.001
Structural conditions		
	Written protocols for managing preoperative anxiety	.47
	Existing preoperative preparation programs	.76
	Used preoperative preparation programs	.90
	Feasibility (local conditions) of parental presence during induction of anesthesia	.01
	Standard of parental presence during induction of anesthesia	.69
	Place of separation of the children from their caregivers	.84
	Routine in anxiety measurement	.16
	Used anxiety measurement tools	—[a]
	Known anxiety measurement tools	<.001
Practices of pharmacological management		
	Regular use of preoperative medication	.99
	Indication-based prescription of premedication, avoiding routine use	.04
	Criteria for deciding on premedication use	.24
	Most commonly used substance	.23
	1st choice for premedication	.999
	Minimum age for administering premedication	<.001
Practices of nonpharmacological management		
	Standard practice of nonpharmacological interventions	.63
	Use of nonpharmacological interventions	<.001

[a]Not applicable (only 4 responses in the EG and only 1 response in the SG, no statistical analysis was carried out).

Pediatric Anesthesia Expertise

The level of pediatric anesthesia expertise demonstrated by the SG was significantly lower than that reported in the EG. This was given by a lower number of professional experience in the SG with a median of 10 years (IQR 6 - 18; total range 1 - 45) compared with a median of 19 years (14-25; 5-35) in the EG (*P*<.001), a lower share of respondents in the SG group of specialists, with 64.6% (64/99, with 13 nonrespondents), compared to 97.6% (80/82) in the EG group (*P*<.001), a lower share of respondents in the SG group reported performing more than 500 pediatric anesthesia cases per year, with 12% (13/108, with 4 nonrespondents), compared to 43.9% (36/82) in the EG group (*P*<0.001; details in Table 2).

XSL•FO
RenderX

Table . Distribution of performed anesthesia case volume per year.

Personal pediatric anesthesia case volume annually	EG[a] (n=82), n (%)	SG[b] (n=108)[c], n (%)
0 - 49	4 (4.9)	50 (46.3)
50 - 99	1 (1.2)	17 (15.7)
100 - 199	13 (15.9)	15 (13.9)
200 - 299	11 (13.4)	7 (6.5)
300 - 399	11 (13.4)	5 (4.6)
400 - 499	6 (7.3)	1 (0.9)
>500	36 (43.9)	13 (12)

[a]EG: Expert Group.

[b]SG: Social Media Group.

[c]4 nonrespondents; total n=112.

Representativity

Both groups showed a similar gender distribution, with 56.6% (45/81, 1 nonrespondent) female respondents in EG compared to 50% (56/112) in SG (*P*=.51) and the same percentage of respondents from Germany (93.8% each; 76/81, with 1 nonrespondent, in EG and 105/112 in SG). In the EG, respondents originated from 3 more countries (Switzerland, Austria, and Italy), whereas in the SG, respondents came from 5 more countries (Switzerland, Austria, Serbia, United Kingdom, and Hungary).

Differences in the level of care across respondents' workplaces were statistically significant (*P*<.001, Table 3). Most respondents came from university hospitals (28/81, 1 nonrespondent, 34.6% in EG vs 33/112, 29.5% in SG) while more respondents came from standard care hospitals in the SG (27/112, 24.1%) than in the EG (6/81, 1 nonrespondent, 7.4%).

Table . Level of care across respondents' workplaces.

	EG[a] (n=81)[b], n (%)	SG[c] (n=112), n (%)
Ambulatory	6 (7.4)	10 (8.9)
Standard care hospital	6 (7.4)	27 (24.1)
Children's hospital	18 (22.2)	11 (9.8)
High care hospital	17 (21)	27 (24.1)
University hospital	28 (34.6)	33 (29.5)
Others	6 (7.4)	4 (3.6)

[a]EG: Expert Group.

[b]1 nonrespondent; total n=82.

[c]SG: Social Media Group.

The annual pediatric anesthesia caseloads varied between groups. In the EG group, most 71.3% (n=57) reported over 1000 cases annually, with smaller proportions handling 500-999 (n=11, 13.8%), 250-499 (n=10, 12.5%), or fewer than 250 cases (n=2, 2.5%). In the SG group, 34.6% (n=36) managed over 1000 cases, 22.1% (n=23) reported 500-999, 18.3% (n=19) had 250-499, and 25% (n=26) handled fewer than 250 cases. Some respondents in both groups did not answer (n=2 in EG and n=8 in SG).

Structural Conditions

In EG, 36 (43.9%) respondents reported having a written standard operating procedure for managing preoperative anxiety, compared with 43 (38.4%) respondents in SG (*P*=.46). A preoperative preparation for children and their caregivers was included as part of anesthesia information by 28 (34.1%) respondents in EG and by 35 (31.3%) respondents in SG (*P*=.76). Among those who reported using specific material, there was no difference in the choice of measures (*P*=.90). The most frequently used materials were "pediatric-specific informed consent", information flyers, and comics (Table 4).

XSL•FO
RenderX

Table . Materials used to help prepare children and their caregivers preoperatively.

	EG[a] (n=28), n (%)	SG[b] (n=35), n (%)
Pediatric-specific informed consent	19 (25.5)	23 (20.5)
Information flyer	16 (21.5)	15 (13.4)
Comics	8 (10.7)	10 (8.9)
A designed mascot	7 (9.4)	8 (7.1)
Videos	4 (5.4)	2 (1.8)
Other[c]	2 (2.7)	3 (2.7)
Hypnosis	1 (1.3)	0 (0)
Guidance through the operating room	2 (2.7)	1 (0.9)

[a]EG: Expert Group.

[b]SG: Social Media Group.

[c]Other used materials mentioned: instruction on how to use topical anesthesia patches, offering website information, the use of soap bubbles, and a virtual operating theater tour.

When asked whether the local structural conditions would generally allow the parents to be present until the children are anesthetized, 52 (63.4%) respondents in the EG and 50 (45%) respondents in the SG answered in the affirmative (*P*=.01). Among those, 38 (46.3%) respondents in the EG and 57 (50.9%) respondents in the SG reported not offering parents to be present during the induction of anesthesia. In EG, 26 (31.7%) respondents reported enabling parental presence while 29 in SG (25,9%). Another 18 (22%) respondents in the EG stated that parental presence depends on the individual workplace within their institution, while 26 (23.2%) respondents in the SG reported the same. The place where the children were separated from their parents or parental substitutes did not differ significantly between the groups.

Separation locations for children from parents did not significantly differ between groups (*P*=.84). Most commonly, separation occurred during transfer to the operating room (EG: 44 out of 80 respondents, 55%; SG: 67 out of 109 respondents, 61.5%). Separation in the induction room was less frequent (EG: 13 out of 80 respondents, 16.3%; SG: 13 out of 109 respondents, 11.9%) and in the holding area similarly rare (EG: 12 out of 80 respondents, 15%; SG: 13 out of 109 respondents, 11.9%). Separation in the operating room itself was reported even less often (EG: 9 out of 80 respondents, 11.3%; SG: 12 out of 109 respondents, 11%), while on the ward it was rarest of all (EG: 2 out of 80 respondents, 2.5%; SG: 4 out of 109 respondents, 3.7%). A small number of respondents did not provide an answer (EG: 2 respondents; SG: 3 respondents).

A total of 95.1% (78/82) of respondents in EG and 99.1% (111/112) in SG reported that children's anxiety is not routinely measured. Regarding anxiety scales, 31.7% (n=33) of EG respondents and 55.8% (n=67) of SG respondents stated that they were not familiar with any. The Yale Preoperative Anxiety Scale was the most recognized scale in the EG, with 25% (n=26) of respondents indicating familiarity with it. In contrast, only 8.3% (n=10) of respondents in the SG reported familiarity with the Yale Preoperative Anxiety Scale. The visual analog scale (VAS) was the most recognized scale in the SG, with 30% (n=36) of respondents indicating familiarity with it. In contrast, only 24% (n=25) of respondents in the EG reported familiarity with the VAS.

Practices of Pharmacological Interventions

The use of pharmacological premedication in daily practice was reported by 80.5% of respondents (66/82) in EG and 79.5% (89/112) in SG, with no statistically significant difference between the 2 groups (*P*>.99), indicating that both groups have a similarly high rate of routine use of premedication.

When it comes to actively avoiding premedication, there was a significant difference between the 2 groups (*P*=.04). In EG, 50% (41/82) tried to avoid premedication, whereas only 34.4% (39/112) in the SG did so.

Both groups showed similar responses (*P*=.24) regarding their decision-making process for administering pharmacologic premedication (refer to Table 5). Individual responses included consulting children or their parents about the need for premedication, with some also specifying the placement of an intravenous line before anesthesia induction.

XSL•FO
RenderX

Table . Criteria for deciding on premedication use. Multiple answers were possible.

	EG[a] (n=82), n (%)	SG[b] (n=112), n (%)
The children are generally premedicated with medication	28 (34.1)	55 (49.1)
According to the child's anxiety	52 (63.4)	52 (46.4)
According to the parents' anxiety	18 (22)	18 (16.1)
According to the child's wishes	38 (46.3	35 (31.3)
According to the parents' wishes	22 (26.8)	25 (22.3)
According to medical history	46 (56.1)	52 (46.4
According to experience/gut feeling	31 (37.8)	46 (41.1)
Individual answer	12 (14.6)	10 (8.9)

[a]EG: Expert Group.

[b]SG: Social Media Group.

In both groups, midazolam was reported as the most frequently used premedication drug (EG: 81/82, 98.8% and SG: 112/112, 100%). In EG, (es-)ketamine (41/82, 50%), clonidine (18/82, 22%), and dexmedetomidine (6/82, 7.3%) were used as well as in SG (42/112, 37.5%; 19/112, 17%; and 11/112, 9.8%, respectively) without significant difference (P=.23). Overall, midazolam was the drug of first choice in both groups (76/80, 2 nonrespondents, 95% in EG vs 105/111, 1 nonrespondent, 94.6% in SG).

The median minimum age for administering premedication was 6 months (6-8; 0-48) in EG and 9.5 months (6-12; 0-36) in SG (P<.001).

Practices of Nonpharmacological Interventions

Nonpharmacological interventions were routinely used by 60 (73.2%) respondents in EG and by 78 (69.6%) respondents in SG (P=.63). There was a significant difference (P<.001) in the selection of which nonpharmacological interventions were used (Table 6). While in the EG parental presence was the most reported intervention (43/60, 71.7%), it was the use of videos in the SG (62/78, 79.5%).

Table . Practices of nonpharmacological interventions. Multiple answers were possible.

	EG[a] (n=60), n (%)	SG[b] (n=78), n (%)
Parental presence	43 (71.7)	38 (48.7)
Videos (tablet, smartphone, etc)	42 (70)	62 (79.5)
Reading or showing books	21 (35)	29 (37.2)
Games	17 (28.3)	14 (17.9)
Other activities[c]	12 (20)	12 (15.4)
Audio books	8 (13.3)	5 (6.4)
Music distraction	7 (11.7)	14 (17.9)
Hypnosis	7 (11.7)	2 (2.6)
Behavioral exercises	7 (11.7)	0 (0)
Clowns	5 (8.3)	4 (5.1)
Virtual reality glasses	2 (3.3)	4 (5.1)

[a]EG: Expert Group.

[b]SG: Social Media Group.

[c]Other activities mentioned in both groups were the use of a floating bird, the integration of cuddly toys, the use of a glitter wand, interactive storytelling, a starry sky projection, and the use of soap bubbles.

Discussion

Principal Results

The respondents to the publicly announced survey on social media demonstrated significantly less pediatric anesthesia expertise than the respondents to the survey among experts. This was evidenced by fewer years of professional experience, fewer board-certified specialists, and a lower pediatric anesthesia caseload. However, when looking at the items related to the practice of pediatric anxiety management, significant differences were found in less than a third. Regardless of the survey group,

XSL•FO
RenderX

our results showed very heterogeneous approaches to the management of preoperative anxiety in pediatric patients.

Our study presents 2 principal findings. First, it remains debatable whether web-based surveys are an effective method for reaching the target group of pediatric anesthesia providers. On the one hand, the respondents to the web-based survey rated their level of expertise lower than those who were involved in a scientific meeting survey. However, specific parameters that best identify an expert in the field of pediatric anesthesia remain undefined. It seems clear that increased experience in this field correlates with a lower rate of complications in children [28]. A high volume of pediatric anesthesia cases likely contributes to a higher level of expertise. Being classified as a specialist (board-certified anesthesiologist) further indicates that a minimum standard of experience in pediatric anesthesia has been met [29]. However having many years of professional experience does not necessarily equate to extensive pediatric anesthesia practice, as hospital structure, hospital focus, and patient demographics may limit exposure to pediatric cases [30,31]. In addition, the higher share of institutions with a higher level of care and a higher number of children's hospitals among experts might indicate pediatric anesthesia expertise due to a higher pediatric caseload. But there may be also anesthesia providers with a high individual pediatric caseload in standard care hospitals. On the other hand, when responses from an EG exhibit significant heterogeneity [16], it is not unexpected that similar heterogeneity would persist when querying a larger (or another) sample. This leads to the conclusion that it is not that obvious as our results may indicate which of the 2 groups can more accurately reflect the actual reality of pediatric anesthesia care.

Further, the dissemination of a web-based survey through social media is debatable. The methodology of web-based surveys offers significant advantages, particularly due to their rapid deployment and extensive reach, which facilitate the swift collection and distribution of data. Similarly, social media, which has become increasingly popular in the medical field, enables the rapid dissemination of insightful opinions and information and underscores the value of web-based surveys [23,32]. Drawbacks of web-based surveys are the inadequate representation of the sample population due to insufficient coverage, the absence of a sampling frame to guide sample selection, nonselection bias, and a low participation rate, which is estimated at approximately 11% [33-35]. Of course, it is difficult to verify data quality with anonymous questions, and there is ongoing research into how to implement attention checks or other means of detecting poor-quality data in web-based surveys [36]. The presence of selection bias within the SG is also possible. This could skew the data, as operating within a "bubble" may predominantly reach individuals already familiar with the topic, potentially also limiting a full representation of reality. An interesting direction for future research could involve comparing groups with similar characteristics to examine whether the survey access method (social media vs conference or "classic") introduces a selection effect related to expertise. With a participation rate of more than 80%, the EG directly addressed at the conference meeting demonstrated a high willingness to participate. Overall, slightly more responses were collected in the SG, even though access was open for an extended period and potentially a higher amount of respondents, indicating a low response rate in this "digital" SG. This suggests that if a survey on a specific topic, such as anxiety in pediatric anesthesia, is announced via social media, it is likely that only a specific subset of individuals, those with a particular interest or relevance to the topic, will actively engage and participate.

The second point, apart from the discussion about whom to ask for pediatric anesthesia surveys, is what both groups have in common: There is a large heterogeneity in applied anxiety management practices. This includes the debated issue of parental presence during anesthesia induction. Although it does not reduce children's anxiety, children have the right to be accompanied by their parents or substitutes. Surprisingly, parental presence during induction remains uncommon [37,38]. Local conditions appear to inhibit parental presence, and even if it was possible in principle, it is often not implemented. Potential reasons for this could include the need for additional staff or carefully coordinated arrangements to manage the logistics of parental involvement, as well as considerations pertaining to hygiene.

The same heterogeneity exists in the question of when which child should receive premedication. This is shown by the many varying approaches regardless of the 2 survey groups. Medication is currently made in a highly inconsistent manner, largely based on individual clinical judgment. When it comes to the application of medication, midazolam holds a high relevance in both groups. However, it has been proven to significantly reduce preoperative anxiety, it also has evident disadvantages including a long recovery time, respiratory adverse effects, and amnestic effects [6,7]. That may explain why all respondents reported using alternative premedication agents such as (es-)ketamine, clonidine, and dexmedetomidine frequently [5]. In addition, the application of nonpharmacological interventions is heterogeneous [15]. But if applied, one of the most favored options is video distraction. This does not seem surprising since video distraction is easy to implement, widely available, and requires no training or infrastructure (unlike, for example, clowns).

With regard to anxiety scales, it is noteworthy that 30% of the experts were unfamiliar with any scales for measuring anxiety. Awareness of specialized scales, such as the modified Yale Preoperative Anxiety Score, was higher among the EG, likely due to its frequent use in studies and the fact that many experts are affiliated with university settings [39]. In contrast, participants in the SG reported slightly greater familiarity with the VAS, a tool widely recognized for its application in pain management [40]. Despite the availability of these tools, their limited use remains puzzling. Broader implementation could enhance the identification of preoperative anxiety and increase awareness of its importance in clinical practice.

Limitations

The study faced several limitations. First, it is prone to bias as there likely was a potential overrepresentation of more tech-savvy individuals in the SG, leading to a demographic discrepancy compared with the EG with a potential risk for self-selection bias. Second, the reach of the web-based survey

XSL•FO
RenderX

could not be sufficiently quantified, and attention checks were omitted, compromising information about the response rate and its quality. The survey was disseminated through a variety of social media platforms, but without considering social media use statistics, which may have biased the sample. Additionally, the anonymity of the survey precluded verification of respondent accuracy.

Conclusion

The respondents from a scientific working group on pediatric anesthesia had more professional experience in this medical subspecialty and also more specific knowledge than survey participants from social media. However, when it comes to the use of strategies that reflect daily practice, the groups differed little and only in general terms. A diverse range of pharmacological and nonpharmacological interventions are used in daily practice and their use seems to be based more on individual preferences. Consequently, there is a need for evidence-based recommendations regarding the appropriate use of these interventions, including indications for their use. Web-based surveys via social media can have the potential to gain insights into daily practice on specific topics like managing preoperative anxiety in pediatric patients. Further studies should investigate whether surveys disseminated through social media yield similar results in other specific subject areas.

Acknowledgments

We acknowledge financial support by Land Schleswig-Holstein within the funding programme Open Access Publikationsfonds. We would like to thank all participants of these surveys. AS would also like to thank his friend and podcast partner Dr Gordon Fink.

Authors' Contributions

AS contributed to the conceptualization, methodology, validation, formal analysis, investigation, resources, data curation, visualization, and writing the original draft. CE was responsible for reviewing and editing the draft and validation. MN contributed to conceptualization, methodology, validation, data curation, writing the original draft, and reviewing and editing the draft. CM was involved in conceptualization; methodology; validation; data curation; and writing, reviewing, and editing the draft.

Conflicts of Interest

AS is the host of a German-language podcast on pediatric anesthesia (“Kinderanästhesie-Talk”). The other authors do not have any conflicts of interest to declare.

Multimedia Appendix 1
Survey to “Preoperative Anxiety Management Practices in Pediatric Anesthesia: A Comparative Analysis of an Online Survey presented to Experts and Social Media Users.”
[DOCX File, 27 KB - pediatrics_v8i1e64561_app1.docx]

Multimedia Appendix 2
Image that was posted for invitation to participate to the online survey for the social media group.
[PNG File, 741 KB - pediatrics_v8i1e64561_app2.png]

References

1. Safetots. URL: https://www.safetots.org [accessed 2025-01-17]
2. Liu W, Xu R, Jia J, Shen Y, Li W, Bo L. Research progress on risk factors of preoperative anxiety in children: a scoping review. Int J Environ Res Public Health 2022 Aug;19(16):9828. [doi: 10.3390/ijerph19169828]
3. Dahmani S, Delivet H, Hilly J. Emergence delirium in children: an update. Curr Opin Anaesthesiol 2014 Jun;27(3):309-315. [doi: 10.1097/ACO.0000000000000076] [Medline: 24784918]
4. Kain ZN, Caldwell-Andrews AA, Maranets I, et al. Preoperative anxiety and emergence delirium and postoperative maladaptive behaviors. Anesth Analg 2004 Dec;99(6):1648-1654. [doi: 10.1213/01.ANE.0000136471.36680.97] [Medline: 15562048]
5. Bromfalk Å, Myrberg T, Walldén J, Engström Å, Hultin M. Preoperative anxiety in preschool children: a randomized clinical trial comparing midazolam, clonidine, and dexmedetomidine. Paediatr Anaesth 2021 Nov;31(11):1225-1233. [doi: 10.1111/pan.14279] [Medline: 34403548]
6. Lethin M, Paluska MR, Petersen TR, Falcon R, Soneru C. Midazolam for anesthetic premedication in children: considerations and alternatives. Cureus 2023 Dec;15(12):e50309. [doi: 10.7759/cureus.50309] [Medline: 38089942]
7. von Ungern-Sternberg BS, Erb TO, Habre W, Sly PD, Hantos Z. The impact of oral premedication with midazolam on respiratory function in children. Anesth Analg 2009;108(6):1771-1776. [doi: 10.1213/ane.0b013e3181a324c3]
8. Jaaniste T, Hayes B, von Baeyer CL. Providing children with information about forthcoming medical procedures: a review and synthesis. Clin Psychol Sci Pract 2007 May;14(2):124-143. [doi: 10.1111/j.1468-2850.2007.00072.x]

XSL•FO
RenderX

9. Kain ZN, Caldwell-Andrews AA, Krivutza DM, et al. Interactive music therapy as a treatment for preoperative anxiety in children: a randomized controlled trial. Anesth Analg 2004 May;98(5):1260-1266. [doi: 10.1213/01.ane.0000111205.82346.c1] [Medline: 15105197]
10. Fortier MA, Chorney JM, Rony RYZ, et al. Children's desire for perioperative information. Anesth Analg 2009 Oct;109(4):1085-1090. [doi: 10.1213/ane.0b013e3181b1dd48] [Medline: 19762736]
11. DeMaso DR, Snell C. Promoting coping in children facing pediatric surgery. Semin Pediatr Surg 2013 Aug;22(3):134-138. [doi: 10.1053/j.sempedsurg.2013.04.004] [Medline: 23870206]
12. Calipel S, Lucas-Polomeni MM, Wodey E, Ecoffey C. Premedication in children: hypnosis versus midazolam. Paediatr Anaesth 2005 Apr;15(4):275-281. [doi: 10.1111/j.1460-9592.2004.01514.x] [Medline: 15787917]
13. Sola C, Devigne J, Bringuier S, et al. Hypnosis as an alternative to general anaesthesia for paediatric superficial surgery: a randomised controlled trial. Br J Anaesth 2023 Mar;130(3):314-321. [doi: 10.1016/j.bja.2022.11.023] [Medline: 36690538]
14. O'Sullivan M, Wong GK. Preinduction techniques to relieve anxiety in children undergoing general anaesthesia. Cont Educ Anaesth Crit Care Pain 2013 Dec;13(6):196-199. [doi: 10.1093/bjaceaccp/mkt014]
15. Kain ZN, Caldwell-Andrews AA, Mayes LC, et al. Family-centered preparation for surgery improves perioperative outcomes in children: a randomized controlled trial. Anesthesiology 2007 Jan;106(1):65-74. [doi: 10.1097/00000542-200701000-00013] [Medline: 17197846]
16. Sablewski A, Miller C, Nemeth M. Practice of preoperative anxiety management in paediatric anaesthesia. a questionnaire survey presented at the Annual Meeting of the Scientific Working Group on Paediatric Anaesthesia 2023. Anästh Intensivmed 2024;65:176-182. [doi: 10.19224/ai2024.176]
17. Social media. Merriam Webster Dictionary. URL: https://www.merriam-webster.com/dictionary/social%20media [accessed 2025-01-17]
18. Pedersen MJ, Nielsen CV. Improving survey response rates in online panels: effects of low-cost incentives and cost-free text appeal interventions. Soc Sci Comput Rev 2016;34(2):229-243. [doi: 10.1177/0894439314563916]
19. Ärztestatistik zum 31. Dezember 2023. Physician statistics as of December 31, 2023 [Article in German]. German Medical Association. URL: https://www.bundesaerztekammer.de/fileadmin/user_upload/BAEK/Ueber_uns/Statistik/AErztestatistik_2023_18.04.2024.pdf [accessed 2025-01-17]
20. Ärztestatistik für das Jahr 2023. Physician statistics for the year 2023 [Article in German]. Austrian Medical Association. URL: https://www.aerztekammer.at/daten-fakten#portlet_com_liferay_journal_content_web_portlet_JournalContentPortlet_INSTANCE_pJnr8UoxPs03 [accessed 2025-01-17]
21. Berufstätige Ärzteschaft nach Hauptfachgebiet und Geschlecht; 2023. Employed physicians by primary specialty and gender; 2023 [Article in German]. Fe´de´ration des me´decins suisses. Association of Swiss Physicians. URL: https://www.fmh.ch/files/pdf30/5.-aerzteschaft-nach-hauptfachgebiet-und-geschlecht.pdf [accessed 2025-01-17]
22. Campbell L, Evans Y, Pumper M, Moreno MA. Social media use by physicians: a qualitative study of the new frontier of medicine. BMC Med Inform Decis Mak 2016 Jul 15;16:91. [doi: 10.1186/s12911-016-0327-y] [Medline: 27418201]
23. Tan JM, Simpao AF, Gálvez Delgado JA. The future of social media, anesthesiology, and the perioperative physician. Anesth Analg 2024 Feb 1;138(2):358-368. [doi: 10.1213/ANE.0000000000006711] [Medline: 38215714]
24. Kelley K, Clark B, Brown V, Sitzia J. Good practice in the conduct and reporting of survey research. Int J Qual Health Care 2003 Jun;15(3):261-266. [doi: 10.1093/intqhc/mzg031] [Medline: 12803354]
25. Eysenbach G. Improving the quality of web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res 2004 Sep 29;6(3):e34. [doi: 10.2196/jmir.6.3.e34] [Medline: 15471760]
26. Kinderanästhesie-Talk podcast mit Armin und Gordon. Pediatric anesthesia talk podcast with Armin and Gordon [Article in German]. Kinderanästhesie-Talk. URL: https://www.kinderanaesthesie-talk.de [accessed 2025-01-17]
27. Sonderfolge #005 - die X-TIGER umfrage. Special episode #005 - the X-TIGER survey [Article in German]. Kinderanästhesie-Talk. URL: https://kinderanaesthesie-talk.podigee.io/25-sonder005 [accessed 2025-01-17]
28. Zgleszewski SE, Graham DA, Hickey PR, et al. Anesthesiologist- and system-related risk factors for risk-adjusted pediatric anesthesia-related cardiac arrest. Anesth Analg 2016 Feb;122(2):482-489. [doi: 10.1213/ANE.0000000000001059] [Medline: 26554463]
29. de Graaff JC, Frykholm P, Engelhardt T, et al. Pediatric anesthesia in Europe: variations within uniformity. Paediatr Anaesth 2024 Sep;34(9):919-925. [doi: 10.1111/pan.14873] [Medline: 38415881]
30. Auroy Y, Ecoffey C, Messiah A, Rouvier B. Relationship between complications of pediatric anesthesia and volume of pediatric anesthetics. Anesth Analg 1997 Jan;84(1):234-235. [doi: 10.1097/00000539-199701000-00060] [Medline: 8989044]
31. Habre W, Disma N, Virag K, et al. Incidence of severe critical events in paediatric anaesthesia (APRICOT): a prospective multicentre observational study in 261 hospitals in Europe. Lancet Respir Med 2017 May;5(5):412-425. [doi: 10.1016/S2213-2600(17)30116-9] [Medline: 28363725]
32. Yeung AWK, Tosevska A, Klager E, et al. Medical and health-related misinformation on social media: bibliometric study of the scientific literature. J Med Internet Res 2022 Jan 25;24(1):e28152. [doi: 10.2196/28152] [Medline: 34951864]
33. Couper MP. Issues of representation in eHealth research (with a focus on web surveys). Am J Prev Med 2007 May;32(5 Suppl):S83-S89. [doi: 10.1016/j.amepre.2007.01.017] [Medline: 17466823]

XSL•FO
RenderX

34. Cook DA, Wittich CM, Daniels WL, West CP, Harris AM, Beebe TJ. Incentive and reminder strategies to improve response rate for internet-based physician surveys: a randomized experiment. J Med Internet Res 2016 Sep 16;18(9):e244. [doi: 10.2196/jmir.6318] [Medline: 27637296]
35. Sammut R, Griscti O, Norman IJ. Strategies to improve response rates to web surveys: a literature review. Int J Nurs Stud 2021 Nov;123:104058. [doi: 10.1016/j.ijnurstu.2021.104058] [Medline: 34454334]
36. Braitman AL, Strowger M, Shipley JL, Ortman J, MacIntyre RI, Bauer EA. Data quality and study compliance among college students across 2 recruitment sources: two study investigation. JMIR Form Res 2022 Dec 9;6(12):e39488. [doi: 10.2196/39488] [Medline: 36485020]
37. Shih MC, Elvis PR, Nguyen SA, Brennan E, Clemmens CS. Parental presence at induction of anesthesia to reduce anxiety: a systematic research and meta-analysis. J Perianesth Nurs 2023 Feb;38(1):12-20. [doi: 10.1016/j.jopan.2022.03.008] [Medline: 35896422]
38. Manyande A, Cyna AM, Yip P, Chooi C, Middleton P. Non-pharmacological interventions for assisting the induction of anaesthesia in children. Cochrane Database Syst Rev 2015 Jul 14;2015(7):CD006447. [doi: 10.1002/14651858.CD006447.pub3] [Medline: 26171895]
39. Zickerman C, Brorsson C, Hultin M, Johansson G, Winsö O, Haney M. Preoperative anxiety level is not associated with postoperative negative behavioral changes in premedicated children. Acta Anaesthesiol Scand 2023 Jul;67(6):706-713. [doi: 10.1111/aas.14240] [Medline: 36928794]
40. Berghmans JM, Poley MJ, van der Ende J, et al. A visual analog scale to assess anxiety in children during anesthesia induction (VAS-I): results supporting its validity in a sample of day care surgery patients. Paediatr Anaesth 2017 Sep;27(9):955-961. [doi: 10.1111/pan.13206] [Medline: 28707384]

Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Surveys
EG: Expert Group
SG: Social Media Group
VAS: visual analog scale

Edited by A Serlachius; submitted 23.07.24; peer-reviewed by K Zhang, Z Ehtesham; revised version received 20.11.24; accepted 08.12.24; published 27.01.25.

Please cite as:
Sablewski A, Eimer C, Nemeth M, Miller C
Preoperative Anxiety Management Practices in Pediatric Anesthesia: Comparative Analysis of an Online Survey Presented to Experts and Social Media Users
JMIR Pediatr Parent 2025;8:e64561
URL: https://pediatrics.jmir.org/2025/1/e64561
doi:10.2196/64561

© Armin Sablewski, Christine Eimer, Marcus Nemeth, Clemens Miller. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 27.1.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Social and Environmental Determinants of Childhood Stunting in Indonesia: National Cross-Sectional Study

Yuni Sufyanti Arief[1*], Dr; Fildzah Cindra Yunita[2*], MPH; Ferry Efendi[3,4,5*], PhD; Fadhaa Aditya Kautsar Murti[6*], SKM; Rifky Octavia Pradipta[1*], MSN; Lisa McKenna[4*], PhD

[1]Department of Fundamental Nursing, Faculty of Nursing, Universitas Airlangga, Jl Mulyorejo, Campus C Universitas Airlangga, Surabaya, Indonesia

[2]Research Group for Health and Wellbeing of Women and Children, Faculty of Public Health, Universitas Airlangga, Banyuwangi, Indonesia

[3]Department of Advanced Nursing, Faculty of Nursing, Universitas Airlangga, Surabaya, Indonesia

[4]School of Nursing and Midwifery, La Trobe University, Melbourne, Australia

[5]Research Center in Advancing Community Healthcare (REACH), Universitas Airlangga, Surabaya, Indonesia

[6]Department of Biostatistics and Population Studies, Faculty of Public Health, Universitas Indonesia, Depok, Indonesia

[*]all authors contributed equally

Corresponding Author:
Yuni Sufyanti Arief, Dr
Department of Fundamental Nursing, Faculty of Nursing, Universitas Airlangga, Jl Mulyorejo, Campus C Universitas Airlangga, Surabaya, Indonesia

Abstract

Background: The cause-effect of stunting is known as a complex factor, including family, environmental, social, and cultural factors, in stunting among children. Yet, the latest updated associated factors emphasizing on social and environmental factors are still limited.

Objective: This study aimed to analyze the latest evidence on the factors associated with stunting, with a particular focus on various factors.

Methods: A secondary data analysis using the 2023 Indonesia Health Survey (Survei Kesehatan Indonesia [SKI] 2023) was conducted. This study analyzed a total of 78,049 (or 81,068 if weighted) children aged 5 years and younger who had a complete response to all interest variables. Bivariate analysis using the Pearson χ^2 test with a *P* value of <.05 for determining a significant association and a multivariate analysis for further analysis of the association between the outcome and each predictor were implemented.

Results: The prevalence of stunting in this study was 15,958/78,049 children (19.69%). In the adjusted analysis, immunization status (adjusted odds ratio [aOR] 1.34, 95% CI 1.22 - 1.48; *P*<.001) and KPS (Kartu Perlindungan Sosial; Social Protection Card) ownership (aOR 1.13, 95% CI 1.05 - 1.21; *P*<.001) were significantly associated with higher odds of stunting. Conversely, children in the wealthiest quintile were significantly less likely to experience stunting compared to those from the poorest families (aOR 0.47, 95% CI 0.42 - 0.52; *P*<.001). Other variables, such as household water sources (aOR 1.18, 95% CI 1.00 - 1.37; *P*=.04), and geographical location, particularly in Sulawesi (aOR 1.23, 95% CI 1.14 - 1.33; *P*<.001) and Papua and Maluku (aOR 1.20, 95% CI 1.08 - 1.33; *P*<.001), were also significantly associated with increased odds of stunting.

Conclusion: Not receiving immunization, consuming water from unimproved sources, ownership of a Social Protection Card, and living in regions such as eastern Indonesia were significantly associated with childhood stunting. These findings emphasize that social and environmental factors remain critical determinants of stunting. Improving multifaceted and holistic interventions, with a focus on immunization coverage, good water access, social protection, and reducing regional disparities, is essential to accelerate progress toward stunting reduction targets.

(JMIR Pediatr Parent 2025;8:e68918) doi:10.2196/68918

KEYWORDS

associated factors; stunting; children under five years; social determinants of health; children

Introduction

Stunting, defined as poor linear growth with a height-for-age z-score less than –2 SDs of the median determined in the World Health Organization's (WHO) Child Growth Standards [1], is still a global public health issue, especially in low- and middle-income countries [2-4]. The condition has been known as a significant indicator of chronic malnutrition and leaves irreversible impediments throughout life [5,6]. Approximately,

XSL•FO
RenderX

148.1 million (22.3%) of children aged 5 years and younger were diagnosed as stunted worldwide in 2022 [4], with an estimated 98% children with stunting residing in low- and middle-income countries [7] and about 52% living in Asia [4]. The consequences of stunting can reflect on further child development, including in terms of health, physical and cognitive, leading to a higher risk of morbidity and mortality [8-10].

According to the Indonesia Health Survey (Survei Kesehatan Indonesia, SKI) in 2023, the prevalence of stunting in Indonesia remains substantial at 21.5%, indicating that about 1 in 5 children ages 5 years and younger is affected, with the highest incidence observed among children aged 24 to 35 months [11]. Digging deeper to the geographical location, huge geographical disparities of children with stunting exist in which eastern regions of Indonesia, namely Papua, Nusa Tenggara, and Sulawesi, indicated a significantly higher prevalence [12]. This percentage of children showed a steady decrease in the past decade [13], yet the number is still far from Indonesia's national target in reducing child stunting to 14% by 2024 [14]. Furthermore, the Joint Malnutrition Estimates (JME) released in 2023 recorded that only one-third of all countries worldwide are on track to cut across half the percentage of children affected by stunting [4]. Reflecting on this evidence, a comprehensive evaluation of existing stunting reduction programs and a more in-depth analysis of the associated factors is needed.

The etiology of stunting is multifactorial. The WHO developed the conceptual framework on childhood stunting [15], explaining the cause-effect of complex factors, including family, environmental, social, and cultural factors, in stunting among children aged 5 years and younger. Previous studies have also justified that maternal factors, such as mother's height, mother's BMI, antenatal care history, mother's education, are considered as another direct factor of stunting among children after the child's factors [2,5,16-18]. While the children-related factors that have been discovered include the child's age, sex, low birth weight, feeding practice, exclusive breastfeeding, lack of food intake, and infection or disease history [5,16,19,20]. Beyond biological and behavioral factors, a growing body of research highlights the importance of socioeconomic [2,18] and environmental conditions, including household wealth, access to clean water, sanitation, hygiene practices, and geographic disparities, as indirect but critical determinants of stunting [17,21-23].

Despite these known pathways, there remains limited large-scale national evidence from Indonesia that focuses specifically on how social and environmental (or exposome) factors influence stunting outcomes. Given Indonesia's vast geographic diversity and persistent regional inequalities, it is essential to examine how broader contextual factors interact with stunting risks. This study aims to fill this gap by analyzing nationally representative data to identify key social and environmental determinants of stunting among Indonesian children ages 5 years and younger. The findings will provide actionable insights for designing more context-specific, equity-oriented interventions and contribute to accelerating national progress toward the 2024 target and Sustainable Development Goals (SDGs).

Methods

Study Design and Data Collection

A secondary data analysis was conducted by extracting data from the 2023 Indonesia Health Survey (Survey Kesehatan Indonesia) for which the survey is the integration of 3 researches: the Basic Health Research (Riset Kesehatan Dasar, RISKESDAS), the Indonesia Nutritional Status Monitoring Survey (Survei Status Gizi Indonesia, SSGI), and Biomedical and dental-and-oral examinations. The survey had included a nationally representative sample of households, households with children aged 5 years and younger, and individuals' characteristics with a total sample of 877,531 household respondents and 314,161 households with children aged 5 years and younger, from 38 provinces and 514 administrative cities or districts across Indonesia.

Sampling Technique and Study Population

In the SKI 2023, stratified sampling technique was used at the block level census and household level of chosen block level census, to get a representative sample for all provinces. A total of 34,065 blocks census was stratified using explicit stratification; meanwhile, implicit stratification was applied for the household level. The response rate of SKI 2023 was 98.74% with 1,191,692 respondents, consisting of interviewing 877,531 respondents of member of households and anthropometry examination of 84,267 respondents of children aged 5 years and younger (see Multimedia Appendix 1). Before collecting data, informed consent was obtained from every respondent. This study analyzed a total of 78,049 children (or 81,068 if weighted) aged 5 years and younger who had a complete response to all interest variables (sex, immunization status, last months' history of diarrhea, place of residence, social protection card ownership, household water sources, water quality, and geographical location). Weight and sampling design were used for adjustments in this analysis.

Data Collection and Procedure

The SKI 2023 took place from August 2023 to early October 2023. There were 3 questionnaires used in this survey, namely: household questionnaire, children aged 5 years and younger questionnaire, and individual questionnaire, all of which reflect the population and health-related issues relevant to Indonesia. This study used the children's data for analysis. Data were requested legally to the Ministry of Health website [24]

Measurement of Stunting and Covariates

The stunting among children aged 5 years and younger was the dependent variable of interest, while several independent variables like socioeconomics and environments were included in the analysis depending on the availability in SKI 2023. Stunting was defined using HAZ (height-for-age z-score), considering the sex, height, weight, and age of individuals. Individuals with a z-score< –2 were categorized as stunted. Our definition matched with the standard defined by the WHO [25].

Water quality was categorized as poor and good, meanwhile household water source was categorized as improved, unimproved, and surface water. Water quality was defined by

XSL•FO
RenderX

the physical parameters of the water. If a household responded "No" to all these physical quality issues (turbidity, color, taste, foam, and odor), their drinking water was categorized as good quality [26]. Improved water sources consisted of packaged water, refilled water, piped water, boreholes or wells with pumps, protected dug wells, protected springs, rainwater collection, water hydrants, water bought from vendors, and water terminals. Unimproved water sources included unprotected dug wells and unprotected springs. Surface water, such as water from rivers, lakes, or irrigation canals, was classified separately. This classification was derived from the Demographic and Health Surveys (DHS) categorization [27].

Last months' history of diarrhea was categorized as yes, no, and don't know. This 3-category classification was used because recall of diarrheal episodes over the previous month can be subjective and uncertain. Respondents may not clearly remember or recognize whether symptoms met the criteria for diarrhea, so the "don't know" option captures this uncertainty. For immunization status, the categorization was divided as yes and no or unsure. Immunization records tend to be more definitive, as caregivers often have vaccination books (KIA [Kesehatan Ibu dan Anak], the Mother Child Health Book, or the pink book) to clearly recall vaccination history. Thus, grouping answers to "no" and "unsure" simplifies analysis by treating any lack of confirmed vaccination as absence of immunization. Female and male were a categorization used for sex. Place of residence was categorized as rural and urban. Social Protection Card (Kartu Perlindungan Sosial, KPS) ownership was categorized as yes and no. Geographical location of children was categorized as Java, Sumatera, Bali and Nusa Tenggara, Kalimantan, Sulawesi, and Papua and Maluku. In this study, the wealthy index was grouped into 5 quintiles as poorest, poor, middle class, wealthier, and wealthiest. Prevalence of stunting was calculated for each category of the covariates to assess distribution patterns.

Statistical Analysis

Initial analysis started with frequency distribution analysis of the sociodemographic characteristics and relevant external factors associated with stunting among children. To assess the frequency distribution, bivariate analysis using Pearson χ^2 test was implemented with a P value of <.05 for determining a significant association. The association between outcomes and predictor variables was analyzed using binary logistic regression as presented in a crude or unadjusted analysis and to examine the association between predictors and stunting. Odds ratios (OR) with 95% CI were reported.

The selection of reference categories was selected based on findings from previous research, which indicate that the risk of stunting tends to increase among children with incomplete immunization, recent episodes of diarrhea, lower wealth quintile status, and those residing in rural areas [28-31]. In line with these findings, the reference groups were chosen to allow meaningful comparison. Finally, a multivariate analysis has been done to assess further association between the outcome and each predictor. All statistical analysis was implemented using SPSS (version 26.0 for Windows; IBM Corp).

Ethical Considerations

This study used secondary, deidentified data from the 2023 Indonesian Health Survey (SKI 2023), which was conducted by the Indonesian Ministry of Health with previous approval from the National Ethics Committee. As this study used publicly available, anonymized data, it was classified as exempt from additional ethics review. The National Ethics Commission classified this study as "exempted" and the Indonesian Ministry of Health collected the data with informed consent, ensuring participants signed a consent form, emphasizing that participation was voluntary and confidential. The Indonesian Ministry of Health has made the data available to the academic community through its website [24].

Results

Prevalence of Stunting Among Covariates

The prevalence of stunting in this study was 15,958/78,049 (19.69%). Among the water and sanitation factors, the prevalence of stunting was dominant in households with poor water quality 665 (21.9%). In addition, households with surface water sources had higher prevalence of stunting 96 (29%) compared to unimproved 636 (25.2%) and improved water sources 15,226 (19.5%).

Among individual factors, we found that the prevalence of stunting was high among children who had diarrhea last month 968 (24.7%) and also male children 8601 (20.8%). Children with no status of vaccination were also seen with higher prevalence of stunting 1593 (25%). In terms of community factors, we found that children who lived in rural areas had a higher prevalence of stunting 7266 (21.7%). In addition, households who had KPS had a higher prevalence of stunting 3439 (23.4%) and also households in the poorest, poorer, and middle class had higher prevalence of stunting 2800 (27.6%), 3395 (23.5%), and 3488 (20.5%), respectively. The prevalence of stunting was also higher in Papua and Maluku 601 (26.2%), Sulawesi 1538 (24.7%), and Kalimantan 1039 (20.5%; see Table 1).

XSL•FO
RenderX

Table . Prevalence of stunting among covariates.

Variables	Prevalence of stunting, n/N (%)
Water quality	
Poor	665/3042 (21.9)
Good	15,293/78,026 (19.6)
Household water sources	
Improved	15,226/78,219 (19.5)
Unimproved	636/2525 (25.2)
Surface water	96/325 (29.6)
Last months' history of diarrhea	
No	14,955/77,038 (19.4)
Yes	968/3920 (24.7)
Don't know	35/110 (31.6)
Sex	
Female	7358/39,752 (18.5)
Male	8600/41,317 (20.8)
Immunization status	
Yes	14,365/74,703 (19.2)
No or unsure	1593/6365 (25)
Place of residence	
Rural	7266/33,548 (21.7)
Urban	8693/47,520 (18.3)
KPS[a] ownership	
No	12,519/66,375 (18.9)
Yes	3439/14,693 (23.4)
Geographical Location	
Java island	8171/43,070 (19)
Sumatera	3556/19,481 (18.3)
Bali and Nusa Tenggara	1053/4914 (21.4)
Kalimantan	1039/5072 (20.5)
Sulawesi	1538/6233 (24.7)
Papua and Maluku	601/2297 (26.2)
Wealth quintile	
Poorest	2800/10,147 (27.6)
Poorer	3395/14,459 (23.5)
Middle class	3488/16,994 (20.5)
Wealthier	3432/19,296 (17.8)
Wealthiest	2843/20,172 (14.1)

[a]KPS : Kartu Perlindungan Sosial (Social Protection Card).

Factors Associated With Stunting

In the bivariate analysis with the unadjusted model (see Table 2), we found that water quality, household water sources, immunization status, KPS ownership, and also wealth quintile were associated with stunting (*P* values<.05). Both geographical and history of diarrhea were partially associated with stunting, as only some categories were significant with stunting (*P* values<.05). However, some independent associations in bivariate analysis were not strong enough to be significant after adjusting with other variables.

XSL•FO
RenderX

Table . Factors associated with stunting among children aged 5 years and younger.

Variables	Unadjusted		Adjusted	
	P value	OR[a] (95% CI)	*P* value	aOR[b] (95% CI)
Water quality				
Not good	Ref[c]	Ref	Ref	Ref
Good	.046	0.87 (0.76-0.99)	.82	0.98 (0.85-1.12)
Household water sources				
Improved	Ref	Ref	Ref	Ref
Unimproved	<.001	1.39 (1.19-1.62)	.04	1.18 (1.00-1.37)
Surface water	<.001	1.74 (1.28-2.36)	.11	1.29 (0.94-1.76)
Last months' history of diarrhea				
Don't know	Ref	Ref	Ref	Ref
Yes	.08	0.52 (0.25-1.08)	.41	0.72 (0.33-1.56)
No	.40	0.71 (0.33-1.49)	.11	0.54 (0.25-1.15)
Sex				
Female	Ref	Ref	Ref	Ref
Male	<.001	1.15 (1.09-1.22)	<.001	1.16 (1.09-1.22)
Immunization status				
Yes	Ref	Ref	Ref	Ref
No or unsure	<.001	1.40 (1.28-1.52)	<.001	1.34 (1.22-1.48)
Place of residence				
Rural	Ref	Ref	Ref	Ref
Urban	<.001	0.80 (0.76-0.85)	.40	0.97 (0.91-1.03)
KPS[d] ownership				
No	Ref	Ref	Ref	Ref
Yes	<.001	1.31 (1.22-1.40)	<.001	1.13 (1.05-1.21)
Geographical location				
Java island	Ref	Ref	Ref	Ref
Sumatera	.17	0.95 (0.89-1.02)	<.001	0.84 (0.79-0.91)
Bali and Nusa Tenggara	.001	1.16 (1.06-1.27)	.94	0.99 (0.91-1.09)
Kalimantan	.03	1.09 (1.00-1.20)	.20	1.06 (0.96-1.16)
Sulawesi	<.001	1.39 (1.29-1.50)	<.001	1.23 (1.14-1.33)
Papua and Maluku	<.001	1.51 (1.37-1.66)	<.001	1.20 (1.08-1.33)
Wealth quintile				
Poorest	Ref	Ref	Ref	Ref
Poorer	<.001	0.80 (0.73-0.88)	<.001	0.83 (0.76-0.91)
Middle class	<.001	0.67 (0.62-0.73)	<.001	0.71 (0.65-0.78)
Wealthier	<.001	0.56 (0.51-0.62)	<.001	0.61 (0.55-0.67)
Wealthiest	<.001	0.43 (0.39-0.47)	<.001	0.47 (0.42-0.52)

[a]OR: odds ratio.

[b]aOR: adjusted odds ratio.

[c]Ref: Reference.

[d]KPS: Kartu Perlindungan Sosial (Social Protection Card).

XSL•FO
RenderX

In the adjusted models (see Table 2), the variables that remained significant were immunization status, KPS ownership, and wealth quintile. We found that children with no immunization status had higher odds of developing stunting (aOR 1.34, 95% CI 1.22-1.48). In addition, children whose households owned KPS also had higher odds of developing stunting (aOR 1.13, 95% CI 1.05-1.21). We also noticed a gradient of decreasing risk along with the increasing status of wealth quintile. Children in the wealthiest (aOR 0.47, 95% CI 0.42-0.52), wealthier (aOR 0.61, 95% CI 0.55-0.67), middle (aOR 0.71, 95% CI 0.65-0.78), and poorer (aOR 0.83, 95% CI 0.76-0.91) classes had lower odds of developing stunting compared to children in the poorest class.

Partial associations in the adjusted model were found in the variables such as household water sources and geographical location (see Table 2). Children whose household water was unimproved had higher odds of developing stunting (aOR 1.18, 95% CI 1.00-1.37), but such association was not found in the surface water categories. Finally, children who lived in Sulawesi (aOR 1.23, 95% CI 1.14-1.33), and Papua and Maluku (aOR 1.20, 95% CI 1.08-1.33) had higher odds of developing stunting compared to children who lived in Java, but the odds of stunting were lower for children in Sumatera (aOR 0.84, 95% CI 0.79-0.91). Such an association was not found in Bali, Nusa Tenggara, and Kalimantan.

Discussion

Principal Findings

In this study, the prevalence of stunting among children aged 5 years and younger was 19.69% (15,958/78,049). Although this figure appears lower than the national estimate reported by SKI 2023, which recorded a prevalence of 21.5% [11], it is important to note that our analysis used a different subset of the same dataset. Specifically, the discrepancy may be due to the application of distinct inclusion criteria in our study that focused on children with complete data for selected socioeconomic and environmental variables. In which, we may have excluded some high-risk groups or regions. Therefore, this finding should not be interpreted as a trend or decline in stunting prevalence over time, but rather as a context-specific estimate based on an analytical sample tailored to explore social and environmental determinants.

A downward trend in stunting prevalence has highlighted an updated figure in this study. Comparing to the overall report of SKI 2023, the existence of variation in the prevalence of stunting, even though using the same dataset, might be attributable to differences in the inclusion criteria for the variable use. As this study includes the set of data on influential factors, more of which are social and environmental factors. This finding is lower than the findings from India (31.7%) [32], Afghanistan (44.7%) [33], Bangladesh (26.7%) [34], Pakistan (40%) [35], and Timor Leste (45.1%) [4]. The difference in findings might rely on the efforts in public health intervention, such as nutritional programs, economic and social development conditions, accessible community-based health services, environmental focus, and the disparities of investment in nutritional-sensitive strategies. Previous studies [36,37] revealed that inadequate investment in nutrition could hinder the progress of reducing stunting to reach the global goals of 40% by 2030. Hence, the positive result of Indonesia's integrated efforts should be in scaling up existing programs and investing more in nutrition-sensitive programs.

This study revealed that children who did not receive immunization are 1.34 times higher odds of being stunted compared to children who received immunization. Some studies are in line with findings across the literature [19,38-42]. This association could be due to interrelated factors, particularly infection rates and nutritional status. Inadequate immunization is linked to the high risk of infectious diseases, which can negatively affect a child's growth and development [43,44]. In addition to direct impact on nutritional status, a study has proven the significant improvement of anthropometric outcomes among children who have received immunization [45]. At this point, addressing stunting requires a comprehensive programmatic approach, integrating immunization programs with maternal and child health, rather than relying solely on nutritional intervention programs.

Our study found that children from households receiving KPS were significantly more likely to be stunted compared to those not receiving the benefit. This is in line with a previous study that mentioned that the Conditional Cash Transfer program does not result in reducing stunting in poor children aged 5 years and younger [46]. On the other side, children of household-owned KPS are significantly associated with stunting, which is an unexpected result, as KPS are originally designed to alleviate poverty and improve access to basic needs, including food, health care, and education. Several potential mechanisms may explain this association. First, the presence of KPS itself is an indicator of household vulnerability. The families receiving it are among the poorest, and the underlying socioeconomic disadvantages may outweigh the benefits received from KPS. Second, while the KPS provides rice subsidies, school allowances, and limited health support, it may not directly address dietary diversity, child feeding practices, or access to quality health care, which are critical determinants of nutritional status. Third, there may be issues related to implementation or adequacy. A study in Palembang, Indonesia, mentions that families with more than 4 members or more, the children have the risk of stunting even if they already get subsidized [47]. The value of support provided may be insufficient to meet a household's nutritional needs. Finally, some households may not use the benefits effectively due to lack of nutrition literacy or limited access to supporting services.

The study found that as the wealth quintile increases, the risk of stunting among children aged 5 years and younger decreases, with children from the wealthiest families being less likely to be stunted than those from the poorest families. Previous studies have proven the same result, that is, children from the poorest families are prone to develop stunting [2,3,16,18]. The relationship might be attributable to economic inequality between quintile groups, where children from wealthiest families often have food security, accessibility to consume a high quality of foods, health care services, improved sanitation, and water resources [48,49]. On the other hand, all these facilities are being a limit for children from the poorest families [18].

XSL•FO
RenderX

Nutrition intervention [50-52], such as providing supplementary foods for children with stunting, has been implemented by the Indonesian Government and showed a significant result in intervening undernutrition issues [51]. Expanding these interventions across Indonesia, with an emphasis on equal access in all regions, is essential for addressing stunting on a larger scale.

In this study, children exposed to unimproved water sources had 1.18 times higher odds of being stunted compared to children who were exposed to improved water sources. A study in Ethiopia, India, Peru, and Vietnam is correspondent with this finding, which showed the consumption of improved water source decreasing the risk of stunting among children [19,53]. Consuming from an unimproved water source increases the infection rate and the incidence of diarrhea among children that indirectly affects nutritional status of children [54]. Unimproved water sources might contain pathogenic microorganisms and other chemical substances that cause diarrhea or other infectious diseases [22]. Some studies justified that intervention on hygiene and sanitation is significantly improving children's growth [55-57], indicating sanitation and hygiene improved water sources intervention must be included in the national program for achieving the stunting reduction target.

In terms of geographical location, the odds of being stunted among children who reside in Sulawesi and Papua and Maluku are 1.23 times and 1.20 times, respectively, compared to those who reside in Java. Meanwhile, children living in Sumatera are less likely to be stunted compared to children living in Java. Common findings also have been proven by studies that tried to map the stunting prevalence in and across Indonesia [12,18]. The rationale is exacerbated by inequality conditions across Eastern Indonesia, of which many regions have limited access to decent health facilities and resources [58,59], particularly the proportion of health care personnel and services as they are centralized in Java and Sumatera. These findings suggest the government should enhance the infrastructure developments, especially in health, and distribute more health personnel outside Java and Sumatera Island.

The findings from this study offer several implications for policy and program planning. First, the identification of social and environmental determinants, such as low household wealth, regional disparities, poor access to clean water, and incomplete immunization. This highlights the need for multisectoral approaches that extend beyond direct nutrition interventions. Nutrition programs should be designed with a broader lens, integrating improvements in public health infrastructure, social protection targeting, sanitation, and health education. For example, linking immunization programs with nutritional screening and counseling may enhance early identification of at-risk children. Second, the geographic disparities observed support the prioritization of region-specific interventions, particularly in Papua, Maluku, and Sulawesi, where stunting remains persistently high. Tailoring intervention packages based on local infrastructure, culture, and needs can increase effectiveness. Finally, the unexpected finding regarding KPS beneficiaries emphasizes the importance of monitoring and evaluating the impact of social programs on nutrition outcomes and modifying them to include behavior change communication, food diversification support, or conditional nutrition services. In this way, evidence from large-scale secondary datasets can directly inform data-driven, equity-focused strategies to reduce stunting nationally.

Strengths and Limitations of the Study

A large dataset as representative of the national population of Indonesia has been used in this study. However, the researcher has limited control over the selection variables, data quality, and indicators for measurements due to the use of secondary dataset. Social desirability bias might exist since the survey used self-reports for gathering the information. Some potentially important determinants of stunting, such as detailed dietary intake, feeding practices, or maternal nutritional status, were not available, and therefore could not be included. Second, the use of self-reported data introduces the possibility of social desirability and recall bias, which may affect the accuracy of responses, particularly in sensitive areas such as household wealth or immunization history. Another limitation is the cross-sectional design of this study, which allows for the identification of correlations between exposures and outcomes but does not permit determination of the temporal sequence of events. As a result, causal inferences about the relationship between the identified risk factors and stunting cannot be made.

Conclusion

This study reinforces the idea that childhood stunting remains a significant public health concern requiring multifaceted interventions. Key social and environmental factors, including incomplete immunization, KPS ownership, low household wealth, use of unimproved water sources, and residence in Sulawesi, Papua, and Maluku were all significantly associated with the increased odds of stunting. These findings offer updated national evidence on the contextual determinants of stunting in Indonesia.

To accelerate progress in stunting reduction, increasing immunization coverage should be prioritized, supported by community-based health education targeting mothers and caregivers. The association between KPS recipients and higher stunting risk suggests that existing welfare programs may need to be strengthened or better integrated with nutrition-sensitive interventions. Furthermore, sanitation factors, particularly access to improved water sources, should receive greater policy attention. Finally, improving access to quality health care across all regions, especially underserved areas, is essential for effective and equitable stunting prevention efforts nationwide.

Data Availability

The datasets analyzed during this study are available from the Indonesia Ministry of Health through the 2023 Indonesia Health Survey (Survei Kesehatan Indonesia [SKI] 2023) data request portal [24].

XSL•FO
RenderX

Conflicts of Interest

None declared.

Multimedia Appendix 1
Sampling technique.
[DOCX File, 270 KB - pediatrics_v8i1e68918_app1.docx]

References

1. WHO/NMH/NHD. Global nutrition targets 2025: stunting policy brief. : World Health Organization; 2014 URL: https://iris.who.int/server/api/core/bitstreams/11706543-4ab1-4123-8b83-d9300d92f6da/content [accessed 2024-06-19]
2. Tamir TT, Gezhegn SA, Dagnew DT, Mekonenne AT, Aweke GT, Lakew AM. Prevalence of childhood stunting and determinants in low and lower-middle income African countries: evidence from standard demographic and health survey. PLOS ONE 2024;19(4):e0302212. [doi: 10.1371/journal.pone.0302212] [Medline: 38662745]
3. Karlsson O, Kim R, Moloney GM, Hasman A, Subramanian SV. Patterns in child stunting by age: a cross-sectional study of 94 low- and middle-income countries. Matern Child Nutr 2023 Oct;19(4):e13537. [doi: 10.1111/mcn.13537] [Medline: 37276243]
4. UNICEF, WHO, World Bank Group. Levels and trends in child malnutrition: key finding of the 2023 edition. : World Health Organization URL: https://iris.who.int/server/api/core/bitstreams/ccd825e2-e6d0-4101-bedd-8189355dcd81/content [accessed 2024-06-19]
5. Siswati T, Sudargo T, Kusnanto H. Understanding determinants of stunted children in poor rural area of Indonesia. Ind Jour of Publ Health Rese & Develop 2018;9(3):188. [doi: 10.5958/0976-5506.2018.00207.3]
6. De Sanctis V, Soliman A, Alaaraj N, Ahmed S, Alyafei F, Hamed N. Early and long-term consequences of nutritional stunting: from childhood to adulthood. Acta Biomed 2021 Feb 16;92(1):e2021168. [doi: 10.23750/abm.v92i1.11346] [Medline: 33682846]
7. World health statistics 2021: monitoring health for the sdgs, sustainable development goals. : WHO; 2021 URL: https://iris.who.int/server/api/core/bitstreams/4339a2a8-d8bc-4f73-8570-204b08c9264f/content [accessed 2024-06-19]
8. Galasso E, Wagstaff A. The aggregate income losses from childhood stunting and the returns to a nutrition intervention aimed at reducing stunting. Economics & Human Biology 2019 Aug;34:225-238. [doi: 10.1016/j.ehb.2019.01.010]
9. Walker SP, Chang SM, Wright A, Osmond C, Grantham-McGregor SM. Early childhood stunting is associated with lower developmental levels in the subsequent generation of children. J Nutr 2015 Apr;145(4):823-828. [doi: 10.3945/jn.114.200261] [Medline: 25833785]
10. De Lucia Rolfe E, de França GVA, Vianna CA, et al. Associations of stunting in early childhood with cardiometabolic risk factors in adulthood. PLoS ONE 2018;13(4):e0192196. [doi: 10.1371/journal.pone.0192196] [Medline: 29641597]
11. Survei Kesehatan Indonesia (SKI). Indonesian Health Survey 2023. : Jakarta Badan kebijakan pembangunan kesehatan. Health Development Policy Agency; 2024 URL: https://www.badankebijakan.kemkes.go.id/ski-2023-dalam-angka/ [accessed 2024-06-17]
12. Ayuningtyas D, Hapsari D, Rachmalina R, Amir V, Rachmawati R, Kusuma D. Geographic and socioeconomic disparity in child undernutrition across 514 districts in Indonesia. Nutrients 2022 Feb 17;14(4):843. [doi: 10.3390/nu14040843] [Medline: 35215492]
13. Has EMM, Krisnana I, Efendi F. Enhancing maternal caregiving capabilities model to prevent childhood stunting: a UNICEF-inspired model. SAGE Open Nurs 2024;10:23779608231226061. [doi: 10.1177/23779608231226061] [Medline: 39911595]
14. Formative evaluation of the national strategy to accelerate stunting prevention. : UNICEF Indonesia; 2024 URL: https://www.unicef.org/indonesia/nutrition/reports/formative-evaluation-national-strategy-accelerate-stunting-prevention [accessed 2024-06-17]
15. Stunting prevalence among children under 5 years of age (survey-based estimates). : World Health Organization URL: https://www.who.int/data/gho/data/indicators/indicator-details/GHO/gho-jme-country-children-aged-5-years-stunted-(-height-for-age--2-sd) [accessed 2024-06-17]
16. Has EMM, Efendi F, Wahyuni SD, et al. Stunting determinants among Indonesian children aged 0-59 month: Evidence from Indonesian family life survey (IFLS) 2014/2015. JGPT 2020;12:815-825 [FREE Full text]
17. Idrus NI, Arsin AA. Determinants of stunting in children aged 6-24 months at Pambusuang Health Centre Working Area, Polewali Mandar Regency, Indonesia. Natl J Community Med 2023;14(12):842-848. [doi: 10.55489/njcm.141220233435]
18. Titaley CR, Ariawan I, Hapsari D, Muasyaroh A, Dibley MJ. Determinants of the stunting of children under two years old in Indonesia: a multilevel analysis of the 2013 Indonesia Basic Health Survey. Nutrients 2019 May 18;11(5):1106. [doi: 10.3390/nu11051106] [Medline: 31109058]
19. Vaivada T, Akseer N, Akseer S, Somaskandan A, Stefopulos M, Bhutta ZA. Stunting in childhood: an overview of global burden, trends, determinants, and drivers of decline. Am J Clin Nutr 2020 Sep 14;112(Suppl 2):777S-791S. [doi: 10.1093/ajcn/nqaa159] [Medline: 32860401]

XSL•FO
RenderX

20. Beal T, Tumilowicz A, Sutrisna A, Izwardy D, Neufeld LM. A review of child stunting determinants in Indonesia. Matern Child Nutr 2018 Oct;14(4):e12617. [doi: 10.1111/mcn.12617] [Medline: 29770565]
21. Jain L, Pradhan S, Aggarwal A, et al. Association of child growth failure indicators with household sanitation practices in India (1998-2021): spatiotemporal observational study. JMIR Public Health Surveill 2024 May 24;10:e41567. [doi: 10.2196/41567] [Medline: 38787607]
22. Banhae Y, Making MA, Abanit YM, et al. Social and physical environment with stunting incidents in toddlers. IJGHR 2023;5:619-628 [FREE Full text] [doi: 10.37287/ijghr.v5i4.2361]
23. Habimana JDD, Uwase A, Korukire N, et al. Prevalence and correlates of stunting among children aged 6-23 months from poor households in Rwanda. Int J Environ Res Public Health 2023 Feb 24;20(5):4068. [doi: 10.3390/ijerph20054068] [Medline: 36901076]
24. Layanan permintaan data. kementerian kesehatan [Article in Indonesian]. Kemenkes. URL: https://layanandata.kemkes.go.id/ [accessed 2025-09-24]
25. Physical status: the use of and interpretation of anthropometry, report of a WHO expert committee. : WHO URL: https://iris.who.int/server/api/core/bitstreams/108e365f-0394-44ef-8d17-3e6b80429814/content [accessed 2024-06-19]
26. Guidelines for Drinking-Water Quality: Fourth Edition Incorporating First Addendum 4th Ed, 1st Add: World Health Organization; 2017. URL: https://iris.who.int/handle/10665/254637 [accessed 2025-06-17]
27. Household drinking water. Guide to DHS Statistics DHS-8. URL: https://dhsprogram.com/data/Guide-to-DHS-Statistics/index.htm#t=Household_Drinking_Water.htm [accessed 2025-06-17]
28. Sheikh N, Sultana M, Ali N, et al. Coverage, timelines, and determinants of incomplete immunization in Bangladesh. TropicalMed 2018;3(3):72. [doi: 10.3390/tropicalmed3030072]
29. Ahmed SM, Brintz BJ, Pavlinac PB, et al. Derivation and external validation of clinical prediction rules identifying children at risk of linear growth faltering. Elife 2023 Jan 6;12:e78491. [doi: 10.7554/eLife.78491] [Medline: 36607225]
30. Devasenapathy N, Ghosh Jerath S, Sharma S, Allen E, Shankar AH, Zodpey S. Determinants of childhood immunisation coverage in urban poor settlements of Delhi, India: a cross-sectional study. BMJ Open 2016 Aug 26;6(8):e013015. [doi: 10.1136/bmjopen-2016-013015] [Medline: 27566644]
31. Regassa R, Belachew T, Duguma M, Tamiru D. Factors associated with stunting in under-five children with environmental enteropathy in slum areas of Jimma town, Ethiopia. Front Nutr 2024;11:1335961. [doi: 10.3389/fnut.2024.1335961] [Medline: 38650636]
32. Prevalence of stunting, height for age (% of children under 5) - India. : World Bank Group URL: https://data.worldbank.org/indicator/SH.STA.STNT.ZS?locations=IN [accessed 2024-06-17]
33. Dadras O, Suwanbamrung C, Jafari M, Stanikzai MH. Prevalence of stunting and its correlates among children under 5 in Afghanistan: the potential impact of basic and full vaccination. BMC Pediatr 2024 Jul 6;24(1):436. [doi: 10.1186/s12887-024-04913-w] [Medline: 38971723]
34. Hossain S, Chowdhury PB, Biswas RK, Hossain M. Malnutrition status of children under 5 years in Bangladesh: a sociodemographic assessment. Child Youth Serv Rev 2020 Oct;117:105291. [doi: 10.1016/j.childyouth.2020.105291]
35. Soofi SB, Khan A, Kureishy S, et al. Determinants of stunting among children under five in Pakistan. Nutrients 2023 Aug 7;15(15):3480. [doi: 10.3390/nu15153480] [Medline: 37571417]
36. Chakravarty N, Tatwadi K, Ravi K. Intergenerational effects of stunting on human capital: where does the compass point? IJMEDPH 2019 Dec 5;9(4):105-111. [doi: 10.5530/ijmedph.2019.4.24]
37. Shekar M, Dayton Eberwein J, Kakietek J. The costs of stunting in South Asia and the benefits of public investments in nutrition. Matern Child Nutr 2016 May;12 Suppl 1(Suppl 1):186-195. [doi: 10.1111/mcn.12281] [Medline: 27187915]
38. Theresia GN, Sudarma V. Immunization status lowers the incidence of stunting in children 1-5 years. World Nutr J 2022;6(1):9-15. [doi: 10.25220/WNJ.V06.i1.0003]
39. Mulyani I, Khairunnas K, Ayunda HM, Syafiq A, Ahmad A, Muliadi T. Exploring the relationship between immunization and stunting: understanding the impact of vaccinations on child growth and development. J-Kesmas 2023;10(1):11. [doi: 10.35308/j-kesmas.v10i1.7364]
40. Shinsugi C, Mizumoto A. Associations of nutritional status with full immunization coverage and safe hygiene practices among Thai children aged 12-59 months. Nutrients 2021 Dec 23;14(1):34. [doi: 10.3390/nu14010034] [Medline: 35010909]
41. Brahima JJ, Noor NN, Jafar N. Immunization and distance relationship status on the birth events 1000 HPK stunting work in bone health district Barebbo. Enfermería Clínica 2020 Jun;30:318-322. [doi: 10.1016/j.enfcli.2019.10.091]
42. Sato R. Association between uptake of selected vaccines and undernutrition among Nigerian children. Hum Vaccin Immunother 2021 Aug 3;17(8):2630-2638. [doi: 10.1080/21645515.2021.1880860] [Medline: 33631085]
43. Black MM, Walker SP, Fernald LCH, et al. Early childhood development coming of age: science through the life course. The Lancet 2017 Jan;389(10064):77-90. [doi: 10.1016/S0140-6736(16)31389-7]
44. Ezeonu C, Uneke C, Ojukwu J, et al. The pattern of pediatric respiratory illnesses admitted in ebonyi state university teaching hospital South-East Nigeria. Ann Med Health Sci Res 2015;5(1):65-70. [doi: 10.4103/2141-9248.149792] [Medline: 25745580]
45. Anekwe TD, Kumar S. The effect of a vaccination program on child anthropometry: evidence from India's Universal Immunization Program. J Public Health (Oxf) 2012 Dec 1;34(4):489-497. [doi: 10.1093/pubmed/fds032]

XSL•FO
RenderX

46. Rukiko MD, Mwakalobo ABS, Mmasa JJ. The impact of Conditional Cash Transfer program on stunting in under five year's poor children. Public Health Pract (Oxf) 2023 Dec;6:100437. [doi: 10.1016/j.puhip.2023.100437] [Medline: 37920185]
47. Rahmawati NF, Fajar NA, Idris H. Faktor sosial, ekonomi, dan pemanfaatan posyandu dengan kejadian stunting balita keluarga miskin penerima PKH di Palembang. Jurnal Gizi Klinik Indonesia 2020;17(1):23. [doi: 10.22146/ijcn.49696]
48. Owino V, Ahmed T, Freemark M, et al. Environmental enteric dysfunction and growth failure/stunting in global child health. PEDIATRICS 2016 Dec;138(6):e20160641. [doi: 10.1542/peds.2016-0641] [Medline: 27940670]
49. Roesler AL, Smithers LG, Wangpakapattanawong P, Moore V. Stunting, dietary diversity and household food insecurity among children under 5 years in ethnic communities of northern Thailand. J Public Health (Oxf) 2019 Dec 20;41(4):772-780. [doi: 10.1093/pubmed/fdy201]
50. Dad F, Dibari F, Kebede A, Lefu E, Ndumiyana T, Butaumocho B. Digitalisation in the WFP fresh food voucher programme: a pilot study from rural Amhara region, Ethiopia. Front Nutr 2023;10:1217794. [doi: 10.3389/fnut.2023.1217794] [Medline: 38024386]
51. Aini MK, Margawati A, Winarni S. Effect of providing supplementary food made from local foods on the nutritional status of stunted toddlers. Jurnal Penelitian Pendidikan IPA 2023;9(SpecialIssue):910-918. [doi: 10.29303/jppipa.v9iSpecialIssue.5465]
52. Fazid S, Haq ZU, Gillani BH, et al. Effectiveness of locally produced ready-to-use supplementary foods on the prevention of stunting in children aged 6-23 months: a community-based trial from Pakistan. Br J Nutr 2024 Apr 14;131(7):1189-1195. [doi: 10.1017/S0007114523002702] [Medline: 38012887]
53. Dearden KA, Schott W, Crookston BT, et al. Children with access to improved sanitation but not improved water are at lower risk of stunting compared to children without access: a cohort study in Ethiopia, India, Peru, and Vietnam. BMC Public Health 2017 Jan 23;17(1):110. [doi: 10.1186/s12889-017-4033-1] [Medline: 28114914]
54. Keats EC, Das JK, Salam RA, et al. Effective interventions to address maternal and child malnutrition: an update of the evidence. Lancet Child Adolesc Health 2021 May;5(5):367-384. [doi: 10.1016/S2352-4642(20)30274-1] [Medline: 33691083]
55. Cumming O, Curtis V. Implications of WASH Benefits trials for water and sanitation. Lancet Glob Health 2018 Jun;6(6):e613-e614. [doi: 10.1016/S2214-109X(18)30192-X] [Medline: 29706563]
56. Hammer J, Spears D. Village sanitation and child health: Effects and external validity in a randomized field experiment in rural India. J Health Econ 2016 Jul;48:135-148. [doi: 10.1016/j.jhealeco.2016.03.003] [Medline: 27179199]
57. Bekele T, Rawstorne P, Rahman B. Effect of water, sanitation and hygiene interventions alone and combined with nutrition on child growth in low and middle income countries: a systematic review and meta-analysis. BMJ Open 2020 Jul 12;10(7):e034812. [doi: 10.1136/bmjopen-2019-034812] [Medline: 32660947]
58. Mahendradhata Y, Trisnantoro L, Listyadewi S, et al. The Republic of Indonesia Health System Review: World Health Organization. Regional Office for South-East Asia; 2017. URL: https://iris.who.int/handle/10665/254716 [accessed 2024-06-17]
59. Joint Committee on Reducing Maternal and Neonatal Mortality in Indonesia, Development, Security, and Cooperation, Policy and Global Affairs, National Research Council, Indonesian Academy of Sciences. Reducing Maternal and Neonatal Mortality in Indonesia: Saving Lives, Saving the Future: National Academies Press; 2014. [doi: 10.17226/18437] [Medline: 24851304]

Abbreviation

KPS: Kartu Perlindungan Sosial (Social Protection Card)
SKI: Survei Kesehatan Indonesia (Indonesia Health Survey)
WHO: World Health Organization

Edited by S Badawy; submitted 18.11.24; peer-reviewed by D Poddighe, LM Hlaing; revised version received 02.07.25; accepted 13.08.25; published 10.10.25.

Please cite as:
Arief YS, Yunita FC, Efendi F, Murti FAK, Pradipta RO, McKenna L
Social and Environmental Determinants of Childhood Stunting in Indonesia: National Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e68918
URL: https://pediatrics.jmir.org/2025/1/e68918
doi:10.2196/68918

© Yuni Sufyanti Arief, Fildzah Cindra Yunita, Ferry Efendi, Fadhaa Aditya Kautsar Murti, Rifky Octavia Pradipta, Lisa McKenna. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 10.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which

XSL•FO
RenderX

permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Comparing Sociodemographic, Health Status and Resources, Macroeconomic Status, and Environmental Factors on Infant Mortality Rates in Bahrain, Kuwait, and Oman: Longitudinal Time-Series Study

Mallak Yasir Al-Saqry; Rawaa Abubakr Abuelgassium Eltayib, MBBS; Al-Hasan Ahmed Al-Busaidi; Moon Fai Chan, PhD

Department of Family Medicine and Public Health, College of Medicine and Health Science, Sultan Qaboos University, Muscat, Oman

Corresponding Author:
Moon Fai Chan, PhD
Department of Family Medicine and Public Health, College of Medicine and Health Science, Sultan Qaboos University, Muscat, Oman

Abstract

Background: The United Nations considers children a crucial national asset and makes their welfare a top priority. However, infant mortality remains a persistent challenge, notably in Arab nations. Bahrain, Kuwait, and Oman, despite sharing similar income brackets and health care systems, differ in health policies, demographics, and maternal-child resource allocation. These countries also faced sharp fiscal deficits during the 2020 COVID-19 crisis. Compared to wealthier nearby nations like the United Arab Emirates, their lower gross domestic product further complicates efforts to reduce the Infant Mortality Rate (IMR) and sustain effective, equitable child health strategies.

Objective: This study aimed to identify factors contributing to the IMR in Bahrain, Kuwait, and Oman by establishing an interpretative framework to examine the influence of sociodemographic, macroeconomic, health status and resource, and environmental factors.

Methods: A longitudinal study collected annual time-series data (1990 - 2022) for Bahrain, Kuwait, and Oman from international open sources. To counterbalance the time-series effects on both IMR and explanatory factors, a generalized least squares model based on the Cochrane-Orcutt procedure with a first-order autoregressive model was used.

Results: Generalized least squares shows that the total fertility rate has a strong effect on IMR among the 3 countries (Oman: β=1.138, *P*<.001; Kuwait: β=.429, *P*=.006; Bahrain: β=.610, *P*=.03). Health status and resources, such as female life expectancy at birth, had an inconsistent impact on the IMR, with a positive effect (β=.103, *P*=.002) for Oman and a negative effect (β=−4.0697, *P*<.001) for Kuwait. Macroeconomic factors, such as female unemployment, were significant in decreasing the IMR only for Kuwait (β=−.076, *P*=.008). Gross domestic product per capita is significant only for Bahrain (β=−.398, *P*<.001). Environmental factors included CO_2 emissions, which negatively impacted Oman's IMR (β=−.077, *P*=.03), and N_2O had a positive effect on Bahrain's IMR (β=.420, *P*=.04).

Conclusions: This study indicated the substantial effects of sociodemographics, health status and resources, macroeconomics, and environment on the IMR in 3 Arab countries. Sociodemographic and health-related factors like female life expectancy, fertility regulation, and female unemployment level were identified as key determinants of infant mortality.

(JMIR Pediatr Parent 2025;8:e73203) doi:10.2196/73203

KEYWORDS

infant mortality rate; sociodemographic; health status and resources; macroeconomic; environment; Oman; Kuwait; Bahrain

Introduction

Background

Infancy is a crucial period in human life, the time of equal or greater dramatic developmental changes than any other in the human lifespan [1]. The most notable ones include capabilities, the complexity of the nervous system, the emergence of sensory and perceptual abilities, the development of communication skills, and many other factors. Therefore, most societies view children as a national asset and allocate a significant portion of their resources to their care and support. However, despite the improvements in health care, the Infant Mortality Rate (IMR) is still a problem in many regions of the world, especially in Arab countries [2]. The World Health Organization (WHO) defines IMR as "the probability of a child born in a specific

XSL•FO
RenderX

year or period dying before reaching the age of one, if subject to age-specific mortality rates of that period" [3]. IMR provides an overview of the background conditions that the child lives in, and it is calculated using the annual number of infant deaths during a year in the numerator, divided by the total annual number of live births in the same year, multiplied by 1000, for the same geographic area and time [4]. According to data from the World Bank, Oman's IMR in 1963 was drastically high, with 219 infant deaths per 1000 live births. The IMR, however, dropped to 9 infant deaths per 1000 live births in 2021 [5]. The same pattern applies to Bahrain; the IMR in 2021 was 5.9 deaths per 1000 live births, compared to 104 deaths in 1963. The declining trend in the IMR for Kuwait is evident, from 99 infant deaths per 1000 live births in 1963 to 8 deaths per 1000 live births in 2021. These 3 Gulf Cooperation Council (GCC) countries exhibit comparable IMR patterns and follow the anticipated worldwide historical decline.

A previous study determined the impact of various health resource determinants on IMR in Oman, considering that total health expenditure has a detrimental and statistically significant effect on IMR [2]. Another important aspect is ensuring that the mother has optimal health during the peripartum period, which substantially impacts the IMR. Mothers with multiple pregnancies, a history of infant mortality, or previous preterm births are associated with higher rates of infant death [6,7]. The leading cause of infant mortality in developing countries is infections, particularly infectious diseases that result in high neonatal mortality [8]. Infant health status also seems to have a significant impact on death rates. Preterm delivery and a low birth weight baby appear to be some of the most prominent causes of increased mortality [7].

Multiple studies have affirmed the relationship of some sociodemographic factors with the likelihood of infant deaths. For instance, a study showed that consanguinity indirectly increases the likelihood of congenital abnormalities, which may increase the risk of death from complications in infants born with these congenital malformations [9]. In addition, a study emphasized the need for implementing a national neonatal screening program to assess the exact burden of high rates of inborn errors of metabolism in Bahrain, aiming to reduce mortality and morbidity through early management [10].

Macroeconomic factors are significant predictors of IMR [2,11]. The countries in the Arabian Gulf displayed a special interest in regional child mortality indicators under the guidance of the Gulf Health Council. Studies reported that the Gulf countries have significantly improved the general health of their communities and significantly decreased IMR compared to the past as a result of the significant expansion of their economies and their performance as measured by their gross domestic product (GDP), both overall and per capita [11] and the same idea presented by another study [2].

The relationship between environment and national per capita income is clear [12]. Moreover, in some nations, there is a correlation between health and income, as they heavily rely on oil and gas exports. Oman, Kuwait, and Bahrain are known for having similar per capita income levels in the GCC countries. However, the widespread burning of fossil fuels over time has a detrimental effect on environmental quality. The primary greenhouse gases responsible for climate change are carbon dioxide (CO_2), nitrous oxide (N_2O), and methane. GCC states are major sources of CO_2 emissions, a significant GHG component. Energy production, particularly the burning of fossil fuels (eg, coal, oil, and gas), and the region's high energy consumption are factors in the increase in CO_2.

Bahrain, Kuwait, and Oman are Arab countries that have the lowest GDP among other GCC members [13]. This suggests that fluctuations in economic productivity could be shaping infant mortality trends. Both Oman and Bahrain reflect comparatively fragile economic conditions for their populations, as evidenced by lower per capita foreign investment and modest central bank reserves [14]. Such indicators suggest a decline in financial resilience, which may limit the ability of expectant mothers to afford essential health care services, thereby affecting both fertility patterns and infant survival rates. Compounding this issue, women in many developing nations often shoulder substantial fiscal hardship, and the resulting gaps in perinatal care access are strongly linked to elevated infant mortality risks [8,15]. This means that their government spending exceeded their revenues, which could lead to debt and inflation problems that affect health care expenditure. Their total fertility rates have declined similarly, from an average of 7.2 in 1960 to 2.8 in 2020, comparable to those of other non-oil Arab countries following the Arab Spring [16]. This indicates that their population growth and structure have undergone significant changes over time, which could impact their social and economic development. In addition, the 3 Arab countries have had almost identical declining rates of infant deaths in the past 30 years. Furthermore, their research performance is the lowest in the GCC region, with a similar number of research articles per million population over the past 25 years [17]. While these countries exhibit similarities in income levels and health care infrastructure, they differ in specific health policies, population demographics, and resource allocations, particularly in relation to maternal and child health. For example, Oman and Bahrain emphasize preventive health care through vaccination programs and public health campaigns in allocating health resources. Kuwait has historically prioritized curative services in its health care strategy [12,14]. In terms of policy structure and vision, Bahrain's health care strategy is increasingly aligned with its economic vision to enhance public health outcomes and support sustainable development, often leveraging international collaborations [15]. Oman's policies focus on expanding access to rural health care, aligning with its commitment to decentralization [2,18]. In contrast, Kuwait's policies focus on advanced medical facilities and specialist care, reflecting a more urban-centered approach [11,19]. In terms of population growth, Kuwait has experienced steady growth, driven primarily by expatriate labor demands. Oman, on the other hand, has a slower, more balanced growth between locals and expatriates, while Bahrain's growth is urban-centric due to its smaller size [20]. By conducting this comparative analysis, this study aims to uncover unique insights into how these factors influence IMR among the 3 countries, and further research is needed to fill the existing gap in the literature.

XSL•FO
RenderX

Purpose of the Study

This study aimed to identify factors contributing to the IMR in Bahrain, Kuwait, and Oman by establishing an interpretative framework to examine the influence of sociodemographic, health status and resources, macroeconomic, and environmental factors.

Methods

Study Design

For 33 years, from 1990 to 2022, this retrospective time-series study gathered data for Bahrain, Kuwait, and Oman. The time frame for the study was selected after the 1990s because these countries did not have access to accurate, official yearly data before that time.

Data Resources

This study gathers yearly secondary data for Oman, Kuwait, and Bahrain. The data and descriptions were collected from the World Bank [5] and the Organization of Islamic Cooperation Statistics Database, which is maintained by the Statistical, Economic, and Social Research and Training Center for Islamic Countries [21].

Ethical Considerations

Ethical approval was obtained from Sultan Qaboos University Medical Research Ethics Committee (#2666). This study used secondary data that did not involve any interaction with individual human participants and presented no reidentification risk due to the aggregated nature.

Sample Size

This study's sample size (number of years) was specified according to GLS with a first-order autoregressive model and using R software ("nlme" and "MASS" library) by the R Foundation. Suppose we expect the slope of the fertility rate on IMR to be 0.6 and the rho to be 0.5 in a first-order autoregressive model. At least, this study required a sample size of 30 years for each country, with approximately 71% power at a 5% type I error.

Data Collection

We follow the evaluation criteria to ensure the degree of relevance and viability of these data [2]. A data cleaning process was also carried out, which was considered one of the key actions taken to ensure the quality of the data. Initially, the team collected data on health status and resources, sociodemographics, macroeconomics, and environment for each country based on available databases from the World Bank [5] and the Statistical, Economic, and Social Research and Training Center for Islamic Countries [21]. For sociodemographic, Bahrain and Kuwait included 10 variables: maternal or paternal educational level, maternal age, parental occupation, consanguinity, total fertility rate (births per woman), infant gender, birth rate, population density, and monthly income. For environmental, all 3 countries had data on 3 variables: CO_2 (metric tons per capita), methane, and N_2O emissions. In macroeconomics, Oman included 3 variables: GDP, GDP per capita, and female unemployment, while Bahrain and Kuwait included 6 variables: GDP, GDP per capita, gross national income, gross national income per capita, female unemployment, and inflation. For health status and resources, Oman and Bahrain included 13 variables: total health care expenditure, prematurity, birth weight, fetal growth, congenital abnormalities, neonatal sepsis, multiple pregnancies, history of preterm birth, history of infant death, delivery room resuscitation, mode of delivery, female life expectancy at birth, and immunization. Kuwait included the same 13 variables plus 5 additional variables: skilled health staff, access to safe water, hospital beds, and the number of doctors and nurses. Furthermore, any variable in this study that did not have data for one of the 3 countries was excluded because it cannot be used to compare across the 3 countries. Those independent variables with high multicollinearity with other variables will also be removed. In addition, variables with 20% or more missing data were eliminated and cannot be included in the analytical process. These variables require imputation, which is only imputed for 2 to 3 years, especially for CO_2 and N_2O in the environmental data for all 3 countries. Multiple regression imputation was used to fill in the missing data gaps for further analysis.

A recent systematic review and meta-analysis in GCC countries [19] provided the foundation for selecting relevant health status and resource, sociodemographic, and macroeconomic variables that affect IMR in the target countries. In addition, variables related to environmental factors were included based on other related studies [12]. Our investigation encompasses diverse independent variables spanning four key categories: macroeconomic, sociodemographic, health status and resources, and environmental. These variables collectively influence IMR, which serves as our research's dependent variable and primary outcome. For further details, refer to Multimedia Appendix 1, which lists the relevant variables.

Statistical Analysis

Descriptive statistics (eg, mean, SD, maximum, and minimum) were used to explore the characteristics of both IMR and explanatory variables for each target country. First, the variables within each factor, as outlined in the Data collection section, were identified as statistically significant factors of IMR across all 3 countries through univariate analysis. These variables, at $P<.05$, were subsequently integrated into a multivariable analysis for each country. To counterbalance the time-series effects on both IMR and explanatory factors, this study used generalized least squares (GLS) regression analysis based on the Cochrane-Orcutt procedure, which controls for a first-order autoregressive model. Other researchers have recommended this approach for analyzing national panels with time-series features [22-24]. By using GLS analysis, we can address our research objectives. In addition, this study assessed correlation ($r\geq0.8$) and collinearity (variance inflation factor≥10) to identify any strong correlations among macroeconomic, sociodemographic, health status and resources, and environmental factors. Variables exhibiting strong correlations were excluded from the analysis [25]. All analyses were conducted using IBM SPSS and EViews 11, with a significance level set at 5%.

XSL•FO
RenderX

Results

Descriptive Characteristics of the Variables in Bahrain, Kuwait, and Oman

This study compiled 33 years of macroeconomic, sociodemographic, health status, and resource, environmental, and IMR data from 1990 to 2022 in three Arab countries (refer to Table 1). Oman significantly reduced IMR, dropping from 31.7 to 6.4 deaths per 1000 live births. Bahrain followed with a decrease from 19.6 to 5.3, and Kuwait experienced a reduction from 14.7 to 6.3 deaths per 1000 live births (refer to Figure 1). However, the average IMR was 10 deaths per 1000 live births in Kuwait and Bahrain, while Oman had a slightly higher average of nearly 14 deaths per 1000 live births. In terms of total fertility rate, Oman had the highest rate at 3.7 births per woman, while Bahrain had the lowest at 2.5 births per woman. When considering female life expectancy at birth, Kuwait had the highest at 79.7 years, and Bahrain had the lowest at 75.8 years. In terms of economics, Oman had the lowest GDP per capita at US $14,056.8, while Kuwait had the highest at US $28,678.9. Regarding CO_2 emissions, Kuwait had the highest level at 23.5 metric tons per capita, while Oman had the lowest at 12.8 metric tons per capita.

Table . Descriptive statistics of variables of Oman, Kuwait, and Bahrain (1990 - 2022). Each variable was transformed into natural logarithms in the analysis.

Country	IMR[a]	TFR[b]	Female LE[c] at birth	GDP[d] per capita (US $)	Female unemployment	CO_2[e] emissions	N_2O[f] emissions
Oman							
Mean (SD)	13.9 (6.5)	3.7 (1.2)	76.9 (2.1)	14056.8 (6971.9)	3.7 (0.7)	12.8 (3.5)	652.9 (239.5)
Range	6.4 - 31.7	2.6 - 6.6	72.3 - 80.0	5984.4 - 25056.8	1.8 - 4.3	6.6 - 17.1	310.7 - 1064.7
Kuwait							
Mean (SD)	10.0 (2.1)	2.6 (0.4)	79.7 (1.7)	28678.9 (13366.9)	3.5 (1.9)	23.5 (4.9)	619.8 (238.8)
Range	6.3 - 14.7	2.1 - 3.3	76.8 - 82.8	8219.5 - 55595.4	1.5 - 7.8	5.4 - 31.3	169.6 - 1003.6
Bahrain							
Mean (SD)	10.1 (4.4)	2.5 (0.6)	75.8 (2.4)	17655.4 (7062.4)	3.8 (0.2)	22.1 (0.8)	101.7 (41.5)
Range	5.3 - 19.6	1.2 - 3.8	71.8 - 79.0	8174.8 - 30152.0	3.6 - 4.7	19.3 - 23.2	50.3 - 181.3

[a]IMR: infant mortality rate.

[b]TFR: total fertility rate.

[c]LE: life expectancy.

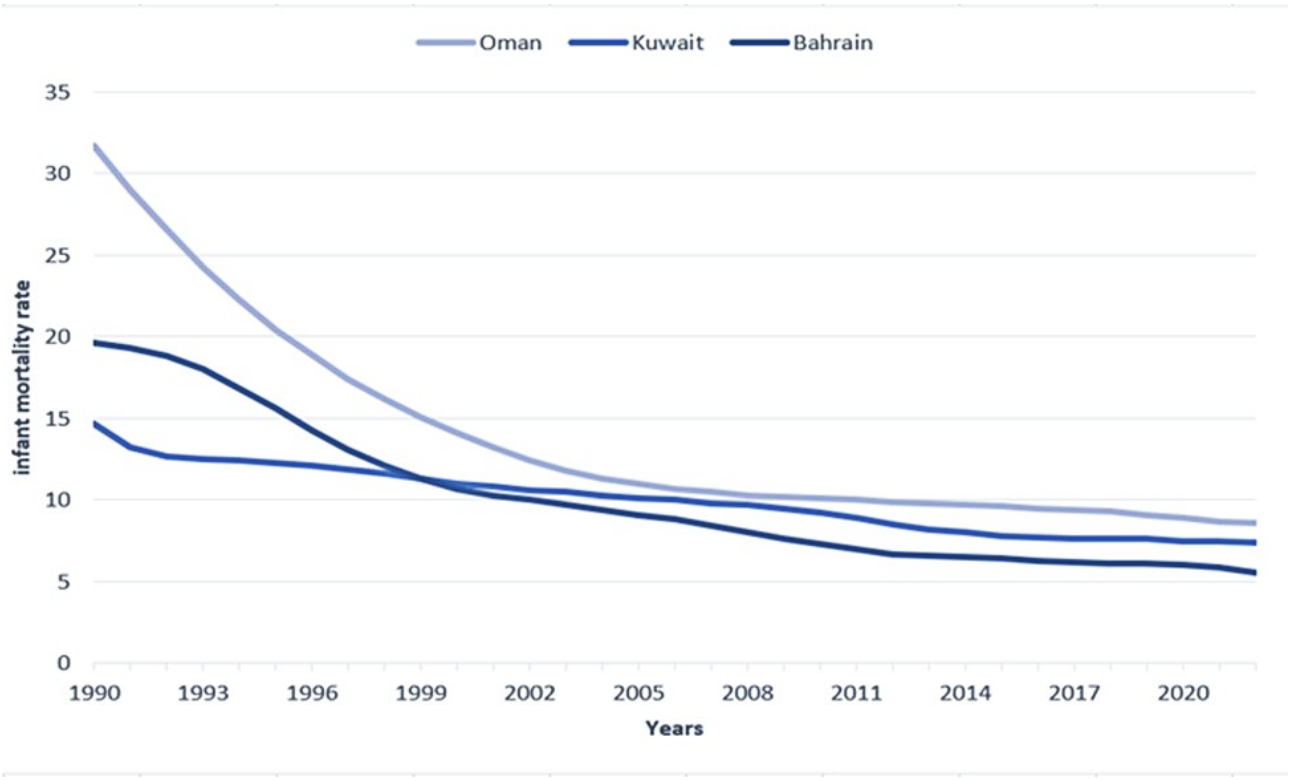
[d]GDP: gross domestic product.

[e]CO_2

[f]N_2O

XSL•FO
RenderX

Figure 1. Infant mortality rate in Oman, Kuwait, and Bahrain (1990 - 2022).



Associated Factors on IMR for Each Country

In the univariable analysis, the total fertility rate and female life expectancy at birth were significant (P<.05) across all sociodemographic and health status and resource variables in all 3 countries. In macroeconomics, female unemployment and GDP per capita (in USD) were significant (P<.05) in all countries. In addition, CO_2 and N_2O emissions in environmental factors were also found to be significant (P<.05) across all countries. These 6 variables were included in the GLS regression model to explore which factors were associated with IMR in each country. Table 2 displays the explanatory factors associated with IMR for each country, showing significance in the model. The analysis reveals that the total fertility rate has a strong effect on IMR among the three countries: Oman (β=1.138, t=8.988, P<.001); Kuwait (β=.429, t=2.965, P=.006); Bahrain (β=610, t=2.310, P=.03). However, the study shows that female life expectancy at birth had an inconsistent impact on the IMR. It had a positive effect on IMR for Oman (β=.103, t=3.541, P=.002) but a negative effect on IMR for Kuwait (β=−4.069, t=5.588, P<.001), while having no significant effect (β=.137, t=0.998, P=.33) on IMR for Bahrain. In addition, the macroeconomic factors represented female unemployment and GDP per capita. Female unemployment was significantly associated with IMR only in Kuwait (β=−.076, t=2.868, P=.008), and GDP per capita was significant only for Bahrain, with a β coefficient of −.398 (t=−3.854, P<.001). Moreover, the model indicates a relationship between CO_2 and N_2O emissions and IMR; specifically, CO_2 emissions have a negative impact on Oman's IMR (β=−.077, t=2.370, P=.03). However, N_2O emissions have a positive and direct effect on the IMR in Bahrain (β=.420; t=2.118, P=.044).

XSL•FO
RenderX

Table . Comparison of the effect of sociodemographic, health status and resources, macroeconomic, and environmental factors (1990 - 2022) on IMR[a] in Oman, Kuwait, and Bahrain by GLS[b] regression model.

	Oman			Kuwait			Bahrain		
Factor	β (SE)[c]	t statistics[d]	*P* value	β (SE)	t statistics	*P* value	β (SE)	t statistics	*P* value
Sociodemographic									
Total fertility rate	1.138 (.126)	8.988	<.001	.429 (.145)	2.965	.006	.610 (.264)	2.310	.03
Health status and resources									
Female life expectancy at birth	.103 (0.029)	3.541	.002	−4.069 (.728)	-5.588	<.001	.137 (.138)	.998	.33
Macroeconomic									
Female unemployment	−.122 (.059)	−2.044	.053	−0.076 (.026)	−2.868	.008	.489 (.365)	1.341	.19
GDP per capita (US $)	−.057 (.054)	−1.053	.30	−.001 (.031)	−.038	.97	−.398 (.103)	−3.854	<.001
Environmental									
CO_2 emissions	−.077 (.032)	−2.370	.03	.015 (.016)	.913	.37	.077 (.068)	1.127	.27
N_2O emissions	−.232 (.195)	−1.190	.25	−.003 (.008)	−.350	.73	.420 (.198)	2.118	.044

[a]IMR: Infant mortality rate.

[b]GLS: Generalized least squares.

[c]SE: standard error.

[d]Statistics: *t*-statistics.

Discussion

Principal Findings

This study used GLS with a first-order autoregressive model to investigate the determinants influencing the IMR in Oman, Bahrain, and Kuwait. These determinants, including fertility, female life expectancy, unemployment, GDP per capita, and environmental pollutants, intertwine uniquely across 3 Arab countries, shaping infant mortality patterns. These contextual determinants highlight how sociodemographic, health resources, macroeconomic, and environmental forces converge to influence newborn survival outcomes in complex, country-specific ways.

The Effects of Sociodemographic Factors on IMR

Among the 3 countries, the sociodemographic determinant, represented by the total fertility rate, has a direct and strong effect on IMR, consistent with the findings of other studies. Internationally, the impact of maternal education on infant mortality may be mediated by fertility [26,27]. Regionally, numerous studies conducted in Oman have examined the impact of various factors on the IMR. Their findings showed that the fertility rate significantly predicts IMR [2,18]. Our study showed that the total fertility rate in Oman is the highest (b=1.138, *P*<.001), followed by Bahrain (b=0.610, *P*=.029) and Kuwait (b=0.429, *P*=.006) in terms of IMR in their respective countries. The total fertility rate represents the number of children that would be born to a woman if she were to live to the end of her childbearing years. A greater probability of complications developing during pregnancy is associated with a higher fertility rate, which implies that the mother will give birth more frequently [19], and any pregnancy complications may increase the risk of mortality for both the infant and the mother [28].

The Effects of Health Status and Resource Factors on IMR

In Oman, the female life expectancy at birth has a direct impact on IMR (β=.103, *P*=.002). However, it has a negative impact on IMR in Kuwait (β=−4.069, *P*<.001), and it is not significant in Bahrain (b=0.137, *P*=.33). This indicates the number of years a female newborn would survive if the mortality patterns at the time of the birth continued to remain the same throughout her life [11]. Oman's first documented IMR was in 1963, which was drastically high. However, this rate dramatically declined across the years until it reached 9 baby deaths per 1000 live births in 2021. Indeed, it was a significant decline, but more needs to be done to maintain it. Since Oman's IMR is still the highest in the GCC despite similar economic conditions, indicating that if the health policies, medical facilities, cultural norms, and economic status, therefore, the mortality patterns that were in place at the time of the female's birth continued to remain the same or worse, the IMR will increase. However, Kuwait's IMR is slightly better, reaching 8 deaths per 1000 live births in 2021. If the mortality patterns and factors associated

XSL•FO
RenderX

with them that were in place at the time of the female's birth continued to remain the same or improved, this would further decrease the IMR. In contrast, the lack of a significant relationship between female life expectancy at birth and IMR in Bahrain may be due to a more direct impact on infant death rather than female life expectancy. Our findings suggest that the IMR in Bahrain is influenced by macroeconomic factors, specifically GDP per capita, as well as environmental factors, particularly N_2O emissions. This pattern differs from the other 2 countries analyzed, where these variables showed varying degrees of impact. These findings suggest that specific factors, such as economic structures and environmental conditions, play a critical role in infant death in Bahrain.

The Effects of Microeconomic Factors on IMR

This study found that female unemployment has a negative effect on the IMR in Kuwait (b=−0.076, *P*=.0008), while it is not significant in Oman (b=−0.122, *P*=.05) and Bahrain (b=0.489, *P*=.19). This finding was consistent with a study done for Macau [29]. However, numerous studies have emphasized the critical significance of a higher proportion of the employed population in lowering the IMR regionally [18] and internationally [30]. In addition, this result contrasts with the GCC region systematic review, which concluded that only paternal working status matters and that maternal employment had no impact on IMR [19]. Being a housewife is associated with providing better care, spending more quality time with the baby, and meeting the child's psychological and physical needs. As a possibility, society has left the child's responsibility and care to the mother alone, and the father has no connection to the matter. Therefore, if the mother pays little attention to her work, the child will remain without care, which leads to a high infant mortality rate. We recommend further research to investigate why female unemployment has a negative impact on the IMR in Kuwait. Additionally, our findings showed that GDP per capita significantly reduced the IMR only in Bahrain (b=−0.398, *P*<.001) but not in Oman (b=−0.057, *P*=.302) or Kuwait (b=−0.0011, *P*=.97). A study in Oman reported a contrasting negative impact of GDP per capita on IMR [2]. This difference may stem from our inclusion of a broader data range and environmental factors such as CO_2 emissions, which exert a more direct influence on IMR in Oman than GDP per capita. Furthermore, the lack of a significant relationship between GDP per capita and IMR in Kuwait could be attributed to the multifactorial nature of health care outcomes in the country. GDP per capita likely impacts healthcare quality and equity rather than directly determining IMR. Other determinants, such as the total fertility rate, female life expectancy at birth, and female unemployment, may dilute the direct effects of GDP per capita on IMR. These findings underscore the importance of context-specific analyses in understanding the intricate relationship between economic indicators and health outcomes.

The Effects of Environmental Factors on IMR

This study has indicated that environmental determinants represented by CO_2 emissions negatively impact Oman's IMR (β=−.077, *P*=.026). A study found that CO_2 emissions and nonrenewable energy are indirectly essential determinants of the IMR [31]. They have varying effects on the different income groups. This implies that nonrenewable energy indirectly increases the mortality rate for people in lower-middle and upper-middle-income countries but reduces it in high-income countries [31]. As indicated earlier, Oman lacks the high-income capacity that would enable it to be a country with higher CO_2 emissions control, so we recommend further studies based on this idea. High nonrenewable energy use can be related to the country's better economic and employment status, so it depends on its ability to control CO_2 emissions. However, previous studies have demonstrated that respiratory disorders and a high mortality rate are primarily caused by environmental pollution. Moreover, the model indicated that the environmental construct in Bahrain is best reflected by N_2O emissions (β=.420, *P*=.044). N_2O emissions contribute to the global accumulation of greenhouse gases, leading to adverse environmental and health effects. Numerous studies have documented the health risks associated with nitrate toxicity, including methemoglobinemia in newborns and its strong correlation with cancer [32].

Limitations and Future Directions

Many variables considered had potential significance according to the previous studies. However, with incomplete data, many variables were excluded from the analysis. Nevertheless, these variables may still affect the IMR in each country, so interpreting the results requires caution due to this issue. Furthermore, more studies using longer longitudinal data are recommended. Another limitation of this research is related to the analysis method. The GLS model does not account for the indirect effects of explanatory variables on IMR. More studies should be recommended to examine its impact on IMR among countries.

Conclusions

This analysis revealed the substantial impact of sociodemographic, health status, and resource factors, as well as macroeconomic and environmental factors, on the IMR in 3 Arab countries. Sociodemographic and health-related factors like female life expectancy, fertility regulation, and female unemployment level were identified as key determinants of infant mortality. Based on the empirical facts regarding the environment, promoting clean energy development to enhance human health is recommended. In other words, the IMRs of these countries are expected to decline even further due to the adoption of environmental quality policies. The results of this study suggest improvements and interventions that consider macroeconomic, environmental, sociodemographic, and health status-related issues.

Data Availability

The data supporting the findings are available from the corresponding author upon reasonable request.

XSL•FO
RenderX

Authors' Contributions

Study design: MFC, RAAE; Data collection and analysis: MFC, MYAS, AAAB; Manuscript preparation: MFC, MYAS, AHAAB, RAAE.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Lists of factors and variables used in the study for each country.
[DOCX File, 17 KB - pediatrics_v8i1e73203_app1.docx]

References

1. Bornstein MH. Human infancy…and the rest of the lifespan. Annu Rev Psychol 2014;65(1):121-158. [doi: 10.1146/annurev-psych-120710-100359] [Medline: 24405360]
2. Al‐Azri M, Al‐Mamari F, Mondal S. Healthcare expenditure and health outcome nexus: Exploring the evidences from Oman. J Public Affairs 2020;20(4):e2329. [doi: 10.1002/pa.2329]
3. World health organization. Indicator Metadata Registry Details. 2022. URL: https://www.who.int/data/gho/indicator-metadata-registry/imr-details/1 [accessed 2023-03-23]
4. Gonzalez RM, Gilleskie D. Infant mortality rate as a measure of a country's health: a robust method to improve reliability and comparability. Demography 2017 Apr;54(2):701-720. [doi: 10.1007/s13524-017-0553-7] [Medline: 28233234]
5. World bank. World Bank Open Data. 2022. URL: https://data.worldbank.org [accessed 2022-03-06]
6. Chibber R, Fouda M, Shishtawy W, et al. Maternal and neonatal outcome in triplet, quadruplet and quintuplet gestations following ART: a 11-year study. Arch Gynecol Obstet 2013 Oct;288(4):759-767. [doi: 10.1007/s00404-013-2796-x] [Medline: 23543239]
7. el-Shafei AM, Sandhu AK, Dhaliwal JK. Perinatal mortality in Bahrain. Aust N Z J Obstet Gynaecol 1988 Nov;28(4):293-298. [doi: 10.1111/j.1479-828x.1988.tb01685.x] [Medline: 3250447]
8. Khurshid F, Ahmad MK, Khan AS, et al. Epidemiological determinants for mortality from neonatal tetanus in Punjab Province, Pakistan (2020). iproc 2020;8(1):e36638. [doi: 10.2196/36638]
9. Sawardekar KP. Genetic analysis of lethal congenital malformations causing perinatal mortality at Nizwa Hospital, Oman. Clin Genet 2004 Sep;66(3):239-243. [doi: 10.1111/j.1399-0004.2004.00293.x] [Medline: 15324324]
10. Aljishi E, Alsahlawi Z. Prevalence and genetic variability of inborn errors of metabolism in Bahrain. Bahrain Medical Bulletin 2019;41(2):84-89 [FREE Full text]
11. Salam AA, Al-Khraif RM. Child mortality transition in the Arabian Gulf: wealth, health system reforms, and development goals. Front Public Health 2019;7:402. [doi: 10.3389/fpubh.2019.00402] [Medline: 32010657]
12. Bader Y, Ganguli S. Analysis of the association between economic growth, environmental quality and health standards in the Gulf Cooperation Council during 1980-2012. MEQ 2019 Aug 5;30(5):1050-1071. [doi: 10.1108/MEQ-03-2018-0061]
13. Tok E. The Gulf Cooperation Council states: crystallization of the regional cooperation and alliances amid dwindling resources. Digest Mid East Studies 2021 Jan;30(1):53-69. [doi: 10.1111/dome.12226]
14. Amar J, Lecourt C, Carpantier JF. GCC Sovereign Wealth Funds: Why do they take control? Journal of International Financial Markets, Institutions and Money 2022 Mar;77:101494. [doi: 10.1016/j.intfin.2021.101494]
15. Li Q, Kanduma E, Ramiro I, et al. Spatial access to continuous maternal and perinatal health care services in low-resource settings: cross-sectional study. JMIR Public Health Surveill 2024 Jul 18;10:e49367. [doi: 10.2196/49367] [Medline: 39024564]
16. Winckler O. The fertility revolution of the Arab countries following the Arab Spring. Middle East Policy 2023 Dec;30(4):26-41. [doi: 10.1111/mepo.12712]
17. Al-Marzouqi AH, Arabi AA. Research performance of the GCC countries: a comparative analysis of quantity and quality. Heliyon 2022 Nov;8(11):e11309. [doi: 10.1016/j.heliyon.2022.e11309] [Medline: 36353177]
18. Eltayib RAA, Al-Azri M, Chan MF. The impact of sociodemographic, macroeconomic, and health status and resources on infant mortality rates in Oman: evidence from 1980 to 2022. Eur J Investig Health Psychol Educ 2023 Jun 7;13(6):986-999. [doi: 10.3390/ejihpe13060075] [Medline: 37366779]
19. Eltayib RAA, Al-Alawi KS, Wirayuda AAB, Al-Azri M, Chan MF. The impact of sociodemographic, macroeconomic, and health status and resources determinants on infant mortality rates in the Gulf Cooperation Council (GCC) countries: A systematic review and meta-analysis. J Neonatal Nurs 2023 Aug;29(4):620-638. [doi: 10.1016/j.jnn.2023.01.008]
20. Al-Flaiti A. Demographics of the GCC – understanding the changes in the local population. Presented at: 64th ISI World Statistics Congress; Jul 19, 2023; Ottawa URL: https://www.isi-next.org/abstracts/submission/746/view/ [accessed 2024-08-12]
21. Statistical, economic and social research and training centre for Islamic countries. SESRIC. 2022. URL: https://www.sesric.org/ [accessed 2022-04-24]

XSL•FO
RenderX

22. Antunes JLF, Waldman EA. Trends and spatial distribution of deaths of children aged 12–60 months in sa˜ o paulo, brazil, 1980–98. : Bulletin of the World Health Organization; 1980.
23. Fotio HK, Gouenet RM, Ngo Tedga P. Beyond the direct effect of economic growth on child mortality in Sub ‐ Saharan Africa: does environmental degradation matter? Sustainable Development 2024 Feb;32(1):588-607. [doi: 10.1002/sd.2694]
24. Jorgenson AK. Political-economic integration, industrial pollution and human health: a panel study of less-developed countries, 1980—2000. Int Sociol 2009;24(1):115-143. [doi: 10.1177/0268580908099156]
25. García-García C, García-García CB, Salmerón R. Confronting collinearity in environmental regression models: evidence from world data. Stat Methods Appl 2021 Sep;30(3):895-926. [doi: 10.1007/s10260-021-00559-5]
26. Subramaniam T, Loganathan N, Yerushalmi E, Devadason ES, Majid M. Determinants of infant mortality in older ASEAN economies. Soc Indic Res 2018 Feb;136(1):397-415. [doi: 10.1007/s11205-016-1526-8]
27. Schellekens J. Maternal education and infant mortality decline: the evidence from Indonesia, 1980–2015. DemRes 2021;45:807-824. [doi: 10.4054/DemRes.2021.45.24]
28. Smith GC, Pell JP, Walsh D. Pregnancy complications and maternal risk of ischaemic heart disease: a retrospective cohort study of 129 290 births. The Lancet 2001 Jun;357(9273):2002-2006. [doi: 10.1016/S0140-6736(00)05112-6]
29. Chan MF, Ng WI, Van IK. Socioeconomic instability and the availability of health resources: their effects on infant mortality rates in Macau from 1957-2006. J Clin Nurs 2010 Mar;19(5-6):884-891. [doi: 10.1111/j.1365-2702.2009.02863.x] [Medline: 19886877]
30. Bugelli A, Borgès Da Silva R, Dowbor L, Sicotte C. The determinants of infant mortality in Brazil, 2010-2020: a Scoping Review. Int J Environ Res Public Health 2021 Jun 15;18(12):6464. [doi: 10.3390/ijerph18126464] [Medline: 34203770]
31. Adeleye BN, Azam M, Bekun FV. Infant mortality rate and nonrenewable energy consumption in Asia and the Pacific: the mediating role of carbon emissions. Air Qual Atmos Health 2023 Jul;16(7):1333-1344. [doi: 10.1007/s11869-023-01347-8]
32. Hakeem KR, Sabir M, Ozturk M, Akhtar Mohd S, Ibrahim FH. Nitrate and Nitrogen Oxides: Sources, Health Effects and Their Remediation. In: Voogt P, editor. Rev Environ Contam Toxicol 2016;242:183-217. [doi: 10.1007/398_2016_11]

Abbreviations

CO_2: carbon dioxide
GCC: Gulf Cooperation Council
GDP: gross domestic product
GLS: generalized least squares
IMR: infant mortality rate
N_2O: nitrous oxide
WHO: World Health Organization

Edited by S Badawy; submitted 27.02.25; peer-reviewed by S Widati, F Pabon-Rodriguez; revised version received 19.07.25; accepted 13.08.25; published 10.10.25.

Please cite as:
Al-Saqry MY, Eltayib RAA, Al-Busaidi AHA, Chan MF
Comparing Sociodemographic, Health Status and Resources, Macroeconomic Status, and Environmental Factors on Infant Mortality Rates in Bahrain, Kuwait, and Oman: Longitudinal Time-Series Study
JMIR Pediatr Parent 2025;8:e73203
URL: https://pediatrics.jmir.org/2025/1/e73203
doi:10.2196/73203

© Mallak Yasir Al-Saqry, Rawaa Abubakr Abuelgassium Eltayib, Al-Hasan Ahmed Al-Busaidi, Moon Fai Chan. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 10.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Parental Experiences of Administering Pediatric Tuina for Sleep and Appetite in Early School-Aged Children With Attention-Deficit/Hyperactivity Disorder: Qualitative Study in Hong Kong

Shu-Cheng Chen[1], PhD; Kwai-Ching Lo[2], PhD; Han Li[1], MA; Pong-Ming Wong[2], MA; Lok-Yi Pang[1], BSc; Jing Qin[1], PhD; Wing-Fai Yeung[3,4,5], PhD

[1]Centre for Smart Health, School of Nursing, The Hong Kong Polytechnic University, Hong Kong, China

[2]School of Chinese Medicine, University of Hong Kong, Hong Kong, China

[3]School of Nursing, The Hong Kong Polytechnic University, Hong Kong, China

[4]Research Center for Chinese Medicine Innovation, The Hong Kong Polytechnic University, Hong Kong, China

[5]Research Institute for Smart Ageing, The Hong Kong Polytechnic University, Hong Kong, China

Corresponding Author:
Wing-Fai Yeung, PhD
School of Nursing, The Hong Kong Polytechnic University, Hong Kong, China

Abstract

Background: Previous research suggested that parent-administered pediatric *tuina* could improve symptoms of attention-deficit/hyperactivity disorder (ADHD), such as sleep quality and appetite.

Objective: This study aimed to explore the experiences and perceptions of parents administering pediatric *tuina* to school-aged children with ADHD in Hong Kong.

Methods: This qualitative study was embedded in a pilot randomized controlled trial on parent-administered pediatric *tuina* for improving sleep and appetite in school-aged children diagnosed with ADHD. Purposive sampling was used to invite 12 parents who attended a pediatric *tuina* training program and delivered the intervention to their children at home for at least 8 weeks. Data were collected through semistructured focus group interviews and individual interviews, which were audio-recorded, transcribed verbatim, and analyzed using thematic analysis.

Results: Two main themes emerged: (1) effects of parent-administered pediatric *tuina* and (2) parents' experience of administering pediatric *tuina*. Parents reported significant improvements in children's sleep quality, appetite, behavior, mental state, and academic performance. Facilitators provided professional guidance and applied a user-friendly course design. Challenges included difficulties in mastering techniques, locating acupuncture points, and time management. Participants suggested the need for more traditional Chinese medicine pattern diagnostic sessions, real-time supervision methods, and extended follow-up to better observe long-term effects.

Conclusions: Parent-administered pediatric *tuina* was perceived to improve children's sleep quality and appetite significantly, along with other aspects of well-being. Professional guidance and a structured training program facilitated implementation, and challenges highlighted the need for more frequent diagnostic sessions, real-time supervision, and extended follow-up.

Trial Registration: ClinicalTrials.gov NCT06007742; https://clinicaltrials.gov/study/NCT06007742

(JMIR Pediatr Parent 2025;8:e65471) doi:10.2196/65471

KEYWORDS

pediatric massage; child; traditional Chinese medicine; TCM; ADHD; qualitative study; complementary medicine; attention deficit; hyperactivity; massage; tuina; tui na; mental health; sleep; appetite; parent; parenting; interview; focus group; anmo; attention-deficit/hyperactivity disorder

Introduction

Attention-Deficit/Hyperactivity Disorder

Attention-deficit/hyperactivity disorder (ADHD) is a common neurodevelopmental disorder in children, affecting approximately 5% of the pediatric population [1]. It is characterized by 3 primary symptoms: inattention, hyperactivity, and impulsivity [2,3]. Children with ADHD often experience additional mental, emotional, or behavioral disorders, which can include learning disorders, sleep disorders, oppositional

XSL•FO
RenderX

defiant disorders, anxiety, and conduct disorders [4]. Among the comorbidities, sleep problems and appetite disturbances are particularly prevalent among school-aged children with ADHD [5,6]. Sleep problems can include difficulty falling asleep, restless sleep, frequent awakenings, and difficulty waking up in the morning [7]. These sleep issues may be caused by the hyperactive and impulsive nature of ADHD, the side effects of medications, or coexisting emotional and behavioral issues [8]. Eating problems are common in children with ADHD, ranging from poor appetite and picky eating to overeating and cravings for unhealthy foods [9]. The causes of these eating problems can include the side effects of ADHD medications, which often suppress appetite, and the impulsivity associated with ADHD [10]. Notably, stimulant medications, which are commonly prescribed for ADHD, can lead to sleep disturbance and eating problems [11]. Sleeping and eating issues can affect the child's physical health, growth, and development, which could complicate the management of ADHD symptoms [5,6]. Strategies such as establishing consistent bedtime routines, creating a calming sleep environment, and encouraging balanced diets are crucial to specifically address sleep and appetite issues [5,6]. Parents and caregivers play a vital role in implementing these coping interventions to help manage symptoms and improve the quality of life for the child and the family [12].

Parent-Administered Pediatric *Tuina*

Pediatric *tuina*, also known as pediatric *anmo* or traditional Chinese medicine (TCM) pediatric massage, is a specialized form of massage therapy tailored for infants and children [13]. It is grounded in TCM principles, which emphasize the harmonious functioning of the body's systems [13]. In ancient Chinese medicine, the term "double *yang* person" was used to describe individuals exhibiting symptoms of ADHD [14]. By targeting specific acupoints, pediatric *tuina* aims to restore the *yin-yang* balance, thereby enhancing overall health and well-being. As an external, noninvasive therapy, it offers a complementary approach to conventional medical treatments, providing a holistic option for pediatric care [13]. This therapeutic technique has been extensively studied for its potential benefits in addressing various clinical conditions and diseases [15] such as diarrhea [16], anorexia [17], torticollis [18], constipation [19], enuresis [20], and functional dyspepsia [21]. Pediatric *tuina* is used to promote the growth and development of healthy children in China [22]. The practice of pediatric *tuina* involves the stimulation of specific areas or acupoints on the body through various manipulation techniques, including pushing, kneading, pressing, rotating, nipping, circular movements, and pounding [13]. These techniques generate different types of stimuli on the skin, which are detected by surface sensory receptors and transmitted to the central nervous system [23]. This sensory input is believed to induce a series of protective and adaptive homeostatic activities within the body. Research has demonstrated that in young children, the skin can rapidly regulate basic and adaptive homeostatic responses [24]. This regulation may be facilitated by a low compensatory basal level of stress-responsive enzymes, allowing for a broad range of physiological responses [25]. The mechanisms behind these responses suggest that pediatric *tuina* may substantially affect the autonomic nervous system, potentially leading to improved clinical outcomes for various pediatric conditions [26].

Research Gap

In recent years, several research studies have preliminarily demonstrated the effects of pediatric *tuina* in treating ADHD. For instance, a randomized controlled trial (RCT) on 120 children with ADHD comparing pediatric *tuina* with medication reported that the Conners scores in the pediatric *tuina* group were significantly lower than those in the control group (Cohen d=0.96, P<.05), as were the ADHD scores (Cohen d=.57, r=0.28, P<.05). The incidence of adverse events was lower in the pediatric *tuina* group (3.33%) than in the control group (16.67%, P=.015) [27]. A systematic review of 11 clinical trials suggested the potential benefits of pediatric *tuina* in improving concentration, mood, sleep, and social functioning in children and adolescents with ADHD [28]. However, the extant literature lacks robust qualitative insights into parents' understanding of using this intervention and the specific implementation as a complementary intervention. Therefore, limited information exists exploring the practicalities, challenges, and perceived benefits of parent-administered pediatric *tuina* for ADHD. The authors' team recently conducted a pilot RCT to further examine parent-administered pediatric *tuina* for improving sleep and appetite in school-aged children with ADHD in Hong Kong. This study is the qualitative part of the pilot RCT, aiming to further explore parents' experiences and perceptions of delivering pediatric *tuina* at home, particularly in parents' experiences on its effects on children's sleep and appetite and parents' experience of administering pediatric *tuina*. This project could provide valuable insights into the real-world application of pediatric *tuina* and offer guidance for parents and health care providers in optimizing this intervention's use in more contexts.

Methods

Ethical Considerations

Ethical approval for the study was granted by the Hong Kong Polytechnic University (HSEARS20230810005). A written informed consent to participate in this study was obtained from the participants. Each participant was assigned a randomly generated code to ensure confidentiality. Each participant received a cash incentive of HK $200 (approximately US $25.64 based on an exchange rate of HK $1=US $0.1282) to acknowledge their participation.

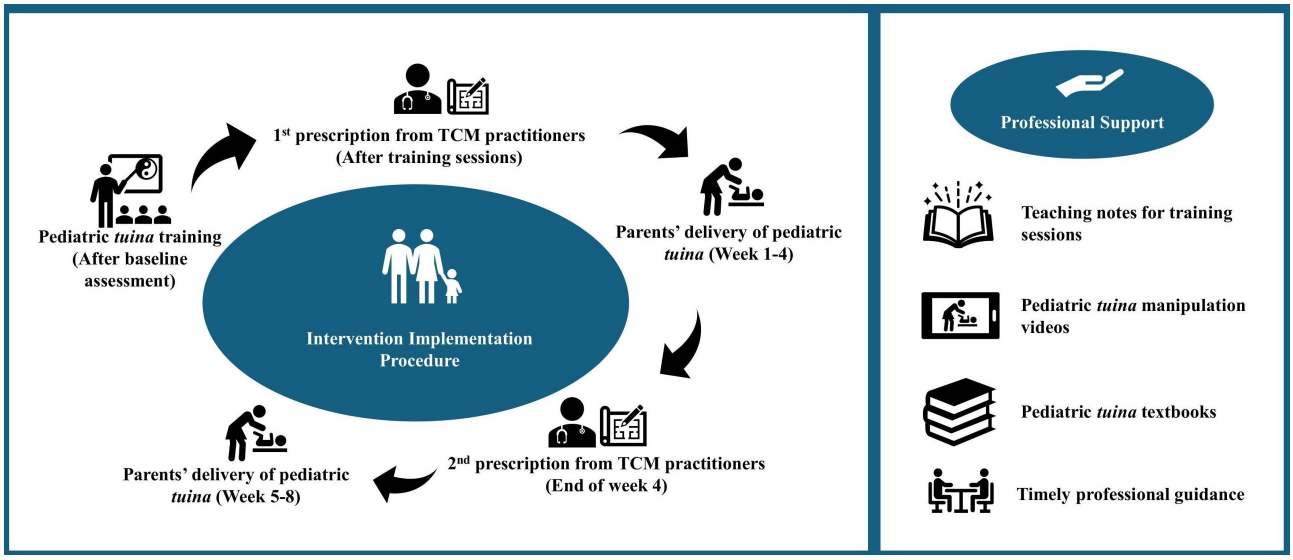
Study Design

This project was registered on ClinicalTrials.gov under the identifier NCT06007742. This study presents the qualitative findings from a pilot RCT investigating the effects of parent-administered pediatric *tuina* on sleep quality and appetite in school-aged children with ADHD in Hong Kong. In the RCT, parents received systematic training from TCM practitioners, including 2 face-to-face sessions (each lasting 2 hours). The first session focused on theoretical knowledge, and the second session covered TCM pattern identification and pediatric *tuina* techniques. Following the training sessions, parents administered pediatric *tuina* to their children at home over an 8-week period on the basis of individualized prescriptions formulated by TCM

XSL•FO
RenderX

practitioners. Each participant in the pediatric *tuina* group received parent-administered pediatric *tuina* sessions every other day, totaling 24 sessions over an 8-week period (at least 3 sessions each week). Each session lasted approximately 25 - 30 minutes. The *tuina* protocol was developed from a 2021 feasibility RCT for ADHD involving 64 parent-child pairs, where 128 individualized pediatric *tuina* prescriptions were analyzed to identify commonly used and safe acupoints [29]. The resulting standardized basic prescription allows TCM practitioners to make individualized modifications based on syndrome differentiation. This TCM diagnosis guided the selection of specific acupoints and manipulation techniques tailored to each child's condition. Details regarding the implementation of the intervention are illustrated in Figure 1. The interviews commenced 1 week after the completion of treatment for the first wave of participants in the RCT, which was conducted in 3 sequential waves. Interviews were strategically scheduled at 3 distinct timepoints, following the conclusion of each treatment wave. This timing ensured that participants had sufficient experiences and perceptions for in-depth exploration and allowed for the prompt collection of data while their experiences were still vivid, ensuring accurate and immediate reflections on the treatment effects. The study's reporting adhered to the Consolidated Criteria for Reporting Qualitative Research's checklists [30].

Figure 1. The implementation of the parent-administered pediatric *tuina* program. TCM: traditional Chinese medicine.



Setting

This study used a qualitative approach with the use of semistructured focus group interviews and individual interviews. The research methodology allows for a great flexibility of the participants to join. The focus group interviews were conducted face-to-face in the campus of the Hong Kong Polytechnic University.

Participants

Participants were parents with children with ADHD. The participants for the interviews were invited from the participants in the pilot RCT who received the parent-administered pediatric *tuina* intervention [31]. Recruitment information was sent to potential participants by WhatsApp message at the end of February 2024, and purposive sampling was applied for recruitment. The children included in the pilot RCT (1) were aged 6 - 8 years; (2) possessed internationally recognized diagnostic information or certification for ADHD; and (3) had a score equal to or higher than 39 (borderline cutoff) of the Sleep Disturbance Scale for Children, which indicated sleep problems of children. The parents included in this study (1) participated in the project on using parent-administered pediatric *tuina* for improving sleep quality and appetite in children with ADHD who completed the 2-month treatment and follow-up assessment of the intervention during the treatment period, (2) were able to communicate in Cantonese fluently, and (3) agreed to participate and were willing to share their experience in applying this intervention. This study focused on children aged 6 - 8 years, representing the early school-age period. This study focused on children aged 6 - 8 years, representing the early school-age period. This focus is driven by the significance of early intervention in ADHD's developmental trajectory and the specific responsiveness of this age group to pediatric *tuina*. Research suggests that early school years are critical for implementing interventions that could substantially alter the course of ADHD, making timely and targeted intervention essential [32]. Furthermore, tactile therapies such as pediatric *tuina* are shown to be highly effective in younger children, who are generally more receptive to such treatments [33].

Data Collection

A semistructured interview guide was created and refined on the basis of previous relevant studies and comments from experts, including 2 TCM practitioners (KCL and PMW) and 2 qualitative researchers (WFY and SCC). The guide comprised 5 open-ended questions detailed in Textbox 1. The focus group interviews were moderated by the first author (SCC), with an assistant moderator (LYP) responsible for note-taking and operating the recording equipment. Both moderators received training from the corresponding author (WFY), a TCM practitioner with extensive research experience in TCM interventions and qualitative methodologies. At the beginning of each interview session, the moderator introduced herself,

XSL•FO
RenderX

clarified the study's purpose and procedures, and emphasized the confidentiality rules. She also explained the questions and facilitated group interaction by providing prompts and pauses, ensuring that the discussion remained focused without imparting any value judgments. Participation in the study was voluntary, and no individuals other than the participants and researchers were present during the interviews. Participants were reassured that, although the sessions were audiotaped, their names would not be recorded.

Textbox 1. Questions for the semistructured interview.

Do you think pediatric *tuina* has changed or affected your child's eating habits?
Do you think pediatric *tuina* has changed or affected your child's sleep?
Besides diet and sleep, in what other aspects do you think pediatric *tuina* has changed or affected your child?
What difficulties did you encounter from learning to performing pediatric *tuina*?
How do you evaluate the content and process of the pediatric *tuina* treatment for attention-deficit/hyperactivity disorder? What are the advantages and areas for improvement?

Data Analysis

All interviews were audiotaped and transcribed verbatim in traditional Chinese before data analysis commenced. All study-related documents and transcripts were deidentified, and the audio files were destroyed once transcription was completed. The transcripts were analyzed using thematic analysis with hierarchical coding [34,35]. The template analysis applied the following steps: (1) an initial reading of the transcripts to identify a priori themes and perform preliminary coding; (2) development of an initial coding template; (3) systematic review of all datasets to refine the template by adding, removing, or merging codes as necessary; and (4) finalization of the template for application to the entire dataset [36]. The first author (SCC) conducted the transcription and initial coding, which were subsequently reviewed for accuracy and consistency by another researcher (HL). Any discrepancies in coding were resolved through consultation with the principal investigator (WFY). Microsoft Word software was used to manage the coding process [37,38]. Descriptive statistics were used to summarize the demographic characteristics of the sample. The Results section presented a summary of the main themes and subthemes, illustrated with participant quotes. For each quote, only the participant codes are provided.

Trustworthiness

This study adhered to the trustworthiness criteria for qualitative research as outlined by Lincoln and Guba [39,40]. For credibility, a semistructured interview guide was developed through 2 group discussions and subsequently pilot-tested during the initial interview session. Purposive sampling was used to select participants capable of providing diverse perspectives and experiences relevant to the intervention delivery. For transferability, the richness of the data was assessed using the saturation theory [41]. Data collection continued until the point of near exhaustion of new information, which was achieved by the third session [42]. Dependability was maintained through independent coding of the collected data by 2 researchers, complemented by regular debriefing sessions with WFY, an individual with substantial expertise in qualitative research. Finally, participants were provided with the findings, including the code tree and quotations, for their feedback and verification to ensure confirmability. This process aimed to minimize bias and ensure that the intervention reflected the true perspectives and experiences of the participants.

Results

General Characteristics of Data

In total, 4 group interviews and 3 individual interviews were conducted in Cantonese between February 2024 and April 2024. The group interviews averaged 86 minutes in duration, ranging from 77 to 96 minutes, and the individual interviews averaged 35.3 minutes, with durations ranging from 30 to 46 minutes. Of the 61 parents invited, 12 ultimately participated. Each interview session included between 1 and 3 participants, none of whom knew each other. Themes and subthemes were initially identified by the fourth interview session and further refined by the seventh session.

Sample Profile

Overall, 12 parents, comprising 10 females (83.3%) and 2 males (16.7%), whose children were diagnosed with ADHD participated in the interviews. The average age of the parents was 40.1 (SD 3.7) years, and the mean age of their children was 6.9 (SD 0.9) years. Detailed demographic information on the participants can be found in Table 1.

XSL•FO
RenderX

Table . Demographic characteristics of participants interviewed (N=12).

Characteristics		Values
Age (years), mean (SD)		
	Parents	40.1 (3.7)
	Child	6.9 (0.9)
Gender (parent), n (%)		
	Male	2 (16.7)
	Female	10 (83.3)
Gender (child), n (%)		
	Male	10 (83.3)
	Female	2 (16.7)
Educational level (parent), n (%)		
	Senior high school	4 (33.3)
	College or above	8 (66.7)
Career (parent), n (%)		
	Professional/semiprofessional	4 (33.3)
	Unskilled worker	1 (8.3)
	Homemaker	5 (41.7)
	Others	2 (16.7)
Family members, mean (SD)		4.3 (1.1)
Family monthly income in HK$[a], n (%)		
	10,001 - 24,999	2 (16.7)
	25,000 - 49,999	7 (58.3)
	50,000 or above	3 (25)
BMI (child), mean (SD)		14.3 (1.8)
Past treatment for ADHD [b] (child), n (%)		
	Medication	0 (0)
	Cognitive behavioral therapy	3 (25)
	Others	1 (8.3)
Current treatment for ADHD (child), n (%)		
	Medication	3 (25)
	Cognitive behavioral therapy	3 (25)
	Others	1 (8.3)

[a]All income values are presented in Hong Kong dollars. For the purpose of this study, the conversion rate used is HK $1=US $0.1282 (as of February 2024).

[b]ADHD: attention-deficit/hyperactivity disorder.

Major Themes

Two themes regarding the participants' experience in applying the parent-administered pediatric *tuina* intervention and participating in the study were identified: (1) effects of parents performing pediatric *tuina* and (2) parents' experience of performing pediatric *tuina*. The specific subthemes under each theme were described. Table 2 presents the code structure.

XSL•FO
RenderX

Table . Code structures.

Themes and subthemes		Code units
Effects of parent-administered pediatric *tuina*		
	Improvements in children's eating	• Increased appetite and food intake • Improved diet structure (less picky eating and trying new things) • Improved gastrointestinal function (indigestion, vomiting, and constipation)
	Improvements in children's sleep	• Improved sleep quality (restlessness, snoring, teeth grinding, sweating, and yelling) • Improved sleep habits (shorter time to fall asleep and able to sleep on their own)
	Improvements in other aspects of children	• Improved behavioral habits (milder behavior) • Improved mental state (relaxed and better emotions) • Improved attention (academic performance) • Improved interpersonal relationships (family and school) • Improved physical condition (bedwetting, rhinitis, weight, and height)
Parents' experience of performing pediatric *tuina*		
	Advantages of this intervention implementation	• User-friendly course design (appropriate difficulty and clear teaching materials) • Professional guidance from instructors • Noninvasive treatment method • Customized diagnosis and treatment • Satisfactory treatment effects (effective and quick results)
	Difficulties encountered during implementation	• Difficulty in operation (knowledge, locating acupuncture points, and techniques) • Difficulty in children's cooperation • Time management difficulties (parents and children)
	Parents' suggestions on improving the intervention	• Increasing guidance during practice and operation • Use of real-time supervision methods (such as electronic records or apps) • Increasing number of diagnostic sessions • Extending treatment and follow-up time

Effects of Parent-Administered Pediatric *Tuina*

This theme encompasses three subthemes: (1) improvements in children's eating, (2) improvements in children's sleep, and (3) improvements in other aspects of children.

Improvements in Children's Eating

Parents observed noticeable improvements in their children's eating habits following the administration of pediatric *tuina*. Many reported an increase in appetite and food intake, as illustrated by one parent who stated, "I think his appetite is better...at least he's willing to eat more, which is an achievement; the most important thing is that he's willing to eat" [Participant 12]. Another parent noted a reduction in the child's resistance to eating: "Normally, if we hurry him to eat, he immediately says he's full, but after doing *tuina*, he says he wants more, and his food intake has increased" [Participant 59]. Additionally, some parents observed an improvement in their children's diet structure, with children becoming less picky and more willing to try new foods. A parent shared, "After the pediatric *tuina*, I felt he started eating meat...he even ate fish that he previously didn't eat" [Participant 1]. Improvements in gastrointestinal function were reported, with one parent noting a remarkable change: "His stools have clearly improved, previously they were like small pellets, similar to Maltesers...during the massage period, his stools became much more normal" [Participant 50]. Another parent highlighted the benefits of stomach massages: "I think massaging his stomach helped with bowel movements...his stomach is more relaxed now, it used to be tight, and his belly was cold before, now it's warm" [Participant 40].

XSL•FO
RenderX

Improvements in Children's Sleep

Parents also reported enhancements in their children's sleep quality and habits after pediatric *tuina*. Improved sleep quality was a common theme, with one parent describing their child's more stable sleep: "Before doing *tuina*, he used to sleep like a whirlwind, rolling from the head to the foot of the bed and back all night long, but now he's more stable and it's less frequent" [Participant 59]. Another parent mentioned a reduction in excessive sweating and sleep disturbances: "He usually sweats a lot while sleeping, even at 4 AM he still sweats, but after the *tuina*, he sweats less...also, he used to yell in his sleep, I had to wake him, about two or three times a week, but this has noticeably reduced now" [Participant 50]. Improved sleep habits, such as shortened time to fall asleep and the ability to sleep independently, were noted. A participant shared, "He sleeps more soundly now; previously, he had no sense of security and needed me to accompany him to sleep, but now, for example, after I massage him and turn off the lights, he is willing to sleep by himself, at least it's the first step" [Participant 40]. Another mom observed, "It takes him less time to fall asleep now; it used to take him two hours to fall asleep, but now it might only take half an hour" [Participant 59].

Improvements in Other Aspects of Children

Beyond eating and sleep, parents observed various other benefits of pediatric *tuina* on their children's behavior and overall well-being. Improvements in behavioral habits were frequently mentioned, with one parent noting a decrease in aggressive behavior: "I think he has fewer outbursts, and so do I...he used to hit people, very bad temper like a volcano...now I feel like he has fewer explosive moments" [Participant 12]. Enhancements in the children's mental state were reported, with one mom describing their child as more relaxed: "I think he's more relaxed, when I massage him, I ask if he likes it, if it hurts...he says he likes it, it's very comfortable...I think his emotions are more relaxed" [Participant 43]. Another parent noticed improved emotional expression: "Previously, he would get very angry if he didn't like what I said, but now he just says, 'Mom, I don't like it, I don't want you to say that,' expressing himself more gently" [Participant 13]. Improvements in attention and academic performance were highlighted by some parents, with one noting, "The homeroom teacher says he's doing okay, although he still gets easily distracted sometimes, but compared to last semester, he has made progress" [Participant 40]. Another parent observed remarkable academic improvements: "My son scored over 70 in listening in the first semester, but after doing *tuina*, he scored 95 in both Chinese and English exams at the end of March; I'm not sure if it had an effect, but I can see his attention has improved" [Participant 52]. Enhanced interpersonal relationships were reported, with one parent stating, "During the *tuina* process, the parent-child relationship improved, he likes to discuss math with his dad, using many methods to calculate, which helps his academics, he feels a sense of achievement, more confident, and even teaches friends how to calculate, and his relationship with classmates has improved" [Participant 15]. Physical conditions, such as bedwetting, rhinitis, weight, and height, were noted to have improved. One parent shared, "After the *tuina*, his nose is no longer as sensitive, it used to be really bad, I even thought about taking him to see a doctor" [Participant 52]. Another parent observed, "Her physical condition has really improved, he eats more, sleeps better, and her weight has increased...she gained a few pounds compared to last semester" [Participant 52]. Bedwetting was reported to have decreased, with one parent stating, "He used to wet the bed, but recently it has decreased" [Participant 43].

Parents' Experience of Performing Pediatric *Tuina*

Parents' experiences of administering pediatric *tuina* include three subthemes: (1) advantages of this intervention implementation, (2) difficulties encountered during implementation, and (3) parents' suggestions on improving the intervention.

Advantages of This Intervention Implementation

Parents highlighted several advantages of implementing pediatric *tuina* for their children. One notable advantage was the user-friendly course design, which many found to be appropriately challenging yet accessible. As one parent explained, "The Chinese medicine doctor starts by explaining things, we initially didn't know much about acupuncture points, but I think the course depth is suitable for us parents" [Participant 31]. Additionally, parents appreciated the professional guidance from instructors, with another parent noting, "I think they did a good job. A Chinese medicine PhD analyzed the problem, and then a *tuina* therapist taught the techniques and let me record videos. After filming, they explained the whole process, answered my questions directly, and didn't make it difficult to grasp. Later, they sent me the technique videos, which was great" [Participant 13]. The noninvasive nature of pediatric *tuina* was valued, with one parent stating that "(Pediatric *tuina*) is more natural and noninvasive, which is already very good" [Participant 1]. Furthermore, parents appreciated the customized diagnosis and treatment plans tailored to their children's specific needs. One parent shared, "The first time I came back to see the doctor, I described my child's situation, and the doctor added two acupuncture points, explaining that it was because of my child's current condition, which I found acceptable" [Participant 43]. Lastly, the satisfactory treatment effects were highlighted, with parents observing quick improvements in their children's overall well-being. As one parent noted, "I think pediatric *tuina* is effective for my child. At least his emotions improved, as well as his appetite, diet, growth, and digestion" [Participant 1]. Another parent remarked, "After two weeks, I noticed he slept better" [Participant 59], and another one observed, "In the first week, I felt he became more obedient and focused" [Participant 4].

Difficulties Encountered During Implementation

Despite the advantages, parents also encountered several difficulties during the implementation of pediatric *tuina*. One common challenge was the difficulty in operation, particularly in terms of knowledge, locating acupuncture points, and mastering techniques. As one parent expressed, "When actually performing the *tuina*, we were guessing. I felt uncertain about the position and pressure, and we were trying to imitate, so some areas were unclear, like using several fingers..." [Participant 43]. Another difficulty was gaining children's

XSL•FO
RenderX

cooperation, with one parent noting, “He found repeating the same thing boring and asked if there was anything else to do” [Participant 40]. Time management posed a considerable challenge for parents and children. One parent mentioned: “I was very busy myself and didn’t have the determination to schedule a specific time for the *tuina*” [Participant 13]. Another parent added, “If I felt it was too late or he was tired that day, I would do one or two techniques and then sleep” [Participant 40].

Parents’ Suggestions on Improving the Intervention

Parents suggested several improvements to enhance the implementation of parent-administered pediatric *tuina*. Increased guidance during practice and operation was a common request. One parent suggested, “It would be better if the doctor could watch the whole process of how I execute it from start to finish. We are beginners and may not notice if we are making mistakes” [Participant 43]. Another parent proposed: “I hope the doctor can check our techniques after a few weeks” [Participant 24]. The use of real-time supervision methods, such as electronic records or applications, was suggested to facilitate the process. As one parent noted, “The paper (logbook) could be converted to phone input, as *tuina* requires using olive oil, and the paper gets oily after filling it out” [Participant 50]. Another parent mentioned, “Using an app would save parents some effort. Besides recording if the points were done, it could also record the time, duration, and timely track the child’s weight, eating, bowel movements, and sleep” [Participant 31]. Parents also expressed a desire for an increased number of diagnostic sessions. One parent stated, “More TCM pattern diagnostic sessions would give us more confidence. Now it’s once every four weeks; if it were every two weeks, we’d feel more assured. Sometimes we are just blindly following instructions” [Participant 59]. Lastly, extended treatment and follow-up time were deemed necessary by some parents to observe long-term effects. As one parent remarked, “I think it needs more follow-up, a few months would be best. I genuinely want to see the long-term effects” [Participant 52].

Discussion

Main Findings

This study explored the effects and parental experiences of administering pediatric *tuina* to improve sleep and appetite in school-aged children with ADHD. This study is the first qualitative investigation into parent-administered pediatric *tuina* for addressing specific issues in children in Hong Kong. Insights from 12 parents were gathered using semistructured focus group interviews and individual interviews. The findings revealed 2 key themes: the effects of pediatric *tuina* on children and parents’ experiences with the intervention. Parents reported significant improvements in their children’s eating habits, sleep quality, and other areas such as behavior, mental state, and academic performance. They also highlighted advantages such as the user-friendly course design and professional guidance but noted challenges in mastering techniques and managing time. Parents suggested more guidance, real-time supervision, frequent diagnostic sessions, and extended follow-up to improve the intervention.

Comparison With Previous Studies

The findings of this study align well with a previous RCT on the effects of pediatric *tuina* for improving children’s sleep quality and habits, eating habits, behavioral regulation, emotional well-being, and parent-child relationship [29]. Improvements on children’s sleep quality and habits are consistent with the results of several previous studies examining the effects of pediatric *tuina* on sleep disturbance [43,44] or sleep problems in populations with different conditions such as bronchitis [45] and pneumonia [46]. The enhancements in eating habits reported by parents are in line with findings from a systematic review of pediatric *tuina* for anorexia in children on 28 RCTs [17]. In this study, a meta-analysis based on 9 RCTs indicated that pediatric *tuina* was superior to Western medicine (mean difference: −0.88, 95% CI −1.27 to −0.5) and Chinese herbs (mean difference: −0.69, 95% CI −1 to −0.38) in terms of improving food intake, suggesting that pediatric *tuina* could be an effective intervention for children with eating difficulties. The improvements in behavioral regulation and emotional well-being noted in this study mirror those documented in research on other pediatric massage therapies. Previous studies have found that children receiving massage therapy exhibit lessened behavioral outbursts, improved self-regulation, enhanced emotional regulation, reduced anxiety, and improved mood [47,48]. Moreover, the findings regarding the enhancement of parent-child relationships resonate with previous research emphasizing the importance of parental involvement in therapeutic outcomes. Studies on parent-involved therapies, such as cognitive behavioral therapy for children with ADHD, have shown that active parental participation is crucial for achieving effective outcomes [49,50]. Parent-administered pediatric *tuina* increases quality time spent between parents and children, thus fostering closer bonds, enhanced communication, and a sense of security. This engagement is similar to the benefits seen in cognitive behavioral therapy, where parental involvement plays a critical role in the success of the intervention.

The findings reveal notable inconsistencies with previous research focused on the effects of parent-administered pediatric *tuina* on children’s attention. While a prior qualitative study on exploring the effects of parent-administered pediatric *tuina* on ADHD in preschool children conducted in Mainland China reported that almost all parents who participated reflected that pediatric *tuina* had minimal effect on improving attention in their children [51], this study reveals considerable improvements in children’s attention and academic performance based on the description from several parents. The possible explanation may be attributed to the context (eg, culture and intervention implementation) and population differences between the two studies. In this study, the participants are school-aged children who may be more responsive to physical touch due to their developmental stage [52] and the academic demands [53] they face, which could enhance the effect of improved attention on academic performance. Additionally, cultural factors in Hong Kong, such as parental involvement and parental warmth in education, may have contributed to the more pronounced effects observed in this study [54]. Besides, the face-to-face TCM pattern diagnosis and parent training of this study may be more

XSL•FO
RenderX

accurate than the web-based intervention implementation mode of the previous study, thereby generating more satisfactory effects on children's attention. These inconsistencies underscore the need for further research to explore the contextual factors that influence the implementation of pediatric *tuina* across different populations and developmental stages.

One unanticipated finding was that pediatric *tuina* produced remarkably fast-acting benefits across various health outcomes, as reported by parents. For instance, one parent observed that their child's sleep quality improved noticeably after just 2 weeks of treatment. Another parent noted that their child's weight, which had been stagnant at 16 or 17 kg for a year, increased rapidly to 18 kg after 4 weeks of pediatric *tuina* therapy. Additionally, another parent observed considerable behavioral changes within the first week, noting that their child became more obedient and focused. Possible explanations for the fast-onset of pediatric *tuina* relate to the young age of participants and the underlying effect theory of pediatric *tuina*. According to the TCM theory, children, particularly those under 6 years of age, are more responsive to sensory stimuli due to their more sensitive organs [23], making them more receptive to external manipulations. This heightened sensitivity potentially allows the effects of pediatric *tuina* to activate the body's self-healing mechanisms quickly [55]. The concentration of pediatric *tuina* acupoints in areas rich in sensory receptors, such as the palms and head, enables effective stimulation of these receptors, thereby initiating quick physiological responses [56]. Furthermore, the specific manipulations used in pediatric *tuina*, such as pressing and rubbing, provide varied sensory stimuli that are rapidly processed by the nervous system, leading to swift improvements in the body [26]. While previous research has primarily focused on the targeted outcomes of pediatric *tuina*, the findings of this study offer new insights into the onset speed of these benefits, challenging the common perception that TCM interventions are primarily suited for chronic conditions and work slowly.

Implications

The findings have remarkable implications for several key stakeholders. For pediatricians, the integration of pediatric *tuina* into conventional ADHD treatment protocols is recommended, particularly for managing common comorbidities such as sleep and eating disorders in young children. For TCM practitioners, developing systematic training programs for parents to administer pediatric *tuina* effectively at home is meaningful for extending the benefits of this therapy beyond clinical settings and addressing a broader range of pediatric conditions. For researchers focusing on parent-administered pediatric *tuina*, future clinical trials should aim to enhance the guidance provided during practice, which can be achieved by developing real-time supervision methods, increasing the frequency of diagnostic sessions, and extending the treatment and follow-up periods. Besides, future research should consider triangulating qualitative findings with quantitative data to enhance the robustness and applicability of the study results.

Limitations

The limitations of this qualitative study should be acknowledged. First, the mixed-method approach, incorporating individual interviews and focus group interviews, was necessitated by time management barriers faced by participants. While this approach allowed great flexibility and participation, it may have introduced variations in the depth and breadth of data collected, potentially affecting the consistency and comparability of the findings. Second, the study was geographically limited to Hong Kong, which may have restricted the generalizability of the results to other populations and cultural contexts. The unique cultural and health care practices in Hong Kong could have influenced parents' perceptions and experiences, potentially differing considerably from those in other regions. Third, only participants who were willing to attend and had completed the intervention period were included, which may have excluded the perspectives of those who declined to participate in the interviews and may have expressed more negative views.

Conclusion

The findings reveal that parent-administered pediatric *tuina* considerably improved children's sleep quality, appetite, behavioral habits, mental state, and academic performance. Parents appreciated the professional guidance and user-friendly course design, which facilitated the intervention's implementation. However, challenges included difficulties in mastering techniques, locating acupuncture points, and managing time. Parents expressed the need for more frequent diagnostic sessions, real-time supervision, and extended follow-up to observe the long-term effects. Future research should address these challenges and consider integrating qualitative findings with quantitative data to enhance the robustness and applicability of the results.

Acknowledgments

This research was supported by a grant from the Chinese Medicine Development Fund (22B2/023A_R1). We wish to thank all participants for their help with this study.

Authors' Contributions

Conceptualization: SCC
Data curation: KCL, HL
Formal analysis: KCL, HL, WFY
Methodology: WFY
Writing – original draft: SCC
Writing – review & editing: PMW, LYP, JQ, WFY

XSL•FO
RenderX

Conflicts of Interest

None declared.

References

1. Diagnostic and Statistical Manual of Mental Disorders, 5th edition: American Psychiatric Association Publishing; 2013. [doi: 10.1176/appi.books.9780890425596]
2. Polanczyk G, de Lima MS, Horta BL, Biederman J, Rohde LA. The worldwide prevalence of ADHD: a systematic review and metaregression analysis. Am J Psychiatry 2007 Jun;164(6):942-948. [doi: 10.1176/ajp.2007.164.6.942] [Medline: 17541055]
3. Pliszka S, AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry 2007 Jul;46(7):894-921. [doi: 10.1097/chi.0b013e318054e724] [Medline: 17581453]
4. Gnanavel S, Sharma P, Kaushal P, Hussain S. Attention deficit hyperactivity disorder and comorbidity: a review of literature. World J Clin Cases 2019 Sep 6;7(17):2420-2426. [doi: 10.12998/wjcc.v7.i17.2420] [Medline: 31559278]
5. Cortese S, Faraone SV, Konofal E, Lecendreux M. Sleep in children with attention-deficit/hyperactivity disorder: meta-analysis of subjective and objective studies. J Am Acad Child Adolesc Psychiatry 2009 Sep;48(9):894-908. [doi: 10.1097/CHI.0b013e3181ac09c9] [Medline: 19625983]
6. Cortese S, Moreira-Maia CR, St Fleur D, Morcillo-Peñalver C, Rohde LA, Faraone SV. Association between ADHD and obesity: a systematic review and meta-analysis. Am J Psychiatry 2016 Jan;173(1):34-43. [doi: 10.1176/appi.ajp.2015.15020266] [Medline: 26315982]
7. Carter KA, Hathaway NE, Lettieri CF. Common sleep disorders in children. Am Fam Physician 2014 Mar 1;89(5):368-377. [Medline: 24695508]
8. Sciberras E, Heussler H, Berthier J, Lecendreux M. Epidemiology and etiology of medical sleep problems in ADHD. In: Sleep and ADHD: An Evidence-Based Guide to Assessment and Treatment: Elsevier; 2019:95-117. [doi: 10.1016/B978-0-12-814180-9.00004-1]
9. Leventakou V, Micali N, Georgiou V, et al. Is there an association between eating behaviour and attention-deficit/hyperactivity disorder symptoms in preschool children? J Child Psychol Psychiatry 2016 Jun;57(6):676-684. [doi: 10.1111/jcpp.12504] [Medline: 26706046]
10. Harris HA, Bowling A, Santos S, Greaves-Lord K, Jansen PW. Child ADHD and autistic traits, eating behaviours and weight: a population-based study. Pediatr Obes 2022 Nov;17(11):e12951. [doi: 10.1111/ijpo.12951] [Medline: 35751176]
11. Stueber A, Cuttler C. Self-reported effects of cannabis on ADHD symptoms, ADHD medication side effects, and ADHD-related executive dysfunction. J Atten Disord 2022 Apr;26(6):942-955. [doi: 10.1177/10870547211050949] [Medline: 34632827]
12. Zwi M, Jones H, Thorgaard C, York A, Dennis JA. Parent training interventions for attention deficit hyperactivity disorder (ADHD) in children aged 5 to 18 years. Cochrane Database Syst Rev 2011 Dec 7;2011(12):CD003018. [doi: 10.1002/14651858.CD003018.pub3] [Medline: 22161373]
13. Shao Y, Yu J. Pediatric Massage [Book in Chinese]: People's Medical Publishing Press; 2021.
14. Xing RW. Miraculous Pivot of Huangdi Neijing [Book in Chinese]: Huazhong University of Science and Technology Publishing House; 2017.
15. Yao Y, Zhao Y. Diseases spectrum study on pediatric tuina in recent 10 years. J Acupunct Tuina Sci 2012 Jun;10(3):181-184. [doi: 10.1007/s11726-012-0599-4]
16. Lu T, Yin L, Chen R, et al. Chinese pediatric tuina on children with acute diarrhea: a randomized sham-controlled trial. Health Qual Life Outcomes 2021 Jan 6;19(1):4. [doi: 10.1186/s12955-020-01636-1] [Medline: 33407547]
17. Liang SB, Lai BY, Cao HJ, et al. Pediatric tuina for the treatment of anorexia in children under 14 years: a systematic review and meta-analysis of randomized controlled trials. Complement Ther Med 2020 Jun;51:102411. [doi: 10.1016/j.ctim.2020.102411] [Medline: 32507428]
18. Chen SC, Ho YS, Kwai-Ping Suen L, et al. Traditional Chinese medicine (TCM) massage for the treatment of congenital muscular torticollis (CMT) in infants and children: a systematic review and meta-analysis. Complement Ther Clin Pract 2020 May;39:101112. [doi: 10.1016/j.ctcp.2020.101112] [Medline: 32379651]
19. Zhou XQ, Hu SP, Li YX. Clinical observation on 40 cases of functional constipation in children treated with pediatric massage. J Tradit Chin Pediatr 2020;16(4):93-95. [doi: 10.16840/j.issn1673-4297.2020.04.25.20]
20. Tong C, He Q, Ho M, Zhong ZH, Wu QB, Chen M. Tuina for enuresis in children: a systematic review and meta-analysis of randomized controlled trials. Front Public Health 2022;10:821781. [doi: 10.3389/fpubh.2022.821781] [Medline: 35493365]
21. Tao Z, Cao Z, Liu Q, et al. Tuina treatment for children and adults with functional dyspepsia: a meta-analysis and systematic review of randomized controlled trials. J Acupunct Tuina Sci 2023 Oct;21(5):413-426. [doi: 10.1007/s11726-023-1400-6]
22. Sun YJ, Li ZP. Clinical application of pediatric massage in child health care [Article in Chinese]. J Hubei Univ Sci Technol (Med Ed) 2021;35(3):241-243. [doi: 10.16751/j.cnki.2095-4646.2021.03.0241]

XSL•FO
RenderX

23. Chen SC, Fu QW, Zhang QX, Yeung WF. Getting to know the effect theory of traditional pediatric tuina in the view of modern medicine in three minor perspectives. Med Acupunct 2024 Aug;36(4):173-177. [doi: 10.1089/acu.2023.0105] [Medline: 39309623]
24. Davies KJA. Adaptive homeostasis. Mol Aspects Med 2016 Jun;49:1-7. [doi: 10.1016/j.mam.2016.04.007] [Medline: 27112802]
25. Tsigos C, Kyrou L, Kassi E, et al. Stress: Endocrine Physiology and Pathophysiology: MDText.com, Inc; 2020. [Medline: 25905226]
26. Homo-Delarche F, Dardenne M. The neuroendocrine-immune axis. Springer Semin Immunopathol 1993;14(3):221-238. [doi: 10.1007/BF00195975] [Medline: 8094904]
27. Wang LJ. Clinical efficacy of pediatric massage in the treatment of attention deficit hyperactivity disorder in children [Article in Chinese]. Appl Mod Med China 2020;14(11):202-204. [doi: 10.14164/j.cnki.cn11-5581/r.2020.11.094]
28. Chen SC, Yu BYM, Suen LKP, et al. Massage therapy for the treatment of attention deficit/hyperactivity disorder (ADHD) in children and adolescents: a systematic review and meta-analysis. Complement Ther Med 2019 Feb;42:389-399. [doi: 10.1016/j.ctim.2018.12.011] [Medline: 30670272]
29. Chen SC, Yu J, Wang HS, et al. Parent-administered pediatric tuina for attention deficit/hyperactivity disorder symptoms in preschool children: a pilot randomized controlled trial embedded with a process evaluation. Phytomedicine 2022 Jul 20;102:154191. [doi: 10.1016/j.phymed.2022.154191] [Medline: 35636174]
30. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007 Dec;19(6):349-357. [doi: 10.1093/intqhc/mzm042] [Medline: 17872937]
31. Ames H, Glenton C, Lewin S. Purposive sampling in a qualitative evidence synthesis: a worked example from a synthesis on parental perceptions of vaccination communication. BMC Med Res Methodol 2019 Jan 31;19(1):26. [doi: 10.1186/s12874-019-0665-4] [Medline: 30704402]
32. Halperin JM, Bédard ACV, Curchack-Lichtin JT. Preventive interventions for ADHD: a neurodevelopmental perspective. Neurotherapeutics 2012 Jul;9(3):531-541. [doi: 10.1007/s13311-012-0123-z] [Medline: 22692794]
33. Chen SC, Lin SL, Wang M, et al. Pediatric massage therapy in infants and children under 5 years: an umbrella review of systematic reviews. Heliyon 2024 Aug 30;10(16):e35993. [doi: 10.1016/j.heliyon.2024.e35993] [Medline: 39211929]
34. Brooks J, McCluskey S, Turley E, King N. The utility of template analysis in qualitative psychology research. Qual Res Psychol 2015 Apr 3;12(2):202-222. [doi: 10.1080/14780887.2014.955224] [Medline: 27499705]
35. King N. Template analysis. University of Huddersfield. URL: https://research.hud.ac.uk/research-subjects/human-health/template-analysis [accessed 2025-01-07]
36. Cassell C, Symon G. Qualitative Organizational Research: Core Methods and Current Challenges: SAGE Publications; 2012. [doi: 10.4135/9781526435620]
37. Kisorio LC, Langley GC. Intensive care nurses' experiences of end-of-life care. Intensive Crit Care Nurs 2016 Apr;33:30-38. [doi: 10.1016/j.iccn.2015.11.002] [Medline: 26791353]
38. Qazi A, Spector A, Orrell M. User, carer and staff perspectives on anxiety in dementia: a qualitative study. J Affect Disord 2010 Sep;125(1-3):295-300. [doi: 10.1016/j.jad.2009.12.015] [Medline: 20089310]
39. Forero R, Nahidi S, De Costa J, et al. Application of four-dimension criteria to assess rigour of qualitative research in emergency medicine. BMC Health Serv Res 2018 Feb 17;18(1):120. [doi: 10.1186/s12913-018-2915-2] [Medline: 29454350]
40. Lincoln YS, Guba EG. Naturalistic Inquiry: SAGE Publications; 1985.
41. Anderson G, Arsenault N. Fundamentals of Educational Research: Routledge; 2005. [doi: 10.4324/9780203978221]
42. Morse JM. Critical analysis of strategies for determining rigor in qualitative inquiry. Qual Health Res 2015 Sep;25(9):1212-1222. [doi: 10.1177/1049732315588501] [Medline: 26184336]
43. Huang CY, Wen L, Liu L, Li L, Xie CX, Gao B. Heart of pediatric massage five meridian method with clear and knead ridge therapy night terrors night to clinical research [In Chinese]. Sichuan TCM 2022;40(5):185-188. [doi: CNKI:SUN:SCZY.0.2022-05-055]
44. Zhang XH. Effect of pediatric massage on sleep disorders in infants and young children [Article in Chinese]. World J Sleep Med 2021;8(3):453-454. [doi: 10.3969/j.issn.2095-7130.2021.03.032]
45. Zhu Y. Effect of pediatric massage on children with adenoid hypertrophy and its effect on sleep quality of children [In Chinese]. Chin Med Abs (Otolaryngol Sci) 2021;36(1):33-35. [doi: 10.19617/j.issn1001-1307.2021.01.33]
46. Wu XL. Chinese massage combined with comprehensive care and improve sleep quality of children with bronchopneumonia effect observation [In Chinese]. World J Sleep Med 2022;9(12). [doi: CNKI:SUN:SMZZ.0.2022-12-016]
47. Field TM. Massage therapy effects. Am Psychol 1998 Dec;53(12):1270-1281. [doi: 10.1037//0003-066x.53.12.1270] [Medline: 9872050]
48. Field T. Massage therapy research review. Complement Ther Clin Pract 2016 Aug;24:19-31. [doi: 10.1016/j.ctcp.2016.04.005] [Medline: 27502797]
49. Lv B, Lv LJ, Yan ZL, Luo L. The relationship between parental involvement in education and children's academic/emotion profiles: a person-centered approach. Child Youth Serv Rev 2019 May;100:175-182. [doi: 10.1016/j.childyouth.2019.03.003]

XSL•FO
RenderX

50. Lee S, Dick BD, Jordan A, McMurtry CM. Psychological interventions for parents of youth with chronic pain: a scoping review. Clin J Pain 2021 Nov 1;37(11):825-844. [doi: 10.1097/AJP.0000000000000977] [Medline: 34475341]
51. Chen SC, Cheng HL, Wang DD, et al. Experience of parents in delivering pediatric tuina to children with symptoms of attention deficit hyperactivity disorder during the COVID-19 pandemic: qualitative findings from focus group interviews. BMC Complement Med Ther 2023 Feb 18;23(1):53. [doi: 10.1186/s12906-023-03891-3] [Medline: 36804041]
52. Hale GA, Lewis M. Attention and Cognitive Development: Springer Science & Business Media; 2012.
53. Chen JL. Grade-level differences: relations of parental, teacher and peer support to academic engagement and achievement among Hong Kong students. Sch Psychol Int 2008;29(2):183-198. [doi: 10.1177/0143034308090059]
54. Shelleby EC, Ogg J. Longitudinal relationships between parent involvement, parental warmth, ADHD symptoms, and reading achievement. J Atten Disord 2020 Mar;24(5):737-749. [doi: 10.1177/1087054719859075] [Medline: 31282242]
55. Arai KI, Lee F, Miyajima A, Miyatake S, Arai N, Yokota T. Cytokines: coordinators of immune and inflammatory responses. Annu Rev Biochem 1990;59:783-836. [doi: 10.1146/annurev.bi.59.070190.004031] [Medline: 1695833]
56. Marieb EN, Hoehn K. Human Anatomy & Physiology: Pearson; 2019.

Abbreviations

ADHD: attention-deficit/hyperactivity disorder
RCT: randomized controlled trial
TCM: traditional Chinese medicine

Edited by S Badawy; submitted 16.08.24; peer-reviewed by Z Lin; revised version received 22.11.24; accepted 28.11.24; published 30.01.25.

Please cite as:
Chen SC, Lo KC, Li H, Wong PM, Pang LY, Qin J, Yeung WF
Parental Experiences of Administering Pediatric Tuina for Sleep and Appetite in Early School-Aged Children With Attention-Deficit/Hyperactivity Disorder: Qualitative Study in Hong Kong
JMIR Pediatr Parent 2025;8:e65471
URL: https://pediatrics.jmir.org/2025/1/e65471
doi:10.2196/65471

© Shu-Cheng Chen, Kwai-Ching Lo, Han Li, Pong-Ming Wong, Lok-Yi Pang, Jing Qin, Wing-Fai Yeung. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 30.1.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Evaluating the Reach, Usage, Human Support Needs, and Clinical Outcomes of Digital Parent Training for Child Oppositional Defiant Disorder Before and During Wartime: Longitudinal Study

Amit Baumel[1], PhD; Or Brandes[1], MA; Chen R Saar[1], PhD

Department of Community Mental Health, University of Haifa, Haifa, Israel

Corresponding Author:
Amit Baumel, PhD
Department of Community Mental Health
University of Haifa
Abba Khoushy Ave 199
Haifa, 3498838
Israel
Phone: 972 48288496
Fax: 972 48288723
Email: abaumel@univ.haifa.ac.il

Abstract

Background: Digital parent training programs (DPTs) have emerged as a scalable solution for treating childhood oppositional defiant disorder (ODD), offering remote access and reduced barriers to care. However, there is limited data on their potential to reach untreated populations and their effectiveness during times of crisis, such as war.

Objective: This study aimed to evaluate the reach, usage patterns, human support needs, and clinical outcomes of a fully remote guided DPT for child ODD, comparing 2 cohorts treated before and during wartime in Israel.

Methods: Parents of children with ODD were enrolled in a human-supported DPT, with 25 families recruited before and 30 during wartime. Data included self-reported questionnaires (measured before-, postintervention, and 3 months after the end of the intervention), platform usage metrics, and clinician assessments.

Results: Most families (62%, 34/55) had not previously received any intervention for their child's behavior problems. Significant self-reported improvements in child behavior (Cohen $d \geq 0.79$) and parenting practices ($0.39 \leq$ Cohen $d \leq 0.87$) were found post intervention. On average, families engaged with the program for 138.6 minutes across 31.4 unique logins, supported by 38.8 minutes of human interaction, primarily via messaging. During wartime, parents completed onboarding significantly faster (15.70 days vs 31.36 days) and were more likely to complete the critical "overcoming disobedience" phase (27/30, 90% vs 17/25, 68%). However, while self-reported changes were similar, clinician-rated recovery from ODD was marginally lower during wartime (13/30, 43% vs 17/25, 68%).

Conclusions: DPTs present an acceptable avenue for care that could reach parents who have not sought treatment through traditional channels. However, this study's results suggest that their clinical effectiveness may be lower under extreme stress conditions such as wartime, underscoring the need for future studies in this area.

(JMIR Pediatr Parent 2025;8:e80420) doi:10.2196/80420

KEYWORDS

parent training; crisis; behavior problems; usage; oppositional defiant disorder; wartime; digital health

Introduction

Oppositional defiant disorder (ODD) is among the most prevalent types of mental disorders affecting young children, and it is crucial to treat it at an early onset [1]. However, the provision of child mental health services is limited [2]. In Israel, the wait times for publicly administered face-to-face mental health interventions are very long, with an ongoing gap between supply and demand that is not easily closed [3]. To address barriers related to service delivery in the treatment of behavior problems, digital parent training programs (DPTs) aimed at treating childhood disruptive behaviors have emerged over the last decade [4-6]. These interventions have demonstrated efficacy in meta-analyses [7-9], with trials reporting at least

XSL•FO
RenderX

moderate effect size improvements in child behaviors for guided DPTs (Cohen *d*>0.50) [7,9,10].

Although DPTs appear to offer a feasible way to increase access to care, it is unclear the extent to which these interventions reduce the mental health treatment gap by reaching parents who have not previously sought treatment for their child's condition. Furthermore, it is uncertain how much human support is needed as an adjunct to DPT usage, especially when the program's design incorporates automated features that potentially reduce the need for human support. Our own study of DPTs for child behavior problems showed that, compared to a standard format, an enhanced intervention in terms of its design increased user engagement (2.5 times higher completion rate) and program efficacy in reducing child behavior problems (Cohen *d*=0.43-0.54) in a self-guided condition [11]. However, the degree of human support required when deploying such interventions remains unclear.

In addition, this study began before the war in Israel (which began on October 7, 2023) and continued during wartime. This unexpected war resulted in a deterioration in mental health and a profound need for mental health support for the whole population [12]. For this reason, we sought to use our data to answer questions relating to the impact of a conflict setting on the acceptability and effectiveness of DPTs. There is a significant gap in the literature, with very limited evidence on whether the use of digital mental health interventions for child routine care differs under conditions of war. A notable study examined enrollment and completion rates of a nationwide guided DPT for children with disruptive behavior before and during the COVID-19 pandemic [13]. In the study, program enrollment did not change significantly under COVID-19 restrictions, while the completion rate actually increased. It remains unclear whether the usage of guided DPTs for child behavior problems increases during wartime, as observed during COVID-19, and what their effectiveness is in terms of clinical outcomes, an area that is yet to be explored.

The main aim of this study was to evaluate the potential deployment of a DPT for child behavior problems as a scalable form of care. In particular, our study (1) examined the extent to which a remote onboarding procedure, including reaching people through social media, could reach parents who had not previously sought treatment for the relevant condition; (2) evaluated the timeline of remotely administered onboarding process, which included contact with a clinician; (3) evaluated the DPT's usage patterns, human support, and effectiveness; and (4) assessed differences in reach, usage, and efficacy in the context of war, which began halfway through the study's deployment.

Methods

Participants and Recruitment Procedure

Eligibility

Parents were eligible to participate if they met the eligibility criteria (see Textbox 1).

Textbox 1. Eligibility criteria.

Inclusion criteria:

- Parents had a child between the ages of 3 and 7 years with an elevated level of behavior problems based on the Eyberg Child Behavior Inventory (ECBI; ECBI problem≥15 and ECBI intensity≥132) [14].
- The behavior problems described by the parents in an interview conducted by a licensed clinician met the criteria for oppositional defiant disorder.
- They had access to a smartphone device and a personal computer with an internet connection.

Exclusion criteria:

- Their child was taking medication or was in regular contact with a professional for behavioral or emotional problems.
- They were currently accessing parenting support elsewhere.
- Their child had been diagnosed with an intellectual disability or developmental delay.

Recruitment Procedure

Parents were recruited for the study from January 1, 2023, to January 10, 2024, through Facebook advertising, a method previously shown to reach broad and diverse populations across socioeconomic backgrounds in ways comparable to traditional recruitment approaches [15]. Because the program and all study materials were provided in Hebrew, the campaign specifically targeted Hebrew-speaking parents of children aged between 3 and 7 years, residing in Israel. There was a planned pause in recruitment between May 2023 and the beginning of October 2023 due to summer and holiday breaks in the education system. Recruitment was then delayed because the war began on October 7, 2023, which meant that the recruitment of the 2 cohorts (before and during wartime) took place during 2 consecutive school years.

Parents registered their interest in participation through the study home page, where they completed a brief eligibility screener as a first step. Screening, interest, and parents' understanding of the terms of the study were confirmed through a phone call with a research assistant, followed by a link to complete the informed consent online. Parents then participated in a remote assessment with an independent clinician (author OB). Eligible participants were then referred to complete the baseline assessment. Those who completed the assessment received login details to the intervention's platform, with complementary guidance from their assigned human supporter. Parents who were not eligible to participate were referred to

XSL•FO
RenderX

local services. No compensation was provided for participation, other than access to the intervention.

Benevolent Parenting Intervention

Multimedia Appendix 1 presents a comprehensive review of Benevolent Parenting DPT. The program is based on predefined decision rules that are either event- or time-based [16], meant to increase user engagement through effort optimization design [17] and therapeutic persuasiveness, which integrate behavior change techniques with persuasive design features specifically for digital delivery [18,19]. This framework complements the taxonomy of behavior change techniques [20] by emphasizing effective operationalization and delivery of techniques in-app (eg, prompts, self-monitoring, feedback, and adaptation), a distinction that is particularly important in digital interventions where technique presence without proper delivery yields limited impact. A self-directed version of the program has been shown in previous research to achieve a high therapeutic persuasiveness evaluation score (4.5/5) and high completion rates among parents [11].

The program incorporates common themes of evidence-based DPTs for childhood disruptive behaviors (eg, overcoming disobedience). Each theme in the program comprises a short 10-20 minute learning phase followed by a 1-2 week focusing phase. The focusing phase is designed to help the desired therapeutic activities become salient in the parents' minds and to help them acquire skills in a nonjudgmental manner, while avoiding the burden and potential failures that may be associated with the idea of "training." For that reason, the program incorporates the following features: (1) call to action: timely digital triggers related to the specific goals of the modules they have completed; (2) creation of salience through self-monitoring and ongoing feedback; and (3) adaptation to user state based on parents' reports, which are used to acknowledge their success and to suggest additional actions.

Human support followed a manual based on our previous work [21,22] and included: an initial message sent when parents first logged into the program, a message following the completion of each learning and focusing phase, contacting parents via the messaging platform if disengagement was identified, response to participant-initiated messages, and a phone conversation offered following the completion of the "overcoming disobedience" module to reinforce parental efforts during the subsequent focusing phase (see Multimedia Appendix 1 for a detailed review). The supporter used a dashboard that provided information on engagement markers and participants' progress.

Measures

Parents were assessed at 3 time points: before the intervention (baseline, T1), immediately after (postintervention, T2), and 3 months after the end of the intervention (follow-up, T3).

Self-Reported Measures

Child behavior problems were assessed using the Intensity and Problem subscales of the 36-item Eyberg Child Behavior Inventory (ECBI) [14,23,24] (α coefficients: ECBI Problems, α=.89 and ECBI Intensity, α=.91). Parental disciplinary behaviors in response to their child's misbehaviors were assessed using 2 Parenting Scale (PS) subscale scores—Overreactivity (11 items) and Laxness (10 items) [25] (α coefficient: Laxness, α=.90 and Overreactivity, α=.82). Task-specific self-efficacy was assessed using items taken from the Parenting Tasks Checklist (PTC) Setting Self-efficacy (six statements) and Behavioral Self-efficacy (six statements) subscales [26] (coefficient : PTC Setting, 0.85; PTC Behavioral, 0.96). Positive parenting practices were assessed using the Alabama Parenting Questionnaire (APQ) Positive Parenting Practices subscale (six items) [27] (coefficient =0.79).

Clinician Assessment of ODD

A structured interview was conducted with the parents, administered by a licensed clinician (clinical child psychologist) at T1 and T2 using a secure online video connection. The clinician was trained by the study's principal investigator (a licensed clinical psychologist with expertise in treating children and their parents) on the interview protocol. The clinician confirmed with the parents that no exclusion criteria were met (at T1) and examined whether the child met the criteria for ODD. To do so, the clinician addressed and documented the child's symptoms of ODD (according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition) reported by the parents (at T1 and T2), following Pelham and colleagues' [28,29] paradigm that demonstrated sufficient internal reliability and validity. Any questions regarding the symptoms of ODD that arose in specific cases were discussed with the study's principal investigator before making a final decision.

Program Usage and Completion Rate

Measures of program usage included the number of login days, unique logins, and total time of use. We also recorded the percentage of people completing the "overcoming disobedience" module, which was deemed the main obligatory component in the intervention, and the percentage of program completion. The metrics of human support documented during the intervention delivery were message content, the occurrence of phone calls, and the time spent during each supportive contact (including the time to take notes).

Statistical Analyses

Demographic, usage, and clinical characteristics are reported as frequencies and percentages for categorical variables, and as mean (SD) for continuous variables. Differences between the 2 study cohorts were calculated using Mann-Whitney *U* tests for continuous variables and chi-square tests for categorical variables (due to sample size limitations). Pre-post differences in outcomes over time were calculated using dependent-sample 1-tailed *t* tests for the total sample and Wilcoxon signed-rank tests within each cohort (pre- and during-wartime) to reduce reliance on normality assumptions given the modest and unequal subgroup sizes. Effect size estimates included Cohen *d* for *t* tests, the Crammer *V* for chi-square tests, and *r* for Mann–Whitney *U* and Wilcoxon tests (calculated based on the *z* value from the test divided by the total number of observations).

We determined the study sample size based on the total participant population, as we had not planned to divide the sample into 2 groups according to wartime conditions. Data on

XSL•FO
RenderX

guided DPTs aimed at treating children at the *clinical* range of behavior problem symptoms point to at least moderate effect size improvement in child behavior problems (eg, child behavior problems: Cohen *d*>0.50, intent-to-treat analyses) [7,9,10]. Even when taking the lower end of this spectrum (an estimated effect size of 0.50), a sample size of 50 participants provides 0.96 power (1-tailed α=.05) to detect significant differences in the continuous variables.

We conducted intent-to-treat analyses for all reported clinical outcomes at postintervention time points. Multiple imputations (5 sets) were generated using predictive mean matching as the imputation. Sensitivity analysis was performed, showing that the statistical test results from complete case analyses were similar to the imputed analyses (completer analyses are presented in Multimedia Appendices 2 and 3). All analyses were performed using SPSS (version 27; IBM Corp).

Ethical Considerations

The study was approved by the institutional review board (ethics committee) of the University of Haifa (342/22). Screening, interest, and parents' understanding of the terms of the study were confirmed through a phone call with a research assistant, followed by a link to complete the informed consent online. Parents who were not eligible to participate were referred to local services. No compensation was provided for participation, other than access to the intervention.

Results

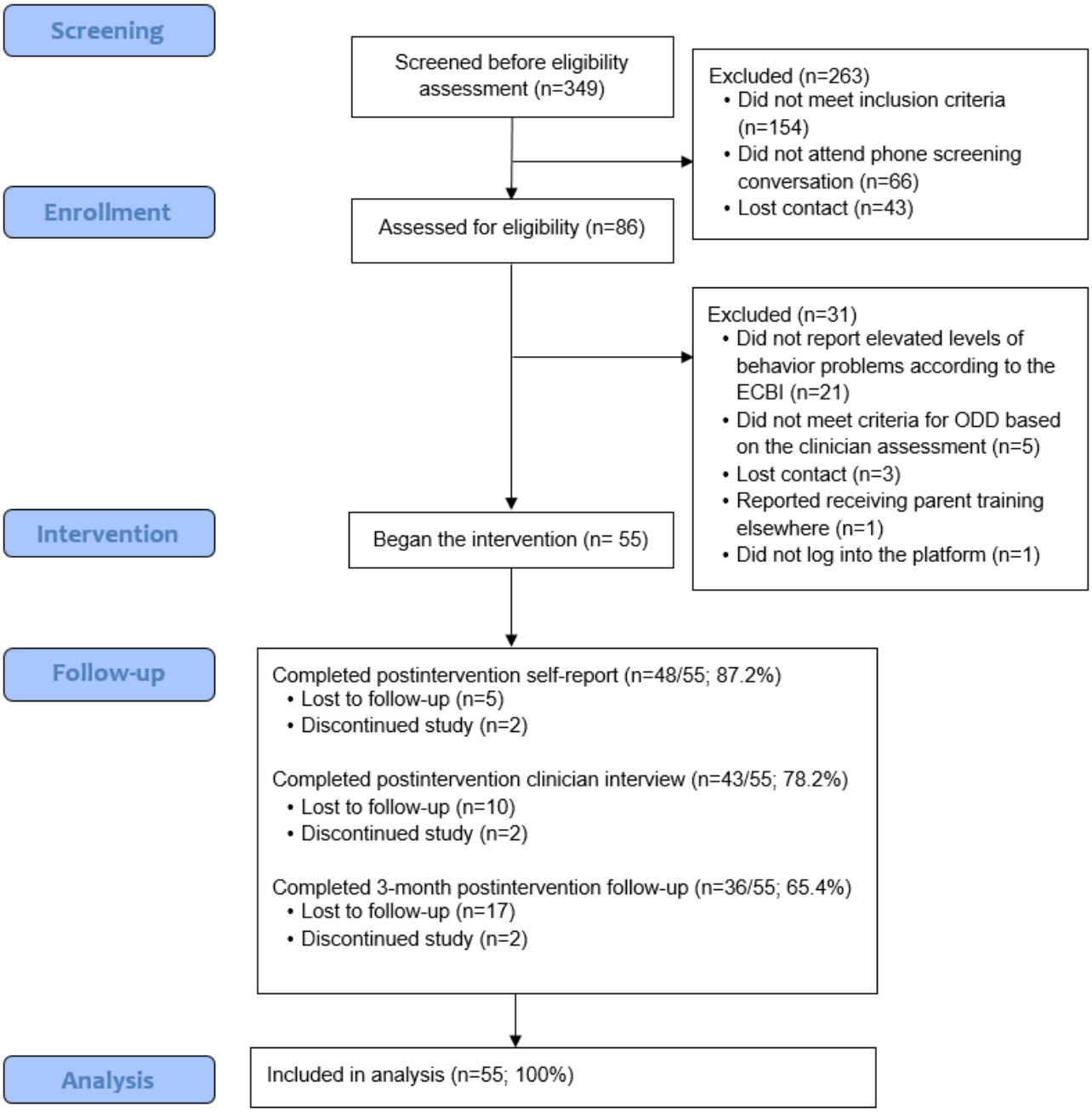
The participant flow diagram is presented in Figure 1, and participant demographics are presented in Table 1. Overall, parents from 55 families with children with ODD enrolled in the study and began the intervention. Among them, 25/55 (46%) families began the intervention and completed their postintervention assessment before wartime, while the remaining 30/55 (54%) began the intervention and completed their postintervention assessment during wartime. The mean age of the children at the beginning of the intervention was 5.33 (SD 1.14) years, and 32/55 (58%) children were boys. The leading parent in all families was the mother, whose mean age was 36.7 (SD 3.54) years. No differences in demographic variables were identified based on intervention cohorts.

Parents in 34/55 families (62%) reported that this was the first intervention they had received for their child's behavior problems. A chi-square test revealed a significant difference between those receiving the intervention for the first time and the rest of the sample in terms of religiosity (secular vs more religious; χ^2_1=4.34; *P*=.04). Among secular families, 14/27 (52%) reported that this was the first intervention they had received for their child's behavioral problems, whereas among traditional or religious families, 22/28 (79%) reported the same. No other differences in demographic or outcome variables were found between these two categories.

It took parents 22.82 (SD 15.80) days on average to complete their onboarding procedure and begin the intervention. There was a significant difference in the time it took parents to begin the intervention based on study cohorts (*P*≤.004; ie, *P*=.004, *P*=.002, and *P*<.001). Specifically, during wartime, it took parents half the time (15.70 days) to begin the intervention than it did before wartime (31.36 days).

XSL•FO
RenderX

Figure 1. Flow of participants through the trial. ECBI Eyberg Child Behavior Inventory; ODD: oppositional defiant disorder.



XSL•FO
RenderX

Table 1. Participant demographic characteristics and onboarding time.

	Total sample (N=55)	Before wartime (N=25)	During wartime (N=30)	Difference	
				Chi-square (*df*) or *Z*[a]	*P* value
Categorical variables, n (%)					
Sex of the child				0.09 (1)[b]	.76
Male	32 (58)	14 (56)	18 (60)		
Female	23 (42)	11 (44)	12 (40)		
Sex of the leading parent				N/A[c]	N/A
Female	55 (100)	25 (100)	30 (100)		
Who participates				0.74 (1)[b]	.39
Both parents	34 (62)	17 (68)	17 (57)		
One parent	21 (38)	8 (32)	13 (43)		
Family structure[d]				N/A	N/A
Single	1(3)	0 (0)	1 (3)		
Married	31 (84)	5 (71)	26 (87)		
Cohabiting	3 (8)	1 (14)	2 (7)		
Divorced	2 (5)	1 (14)	1 (3)		
Widowed	0 (0)	0 (0)	0 (0)		
Education[e]				0.10 (1)[b]	.75
High school	10 (18)	5 (20)	5 (17)		
Above	45 (82)	20 (80)	25 (83)		
House-level income[f]				1.79 (2)[b]	.40
<15,000	13 (24)	8 (32)	5 (17)		
15,000-18,000	12 (22)	5 (20)	7 (23)		
>18,000	30 (56)	12 (48)	18 (60)		
Religiosity				2.86 (2)[b]	.24
Secular	27 (49)	13 (52)	14 (47)		
Traditional	16 (29)	9 (36)	7 (23)		
Religious	12 (22)	3 (12)	9 (30)		
Weekly working hours[e]				1.14 (3)[b]	.76
Under 10	12 (22)	5 (20)	7 (23)		
10-29	7 (13)	3 (12)	3 (12)		
30-39	18 (33)	7 (28)	11 (37)		
More than 39	18 (33)	10 (40)	8 (27)		
First intervention[g]				0.87 (1)[b]	.35
Yes	36 (66)	18 (72)	18 (60)		
No	19 (35)	7 (28)	12 (40)		
Continuous variables, mean (SD)					
Parent age (years)[e]	36.70 (3.54)	36.64 (3.30)	36.74 (3.78)	–0.43[a]	.67
Child age (years)	5.33 (1.14)	5.29 (1.04)	5.36 (1.24)	–0.26[a]	.79

XSL•FO
RenderX

	Total sample (N=55)	Before wartime (N=25)	During wartime (N=30)	Difference	
				Chi-square (*df*) or *Z*[a]	*P* value
Number of children in family	2.60 (.99)	2.80 (1.15)	2.40 (.81)	–1.46[a]	.14
Onboarding process					
Time from screening to intake completion (days)	20.07 (13.38)	26.48 (16.67)	14.73 (6.20)	–2.89[a]	.004[h]
Time from intake completion to first login (days)	2.74 (4.99)	4.88 (6.62)	0.97 (1.65)	–3.07[a]	.002[h]
Total time from screening to first login (days)	22.82 (15.80)	31.36 (17.33)	15.70 (6.62)	–3.53[a]	<.001[h]

[a]The calculated standardized value (*Z*) of the Mann-Whitney *U* test.

[b]Chi-square test.

[c]N/A: not applicable.

[d]This question was accidentally not presented to the first 18 participants in the first cohort, and for this reason, we did not statistically examine the differences between the 2 cohorts in terms of this variable.

[e]Refers to the parent leading the intervention.

[f]In Israeli shekels (1 shekel was approximately US $3.8 at the time of the study).

[g]This was the first intervention the parents had received with the target of treating their child's behavioral problems.

[h]Significant results.

Program Usage and Completion

Program usage and completion rates are presented in Table 2. The mean time to complete the program was 12.34 (SD 5.18) weeks and included an average usage time of 138.6 (SD 63.41) minutes. Altogether, parents from 44/55 families (80%) completed the "overcoming disobedience" theme, and parents from 35/55 families (64%) completed the whole intervention. The total human support time invested on average per family was 38.81 (SD 35.32) minutes, most of which was spent on text messaging (mean time 30.2, SD 29.9 minutes).

Parents who completed the interventions during wartime logged into the program on significantly more days (r=.28; P=.04), and significantly more of them completed the "overcoming disobedience" theme (Cramer V=.27; P=.04). Parents from this cohort also received more messages from the human supporter (Cramer V=.28; P=.04). It is important to note that, during wartime, parental usage was higher on all metrics (eg, 70%, 21/30 program completers compared to 56%, 14/25 in the cohort before the war), although the results did not reach the level of statistical significance.

XSL•FO
RenderX

Table 2. Program completion and usage metrics.

Program usage	Total sample (N=55)	Before wartime (N=25)	During wartime (N=30)	Difference		
				$\chi^2(df)$ or Z[a]	Cramer V or r[b]	P value
Categorical variable, n (%)						
"Overcoming disobedience" theme completers	44 (80)	17 (68)	27 (90)	4.12 (1)[c]	0.27[d]	.04[e]
Program completers	35 (63.6)	14 (56)	21 (70)	1.16 (1)[c]	0.14[d]	.28
Continuous variables, mean (SD)						
Number of login days	27.7 (12.73)	23.88 (13.11)	30.83 (11.70)	–2.07[a]	0.28[b]	.04[e]
Unique logins	31.4 (14.64)	28.20 (16.11)	34.03 (12.97)	–1.43[a]	0.19[b]	.15
Usage time (minutes)	138.6 (63.41)	120.28 (66.84)	148.30 (59.42)	–1.16[a]	0.16[b]	.24
Time using the program (weeks)	12.35 (5.18)	11.70 (6.38)	12.89 (3.96)	–1.24[a]	0.17[b]	.21
Human support, mean (SD)						
Messages sent by parents	5.90 (5.95)	6.12 (6.33)	5.67 (5.71)	–0.09[a]	0.01[b]	.93
Messages sent by the supporter	13.40 (4.93)	11.88 (4.80)	14.63 (4.77)	–2.07[a]	0.28[b]	.039[e]
Supporter time spent messaging (minutes)	30.20 (29.29)	35.44 (40.12)	25.87 (15.13)	–0.31[a]	0.04[b]	.75
Phone conversations	0.80 (0.92)	0.88 (1.09)	0.70 (0.75)	–0.28[a]	0.04[b]	.77
Supporter time spent in phone conversation (minutes)	8.60 (11.83)	8.84 (12.91)	8.40 (11.06)	–0.03[a]	0.004[b]	.97
Total human support time[f]	38.81 (35.32)	44.28 (48.17)	34.27 (18.83)	–0.13[a]	0.02[b]	.90

[a]The Z statistic in this table represents the calculated standardized value of the Mann-Whitney *U* test.

[b]Represents the respective effect size.

[c]Chi-square test.

[d]Cramer *V*.

[e]Significant results.

[f]Includes the time it took the supporter to write messages, document notes, and discuss cases with the supervisor.

Intervention Outcomes

Descriptive statistics and statistical differences in self-reported changes in child behaviors and parenting variables at postintervention and follow-up time points are presented in Table 3. Statistical differences in self-reported changes between the 2 cohorts are presented in Table 4. Significant improvements were found among all outcome variables postintervention (compared to baseline), with large effect size improvements in child behavior problems (ECBI Cohen *d*=0.79-0.83), medium to large effect size improvements in parenting styles (PS Cohen *d*=0.52-0.87), and medium effect size improvements in task-specific sense of efficacy (PTC Cohen *d*=0.57-0.65) and positive parenting practices (APQ Cohen *d*=0.39). Effects remained significant at follow-up time points for all outcome variables, with descriptively larger effect sizes than postintervention (eg, ECBI *Cohend*=1.02-1.10). No differences were found between the 2 cohorts in terms of self-reported variables.

Changes in cases not meeting the ODD criteria postintervention based on the clinician interviews are presented in Table 5. The impact of wartime on not meeting the criteria for ODD postintervention was found to be marginally significant (*P*=.07). In the prewartime cohort, 17/25 children (68%) did not meet the criteria for ODD following the intervention; during wartime, 13/30 children (43%) did not meet the criteria for ODD following the intervention.

XSL•FO
RenderX

Table 3. Descriptive statistics and differences in reported changes from baseline to postintervention and follow-up time points.

Measures	Baseline	Postintervention	Follow-up[a]	Baseline to postintervention			Baseline to follow-up		
				t test (*df*) or *Z*[b]	Cohen *d* or *r*[c]	*P* value	*t* test (*df*) or *Z*[b]	Cohen *d* or *r*[c]	*P* value
Total (N=55), mean (SD)									
ECBI[b] Intensity	164.16 (20.56)	138.75 (28.78)	132.88 (23.91)	6.12 (54)[e]	0.83[f]	<.001[g]	8.16 (54)	1.10	<.001[g]
ECBI Problems	23.96 (4.54)	17.40 (8.03)	15.89 (7.08)	5.83 (54)[e]	0.79[f]	<.001[g]	7.55 (54)	1.02	<.001[g]
PS[h] Laxness	3.45 (1.19)	2.96 (1.06)	2.76 (.74)	3.88 (54)[e]	0.52[f]	<.001[g]	4.62 (54)	0.62	<.001[g]
PS Overreactivity	3.55 (.68)	2.81 (1.00)	2.73 (.78)	6.43 (54)[e]	0.87[f]	<.001[g]	8.52 (54)	1.15	<.001[g]
PTC[i] Setting	64.33 (14.76)	75.92 (16.57)	78.32 (12.33)	–4.82 (54)[e]	–0.65[f]	<.001[g]	–6.07 (54)	–0.82	<.001[g]
PTC Behavioral	49.42 (24.11)	65.05 (22.88)	72.30 (15.51)	–4.20 (54)[e]	–0.57[f]	<.001[g]	–6.81 (54)	–0.92	<.001[g]
APQ[j]	4.30 (.45)	4.46 (.40)	4.45 (.32)	–2.86 (54)[e]	–0.39[f]	.006[g]	–2.69 (54)	–0.36	.01[g]
Before wartime (n=25), mean (SD)									
ECBI Intensity	165.08 (22.78)	136.39 (30.02)	129.02 (24.05)	–3.50	0.70	<.001[g]	–4.08	0.81	<.001[g]
ECBI Problems	23.40 (4.44)	17.09 (6.80)	14.48 (6.41)	–3.13	0.63	.002[g]	–3.84	0.70	<.001[g]
PS Laxness	3.36 (1.16)	2.81 (1.08)	2.64 (0.64)	–2.22	0.44	.03[g]	–2.52	0.50	.01[g]
PS Overreactivity	3.70 (0.65)	2.96 (1.07)	3.03 (0.73)	–3.34	0.67	<.001[g]	–3.47	0.69	<.001[g]
PTC Setting	64.30 (16.23)	75.03 (17.00)	78.40 (10.71)	–2.50	0.50	.01[g]	–3.54	0.70	<.001[g]
PTC Behavioral	44.72 (21.94)	65.92 (21.48)	72.08 (16.60)	–3.46	0.70	<.001[g]	–4.18	0.84	<.001[g]
APQ	4.43 (0.43)	4.48 (0.36)	4.50 (0.34)	–.87	0.17	.39	–.87	0.17	.39
During wartime (n=30), mean (SD)									
ECBI Intensity	163.40 (18.87)	140.72 (28.07)	136.10 (23.70)	–3.75	0.68	<.001[g]	–4.47	0.82	<.001[g]
ECBI Problems	24.43 (4.64)	17.65 (9.03)	17.07 (7.49)	–3.67	0.67	<.001[g]	–4.06	0.67	<.001[g]
PS Laxness	3.54 (1.22)	3.09 (1.05)	2.86 (0.80)	–2.60	0.47	.009[g]	–3.08	0.56	.002[g]
PS Overreactivity	3.43 (0.97)	2.69 (0.95)	2.46 (0.73)	–4.00	0.73	<.001[g]	–4.44	0.81	<.001[g]
PTC Setting	64.36 (13.70)	76.66 (16.46)	78.25 (13.72)	–2.95	0.54	.003[g]	–3.63	0.66	<.001[g]
PTC Behavioral	53.33 (25.31)	64.32 (24.31)	72.48 (14.82)	–1.91	0.35	.06	–3.22	0.59	.001[g]
APQ	4.20 (0.45)	4.43 (0.43)	4.40 (0.29)	–2.71	0.49	.007[g]	–2.21	0.40	.03[g]

[a]The 3-month postintervention follow-up.

[b]The *Z* statistic in this table represents the calculated standardized value of the Wilcoxon test.

[c]Represents the respective effect size.

[d]ECBI: Eyberg Child Behavior Inventory.

[e]*t* test.

[f]Cohen d.

[g]Significant results.

[h]PS: Parenting Scale.

[i]PTC Behavioral: Parenting Tasks Checklist.

XSL•FO
RenderX

[j]APQ: Alabama Parenting Questionnaire, Positive Parenting Practices Subscale.

Table 4. Statistical differences in reported changes between the 2 cohorts.

Measures	Baseline: postreported change					Baseline: follow-up–reported change				
	Before wartime (n=25)	During wartime (n=30)	Differences			Before wartime (n=25)	During wartime (n=30)	Differences		
	Mean (SD)	Mean (SD)	*Z* [a]	*r*	*P* value	Mean (SD)	Mean (SD)	*Z*	*r*	*P* value
ECBI[b] Intensity	–28.70 (32.43)	–22.68 (29.61)	–.84	.11	.40	–36.06 (29.27)	–27.30 (27.59)	–1.43	.19	.15
ECBI Problems	–6.31 (7.82)	–6.78 (8.89)	–.33	.04	.74	–8.91 (7.62)	–7.36 (8.24)	–1.23	.17	.22
PS[c] Laxness	–.54 (.95)	–.46 (.83)	–.19	.03	.85	–.71 (1.22)	–.68 (1.04)	–.042	.06	.97
PS Overreactivity	–.74 (1.09)	–.74 (.77)	–.21	.03	.83	–.66 (.70)	–.97 (.72)	–1.31	.18	.19
PTC[d] Setting	10.72 (18.24)	12.30 (17.72)	–.51	.07	.61	14.09 (15.83)	13.89 (18.31)	–.41	.06	.69
PTC Behavioral	21.20 (22.28)	10.98 (30.85)	–1.45	.20	.15	27.30 (21.79)	19.14 (27.03)	–1.36	.18	.17
APQ[e]	.06 (.36)	.24 (.41)	–1.41	.19	.16	.08 (.35)	.21 (.45)	–1.36	.18	.17

[a]The Z statistic in this table represents the calculated standardized value of the Wilcoxon test (*r* represents the respective effect size).

[b]ECBI: Eyberg Child Behavior Inventory.

[c]PS: Parenting Scale.

[d]PTC Behavioral: Parenting Tasks Checklist.

[e]APQ: Alabama Parenting Questionnaire, Positive Parenting Practices Subscale.

Table 5. Postintervention changes in meeting oppositional defiant disorder criteria based on clinician assessment.

Cohort	Number of symptoms preintervention	Number of symptoms postintervention	Cases not meeting ODD[a] criteria postintervention	Difference between the cohorts in the ODD criteria change	
	Mean (SD)	Mean (SD)	n (%)	Chi-square (*df*)	*P* value
Total (N=55)	5.20 (.99)	3.04 (1.87)	30 (55)	3.35 (1)	.07
Before wartime (n=25)	5.24 (1.20)	2.52 (1.54)	17 (68)		
During wartime (n=30)	5.17 (.80)	3.47 (2.03)	13 (43)		

[a]ODD: oppositional defiant disorder

Discussion

Principal Findings

This study found that the DPT primarily reached parents who had not received care for the current condition. The demographic characteristics of our sample, particularly regarding education, income, and religiosity, were comparable to national data for parents in Israel, supporting the representativeness of the study population [30-32]. In addition, the DPT was found to be effective at reducing child behavior problems and improving parenting-related variables. Differences were identified between the study cohorts based on the context of war in the region.

This study found that the remote recruitment procedure was successful at reaching mostly parents who had never received an intervention for their child's ODD (34/55, 62%). This finding aligns with broader research showing that digital and remote mental health interventions can indeed increase access and reach new people in need, or earlier in the prodromal process [33,34]. It is important to note that this study also found that we were able to reach more families for the first time (22/28, 79%) if they were nonsecular. It could be that, in Israel, secular families are more likely to seek psychological services independently, but this needs to be further examined in future studies.

In terms of program usage, most parents (44/55, 80%) completed the "overcoming disobedience" theme, the most important skill area in the program. Parents also used the program for more than 2 hours (138.6 minutes) on average, scattered across multiple sessions (a total of 31.4 unique logins). This pattern of use differs completely from that of therapist-led parent training, which is based on a much smaller number of sessions, each lasting 40-50 minutes [35]. It could be that this pattern of use (ie, in small pockets of available time) is more relevant to parents who decide to use digital interventions to self-manage their child's state. The total human support time spent during this program was quite small (an average of 38.81 minutes), with parents preferring to message the supporter rather than engage in phone conversations. It is worth noting that studies in which support is primarily provided through phone calls have reported a higher level of human support (eg, [10,36]). It would be interesting to further investigate the extent to which parents

XSL•FO
RenderX

prefer phone calls when text messaging is available and how this choice influences the outcomes.

In terms of wartime impact, the results showed that, during wartime, parents completed their onboarding process in half the time it took before the war. Parents also used the program more extensively, with 90% (27/30) completing the "overcoming disobedience" skill acquisition phase and logging into the program 7 more days than the cohort participating before wartime. The greater volume of supporter messages observed during wartime is best interpreted as a protocol-triggered outreach message based on a higher share of parents reaching key phases in the program (eg, "overcoming disobedience"); notably, parent-initiated messages were similar across cohorts, and total support time did not differ. This usage pattern fits with the patterns described by Sakari et al [13] in comparing the use of a DPT before and during the COVID-19 pandemic. That report indicated that program completion rates actually increased during the COVID-19 epidemic. It is plausible that the growing need for support during times of crisis is manifested in increased use of the digital intervention. However, while our findings indicated comparable improvements based on parental self-reports, our study revealed a close to significant difference between the 2 cohorts in the percentage of children not meeting the criteria for ODD post intervention based on clinician assessment (13/30, 43% recovered during wartime vs 17/25, 68% before the war). Although this is only a marginally significant result, it suggests a potential trend toward an effect, mainly because of the descriptively large difference in percentages of children meeting the ODD criteria.

Research has indicated that environmental stressors, such as those present during wartime, can significantly affect the efficacy of mental health interventions. For instance, studies have shown that ongoing stress and trauma can complicate the treatment process (eg, [37]). Supporting this notion, during the war that began on October 7, 2023, a study examined the prevalence of mental illness and reported prevalence rates of generalized anxiety disorder and depression of over 42% in an Israeli representative sample [12]. In our study, it could be that the ability of parents to use coping strategies was strained, thereby impacting the overall effectiveness of the parent training intervention. It is also possible that parents' own mental health, particularly symptoms of anxiety and depression, played a role in both their engagement with and response to the intervention during wartime. Elevated distress may have limited parents' capacity to apply therapeutic strategies consistently, potentially contributing to the lower clinician-rated recovery rates observed in this period. However, we did not have any relevant data to assess whether parental mental health impacted both the increased usage and decreased effectiveness. Future studies could benefit from incorporating brief parent mental health screeners to examine how parental anxiety and depression relate to engagement patterns and intervention outcomes, as well as whether improvements in the parent–child relationship lead to secondary benefits in parental well-being.

While this paper was not designed as a cost-benefit analysis, cost and clinician time are relevant factors when considering the scalability of an intervention and are therefore worth noting. The direct cost per treatment in this study included 2 clinician assessments (30 minutes each, before and after the intervention) and an average of less than an hour of human support during the intervention. Regarding the latter, the supporter spent less than 40 minutes on average providing support, including note-taking. Assuming a cost of approximately Israeli Shekels (ILS) 200 per clinician assessment and ILS 100 per hour of human support (including overheads), the direct cost per family is estimated at ILS 500 (≈US $130; approximately ILS 1=US $3.8 at the time of the study). These estimates exclude costs related to upgrading and maintaining the platform, office needs, administrative tasks, and management. Overall, the time and cost required for this guided DPT are considerably lower than those reported for traditional behavior parent training programs, underscoring the model's scalability potential.

Limitations

This study implemented a 1-arm intervention condition without a control group. It was not feasible to deploy a no-treatment control condition while examining the real-world use of an intervention, as the recruitment and promotion of the intervention (and study) would have differed. An ethical consideration also arises during wartime, in that it would not be ethical to withhold a timely digital intervention when people may need it the most. The absence of a control condition means that the overall pre- to postintervention effects could be attributed to additional factors. However, the reported effects are similar to those reported in a randomized controlled pilot trial of the same DPT in its unguided format [11]. Another limitation concerns our operationalization of engagement, which focused on objective indicators of usage such as log data, completion rates, duration, and navigation patterns. While these measures are commonly used and provide valuable insights into user behavior, they do not capture the full spectrum of engagement [38,39]. Future studies should complement such objective measures with indicators of experience, including satisfaction, engagement in therapeutic activities, affective responses, and attention. Integrating both behavioral and experiential dimensions of engagement would allow a more comprehensive understanding of how parents interact with digital interventions and how engagement relates to outcomes.

Conclusions

DPTs present a form of care that could reach parents who have not sought treatment through traditional channels. These programs are acceptable, with preliminary evidence showing them to be highly used and effective. Examining the impact of DPTs during crisis times provides valuable insights into the potential use of these scalable interventions, which have a particular advantage in terms of deployment during crises. Stakeholders should have an articulated plan for the deployment of such interventions. Such strategic planning can not only address immediate needs during a crisis but also contribute to long-term public health strategies by integrating DPTs as a regular component of mental health care provision. Future research should explore ways to further optimize human support models, assess the role of parental mental health in engagement and outcomes, and evaluate the program's scalability across diverse real-world settings.

XSL•FO
RenderX

Funding

This study was funded by The Israel National Institute for Health Policy Research. The funder had no role in the design, data collection, analysis, or preparation of the manuscript.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

Amit Baumel received grant funding from The Israel National Institute for Health Policy Research, the National Institutes of Health, and the Israel Science Foundation. He has provided consultancy services to ifeel online.

Multimedia Appendix 1
A detailed review of Benevolent Parenting Intervention.
[DOCX File , 291 KB - pediatrics_v8i1e80420_app1.docx]

Multimedia Appendix 2
Completers' sample—descriptive statistics and differences in reported changes between baseline and postintervention time points.
[DOCX File , 15 KB - pediatrics_v8i1e80420_app2.docx]

Multimedia Appendix 3
Completer's sample—postintervention changes in meeting oppositional defiant disorder criteria based on clinician assessment.
[DOCX File , 15 KB - pediatrics_v8i1e80420_app3.docx]

References

1. Nock MK, Kazdin AE, Hiripi E, Kessler RC. Lifetime prevalence, correlates, and persistence of oppositional defiant disorder: results from the National Comorbidity Survey Replication. J Child Psychol Psychiatry 2007;48(7):703-713. [doi: 10.1111/j.1469-7610.2007.01733.x] [Medline: 17593151]
2. Paula CS, Bordin IAS, Mari JJ, Velasque L, Rohde LA, Coutinho ESF. The mental health care gap among children and adolescents: data from an epidemiological survey from four Brazilian regions. PLoS One 2014;9(2):e88241 [FREE Full text] [doi: 10.1371/journal.pone.0088241] [Medline: 24558382]
3. Perspective on the mental health insurance reform [Article in Hebrew]. State Comptroller of Israel. 2020. URL: https://library.mevaker.gov.il/sites/DigitalLibrary/Pages/Reports/3285-11.aspx [accessed 2020-06-02]
4. Breitenstein SM, Gross D, Christophersen R. Digital delivery methods of parenting training interventions: a systematic review. Worldviews Evid Based Nurs 2014;11(3):168-176. [doi: 10.1111/wvn.12040] [Medline: 24842341]
5. Jones DJ, Forehand R, Cuellar J, Kincaid C, Parent J, Fenton N, et al. Harnessing innovative technologies to advance children's mental health: behavioral parent training as an example. Clin Psychol Rev 2013;33(2):241-252 [FREE Full text] [doi: 10.1016/j.cpr.2012.11.003] [Medline: 23313761]
6. Baumel A, Pawar A, Mathur N, Kane JM, Correll CU. Technology-assisted parent training programs for children and adolescents with disruptive behaviors: a systematic review. J Clin Psychiatry 2017;78(8):e957-e969. [doi: 10.4088/JCP.16r11063] [Medline: 28493653]
7. Baumel A, Pawar A, Kane JM, Correll CU. Digital parent training for children with disruptive behaviors: systematic review and meta-analysis of randomized trials. J Child Adolesc Psychopharmacol 2016;26(8):740-749. [doi: 10.1089/cap.2016.0048] [Medline: 27286325]
8. Thongseiratch T, Leijten P, Melendez-Torres GJ. Online parent programs for children's behavioral problems: a meta-analytic review. Eur Child Adolesc Psychiatry 2020;29(11):1555-1568. [doi: 10.1007/s00787-020-01472-0] [Medline: 31925545]
9. Baumel A, Mathur N, Pawar A, Muench F. Psychosocial interventions for children with externalized behavior problems: an updated meta-analysis of moderator effects. J Child Fam Stud 2021;30(1):65-86. [doi: 10.1007/s10826-020-01863-6]
10. Day JJ, Sanders MR. Do parents benefit from help when completing a self-guided parenting program online? A randomized controlled trial comparing triple p online with and without telephone support. Behav Ther 2018;49(6):1020-1038. [doi: 10.1016/j.beth.2018.03.002] [Medline: 30316482]
11. Baumel A, Brandes O, Brendryen H, Muench F, Kane JM, Saar C. The impact of therapeutic persuasiveness on engagement and outcomes in unguided interventions: A randomized pilot trial of a digital parent training program for child behavior problems. Internet Interv 2023;34:100680 [FREE Full text] [doi: 10.1016/j.invent.2023.100680] [Medline: 37840647]

XSL•FO
RenderX

12. Levi-Belz Y, Groweiss Y, Blank C, Neria Y. PTSD, depression, and anxiety after the October 7, 2023 attack in Israel: a nationwide prospective study. EClinicalMedicine 2024;68:102418 [FREE Full text] [doi: 10.1016/j.eclinm.2023.102418] [Medline: 38586476]
13. Lintula S, Sourander A, Hinkka-Yli-Salomäki S, Ristkari T, Kinnunen M, Kurki M, et al. Enrollment and completion rates of a nationwide guided digital parenting program for children with disruptive behavior before and during COVID-19. Eur Child Adolesc Psychiatry 2025;34(2):739-749. [doi: 10.1007/s00787-024-02523-6] [Medline: 39141106]
14. Eyberg SM, Pincus D. Eyberg Child Behavior Inventory and Sutter-Eyberg Student Behavior Inventory: Professional Manual. Odesa, FL: Psychological Assessment Recourses; 1999.
15. Thornton L, Batterham PJ, Fassnacht DB, Kay-Lambkin F, Calear AL, Hunt S. Recruiting for health, medical or psychosocial research using Facebook: Systematic review. Internet Interv 2016;4:72-81 [FREE Full text] [doi: 10.1016/j.invent.2016.02.001] [Medline: 30135792]
16. Muench F, Baumel A. More than a text message: Dismantling digital triggers to curate behavior change in patient-centered health interventions. J Med Internet Res 2017;19(5):e147 [FREE Full text] [doi: 10.2196/jmir.7463] [Medline: 28550001]
17. Baumel A, Muench FJ. Effort-optimized intervention model: Framework for building and analyzing digital interventions that require minimal effort for health-related gains. J Med Internet Res 2021;23(3):e24905 [FREE Full text] [doi: 10.2196/24905] [Medline: 33709943]
18. Baumel A, Faber K, Mathur N, Kane JM, Muench F. Enlight: A comprehensive quality and therapeutic potential evaluation tool for mobile and web-based eHealth interventions. J Med Internet Res 2017;19(3):e82 [FREE Full text] [doi: 10.2196/jmir.7270] [Medline: 28325712]
19. Baumel A, Yom-Tov E. Predicting user adherence to behavioral eHealth interventions in the real world: examining which aspects of intervention design matter most. Transl Behav Med 2018;8(5):793-798. [doi: 10.1093/tbm/ibx037] [Medline: 29471424]
20. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. Health Psychol 2008;27(3):379-387. [doi: 10.1037/0278-6133.27.3.379] [Medline: 18624603]
21. Baumel A, Tinkelman A, Mathur N, Kane JM. Digital peer-support platform (7Cups) as an adjunct treatment for women with postpartum depression: Feasibility, acceptability, and preliminary efficacy study. JMIR Mhealth Uhealth 2018;6(2):e38 [FREE Full text] [doi: 10.2196/mhealth.9482] [Medline: 29439944]
22. Baumel A, Correll CU, Hauser M, Brunette M, Rotondi A, Ben-Zeev D, et al. Health technology intervention after hospitalization for schizophrenia: Service utilization and user satisfaction. Psychiatr Serv 2016;67(9):1035-1038. [doi: 10.1176/appi.ps.201500317] [Medline: 27247171]
23. Burns GL, Patterson DR. Conduct problem behaviors in a stratified random sample of children and adolescents: New standardization data on the Eyberg Child Behavior Inventory. J. Consult Clin Psychol 1990;2(4):391-397. [doi: 10.1037//1040-3590.2.4.391]
24. Burns GL, Patterson DR. Normative data on the eyberg child behavior inventory and sutter-eyberg student behavior inventory: Parent and teacher rating scales of disruptive behavior problems in children and adolescents. Child & Family Behavior Therapy 2001;23(1):15-28. [doi: 10.1300/J019v23n01_02]
25. Arnold DS, O'Leary SG, Wolff LS, Acker MM. The parenting scale: a measure of dysfunctional parenting in discipline situations. Psychol Assess 1993;5(2):137-144. [doi: 10.1037//1040-3590.5.2.137]
26. Sanders MR, Woolley ML. Parenting tasks checklist. Parenting and Family Support Centre. 2005. URL: https://pfsc.psychology.uq.edu.au/files/2548/Parenting%20Tasks%20Checklist.pdf [accessed 2025-11-21]
27. Frick PJ. Alabama Parenting Questionnaire. APA PsycNet.: University of Alabama; 1991. URL: https://doi.org/10.1037/t58031-000
28. Barkley R. Defiant Children: A Clinician's Manual for Parent Training. New York: Guilford Press; 1997.
29. Pelham WE, Gnagy EM, Greenslade KE, Milich R. Teacher ratings of DSM-III-R symptoms for the disruptive behavior disorders. J Am Acad Child Adolesc Psychiatry 1992;31(2):210-218. [doi: 10.1097/00004583-199203000-00006] [Medline: 1564021]
30. Press Information Bureau, India. 2024. URL: https://www.pib.gov.in/PressReleasePage.aspx?PRID=2141561 [accessed 2025-11-19]
31. Persons aged 20 and over, by extent of religiosity and by selected characteristics: 2021 (Social Survey, Table 13). Central Bureau of Statistics (CBS). URL: https://www.cbs.gov.il/he/publications/doclib/2022/28.shnatonpublicattitudesandperceptions/st28_06x.pdf [accessed 2024-11-15]
32. Education at a glance 2023: OECD indicators. OECD. 2023. URL: https://www.oecd.org/en/publications/education-at-a-glance-2023_e13bef63-en/full-report.html [accessed 2025-11-21]
33. Baumel A, Baker J, Birnbaum ML, Christensen H, De Choudhury M, Mohr DC, et al. Summary of key issues raised in the technology for early awareness of addiction and mental illness (TEAAM-I) meeting. Psychiatr Serv 2018;69(5):590-592 [FREE Full text] [doi: 10.1176/appi.ps.201700270] [Medline: 29334875]
34. Birnbaum M, Garrett C, Baumel A, Germano N, Sosa D, Ngo H, et al. Examining the effectiveness of a digital media campaign at reducing the duration of untreated psychosis in New York State: Results from a stepped-wedge randomized controlled trial. Schizophr Bull 2024;50(3):705-716. [doi: 10.1093/schbul/sbae018] [Medline: 38408135]

XSL•FO
RenderX

35. Baumel A. The treatment of childhood disruptive behavior disorders in ambulatory mental health centers. J Child Fam Stud 2017;27(4):1110-1114. [doi: 10.1007/s10826-017-0957-4]
36. Sourander A, McGrath PJ, Ristkari T, Cunningham C, Huttunen J, Lingley-Pottie P, et al. Internet-assisted parent training intervention for disruptive behavior in 4-year-old children: A randomized clinical trial. JAMA Psychiatry 2016;73(4):378-387. [doi: 10.1001/jamapsychiatry.2015.3411] [Medline: 26913614]
37. Betancourt TS, Meyers-Ohki SE, Charrow AP, Tol WA. Interventions for children affected by war: an ecological perspective on psychosocial support and mental health care. Harv Rev Psychiatry 2013;21(2):70-91 [FREE Full text] [doi: 10.1097/HRP.0b013e318283bf8f] [Medline: 23656831]
38. Baumel A. Therapeutic activities as a link between program usage and clinical outcomes in digital mental health interventions: a proposed research framework. J Technol Behav Sci 2022;7(2):234-239. [doi: 10.1007/s41347-022-00245-7]
39. Perski O, Blandford A, West R, Michie S. Conceptualising engagement with digital behaviour change interventions: a systematic review using principles from critical interpretive synthesis. Transl Behav Med 2017;7(2):254-267 [FREE Full text] [doi: 10.1007/s13142-016-0453-1] [Medline: 27966189]

Abbreviations

APQ: Alabama Parenting Questionnaire
DPT: Digital Parent Training
ECBI: Eyberg Child Behavior Inventory
ILS: Israeli Shekels
ODD: oppositional defiant disorder.
PS: Parenting Scale
PTC: Parenting Tasks Checklist

Edited by J Hagström; submitted 10.07.25; peer-reviewed by E Neter, J Jent; comments to author 15.10.25; revised version received 23.10.25; accepted 27.10.25; published 22.12.25.

Please cite as:
Baumel A, Brandes O, Saar CR
Evaluating the Reach, Usage, Human Support Needs, and Clinical Outcomes of Digital Parent Training for Child Oppositional Defiant Disorder Before and During Wartime: Longitudinal Study
JMIR Pediatr Parent 2025;8:e80420
URL: https://pediatrics.jmir.org/2025/1/e80420
doi:10.2196/80420
PMID:

©Amit Baumel, Or Brandes, Chen R Saar. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 22.12.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Enhancing Adherence and Mental Well-Being in Pediatric Growth Hormone Therapy: Feasibility Prospective Observational Study of a Family-Centered Digital Companion

Antonio de Arriba Muñoz[1,2], MD, PhD; Amalia M García-Durán[1,2], MD, MSc; Patricia Sanz-Aznar[1,2], MD, MSc; Silvia Quer-Palomas[3], MSc, PhD; Ioannis Bilionis[3], BEng, MSc; Alba Xifra-Porxas[3], PhD; Joia Nuñez[3], MD, MSc; Ricardo C Berrios[3], BSc; Luis Fernández-Luque[3], PhD

[1]Endocrinology Pediatric Unit, Hospital Universitario Miguel Servet, Zaragoza, Spain

[2]Instituto de Investigación Sanitaria de Aragón, Zaragoza, Spain

[3]Adhera Health Inc, 101 Cooper St, Santa Cruz, CA, United States

Corresponding Author:
Luis Fernández-Luque, PhD
Adhera Health Inc, 101 Cooper St, Santa Cruz, CA, United States

Abstract

Background: Managing a child undergoing growth hormone treatment (GHt) can be burdensome for the families, which can lead to psychological problems and poor treatment adherence. The Adhera Caring Digital Program (ACDP) is a mobile-based digital health intervention designed to support the physical and mental well-being of families of individuals with chronic conditions.

Objective: This study aimed to evaluate the clinical feasibility of a digital intervention to support families by focusing on caregivers of children undergoing GHt and its impact on treatment adherence.

Methods: This is a prospective observational study. A total of 51 caregivers of children undergoing GHt with low adherence (below 85%) to treatment were recruited at the Pediatric Endocrinology Unit at the Miguel Servet Children's University Hospital and enrolled into the ACDP for 3 months.

Results: A total of 51 parents participated in the digital intervention for 3 months. The use of ACDP was associated with a significant increase in adherence rate (P<.001). At baseline, all families had suboptimal adherence (below 85%), and after the intervention, 75% (n=38) of the families reached optimal levels of adherence. Also, the perceived pain of injection was reduced, as well as anxiety and stress. Initially, 21.56% (n=11) of caregivers reported depression symptoms, categorized as mild (11.76%, n=6), moderate (7.84%, n=4), and extremely severe (1.96%, n=1), while post intervention, only 1.96% (n=1) of caregivers reported depression as "severe." Anxiety levels at baseline were reported by a total of 23.53% (n=12) of caregivers (mild: 7.84%, n=4, moderate: 13.73%, n=7, and severe: 1.96%, n=1). After the intervention, only 11.76% (n=6) reported mild (5.88%, n=3) or moderate (5.88%, n=3) anxiety levels. Initially, 23.5% (n=12) of caregivers reported stress as mild (7.84%, n=4), moderate (13.72%, n=7), and severe (1.96%, n=1) stress, and following the intervention, these symptoms reduced to 7.84% (n=4) (mild: 5.88%, n=3, severe: 1.96%, n=1).

Conclusions: The ACDP is a promising tool, and it has been demonstrated to significantly increase the adherence rate, adding value to the patient and caregiver journey, and improving the management of growth hormone deficiency while promoting the overall well-being of family caregivers. Our results show that the digital support provided by the solution significantly increased the quality of life of the caregivers by increasing their psychological, emotional, and social well-being and decreasing their depression, anxiety, and stress symptoms.

Trial Registration: ClinicalTrials.gov NCT04812665; https://clinicaltrials.gov/study/NCT04812665

(JMIR Pediatr Parent 2025;8:e67102) doi:10.2196/67102

KEYWORDS

growth hormone; hormone therapy; caregiver fatigue; well-being; pediatric; paediatric; digital health; digital intervention

XSL•FO
RenderX

Introduction

Background

Growth hormone (GH) deficiency (GHD) in the pediatric population causes short stature [1]. Children affected by GHD have also been reported to have worse quality of life, cognitive function, and fatigue than those with normal height [2,3]. Short stature in children is also associated with anxiety, depression, and social withdrawal [4-11]. Importantly, recent findings suggest that poor emotional well-being and health-related quality of life (HrQoL) of caregivers and/or parents are also negatively related to children's HrQoL, particularly in the context of pediatric health conditions.

These children's families are responsible for managing the disease. Within the family, family caregivers are the ones managing its treatment (daily injections of recombinant human GH) and the children's mental health. Caring might be burdensome and challenging [12,13], exposing the family caregiver to the risk of developing psychological problems [14]. Indeed, parental stress has been described as one of the consequences of managing GHD in children, leading to poorer adherence to GH therapy (GHt) and an impact on their environment and health [15,16]. Overall, family caregiver fatigue has been found to significantly impact the well-being of the caregiver and the patient living with a chronic condition [17]. However, the impact of the family caregiver specifically on GHDs remains unclear [18,19].

Digital health (DH) solutions are transforming the health care sector, as they can be a cost-effective option that allows accessible family-centered and personalized interventions. Indeed, mobile interventions have been proven effective in supporting caregivers in the management of chronic conditions [20]. One such innovation is the Easypod system, an electronic, fully automated device designed to streamline the GH treatment process. This system provides reliable real-time injection data, enabling health care providers to monitor patients' progress and make more informed treatment decisions. By identifying nonadherent patients earlier, the Easypod allows for more targeted support, enhancing both treatment adherence and outcomes [21].

The Adhera Caring Digital Program

The Adhera Caring Digital Program (ACDP) is a comprehensive, digitally delivered program designed to support the physical and mental well-being of family caregivers of individuals with chronic conditions. It aims to improve self-management and health outcomes for both the patient and their family caregiver [22]. The ACDP includes access to a mobile app for family caregivers, which is integrated into an artificial intelligence–powered platform that includes integrated data from injector devices, as well as tools for supporting clinicians to follow up on the health of the families.

This study aimed to evaluate the clinical feasibility of a digital intervention to support families by focusing on caregivers of children undergoing GHt and its impact on treatment adherence.

Previous Research

GHt for children is a critical yet challenging process that often demands significant effort from family caregivers. The burden of managing GHt can negatively impact the psychological well-being of caregivers and adherence to the treatment protocol, which, in turn, affects the health outcomes of the children undergoing treatment. This challenge necessitates the development of effective support systems for caregivers to ensure better adherence and overall health outcomes.

Recent advancements in digital health interventions have shown promising results in supporting caregivers of children with chronic conditions, including those undergoing GHt. Studies have demonstrated that digital tools can provide substantial benefits by improving treatment adherence and enhancing the mental health of caregivers. For instance, a recent study by Dimitri et al (2021) [23] found that digital interventions could significantly enhance treatment adherence in children with GHDs by providing real-time support and monitoring capabilities.

In another study, Savage et al [13] highlighted the transformative potential of DH platforms in pediatric endocrinology, emphasizing how patient-generated data and interactive support can lead to more integrated and personalized care models. This approach improves not only adherence but also the overall quality of care provided to patients.

The mental health and well-being of caregivers are crucial factors in ensuring successful GHt management. Zhai et al [24] reported the positive impact of DH interventions on reducing caregiver stress and anxiety, which, in turn, improved their ability to manage the treatment regimen effectively [24]. These findings underscore the importance of addressing the psychological needs of caregivers through innovative digital solutions.

Additionally, Lorca-Cabrera et al [25] explored the role of mobile health applications in supporting self-management and emotional well-being among caregivers. Their research showed that these applications could reduce the psychological burden on caregivers, thereby improving their overall quality of life and enhancing their capacity to support their children's treatment [25].

The ACDP builds upon these foundations by offering a comprehensive digital health intervention designed to support the physical and mental well-being of caregivers managing children undergoing GHt. This study aims to evaluate the clinical feasibility of ACDP and its impact on treatment adherence, contributing to the growing body of evidence supporting the integration of DH solutions in chronic disease management.

Methods

Overview

Family caregivers (ie, parents) of children with suboptimal adherence to GHt were recruited to the study at the Pediatric Endocrinology Unit at the Miguel Servet Children's University Hospital and were provided with access to the ACDP for 3

XSL•FO
RenderX

months. The protocol was prospectively registered in ClinicalTrials.gov (NCT04812665).

Participants were assessed twice (at recruitment and at 3 months' follow-up). The data collected were (1) demographic data (only at recruitment); (2) positive mood assessed with the Positive and Negative Affect Schedule (PANAS) [26]; (3) distress assessed using the Depression Anxiety and Stress Scale-21 (DASS-21) [27], general well-being assessed using the Mental Health Continuum Short Form (MHC-SF) [28], and self-efficacy assessed using the Generalized Self-Efficacy Scale (GSES) [29]; (4) HrQoL assessed using the KIDSCREEN-10 [30] and the Quality of Life in Short Stature Youth (QoLISSY) [31]; and (5) GHt adherence (%) by Easypod-Connect.

Recruitment

The inclusion criteria were as follows:

- Adherence to GHt monitored in the last month prior to enrollment indicates a ratio less than 85%.
- Family caregivers (and legal guardians) of children who receive GHt in accordance with approved indications in Spain.
- Explicit agreement on data sharing regarding adherence to GHt gathered through the Easypod-Connect.
- Participants must be able to interact with mobile phones and be willing to install the mobile-based solution of the study in their smartphone.
- Participants must sign the specific informed consent form for the study.

Only one legal guardian per child can participate in the study.

Procedure

The ACDP is a noninvasive, digitally delivered intervention designed to support family caregivers of children with chronic conditions. Specifically tailored for the context of GHt, the ACDP offers condition-specific educational content, evidence-based caregiving strategies, and self-management tools to help caregivers monitor progress and remain engaged with their child's treatment. To promote emotional well-being and adherence, the program delivers personalized motivational messages generated by an artificial intelligence–driven health recommender system. This system tailors its recommendations using both objective and patient-reported data: objective adherence data are collected via Easypod-Connect, an electronic auto-injector device that monitors and transmits GH administration data, while patient-reported outcomes are assessed at baseline and at 3-month follow-up using validated psychometric instruments (see Table 1). The ACDP is part of the Adhera Health Precision Digital Companion Platform [32], which has been developed using the best practices regarding data protection and quality management in accordance with the ISO (International Organization for Standardization) 27001 and ISO 13465 guidelines.

Table . SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) table.

Procedures	Visit 1 (baseline)	Visit 2 (3 mo)	Digital health intervention period	Follow-up (post intervention)
Screening for inclusion criteria	✓			
Informed consent	✓			
Baseline HrQoL[a] questionnaire (QoLISSY)[b]	✓			
Emotional well-being assessment (PANAS[c])	✓			
Self-efficacy (GSES[d])	✓			
Adherence monitoring		✓	✓ (throughout intervention)	✓
Digital support program usage			✓	
Child's growth monitoring	✓		✓	
Caregiver's QoL[e] follow-up (QoLISSY)		✓		✓

[a]HrQoL: health-related quality of life.

[b]QoLISSY: Quality of Life in Short Stature Youth.

[c]PANAS: Positive and Negative Affect Schedule.

[d]GSES: Generalized Self-Efficacy Scale.

[e]QoL: quality of life.

Statistical Analysis

Participants' questionnaire answers were digitally recorded through a Microsoft Forms form and extracted to a Microsoft Excel database. Descriptive analysis (means, SDs, and percentages) was used for demographic data. After checking the normality of each variable, pre-post *P* values of the psychometrics' parameters were checked using the Student *t* and Wilcoxon tests.

XSL•FO
RenderX

Ethical Considerations

This study protocol was reviewed and approved by the Spanish Ethics Committee C.P.-C.I. PI20/494. Written informed consent was obtained from participants (or their parent/legal guardian/next of kin) to participate in the study.

The privacy and confidentiality of all research participants were strictly maintained; all data were de-identified before analysis, and no personally identifiable information was collected or reported. Participants were not compensated for their participation in this study.

Results

Participants' Characteristics

A total of 65 parents provided informed consent. Of these, 14 were excluded from the analysis, as they did not access the digital intervention. The final sample's (n=51) characteristics are described in Table 2. Participants were 42.14 (SD 5.78) years old on average, and the sample mostly comprised women (n=35, 68.6%). The average age of the child taken care of was 7.9 (SD 2.9) years, receiving GHt for 36.51 (SD 28.43) months. Regarding the education level, 15 (29.4%) caregivers hold a university degree, 20 (39.2%) have professional training, 12 (23.5%) finished high school, and 4 (7.8%) finished primary school.

Table . Descriptive characteristics of the sample (N=51).

Characteristic	Value
Caregiver's gender, n (%)	
Male	16 (31.4)
Female	35 (68.6)
Caregiver's age (years), mean (SD)	41.45 (7.59)
Caregiver's marital status, n (%)	
Single	10 (19.6)
Married	33 (64.7)
Divorced	8 (15.7)
Education, n (%)	
Primary education	4 (7.8)
Secondary education/high school	12 (23.5)
Professional training	20 (39.2)
University degree	15 (29.4)
Child's gender, n (%)	
Male	25 (49.0)
Female	26 (51.0)
Child's age (years), mean (SD)	7.98 (2.98)
Time under treatment (months), mean (SD)	36.51 (28.43)

Statistical Analysis

Quality of Life of Children

Almost all the psychometric questionnaires' results showed significant differences (ie, $P<.05$) after using the ACDP for 3 months (Table 3 and Figure 1). General health and quality of life were significantly improved based on KIDSCREEN-10 [30] and QoLISSY [31] psychometrics. General and Social well-being also improved significantly, while emotional well-being has improved as QoLISSY emotional scale scores increased, and the PANAS [26] indicated a statistically significant increase in positive affect (mood) as well as a decrease in negative affect. Social well-being also enhanced significantly according to both MHC-SF [28] and QoLISSY questionnaires. Self-efficacy, assessed using the GSES [29], increased, as did the QoLISSY coping score.

XSL•FO
RenderX

Table . Comparison of family caregiver characteristics at baseline and 3 months after the intervention

Variable	Baseline	3 months	Statistic	*P* value	Effect size (η^2)
PANAS[a]					
Positive Affect	30.78±7.27	36.53±8.65	-4.5	<.001	0.115
Negative Affect	18.98±6.02	14.57±4.18	85	<.001	0.154
DASS-21[b]					
Depression Scale	2.98±3.15	1.45±2.10	106	<.001	0.075
Anxiety Scale	2.41±1.95	1.24±1.61	160	<.001	0.098
Stress Scale	5.71±3.15	3.06±3.18	151.5	<.001	0.149
MHC-SF[c]					
General wellbeing	0.62±0.17	0.69±0.21	363	.008	0.037
Emotional wellbeing	0.67±0.20	0.71±0.20	241	.15	0.011
Psychological well-being	0.67±0.18	0.72±0.23	454	.17	0.013
Social wellbeing	0.52±0.19	0.65±0.22	-3.7	<.001	0.086
GSES[d]	31.31±5.51	33.43±5.31	336	.04	0.036
KIDSCREEN 10					
HRQoL[e]	49.19±10.82	60.89±16.86	194	<.001	0.146
General Health	3.43±0.81	4.22±0.81	40.5	<.001	0.191
QoLISSY[f]					
HrQoL	74.94±15.93	80.67±14.46	452	.048	0.034
Emotional scale	79.41±15.07	82.35±13.53	442	.28	0.01
Physical scale	75.57±19.51	81.94±18.38	351.5	.04	0.028
Social Scale	69.83±20.35	77.72±18.15	294.5	.02	0.04
Coping scale	40.98±17.25	48.48±21.32	347.5	.01	0.036
Height-related beliefs scale	78.31±25.96	66.30±28.20	208.5	.004	0.047
Treatment scale	53.54±17.77	67.37±21.93	197.5	<.001	0.107
Child's future scale	73.63±25.57	82.65±17.98	290.5	.04	0.04
Effects of child's short stature on family scale	68.45±18.94	77.72±18.20	333.5	.009	0.059
Treatment Adherence (%)	80.09±4.87	88.75±10.03	98.5	<.001	0.232
Treatment adherence ≥85%	0 (0%)	41 (80.4%)	—[g]	—	—

[a]PANAS: Positive and Negative Affect Schedule.

[b]DASS-21: Depression Anxiety and Stress Scale-21.

[c]MHC-SF: Mental Health Continuum Short Form.

[d]GSES: Generalized Self-Efficacy Scale.

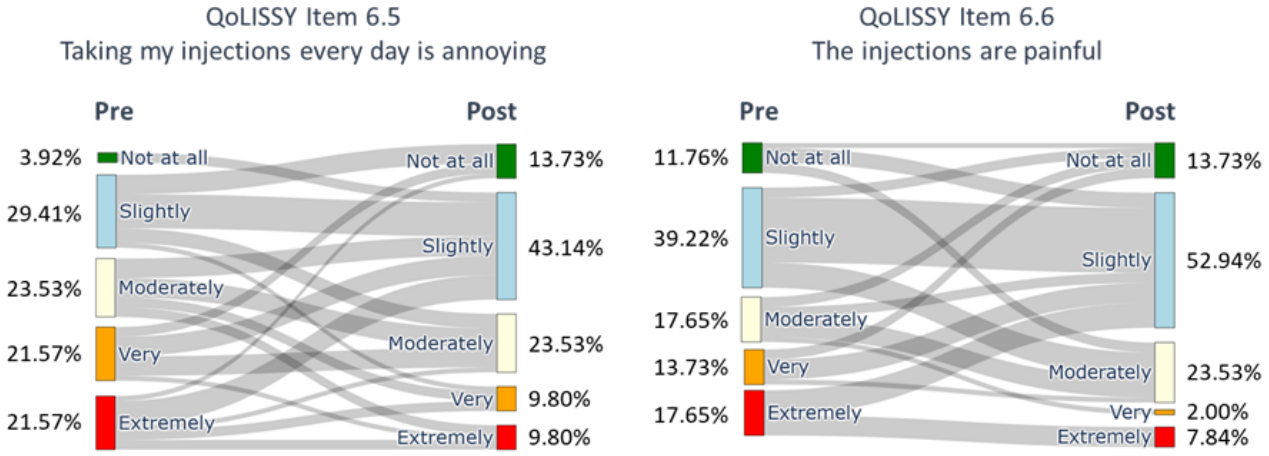
[e]HrQoL: health-related quality of life.

[f]QoLISSY: Quality of Life in Short Stature Youth.

[g]Not applicable.

XSL•FO
RenderX

Figure 1. Changes in quality of life in youth with short stature (baseline and 12 wk).

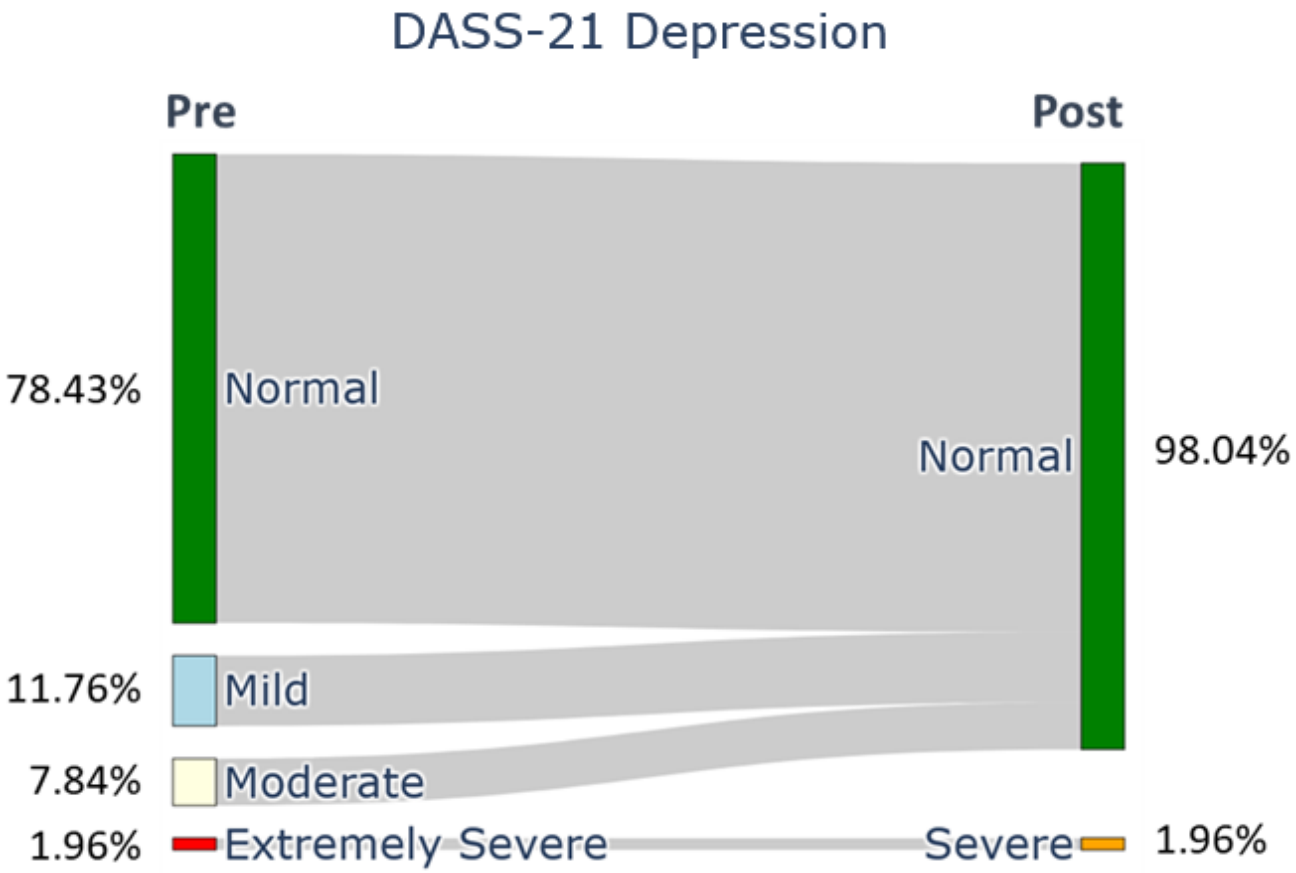


Mental Well-Being of Parents

After the ACDP, the participants showed a significant difference in all the QoLISSY subscales except for the emotional (P=.28) scales. Meaningful results were found in the physical and social dimensions and in the child's future perception, coping, treatment, height-related beliefs, and effects of the child's short stature on the family scale. Concerning the mental health symptoms, the depression (Figure 2), anxiety (Figure 3), and stress (Figure 4) symptoms measured by the DASS-21 were reduced after the 3-month digital intervention.

Finally, the use of the ACDP was associated with a significant increase in the adherence rate (P<.001). At the baseline, all the families had suboptimal adherence (below 85%); after the intervention, 75% (n=38) of the families reached optimal levels of adherence. The QoLISSY item regarding perceived pain of injection was also reduced, which might explain that improved social well-being and reduced anxiety and stress were associated with reduced perceived pain from injection and overall contributed to improved adherence.

Figure 2. Depression symptoms of family caregivers (baseline and 12 wk).



XSL•FO
RenderX

Figure 3. Stress symptoms of family caregivers (baseline and 12 wk).

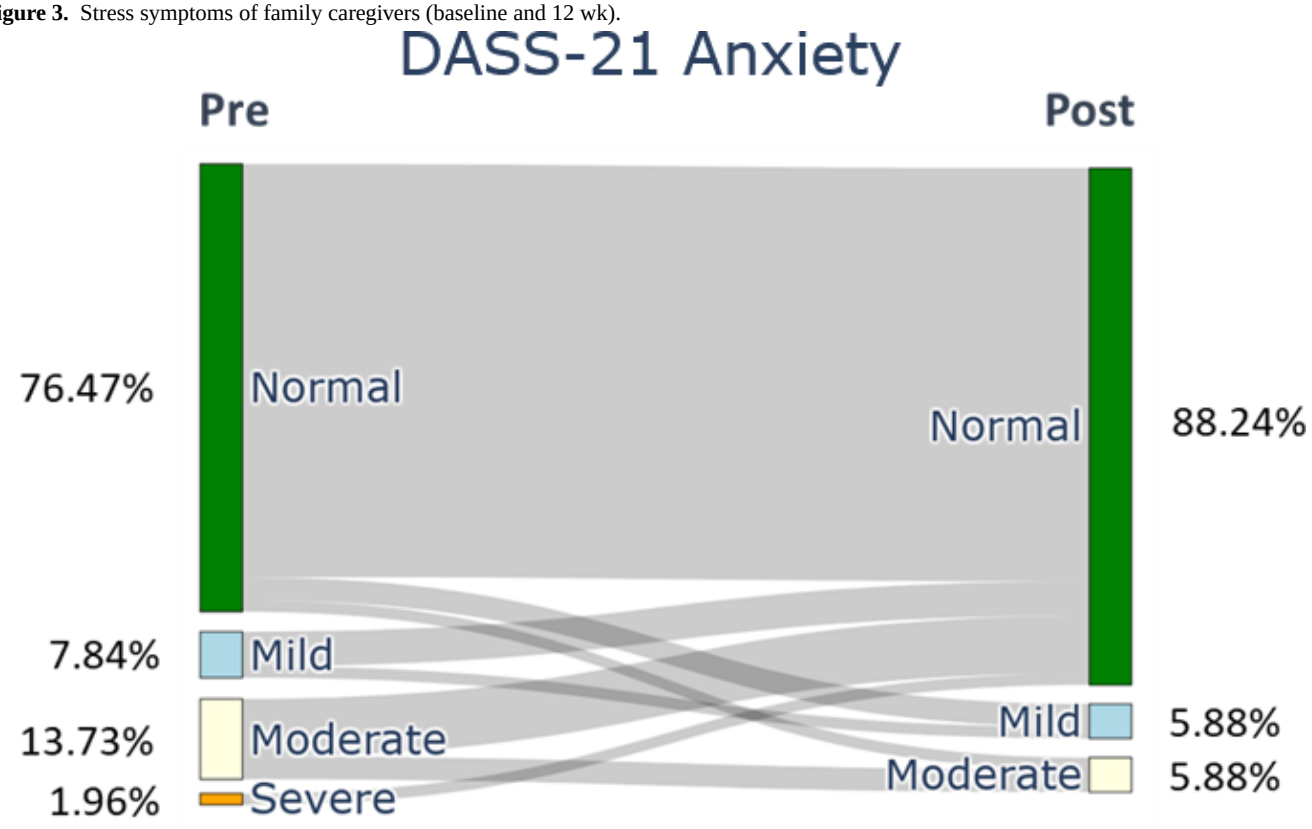
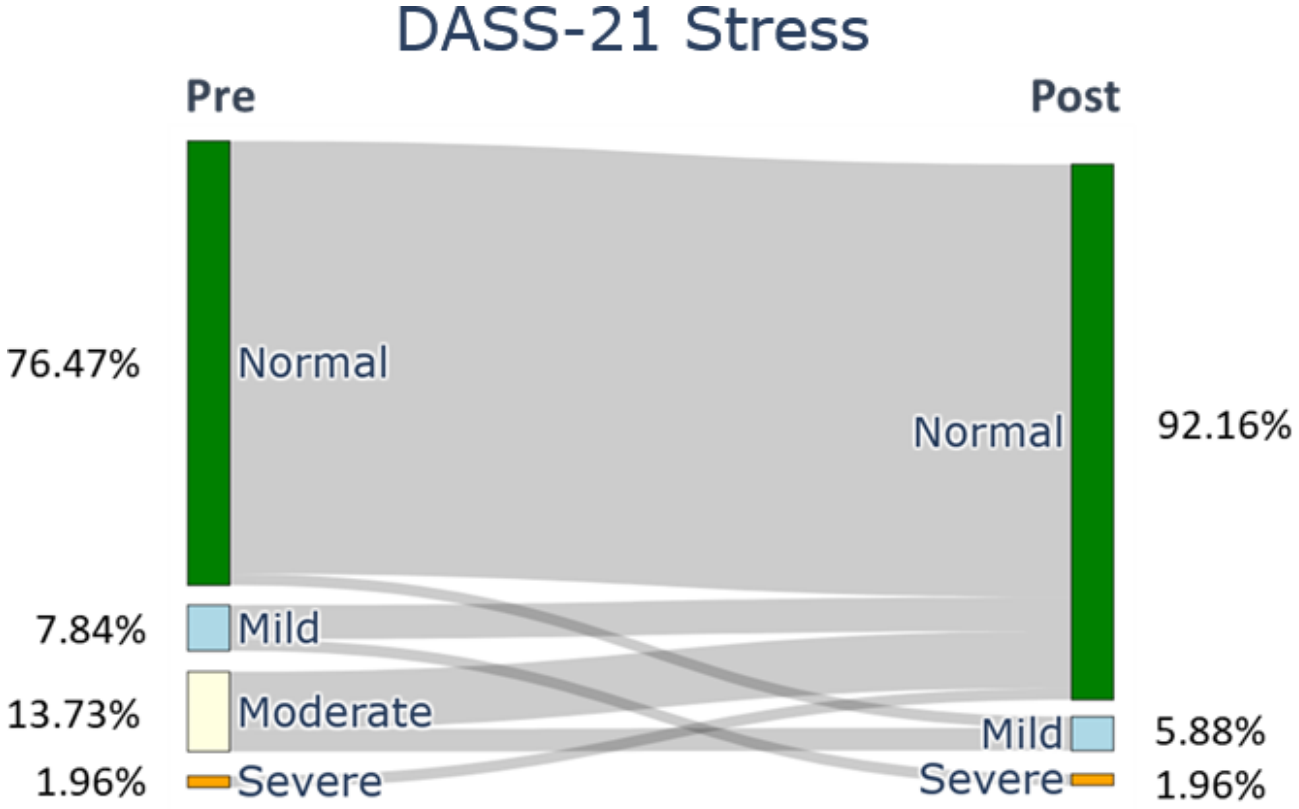


Figure 4. Stress symptoms of family caregivers (baseline and 12 wk).



Adult Growth Prediction

In this study, growth data (height) have been analyzed post hoc for studying the impact of the intervention on patients treated with GH in a post hoc explorative analysis phase. In this sense, patients' growth estimations are calculated by means of deviation from baseline children's growth charts, based on the participants' adherence levels to GHt. Specifically, measurements of patients' height were collected in four fixed

XSL•FO
RenderX

time points: (1) 6 months before treatment, (2) start of treatment, (3) start of the study, and (4) 6 months after the start of the study. Finally, another important variable ΔHSDS (change in height standard deviation score) that has been computed is the change in height deviation values between consecutive time points. The impact of the intervention in the growth status was analyzed by focusing on the patients who switched from medium to high adherence (~70% of the participants). Thus, assuming that without participation in the study, the patients' adherence levels would have been medium, and the overall effect on mean ΔHSDS was computed by comparing the 48-month estimations of medium-only (hypothetical) cases with the real situation (70% high and 30% medium adherence, based on data analysis).

The average estimated ΔHSDS value for patients with medium adherence was 0.9, while that of the real (70% high and 30% medium adherence) cases was 1.04. Hence, an increase of 0.14 was observed in terms of ΔHSDS, meaning that the average participant is going to grow more thanks to the intervention. In other words, the increase in ΔHSDS indicates a reduction in the height gap between the patient's actual growth and the expected growth based on baseline charts. This suggests improved growth outcomes due to better adherence to the treatment.

Discussion

Principal Results

The management of children undergoing GHt has been reported to be burdensome [14]; specifically, it can be a time-consuming and exhausting process as family caregivers need to (1) ensure that their children receive the injections at the right time and at the correct dosage while providing emotional support and (2) address any mental health issues that may arise. Family caregivers' fatigue and stress can negatively influence treatment adherence and the child's health [14,15]. This research contributes to the emerging work in supporting family caregivers of children undergoing GHt using digital tools [28] by showing that the ACDP can effectively empower family caregivers of children with GHD, including improvements in the well-being of both parents and children while promoting self-management of the condition.

Participants have reported a better quality of life and general health, as well as improvements in key points such as cognitive symptoms, mood, and emotional and social well-being. Most families involved in the study achieved optimal levels of adherence after the study. We found a statistically significant increase in positive affect (from 30.78, SD 7.27 at baseline to 36.53, SD 8.65 at the 3-month follow-up) with a statistically significant decrease in negative affect (from 18.98, SD 6.02 to 14.57, SD 4.18), which was measured using the PANAS. Also, the MHC-SF revealed a statistically significant increase in general well-being (from 0.62, SD 0.17 to 0.69, SD 0.21), social well-being (from 0.52, SD 0.19 to 0.65, SD 0.22) and general self-efficacy (from 31.31, SD 5.51 to 33.43, SD 5.31), with an increase in emotional (from 0.67, SD 0.20 to 0.71, SD 0.20), and psychological well-being (from 0.67, SD 0.18 to 0.72, SD 0.23). KIDSCREEN-10 revealed a statistically significant increase in HrQoL (from 49.19, SD 10.82 at baseline to 60.89, SD 16.86 at the 3-month follow-up) and a statistically significant increase in general health (3.43, SD 0.81 to 4.22, SD 0.81). Regarding the quality of life of youths with short stature, we found a statistically significant increase in scores on the physical scale (from 75.57, SD 19.51 to 81.94, SD 18.38), social scale (from 69.83, SD 20.35 to 77.72, SD 18.15), coping scale (from 40.98, SD 17.25 to 48.48, SD 21.32), height-related beliefs scale (from 8.31, SD 25.96 to 66.30, SD 28.20), treatment scale (from 53.54, SD 17.77 to 67.37, SD 21.93), and child's future scale (from 73.63, SD 25.57 to 82.65, SD 17.98), as well as an increase in HrQoL (from 74.94, SD 15.93 to 80.67, SD 14.46), and emotional scale (from 79.41, SD 15.07 to 82.35, SD 13.53). Lastly, we found statistically significant increases in growth rate on the child's short stature on the family's section of the QoLISSY (from 68.45, SD 18.94 to 77.72, SD 18.20) and treatment adherence (from 80.27, SD 4.77 to 88.98, SD 9.84).

Our findings show that at baseline, 21.56% (n=11) of caregivers reported depression symptoms, categorized as mild (11.76%, n=6), moderate (7.84%, n=4), and extremely severe (1.96%, n=1). Post intervention, depression was reduced to only severe (1.96%, n=1). Anxiety levels at baseline were mild (7.84%, n=4), moderate (13.73%, n=7), and severe (1.96%, n=1) for 23.53% (n=12) of caregivers. After the intervention, 11.76% (n=6) of caregivers reported mild (5.88%, n=3) or moderate (5.88%, n=3) anxiety levels. Stress symptoms also improved; initially, 23.5% (n=12) reported mild (7.84%, n=4), moderate (13.72%, n=7), and severe (1.96%, n=1) stress. Following the intervention, stress symptoms reduced to 7.84% (n=4), with only mild (5.88%, n=3) and severe (1.96%, n=1) symptoms remaining.

Limitations

This is a local study conducted in Zaragoza (Spain) with a small sample and no comparison arm. Because of inclusion/exclusion criteria, people with low digital literacy were not able to participate. Although the general prevalence of GHD is higher in boys, most caregivers participating in this study had daughters who have GHD; thus, parents of boys with GHD might have been underrepresented.

Comparison With Prior Work

The findings from this study align with and extend previous research on digital interventions aimed at supporting family caregivers of children undergoing GHt. Prior studies have highlighted the significant burden on family caregivers managing GHt, including the physical, emotional, and psychological stress that can negatively impact treatment adherence and the overall health of the child [13]. The ACDP demonstrates notable advancements in this area by providing a comprehensive digital health intervention that effectively supports both the physical and mental well-being of caregivers [33].

Previous research by Arriba et al [34] suggested that mobile solutions could potentially improve GHt adherence by addressing the emotional states of parents and caregivers. Our study, albeit observational, provides further evidence that digital tools appear to significantly enhance adherence rates by improving caregivers' psychological states. In particular, our study revealed a statistically significant increase in treatment

XSL•FO
RenderX

adherence from baseline (below 85%) to postintervention levels, with 75% of families reaching optimal adherence.

Furthermore, the mental well-being of caregivers showed substantial improvement, a finding consistent with earlier work by de Arriba et al [34], which highlighted the positive impact of the ACDP on caregivers' mental health. Our findings show that at baseline, 21.56% (n=11) of caregivers reported depression symptoms, categorized as mild (11.76%, n=6), moderate (7.84%, n=4), and extremely severe (1.96%, n=1). Anxiety and stress levels also showed marked reductions, aligning with the findings from the study by Cervera-Torres et al [22], which emphasized the importance of digital health support for emotional and self-management needs.

Moreover, our study's comprehensive assessment of quality of life and well-being metrics—using tools such as the PANAS, MHC-SF, and KIDSCREEN-10—demonstrated significant improvements in cognitive symptoms, mood, emotional and social well-being, and general health. These results further extend the insights from the study by Savage et al [13], which discussed the transformative potential of patient-generated data in integrated care models for GHt. The significant increases in positive affect, general well-being, social well-being, and self-efficacy among participants underscore the holistic benefits of digital health interventions.

Conclusions

In conclusion, the ACDP showed favorable acceptance for family caregivers of children undergoing GHt. It is a promising tool and has been demonstrated to add value to the patient and caregiver journey by improving GHD management while supporting the overall well-being of family caregivers. It has helped parents improve their mental well-being as well as treatment adherence. This study provides insights into how digital interventions can better support families of children undergoing GHt.

Acknowledgments

This investigator-initiated study was financially supported by Merck Healthcare KGaA, Darmstadt, Germany (CrossRef Funder ID 10.13039/100009945). Merck Healthcare KGaA reviewed the manuscript for medical accuracy only before its submission. The authors are fully responsible for the content of this manuscript, and the views and opinions described in the publication reflect solely those of the authors.

Conflicts of Interest

This study describes a digital solution commercialized by Adhera Health. Adhera Health and AdAM have collaborations with Merck Healthcare KGaA beyond this study. SQP, IB, AX-P, RCB and LF-L are employees of Adhera Health. JN is former employee of Adhera Health.

References

1. Dattani MT, Malhotra N. A review of growth hormone deficiency. Paediatr Child Health (Oxford) 2019 Jul;29(7):285-292. [doi: 10.1016/j.paed.2019.04.001]
2. Stephen MD, Varni JW, Limbers CA, et al. Health-related quality of life and cognitive functioning in pediatric short stature: comparison of growth-hormone-naïve, growth-hormone-treated, and healthy samples. Eur J Pediatr 2011 Mar;170(3):351-358. [doi: 10.1007/s00431-010-1299-z] [Medline: 20886355]
3. Varni JW, Limbers CA, Bryant WP, Wilson DP. Multidimensional Fatigue Scale. Child Health Care 2012 Apr 30;41(2):162-181. [doi: 10.1080/02739615.2012.657068]
4. Skuse D, Gilmour J, Tian CS, Hindmarsh P. Psychosocial assessment of children with short stature: a preliminary report. Acta Paediatr Suppl 1994 Dec;406:11-16. [doi: 10.1111/j.1651-2227.1994.tb13413.x] [Medline: 7734805]
5. Stabler B. Impact of growth hormone (GH) therapy on quality of life along the lifespan of GH-treated patients. Horm Res 2001;56 Suppl 1:55-58. [doi: 10.1159/000048136] [Medline: 11786687]
6. Stabler B, Clopper RR, Siegel PT, Stoppani C, Compton PG, Underwood LE. Academic achievement and psychological adjustment in short children. J Dev Behav Pediatr 1994 Feb;15(1):1-6. [doi: 10.1097/00004703-199402000-00001]
7. Abbott D, Rotnem D, Genel M, Cohen DJ. Cognitive and emotional functioning in hypopituitary short-statured children. Schizophr Bull 1982;8(2):310-319. [doi: 10.1093/schbul/8.2.310] [Medline: 7112044]
8. Sartorio A, Conti A, Molinari E, Riva G, Morabito F, Faglia G. Growth, growth hormone and cognitive functions. Horm Res 1996;45(1-2):23-29. [doi: 10.1159/000184754] [Medline: 8742114]
9. Wheeler PG, Bresnahan K, Shephard BA, Lau J, Balk EM. Short stature and functional impairment: a systematic review. Arch Pediatr Adolesc Med 2004 Mar;158(3):236-243. [doi: 10.1001/archpedi.158.3.236] [Medline: 14993082]
10. Sandberg DE, Bukowski WM, Fung CM, Noll RB. Height and social adjustment: are extremes a cause for concern and action? Pediatrics 2004 Sep;114(3):744-750. [doi: 10.1542/peds.2003-1169-L] [Medline: 15342848]
11. Abe S, Okumura A, Mukae T, et al. Depressive tendency in children with growth hormone deficiency. J Paediatr Child Health 2009 Nov;45(11):636-640. [doi: 10.1111/j.1440-1754.2009.01586.x] [Medline: 19845844]
12. Ranke MB, Wit JM. Growth hormone - past, present and future. Nat Rev Endocrinol 2018 May;14(5):285-300. [doi: 10.1038/nrendo.2018.22] [Medline: 29546874]

XSL•FO
RenderX

13. Savage MO, Fernandez-Luque L, Graham S, et al. Adherence to r-hGH therapy in pediatric growth hormone deficiency: Current perspectives on how patient-generated data will transform r-hGH treatment towards integrated care. Patient Prefer Adherence 2022;16:1663-1671. [doi: 10.2147/PPA.S271453] [Medline: 35846871]
14. Raina P, O'Donnell M, Schwellnus H, et al. Caregiving process and caregiver burden: conceptual models to guide research and practice. BMC Pediatr 2004 Jan 14;4:1. [doi: 10.1186/1471-2431-4-1] [Medline: 14723791]
15. Silva N, Bullinger M, Sommer R, Rohenkohl A, Witt S, Quitmann J. Children's psychosocial functioning and parents' quality of life in paediatric short stature: The mediating role of caregiving stress. Clin Psychol Psychother 2018 Jan;25(1):e107-e118. [doi: 10.1002/cpp.2146] [Medline: 28960605]
16. Eckshtain D, Ellis DA, Kolmodin K, Naar-King S. The effects of parental depression and parenting practices on depressive symptoms and metabolic control in urban youth with insulin dependent diabetes. J Pediatr Psychol 2010 May;35(4):426-435. [doi: 10.1093/jpepsy/jsp068] [Medline: 19710249]
17. Beydoun J, Nasrallah L, Sabrah T, Caboral-Stevens M. Towards a definition of caregiver fatigue: A concept analysis. ANS Adv Nurs Sci 2019;42(4):297-306. [doi: 10.1097/ANS.0000000000000262] [Medline: 30839335]
18. Graham S, Auyeung V, Weinman J. Exploring potentially modifiable factors that influence treatment non-Adherence amongst pediatric growth hormone deficiency: A qualitative study. Patient Prefer Adherence 2020;14:1889-1899. [doi: 10.2147/PPA.S268972] [Medline: 33116433]
19. Alsaigh R, Coyne I. Mothers' experiences of caring for children receiving growth hormone treatment. J Pediatr Nurs 2019;49:e63-e73. [doi: 10.1016/j.pedn.2019.09.005] [Medline: 31575443]
20. Mayberry LS, Berg CA, Harper KJ, Osborn CY. The design, usability, and feasibility of a family-focused diabetes self-care support mHealth intervention for diverse, low-income adults with type 2 diabetes. J Diabetes Res 2016;2016:7586385. [doi: 10.1155/2016/7586385] [Medline: 27891524]
21. Koledova E, Stoyanov G, Ovbude L, Davies PSW. Adherence and long-term growth outcomes: results from the easypod. Endocr Connect 2018 Aug;7(8):914-923. [doi: 10.1530/EC-18-0172] [Medline: 29976785]
22. Cervera-Torres S, Núñez-Benjumea FJ, de Arriba Muñoz A, Chicchi Giglioli IA, Fernández-Luque L. Digital health for emotional and self-management support of caregivers of children receiving growth hormone treatment: a feasibility study protocol. BMC Med Inform Decis Mak 2022 Aug 13;22(1):215. [doi: 10.1186/s12911-022-01935-1] [Medline: 35964116]
23. Dimitri P, et al. An eHealth Framework for Managing Pediatric Growth Disorders and Growth Hormone Therapy. J Med Internet Res 2021 May(5). [doi: 10.2196/27446]
24. Zhai S, Chu F, Tan M, Chi NC, Ward T, Yuwen W. Digital health interventions to support family caregivers: An updated systematic review. Journal of Digital Health 2023;9(4):145-158. [doi: 10.1177/20552076231171967]
25. Lorca-Cabrera J, Martí-Arques R, Albacar-Riobóo N, Raigal-Aran L, Roldan-Merino J, Ferré-Grau C. Mobile applications for caregivers of individuals with chronic conditions and/or diseases: Quantitative content analysis. Int J Med Inform 2021 Jan;145:104310. [doi: 10.1016/j.ijmedinf.2020.104310] [Medline: 33161319]
26. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. J Pers Soc Psychol 1988 Jun;54(6):1063-1070. [doi: 10.1037//0022-3514.54.6.1063] [Medline: 3397865]
27. Lovibond PF, Lovibond SH. The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. Behav Res Ther 1995 Mar;33(3):335-343. [doi: 10.1016/0005-7967(94)00075-u] [Medline: 7726811]
28. Keyes CLM, Wissing M, Potgieter JP, Temane M, Kruger A, van Rooy S. Evaluation of the Mental Health Continuum-Short Form (MHC-SF) in Setswana-speaking South Africans. Clin Psychol Psychother 2008;15(3):181-192. [doi: 10.1002/cpp.572] [Medline: 19115439]
29. Schwarzer R, Jerusalem M. Self-efficacy measurement: Generalized Self-Efficacy Scale. In: Measures in Health Psychology: A User's Portfolio 1995. URL: https://www.researchgate.net/publication/284672098_Measures_in_Health_Psychology_A_User's_Portfolio_Causal_and_Control_Beliefs
30. Ravens-Sieberer U, Erhart M, Rajmil L, et al. Reliability, construct and criterion validity of the KIDSCREEN-10 score: a short measure for children and adolescents' well-being and health-related quality of life. Qual Life Res 2010 Dec;19(10):1487-1500. [doi: 10.1007/s11136-010-9706-5] [Medline: 20668950]
31. Bullinger M, Quitmann J, Power M, et al. Assessing the quality of life of health-referred children and adolescents with short stature: development and psychometric testing of the QoLISSY instrument. Health Qual Life Outcomes 2013 May 7;11(1):76. [doi: 10.1186/1477-7525-11-76] [Medline: 23648112]
32. Adhera precision digital companion: your partner in pediatric health management. Adhera Health. URL: https://www.adherahealth.com/precisiondigitalcompanion [accessed 2025-09-23]
33. Arriba D. Can a mobile solution improve adherence to growth hormone treatment by modifying the emotional state of parents/caregivers? Presented at: Spanish Congress of Pediatric Endocrinology; May 10-12, 2023; Palma Malloca, Spain.
34. Arriba D. Supporting the mental wellbeing of caregivers of children under growth hormone treatment: mix-methods evaluation of the Adhera® Caring Program. 2022 Presented at: 60th Annual ESPE (ESPE 2022); Sep 15-17, 2022; Rome, Italy.

XSL•FO
RenderX

Abbreviations

ACDP: Adhera Caring Digital Program
DASS-21: Depression Anxiety and Stress Scale-21
DH: digital health
GH: growth hormone
GHD: growth hormone deficiency
GHt: growth hormone therapy
GSES: Generalized Self-Efficacy Scale
HrQoL: health-related quality of life
ISO: International Organization for Standardization
MHC-SF: Mental Health Continuum Short Form
PANAS: Positive and Negative Affect Schedule
QoLISSY: Quality of Life in short stature youths
ΔHSDS: change in height standard deviation score

Edited by S Badawy; submitted 02.10.24; peer-reviewed by J Cancela; revised version received 14.07.25; accepted 17.08.25; published 27.10.25.

Please cite as:
de Arriba Muñoz A, García-Durán AM, Sanz-Aznar P, Quer-Palomas S, Bilionis I, Xifra-Porxas A, Nuñez J, Berrios RC, Fernández-Luque L
Enhancing Adherence and Mental Well-Being in Pediatric Growth Hormone Therapy: Feasibility Prospective Observational Study of a Family-Centered Digital Companion
JMIR Pediatr Parent 2025;8:e67102
URL: https://pediatrics.jmir.org/2025/1/e67102
doi:10.2196/67102

© Antonio de Arriba Muñoz, Amalia M García-Durán, Patricia Sanz-Aznar, Silvia Quer-Palomas, Ioannis Bilionis, Alba Xifra-Porxas, Joia Nuñez, Ricardo C Berrios, Luis Fernández-Luque. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 27.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Exploring the Acceptance and Opportunities of Using a Specific Generative AI Chatbot to Assist Parents in Managing Pediatric Rheumatological Chronic Health Conditions: Mixed Methods Study

Cheryl W Y Lau[1], MSc; Klaudia Kupiec[2,3], MSc; Polly Livermore[2,3,4], MSc, PhD

[1]UCL Interaction Centre, Department of Computer Science and Division of Psychology and Language Sciences, University College London, 20 Bedford Way, London, United Kingdom

[2]Rheumatology Department, Great Ormond Street Hospital for Children NHS Foundation Trust, London, United Kingdom

[3]Infection, Immunity, and Inflammation Research and Teaching Department, Great Ormond Street Institute of Child Health, University College London, London, United Kingdom

[4]NIHR Great Ormond Street Hospital Biomedical Research Centre, UCL Great Ormond Street Institute of Child Health, London, United Kingdom

Corresponding Author:
Cheryl W Y Lau, MSc
UCL Interaction Centre, Department of Computer Science and Division of Psychology and Language Sciences, University College London, 20 Bedford Way, London, United Kingdom

Abstract

Background: Health care chatbots can be used to support patients and their families with everyday decision-making. While there is some research on integrating artificial intelligence into pediatric care, no study has focused on the opportunity of implementing a generative artificial intelligence chatbot for pediatric rheumatology. Pediatric rheumatology conditions require intense family input, which can often leave families struggling to navigate disease flares, pain, fatigue, medication side effects and adherence, and support of their child, often when pediatric rheumatology departments are shut. Understanding how we can support families better, without the need for increased personnel, will have implications for the health care systems.

Objective: The study aimed to explore parental and children and young people's acceptance of chatbot use in a pediatric context, and understand how a chatbot could be specifically used for managing a child's chronic health condition.

Methods: This study was a mixed methods design, using both a family workshop and a subsequent questionnaire.

Results: In total, 22 participants contributed to the qualitative design using the world café methodology at a workshop, and 47 participants (36 parents and 11 children and young people) completed quantitative data via a questionnaire. Participants expressed their likelihood of using chatbot technology, including ChatGPT, due to its accessibility. However, participants had significantly greater intention (parents: $P<.001$; children and young people: $P=.006$) to use a specific chatbot over ChatGPT, due to increased trust, credibility, and specificity in design. Children and young people and parents should be distinguished as 2 user groups in chatbot design, reflecting their specific needs in chatbot features and personalization.

Conclusions: Overall, the study reinforced the need for a specialized and trusted chatbot designed with input from health professionals to assist families in managing complex chronic health conditions to support families in between appointments and complement existing face-to-face care. Future research should evaluate users' engagement with a functional prototype to investigate its usefulness and explore its implementation into families' everyday lives. Importantly, the current findings have broader implications for the field of pediatric health care, as similarly tailored chatbot interventions could benefit families who are managing other chronic health conditions.

(JMIR Pediatr Parent 2025;8:e70409) doi:10.2196/70409

KEYWORDS

pediatric health care chatbot; technology acceptance; parental attitudes; children and young people's involvement; chronic disease management; AI hesitancy; chronic health condition; artificial intelligence

Introduction

Background

Generative artificial intelligence (GenAI) tools, such as ChatGPT and health care chatbots, have become increasingly accessible. However, their adoption into health care is still in its infancy. Pediatric rheumatological chronic conditions are autoimmune disorders where the body wrongly attacks itself, as such they have no clear etiology and cure [1]. Juvenile idiopathic arthritis is the most common rheumatological condition affecting one in every thousand children and young

XSL•FO
RenderX

people, causing painful joint inflammation and damage often into adulthood [2,3]. Trial and error of treatments are often needed to manage symptoms and hopefully send children and young people into remission, where the disease becomes inactive. Parents need to take charge of managing their child's health, especially when health professionals are unavailable [4]. Thus, managing a chronic condition can cause a psychological burden to children and young people and their families.

Health professionals often use medical jargon, while parents favor more neutral and simpler terminology for their children [5]. This widens a gap in effective family-clinician communication, which could manifest in medical nonadherence and impact overall treatment efficiency [6]. As parents need to interpret complex information to an appropriate comprehension level for their children, their emotional burden also increases [7-10].

Emerging research on chatbots has demonstrated their opportunities and limitations in health care applications. ChatGPT is a general large language model (LLM) that has been found to be feasible in generating detailed and empathetic responses to patients' health inquiries [11]. Yet, it is prone to fabricate academic sources, a phenomenon known as "hallucination" [12]. ChatGPT also requires clear input from users to generate more accurate responses, than using ambiguous prompts [13].

Existing health care chatbots have shown promise in improving patient outcomes through integrated care [12,14]. Seeking health information web-based health information could be appealing due to its convenience, availability, and privacy when health professionals are unavailable [15]. Compared to general internet resources, chatbot use could reduce engagement with inaccurate and often overwhelming amounts of information on the internet [16]. However, maintaining clinician-patient communication remains important to prevent self-diagnosis [17]. Therefore, there is a need for a trusted and accessible resource to support families' decision-making, alongside health care providers.

It is crucial to understand users' adoption intention to ensure successful embedment of artificial intelligence (AI) intervention into their everyday lives [18,19]. Based on Ajzen's [20] theory of planned behavior, research on chatbot acceptance in health care [21,22] has identified key factors influencing adoption intention. The theory posits that an individual's behavior is determined by their behavioral intention, which is influenced by personal attitudes, subjective norms, and perceived behavioral control. Personal attitudes are suggested to be the most influential factor of behavioral intention as attitudes reflect individuals' own beliefs and schemata [20,23]. For example, Nadarzynski et al [21] found that perceived usefulness, perceived ease-to-use, and curiosity, predicted acceptance of chatbots, though lack of trust and humanness remain concerns. In pediatric care, parental attitudes toward general AI use reveal safety and ethical concerns [24,25].

A limitation of existing studies is that findings might not be generalizable to children with diverse medical backgrounds. For instance, only 24 out of 804 (3%) parents had experience with child hospitalization in Sisk et al [26]. Haley et al [27] found that parents of a child who had been hospitalized significantly prioritized AI accuracy, than those who had not. These families might have unique experiences with medical care, increasing barriers to adopting a novel intervention.

Existing research has also neglected children and young people's involvement as they often considered parental attitudes. Involving users in the development of AI health technology could increase transparency and trust while preventing dissatisfaction and disengagement [28,29].

Research Aims

The ongoing "IMPACT" (Interventions to Improve Mental Health Support in Families With Children and Young People With Chronic Rheumatological Conditions) project [30] aims to design, develop, and test a chatbot intervention to support families between appointments for pediatric rheumatological conditions. However, as part of this work, an opportunity arose to gain an understanding of parental and child thinking surrounding AI in general in health care. We, therefore, aimed to explore the attitudes and technology acceptance perspectives of parents and their children and young people. The overall aim is not for a chatbot to replace existing traditional care, but to enhance the support of families between appointments.

This study consists of 2 methodologies. The first piece of work presents data from a family co-design workshop, where families' opinions on using a chatbot in a pediatric health care context were gathered. Subsequently, a questionnaire was conducted to follow up on the findings identified at the workshop. This mixed methods design allows further probing of the data from the workshop and thus aids a richer insight into perspectives of AI in health care. This study presents both (1) the workshop and (2) the questionnaire, split into separate methods and results, with a combined discussion.

This study aims to address the following research questions (RQs): (RQ1) What are parental and children and young people's general attitudes and behavioral intentions toward chatbot use, such as ChatGPT? (RQ2) What are parental and children and young people's attitudes and behavioral intentions toward the potential use of a chatbot specifically designed for pediatric rheumatology and do they differ when considering ChatGPT? (RQ3) What are the opportunities and concerns parents and children and young people might have toward chatbot features and content?

Methods

Study Design

The methods section will first present information relevant to the workshop, followed by the questionnaire. This study used a mixed methods design. The main aim was to use qualitative data to understand the acceptance and use of a rheumatology-specific chatbot for parents. Quantitative data have been added to briefly outline the current use of GenAI or similar, with the main focus investigating the attitudes and intentions of using AI to inform health care management. The main target audience was parents, however, as their children also attended the family workshop, we felt it would be an opportunity to seek their perspectives.

XSL•FO
RenderX

Ethical Considerations

Ethical approval was granted by the Research Ethics Committee at National Health Service (NHS) Health Research Authority, Leeds West Research Ethics Committee, and HRA and Health and Care Research Wales (IRAS 329476). The research project has been reviewed and approved locally at Great Ormond Street Hospital for Children NHS Foundation Trust for capacity and capability. The "IMPACT" study officially opened at Great Ormond Street Hospital for Children on November 10, 2023 (study: 23IR07). Informed consent was sought from all participants. Secondary analysis utilising existing data from the IMPACT study was obtained with primary consent for participating in the project. Quantitative data was fully anonymised, whilst qualitative data was deidentified as outlined in the participant information sheets and consent forms. Participation was voluntary, and no compensation was received.

Family Workshop (May 2024, London)

Design

The workshop used the world café forum method, a qualitative participatory method used in health research [31-34]. In groups, participants rotate around tables to take part in different discussions. The host of each table remains to facilitate the cross-pollination of ideas from previous groups [33]. Participants are encouraged to express themselves creatively in texts or drawings [32].

The corresponding author acted as a table host to guide discussions. A young adult in remission from juvenile idiopathic arthritis and their parent acted as facilitators to maximize participant comfort and engagement, as they shared similar experiences. Another researcher acted as a notetaker. As part of the larger study, there were 7 other tables with different research focuses.

At our table, participants familiarized themselves with 3 sets of questions and ChatGPT responses regarding pediatric rheumatological conditions in a concept testing activity (Multimedia Appendix 1). These 2 conditions were used in relation to participants' personal experiences. ChatGPT was prompted to generate responses appropriate for either a 6-year-old child or a 13-year-old teenager. Participants were then asked to discuss their likes, critiques, and opportunities regarding these responses.

Participants

Families living with a pediatric rheumatological condition requested to attend the workshop after receiving a flyer from their local health care team across the United Kingdom as they attended clinical appointments or via social media advertisements from relevant charities. There were no restrictions on who could attend and whole families were encouraged to attend. To protect families' anonymity, limited demographic and identifiable information was collected. Inclusion criteria were that families needed to have experience with a pediatric rheumatology condition and be able to speak English. The participants had received rheumatology care from different parts of the United Kingdom. The main target group for this study was parents and carers, as the chatbot created as part of the IMPACT study is targeting parents and carers in the first instance. However, as children and young people also attended the workshop with their parents, their views were also explored to understand the differences and similarities between caregivers and children and young people.

Materials

As the world café method collects creative qualitative output, participants were provided with sticky notepads, colored pens, and paper to share their ideas. Printed handouts of ChatGPT responses were also provided. A computer was used to host a live interactive demonstration of ChatGPT.

Procedure

Participants were divided into 8 groups that rotated among 8 tables every 20 minutes, with 3 breaks provided to avoid fatigue. Prior to the main activity, the host, facilitators, and participants introduced themselves to one another.

To enable conversations to occur freely, audio recording was not conducted at any table at the workshop. However, detailed notes were taken by 2 notetakers, who then cross-compared their notes to ensure objectivity [35]. Hand-written notes by the participants were also collected. At our station, we conducted a live demonstration using ChatGPT to ease participants into the discussion. Then, participants were asked a set of structured questions and probes, 5 minutes after reading the ChatGPT responses. At the end, all participants and researchers gathered to have a debrief.

Other tables had similar setups. Detailed compiled notes were shared among the researchers electronically postworkshop to be used as secondary data if relevant. One of the other tables explored participants' consensus on chatbot features in a brainstorming activity, which generated relevant findings to answer RQ3. The findings from the brainstorming activity were summarized by notetakers and therefore no transcripts are available. This strategy helped enrich the dataset and allowed cross-comparisons between data compiled by different researchers, increasing interrater reliability.

Analytical Approach

A qualitative descriptive method was followed to stay close "to the surface of words and events" on a semantic level [36]. Trends were noted as the groups progressed leading to data saturation, but with specific attention to ensuring all participants were encouraged to share their perspectives, Since notes taken from the world café forums were already interpreted to some extent, this approach could mitigate further interpretative bias. The "IMPACT" Chief Investigator (PL), who is a senior pediatric rheumatology nurse with qualitative expertise, and Research Facilitator (KK) oversaw the data process and analysis.

For the concept testing activity, a deductive approach was appropriate as the questions were designed according to the predefined categories of "likes," "critiques," and "opportunities."

Questionnaire

Design

The questionnaire design was informed by our workshop findings and a pilot study (n=22) was conducted to test the

XSL•FO
RenderX

comprehensibility and relevance of questions. A nonstandardized questionnaire was devised for the purpose of this study to allow for bespoke questions to build upon workshop findings. The potential issues of language barrier, AI literacy, and children's comprehension level were considered. It was decided that the wording of questions should be kept simple and the number of question items on each construct should be reduced.

Using pilot feedback from the workshop, iterations were made. Initially, the term "ChatGPT" was used instead of "generative AI" or "chatbot" in the questions to provide clarity to those with less knowledge in GenAI. However, it might have measured attitudes specifically toward ChatGPT. For example, a parent said they would not use ChatGPT because "it doesn't give source references for its reply." While fabrication might be observed in ChatGPT, a specific chatbot could eliminate this issue. Therefore, questions were rephrased to measure and compare attitudes toward ChatGPT or similar GenAI and a rheumatological-specific chatbot. The final questionnaire was distributed electronically to ensure completion.

Participants

Participants were recruited separately from the workshop. Using a purposive sampling method, families who had already expressed interest in the "IMPACT" study were emailed the questionnaire link. Parents were the point of contact and were asked to share the child questionnaire link with their child if they were aged 8 years and older and wanted to take part. We asked that each family be represented by one parent only, but their children and young people may have also completed a questionnaire. This sample might have overlapped with the sample of the workshop and pilot study due to the anonymity provided through the questionnaire, the numbers of these are therefore unknown.

Materials

Two versions of the questionnaire were designed, one for parents and one for children and young people, consisting of 13 and 11 questions, respectively. Participants were asked for their age, current internet health information–seeking behavior, and their current use of ChatGPT or similar GenAI. Then, participants were introduced to ChatGPT. Next, they were asked about their behavioral intention of using ChatGPT for seeking health information. This was followed by a short answer question where participants were asked to explain their rating. Participants were then presented with a scenario of a health care chatbot specifically designed by health professionals for pediatric rheumatological conditions. They were asked to rate their intention toward using this specific chatbot and explain whether their attitudes differed regarding the general and specific chatbot. Additionally, parents were asked whether their behavioral intention to use a chatbot for health care differed when it was for their child's health or their own health.

Procedure

The questionnaire was reviewed by the "IMPACT" Chief Investigator and Research Facilitator for iterations. The questionnaire was distributed through REDCap (Research Electronic Data Capture; Vanderbilt University) and sent out via email on June 21, 2024, to 60 families. A reminder was sent on June 25, 2024, and access to the questionnaire was closed on July 1, 2024.

Analytical Approach

Using Likert rating and open-ended questions, the questionnaire generated both quantitative and qualitative data. To investigate whether there is a within-group attitudinal difference in using ChatGPT and a rheumatologically specific chatbot for health, a post hoc 2-tailed Wilcoxon signed rank test was conducted. As the data were not normally distributed, the nonparametric design was used to interpret the data. Reliability measures were not used due to the minimal questionnaire design, considering sample characteristics. SPSS Statistics (version 29; IBM Corp) was used for quantitative analysis.

Braun and Clarke's [37,38] and Bryne's [39] 6 phases of reflexive thematic analysis were used to interpret the qualitative data. The steps followed included (1) familiarization with the data where participants' responses were read through to understand the overall tone and content; (2) ascribing primary codes; (3) secondary inductive coding; (4) clustering codes together to identify common ideas, factors, and findings; (5) transforming clusters into relevant and understandable themes; and (6) creating the report [37-39]. The entire analytical process and any discrepancies were regularly discussed with the "IMPACT" team (PL and KK). An audit trail and reflective data were kept at every step. An inductive thematic approach was used to analyze open-text responses to avoid overlooking unexpected themes [37]. Data were analyzed at a semantic level, staying true to participants' perspectives, which is appropriate for understanding individual stories and contexts in health research [40].

Results

The results section will first present the family workshop findings, followed by findings from the questionnaire.

Workshop Findings

Two tables at the co-design workshop explored possible chatbot features and the opportunity of using a chatbot in pediatric rheumatological care, respectively. In total, there were 8 groups of mixed participants which included children and young people (n=9; age range 5 - 26 y; mean age 13.3, SD 6.3 y) and parents (n=13). Each group consisted of 2 - 5 participants.

Chatbot Features

Personalization

Participants felt that the chatbot needs to evolve with them. For instance, families felt that simple language should be used at the beginning of diagnosis. However, explanations should become more advanced in the subsequent years as families become more familiar and do not want to feel patronized. An opportunity proposed by one participant was the idea of a "science-ometer" slider for users to dictate how scientific they wish the explanation to be. Overall, participants thought that the chatbot should be tailored to the individual patient's age, personality, and neurodiversity.

XSL•FO
RenderX

Tone

Participants thought that the specific chatbot should have a friendly, reassuring, and trustworthy tone. However, they attributed most of the trustworthiness to the endorsement by the NHS behind the design of the chatbot. Children and young people thought that the chatbot should not feel medical at all but like a peer. However, parents wanted to talk to a mentor figure, whether that is a parent with more experience or a health professional.

Anthropomorphism

The younger participants wanted to pick an animal avatar that "felt right" for them, such as a dolphin. This feature was less important for older participants and parents, who prioritized the content. They also expressed that the chatbot name or avatar would not affect their intended use. However, they also proposed other symbols to represent the chatbot, such as a torch or volcano.

Concept Testing

Conducting concept testing is advantageous in the early development of an intervention to reduce the risk of users not liking the concept, leading to limited adoption [41]. Table 1 provides a summary of users' likes, critiques, and posed opportunities.

Table . Summary of concept testing findings.

Categories	Comments
Likes	• Visual Imagery aids explanation and understanding. • Storytelling narrative is relatable. • The more technical version actually explains how the illness works well.
Critiques	• Children of similar ages do not always think in the same way, since they are exposed to different things. • Unless age is put into the prompt, users are shown information that is too confusing. • The analogy used in the 13-year-old explanation attempted to sound more technical but still used the castle analogy that was used in the explanation for a 6-year-old. It was confusing and inappropriate.
Opportunities	• Doctors' and experts' input is required for the chatbot to be reliable. • Doctors should be able to see a record of questions asked by the families to aid communication. • The child should be considered as a user for autonomy.

Questionnaire Findings

Overview

A total of 47 participants were recruited, including 36 parents and 11 children and young people (see Table 2 for demographic information). Responses to closed questions are summarized in descriptive statistics first, followed by statistical analyses. Qualitative findings are supported by the use of participant quotes ("P" denotes parent and "CYP" denotes child or young person quotes). Subsequently, qualitative analysis of responses to open-ended questions is discussed.

XSL•FO
RenderX

Table . Demographic information of parent and children and young people participants[a].

Characteristics	Parents (n=36)	Children and young people (n=11)
Age (years)		
Age of child or self, mean (SD)	11.1 (4.0)	14.8 (5.9)
Range	4 - 19	9 - 29
Time since diagnosis of child or self, n (%)		
Less than 6 months ago	0 (0)	0 (0)
6 - 12 months ago	3 (8)	1 (9)
Over 1 year ago	6 (16)	0 (0)
Over 2 years	27 (73)	10 (91)
Diagnosis, n (%)		
JIA[b]	14 (39)	4 (36)
JDM[c]	9 (25)	2 (18)
Behcet's/CAPS[d]/CRMO[e]/PFAPA[f]	5 (14)	4 (36)
Castleman/mixed connective tissue/morphea/rare genetic disorder/scleroderma/SLE[g]	8 (22)	1 (9)

[a]Parents and children and young people may not be from the same families.

[b]JIA: juvenile idiopathic arthritis.

[c]JDM: juvenile dermatomyositis.

[d]CAPS: cryopyrin-associated periodic syndrome.

[e]CRMO: chronic recurrent multifocal osteomyelitis.

[f]PFAPA: periodic fever aphthous stomatitis.

[g]SLE: systemic lupus erythematosus.

Descriptive Statistics

A total of 26 (70%) parents stated that they had heard of ChatGPT or other GenAI before, but only 14 (39%) of these said they had used any AI platforms. Of those who had, they used it for work purposes (n=11), while others (n=3) used it for general questions or "only experimented" with it. On the other hand, all 11 children and young people (100%) had heard of the technology. Less than half (n=5, 45%) had used it before; for learning (n=3), research work (n=1), and asking general questions "like the Snapchat AI" (n=1). Participants rated their self-confidence in using ChatGPT or similar GenAI technology on a 5-point Likert scale (1=not at all confident, 5=extremely confident), which was found to be low for both parents (median 2, IQR 1-3) and children and young people (median 2, IQR 1-4).

Participants were also asked to rate their likelihood of using ChatGPT or similar GenAI technology on a 5-point Likert scale (1=not at all likely, 5=extremely likely). Children and young people gave a high rating for their likelihood to use a specific chatbot (median 4, IQR 3-4) compared to ChatGPT (median 2, IQR 1-4), with a larger discrepancy indicated in the latter. Parents also rated the intended use of a specific chatbot (median 4, IQR 4-5) higher than ChatGPT (median 3, IQR 2-4) in managing their child's condition. Additionally, parents' ratings for using ChatGPT for their child's health were slightly lower than using it for their own health (median 4, IQR 2-4).

Inferential Statistics

A Wilcoxon signed rank test confirmed that there was a statistically significant difference in parents' attitudes toward using either a general or specific chatbot to assist in managing their child's health (z score=3.8; P<.001; r=0.63). Children and young people's attitudes were consistent with those of their parents (z score=2.5; P=.006; r=0.75). A total of 21 parents and 8 children and young people self-reported to be more likely to use a specific health chatbot than a general chatbot like ChatGPT. The likelihood of use was tied among 13 parents and 2 children and young people. In addition, 2 parents were more inclined to use ChatGPT than a specific chatbot for their child.

Qualitative Analysis of Questionnaire

Two follow-up questions were asked to better understand the reasons behind their ratings. Three themes were identified: accessibility, trust, and credibility in a chatbot, and specificity of chatbot design. Each theme was divided into subthemes, with quotes from participants as supporting evidence. Two subthemes in accessibility and trust and credibility did not include any quotes from children and young people because their responses were not relevant to the particular subthemes.

Theme 1: Accessibility

Limited Accessibility to Health Care Professionals

None of the children and young people mentioned the role of health professionals, whilst one participant noted their dependence on their parents. Parents expressed how using a

XSL•FO
RenderX

chatbot can mitigate the issue of having limited accessibility to health care professionals when they have questions about their child's health. As a result, many noted that they seek advice anywhere and appreciate any help. For example:

> *Any help is better than no help.* [P2]
>
> *I know the doctors do not have the time to spend with us to answer all our questions.* [P22]

Efficient Tool for Information-Seeking

One child or young person mentioned that they did not think of using ChatGPT for seeking health information before but for academic purposes only. Parents perceived the chatbot to be an efficient tool in terms of time and accessibility for information seeking, even when they were specifically asked about ChatGPT.

> *I think it's the way forward to get immediate access to health information, I've just been hesitant to use it previously but can now see the benefits of using it.* [P9]

Comprehension Accessibility

Another aspect of accessibility was the level of comprehension of health information. Parents thought chatbot-generated information could be rational, tailored, and understandable for the child. A parent said they would value tailored chatbot answers due to challenges with accessing health professionals.

> *Because it would give rational and factual information rather than trying to get answers that would not be appropriate for my child.* [P14]

Theme 2: Trust and Credibility in a Chatbot

Concerns Regarding ChatGPT's Inaccuracy

Both parents and children and young people expressed a lack of trust and confidence regarding the inaccuracy of ChatGPT on 2 levels: its open-source nature and its processing ability of complex medical information. Participants thought that ChatGPT could learn from sources that are not verified, resulting in unreliable, fabricated, or biased output. Participants also expressed distrust toward ChatGPT specifically for health care purposes, due to how complex medical information could be.

> *[ChatGPT] It is open source so [it] may use unreliable or biased sources and it is dependent upon the prompts provided so in a medical context it could be easy to get it wrong and receive inaccurate responses.* [P34]
>
> *Mainly [I have not used it] because I hadn't thought of doing so. After some thought, I wouldn't trust the information to be accurate.* [CYP3]

Unfamiliarity With Using the Technology Limits Trust

Some parents voiced their unfamiliarity with chatbot technology which led them to not having tried ChatGPT before. Therefore, they were not certain about its usefulness. Yet, all parents seemed open-minded to give the technology a try.

> *I prefer to speak to a person who can understand nuance but would be open-minded to give AI a go ... the proof would be in the experience.* [P32]

Reliance on Other Credible Sources

Participants compared chatbot use for health care to other sources that are deemed more credible, such as NHS resources and published research papers. Some participants sounded hesitant as they said that they expressed uncertainty about ChatGPT's accuracy and reliability.

> *I tend to look for the NHS website or research papers that have been published on the topic rather than asking a chatbot type for answers more so because I then can cite the information and figure out where it's all come from. I am not sure if you can do that with ChatGPT.* [CPY4]

Theme 3: Specificity of Chatbot Design

Active Involvement of Health Care Professionals

Input by health professionals and experts in the design of a specific chronic health-focused chatbot was perceived to increase its accuracy and reliability, compared to ChatGPT. Participants expressed increased comfort with using a specifically designed chatbot. However, participants' perception was solely based on their expectations rather than experience as the chatbot has not been developed yet.

> *Due to it being more regulated and designed by health professionals who will hopefully monitor effectiveness and reliability of content.* [P25]
>
> *If the information is given by a specialist who deals in these illnesses day in [and] day out, I am way more inclined to trust the information given due to it being a reputable source. It's a confident way to ask information and receive in a familiar way with the added comfort of knowing it is from a reputable source. Which is why my opinion changed rather drastically in a positive way [compared to ChatGPT].* [CYP4]

Fit-for-Purpose

All participants expressed that they were more inclined to use a chatbot that is specialized in rheumatology compared to a general chatbot like ChatGPT, GenAI, or Google. The importance of specialization due to the rarity and complexity of conditions and symptoms was highlighted.

> *It's important to us to have a resource available for this chronic condition that is not the same as Google.* [P28]
>
> *If it's specific to JDM, I would be far more likely to use it [than ChatGPT]. JDM is so rare, that questions wouldn't be answered unless it was programmed specifically for JDM.* [P5]
>
> *Rheumatological conditions can have such a vast array of symptoms that a nonhealth backed system could become quite scaremongering in leading to false information. If using a platform that has already narrowed down the results to trusted rheumatology*

XSL•FO
RenderX

information, I would feel a lot more comfortable using it [than ChatGPT]. [CYP3]

Discussion

Principal Findings

Using a mixed methods approach, we were interested in exploring both parental and children and young people's attitudes and behavioral intentions toward using ChatGPT, a general chatbot that is commercially available in a health care context (RQ1), as well as their attitudes and behavioral intentions toward using a chatbot that would be specifically designed for pediatric rheumatology. The major difference between these 2 applications concerns the content returned to families, with a specifically created disease-specific chatbot only having access to a "closed system" of physician-endorsed data, rather than the ability to search the internet and bring back results with no safety netting from a health professional. We wanted to investigate whether the behavior intentions differed and if so, how (RQ2). Opportunities and concerns raised by children and young people and parents toward chatbot features and content were identified to indicate practical design implications (RQ3).

Children and Young People and Parental Attitudes and Behavioral Intentions Toward ChatGPT and a Specific Chatbot (RQ1, RQ2)

The themes that emerged from the qualitative data contribute to our understanding of participants' attitudes and behavioral intentions supported by the quantitative data. The accessibility of the chatbot to families was a key influencing factor in adoption intention. Parents explained that they would be likely to use the chatbot as they saw it as a time-efficient and easily accessible tool to turn to when health professionals are not available. Parents found chatbot technology, including ChatGPT, to be more direct and quicker in giving them the answers they need than other web-based resources. This may explain why parents were equally likely to use it for their own health and their child's health. While it was not measured whether parents have health conditions themselves, they seemed to hold some health behavior motivation and curiosity toward a new accessible intervention. The findings are in line with previous research, which identified curiosity, perceived ease-of-use, and convenience to be motivators of health care chatbot adoption [21,42]. Chatbots, whether generally or specifically designed, could bring convenience to parents when health information-seeking. The integration of GenAI into the health care system is believed to have a positive impact on supporting medical research and decision-making for patients, families, and health care workers [43].

Our results showed that there was a statistically significant difference between participants' likelihood of using ChatGPT and a specific chatbot for managing their child's chronic health condition. Both parents and children and young people were significantly more likely to use the specific chatbot than ChatGPT for this purpose.

Trust and credibility in a chatbot was another theme identified. It highlighted participants' concerns regarding ChatGPT's accuracy which limited trust. They questioned its reliability due to open-sourcing and fabrication tendencies. Existing studies have consistently identified trust as a crucial factor in converting new users to adopt a novel technology intervention like a chatbot across contexts [21-23]. Additionally, participants thought that ChatGPT might not understand complex medical information in pediatric rheumatology and provide accurate responses. Participants' unfamiliarity with ChatGPT might have also contributed to the overall low rate of current use. Despite finding ChatGPT accessible, participants would rather obtain internet resources from trusted sources, like the NHS website. Participants demonstrated careful evaluation of ChatGPT content, which is congruent with how patients processed and sought health information on the internet in Sillence et al [44]. While perceived ease-of-use and convenience could increase adoption intention to using a health care chatbot, users must first establish trust [23]. This is supported by Abbasian et al [45] who found that accuracy, trustworthiness, and empathy should be assessed when evaluating health care–specific chatbots.

What differentiated participants' attitudes toward ChatGPT and the specific chatbot was the addition of health professionals' input and the specific design focus in the latter. The theme of specificity of chatbot designs showed that users expected the specific chatbot to be specially trained to recognize information related to rheumatological conditions. A strong need for a resource specific to pediatric rheumatology was expressed due to the disease's complexity. The specialized tool was perceived to be more reliable than ChatGPT, increasing users' trust in its evidence-based input and monitored output. Participants displayed a high level of trust toward the specific chatbot and made comparisons to ChatGPT. Participants' trust toward the specific chatbot might be explained by the theory of planned behavior [20]. It posits that subjective norm influences behavioral intention, besides attitudes. Participants might have attributed their trust in health providers to trust in the chatbot [23,46]. Participants of this study have demonstrated great engagement with the wider research project, which is advocated by health professionals they trust. Hence, families might have relied on health professionals' opinions to form a strong subjective norm to follow, thereby increasing their adoption intention. This is further supported by findings from the review by Tangsrivimol et al [47] assessing the benefits and limitations of currently available chatbots such as ChatGPT and similar chatbots relying on GenAI. They have highlighted issues with existing chatbots by discussing ethical considerations and challenges with data governance and privacy concerns, as well as issues relating to inaccurate and misleading information provided by freely available chatbots based on erroneous algorithms and hallucination. Using an LLM for managing a child's illness raises ethical concerns around safety, accountability, and privacy. Incorrect advice could cause harm, and there is no clear responsibility if things go wrong. Sharing sensitive health information also risks breaching confidentiality. Additionally, reliance on LLMs might undermine trust in health care professionals and could introduce bias, leading to unequal care. The aim of health care–specific chatbots is to overcome these issues by providing secure platforms and providing content, and features tailored to the audiences they are targeting,

XSL•FO
RenderX

whilst still encouraging engagement with existing health care teams.

Besides trust, another concern raised in previous literature on health care chatbot adoption was the lack of humanness, compared to interactions with a health professional [21]. However, we argue that lack of humanness may not always be a concern. Reducing human-human interactions could be beneficial, such as creating a stigma-free safe space. Under the theme of accessibility, the subtheme of comprehension accessibility discussed the need for a tool that can provide understandable, tailored, and rational information. Indeed, stigmatizing health-related experiences could reduce patients' engagement in medical care, treatment adherence, and help-seeking behavior [48]. Therefore, chatbot use might reduce any perceived stigma in patient-clinician interactions and provide tailored answers that users can understand. As a result, it could promote positive patient-clinician relationships and treatment outcomes.

Through analyzing families' attitudes and behavioral intentions, it was identified that users need a tool that is highly accessible to compensate for limited contact with health professionals; that they can trust, such as being backed by credible experts; and that they can depend upon to provide accurate answers to questions specific to pediatric rheumatology. However, it is important to note that this tool is seen as an aide to support the family in everyday life situations, and should be a trusted source of information. Moreover, it should not be used as a replacement for existing care provided by health care teams but rather as a platform that should be used in conjunction with existing face-to-face care from health care providers.

Opportunity of a Pediatric Chatbot (RQ3)

Through concept testing, the visual imagery and storytelling narrative used by ChatGPT were well-liked and thought to be appropriate for children and young people. However, they noted that children of the same age could behave and think very differently. In line with Vygotsky's [49] sociocultural theory, children's cognitive development is influenced by their social interactions and environment, irrespective of biological age. Hence, it might not be effective to dictate the level of comprehension in chatbot-generated output solely by age.

Younger participants and adults expressed different preferences for chatbot features and tone. Currently, parents are identified as the main user who will primarily use the chatbot either by themselves or with their children. Participants in concept testing discussed that children and young people should be considered as its own user group. There is therefore an opportunity to create a separate user interface and persona to engage children.

A study examined the impact of personas in a health care chatbot on adult users' engagement [50]. It drew on the social response theory [51], which argues that users react to computers with human-like attributes similarly to human-human interactions. The study created the personas representing a hospital institution, expert, peer, and dialogical self to measure the effect of age and gender on affective bond and use. While the study concluded with mixed findings, future research could investigate the impact of different chatbot personas on intervention engagement in children, young people, and parents. However, the functionality and usefulness of a chatbot intervention should still be prioritized over social features [52]. This is particularly highlighted by a scoping review that reviewed health-related chatbots more closely. They found that mental health and well-being–promoting chatbots need to prioritize content and functionality above everything else. For example, they found that only 44% of chatbots successfully addressed suicidal thoughts. Thus, demonstrating the need to focus on safety to safeguard vulnerable populations [53].

Limitations

Since participants were recruited voluntarily, they may be subject to social desirability bias toward the research project and team, as well as the recruitment of families from social media who equally may be biased toward AI. Additionally, some participants may have completed both the workshop and questionnaire, potentially increasing bias compared to those who only completed the survey. However, by asking participants to explain their ratings on chatbot use, they were encouraged to engage more deeply with the topic which increased objectivity [52].

The forced-choice design limits interpretation, as participants had to select the preferred option even if they were dissatisfied with both. This approach captures relative preference but may obscure low overall acceptance. Participants' attitudes were also measured based on a hypothetical scenario of chatbot use, which may not be representative of a real-life situation. However, a study found that behavior is better predicted by actual experience, than attitudes that were formed based on the stimuli provided by the researcher [54]. It was not feasible in this study since the chatbot is yet to be developed. Future research could compare changes in participants' attitudes after the chatbot has been developed. This could generate insights into how well the chatbot is embedded in users' everyday lives, which is a common concern in AI health care technology [18].

While the use of a mixed methods approach has mitigated some limitations, it increased the complexity of the study. Questions from the questionnaire measure generated both quantitative and qualitative data. This was in addition to the qualitative data from the family workshop, which consisted of primary and secondary datasets. In addition, findings from one method slightly overlapped with findings from another. As a result, it increased the difficulty in data processing and interpretation. Findings from different methods had to be carefully evaluated to ensure a holistic understanding of the research problem and research questions and a clear audit trail and regular team meetings were essential to identify potential biases. Additionally, the sample size for children and young people was too small to allow for more in-depth interpretations of the findings. Children and young people were included in this study as they attended the workshop alongside their parents, and it provided an opportunity to collect preliminary data on their views. Further research could investigate their viewpoint in more detail to understand their views on GenAI and health-specific chatbots.

As health care chatbots can have a wide spectrum of applications and target audiences, a limitation in the research field is that it is hard to compare study results. To illustrate, a recent

XSL•FO
RenderX

systematic review on health care chatbots by Laymouna et al [55] found that only 10 out of 161 (6%) studies reviewed were designed for chronic health patients. Health care chatbots could also serve different functionalities, such as everyday management, education, and administrative support. Another review on chatbots for chronic patients [56] only discovered 10 published studies, confirming that the research field is still in its infancy. Moreover, 60% of studies looked at different chronic health conditions. It is important therefore to consider developing specialized chatbots for different conditions as they potentially vary in symptoms, causes, and management.

Conclusions

This study contributes to the body of literature on AI in pediatric health care, by exploring parental and children and young people's attitudes and acceptance toward a specialized GenAI chatbot for pediatric rheumatology. While this study focused on pediatric rheumatology, findings might be generalizable to other chronic pediatric health conditions. The study also adds to the existing studies on health care chatbots, as the preference for a specific chatbot is demonstrated over a general chatbot, like ChatGPT. Families wanted a chatbot that was accessible and able to "translate" medical information into language suitable for individuals' comprehension levels. Moreover, trust and credibility regarding the chatbot's input, design, and regulation promoted users' adoption intention. As the current "IMPACT" study is based on the concept of a specialized pediatric chatbot, future work should continue to involve users in chatbot development. A chatbot developed for specific pediatric conditions could drastically change the way patients and caregivers seek health information digitally. Not only will families receive the information they want when they need it but also they could be empowered in chronic health management, whilst maintaining a partnership with their child's health professionals.

Acknowledgments

The study is part of a wider research project led by Great Ormond Street Hospital for Children NHS Foundation Trust in London, United Kingdom. We would like to express gratitude to the IMPACT (Interventions to Improve Mental Health Support in Families With Children and Young People With Chronic Rheumatological Conditions) steering group for their support throughout this project and to all the children, young people, and parents who took part. The steering group comprises Eire Byrne, Natalia Kasaru, Morgan Pawlett, Cameron Papantoniou, Emily Earle, Nathanael Bourns, Rachel Pulfree-Blythe, Eunice Kasaru, Emma Piepenstock, Gemma Molyneux, and Heather Rostron [30]. This study is funded by a National Institute for Health and Care Research (NIHR) Advanced Clinical Academic Research Fellowship (ICA-ACAF-302864).

Data Availability

The datasets generated or analyzed during this study are not publicly available due to them containing identifiable information regarding the participants but are available from the corresponding author upon reasonable request.

Authors' Contributions

CWYL conducted the research and wrote the manuscript with significant input and supervision from KK and PL in every process. KK also engaged in data collection for the questionnaire study. KK and PL were significantly involved in data processing and analysis. PL oversaw the whole study and the wider research project. All authors read and approved the final paper.

Conflicts of Interest

PL is currently receiving a personal fellowship award from the National Institute for Health and Care Research (NIHR) fellowship for nonmedical health care professionals (ACAF reference 302864), and as PPIE colead for the NIHR Great Ormond Street Hospital for Children (GOSH) BRC, she receives some salary support from the NIHR Biomedical Research Center at GOSH. PL is also a senior center affiliate at the Center for Adolescent Rheumatology Versus Arthritis at University College London (UCL) University College London Hospitals (UCLH), and GOSH, which is supported by Versus Arthritis (21593).

Multimedia Appendix 1
World café concept testing questions.
[DOCX File, 17 KB - pediatrics_v8i1e70409_app1.docx]

References

1. Schaller JG. The history of pediatric rheumatology. Pediatr Res 2005 Nov;58(5):997-1007. [doi: 10.1203/01.PDR.0000182823.85717.48] [Medline: 16183803]
2. Egert Y, Egert T, Costello W, Prakken BJ, Smith EMD, Wulffraat NM. Children and young people get rheumatic disease too. Lancet Child Adolesc Health 2019 Jan;3(1):8-9. [doi: 10.1016/S2352-4642(18)30374-2] [Medline: 30473439]
3. Juvenile idiopathic arthritis. National Rheumatoid Arthritis Society. 2022. URL: https://nras.org.uk/resource/juvenile-idiopathic-arthritis/

XSL•FO
RenderX

#:~:text=Approximately%2012%2C000%20children%20and%20young,children%20can%20get%20inflammatory%20arthritis [accessed 2024-08-10]
4. Smith BA, Kaye DL. Treating parents of children with chronic health conditions: the role of the general psychiatrist. FOC 2012 Jul;10(3):255-265. [doi: 10.1176/appi.focus.10.3.255]
5. Hunter JD, Robertson EG, Hetherington K, et al. What's in a name? Parents' and healthcare professionals' preferred terminology for pathogenic variants in childhood cancer predisposition genes. J Pers Med 2022 Aug 18;12(8):1327. [doi: 10.3390/jpm12081327] [Medline: 36013276]
6. Martin LR, Williams SL, Haskard KB, Dimatteo MR. The challenge of patient adherence. Ther Clin Risk Manage 2005 Sep;1(3):189-199. [Medline: 18360559]
7. Shaw A, Ibrahim S, Reid F, Ussher M, Rowlands G. Patients' perspectives of the doctor-patient relationship and information giving across a range of literacy levels. Patient Educ Couns 2009 Apr;75(1):114-120. [doi: 10.1016/j.pec.2008.09.026] [Medline: 19041210]
8. Dahm M. Coming to terms with medical terms—exploring insights from native and non-native english speakers in patient-physician communication. HJLCB 2012;49(49):79-98. [doi: 10.7146/hjlcb.v25i49.97739]
9. Fujimori M, Uchitomi Y. Preferences of cancer patients regarding communication of bad news: a systematic literature review. Jpn J Clin Oncol 2009 Apr;39(4):201-216. [doi: 10.1093/jjco/hyn159] [Medline: 19190099]
10. Torres-Made MD, Peláez-Ballestas I, García-Rodríguez F, et al. Development and validation of the CAREGIVERS questionnaire: multi-assessing the impact of juvenile idiopathic arthritis on CAREGIVERS. Pediatr Rheumatol Online J 2020 Jan 14;18(1):3. [doi: 10.1186/s12969-020-0400-z] [Medline: 31937332]
11. Ayers JW, Poliak A, Dredze M, et al. Comparing physician and artificial intelligence chatbot responses to patient questions posted to a public social media forum. JAMA Intern Med 2023 Jun 1;183(6):589-596. [doi: 10.1001/jamainternmed.2023.1838] [Medline: 37115527]
12. Xiao D, Meyers P, Upperman JS, Robinson JR. Revolutionizing healthcare with ChatGPT: an early exploration of an AI language model's impact on medicine at large and its role in pediatric surgery. J Pediatr Surg 2023 Dec;58(12):2410-2415. [doi: 10.1016/j.jpedsurg.2023.07.008] [Medline: 37544801]
13. Lyu Q, Tan J, Zapadka ME, et al. Translating radiology reports into plain language using ChatGPT and GPT-4 with prompt learning: results, limitations, and potential. Vis Comput Ind Biomed Art 2023 May 18;6(1):9. [doi: 10.1186/s42492-023-00136-5] [Medline: 37198498]
14. Huang MY, Weng CS, Kuo HL, Su YC. Using a chatbot to reduce emergency department visits and unscheduled hospitalizations among patients with gynecologic malignancies during chemotherapy: a retrospective cohort study. Heliyon 2023 May;9(5):e15798. [doi: 10.1016/j.heliyon.2023.e15798] [Medline: 37206031]
15. Berger M, Wagner TH, Baker LC. Internet use and stigmatized illness. Soc Sci Med 2005 Oct;61(8):1821-1827. [doi: 10.1016/j.socscimed.2005.03.025]
16. Khoo K, Bolt P, Babl FE, Jury S, Goldman RD. Health information seeking by parents in the internet age. J Paediatr Child Health 2008;44(7-8):419-423. [doi: 10.1111/j.1440-1754.2008.01322.x] [Medline: 18564080]
17. Ahmad F, Hudak PL, Bercovitz K, Hollenberg E, Levinson W. Are physicians ready for patients with internet-based health information? J Med Internet Res 2006 Sep 29;8(3):e22. [doi: 10.2196/jmir.8.3.e22] [Medline: 17032638]
18. Andersen TO, Nunes F, Wilcox L, Kaziunas E, Matthiesen S, Magrabi F. Realizing AI in healthcare: challenges appearing in the wild. Presented at: CHI EA '21: the 2021 CHI Conference on Human Factors in Computing Systems; May 8, 2021; Yokohama, Japan. [doi: 10.1145/3411763.3441347]
19. Rapp A, Curti L, Boldi A. The human side of human-chatbot interaction: a systematic literature review of ten years of research on text-based chatbots. Int J Hum Comput Stud 2021 Jul;151:102630. [doi: 10.1016/j.ijhcs.2021.102630]
20. Ajzen I. The theory of planned behavior. Organ Behav Hum Decis Process 1991 Dec;50(2):179-211. [doi: 10.1016/0749-5978(91)90020-T]
21. Nadarzynski T, Miles O, Cowie A, Ridge D. Acceptability of artificial intelligence (AI)-led chatbot services in healthcare: a mixed-methods study. Digital Health 2019;5:2055207619871808. [doi: 10.1177/2055207619871808] [Medline: 31467682]
22. Zhang P, Boulos MNK. Generative AI in medicine and healthcare: promises, opportunities and challenges. Future Internet 2023;15(9):286. [doi: 10.3390/fi15090286]
23. Brachten F, Kissmer T, Stieglitz S. The acceptance of chatbots in an enterprise context—a survey study. Int J Inf Manage 2021 Oct;60. [doi: 10.1016/j.ijinfomgt.2021.102375]
24. Berghea EC, Ionescu MD, Gheorghiu RM, et al. Integrating artificial intelligence in pediatric healthcare: parental perceptions and ethical implications. Children (Basel) 2024 Feb 14;11(2):240. [doi: 10.3390/children11020240] [Medline: 38397353]
25. Lim-Dy A, Saikia S, Pathak Y. Ethical issues using AI in the field of pediatrics. In: Ethical Issues in AI for Bioinformatics and Chemoinformatics: CRC Press; 2023:136-148.
26. Sisk BA, Antes AL, Burrous S, DuBois JM. Parental attitudes toward artificial intelligence-driven precision medicine technologies in pediatric healthcare. Children (Basel) 2020 Sep 20;7(9):145. [doi: 10.3390/children7090145] [Medline: 32962204]
27. Haley LC, Boyd AK, Hebballi NB, et al. Attitudes on artificial intelligence use in pediatric care from parents of hospitalized children. J Surg Res 2024 Mar;295:158-167. [doi: 10.1016/j.jss.2023.10.027] [Medline: 38016269]

XSL•FO
RenderX

28. Visram S, Leyden D, Annesley O, Bappa D, Sebire NJ. Engaging children and young people on the potential role of artificial intelligence in medicine. Pediatr Res 2023 Jan;93(2):440-444. [doi: 10.1038/s41390-022-02053-4] [Medline: 35393524]
29. Klos MC, Escoredo M, Joerin A, Lemos VN, Rauws M, Bunge EL. Artificial intelligence-based chatbot for anxiety and depression in university students: pilot randomized controlled trial. JMIR Form Res 2021 Aug 12;5(8):e20678. [doi: 10.2196/20678] [Medline: 34092548]
30. Livermore P. The IMPACT Study. URL: https://www.theimpactstudy.co.uk/ [accessed 2024-11-28]
31. Brown J. The World Café: Shaping Our Futures Through Conversations That Matter: ReadHowYouWant; 2010:157-175.
32. Löhr K, Weinhardt M, Sieber S. The "World Café" as a participatory method for collecting qualitative data. Int J Qual Methods 2020 Jan 1;19:1609406920916976. [doi: 10.1177/1609406920916976]
33. MacFarlane A, Galvin R, O'Sullivan M, et al. Participatory methods for research prioritization in primary care: an analysis of the World Café approach in Ireland and the USA. Fam Pract 2017 Jun 1;34(3):278-284. [doi: 10.1093/fampra/cmw104] [Medline: 27677298]
34. Schiele H, Krummaker S, Hoffmann P, Kowalski R. The "research world café" as method of scientific enquiry: combining rigor with relevance and speed. J Bus Res 2022 Feb;140:280-296. [doi: 10.1016/j.jbusres.2021.10.075]
35. Miles MB, Huberman M, Saldana J. Qualitative Data Analysis: A Methods Sourcebook, 3rd edition: Sage; 2014.
36. Colorafi KJ, Evans B. Qualitative descriptive methods in health science research. HERD 2016 Jul;9(4):16-25. [doi: 10.1177/1937586715614171] [Medline: 26791375]
37. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
38. Braun V, Clarke V. One size fits all? What counts as quality practice in (reflexive) thematic analysis? Qual Res Psychol 2021 Jul 3;18(3):328-352. [doi: 10.1080/14780887.2020.1769238]
39. Byrne D. A worked example of Braun and Clarke's approach to reflexive thematic analysis. Qual Quant 2022 Jun;56(3):1391-1412. [doi: 10.1007/s11135-021-01182-y]
40. Campbell K, Orr E, Durepos P, et al. Reflexive thematic analysis for applied qualitative health research. TQR 2021;26(6):2011-2028. [doi: 10.46743/2160-3715/2021.5010]
41. Sproll S, Peissner M, Sturm C. From product concept to user experience: exploring UX potentials at early product stages. Presented at: NordiCHI '10: the 6th Nordic Conference on Human-Computer Interaction: Extending Boundaries; Oct 16-20, 2010; Reykjavik, Iceland. [doi: 10.1145/1868914.1868968]
42. Chang IC, Shih YS, Kuo KM. Why would you use medical chatbots? Interview and survey. Int J Med Inform 2022 Sep;165:104827. [doi: 10.1016/j.ijmedinf.2022.104827] [Medline: 35797921]
43. Temsah MH, Aljamaan F, Malki KH, et al. ChatGPT and the future of digital health: a study on healthcare workers' perceptions and expectations. Healthcare (Basel) 2023 Jun 21;11(13):1812. [doi: 10.3390/healthcare11131812] [Medline: 37444647]
44. Sillence E, Briggs P, Harris PR, Fishwick L. How do patients evaluate and make use of online health information? Soc Sci Med 2007 May;64(9):1853-1862. [doi: 10.1016/j.socscimed.2007.01.012]
45. Abbasian M, Khatibi E, Azimi I, et al. Foundation metrics for evaluating effectiveness of healthcare conversations powered by generative AI. NPJ Digital Med 2024 Mar 29;7(1):82. [doi: 10.1038/s41746-024-01074-z] [Medline: 38553625]
46. Liao YT, Vitak J, Kumar P, Zimmer M, Kritikos K. Understanding the role of privacy and trust in intelligent personal assistant adoption. In: Information in Contemporary Society: 14th International Conference, iConference 2019: Springer International Publishing; 2019:102-113. [doi: 10.1007/978-3-030-15742-5_9]
47. Tangsrivimol JA, Darzidehkalani E, Virk HUH, et al. Benefits, limits, and risks of ChatGPT in medicine. Front Artif Intell 2025;8:1518049. [doi: 10.3389/frai.2025.1518049] [Medline: 39949509]
48. Stangl AL, Earnshaw VA, Logie CH, et al. The Health Stigma and Discrimination Framework: a global, crosscutting framework to inform research, intervention development, and policy on health-related stigmas. BMC Med 2019 Feb 15;17(1):31. [doi: 10.1186/s12916-019-1271-3] [Medline: 30764826]
49. Vygotsky LS. The Development of Higher Psychological Processes: Harvard University Press; 1978, Vol. 6:23-43.
50. Nißen M, Rüegger D, Stieger M, et al. The effects of health care chatbot personas with different social roles on the client-chatbot bond and usage intentions: development of a design codebook and web-based study. J Med Internet Res 2022 Apr 27;24(4):e32630. [doi: 10.2196/32630] [Medline: 35475761]
51. Nass C, Moon Y. Machines and mindlessness: social responses to computers. J Soc Issues 2000 Jan;56(1):81-103. [doi: 10.1111/0022-4537.00153]
52. Wang X, Luo R, Liu Y, Chen P, Tao Y, He Y. Revealing the complexity of users' intention to adopt healthcare chatbots: a mixed-method analysis of antecedent condition configurations. Inf Process Manag 2023 Sep;60(5):103444. [doi: 10.1016/j.ipm.2023.103444]
53. Xue J, Zhang B, Zhao Y, et al. Evaluation of the current state of chatbots for digital health: scoping review. J Med Internet Res 2023 Dec 19;25:e47217. [doi: 10.2196/47217] [Medline: 38113097]
54. Singer E, Couper MP. Some methodological uses of responses to open questions and other verbatim comments in quantitative surveys. Methods Data Anal 2017:115-134. [doi: 10.12758/mda.2017.01]

XSL•FO
RenderX

55. Laymouna M, Ma Y, Lessard D, Schuster T, Engler K, Lebouché B. Roles, users, benefits, and limitations of chatbots in health care: rapid review. J Med Internet Res 2024 Jul 23;26:e56930. [doi: 10.2196/56930] [Medline: 39042446]
56. Schachner T, Keller R, V Wangenheim F. Artificial intelligence-based conversational agents for chronic conditions: systematic literature review. J Med Internet Res 2020 Sep 14;22(9):e20701. [doi: 10.2196/20701] [Medline: 32924957]

Abbreviations

AI: artificial intelligence
GenAI: generative artificial intelligence
IMPACT: Interventions to Improve Mental Health Support in Families With Children and Young People With Chronic Rheumatological Conditions
LLM: large language model
NHS: National Health Service
REDCap: Research Electronic Data Capture

Edited by S Badawy; submitted 20.12.24; peer-reviewed by S Mohanadas, S Kumar, X Ji; revised version received 01.05.25; accepted 20.05.25; published 01.07.25.

Please cite as:
Lau CWY, Kupiec K, Livermore P
Exploring the Acceptance and Opportunities of Using a Specific Generative AI Chatbot to Assist Parents in Managing Pediatric Rheumatological Chronic Health Conditions: Mixed Methods Study
JMIR Pediatr Parent 2025;8:e70409
URL: https://pediatrics.jmir.org/2025/1/e70409
doi:10.2196/70409

© Cheryl W Y Lau, Klaudia Kupiec, Polly Livermore. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 1.7.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Evaluating the Impact of Pediatric Digital Mental Health Care on Caregiver Burnout and Absenteeism: Longitudinal Observational Study

Darian Lawrence-Sidebottom[1*], PhD; Kelsey McAlister[2*], PhD; Aislinn Brenna Beam[1], PhD; Rachael Guerra[1], PhD; Amit Parikh[1], MD; Monika Roots[1], MD; Donna McCutchen[1], LCSW; Landry Goodgame Huffman[1], PhD; Jennifer Huberty[1,2], PhD

[1]Bend Health, Inc, 321 East Washington Ave #200, Madison, WI, United States

[2]Fit Minded, Inc, Phoenix, AZ, United States

[*]these authors contributed equally

Corresponding Author:
Darian Lawrence-Sidebottom, PhD
Bend Health, Inc, 321 East Washington Ave #200, Madison, WI, United States

Abstract

Background: Caregivers of children with mental health challenges are at heightened risk for burnout and absenteeism. This strain affects both their well-being and work performance, contributing to widespread workplace issues. Digital mental health interventions (DMHIs) are increasingly used to support pediatric mental health, but their impact on caregiver outcomes remains underexplored.

Objective: This study aimed to explore the associations between caregiver burnout, absenteeism (ie, missing work), comorbid symptoms, and child mental health problems, and to assess whether caregiver burnout and absenteeism improved as their child participated in a pediatric DMHI.

Methods: This retrospective study included 6506 caregivers whose children (aged 1 - 17 years) received care from Bend Health, Inc, a pediatric DMHI providing digital-based therapy and coaching, digital content, and caregiver support. Caregiver burnout, absenteeism, comorbid symptoms, and child mental health symptoms were measured by monthly assessments. Cumulative link models were used to assess the associations of between child symptoms and caregiver outcomes and to assess changes in caregiver outcomes over the course of the DMHI. Analyses of baseline associations included the full sample (n=6506), while analyses of pre-post changes in caregiver outcomes were conducted in caregivers with elevated burnout (n=2121) and absenteeism (n=1327) who had an assessment after starting care.

Results: At baseline, 45.96% (2990/6506) of caregivers reported elevated burnout and 28.96% (1884/6506) reported elevated absenteeism. More severe burnout was associated with having a child with elevated symptoms of any type (all P<.01). More severe absenteeism was significantly associated with having a child with elevated symptoms of depression (z=3.33; P<.001), anxiety (z=3.96; P<.001), inattention (z=2.48; P=.013), and hyperactivity (z=2.12; P=.03). Burnout decreased for 68.64% (1456/2121) and absenteeism decreased for 87.26% (1158/ 1327). Greater months in care was associated with less severe caregiver burnout (z=−5.48; P<.001) and absenteeism (z=−6.74; P<.001).

Conclusions: DMHIs for children may reduce caregiver burnout and absenteeism. These findings emphasize the value of employers offering pediatric DMHIs as part of employee benefits, potentially enhancing workplace outcomes.

(JMIR Pediatr Parent 2025;8:e67149) doi:10.2196/67149

KEYWORDS

digital mental health intervention; mental health; mental illnesses; mental disorders; child behavioral health; child behavior; workplace outcomes; pediatrics; children; youth; adolescents; adolescence; teenagers; digital; digital health; digital technology; digital interventions

Introduction

Children and adolescents in the United States aged 3-17 years are experiencing record levels of mental and behavioral health issues such as anxiety, depression, and attention-deficit/hyperactivity disorder (ADHD), which can contribute to increased stress, fatigue, sleep disturbances, and overall strain on family well-being [1,2]. Alongside the decline of pediatric mental health in recent years, fewer caregivers have reported that they are coping with the demands of parenting,

XSL•FO
RenderX

citing increased emotional distress, worry, feelings of helplessness, and family strain [2-5]. As a response to the crisis in caregiver mental health and well-being, the US Surgeon General issued a 2024 advisory calling for greater support for parent and caregiver mental health to improve family well-being [4].

There is substantial evidence that caregivers of children with mental health challenges are particularly vulnerable to poor mental health outcomes, as they work to meet their children's complex needs [6,7]. Caregivers whose children experience emotional and behavioral problems are under additional strain, as they frequently experience elevated parental stress, fatigue, and poor sleep [6-11]. This degradation of caregiver well-being ultimately spills into different areas of life [12], including both family and professional responsibilities.

In a survey of parents who were concerned about their children's mental health, 48% said that their concerns impacted their performance at work in some way—including challenges such as frequent disruptions during the workday and difficulty concentrating on the job [13]. Caregivers may also have to miss work, given the need to take time off for their child's medical appointments, as well as to tend to their own recuperation and care [13,14]. For example, 46% of caregivers of a child with ADHD reported reducing their weekly work hours, and 11% stopped working altogether after their child's diagnosis [15]. Burnout and absenteeism impact both caregivers and employers, leading to reduced work performance, higher employee turnover, and significant productivity costs [16,17]. Thus, the issue of caregiver well-being is critical for society as a whole, including the health care system, individuals and families, and also businesses. Given evidence suggesting the deterioration of caregiver workplace outcomes associated with caring for a child with mental health challenges, there is a need for effective treatments for both child and caregiver well-being.

Digital mental health interventions (DMHIs) in academic and commercial settings have proven effective in treating common mental and behavioral health problems in children [18-22], offering accessible and cost-effective solutions compared with standard care [23,24]. Our previous research demonstrates that a commercially available DMHI can effectively improve mental health in children and adolescents [18,19]. Additionally, multiple systematic reviews highlight DMHIs as a highly promising solution for youth mental health [20,21]. More recently, a digital platform integrating both asynchronous and synchronous support successfully reduced anxiety and depression in a large sample of Australian youth [22]. Although these interventions primarily focus on the child, our previous findings suggest that caregivers may experience secondary benefits (eg, improvements in sleep and stress) when their children receive care through a pediatric DMHI [10]. However, the impact of pediatric DMHIs on caregiver burnout and absenteeism remains underexplored. This gap in knowledge is critical, as understanding caregiver well-being is essential to supporting their ability to manage both their child's treatment and their own work and personal responsibilities effectively.

Using retrospective analyses, the purpose of this study was to (1) explore associations between caregiver burnout, absenteeism, comorbid symptoms, and child mental health problems among caregivers seeking mental health treatment for their children, and (2) assess whether caregiver burnout and absenteeism improved while their child participates in a pediatric DMHI.

Methods

Design and Participants

This study is part of a broader research effort examining the impact of a pediatric DMHI on child and caregiver outcomes. While we have published other analyses among youth and caregivers who participate in care with Bend Health [10,18,19,25], this is the first study to specifically assess the relationship between child mental health challenges and caregiver workplace outcomes (absenteeism and burnout). Caregivers of children (aged 1-17 years) participating in care with Bend Health, Inc, a collaborative care pediatric DMHI, were eligible for inclusion in this study if (1) they completed the caregiver assessments (burnout, absenteeism, sleep problems, and parental stress) at baseline (before the start of care), and (2) their child attended at least 1 session with a Bend Health practitioner (behavioral care manager [BCM], behavioral health coach [coach], or therapist) between January 1, 2023, and September 16, 2024. A total of 6508 caregivers were eligible for inclusion.

Ethical Considerations

Caregivers provide informed consent during enrollment in care with Bend Health, Inc, for primary data collection required for regular participation in care and they also agree to the use of their data in further analyses. Caregivers agree to these terms on behalf of their children and themselves, and adolescents (aged 13-17 years) also assent on their own behalf. For the purposes of this study, only deidentified data were used. There was no compensation for participation in this study because the analysis was retrospective. Study procedures were approved by the Biomedical Research Alliance of New York (Study 23-12-034-1374; approved June 5, 2023). No portion of this manuscript used generative artificial intelligence for development or writing.

Treatment

Bend Health, Inc, is a collaborative care DMHI, which delivers comprehensive mental health care to members (aged 1-17 years) and their caregivers. Care with Bend Health is described elsewhere in more detail [18,19]. Briefly, members can enroll via referral from their primary care provider, via insurance or employer benefits, or through direct-to-consumer channels. After enrollment in the web-based platform, a BCM is assigned to each member to coordinate care and communicate with external providers (eg, primary care providers), per the collaborative care model. The BCM assembles the care team, assigning a coach, and sometimes a therapist, based on coverage and each member's unique needs, and then they continue to oversee each member's care. Module-based care programs are assigned to each member to directly address a particular symptom domain (eg, anxiety or depression) and in an age-appropriate manner. In synchronous video-based sessions, the practitioners on a member's care team deliver

XSL•FO
RenderX

evidence-based care as aligned with the care plan. Members may attend multiple sessions monthly with their care team, and they may also receive care from a psychiatric provider if medication management is referred. While care with the DMHI targets the pediatric member, caregivers are closely involved in care and may receive mental health and behavior change tools to implement personally or in their interactions with their child or adolescent. Caregivers are required to attend sessions for safety reasons if their child is younger than 13 years.

Measures

The member's (ie, the child's) demographic information, including the date of birth, sex at birth (male, female, or other), gender (male, female, transgender, nonbinary, or other), and race or ethnicity, is provided by caregivers at enrollment with Bend Health, Inc. The race or ethnicity options are specified in Textbox 1. Starting May 26, 2023, the options were expanded to be more inclusive of a diverse population, and multiple responses were allowed.

Textbox 1. Race or ethnicity response options during enrollment, including options added to the demographic questions partway through the study period.

Ethnicity response options

- American Indian or Alaska Native
- Asian
- Black or African American
- Hispanic or Latino
- Native Hawaiian or other Pacific Islander
- White
- Other (removed from the list of options starting May 26, 2023)
- Chinese (added to the list of options starting May 26, 2023)
- Vietnamese (added to the list of options starting May 26, 2023)
- Filipino (added to the list of options starting May 26, 2023)
- Korean (added to the list of options starting May 26, 2023)
- Japanese (added to the list of options starting May 26, 2023)
- Chamorro (added to the list of options starting May 26, 2023)
- Other Asian (added to the list of options starting May 26, 2023)
- Some other race or multi-racial (added to the list of options starting May 26, 2023)
- Mexican, Mexican Am, Chicano (added to the list of options starting May 26, 2023)
- Puerto Rican (added to the list of options starting May 26, 2023)
- Cuban (added to the list of options starting May 26, 2023)
- Another Hispanic, Latino, or Spanish origin (added to the list of options starting May 26, 2023)

As part of care at Bend, caregivers and adolescents (aged 13-17 years) complete mental health assessments during enrollment, and they also complete follow-up assessments every month during care to measure both caregiver and member symptoms. Caregivers complete assessments to measure caregiver burnout, absenteeism (missing work), sleep problems, and parental stress, as well as inattention, hyperactivity, and oppositional symptoms for their child or adolescent (caregiver report). Caregivers of children (aged 1-12 years) also complete assessments to measure their child's anxiety, depressive symptoms, and sleep problems (caregiver report). Adolescents (aged 13-17 years) complete their own assessments to measure anxiety, depression, and sleep problems (self-report).

For all assessments except burnout, screener items are used to flag symptoms requiring further assessment. When responses to the screener items are flagged (indicating probable symptoms), the caregiver or the adolescent screens-in and completes a full validated assessment. In 2024, Bend Health's method of screening-in to the validated assessments changed. From January 1, 2023, to January 22, 2023, caregivers and adolescents completed all screeners at each assessment, followed by validated assessments based on screener responses. From January 23, 2024, onward, if an assessment is screened-in, all following assessments for that symptom are automatically screened-in. From January 23, 2024, to August 9, 2024, screeners were not taken if past assessments were screened-in. From August 9, 2024, onward, screeners were taken in addition to validated assessments when past assessments were screened-in. Once all assessments are completed (after approximately 5-25 minutes), the caregiver and child or adolescent are shown a summary of their results, including an indication of whether any symptoms were mild to severe. The assessment results are also viewed by BCMs and the care team to monitor treatment progress and make adjustments to the care plan, as necessary.

XSL•FO
RenderX

Caregiver Symptoms

Caregiver symptoms were assessed using Bend Health's regular symptom assessments, which measure a caregiver's well-being while their child is in care. To assess caregivers' work burnout, caregivers respond to a single question [16,26]: "Overall, based on your definition of burnout, how would you rate your level of burnout?" Caregivers respond using the following options: (1) "I enjoy my work. I have no symptoms of burnout" (no burnout), (2) "Occasionally I am under stress, and I don't always have as much energy as I once did, but I don't feel burned out" (low burnout), (3) "I am definitely burning out and have one or more symptoms of burnout such as physical and emotional exhaustion" (mild burnout), (4) "The symptoms of burnout that I'm experiencing won't go away. I think about frustration at work a lot" (moderate burnout), and (5) "I feel completely burned out and often wonder if I can go on. I am at the point where I may need some changes or may need to seek some sort of help" (severe burnout). Studies have demonstrated that this single-time burnout measure is valid and reliable [26-28]. This item has demonstrated good concurrent validity with the emotional exhaustion subscale of the Maslach Burnout Inventory, supporting its reliability in assessing burnout [29].

To assess caregivers' work absenteeism, defined as missing full or partial days of work, caregivers are asked the screening question: "During the past four (4) weeks, have you missed part of or an entire day of work? Have you had to come in early, go home late or work on your day off?" Responses are "Yes" or "No," and caregivers are prompted to complete section B5 of the Health and Work Performance Questionnaire (HPQ) if they respond "Yes" [30]. B5 of the HPQ includes 5 items asking the number of days (range: 0-28) in the past 4 weeks that the caregiver (1) missed an entire day of work due to problems with their own physical or mental health, (2) missed an entire day of work for any other reason (including vacation), (3) missed part of a workday due to problems with their own physical or mental health, (4) missed part of a workday for any other reason (including vacation), and (5) came in early, went home late, or worked on a day off (extended workdays). The final item is not used to assess absenteeism and thus was not considered in this *study. Section* B5 of the HPQ has demonstrated good validity, showing strong correlations with objective measures of work performance and self-reported job performance [30].

To assess caregiver sleep problems, caregivers are asked to respond to the screener question: "During the past two (2) weeks, how much (or how often) have you had problems sleeping—that is, trouble falling asleep, staying asleep, or waking up too early?" Responses are on a 5-item Likert-type scale (0=Not at all, 4=Nearly every day). If the response is 2 or greater, the caregiver completes the Insomnia Severity Index (ISI), which includes 7 items about sleep difficulties [31]. Responses to each question are on a 5-item Likert-type scale (0=None, 5=Very severe). The ISI shows strong validity, correlating well with clinician-rated insomnia and sleep diary measures [31].

To assess parental stress, caregivers complete the Parental Stress Scale (PSS) [32], which queries a caregiver's feelings about their caregiving responsibilities and their relationship with their child or children. First, they respond to the following 2 items from the PSS: "The major source of stress in my life is my child" and "Having a child leaves little time and flexibility in my life." Best-fit responses are selected on a 5-item Likert-type scale (1=Strongly disagree, 5=Strongly agree). If the response to either question is 3 (undecided) or greater, the caregiver completes the remaining 16 items of the PSS. Some items on the PSS are framed as a negative caregiving experience (eg, "Having children has been a financial burden"), with greater responses indicating more severe parental stress. Other items are framed as a positive caregiving experience (eg, "I am happy in my role as a parent"), with greater responses indicating less severe parental stress (reverse items). The PSS shows good validity, correlating strongly with related measures of parental stress and well-being [32].

Child and Adolescent Mental Health Symptoms

All assessments of mental health for children (aged 1-12 years) are completed by the caregiver (caregiver report), including assessments of anxiety, depression, sleep problems, ADHD symptoms (inattention, hyperactivity, and opposition), and sleep problems. Adolescents (aged 13-17 years) complete their own assessments of anxiety, depression, and sleep problems (self-report), but their caregivers complete the assessment for ADHD, given the need for proxy report on these symptoms. For all assessments, the reporter (caregiver or self) responds to a few screening items to flag mental health symptoms. If mental health symptoms are flagged by these screeners, the reporter completes a full validated assessment to further quantify outcomes.

For child symptoms of anxiety, depression, and sleep problems, caregivers of children respond to screener items from the *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition, Text Revision) (*DSM-V-TR*) Cross-Cutting Symptom Measure screeners [33]. If a response of 2 or greater is given to any screener, they complete the corresponding PROMIS (Patient-Reported Outcomes Measurement Information System) anxiety, depression, or sleep assessment [34]. Responses to the anxiety and depression PROMIS assessments are made using a 5-item Likert scale, with greater response values always indicating more severe or frequent symptoms (1=Never, 5=Almost always). Responses to the sleep PROMIS assessment are made using different 5-item Likert scales (depending on the question; eg, 1=Not at all, 5=Very much), with greater responses on some items indicating more severe or frequent symptoms and greater responses on other items indicating less severe or infrequent symptoms (reverse items).

For adolescent symptoms of anxiety, depression, and sleep problems, adolescents respond to items derived from the following respective screeners: Generalized Anxiety Disorder 2-item (anxiety) [35], Patient Health Questionnaire 2-item (depression) [36], and *DSM-V-TR* Cross-Cutting Symptom Measure screener for sleep (sleep problems) [33]. If there is an aggregate screener score of 2 or greater, they complete the corresponding validated assessment. For anxiety symptoms, adolescents complete the full Generalized Anxiety Disorder 7-item (GAD-7) [35]. For depressive symptoms, adolescents complete a version of the Patient Health Questionnaire 9-item

XSL•FO
RenderX

that is modified for adolescents (PHQ-9A), excluding the item about suicidal ideation [36]. For sleep problems, adolescents complete the self-report version of the PROMIS sleep assessment [37], which includes the same items as the caregiver report version used for children.

For child and adolescent symptoms of ADHD, caregivers respond to 2 *DSM-V-TR* Cross-Cutting Symptom Measure items to screen for symptoms of inattention and hyperactivity (1 question) and opposition (1 question) [33]. If symptoms are flagged given responses to these screeners, caregivers complete all of or some of the subsets of the Swanson Nolan and Pelham Rating Scale version 4 (SNAP-IV) assessment [35], which includes 3 groups of questions measuring symptoms of inattention (items 1 - 9), hyperactivity (items 10 - 18), and opposition (items 19 - 26). Responses to all items are on a Likert scale from 0 (Not at all) to 3 (Very much). From January 1, 2023, to March 31, 2024, a score of 1 or greater to the screener about inattention and hyperactivity prompted the completion of only the inattention and hyperactivity items, and a score of 1 or greater to the screener about opposition prompted the completion of only the opposition items [6]. Beginning April 1, 2024, caregivers complete all 26 questions of the SNAP-IV if their response to either screening question is 1 or greater. See the Multimedia Appendix 1 for further details on all measures used.

Outcome Calculations

Caregiver outcomes were calculated as follows. Using established criteria [27], elevated burnout was defined as a burnout score of 3 or more (mild to severe burnout). For absenteeism, reported partial days of work missed (items 3 and 4) were considered 0.5 days missed, so days of work missed was calculated as the sum of the number of full days missed (items 1 and 2) plus the sum of the number of partial days missed: item response 1 + item response 2+ (0.5 × (item response 3+ item response 4)). If the absenteeism assessment was screened-out, the number of days of work missed was 0. If the number of days of work missed exceeded 28, this value was replaced with 28. Given that the standard work week is five 8-hour days, severity of absenteeism was determined as follows: “No missed work” (screen-out or days of work missed is 0), “Missed less than one week of work” (days of work missed is 0.5-4.5), “Missed one to two weeks of work” (days of work missed is 5-9.5), “Missed two to three weeks of work” (days of work missed is 10-14.5), and “Missed three or greater weeks of work” (days of work missed is 15 or greater). Elevated absenteeism was considered missing work for 0.5 days or greater in the past 28 days. Caregiver sleep score was calculated by aggregating the responses to all 7 ISI items, for a total score of 0-28. Elevated sleep problems were considered moderate severity or severe insomnia symptoms, per the defined ranges of clinically significant sleep problems [31]. Parental stress was calculated by aggregating responses to the 18 items (with scores reversed for the reverse items), for a total score of 18-90. Elevated parental stress was considered a score of 42 or greater, given severity thresholds used by others [38,39].

Child and adolescent mental health outcomes were calculated as follows. Child anxiety and depressive symptom scores, as well as child and adolescent sleep scores, were calculated by aggregating the responses to the respective PROMIS assessments (with scores reversed for the reverse items) and then converting these total scores to *T*-scores using standardized conversion criteria [34,37,40]. Adolescent anxiety scores were calculated by aggregating responses to the GAD-7 [35]. Adolescent depression raw scores were calculated by aggregating responses to the PHQ-9A and then multiplied by 9, divided by 8, and rounded to the nearest whole number to account for the single omitted item. Inattention, hyperactivity, and oppositional symptom scores were calculated by aggregating the responses to the items in each of the symptom subsets of the SNAP-IV [41]. Symptom severity was determined for all child and adolescent symptoms using previously defined criteria [34,37,39,41-43].

For all analyses, caregiver burnout was reported based on response to the single item, and caregiver absenteeism was reported as severity of absenteeism and number of days of work missed. We chose this analytic approach to ensure that results are robust to minor changes to the screening and assessment methods (Multimedia Appendix 1). Therefore, for all outcomes except caregiver burnout and workplace absenteeism, symptom severity was analyzed as “elevated” or “not elevated.” For all symptoms except caregiver burnout, absenteeism, and parental stress, outcomes were classified as elevated if symptom severity was moderate to severe, and not elevated if the assessment was screened out or symptom severity was low to mild. A decrease in burnout or absenteeism from baseline (first assessment) was defined as a decrease in burnout score or a decrease in number of days of work missed, respectively.

Statistical Analysis

Caregiver Burnout and Workplace Absenteeism at Baseline

Caregiver outcomes at baseline (first assessment before beginning care with the DMHI) were analyzed for all caregivers with complete caregiver assessments (n=6508). Caregivers with duplicate baseline assessments (n=2) were removed for a sample size of 6506. The following characteristics were described for these caregivers: mean child age (at baseline), child sex, child race or ethnicity, type of participation with the DMHI (BCM intake only, coaching only, coaching and therapy, or therapy only), and duration of participation with the DMHI (first event to last event). Burnout and absenteeism scores were reported, as well as group trends for the number of days of work missed. Cumulative link models (CLMs) were used to assess whether workplace outcomes were associated with caregiver’s comorbid symptoms. For burnout, the predictors were elevated absenteeism, elevated sleep problems, and elevated parental stress. For absenteeism, the predictors were elevated burnout, elevated sleep problems, and elevated parental stress. Child (child and adolescent, grouped for analyses) characteristics and mental health symptoms were assessed to identify associations between predictors and caregiver burnout and workplace absenteeism. Only caregivers of children and adolescents aged 6 years or older (given age validation for pediatric assessments) and whose child had all mental health assessments complete were included in analyses (n=5628; Multimedia Appendix 1).

XSL•FO
RenderX

CLMs were used to determine whether the following child characteristics and mental health symptoms were associated with the severity of caregiver workplace outcomes (burnout and absenteeism): age (child vs teen), sex (female vs nonfemale), elevated depression, elevated anxiety, elevated inattention, elevated hyperactivity, elevated opposition, and elevated sleep problems.

Change in Caregiver Burnout and Workplace Absenteeism

Change in caregiver burnout and workplace absenteeism over their child's care with the DMHI was assessed for caregivers with elevated burnout and elevated workplace absenteeism at baseline who also met the following inclusion criteria: baseline assessment completed within 2 months of beginning care with the DMHI (ie, for an accurate assessment of mental health status at care start), and had at least 1 completed follow-up assessment after the start of care with the DMHI (see Multimedia Appendix 1 for details on exclusions). Ultimately, 2121 were included in the analyses for change in burnout and 1327 were included in the analyses for change in absenteeism. Percentages of caregivers with a decrease and increase in workplace symptoms— for both burnout and absenteeism (number of days of work missed)—were reported for the caregivers' first follow-up assessment during care as well as their last follow-up assessment during care. Percentages of caregivers with elevated workplace outcomes at these time points were also reported, and the percentages of caregivers with a decrease in workplace symptoms *reported at any time during care* were reported. Finally, percentages of caregivers with nonelevated workplace symptoms at baseline and elevated workplace symptoms at the last follow-up were reported. For absenteeism, reported decreases in the number of days worked were compared with zero using Wilcoxon signed rank tests.

For caregivers of a child with elevated mental health symptoms at baseline, the maximal percent decrease in child mental health symptom severity during care was calculated. The maximal decrease in child's mental health symptom severity was compared between groups using Wilcoxon signed rank sums tests for caregivers with a decrease in workplace symptoms versus those with no decrease in workplace symptoms at last follow-up. Only caregivers of a child with elevated symptoms at baseline and a follow-up assessment after the start of care were included in these analyses (Multimedia Appendix 1; n=1739 included in burnout and n=1041 included in absenteeism).

CLMs were used to determine whether months in care were associated with lower severity of burnout and absenteeism, and comorbid caregiver symptoms, child characteristics, and child mental health symptoms were assessed as potential covariates in these models. The basic model for each workplace symptom included months in care as a fixed effect. Likelihood ratio tests were used to compare this basic model with an identical model including a single potential covariate added as a fixed effect. The potential covariates assessed were elevated comorbid caregiver symptoms, child's age group (child vs teen), child's sex (female vs nonfemale), and child's mental health symptoms. Only predictors that significantly improved model fit were retained in the final model (see Multimedia Appendix 1 for comprehensive results from likelihood ratio tests). For burnout, all comorbid caregiver symptoms were retained, as well as child sex, and all child mental health symptoms. For absenteeism, all comorbid caregiver symptoms were retained, as well as the following child mental health symptoms: depression, anxiety, inattention, hyperactivity, and sleep. Only assessments taken after beginning care with the DMHI were considered in the CLMs.

For all CLMs, coefficient estimates were used to determine whether each predictor was associated with the severity of workplace symptoms. Throughout, the alpha-level was set to .05 for all analyses. Standard descriptive statistics (percentages; mean, SD; and median, IQR were used to describe data. Data were analyzed with RStudio (version 2023.03.0+386; Posit, PBC) [44].

Results

Overview

Overall, caregivers included in the analyses (N=6506) cared for children with a mean age of 10.58 (SD 3.81) years, and 49.86% (3244) of the children were female. In terms of reported race and ethnicity, 50.63% (3294) were white and 32.02% (2083) identified as "Other" or multiple race and ethnicity options. While all children had at least 1 session with a Bend Health practitioner, 16.25% (1057) completed only their BCM intake session, 59.67% (3882) were in coaching only, 22.69% (1476) were in coaching and therapy, and 1.40% (91) were in therapy only. The duration of participation in care with the DMHI was a median of 3.46 (1.7 - 5.9) months.

Caregiver Burnout and Workplace Absenteeism at Baseline

At baseline, 8.84% of caregivers (575) reported no symptoms of burnout, 45.20% (2941) reported low burnout, 33.60% (2186) reported mild burnout, 6.87% (447) reported moderate burnout, and 5.49% (357) reported severe burnout. In terms of absenteeism, 71.04% (4622) reported no missed work, 17.05% (1109) missed less than 1 week of work, 7.49% (487) missed 1-2 weeks of work, 2.29% (149) missed 2-3 weeks of work, and 2.14% (139) missed 3 or greater weeks of work. For those with any absenteeism (n=1884), they reported a median of 4 (2-7) days missed.

In terms of percentages of caregivers with elevated outcomes at baseline, 45.96% (2990) had elevated burnout, 28.96% (1884) had elevated absenteeism, 12.76% (830) had elevated sleep problems, and 17.57% (1143) had elevated parental stress. More severe levels of burnout were significantly associated with elevated absenteeism (z=15.30; P<.001), elevated sleep problems (z=20.41; P<.001), and elevated parental stress (z=15.30; P<.001). This same pattern was observed for severity of absenteeism; greater absenteeism was associated with elevated caregiver outcome severity of all types (all P<.001; Table 1).

More severe symptoms of burnout were significantly associated with having a younger child (child vs adolescent; z=3.20; P=.001), as well as having a child with elevated symptoms of

XSL•FO
RenderX

any type (all $P<.01$). Child sex was not associated with the severity of burnout symptoms. More severe absenteeism was associated with having a child with elevated symptoms of depression ($z=3.33$; $P<.001$), anxiety ($z=3.96$; $P<.001$), inattention ($z=2.48$; $P=.01$), and hyperactivity ($z=2.12$; $P=.03$). Child age and sex, as well as opposition and sleep problems, were not associated with the severity of absenteeism. Comprehensive results for all predictors in these analyses are reported in Table 2.

Table . Results from analyses assessing whether the severity of caregiver symptoms is associated with elevated comorbid caregiver symptoms.

Outcome (caregiver outcome severity)	Predictor (elevated comorbid caregiver symptom)	Estimate (SE)	*z* value	*P* value
Burnout	Absenteeism	0.81 (0.05)	15.30	<.001
	Sleep problems	1.49 (0.07)	20.41	<.001
	Parental stress	1.44 (0.06)	20.39	<.001
Absenteeism	Burnout	0.83 (0.06)	13.96	<.001
	Sleep problems	0.56 (0.08)	7.24	<.001
	Parental stress	0.35 (0.07)	5.07	<.001

Table . Results from analyses assessing whether the severity of caregiver symptoms is associated with their child's characteristics (demographics and symptoms).

Outcome (caregiver symptom severity)	Predictor (child's characteristic)	Estimate (SE)	*z* value	*P* value
Burnout	Age (child aged 6-12 years)	0.18 (0.06)	3.20	.001
	Sex (female)	−0.03 (0.05)	−0.59	.56
	Depression (elevated)	0.19 (0.06)	3.03	.002
	Anxiety (elevated)	0.27 (0.06)	4.81	<.001
	Inattention (elevated)	0.43 (0.06)	7.01	<.001
	Hyperactivity (elevated)	0.26 (0.08)	3.23	.001
	Opposition (elevated)	0.46 (0.06)	7.23	<.001
	Sleep problems (elevated)	0.25 (0.05)	4.58	<.001
Absenteeism	Age (child aged 6-12 years)	0.07 (0.06)	1.11	.27
	Sex (female)	0.02 (0.06)	0.34	.74
	Depression (elevated)	0.24 (0.07)	3.33	<.001
	Anxiety (elevated)	0.26 (0.07)	3.96	<.001
	Inattention (elevated)	0.18 (0.07)	2.48	.01
	Hyperactivity (elevated)	0.20 (0.09)	2.12	.03
	Opposition (elevated)	0.11 (0.07)	1.51	.13
	Sleep problems (elevated)	0.10 (0.06)	1.57	.12

Change in Caregiver Burnout and Workplace Absenteeism

For 2121 caregivers with elevated burnout at baseline and a follow-up assessment after beginning care, the first-follow-up was completed after a median of 0.90 months (0.66 - 1.13) in care with the DMHI. At this time, 49.88% (1058/2121) of caregivers with elevated burnout at baseline had a decrease in burnout symptom severity, 7.97% (169/2121) had an increase in severity, and 62.47% (1325/2121) still had elevated burnout. At the last follow-up assessment during care with the DMHI, taken after a median of 2.80 months (1.27 - 5.40) in care, 56.58% (1200/2121) of caregivers with elevated burnout at baseline had a decrease in burnout symptom severity, 6.74% (143/2121) had an increase in severity, and 54.17% (1149/2121) still had elevated burnout. The percentages of burnout severity at baseline and last follow-up are reported in Figure 1. Overall, 68.64% (1456/2121) of caregivers reported a decrease in burnout at any point during care, with the first decrease reported after a median of 1.10 months (0.80 - 1.97). At the last follow-up, children of caregivers with a decrease in burnout (n=977) had larger improvements in their own mental health than children of caregivers with no decrease in burnout (n=762; median −65.63%, IQR −100.00 to −40.00 vs median −52.51%, IQR −95.81 to −28.57; $z=-5.22$; $P<.001$). For caregivers with nonelevated burnout at baseline, 9.61% (338/3178) met the criteria for elevated burnout at their last follow-up during care.

XSL•FO
RenderX

Figure 1. Burnout symptom severity for caregivers with elevated burnout at baseline and a follow-up assessment (n=2121) reported for the baseline and last follow-up assessments.

XSL•FO
RenderX

In the analysis of burnout symptom severity during care with the DMHI, greater months in care was significantly associated with less severe symptoms of burnout (z=−5.76; P<.001). All elevated comorbid caregiver symptoms were associated with more severe burnout during care (all P<.001). The following child characteristics were associated with more severe symptoms of burnout: female sex (z=4.50; P<.001), elevated depression (z=2.01; P=.04), elevated hyperactivity (z=3.05; P=.002), and elevated sleep problems (z=4.18; P<.001). Child anxiety, inattention, and opposition were not associated with caregiver burnout during care (both P>.10).

At the first follow-up assessment during care with the DMHI, taken after a median of 0.93 months (0.70 - 1.20) in care, 73.25% (972/1327) of caregivers with elevated absenteeism at baseline had a decrease in number of days of work missed, 22.08% (293/1327) had an increase in days of work missed, and 60.14% (798/1327) still had elevated absenteeism. At the last follow-up assessment during care with the DMHI, taken after a median of 2.97 months (1.37 - 5.45) in care, 76.56% (1016/1327) of caregivers with elevated absenteeism at baseline had a decrease in absenteeism, 19.22% (255/1327) had an increase in absenteeism, and 52.75% (700/1327) still had elevated absenteeism. The percentages of amount of work missed at baseline and last follow-up are reported in Figure 2.

Overall, 87.26% (1158/1327) of caregivers reported a decrease in absenteeism at any point during care, with the first decrease reported after a median of 1.00 months (0.76 - 1.57). Caregivers with elevated absenteeism at baseline had a median decrease of 2 (4-0) days of work missed at first follow-up (z=−17.9; P<.001), and 2 (4.5-.5) fewer days of work at last follow-up (z=−19.2; P<.001). At the last follow-up, children of caregivers with a decrease in absenteeism (n=802) had larger improvements in their own mental health than children of caregivers with no decrease in absenteeism (n=239; median −64.29%, IQR −100.00 to −39.13 vs median −57.14%, IQR −91.75 to −28.57; z=−2.65; P=.008). For caregivers with nonelevated absenteeism at baseline, 10.95% (506/4622) reported missing any amount of work at their last follow-up during care.

In the analysis of change in absenteeism over time, greater months in care was significantly associated with lower levels of absenteeism (z=−6.72; P<.001). Elevated comorbid burnout significantly associated with higher levels of absenteeism during care (z=6.89; P<.001) and elevated child anxiety was marginally associated with higher levels of absenteeism (z=1.75; P=.08). Elevated comorbid sleep and elevated comorbid stress, as well as having a child with elevated depression, inattention, hyperactivity, and sleep, were not associated with absenteeism during care.

XSL•FO
RenderX

Figure 2. Amount of work missed for caregivers with elevated absenteeism at baseline and a follow-up assessment (n=1327) reported for the baseline and last follow-up assessments.

XSL•FO
RenderX

Discussion

Principal Results

Using retrospective analysis, the purpose of this study was to (1) explore associations between caregiver burnout, absenteeism, comorbid symptoms, and child mental health problems among caregivers seeking mental health treatment for their children, and (2) assess whether caregiver burnout and absenteeism improved while their child participates in a pediatric DMHI.

Before beginning care with the DMHI, 46% (2990/6506) of caregivers had elevated burnout and 29% (1884/5606) had elevated workplace absenteeism. Child characteristics and mental health symptom presentation were significantly associated with their caregiver's workplace symptoms. Furthermore, while their child participated in care, 69% (1456/2121) of caregivers reported a decrease in burnout and 87% (1158/1327) reported a decrease in absenteeism. These changes were notable after only 1 month in care, with 50% (1058/2121) of caregivers reporting reduced burnout, and nearly 3 in 4 (972/1327, 73%) reporting a reduction in the number of days of work missed. Greater time in the DMHI significantly associated with less severe workplace symptoms, and children of caregivers with improvement in workplace symptoms reported larger improvements in pediatric outcomes than those whose caregiver did have improvement in workplace symptoms.

We found that symptoms of elevated burnout and workplace absenteeism were prevalent in caregivers before starting care with the pediatric DMHI, as almost half and about one-third reported elevated burnout and absenteeism, respectively. It is well known that workplace burnout and absenteeism, which are at historic highs [45,46], are perpetuated by family-related stress, particularly a child's mental health difficulties [14,47-51]. Parents spend a significant amount of time managing their children's mental and behavioral health needs, which is exacerbated by lack of access to and knowledge of evidence-based mental health treatment options for their children [48,52]. Thus, it is unsurprising that percentages of burnout (2990/6506, 46%) and workplace absenteeism (1884/6506, 29%) were high among caregivers actively seeking treatment for their child's mental health challenges.

Burnout was higher among those caring for a child with any elevated mental health symptom severity, and absenteeism was higher among those caring for a child with elevated internalizing (ie, anxiety and depression), inattention, and hyperactivity symptoms. These findings align with previous literature suggesting a reciprocal relationship, where a child's mental health challenges exacerbate caregiver sleep problems and stress [53,54], which can contribute to caregiver burnout and absenteeism [55-57]. In turn, while some studies highlight the additional burden of parenting a child with mental health and behavioral challenges [6-9,11,58], caregiver burnout may exacerbate child mental health challenges by reducing the caregiver's capacity to provide emotional support and consistent care [59,60]. Given the complex bidirectional relationship between child-caregiver well-being [54], it is critical to highlight interventions that may produce benefit for both caregivers and their children. As the first study to examine both caregiver absenteeism and burnout across multiple child mental health challenges, this work builds on prior studies that have focused on single conditions (eg, ADHD and autism) or isolated workplace outcomes [15], contributing to a broader understanding of the link between caregiver and child well-being.

While children were in care with the DMHI, their caregivers exhibited significant improvements in workplace symptoms. Burnout decreased in 69% (1456/2121) of caregivers and absenteeism decreased in 87% (1158/1327) at any point during care, with caregivers reporting that they missed 2 fewer days of work at the end of their child's care than initially reported at baseline. Other studies have reported that caregivers whose children engage in traditional modes of mental and behavioral health care evince corresponding improvements, such as decreases in parental stress, sleep problems, anxiety, and depression [61,62]. In a study of caregivers and youth participating in a DMHI, Grodberg et al [48] found that increases in caregiver productivity throughout care were linked to increases in caregivers' feelings of connectedness to their children. Similarly, our recent evidence also suggests that caregivers whose children engage in a pediatric DMHI report decreased parental stress and sleep problems [10]. The present findings extend this work by demonstrating that these caregiver benefits also translate into occupational outcomes, with greater time in care associated with reductions in both burnout and absenteeism. Notably, improvements in caregiver workplace symptoms were associated with larger improvements in child mental health symptoms during care. These results are largely in-line with the broader literature that indicates a bidirectional relationship between caregiver and child well-being [53-57]. Our findings highlight the opportunity for employers to manage employees' burnout and absenteeism by providing mental health care not only for employees themselves but also for their children and families.

Strengths and Limitations

Our study has several strengths. This is the first study, to our knowledge, to address the potential downstream benefits of pediatric care with a DMHI on the workplace symptoms of their caregivers. The deterioration of parent and caregiver well-being has been increasing in prevalence and was called out in 2024 by the US Surgeon General as a critical problem [4]. We demonstrate that addressing child mental health may be an effective avenue to reduce caregiver strain and workplace problems. From an analytic standpoint, this study draws data from a large sample, with more than 6000 caregivers included in analyses of mental health symptoms at baseline, more than 2000 change in burnout analyses, and more than 1000 for change in absenteeism analyses. Additionally, this study assesses outcomes associated with an established, commercial, and successful DMHI, which has been shown to be effective in addressing child and adolescent mental health challenges [18,19,25]. Our findings overall contribute to a growing body of evidence supporting the use of DMHIs—which are typically more flexible and accessible than traditional care—to address both pediatric and caregiver well-being.

XSL•FO
RenderX

There are some limitations of this study. This was a retrospective study that prevented us from drawing any causal conclusions, and we relied on self-report measures to obtain information regarding all outcomes of interest. Further research using an experimental design and using objective measures where possible (eg, reports of caregiver absences from work) is necessary to determine whether involvement in a pediatric DMHI precipitates improvements in caregiver workplace symptoms. While some improvement may be expected due to regression to the mean following a child's referral to care, our findings suggest that greater time in care contributes to continued reductions in burnout and absenteeism. Controlled studies are needed to further clarify the extent to which these changes reflect treatment effects versus natural symptom resolution over time. We also did not collect demographic information on caregivers, which limits our ability to examine whether caregiver characteristics (eg, age and biological sex) influenced burnout and absenteeism.

Another limitation of this study is that we did not ask caregivers whether they were employed, their type of employment, or their hours worked per week. The burnout and absenteeism measures used in this study do not define "work," and caregivers responded based on their interpretation of what "work" was, full-time, part-time, paid, or unpaid. As a result, we were unable to differentiate between burnout and absenteeism among caregivers who were employed in different capacities or engaged in informal caregiving roles. Without these data, we cannot determine whether reductions in absenteeism reflect actual changes in workplace behavior, time away from caregiving responsibilities, or broader improvements in caregiver functioning. Future studies should consider frequency of occurrence and types of employment and inclusion of caregivers who engage in informal caregiving and other unpaid work when considering burnout and absenteeism [63]. We used a single-item burnout measure and a single section from the HPQ questionnaire to assess absenteeism, which prevented us from comprehensively assessing our workplace outcomes. These decisions were made to simplify the assessment process and limit burden. While we considered the possibility that improvements in child mental health could be linked to improvements in caregiver workplace symptoms, we did not examine the specific types of mental health symptoms or care targets, as these were beyond the scope of this study. Future studies should account for a variety of children's mental health symptoms and more comprehensively assess caregivers' burnout, absenteeism, and presenteeism to address these limitations.

Finally, the nature of administering assessments and screeners changed partway through the study. Given that the burnout assessment did not have a corresponding screener and the absenteeism screener was simply used to identify no absenteeism, we do not expect that these methodological changes had any substantive impact on our main findings. While the total scores for the other caregiver and child mental health outcomes may have been affected by the changes in the screening methods, we only assessed whether elevated versus nonelevated symptoms predicted caregiver workplace outcomes. Thus, we expect that our findings are robust to these small methodological changes.

Conclusions

Caregivers are growing increasingly concerned about their children's mental health, which in turn is impacting their well-being and performance in the workplace. This study provides promising preliminary evidence that caregivers show decreases in their burnout and absenteeism when their children participate in a pediatric DMHI. As such, employers should consider offering pediatric digital mental health care to employees with children experiencing mental health difficulties, which may mitigate burnout and absenteeism. While these findings highlight the potential benefits of digital mental health care for working caregivers, future research should compare DMHIs with traditional face-to-face mental health care to determine their relative effectiveness and accessibility.

Conflicts of Interest

DLS, MR, and DM are employed by Bend Health, and Bend Health delivered the treatment used in this retrospective study. JH is a paid consultant of Bend Health. KM is an employee of JH and Fit Minded. However, authors' employment status and/or salary are not dependent upon the results of their research.

Multimedia Appendix 1
Supplemental methods.
[DOCX File, 17 KB - pediatrics_v8i1e67149_app1.docx]

References

1. Henderson MD, Schmus CJ, McDonald CC, Irving SY. The COVID-19 pandemic and the impact on child mental health: a socio-ecological perspective. Pediatr Nurs 2020;46(6):267-290.
2. Lebrun-Harris LA, Ghandour RM, Kogan MD, Warren MD. Five-year trends in US children's health and well-being, 2016-2020. JAMA Pediatr 2022 Jul 1;176(7):e220056. [doi: 10.1001/jamapediatrics.2022.0056] [Medline: 35285883]
3. Sloan CJ, Mailick MR, Hong J, Ha JH, Greenberg JS, Almeida DM. Longitudinal changes in well-being of parents of individuals with developmental or mental health problems. Soc Sci Med 2020 Nov;264:113309. [doi: 10.1016/j.socscimed.2020.113309] [Medline: 32858491]

XSL•FO
RenderX

4. Parents under pressure: the US surgeon general's advisory on the mental health & well-being of parents. US Surgeon General. 2024. URL: https://www.hhs.gov/sites/default/files/parents-under-pressure.pdf [accessed 2025-05-28]
5. Patrick SW, Henkhaus LE, Zickafoose JS, et al. Well-being of parents and children during the COVID-19 pandemic: a national Survey. Pediatrics 2020 Oct;146(4):e2020016824. [doi: 10.1542/peds.2020-016824] [Medline: 32709738]
6. Lohaus A, Chodura S, Möller C, et al. Children's mental health problems and their relation to parental stress in foster mothers and fathers. Child Adolesc Psychiatry Ment Health 2017;11(43):43. [doi: 10.1186/s13034-017-0180-5] [Medline: 28878817]
7. Theule J. Predicting Parenting Stress in Families of Children With ADHD: University of Toronto Ontario; 2010.
8. Alfano CA, Gamble AL. The role of sleep in childhood psychiatric disorders. Child Youth Care Forum 2009 Dec 1;38(6):327-340. [doi: 10.1007/s10566-009-9081-y] [Medline: 19960111]
9. Cortese S, Faraone SV, Konofal E, Lecendreux M. Sleep in children with attention-deficit/hyperactivity disorder: meta-analysis of subjective and objective studies. J Am Acad Child Adolesc Psychiatry 2009 Sep;48(9):894-908. [doi: 10.1097/CHI.0b013e3181ac09c9] [Medline: 19625983]
10. Huffman LG, Lawrence-Sidebottom D, Huberty J, et al. Sleep problems and parental stress among caregivers of children and adolescents enrolled in a digital mental health intervention. Front Child Adolesc Psychiatry 2023;2:1265095. [doi: 10.3389/frcha.2023.1265095] [Medline: 39816884]
11. Mesman J, Koot HM. Child-reported depression and anxiety in preadolescence: I. Associations with parent- and teacher-reported problems. J Am Acad Child Adolesc Psychiatry 2000 Nov;39(11):1371-1378. [doi: 10.1097/00004583-200011000-00011] [Medline: 11068892]
12. Bakker A, Demerouti E. Job demands-resources model of burnout. J Work Organ Psychol 2013 Jan;29(3):107-115. [doi: 10.5093/tr2013a16]
13. Christenson JD, Crane DR, Malloy J, Parker S. The cost of oppositional defiant disorder and disruptive behavior: a review of the literature. J Child Fam Stud 2016 Sep;25(9):2649-2658. [doi: 10.1007/s10826-016-0430-9]
14. Gawlik KS, Melnyk BM, Mu J, Tan A. Psychometric properties of the new working parent burnout scale. J Pediatr Health Care 2022;36(6):540-548. [doi: 10.1016/j.pedhc.2022.05.020] [Medline: 35811259]
15. Noe L, Hankin C. Pmh10: health outcomes of childhood attention-deficit/hyperactivity disorder (ADHD): health care use and work status of caregivers. Value Health 2001 Sep;4(2):142-143. [doi: 10.1046/j.1524-4733.2001.40202-196.x]
16. Schonfeld IS, Bianchi R. From Burnout to Occupational Depression: Recent Developments in Research on Job-Related Distress and Occupational Health. Front Public Health 2021;9:796401. [doi: 10.3389/fpubh.2021.796401] [Medline: 34957039]
17. Strömberg C, Aboagye E, Hagberg J, Bergström G, Lohela-Karlsson M. Estimating the effect and economic impact of absenteeism, presenteeism, and work environment-related problems on reductions in productivity from a managerial perspective. Value Health 2017 Sep;20(8):1058-1064. [doi: 10.1016/j.jval.2017.05.008] [Medline: 28964437]
18. Huffman LG, Lawrence-Sidebottom D, Huberty J, et al. Using digital measurement-based care for the treatment of anxiety and depression in children and adolescents: observational retrospective analysis of Bend Health data. JMIR Pediatr Parent 2023 Apr 20;6:e46154. [doi: 10.2196/46154] [Medline: 37079366]
19. Lawrence-Sidebottom D, Huffman LG, Huberty J, et al. Using digital measurement-based care to address symptoms of inattention, hyperactivity, and opposition in youth: retrospective analysis of Bend Health. JMIR Form Res 2023 Apr 26;7:e46578. [doi: 10.2196/46578] [Medline: 37099379]
20. Bryant BR, Sisk MR, McGuire JF. Efficacy of gamified digital mental health interventions for pediatric mental health conditions: a systematic review and meta-analysis. JAMA Pediatr 2024 Nov 1;178(11):1136-1146. [doi: 10.1001/jamapediatrics.2024.3139] [Medline: 39312259]
21. Khanna MS, Carper M. Digital mental health interventions for child and adolescent anxiety. Cogn Behav Pract 2022 Feb;29(1):60-68. [doi: 10.1016/j.cbpra.2021.05.003]
22. Alvarez-Jimenez M, Gleeson JF, Rice S, Gonzalez-Blanch C, Bendall S. Online peer-to-peer support in youth mental health: seizing the opportunity. Epidemiol Psychiatr Sci 2016 Apr;25(2):123-126. [doi: 10.1017/S2045796015001092] [Medline: 26880239]
23. Catarino A, Harper S, Malcolm R, et al. Economic evaluation of 27,540 patients with mood and anxiety disorders and the importance of waiting time and clinical effectiveness in mental healthcare. Nat Mental Health 2023 Sep 1;1(9):667-678. [doi: 10.1038/s44220-023-00106-z]
24. Jankovic D, Bojke L, Marshall D, et al. Systematic review and critique of methods for economic evaluation of digital mental health interventions. Appl Health Econ Health Policy 2021 Jan;19(1):17-27. [doi: 10.1007/s40258-020-00607-3] [Medline: 32803521]
25. Lawrence-Sidebottom D, Huffman LG, Beam A, et al. Improvements in sleep problems and their associations with mental health symptoms: a study of children and adolescents participating in a digital mental health intervention. Digit Health 2024;10(20552076241249928):20552076241249928. [doi: 10.1177/20552076241249928] [Medline: 38736734]
26. Rohland BM, Kruse GR, Rohrer JE. Validation of a single‐item measure of burnout against the Maslach burnout inventory among physicians. Stress Health 2004 Apr;20(2):75-79. [doi: 10.1002/smi.1002]

XSL•FO
RenderX

27. Dolan ED, Mohr D, Lempa M, et al. Using a single item to measure burnout in primary care staff: a psychometric evaluation. J Gen Intern Med 2015 May;30(5):582-587. [doi: 10.1007/s11606-014-3112-6] [Medline: 25451989]
28. Mateo-Rodríguez I, Knox E, Oliver-Hernandez C, Daponte-Codina A. Validation of a single-item screening measure of burnout in a sample of Spanish health workers. Soc Sci (Basel) 2023 Oct;12(10):546. [doi: 10.3390/socsci12100546]
29. West CP, Dyrbye LN, Satele DV, Sloan JA, Shanafelt TD. Concurrent validity of single-item measures of emotional exhaustion and depersonalization in burnout assessment. J Gen Intern Med 2012 Nov;27(11):1445-1452. [doi: 10.1007/s11606-012-2015-7] [Medline: 22362127]
30. Kessler RC, Barber C, Beck A, et al. The World Health Organization health and work performance questionnaire (HPQ). J Occup Environ Med 2003 Feb;45(2):156-174. [doi: 10.1097/01.jom.0000052967.43131.51] [Medline: 12625231]
31. Bastien CH, Vallières A, Morin CM. Validation of the insomnia severity index as an outcome measure for insomnia research. Sleep Med 2001 Jul;2(4):297-307. [doi: 10.1016/s1389-9457(00)00065-4] [Medline: 11438246]
32. Berry JO, Jones WH. The Parental Stress Scale: initial psychometric evidence. J Soc Pers Relat 1995 Aug;12(3):463-472. [doi: 10.1177/0265407595123009]
33. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, 5th edition: American Psychiatric Publishing, Inc; 2013. [doi: 10.1176/appi.books.9780890425596]
34. Irwin DE, Gross HE, Stucky BD, et al. Development of six PROMIS pediatrics proxy-report item banks. Health Qual Life Outcomes 2012 Feb 22;10:22. [doi: 10.1186/1477-7525-10-22] [Medline: 22357192]
35. Mossman SA, Luft MJ, Schroeder HK, et al. The generalized anxiety disorder 7-item scale in adolescents with generalized anxiety disorder: signal detection and validation. Ann Clin Psychiatry 2017 Nov;29(4):227-234A. [Medline: 29069107]
36. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001 Sep;16(9):606-613. [doi: 10.1046/j.1525-1497.2001.016009606.x] [Medline: 11556941]
37. Forrest CB, Meltzer LJ, Marcus CL, et al. Development and validation of the PROMIS pediatric sleep disturbance and sleep-related impairment item banks. Sleep 2018 Jun 1;41(6). [doi: 10.1093/sleep/zsy054] [Medline: 29546286]
38. Kumari R, Kohli A, Malhotra P, Grover S, Khadwal A. Burden of caregiving and its impact in the patients of acute lymphoblastic leukemia. Ind Psychiatry J 2018;27(2):249-258. [doi: 10.4103/ipj.ipj_75_18] [Medline: 31359980]
39. Singh NN, Lancioni GE, Winton ASW, et al. Mindfulness-based positive behavior support (MBPBS) for mothers of adolescents with autism spectrum disorder: effects on adolescents' behavior and parental stress. Mindfulness (N Y) 2014 Dec;5(6):646-657. [doi: 10.1007/s12671-014-0321-3]
40. Sherlock P, Blackwell CK, Kallen MA, et al. Measuring PROMIS® emotional distress in early childhood. J Pediatr Psychol 2022 May 13;47(5):547-558. [doi: 10.1093/jpepsy/jsac029] [Medline: 35552432]
41. Swanson JM, Sandman CA, Deutsch C, Baren M. Methylphenidate hydrochloride given with or before breakfast: I. Behavioral, cognitive, and electrophysiologic effects. Pediatrics 1983 Jul;72(1):49-55. [Medline: 6866591]
42. Hall CL, Guo B, Valentine AZ, et al. The validity of the SNAP-IV in children displaying ADHD symptoms. Assessment 2020 Sep;27(6):1258-1271. [doi: 10.1177/1073191119842255] [Medline: 30991820]
43. Johnson JG, Harris ES, Spitzer RL, Williams JBW. The patient health questionnaire for adolescents: validation of an instrument for the assessment of mental disorders among adolescent primary care patients. J Adolesc Health 2002 Mar;30(3):196-204. [doi: 10.1016/s1054-139x(01)00333-0] [Medline: 11869927]
44. RStudio Team. RStudio: Integrated Development for R: RStudio, PBC. URL: http://www.rstudio.com/ [accessed 2025-05-28]
45. Labor force statistics from the current population survey. US Bureau of Labor Statistics. 2022 Jan 1. URL: https://www.bls.gov/cps/cpsaat46.htm [accessed 2025-05-28]
46. Abramson A. Burnout and stress are everywhere. Monit Psychol 2022 Jan 1;53(1):73 [FREE Full text]
47. Ford MT, Heinen BA, Langkamer KL. Work and family satisfaction and conflict: a meta-analysis of cross-domain relations. J Appl Psychol 2007 Jan;92(1):57-80. [doi: 10.1037/0021-9010.92.1.57] [Medline: 17227151]
48. Grodberg D, Bridgewater J, Loo T, Bravata D. Examining the relationship between pediatric behavioral health and parent productivity through a parent-reported survey in the time of COVID-19: exploratory study. JMIR Form Res 2022 Aug 18;6(8):e37285. [doi: 10.2196/37285] [Medline: 35616439]
49. Krouse SS, Afifi TD. Family-to-work spillover stress: coping communicatively in the workplace. J Fam Commun 2007 Apr 4;7(2):85-122. [doi: 10.1080/15267430701221537]
50. Roskam I, Aguiar J, Akgun E, et al. Parental burnout around the globe: a 42-country study. Affect Sci 2021;2(1):58-79. [doi: 10.1007/s42761-020-00028-4] [Medline: 33758826]
51. Stracke M, Heinzl M, Müller AD, et al. Mental health is a family affair-systematic review and meta-analysis on the associations between mental health problems in parents and children during the COVID-19 pandemic. Int J Environ Res Public Health 2023 Mar 2;20(5):4485. [doi: 10.3390/ijerph20054485] [Medline: 36901492]
52. Coe E, Enomoto K, Herbig B, Kothari A, Steuland J. COVID-19 and burnout are straining the mental health of employed parents. 2021. URL: https://www.mckinsey.com/industries/healthcare/our-insights/covid-19-and-burnout-are-straining-the-mental-health-of-employed-parents [accessed 2025-05-28]
53. Martin CA, Papadopoulos N, Chellew T, Rinehart NJ, Sciberras E. Associations between parenting stress, parent mental health and child sleep problems for children with ADHD and ASD: systematic review. Res Dev Disabil 2019 Oct;93:103463. [doi: 10.1016/j.ridd.2019.103463]

XSL•FO
RenderX

54. Stone LL, Mares SHW, Otten R, Engels R, Janssens JMAM. The co-development of parenting stress and childhood internalizing and externalizing problems. J Psychopathol Behav Assess 2016;38(76–86):76-86. [doi: 10.1007/s10862-015-9500-3] [Medline: 27069304]
55. Bailey SK, Haggarty J, Kelly S. Global absenteeism and presenteeism in mental health patients referred through primary care. WOR 2016;53(2):399-408. [doi: 10.3233/WOR-152172]
56. Bubonya M, Cobb-Clark DA, Wooden M. Mental health and productivity at work: does what you do matter? Labour Econ 2017 Jun;46:150-165. [doi: 10.1016/j.labeco.2017.05.001]
57. Hilton MF, Sheridan J, Cleary CM, Whiteford HA. Employee absenteeism measures reflecting current work practices may be instrumental in a re-evaluation of the relationship between psychological distress/mental health and absenteeism. Int J Methods Psychiatr Res 2009;18(1):37-47. [doi: 10.1002/mpr.275] [Medline: 19194855]
58. Becker SP. ADHD and sleep: recent advances and future directions. Curr Opin Psychol 2020 Aug;34:50-56. [doi: 10.1016/j.copsyc.2019.09.006] [Medline: 31629217]
59. Meltzer H, Ford T, Goodman R, Vostanis P. The burden of caring for children with emotional or conduct disorders. Int J Family Med 2011;2011(801203):801203. [doi: 10.1155/2011/801203] [Medline: 22295194]
60. Mikolajczak M, Raes ME, Avalosse H, Roskam I. Exhausted parents: sociodemographic, child-related, parent-related, parenting and family-functioning correlates of parental burnout. J Child Fam Stud 2018 Feb;27(2):602-614. [doi: 10.1007/s10826-017-0892-4]
61. Katzmann J, Döpfner M, Görtz-Dorten A. Child-based treatment of oppositional defiant disorder: mediating effects on parental depression, anxiety and stress. Eur Child Adolesc Psychiatry 2018 Sep;27(9):1181-1192. [doi: 10.1007/s00787-018-1181-5] [Medline: 29948233]
62. Mihaila I, Hartley SL. Parental sleep quality and behavior problems of children with autism. Autism 2018 Apr;22(3):236-244. [doi: 10.1177/1362361316673570] [Medline: 27899714]
63. Gérain P, Zech E. Informal caregiver burnout? Development of a theoretical framework to understand the impact of caregiving. Front Psychol 2019;10(1748):1748. [doi: 10.3389/fpsyg.2019.01748] [Medline: 31428015]

Abbreviations

ADHD: attention-deficit/hyperactivity disorder
BCM: behavioral care manager
CLM: cumulative link model
DMHI: digital mental health intervention
***DSM-V-TR*:** *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition, Text Revision)
GAD-7: Generalized Anxiety Disorder-7
HPQ: Health and Work Performance Questionnaire
ISI: Insomnia Severity Index
PHQ-9A: Patient Health Questionnaire-9 adolescent version
PROMIS: Patient-Reported Outcomes Measurement Information System
PSS: Parental Stress Scale
SNAP-IV: Swanson Nolan and Pelham Rating Scale version 4

Edited by S Badawy; submitted 03.10.24; peer-reviewed by B Do, N Hodgson; revised version received 16.04.25; accepted 23.04.25; published 27.06.25.

Please cite as:
Lawrence-Sidebottom D, McAlister K, Beam AB, Guerra R, Parikh A, Roots M, McCutchen D, Goodgame Huffman L, Huberty J Evaluating the Impact of Pediatric Digital Mental Health Care on Caregiver Burnout and Absenteeism: Longitudinal Observational Study
JMIR Pediatr Parent 2025;8:e67149
URL: https://pediatrics.jmir.org/2025/1/e67149
doi:10.2196/67149

© Darian Lawrence-Sidebottom, Kelsey McAlister, Aislinn Brenna Beam, Rachael Guerra, Amit Parikh, Monika Roots, Donna McCutchen, Landry Goodgame Huffman, Jennifer Huberty. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 27.6.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete

XSL•FO
RenderX

bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Exploring Service Users' Experiences of a Community-Based Intervention to Improve Follow-Up at Bharatpur Eye Hospital in Nepal: Qualitative Study

Manisha Shrestha[1*], MS; Gopal Bhandari[1*], M. Optom; Sadhan Bhandari[1*], BPH; Gudlavalleti Venkata Satyanarayana Murthy[2,3,4*], MD; Ruchi Priya[2,3*], MPH; Binod Pandey[1*], Dip (Ophthalmic Science); Daya Shankar Chaudhary[1*], MA; Puspa Giri[1*], MS; Sureshkumar Kamalakannan[2,3,5*], PhD; Operational Research Capacity Building Study Group[6*]

[1]Bharatpur Eye Hospital, Bharatpur, Nepal

[2]Indian Institute of Public Health, Hyderabad, India

[3]Pragyaan Sustainable Health Outcomes Foundation, Hyderabad, India

[4]London School of Hygiene and Tropical Medicine, London, United Kingdom

[5]Department of Social Work Education and Community Well-Being, Northumbria University, Coach Lane Campus, Newcastle Upon Tyne, United Kingdom

[6]

[*]all authors contributed equally

Corresponding Author:
Sureshkumar Kamalakannan, PhD
Indian Institute of Public Health, Hyderabad, India

Abstract

Background: Follow-up to eye care services for children, especially in the context of Nepal, is essential for ensuring a continuum of care. Hence, as a continued effort, we designed this study to explore the service users' experience of a community-based intervention to improve follow-up at Bharatpur Eye Hospital (BEH) in Nepal.

Objective: This study aimed to explore service users' experiences and perceptions of the community-based follow-up intervention for eye care services implemented by BEH in Nepal.

Methods: A qualitative study using an in-depth interview approach was used. Participants were purposively selected for this research study. Participants who were part of a quasi-experimental study conducted to improve follow-up services in BEH and their service catchment area were chosen. Participants who had not attended even a single follow-up visit and participants who attended at least one follow-up were recruited for this qualitative study. Based on the distance from the base hospital and the follow-up status, 65 participants were initially found eligible for the qualitative study. However, only 17 participants were available and consented. Topic guides were developed for the purpose of in-depth interviews specifically for participants who had not attended even the first follow-up visits and those who attended at least one follow-up visit. A total of 2 ophthalmic assistants, who were not a part of the main intervention study, conducted the interviews.

Results: In total, 17 service users whose children were receiving services from BEH participated in the qualitative study. We identified 4 key themes that provided invaluable information about the barriers and facilitators to follow-up as well as the experiences (positive or negative) of the participants that need to be considered in any future initiatives to improve follow-up in Nepal.

Conclusions: This study highlights the need for systematic development of interventions to address the unmet need for eye care services in the community through innovative, scalable solutions. As a next step, the BEH team will be working to develop such scalable solutions for Nepal. Such interventions will also need to be optimized for similar settings and countries to meet the goals of universal health coverage, vision 2030, and sustainable development goals worldwide.

Trial Registration: ClinicalTrials.gov NCT04837534; https://clinicaltrials.gov/study/NCT04837534

(JMIR Pediatr Parent 2025;8:e65023) doi:10.2196/65023

KEYWORDS

qualitative study; barriers; facilitators; Nepal; follow-up; eye care services; child health; follow-up care

XSL•FO
RenderX

Introduction

Background

Nepal's National Health Policy 2019 recommends the development and expansion of eye care services through public-private partnerships in all 3 tiers of primary care provided through the government health systems. It provides guidance on the integration of primary eye care with primary health care and the coordination of eye care programs by a dedicated eye unit at the federal ministry of health [1]. One such effort is the Retina Eye Care of Nepal (RECON) project, which was designed to strengthen retina eye care services in Nepal [2]. This initiative was a well-planned health education intervention targeting physicians' knowledge about diabetic retinopathy. Evidence from the evaluation of this initiative identified an increase in the number of referrals and attendance of patients for diabetic retinopathy screening with the change in knowledge and referral mechanism [3].

However, providing referrals does not mean the care is complete. Follow-up for eye care services for children, especially in the context of Nepal, is essential for ensuring a continuum of care [4]. Counseling and follow-up with patients are the key factors in improving the usage of health care services [5]. An exploratory analysis of data from one single hospital (Bharatpur Eye Hospital [BEH]), spanning from January 1, 2019, to January 7, 2019, revealed that only 22% of children aged 0-16 years attended at least one follow-up visit and the remaining 78% could not attend for various reasons. There are several studies conducted to find the impact of interventions, such as SMS text messaging, phone calls, and counseling to improve adherence to follow-up care in both adult and pediatric populations. One of the studies has shown that SMS text messaging reminders significantly improved follow-up adherence in pediatric cataract treatment compared to the control group [6].

A quasi-experimental study was carried out in Nepal by the BEH team to find the effectiveness of follow-up interventions, particularly counseling with the provision of information leaflets and reminders through phone calls and text messages to improve the follow-up rates in comparison to the existing standard care. The primary outcome of the study was measured by the number of children completing all 3 follow-up visits in different intervention groups. This research showed no statistically significant difference in the proportion of follow-up between the intervention groups. Only 3% (8/264) of children completed all 3 follow-ups, but the overall compliance with follow-up was only 0.76%, with more follow-ups in the reminder with SMS text messaging and phone call groups [7]. There may be several reasons for the poor adherence to follow-up visits, but it was hypothesized that COVID-19 was the major contributor since the study was conducted during the peak COVID-19 time. Hence, as a continued effort, we designed this study to explore the service users' experience of a community-based intervention to improve follow-up at BEH in Nepal. We believed that this study would provide invaluable information on the reasons for the poor follow-up outcomes from the quasi-experimental study and the potential drivers of developing a culturally relevant, context-specific intervention for improving follow-up to ensure a continuum of eye care in the communities of Nepal.

Primary Objective

The primary objective of this research study was to explore service users' experiences and perceptions of the community-based follow-up intervention for eye care services implemented by BEH in Nepal.

Methods

Study Design

The study design was a qualitative study using an in-depth interview approach.

Setting

The interview was conducted by visiting the participants' homes. The purpose of the study was to understand why the participants did not visit the hospital for follow-up. Hence, interviewing them at their residence was identified to be a feasible and effective option.

Study Duration

The study duration was 1 month, from January 15 to February 16, 2024.

Participants

Participants were purposively selected for this research study. Participants who were part of a quasi-experimental study conducted to improve follow-up services in BEH and their service catchment area were chosen. Participants who had not attended even a single follow-up visit and participants who attended at least one follow-up were recruited for this qualitative study. Participants were selected irrespective of the intervention groups they were enrolled in during the quasi-experimental study. The participants were residing within a 20-km radius of BEH, and the interviews were conducted in the participant's residence. Participants with relatively serious eye problems requiring multiple follow-ups were included. Based on the distance from the base hospital and the follow-up status, 65 participants were initially found eligible for the qualitative study. However, only 17 participants were available and consented. The interviews were conducted with these 17 participants.

Data Collection Process

Topic guides were developed by an expert in qualitative research, who was our research guide, for the purpose of conducting in-depth interviews specifically for participants who had not attended even the first follow-up visit and those who attended at least one follow-up visit. Overall, 2 ophthalmic assistants, who were not a part of the main intervention study, conducted the interviews. These interviewers had a brief orientation on the topic guide and interview process to ensure consistency in the conduct of the interviews. The topic guides were piloted with a few participants before interviewing the actual participants. After providing prior information and obtaining written consent from each participant, the interview was carried out in their own communities, as it was not feasible for the participants to attend the hospital for interview purposes. During the interview process, one of the ophthalmic assistants

XSL•FO
RenderX

conducted the interviews, and the other person was involved in observing and taking notes. Interviews were conducted with the parents or guardians of the children who received eye care services from BEH. The interview participants were the parents/service users who accompanied the child to the hospital during the initial checkup. All the interviews were audio-recorded using a smartphone with consent from participants. We chose to stop the interviews based on the principles of data saturation, that is, when no further information was provided by the participants interviewed.

Data Analysis

We used the framework approach to analyze the qualitative data from this study. Interviews were audio-recorded, and the recorded interviews were transcribed verbatim. The interviews were conducted in the local language (Nepali). Hence, the audio recordings were first transcribed verbatim, and subsequently, the transcribed interview transcripts were translated and back-translated to ensure consistency in English by the other members of the study team. The transcribed data were read a multiple number of times to ensure familiarity. Codes were then identified to understand the framework for analysis. The codes and categories identified from the transcripts were then applied to that framework. The charted data were then carefully interpreted. We carried out member checking to triangulate data and to ensure data confirmability.

Ethical Considerations

Ethics approval was obtained from the Ethical Review Board of the Nepal Health Research Council (ethical review board protocol registration number 761/2020 P and ClinicalTrials.gov number: NCT04837534). Written consent was obtained from the parents or guardians via a consent form before enrolling them in the study. All the information collected was secured and stored safely by the principal investigators. The data were completely anonymized for the purpose of privacy and confidentiality. The participants were not compensated for participating in the study.

Results

Overview

In total, 17 service users whose children were receiving services from BEH participated in the qualitative study. Details of the participants are provided in Table 1. Participants represented the actual communities in Nepal on important sociodemographics. We identified 4 key themes that provided invaluable information about the barriers and facilitators to follow-up as well as the experiences (positive or negative) of the participants that need to be considered in any future initiatives to improve follow-up in Nepal.

Table . Characteristics of study participants.

Interviewee	Relation with child	Age (years)	Education[a]	Profession	Child age (in years)	Approximate distance from hospital (in km)
1	Mother	25	Secondary	Housewife	2	5
2	Father	30	Secondary	Driver/business	6	5
3	Father	34	Secondary	Business	7	15
4	Mother	28	Primary	Housewife	2	7
5	Mother	35	Secondary	Business	9	18
6	Father	40	Secondary	Plumber	9	16
7	Mother	22	Illiterate	Housewife	1	54
8	Mother	40	Secondary	Housewife	10	34
9	Father	35	Secondary	Contractor	1	17
10	Father	30	Above secondary	Business	1	9
11	Mother	29	Secondary	Housewife	2	11
12	Mother	30	Secondary	Business	1	10
13	Mother	40	Illiterate	Housewife	4	12
14	Father	45	Secondary	Business	10	8
15	Father	40	Secondary	Unemployed	3	13
16	Mother	29	Secondary	Farming	4	6
17	Father	50	Primary	Retired/farming	10	8

[a]Illiterate: unable to read and write in Nepali; primary: up to grade 5; secondary: grades 6 to 10.

Barriers to Follow-Up

The main reasons for barriers to follow-up were (1) ignorance about the eye problem and the potential solutions, (2) the poor financial situation of the service users, and (3) lack of satisfactory experience from the service providers during follow-up. Service users lacked awareness about the importance

XSL•FO
RenderX

of regular follow-up for their children's eye condition. Some also found it very uncomfortable to go out and discuss this with others in the community for further support. This was particularly because they were financially poor and could not afford to spend time and seek this advice as well as the treatment charges in hospitals that may be imposed when they follow advice from the community. Hence, they did not attend the follow-up visit as advised by the BEH follow-up intervention.

Many expressed financial constraints as a barrier to follow-up. The costs incurred in the treatment and travel were not affordable for them. Also, they were skeptical about whether the medications, treatment, and investigation would fall under the insurance subsidy or not. Therefore, it was difficult for the service users to abide by the advice related to follow-up that was suggested.

> *People keep asking us to take our child to different places but its only us who know our situation – Not easy*

Many parents were busy and had to take off time from their routine schedules including their work commitments, which made it nonfeasible to comply with the advice for follow-up. As their children were studying and attending school, it was difficult to match their schedule to bring the child for follow-up as advised by the service providers. Lack of school attendance was considered by the service users as a huge loss. Also, the distance of the hospital from home was a barrier, as it cost time and money to travel to the hospital from their faraway residence.

> *My child needs to go to school, so difficult to come for follow-up during the school hours.*

The child was not compliant with the treatment given, like not wearing the glasses prescribed. Some parents were unsure if the child was asked to bring it for follow-up or not. There were a few service users whose children felt better with the initial treatment and so did not continue to follow up.

> *I do not recall being called for follow up.*

Experiences and Perceptions

During the interview, service users felt that their presence was not given any importance. Service users expressed that BEH was the main center for eye care in Chitwan and it was mostly overcrowded, implying a long waiting time, not just at one counter but in all the counters, rooms, and departments they visited. The system and pathway that service users were advised to follow were perceived to be outdated, and there was no fast-track or exclusive service for those referred by their own staff and their own catchment area, thus making the experience not very satisfactory. This was especially the case for those who could not afford the service and for those who required access to the service on an urgent basis. The service users suggested that it would have been better if there was a fast-track eye checkup system, especially for very small children and those who were invited for a follow-up appointment.

> *One whole day was wasted for eye checkup at BEH, no one valued our time, we are not sure why did they ask us to come for making us wait for so long*

The service users also felt that some hospital staff did not respond well. They expressed that the BEH support staff were busy on the phone and did not have a friendly approach. Some felt that there was miscommunication about the dates and time for follow-up and a lack of timely information provision and advice related to their felt needs. In addition, a few service users expressed that they were unable to recollect their experiences accurately as it has been a long time since they visited the hospital for follow-up.

> *I was there in the queue for 3 hours and when my turn came, I was handed out the paper and told to come the next day, that is unfair, they should have informed me on time, it is not possible for me to come here daily. I have a shop to run and so many errands at home!*

Service users also shared their positive experiences during the follow-up. They expressed that BEH was well known in our communities; therefore, whenever there was any eye care need, service users preferred visiting BEH rather than other centers (medical or optical shops). Some service users liked that the system was available to access eye care and felt that their experience was comfortable at BEH. One the key features liked by service users was proper signage, which guided them in identifying and accessing different departments. The token system for registration and access to respective departments without any waiting time and smaller queues and the presence of a separate department for children, which made the experience comfortable for the kids and their parents.

> *It has a homely environment and feels like a second home.*

Service users also felt that both clinical and nonclinical staff were well-behaved and had a friendly attitude. The doctors and other clinical staff used very simple and understandable advice. They expressed that the service providers had explained the procedures and treatment options clearly that made it very easy to understand and make decisions. Incidentally, some people experienced less crowd during their visit, so their experience was smooth and less time-consuming.

> *All staffs even the guard were very friendly to me.*

Service users felt that the doctors provided good treatment, provided patient education, and stressed the importance of follow-up visits. The counselor and other clinical staff were observed to have stressed the role of proper treatment options and a good healthy lifestyle to reduce eye problems (such as reducing screen time, having a good healthy diet, and importance of outdoor activities for children).

> *The eye check-up went easily, it was not at all complicated as anticipated.*

Drivers for the Follow-Up

One of the important facilitators for implementing any intervention at BEH was the trustworthiness and brand name of the service provider. Being the oldest and biggest eye care center in Chitwan, BEH has earned its reputation; people perceive it to be the key service provider for that the region.

XSL•FO
RenderX

This is the oldest and biggest centre for eyes in Chitwan, why would I go anywhere else?

Service providers expressed that the eye camps were regularly held by the BEH at schools and localities, which refer patients to the base hospital (BEH). They felt that the service providers helped with information regarding the importance of preschool vision screening. The hospital also provided a national health insurance scheme, so it was very economical to get treatment there. There was also a subsidy system for low-income patients, so no one was denied basic eye care at BEH. Related to the intervention, participants felt that the reminder phone call from the hospital was very useful and helped people to remind themselves of the upcoming follow-up date.

Discussion

Principal Findings

This qualitative study aimed to explore the reasons for poor follow-up for eye care services and the experiences of service users receiving pediatric eye care at BEH. The findings revealed a complex interplay of factors influencing adherence to follow-up appointments, encompassing barriers, negative experiences, positive experiences, and facilitators. Lack of information and awareness about the eye problem and the required care, poor experience in accessing follow-up care, opportunity cost, and financial constraints have been the key reasons for poor follow-up. In addition, the COVID-19 pandemic and the naturally recovered service users who may not need a follow-up may be the contributors to poor follow-up that must be considered.

These reasons for poor follow-up were the commonly identified barriers to accessing any health or rehabilitation, particularly in the context of low- and middle-income countries [8]. In a country like Nepal, the geographical access barriers could be an additional drawback, which was not evident from this study [9-11]. However, the experiences of those who attended the follow-up provided very useful insights about the important aspects to ensure during the development of any pathway for follow-up [12,13]. They stress the importance of systematically developing a specific pathway that is sensitive to the context and culture of the service users in the catchment area [14-16]. They also highlight the need for sensitizing the service providers to the fact that the delivery of health care services may not have the same process and pathways for all service users [17].

The positive experiences from this study reveal some of the important aspects that need to be considered while developing such follow-up pathways for improving the effectiveness and quality of service provision [18]. This is applicable not just to eye care but to all kinds of health care provision services [19,20]. Service providers, including field workers and ground staff; organization of care; and delivery of services must be carefully optimized for improving service efficiency [21]. Our study highlights these important drivers for improving eye care services [22].

The implications of this study highlight the need for more research into the interventions for follow-up, especially for eye care services in Nepal and similar contexts. Much of the care that are globally available is provided within an institution [3-7]. However, for eye care services, this approach needs to be different, and it should include community-based care connecting service users in the community to the service providers at the institutions [23,24]. Technology can be a huge advantage in developing such kinds of interventions. Hence, more research is required on the systematic development and evaluation of comprehensive interventions that can promote a continuum of care [25].

This study also has a few practice and policy implications. Increasing awareness about the problem and potential solutions at the first point of contact can promote the information required to identify choices of care and make appropriate decisions about it. Similarly, the optimization of insurance coverage for socially disadvantaged communities and economically deprived service users by ratifying existing policies or expanding and implementing coverage to provide financial relief for service users can add value and improve service users' experience positively [26].

Limitations and Strengths

This study also comes with a few limitations. Since the initial experimental study was conducted during the COVID-19 pandemic, it was difficult to locate the participants for recruitment. We collected data 2 years post COVID-19, but soon after, the experimental study to test the intervention effectiveness was completed. Although this might appear to contaminate the results, the authors did not identify any potential limitations or recall issues related to the objective of this study during the study. Also, the other stakeholders, such as service providers and administrators, were not interviewed. Doing so might provide their perspectives for understanding the actual context. The interview was recorded in Nepali and was later translated in English. This may have resulted in inadequate reporting of the emotional aspects of the interview. These aspects need to be carefully considered in future studies on this topic. The study also had a few strengths. This study was actually an extension of a quasi-experimental study to understand the lack of statistically significant differences in the findings of that quantitative study. This study enabled us to understand the reasons for systematically developing and evaluating interventions. The participants were those with a need to attend follow-ups but did not turn up. Hence, the data from interviews relate very closely to the purpose of the study. Data triangulation, through repeated verification of audio recordings and transcriptions, was completed. We also carried out member checking and added rigor to this study.

Conclusion

This study provides immensely valuable insights. It highlights the need for systematic development of interventions to address the unmet need for eye care services in the community through innovative, scalable solutions. As a next step, the BEH team will be working to develop such scalable solutions for Nepal. Such interventions will also need to be optimized for similar settings and countries to meet the goals of universal health coverage, vision 2030, and sustainable development goals worldwide.

XSL•FO
RenderX

Acknowledgments

We gratefully acknowledge the Seva Foundation (United States) and Seva Canada for funding this project. Additionally, we thank the Indian Institute of Public Health, Hyderabad, and the Pragyaan Sustainable Health Outcomes (PRASHO) Foundation for their valuable guidance and support throughout the project. We also extend our gratitude to the management and staff of Bharatpur Eye Hospital (BEH) for their contributions to various aspects of this study.

The Operational Research Capacity Building Study Group consisted of the following members: Indian Institute of Public Health, Hyderabad (Public Health Foundation of India): Prof Gudlavalleti Venkata Satyanarayana Murthy, Dr Sureshkumar Kamalakannan, Ms Ruchi Priya, Dr Rajan Shukla, Dr Shailaja Tetali, Dr Anirudh G Gudlavalleti, Dr Varun Agiwal, Mr Hira Pant, Dr Sirshendu Chaudhuri, Dr Nirupama AY and Dr Yashaswini Kumar. SEVA: Dr Suzanne Gilbert, Dr Ken Bassett, Ms Priya Adisesha Reddy, Ms Parami Dhakhwa, Mr Ram Prasad Kandel, Dr Binita Sharma, Mr Kuldeep Singh and Mr Prasanna Sharma.

Data Availability

The data collected have been presented in the manuscript. Any request for additional data will be reviewed by the advisory committee and will be shared upon request.

Authors' Contributions

MS, GB, SB, BP, SKK, RP, DSC, and PG conceptualized and designed the study. SKK finalized the topic guide for the interview. Deepak Kumar Yadav and Prakash Malla were responsible for conducting and recording the interview. Debaki Acharya conducted the data collection and data entry. MS, GB, SB, BP, SKK, and RP did the data analysis. MS, GB, SB, SKK, and RP drafted the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

References

1. Gurung R, Oli RU. Primary eye care in Nepal: current situation and recommendations for integration. Community Eye Health 2021;34(113):s13-s14. [Medline: 36033419]
2. Shrestha A, Shrestha C, Karki P, Gurung HM, Naito T. Strengthening retina eye care services in Nepal: retina eye care of Nepal project. BMC Health Serv Res 2020 Oct 27;20(1):986. [doi: 10.1186/s12913-020-05850-x] [Medline: 33109192]
3. Shrestha R, Singh P, Dhakwa P, et al. Augmenting the referral pathway for retinal services among diabetic patients at Reiyukai Eiko Masunaga Eye Hospital, Nepal: a non-randomized, pre-post intervention study. BMC Health Serv Res 2023 Feb 8;23(1):126. [doi: 10.1186/s12913-023-09105-3] [Medline: 36750897]
4. Rai SKC, Thapa H, Kandel RP, Ishaq M, Bassett K. Clinical and cost impact of a pediatric cataract follow-up program in western Nepal and adjacent northern Indian States. J AAPOS 2014 Feb;18(1):67-70. [doi: 10.1016/j.jaapos.2013.09.008] [Medline: 24568986]
5. Bhattarai B, Thapa HB, Bashyal S, et al. Structured counselling and regular telephonic follow up to improve referral flow and compliance in Nepal for Diabetic Retinopathy(SCREEN-D Study): a randomised controlled trial. BMC Health Serv Res 2024 Feb 10;24(1):188. [doi: 10.1186/s12913-024-10647-3] [Medline: 38336691]
6. Lin H, Chen W, Luo L, et al. Effectiveness of a short message reminder in increasing compliance with pediatric cataract treatment: a randomized trial. Ophthalmology 2012 Dec;119(12):2463-2470. [doi: 10.1016/j.ophtha.2012.06.046] [Medline: 22921386]
7. Shrestha M, Bhandari G, Kamalakannan S, et al. Evaluating the effectiveness of interventions to improve the follow-up rate for children with visual disabilities in an eye hospital in Nepal: nonrandomized study. JMIR Pediatr Parent 2023 Feb 23;6:e43814. [doi: 10.2196/43814] [Medline: 36821366]
8. Ibbotson JL, Luitel B, Adhikari B, et al. Overcoming barriers to accessing surgery and rehabilitation in low and middle-income countries: an innovative model of patient navigation in Nepal. World J Surg 2021 Aug;45(8):2347-2356. [doi: 10.1007/s00268-021-06035-1] [Medline: 33893524]
9. Syed ST, Gerber BS, Sharp LK. Traveling towards disease: transportation barriers to health care access. J Community Health 2013 Oct;38(5):976-993. [doi: 10.1007/s10900-013-9681-1] [Medline: 23543372]
10. Gogate P, Patil S, Kulkarni A, et al. Barriers to follow-up for pediatric cataract surgery in Maharashtra, India: how regular follow-up is important for good outcome. The Miraj Pediatric Cataract Study II. Indian J Ophthalmol 2014 Mar;62(3):327-332. [doi: 10.4103/0301-4738.116465] [Medline: 24008794]
11. Eriksen JR, Bronsard A, Mosha M, Carmichael D, Hall A, Courtright P. Predictors of poor follow-up in children that had cataract surgery. Ophthalmic Epidemiol 2006 Aug;13(4):237-243. [doi: 10.1080/09286580600672213] [Medline: 16877282]

XSL•FO
RenderX

12. Thompson AC, Thompson MO, Young DL, et al. Barriers to follow-up and strategies to improve adherence to appointments for care of chronic eye diseases. Invest Ophthalmol Vis Sci 2015 Jul;56(8):4324-4331. [doi: 10.1167/iovs.15-16444] [Medline: 26176869]
13. Bergin RJ, Yao-Dong Yu A, White V, Emery J. Discussions with patients about referral pathways and costs in the diagnosis and treatment of colorectal cancer in Victoria, Australia. Aust J Gen Pract 2024;53(1-2):70-77. [doi: 10.31128/AJGP/01-23-6691] [Medline: 38316485]
14. Spinelli M, Preti E, Kassa TT, et al. Cultural considerations in the assessment of sensitivity in low-income caregivers in Ethiopia. Front Psychol 2023;14:1163773. [doi: 10.3389/fpsyg.2023.1163773] [Medline: 37179883]
15. Brilliant GE, Lepkowski JM, Zurita B, Thulasiraj RD. Social determinants of cataract surgery utilization in south India. The Operations Research Group. Arch Ophthalmol 1991 Apr;109(4):584-589. [doi: 10.1001/archopht.1991.01080040152048] [Medline: 1901487]
16. Snellingen T, Shrestha BR, Gharti MP, Shrestha JK, Upadhyay MP, Pokhrel RP. Socioeconomic barriers to cataract surgery in Nepal: the South Asian cataract management study. Br J Ophthalmol 1998 Dec;82(12):1424-1428. [doi: 10.1136/bjo.82.12.1424] [Medline: 9930276]
17. Røsstad T, Garåsen H, Steinsbekk A, Sletvold O, Grimsmo A. Development of a patient-centred care pathway across healthcare providers: a qualitative study. BMC Health Serv Res 2013 Apr 1;13:121. [doi: 10.1186/1472-6963-13-121] [Medline: 23547654]
18. Seys D, Bruyneel L, Deneckere S, et al. Better organized care via care pathways: a multicenter study. PLoS One 2017;12(7):e0180398. [doi: 10.1371/journal.pone.0180398] [Medline: 28672030]
19. Rai V. COVID-19 and kidney: the importance of follow-up and long-term screening. Life (Basel) 2023 Oct 30;13(11):2137. [doi: 10.3390/life13112137] [Medline: 38004277]
20. Papageorgiou C, Apalla Z, Manoli SM, Lallas K, Vakirlis E, Lallas A. Melanoma: staging and follow-up. Dermatol Pract Concept 2021 Jul 1;11(Suppl 1):e2021162S. [doi: 10.5826/dpc.11S1a162S] [Medline: 34447611]
21. Yinusa A, Faezipour M. Optimizing healthcare delivery: a model for staffing, patient assignment, and resource allocation. Appl Syst Innov 2023;6(5):78. [doi: 10.3390/asi6050078]
22. Singh P, Jain N, Verma S, Sharma B. Commentary: ophthalmology training programs: optimization of human resource to supplement clinical expertise and strengthen eye care delivery systems. Indian J Ophthalmol 2023 Jan;71(1):274-275. [doi: 10.4103/ijo.IJO_2222_22] [Medline: 36588249]
23. Bechange S, Buttan S. Effectiveness of community-based eye care: process and considerations. Lancet Glob Health 2022 Apr;10(4):e451-e452. [doi: 10.1016/S2214-109X(22)00032-8] [Medline: 35303442]
24. Musch DC, Andrews C, Schumann R, Baker J. A community-based effort to increase the rate of follow-up eye examinations of school-age children who fail vision screening: a randomized clinical trial. J AAPOS 2020 Apr;24(2):98.e1-98.e4. [doi: 10.1016/j.jaapos.2019.12.012] [Medline: 32151570]
25. Das T, Dhoj Sapkota Y. Promoting technology-enabled primary eye care in South-East Asia. Community Eye Health 2021;34(113):s7-s8. [Medline: 36033409]
26. Ghimire S, Ghimire S, Khanal P, Sagtani RA, Paudel S. Factors affecting health insurance utilization among insured population: evidence from health insurance program of Bhaktapur district of Nepal. BMC Health Serv Res 2023 Feb 15;23(1):159. [doi: 10.1186/s12913-023-09145-9] [Medline: 36793046]

Abbreviations

BEH: Bharatpur Eye Hospital
RECON: Retina Eye Care of Nepal

Edited by S Badawy; submitted 06.08.24; peer-reviewed by B Bhattarai, H Pratomo, PRITI SINGH; revised version received 16.03.25; accepted 14.04.25; published 25.06.25.

Please cite as:
Shrestha M, Bhandari G, Bhandari S, Murthy GVS, Priya R, Pandey B, Chaudhary DS, Giri P, Kamalakannan S, Operational Research Capacity Building Study Group
Exploring Service Users' Experiences of a Community-Based Intervention to Improve Follow-Up at Bharatpur Eye Hospital in Nepal: Qualitative Study
JMIR Pediatr Parent 2025;8:e65023
URL: https://pediatrics.jmir.org/2025/1/e65023
doi:10.2196/65023

XSL•FO
RenderX

©Manisha Shrestha, Gopal Bhandari, Sadhan Bhandari, Gudlavalleti Venkata Satyanarayana Murthy, Ruchi Priya, Binod Pandey, Daya Shankar Chaudhary, Puspa Giri, Sureshkumar Kamalakannan, Operational Research Capacity Building Study Group. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 25.6.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Perspectives of Adolescents and Young Adults With Inflammatory Bowel Disease on a Biopsychosocial Transition Intervention: Qualitative Interview Study

Brooke Allemang[1], PhD; Ashleigh Miatello[1], MA; Mira Browne[1,2], HBSc; Melanie Barwick[1,3,4], PhD; Pranshu Maini[1,2], BHSc; Joshua Eszczuk[5]; Chetan Pandit[6], MSc; Tandeep Sadhra[7]; Laura Forhan[8], BSc; Natasha Bollegala[9,10], MSc, MD; Nancy Fu[11], MHSc, MD; Kate Lee[12], MBA, PhD; Emily Dekker[12]; Irina Nistor[12], PhD; Sara Ahola Kohut[1,13], PhD; Laurie Keefer[14], PhD; Anne Marie Griffiths[1,13,15], MD; Thomas D Walters[1,13,15], MBBS, MSc; Samantha Micsinszki[16], PhD; David R Mack[17,18], MD; Sally Lawrence[19,20], MBChB; Karen I Kroeker[21], MSc, MD; Jacqueline de Guzman[12], MSc; Aalia Tausif[12], MBBS, MPH, MD; Claudia Tersigni[1,13], MSc; Samantha J Anthony[1,22*], PhD; Eric I Benchimol[1,13,15,23*], MD, PhD

[1]Child Health Evaluative Sciences, SickKids Research Institute, The Hospital for Sick Children, Toronto, ON, Canada

[10]Department of Medicine, University of Toronto, Toronto, ON, Canada

[11]Division of Gastroenterology, Department of Medicine, University of British Columbia, Vancouver, BC, Canada

[12]Crohn's and Colitis Canada, Toronto, ON, Canada

[13]SickKids Inflammatory Bowel Disease Centre, Division of Gastroenterology, Hepatology and Nutrition, The Hospital for Sick Children, 555 University Avenue, Toronto, ON, Canada

[14]Division of Gastroenterology, Icahn School of Medicine at Mount Sinai, New York, NY, United States

[15]Department of Paediatrics and Institute of Health Policy, Management and Evaluation, University of Toronto, 555 University Avenue, Toronto, ON, Canada

[16]CanChild Centre for Childhood Disability Research and the School of Rehabilitation Science, McMaster University, Hamilton, ON, Canada

[17]CHEO Inflammatory Bowel Disease Centre, Division of Gastroenterology, Hepatology and Nutrition, Children's Hospital of Eastern Ontario, Ottawa, ON, Canada

[18]Department of Pediatrics, University of Ottawa, Ottawa, ON, Canada

[19]Division of Gastroenterology, Hepatology and Nutrition, BC Children's Hospital, Vancouver, BC, Canada

[2]Faculty of Health Sciences, McMaster University, Hamilton, ON, Canada

[20]Department of Pediatrics, University of British Columbia, Vancouver, BC, Canada

[21]Division of Gastroenterology, Department of Medicine, University of Alberta, Edmonton, AB, Canada

[22]Factor-Inwentash Faculty of Social Work, University of Toronto, Toronto, ON, Canada

[23]ICES, Toronto, ON, Canada

[3]Department of Psychiatry, University of Toronto, Toronto, ON, Canada

[4]Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

[5]Faculty of Kinesiology, University of Alberta, Edmonton, AB, Canada

[6]ETH Zurich, Zurich, Switzerland

[7]Faculty of Health, York University, Toronto, ON, Canada

[8]Department of Molecular and Cellular Biology, University of Guelph, Guelph, ON, Canada

[9]Division of Gastroenterology, Women's College Hospital, Toronto, ON, Canada

[*]these authors contributed equally

Corresponding Author:
Eric I Benchimol, MD, PhD
Child Health Evaluative Sciences, SickKids Research Institute, The Hospital for Sick Children, Toronto, ON, Canada

Abstract

Background: The transition from pediatric to adult health care marks a complex and pivotal process for adolescents and young adults with inflammatory bowel disease (IBD). This group requires support regarding disease self-management, skill development, and system navigation in preparation for transition. Evidence-based interventions are needed to promote optimal health and psychosocial outcomes for adolescents and young adults with IBD during this period.

XSL•FO
RenderX

Objective: A qualitative study embedded within a randomized controlled trial was conducted to evaluate the perceived impact of a biopsychosocial transition intervention on the transition experiences of adolescents and young adults, their views on the intervention, and recommendations for future care.

Methods: This patient-oriented research study used a qualitative descriptive design. Virtual semistructured interviews were held with 21 adolescents and young adults with IBD (16 - 18 y) enrolled in the randomized controlled trial (intervention arm n=11 and control arm n=10). Interviews were audio-recorded, transcribed, and analyzed using an inductive approach to reflexive thematic analysis. Five members of a Youth Advisory Panel with lived experience of IBD collaborated throughout data analysis, interpretation, and the presentation of findings.

Results: We constructed three themes through our analysis: (1) making meaning of transitions in care; (2) perceptions and impact of the biopsychosocial transition intervention; and (3) considerations for future transition care, including the importance of individualized support.

Conclusions: Our findings illustrate the importance of relationships and the impact of a biopsychosocial intervention on adolescents' and young adults' confidence, knowledge, and self-management skills during transition. The results, which indicate the criticality of tailoring transition supports according to adolescents' and young adults' preferences and characteristics, will be used to refine the biopsychosocial intervention before it can be scaled and spread.

(JMIR Pediatr Parent 2025;8:e64618) doi:10.2196/64618

KEYWORDS

gastroenterology; inflammatory bowel disease; biopsychosocial; patient-oriented research; transition to adult care; qualitative methods; young adults; qualitative; adolescents; patient perspectives; Crohn's disease

Introduction

The transition from the pediatric to the adult health care system can be a complex period for adolescents and young adults with inflammatory bowel disease (IBD) and their families [1]. In adult care, adolescents and young adults are expected to self-advocate, communicate with providers, understand their health history, and manage their health with greater independence [2,3]. However, service disruptions at the pediatric-adult juncture, shifts in parental involvement, a lack of readiness for transition, and differing treatment philosophies and models of care can complicate the transition process [1,4]. While the transition from pediatric to adult care for adolescents and young adults with IBD has been well studied and identified as a priority area for policy and program development [5-7], evidence-based transition interventions that account for the priorities of adolescents and young adults are needed.

Adolescents and young adults with IBD face a series of challenges around the transition from pediatric to adult care [1]. Psychosocial stressors are prominent at this stage of life, including the emergence or worsening of mental health conditions, changing roles within the family, and co-occurring transitions in the areas of employment, education, and living [8]. Termination of longstanding relationships with pediatric providers and expectations for autonomous management of one's health condition following a transfer out of pediatric care can exacerbate the challenges associated with this period [1,9]. Additionally, this group is susceptible to poor health outcomes and high health care costs should the transition from pediatric to adult care be disjointed [10-12]. Therefore, a purposeful, coordinated, and planned transition from the pediatric to the adult health care system is required to ensure adolescents and young adults with IBD can achieve the best possible health and psychosocial outcomes during a complex developmental period [13].

Transition interventions for adolescents and young adults with IBD to date have typically included joint pediatric-adult clinic visits, face-to-face education about disease processes and self-management, and meetings with allied health professionals focused on self-efficacy and goal setting [14]. However, transition intervention components are highly variable and limited research has focused on adolescents' and young adults' perspectives of the most valuable and well-received aspects of such interventions [14]. Further, there is no level-one evidence (eg, randomized controlled trials [RCTs]) for any intervention in transition in IBD [15]. To improve the standards for health care delivery and transition care across Canada for adolescents and young adults with IBD, a biopsychosocial transition intervention was developed and is currently being evaluated in a type 1 hybrid effectiveness-implementation trial (ClinicalTrials.gov NCT05221281) [16]. While various functional and implementation outcomes are being assessed within the RCT using standardized measures, qualitative research can elucidate adolescents' and young adults' needs and experiences of the intervention to support the translation of findings into practice [17]. Thus, the objectives of this study were to explore adolescents' and young adults' transition experiences, perceptions of the transition intervention, and recommendations for future transition care to inform the refinement of the intervention.

Methods

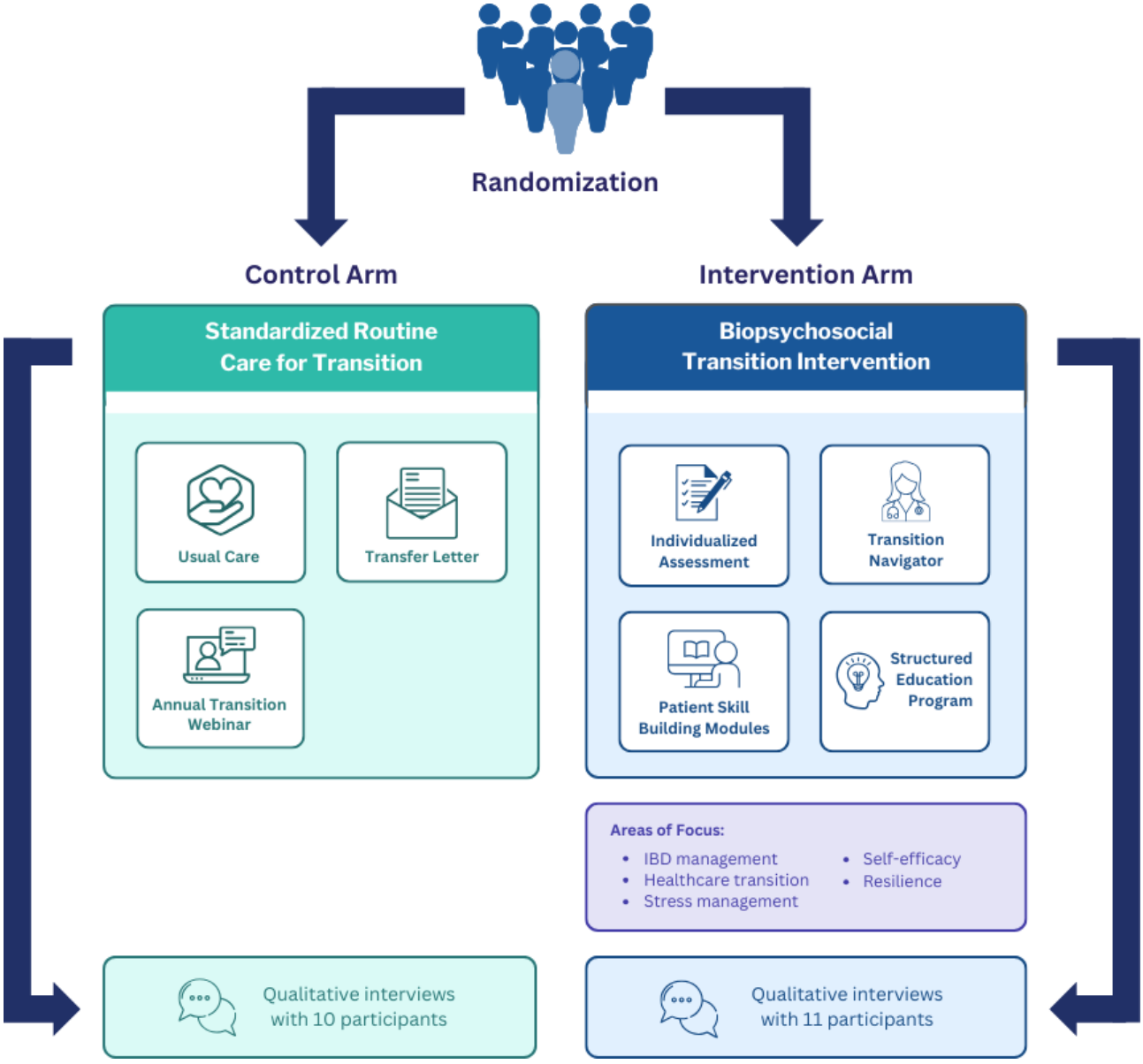
Study Design and Population

This patient-oriented research study [18] adopted a qualitative descriptive design [19] to understand the needs and experiences of adolescents and young adults with IBD during the transition while concurrently assessing the perceived impact and acceptability of the biopsychosocial transition intervention. It was embedded within an ongoing multicenter RCT evaluating the effectiveness of the transition intervention among

XSL•FO
RenderX

adolescents and young adults with IBD [16]. A qualitative descriptive design was used to explore the perspectives of adolescents and young adults in addition to the outcomes being assessed in the RCT [16,19]. The intervention consisted of (1) an individualized assessment, (2) a transition navigator, (3) patient skill-building delivered via online modules, and (4) a structured education program (see Figure 1 for an overview of the RCT design) [16]. Half of the RCT participants were randomized to the biopsychosocial intervention, and half received a standardized version of routine care for transition [16]. Adolescents and young adults in the intervention arm received support from a transition navigator. They had access to online skill-building activities and an online education program with topics focused on IBD management, resilience, health care transition, self-efficacy, and stress management for the duration of the study [16]. Though the RCT has 3 study sites at Canadian tertiary care centers, this study explored the perspectives of adolescents and young adults at the study site, which has the largest cohort of participants and has participants who had access to the intervention for the longest duration.

Figure 1. Overview of RCT design. IBD: inflammatory bowel disease; RCT: randomized controlled trial.



In embracing a patient-oriented research approach [18], the study investigators collaborated with a project-specific Youth Advisory Panel (YAP) consisting of 5 patient partners with diverse backgrounds, expertise, and lived experience with IBD. YAP members were recruited from an existing national IBD advisory council. The national IBD advisory council was involved in a previous qualitative study conducted by our team [20]. Subsequently, select advisory panel members expressed the desire to become involved in this study to further explore and contribute to the qualitative findings. The YAP consisted of 3 male and 2 female members aged 18 - 30 years from across Canada, thereby increasing the study's transferability with enhanced diversity of input and representation of health care experiences. The YAP members actively contributed to data analysis, interpretation, presentation of results, and preparing this article, helping align research findings with patient-identified priorities [18]. This collaborative partnership and bidirectional flow of knowledge helped cultivate a sense

XSL•FO
RenderX

of ownership in members while capturing nuanced insights often overlooked in traditional research paradigms. YAP members were supported and mentored by 2 study team members (BA and AM) throughout the process. Study investigators and YAP members frequently corresponded via email. They held virtual weekly or biweekly progress meetings over 3 months (March-May 2024) with flexible agendas to promote clarity of purpose, efficient use of time, and active participation during meetings.

Eligibility and Sampling

Study procedures are available in a prior publication [20]. Briefly, eligible qualitative participants were the following: (1) aged 16 - 20 years, (2) English-speaking, (3) diagnosed with IBD, (4) enrolled in the RCT at the SickKids study site for at least six months, and (5) capable of providing informed consent. Purposive sampling [21] was used to select a clinically and demographically diverse sample of adolescents and young adults in the intervention and control arms, with varying levels of engagement with the intervention. We discontinued recruitment once we gleaned a breadth and depth of relevant information from participants to answer our study questions [22].

Data Collection

A female qualitative researcher with a social work background conducted individual interviews with adolescents and young adults using an institutional account of Microsoft Teams (Microsoft Corp). A semistructured interview guide, developed with YAP members and an interdisciplinary team of IBD clinicians and researchers, was used. Interview questions focused on adolescents' and young adults' experiences preparing for or undergoing health care transitions, perceptions of the biopsychosocial intervention, and recommendations for future transition care in IBD. Consent was obtained, and interviews were digitally recorded, transcribed, verified, and anonymized before analysis. Reflective memos were used during data analysis to highlight striking patterns and impressions of the interview data [23]. Participants received a US $20 electronic gift card and 1 volunteer hour for completing an interview.

Data Analysis

An inductive approach to reflexive thematic analysis [23,24] was used to analyze the data. Interview transcripts were reviewed by 2 coders (BA and M Browne) who reflected on their positionality, assumptions, and social locations in reference to the data. The coders then engaged in line-by-line coding inductively, designating codes to portions of interview text to categorize shared ideas [23,24]. They met consistently during the coding process to consider their perceptions of the data, important codes, and emerging patterns and to begin collectively making sense of the data [23]. Codes were grouped into themes to capture the meaning and key concepts within the data, and relationships between codes and themes were examined using mind maps. YAP members independently reviewed the list of codes and preliminary mind maps. YAP members shared their opinions on organizing concepts, developing themes and figures, and determining which ideas were most important to convey synchronously at online team meetings using the Microsoft Teams platform and asynchronously using collaborative documents. The preliminary themes, codeveloped with the YAP, were presented to the larger team for input, refined, and final themes were named and consolidated through discussion. Analysis was conducted using NVivo (version 14; Lumivero).

Ethical Considerations

Institutional approval for this study was obtained from The Hospital for Sick Children (SickKids) Research Ethics Board (REB #1000078476). Informed consent was obtained for each participant in the RCT and prior to enrollment in this substudy.

Results

Overview

A total of 21 adolescents and young adults were interviewed between May and September 2023 (intervention arm=11 and control arm=10). Participants were aged between 16 and 18 years, primarily female, and at different stages of health care transition. The demographic and clinical characteristics of the participants are presented in Table 1. Participant identifiers beginning with "C" denote control arm participants, and those beginning with "I" indicate intervention arm participants in the results. We constructed three themes through our analysis: (1) making meaning of transitions in care; (2) perceptions and impact of the biopsychosocial transition intervention; and (3) considerations for future transition care, including the importance of tailored supports.

XSL•FO
RenderX

Table . Participant characteristics (N=21).

		Values, n (%)
Demographic characteristics		
Gender		
	Female	13 (61.9)
	Male	7 (33.3)
	Nonbinary	1 (4.8)
Age (years)		
	16	2 (9.5)
	17	15 (71.4)
	18	4 (19.1)
Ethnicity		
	Black	4 (19)
	South Asian	6 (28.6)
	White	9 (42.9)
	Other or multiracial	2 (9.5)
Immigration status (participant)		
	Born in Canada	19 (90.5)
	Immigrated to Canada	2 (9.5)
Immigration status (parents)		
	Born in Canada	7 (33.3)
	Immigrated to Canada	14 (66.7)
Sexual orientation[a]		
	Bisexual	2 (9.5)
	Gay or lesbian	2 (9.5)
	Heterosexual or straight	15 (71.5)
	Other	2 (9.5)
Household income of family of origin (US $)		
	0 - 49,999	1 (4.8)
	50,000 - 99,999	1 (4.8)
	100,000 - 149,999	3 (14.3)
	150,000 - 199,000	3 (14.3)
	200,000+	3 (14.3)
	I do not know	10 (47.5)
Study arm		
	Control arm	10 (47.6)
	Intervention arm	11 (52.4)
Highest level of parental education		
	High school	1 (4.8)
	Some postsecondary	1 (4.8)
	Graduated postsecondary	19 (90.4)
Vocational status[b]		
	Employed (full or part-time)	6 (28.6)

XSL•FO
RenderX

			Values, n (%)
		High school student	18 (85.7)
		Postsecondary student	1 (4.8)
		Not currently in school or employed	0 (0)
Clinical characteristics			
	Diagnosis type		
		Crohn disease	15 (71.4)
		Inflammatory bowel disease type	
		IBDU[c]	2 (9.5)
		UC[d]	4 (19.1)
	Age at diagnosis (years)		
		≤5	2 (9.5)
		6 - 12	5 (23.8)
		13 - 17.9	14 (66.7)
	Family history of IBD[e]		
		Yes	7 (33.3)
		No	14 (66.7)
	Transferred to adult gastroenterologist at the time of interview?		
		Yes	4 (19.1)
		No	17 (80.9)

[a]Response categories based on participants' language.

[b]Multiple response options were possible.

[c]IBDU: inflammatory bowel disease type unclassified.

[d]UC: ulcerative colitis.

[e]IBD: inflammatory bowel disease.

Theme #1: Making Meaning of Transitions in Care

Overview

Adolescents and young adults expressed a range of reflections on the meaning of the transition from pediatric to adult health care. Their conceptualizations of this transition ranged from "switching doctors" to more existential thoughts about the health care transition, marking the loss of childhood. The meanings ascribed to health care transitions appeared to influence adolescents' and young adults' feelings about entering adult care and their overall readiness to engage in self-care tasks with greater autonomy.

On one end of the spectrum, adolescents and young adults described the transition to adult care as "an inevitability and a necessity" [C-036] once they were aged 18 years. Participants with this view seemed to understand transition as moving from one specialist to the next, with expectations that care would be delivered similarly. Those who conceptualized this change as primarily related to switching providers without ascribing a deeper philosophical meaning to transition tended to express minimal concerns or worries about entering the adult system. Many of these participants had well-managed IBD or family members (eg, parents or siblings) with IBD who were already receiving treatment in the adult system. As described by 1 participant, "For me, it's not a big deal, you're just switching doctors. And it'll just be the same thing over there anyway, so I'm not really stressed out about it." [C-001]. Importantly, however, those with this mindset had not yet transferred or been exposed to the adult care environment.

Others reflected that the transition to adult health care aligned with the launch from adolescence to young adulthood. Many adolescents and young adults viewed the health care transition as a signal that they were now "grownups" [I-039] who would be required to assume new roles and responsibilities within and outside their IBD management. Some adolescents and young adults felt the transition allowed them to reflect on their growth and development. There was an overarching sense of hope for the future, while, at times, this was coupled with feelings of sadness about the loss of relationships with familiar pediatric providers: "I mean, it's a sign of maturity and that I'm growing. It's kind of sad in that way, but you know, it's a part of life." [C-031]. Most participants accepted the transition and described it as a period in which they would take greater initiative, advocate for themselves, learn more about their health history, and plan their appointments. One participant shared:

> *I look at [transition] as me having to know a lot about myself, especially where I am with my health. At the end of the day, my mother has to stop bringing me to*

XSL•FO
RenderX

> *the appointments, I can't bring her all the time, right? Because it's that independent thing that comes in. So I think it's just a learning experience about myself, learning about where I am with my health, knowing everything that I need to know for myself so I don't have to depend on anybody else to know it for me.* [I-021]

Most participants felt motivated, empowered to take ownership of their care, and even excited to enter a new environment, mainly due to the reputations of the adult IBD clinics or specialists and their confidence in their ability to self-advocate. However, a few adolescents and young adults expressed some hesitance about moving into adult care due to the perceived expectations of adult providers: "While new things are exciting, they're also unknown and unknown things are scary. [My adult team] will have expectations for grownups, but I don't really feel like a grownup" [I-039]. The following subtheme delves into the role of relationships between adolescents and young adults and their support networks.

Relationality and Transitions to Adult Care

Trusting relationships with health care providers, family members, and peers emerged as transition facilitators for adolescents and young adults. When participants had strong and supportive relationships with their pediatric health care providers, they expressed confidence in their adult IBD providers' ability to meet their needs: "I have lots of trust in my pediatric doctor, so if he recommended me to this one then this one must be pretty great." [C-014]. Adolescents and young adults outlined their hopes for developing trust with their new providers in adult care and shared examples of factors promoting engagement with clinicians. These included providers offering clear and detailed responses to adolescents' and young adults' questions, adopting a nonjudgmental stance, being transparent about treatment plans, offering adolescents and young adults choices, listening intently to their concerns, and asking for adolescents' and young adults' input on health-related decisions.

Adolescents and young adults receiving the biopsychosocial intervention described their relationship with the transition navigator as being one of the most beneficial aspects of this study. Many felt the navigator played a key role in preparing them for the transition by serving as a point of contact for any questions or concerns and "checking in" with adolescents and young adults, particularly between their final pediatric and first adult appointments. Adolescents and young adults described the transition navigator as demonstrating genuine care for their well-being, offering support with the transition to postsecondary education, encouraging the development of self-management skills, and providing anticipatory guidance about what to expect in adult care. "[My transition navigator] made that effort to make me feel like she's not just a transition navigator, she's a person that actually cares about me." [I-015]. The quality of their relationship with the transition navigator also prompted some adolescents and young adults to open up about their emotions and mental health. In one case, this led to a participant receiving a diagnosis for longstanding anxiety symptoms and subsequently accessing mental health supports:

> *Before I got diagnosed with generalized anxiety, I talked to my transition navigator about how I was feeling and how I didn't really know how to cope. She helped me make the decision to go see a doctor about it to see if [I] could get prescribed medication or get some sort of diagnosis. Even though I was kind of on edge about going to a doctor for something that sounded so silly in my brain, she helped me calm myself about it.* [I-016]

Lastly, adolescents' and young adults' relationships with family members and peers facilitated the acquisition of self-management skills and enhanced confidence in preparation for transition. They described the pivotal roles their parents played in helping them cope with IBD and how they are taking more responsibility for specific tasks over time:

> *My parents have always been supportive and on top of it, maybe even a little more than I have. Because at first, I was in denial, I was like, "no, my IBD's not that bad". But they were keeping me on top of my medication and stuff, especially when I was younger, my mom helped me a lot with that. I've become a little more independent now and I'm able to take medication on my own.* [I-020]

Many outlined the value of having parents, siblings, and extended family members offering emotional support (eg, listening, reassuring, or encouraging), instrumental support (eg, teaching how to refill prescriptions), and advice as they approach the transition to adult care. Parents often served as mentors to adolescents and young adults, coaching them to assume greater responsibility for their care and IBD management incrementally. Most participants were aware their roles would change in adult care and were working with parents to practice skills and negotiate what these new roles would be like posttransfer.

The transition experience appeared to be constructed in relation to others. Trusting relationships with health care providers, family members, and peers were found to promote confidence and readiness to engage in the tasks required to manage IBD care during transition. Adolescents' and young adults' ability to communicate their needs openly to others (and feel validated by them) was a priority for participants, and supportive relationships helped facilitate this.

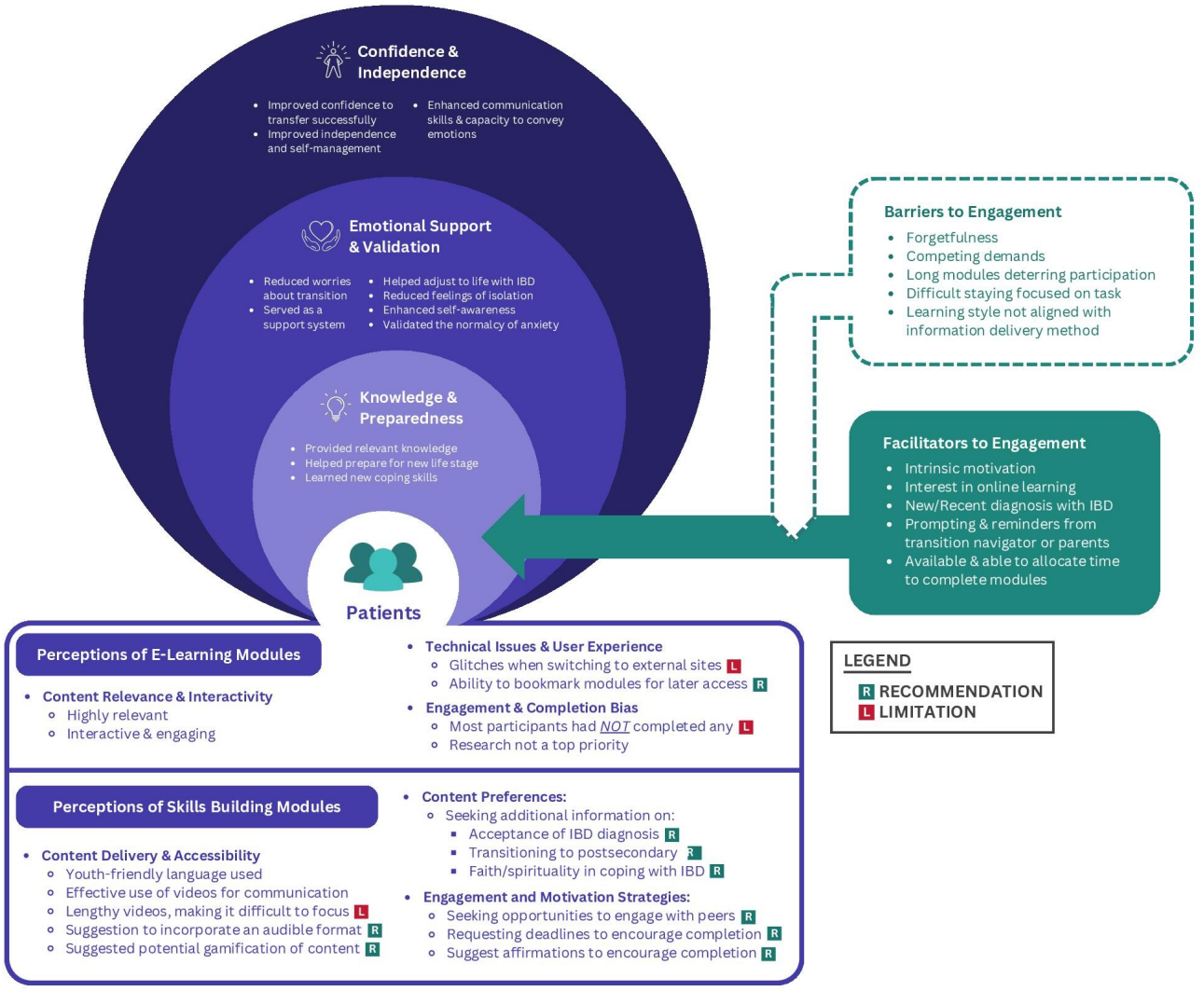
Theme #2: "It Gets Me Ready to Start Doing Things on My Own": Perceptions and Impact of the Biopsychosocial Transition Intervention

Overview

A combination of adolescents' and young adults' communication preferences, personality characteristics (eg, curiosity, motivation, or social), learning styles, and sources of support influenced their uptake of and perspectives on the intervention. Participants' perceptions of the intervention's impact fell into three categories: (1) knowledge and preparedness, (2) emotional support and validation, and (3) confidence and independence. Additionally, barriers and facilitators to engagement with the intervention were described by adolescents and young adults (Figure 2).

XSL•FO
RenderX

Figure 2. Impact and perceptions of the biopsychosocial transition intervention. IBD: inflammatory bowel disease.



Knowledge and Preparedness

Adolescents' and young adults' experiences of the intervention indicated that acquiring knowledge helped foster a sense of agency and supported their transition readiness. Core components of the transition intervention helped adolescents and young adults envision their transition journeys while arming them with the competencies required to succeed in adult care and life. Participants receiving the intervention expressed positive sentiments about their experiences in the trial, noting that it catalyzed personal growth and empowerment. Shifting from a mindset of passive acceptance to one of proactive engagement in navigating the complexities of transition, many participants, with curious mindsets, described applying newly acquired skills and knowledge in their daily lives to improve aspects of pain management, communication, and self-regulation:

> *The transition from pediatric care to adult healthcare is one that's not easy, [but] there are things that you can learn in order to be more successful during transition with respect to being an adult. I think it's really just using your skills, engaging in things like mindfulness, and building your confidence so that you can communicate with your healthcare team as best as you can.* [I-019]

A few participants even considered the newfound sense of agency to extend beyond health care transitions to encompass broader life transitions, such as education, career choices, and relationships:

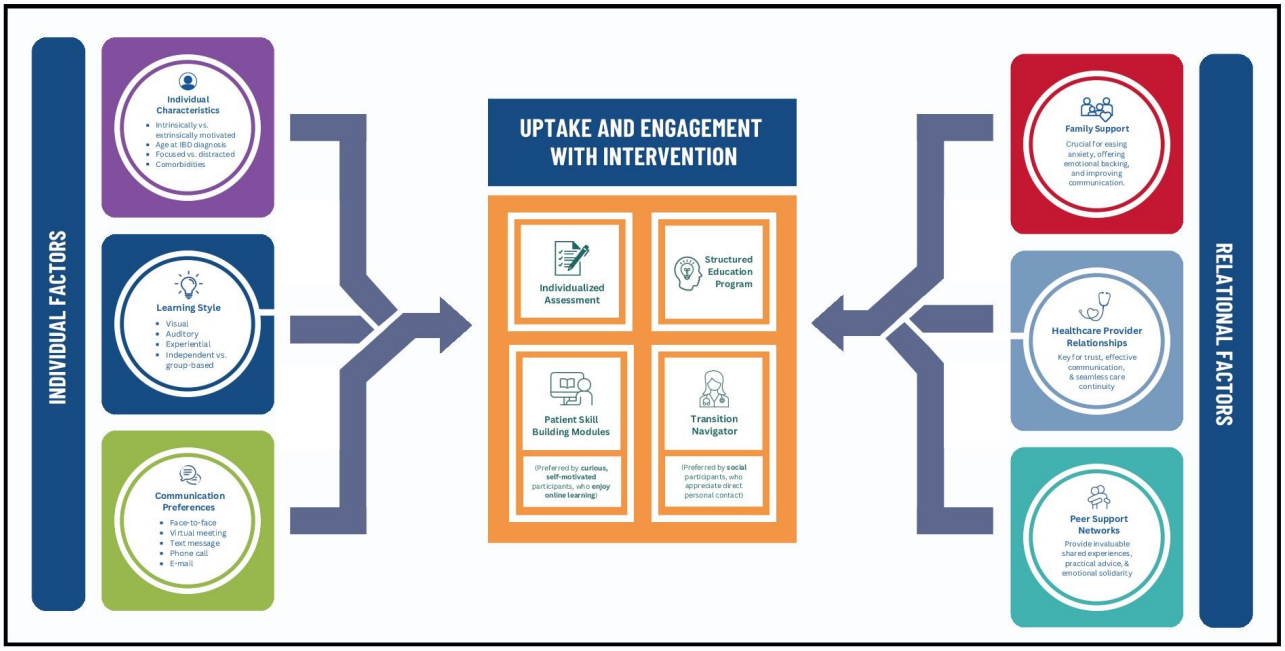
> *Before I started this, I barely even knew what transition was! It was very foreign to me and it was almost scary because I didn't know what to expect. Especially in addition to going from high school to university, there was just a lot of stuff going on in relation to transition. So having these modules, having this information is something that has definitely helped me in that sense.* [I-007]

Emotional Support and Validation

Given the myriad of psychosocial stressors and challenges inherent in transitioning from pediatric to adult care, adolescents and young adults voiced that validation and emotional support were important. Participants in the intervention arm found these types of support in different intervention components based on their individual characteristics and relational factors (Figure 3).

XSL•FO
RenderX

Figure 3. Factors influencing engagement with the intervention. IBD: inflammatory bowel disease.



Most adolescents and young adults who were social found that having direct access to a transition navigator (eg, via text or email) offered reassurance and interpersonal connection; one such adolescent or young adult shared: "100% talking to [my transition navigator is the most helpful component of the intervention] because I'm a people person, so talking to somebody is very helpful, whereas I just get bored doing the modules and stuff." [I-016]. Other participants with similar personality characteristics felt that having a transition navigator helped foster a trusting relationship that extended beyond clinical interactions, providing them with an open outlet to voice their hopes, fears, and concerns regarding their transition to adult care. Many adolescents and young adults even felt immediately more prepared to transition, knowing that their transition navigators represented a dependable source of information that they could turn to and confide in during times of need: "I did get a person [transition navigator] who I can text about anything I'm struggling with. They've definitely helped me be open about how I'm feeling." [I-007]

Other adolescents and young adults voiced that the variety of concepts covered in the skills-building modules validated their concerns and helped them feel less alone in coping with the challenges of living with IBD: "if they're making modules like this, I'm not the only one that's feeling like this." [I-020]. Regardless of their personality traits, most adolescents and young adults described being well supported by their transition navigator in making informed decisions, whether that be related to accessing postsecondary accommodations or scholarships, obtaining referrals to relevant resources (eg, mental health services, volunteer opportunities, or support groups), or learning about the expectations of adult IBD providers.

Confidence and Independence

Adolescents and young adults outlined how the intervention promoted confidence in preparation for adult care. Some adolescents and young adults viewed the skills-building modules as the most relevant and beneficial aspect of the intervention because they gained independence through acquiring new strategies. Participants who were self-motivated and enjoyed online learning appreciated the wealth of information offered on a range of topics and the ability to access the modules at their own pace given their busy schedules at this stage of life (eg, planning for postsecondary education, participating in extracurricular activities, or working). Additionally, most adolescents and young adults felt that the skills and knowledge developed through the intervention could be applied to their illness and beyond: "I feel like the skills are the most applicable to your everyday life. You can use them with Crohn's or without Crohn's. They teach you how to deal with any obstacle you might have in that sense." [I-019]

Many adolescents and young adults outlined the impact of the intervention in its entirety on their feelings of confidence and preparedness for a new care environment:

> *To have a navigator or to have modules, I just feel more comfortable now and more confident. Because even before I was like, "what's going to happen when I turn 18? I don't want to leave [pediatric hospital] because I just feel like they know all about everything I've been going through and have helped me.*" [I-020]

While all participants receiving the intervention approved of its impact on their knowledge, skills, emotional well-being, confidence, and overall preparedness for transitioning to adult care, each adolescents' and young adults' preferences and personality traits impacted how and where they experienced the greatest benefit.

Barriers and Facilitators to Engagement

As outlined in Figure 3, a series of individual, intervention-specific, and familial characteristics supported or hindered adolescents' and young adults' engagement with the intervention and in their overall health care.

Individual characteristics that facilitated engagement included being newly diagnosed with IBD, having strong relationships

XSL•FO
RenderX

with health care providers, and feeling well supported by family members and peers. Adolescents and young adults with recent diagnoses were motivated to complete the skills-building modules because they were interested in developing a higher-level understanding of their illness, including symptom management, self-care, and peer support. Adolescents and young adults who were intrinsically motivated and had learning styles conducive to online learning with visual aids, audio, and text-based materials favorably viewed the presentation of the modules. Consequently, these individuals did not require much prompting as they were driven to learn and expand their skill sets of their own accord.

The support systems adolescents and young adults had in place were critical to the uptake of the intervention, particularly for those who described themselves as forgetful. Most participants benefited from the navigator prompting or reminding them to complete the modules and appreciated the navigator's persistence in communicating with them. Adolescents and young adults with comorbidities (eg, diabetes, arthritis, or anxiety) seemed to require more encouragement from the transition navigator or family members to support module completion, given they were managing multiple illnesses, appointments, and medication regimens. Some adolescents and young adults described completing the modules alongside parents who were interested in learning and supporting their adolescents or young adults, aiding participants who may otherwise have lacked interest in engaging with the content: "My mom was super on top of it [skills-building modules], and she's like, 'come do the modules with me'" [I-020]. When these supports were available, adolescents and young adults seemed better able to complete the materials and solidify their learnings through conversation and questions.

Regarding barriers to engaging with the intervention and completing the skills-building modules, most adolescents and young adults cited competing demands (eg, examinations, work, family, or romantic relationships) and forgetfulness as factors influencing their ability to commit time toward modules, despite their interest in the content. Some participants felt it challenging to initiate contact with the navigator or begin a new module without prompting because the research was admittedly not their top priority:

> *Sometimes, it's hard for me to open the tablet and go on there [to do the modules] because it's not the first thing that comes to my mind. Every day, I wake up, and I'm like, "Okay, I have to do this and that today. I also have to message this person [transition navigator]," and I don't get around to doing it.* [I-021]

The length of the modules was described by several participants as a deterrent, especially for those with difficulty staying on task. Some adolescents and young adults struggled to remain engaged and interested in the skills being discussed, inadvertently leading them to become distracted:

> *With the modules, I get distracted very easily, so it's been very hard for me to stay on task. I've been struggling to remember since the end of grade 11 to do these modules. It's not that they're boring per se, it's that I'm not focused enough, ever.* [I-016]

Finally, adolescents and young adults whose learning preferences were at odds with how information was conveyed in the modules and educational curriculum faced barriers to retaining knowledge. For instance, participants who were visual learners expressed difficulties taking in the information and solidifying their learning, given that most of the content was delivered via a speaker on camera without visuals to illustrate concepts. This led to feelings of frustration and a lack of motivation to stay engaged for some:

> *I don't know if it's because I'm a visual person, but sometimes it's really hard for me to sit down and watch somebody talk for 20 minutes. Something about it disengages me. My ears are open, but I'm not really taking in everything.* [I-021]

In summary, each adolescent's or young adult's learning styles, needs, and preferences were important factors to consider when using and evaluating the intervention.

Theme #3: Considerations for Future Transition Care

Overview

Adolescents and young adults in both arms of the trial highlighted a "gentle transition," defined as a period of overlap between pediatric and adult IBD providers or a joint visit with pediatric and adult providers, as an approach that would help reduce stress and illustrate that "the first team trusts the second team fully" [C-006]. Most participants also felt the topic of transition should be raised, and the process started early (around being aged 16 years) to allow ample time for gradual skill acquisition:

> *I'd say [introduce transition] at about 16 because 18 is when transition starts and throughout the journey, you don't really realize how little time you have until it's right there and it's knocking on your doorstep. But if you start teaching what they need to learn at around 16, I think they'll be able to develop skills and become more mature and be able to deal with those things as time goes on.* [I-019]

Adolescents and young adults approved of the value of a clinician (eg, transition navigator) responsible for "guiding [youth] through the transition process" [C-006], offering advice, addressing transition-related concerns, and providing service navigation. They felt having a trusted person they could go to (as opposed to a website or app) would allow them to practice the communication and advocacy skills needed for adult care in real time:

> *If you can have someone that people can reach out to and talk to, actually face-to-face whether it's Zoom, texting, calling, or emailing, I feel like that would be beneficial just so they know they're actually talking to someone. And that would help with socializing and getting them used to adult responsibilities and communicating on their own.* [C-013]

Others suggested providing adolescents and young adults with case scenarios that commonly arise for transition-age youth

XSL•FO
RenderX

with IBD to role play, followed by discussions about how to respond to different situations. They felt this approach would help them solidify experiential knowledge, build confidence, and prepare them for possible challenges:

> *I think it would be the most helpful to have [youth] actually do a fake phone call. Because if you're talking about something like a conversation, it's better to learn it in its application and learn to try to say things yourself rather than knowing that you have to do something like, "oh, I should say that, I should do this". Being forced to deal with some of the discomfort that might come along with the conversations and practicing that would be beneficial.* [C-036]

Finally, participants advocated for group-based education sessions (either in person or online) to support their learning. Those in the intervention arm felt that providing a method for adolescents and young adults with IBD to (optionally) interact with one another through the online platform would allow them to feel more connected and less alone.

Recommendations for Refinement of Biopsychosocial Intervention

Adolescents and young adults in the intervention arm highlighted the importance of keeping participants engaged in the intervention (and their care more broadly) around the time of transition when young people face competing priorities; thus, they suggested shortening the modules into "bite-sized" [I-007] pieces to improve their delivery. Several adolescents and young adults were interested in audio versions of the skills-building modules based on their learning styles and preferences. Many participants thought including games, knowledge tests, or offering awards for completion could help participants stay motivated and on task. Most participants were satisfied with the range of topics available regarding the module content. However, a few adolescents and young adults felt having materials focused on accepting IBD and adjusting to life with a chronic illness would be beneficial to them, especially for those newly diagnosed or experiencing challenges coping with IBD. Others suggested incorporating education focused on diversity within IBD, including the roles of faith, cultural traditions, and food customs in IBD management. Lastly, some adolescents and young adults felt the transition to postsecondary (education or employment) should be elaborated upon in the modules based on their experiences, especially advocating for themselves with teachers or employers and accessing accommodations.

Discussion

Principal Findings

Using qualitative methods, this study offered a detailed understanding of the experiences, priorities, and needs of adolescents and young adults with IBD during the pediatric-adult transition. Learning about the biopsychosocial intervention from adolescents' and young adults' perspectives contextualized the RCT results and provided insights about engagement, acceptability, and future directions. Our findings revealed the importance of making meaning during health care transition, the impact of the biopsychosocial transition intervention, and adolescents' and young adults' viewpoints on future transition care.

Regarding conceptualizations of the transition to adult care, adolescents and young adults with IBD expressed various ideas about its meaning. Hislop et al [25] outlined a similar range of views regarding the transition to adult care from youth with chronic conditions, from "laid back" to "anxious." Additionally, the youth in their study expressed the value of social interaction with family, peers, and professionals to assist with the transition from pediatric to adult care [25]; findings echoed in the present study. Of note, most participants in our study had not yet transferred to adult care at the time of data collection, possibly influencing their conceptualizations of transition. Understanding adolescents' and young adults' views on the meaning of transition and the quality of their interpersonal relationships could support the development of personalized transition plans in clinical settings that consider their readiness. It is also important to examine whether adolescents' and young adults' conceptualizations of transition before they enter adult care impact their capacity for self-management and experiences posttransfer.

This study validates the importance of relational support for adolescents and young adults with IBD, which helped facilitate engagement with the intervention and readiness for transition. Fostering positive relationships with health care providers, family members, peers, or community members may play an important role in promoting flourishing, a known predictor of physical and mental health [26,27]. Given adolescents and young adults are often experiencing multiple life transitions simultaneously, external support is critical [26]. Future research could explore the development and evaluation of companion modules or educational resources for family members supporting adolescents and young adults with IBD.

Tailoring educational resources and support to align with the needs of adolescents and young adults arose as a prominent concept in this study. This included considering adolescents' and young adults' communication preferences, learning styles, familial or community supports, and pre-existing traits, including age at IBD onset and personality characteristics, in designing and delivering patient education. Individualizing care according to genetic, social, and individual- and family-specific factors is a key tenet of precision child health, an emerging paradigm for pediatric quality and safety [28]. Precision child health focuses on the unique needs and characteristics of pediatric patients and their families to provide proactive, person-centered care [28]. Moreover, offering personalized support for adolescents and young adults with chronic conditions transitioning to adult care according to their level of preparedness has been endorsed in the literature. Charles et al [29] identified a typology of transition readiness for adolescents and young adults with congenital heart disease, suggesting that different groups require varying levels of support in preparation for the transition, from minimal intervention required to "follow-up needed" to "at-risk." A transition intervention that is customized based on the ethnocultural needs of adolescents and young adults with traumatic brain injury has also been described and reported [30]. Further, the IBD literature demonstrates the importance of

XSL•FO
RenderX

delivering culturally sensitive care that recognizes the impact of health inequities, cultural values and beliefs, and the roles of implicit or explicit biases on patients' experiences navigating the health care system [31]. Our results provide evidence of the criticality of attending to adolescents-, young adults-, family-, and system-level factors in providing transition care to promote optimal experience, uptake, engagement, and outcomes.

Patient navigators have been identified as a promising intervention for adolescents and young adults with chronic conditions transitioning to adult care [32,33]. Our results confirmed the value and acceptability of the relational support offered by a transition navigator, with participants detailing the navigator's impact on their experiences and outcomes during the transition. This was especially apparent for adolescents and young adults with challenging diagnostic journeys, mental health concerns, and co-occurring conditions. This speaks to the potential usefulness of a transition navigator intervention for adolescents and young adults with chronic health conditions or mental health conditions more broadly. Given the logistical challenges of holding joint pediatric-adult clinic appointments in North America, cross-appointed navigators could be a favorable option for promoting continuity of care [34,35]. Further exploration of individual characteristics, including personality traits and existing supports, and how these relate to engagement during transition is warranted. Adolescents and young adults in our study expressed their interest in gamified transition resources to enhance motivation to engage with educational materials. Indeed, a recent scoping review identified that gamification improves patient engagement and biopsychosocial outcomes and could represent a valid approach to cancer patient education [36]. Future research could explore gamification within IBD care and its impact on patient experience, knowledge, and outcomes. Finally, given the complexity of factors (eg, communication preferences, personality, or learning styles) influencing adolescents' and young adults' transition needs, future iterations of the biopsychosocial transition intervention could consider the integration of artificial intelligence to support adolescents and young adults. This would enable tailored guidance when navigator support is unavailable (eg evenings or weekends) or when adolescents and young adults prefer more self-directed approaches.

Limitations and Future Directions

This study's results should be considered in light of some limitations. Sampling bias could be a concern given that the qualitative study participants were enrolled in an RCT and consisted of mostly female participants. Regarding transferability, our findings may not apply to all adolescents and young adults with IBD or those in different health care systems or regions. Additionally, only 1 participant had completed any education modules at the time of the interview, so we could not assess participants' perceptions of this aspect of the intervention. To enhance trustworthiness, we used member checking with the YAP. YAP members reviewed and confirmed the data and interpretations, which helped ensure our findings' accuracy. Following initial coding and analysis based on their lived experiences, they provided their insights and perspectives. Finally, they co-authored, reviewed, and offered feedback on this paper.

Future research in this field could examine the experiences of adolescents and young adults with IBD in various cultural and socioeconomic contexts. This would allow for a more complete understanding of the transition process and different groups' unique challenges given research has shown that access to resources, cultural values, health literacy, family roles, faith, and stigma play important roles in the daily realities of individuals with IBD [31,37]. Qualitative research involving data collection with adolescents and young adults at multiple time points (eg, pretransfer, during the transition, or posttransfer) could offer unique insights into how their care needs and priorities evolve to support the development of tailored interventions. Finally, the development and evaluation of resources targeting caregivers and parents of adolescents and young adults with IBD could be considered, given their critical roles in mentoring and coaching adolescents and young adults during transition.

Conclusions

Incorporating qualitative data within the RCT enabled a multifaceted exploration of the acceptability of a biopsychosocial transition intervention through different sources of information to support the translation of findings into practice. Our findings provide important insights into the needs and experiences of adolescents and young adults with IBD during the transition, including the criticality of considering individual, family, and system-level factors when implementing clinical interventions for this population. These results will contribute to developing youth-friendly resources and possibly refining the biopsychosocial transition intervention before scale and spread.

Acknowledgments

The authors thank the adolescents and young adults who participated in this study and the Crohn's and Colitis Canada Youth Advisory Panel (including but not limited to Gary Gill, PM, Diana Marcovici, CP, and TS) for their valuable contributions to this research. The authors are grateful to the following people for help with the design and conceptualization of this study: Usha Chauhan, Sneha Dave, Marla Dubinsky, Johanna Escher, Thea Ewert, Karen Frost, Daniel Green, Jennifer Jones, Lydia Knorr, Dominique Levesque, Meranda Nakhla, Susan Samuel, and Alene Toulany. The authors also acknowledge the contribution of the External Advisory Committee for this project: Dan Turner, Marla Dubinsky, Johanna Escher, John Marshall, Meranda Nakhla, Geoffrey Nguyen, Susan Samuel, Alene Toulany, and Daniel Green. This study was supported by a grant from the Leona M. and Harry B. Helmsley Charitable Trust and Crohn's and Colitis Canada. This study was also supported by The Canadian Children IBD Network (with funding provided by the CH.I.L.D. Foundation). The funding sources did not support this study's design,

XSL•FO
RenderX

collection, data analysis and interpretation, paper preparation, or the decision to submit this paper for publication. DRM is partly supported by a Distinguished Clinical Chair in Pediatric IBD through the Faculty of Medicine, University of Ottawa. EIB holds the Northbridge Financial Corporation Chair in Inflammatory Bowel Disease, a joint Hospital-University Chair between the University of Toronto, The Hospital for Sick Children, and the SickKids Foundation.

Conflicts of Interest

LK is an equity owner and scientific advisor to Trellus Health, and a consultant to Pfizer and Coprata Health. EIB has acted as a consultant for McKesson Canada and the Dairy Farmers of Ontario for matters unrelated to medications used to treat inflammatory bowel disease. He has also acted as a consultant for the Canadian Drug Agency. SAK is a colicense owner of the iPeer2Peer Program. SL is a speaker or consultant for Abbvie, Janssen, Takeda, and Celltrion. KIK has received honoraria from Abbvie, Janssen, Celltrion, Pfizer, Takeda, and has acted as a consultant for the CADTH. KL has consulted for AbbVie Corp, Janssen, and Takeda.

References

1. Gray WN, Resmini AR, Baker KD, et al. Concerns, barriers, and recommendations to improve transition from pediatric to adult IBD care: perspectives of patients, parents, and health professionals. Inflamm Bowel Dis 2015 Jul;21(7):1641-1651. [doi: 10.1097/MIB.0000000000000419] [Medline: 25966837]
2. Kohut SA, Keefer L. Building a self-management toolkit for patients with pediatric inflammatory bowel disease: introducing the resilience 5. Gastroenterol Clin North Am 2023 Sep;52(3):599-608. [doi: 10.1016/j.gtc.2023.05.005] [Medline: 37543403]
3. Foster A, Chan JM, Wine E, et al. Transition readiness in youth with inflammatory bowel disease. J Pediatr 2023 Jul;258:113403. [doi: 10.1016/j.jpeds.2023.113403] [Medline: 37019332]
4. Abraham BP, Kahn SA. Transition of care in inflammatory bowel disease. Gastroenterol Hepatol (N Y) 2014 Oct;10(10):633-640. [Medline: 27540335]
5. Fu N, Bollegala N, Jacobson K, et al. Canadian consensus statements on the transition of adolescents and young adults with inflammatory bowel disease from pediatric to adult care: a collaborative initiative between the Canadian IBD Transition Network and Crohn's and Colitis Canada. J Can Assoc Gastroenterol 2022 Jun;5(3):105-115. [doi: 10.1093/jcag/gwab050] [Medline: 35669843]
6. Maddux MH, Drovetta M, Hasenkamp R, et al. Using a mixed-method approach to develop a transition program for young adults with inflammatory bowel disease. J Pediatr Gastroenterol Nutr 2020 Feb;70(2):195-199. [doi: 10.1097/MPG.0000000000002478] [Medline: 31978016]
7. Zhao X, Bjerre LM, Nguyen GC, et al. Health services use during transition from pediatric to adult care for inflammatory bowel disease: a population-based study using health administrative data. J Pediatr 2018 Dec;203:280-287. [doi: 10.1016/j.jpeds.2018.08.021] [Medline: 30266506]
8. Greenley RN, Hommel KA, Nebel J, et al. A meta-analytic review of the psychosocial adjustment of youth with inflammatory bowel disease. J Pediatr Psychol 2010 Sep;35(8):857-869. [doi: 10.1093/jpepsy/jsp120] [Medline: 20123705]
9. Gray WN, Schaefer MR, Resmini-Rawlinson A, Wagoner ST. Barriers to transition from pediatric to adult care: a systematic review. J Pediatr Psychol 2018 Jun 1;43(5):488-502. [doi: 10.1093/jpepsy/jsx142] [Medline: 29190360]
10. Cole R, Ashok D, Razack A, Azaz A, Sebastian S. Evaluation of outcomes in adolescent inflammatory bowel disease patients following transfer from pediatric to adult health care services: case for transition. J Adolesc Health 2015 Aug;57(2):212-217. [doi: 10.1016/j.jadohealth.2015.04.012] [Medline: 26206442]
11. Goodhand J, Dawson R, Hefferon M, et al. Inflammatory bowel disease in young people: the case for transitional clinics. Inflamm Bowel Dis 2010 Jun;16(6):947-952. [doi: 10.1002/ibd.21145] [Medline: 19834978]
12. Karve S, Candrilli S, Kappelman MD, Tolleson-Rinehart S, Tennis P, Andrews E. Healthcare utilization and comorbidity burden among children and young adults in the United States with systemic lupus erythematosus or inflammatory bowel disease. J Pediatr 2012 Oct;161(4):662-670. [doi: 10.1016/j.jpeds.2012.03.045] [Medline: 22578787]
13. Goodhand J, Hedin CR, Croft NM, Lindsay JO. Adolescents with IBD: the importance of structured transition care. J Crohns Colitis 2011 Dec;5(6):509-519. [doi: 10.1016/j.crohns.2011.03.015] [Medline: 22115368]
14. Chan P, McNamara J, Vernon-Roberts A, et al. Systematic review: practices and programs in inflammatory bowel disease transition care. Inflamm Bowel Dis 2024 Aug 28:izae190. [doi: 10.1093/ibd/izae190] [Medline: 39197100]
15. Marani H, Fujioka J, Tabatabavakili S, Bollegala N. Systematic narrative review of pediatric-to-adult care transition models for youth with pediatric-onset chronic conditions. Child Youth Serv Rev 2020 Nov;118:105415. [doi: 10.1016/j.childyouth.2020.105415]
16. Bollegala N, Barwick M, Fu N, et al. Multimodal intervention to improve the transition of patients with inflammatory bowel disease from pediatric to adult care: protocol for a randomized controlled trial. BMC Gastroenterol 2022 May 18;22(1):251. [doi: 10.1186/s12876-022-02307-9] [Medline: 35585484]
17. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. Implementation Sci 2012 Dec;7(1):50. [doi: 10.1186/1748-5908-7-50]

XSL•FO
RenderX

18. Strategy for patient-oriented research: patient engagement framework. Canadian Institutes of Health Research. 2019. URL: http://www.cihr-irsc.gc.ca/e/48413.html [accessed 2025-03-22]
19. Sandelowski M. Whatever happened to qualitative description? Res Nurs Health 2000 Aug;23(4):334-340. [doi: 10.1002/1098-240x(200008)23:4<334::aid-nur9>3.0.co;2-g] [Medline: 10940958]
20. Allemang B, Browne M, Barwick M, et al. Mental health experiences of adolescents and young adults with inflammatory bowel disease during transition to adult care: a qualitative descriptive study. J Pediatr 2024 Oct;273:114123. [doi: 10.1016/j.jpeds.2024.114123] [Medline: 38815748]
21. Etikan I, Musa SA, Alkassim RS. Comparison of convenience sampling and purposive sampling. AJTAS 2016;5(1):1. [doi: 10.11648/j.ajtas.20160501.11]
22. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: guided by information power. Qual Health Res 2016 Nov;26(13):1753-1760. [doi: 10.1177/1049732315617444] [Medline: 26613970]
23. Braun V, Clarke V. Thematic Analysis: A Practical Guide: Sage Publications; 2021.
24. Braun V, Clarke V. Reflecting on reflexive thematic analysis. Qual Res Sport Exerc Health 2019 Aug 8;11(4):589-597. [doi: 10.1080/2159676X.2019.1628806]
25. Hislop J, Mason H, Parr JR, Vale L, Colver A. Views of young people with chronic conditions on transition from pediatric to adult health services. J Adolesc Health 2016 Sep;59(3):345-353. [doi: 10.1016/j.jadohealth.2016.04.004] [Medline: 27287962]
26. Padley N, Moubayed D, Lanteigne A, et al. Transition from paediatric to adult health services: aspirations and practices of human flourishing. Int J Qual Stud Health Well-being 2023 Dec;18(1):2278904. [doi: 10.1080/17482631.2023.2278904] [Medline: 37994797]
27. VanderWeele TJ. On the promotion of human flourishing. Proc Natl Acad Sci USA 2017 Aug;114(31):8148-8156. [doi: 10.1073/pnas.1702996114]
28. Costain G, Cohn RD, Malkin D. Precision child health: an emerging paradigm for paediatric quality and safety. Curr Treat Options Pediatr 2020;6(4):317-324. [doi: 10.1007/s40746-020-00207-2] [Medline: 38624480]
29. Charles S, Mackie AS, Rogers LG, et al. A typology of transition readiness for adolescents with congenital heart disease in preparation for transfer from pediatric to adult care. J Pediatr Nurs 2021;60:267-274. [doi: 10.1016/j.pedn.2021.07.016] [Medline: 34352719]
30. Oyesanya TO, Ibemere SO, Loflin C, et al. "If you respect me, you are respecting my culture": methods and recommendations for personalizing a TBI transitional care intervention. Brain Inj 2023 Jul 3;37(8):746-757. [doi: 10.1080/02699052.2023.2208881] [Medline: 37144496]
31. Chedid V, Targownik L, Damas OM, Balzora S. Culturally sensitive and inclusive IBD care. Clin Gastroenterol Hepatol 2025 Feb;23(3):440-453. [doi: 10.1016/j.cgh.2024.06.052] [Medline: 39321949]
32. Allemang B, Allan K, Johnson C, et al. Impact of a transition program with navigator on loss to follow-up, medication adherence, and appointment attendance in hemoglobinopathies. Pediatr Blood Cancer 2019 Aug;66(8):e27781. [doi: 10.1002/pbc.27781] [Medline: 31045326]
33. Manwani D, Doyle MH, Davidson L, et al. Transition navigator intervention improves transition readiness to adult care for youth with sickle cell disease. Acad Pediatr 2022 Apr;22(3):422-430. [doi: 10.1016/j.acap.2021.08.005] [Medline: 34389516]
34. Betz CL, O'Kane LS, Nehring WM, Lobo ML. Systematic review: health care transition practice service models. Nurs Outlook 2016;64(3):229-243. [doi: 10.1016/j.outlook.2015.12.011] [Medline: 26992949]
35. Gabriel P, McManus M, Rogers K, White P. Outcome evidence for structured pediatric to adult health care transition interventions: a systematic review. J Pediatr 2017 Sep;188:263-269. [doi: 10.1016/j.jpeds.2017.05.066] [Medline: 28668449]
36. Poliani A, Gnecchi S, Villa G, Rosa D, Manara DF. Gamification as an educational approach for oncological patients: a systematic scoping review. Healthcare (Basel) 2023 Dec 7;11(24):3116. [doi: 10.3390/healthcare11243116] [Medline: 38132006]
37. Mukherjee S, Beresford B, Atkin K, Sebastian S. The need for culturally competent care within gastroenterology services: evidence from research with adults of South Asian origin living with inflammatory bowel disease. J Crohns Colitis 2021 Jan 13;15(1):14-23. [doi: 10.1093/ecco-jcc/jjaa117] [Medline: 32577761]

Abbreviations:

C: control arm participant
I: intervention arm participant
IBD: inflammatory bowel disease
RCT: randomized controlled trial
YAP: Youth Advisory Panel

XSL•FO
RenderX

Edited by A Rossi; submitted 26.07.24; peer-reviewed by J Soldera, Z Lawal; revised version received 20.12.24; accepted 15.02.25; published 02.04.25.

Please cite as:
Allemang B, Miatello A, Browne M, Barwick M, Maini P, Eszczuk J, Pandit C, Sadhra T, Forhan L, Bollegala N, Fu N, Lee K, Dekker E, Nistor I, Ahola Kohut S, Keefer L, Griffiths AM, Walters TD, Micsinszki S, Mack DR, Lawrence S, Kroeker KI, de Guzman J, Tausif A, Tersigni C, Anthony SJ, Benchimol EI
Perspectives of Adolescents and Young Adults With Inflammatory Bowel Disease on a Biopsychosocial Transition Intervention: Qualitative Interview Study
JMIR Pediatr Parent 2025;8:e64618
URL: https://pediatrics.jmir.org/2025/1/e64618
doi:10.2196/64618

© Brooke Allemang, Ashleigh Miatello, Mira Browne, Melanie Barwick, Pranshu Maini, Joshua Eszczuk, Chetan Pandit, Tandeep Sadhra, Laura Forhan, Natasha Bollegala, Nancy Fu, Kate Lee, Emily Dekker, Irina Nistor, Sara Ahola Kohut, Laurie Keefer, Anne Marie Griffiths, Thomas D Walters, Samantha Micsinszki, David R Mack, Sally Lawrence, Karen I Kroeker, Jacqueline de Guzman, Aalia Tausif, Claudia Tersigni, Samantha J Anthony, Eric I Benchimol. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 2.4.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Perspectives on Swedish Regulations for Online Record Access Among Adolescents With Serious Health Issues and Their Parents: Mixed Methods Study

Josefin Hagström[1], MSc; Charlotte Blease[1,2], PhD; Arja Harila[3], MD, PhD; Päivi Lähteenmäki[4,5], MD, PhD; Isabella Scandurra[6†], PhD; Maria Hägglund[1,7], PhD

[1]Participatory eHealth and Health Data Research Group, Department of Women's and Children's Health, Uppsala University, Uppsala, Sweden
[2]Digital Psychiatry, Department of Psychiatry, Beth Israel Deaconess Medical Center, Boston, United States
[3]Pediatric Oncology, Department of Women's and Children's Health, Uppsala University, Uppsala, Sweden
[4]Department of Pediatrics and Adolescent Medicine, Turku University, Turku University Hospital, Turku, Finland
[5]Pediatric Oncology and Pediatric Surgery, Department of Women's and Children's Health, Karolinska Institute, Stockholm, Sweden
[6]Informatics, School of Business, Örebro University, Örebro, Sweden
[7]MedTech Science & Innovation Centre, Uppsala University Hospital, Uppsala, Sweden
[†]deceased

Corresponding Author:
Josefin Hagström, MSc
Participatory eHealth and Health Data Research Group
Department of Women's and Children's Health
Uppsala University
Dag Hammarskjölds väg 14B
Uppsala, 752 37
Sweden
Phone: 46 734697474
Email: josefin.hagstrom@uu.se

Abstract

Background: With the increasing implementation of patient online record access (ORA), various approaches to access to minors' electronic health records have been adopted globally. In Sweden, the current regulatory framework restricts ORA for minors and their guardians when the minor is aged between 13 and 15 years. Families of adolescents with complex health care needs often desire health information to manage their child's care and involve them in their care. However, the perspectives of adolescents with serious health issues and their parents have not been studied.

Objective: This study aims to qualitatively and quantitatively investigate the perceived benefits and risks of ORA and the awareness of and views on ORA regulations among adolescents with serious health issues and their parents in Sweden.

Methods: We used a convergent mixed methods (qualitative and quantitative) design, consisting of a survey and semistructured individual interviews with adolescents with serious health issues (aged 13-18 y) and their parents. Participants were recruited via social media and in clinics. Quantitative data were presented descriptively. Interviews were audio recorded, transcribed, and analyzed using inductive thematic content analysis.

Results: The survey population included 88 individuals (adolescents: n=31, 35%; parents: n=57, 65%). Interviews were completed by 8 (26%) of the 31 adolescents and 17 (30%) of the 57 parents. The mean age of the surveyed adolescents was 16 (SD 1.458) years, and most of the parents (29/57, 51%) were aged 45 to 54 years. The surveys indicated that most of the parents (51/56, 91%) were critical of the access gap, and most of the adolescents (20/31, 65%) were unaware of the age at which they could gain access. In the interviews, adolescents and parents identified benefits related to ORA that were categorized into 6 themes (*empowering adolescents*, *improved emotional state*, *enhanced documentation accuracy*, *improved partnership and communication*, *supported parental care management*, and *better prepared for appointments*) and risks related to ORA that were categorized into 4 themes (*emotional distress and confusion*, *threatened confidentiality*, *increased burden*, and *low usability*). Adolescents' and parents' views on ORA regulations were categorized into 3 themes (*challenges of the access gap*, *balancing respect for autonomy and support*, and *suggested regulatory change*).

XSL•FO
RenderX

Conclusions: In Sweden, ORA regulations and a lack of available information cause significant inconvenience for adolescents with serious health issues and their parents. Views on access age limits differed, with adolescents expressing their perceived need for independent access, while parents exhibited concerns about adolescents having ORA. The findings indicated the importance of increased education, dialogue, and flexibility to uphold confidential and consistent delivery of adolescent health care. Further exploration is needed to understand the experiences of adolescents and parents in diverse clinical and geographic contexts, as well as the perspectives of pediatric health care professionals on restrictive ORA regulations.

(JMIR Pediatr Parent 2025;8:e63270) doi:10.2196/63270

KEYWORDS

health care professionals; adolescent health; patient-accessible electronic health record; electronic health record; patient portal; survey; eHealth; interviews

Introduction

Background

Worldwide, online record access (ORA) enables more patients and caregivers to read their health records via patient portals. Electronic health records (EHRs) often include clinical notes, laboratory test results, and medications. In the United States, the practice of sharing clinical notes with patients is referred to as "open notes" [1]. In the European Union, individuals have a right to access their health information in registries such as EHRs, under the General Data Protection Regulation. A proposed European Health Data Space will provide patients with access to their EHRs throughout Europe. A growing body of research [2] indicates that ORA benefits for adolescents and parents are similar to those for adults (eg, better recall, increased treatment adherence, and an increased sense of control [1,3,4]). Unique benefits for adolescents and parents may also include increased autonomy [5] and a supported transition from adolescent to adult health care [6,7].

Despite potential benefits, access to pediatric records is often restricted due to concerns about confidentiality, particularly during adolescence. While most young children benefit from parental proxy access, adolescents may be deterred from seeking help for sensitive health care issues if parental monitoring remains possible, leading to potential ethical concerns and a need to protect the developing autonomy of the young person [8]. As a result, 1 policy response has been to limit adolescents' and parents' access when the child becomes an adolescent. However, the implementation of patient-accessible EHRs (PAEHRs) for parents and adolescents differs globally [9-11]. A variety of access control practices attempting to balance parents' and adolescents' needs have been adopted, with approaches either based on set access limits or case-by-case assessment.

Sweden has an advanced ORA system, facilitated through the national PAEHR 1177 Journal. A regulatory framework implemented in 2017 grants parents default access to their child's PAEHR from birth until the child turns 13 years of age, after which the adolescent gains their own access at the age of 16 years. Parents' loss of access to their child's PAEHR when the child turns 13 years of age was due to concerns that teens may refrain from seeking care for sensitive issues, such as birth control, sexual health, or mental health, if they know that their parents have access to their records. In the first regulatory framework, adolescents themselves gained access to their records only at the age of 18 years, but this age limit was later lowered to 16 years, based on the argument that most teenagers are mature enough to make informed decisions about their health at this age. More than half (50.5%) of adolescents access their records from the age of 16 years [12]. The "access gap," when the child is aged between 13 and 15 years, a period during which neither the child nor the parent has access, has been criticized for hindering active participation and engagement in health care, especially by parents of children with serious illness [13,14]. There is an option for both guardians and minors to apply for extended access under special circumstances (such as chronic illness) when the child is aged between 13 and 15 years. The application process involves filling out and submitting a specific paper form to the health care provider, followed by a maturity assessment and approval by the health care provider's operations manager. To approve the application, health care professionals (HCPs) assess needs and risks, as well as the minor's level of maturity and wishes. The process must be repeated for each clinic where the minor is receiving care. However, few applications for extended access from either adolescents or parents have been observed [12]. Thus, although the restrictive policies are intended to ensure safety, their consequences for adolescents with serious health issues and their parent caregivers may be dire and have not been studied.

Several topic experts have noted the unique need for ORA among families where adolescents are undergoing treatment or have extensive contact with health care systems [15,16]. In previous research in Sweden, we found that adolescents with lower self-reported health may have less interest in being able to control who can access their records and to conceal information from relatives [17]. Indeed, many adolescents depend on their parents for health care management [6]. In addition, in an interview study, adolescents aged 13 to 17 years with cancer and blood disorders report that, after reading their records, they are better able to prepare for clinical consultations and are able to check accuracy; moreover, examining their test results makes it easier to talk to HCPs [7]. Parents of children who are critically ill report similar benefits: the ability to check accuracy [18], better understanding [18], improved recall of information [19,20], reduced anxiety [21], and an increased sense of control [21]. They also reported that ORA makes them better able to advocate for their child [18].

Parents offer complex home-based health care and provide emotional support in advocating for their child. Rather than communicating directly with HCPs, adolescents often prefer

XSL•FO
RenderX

asking questions via their parents [6,7]. Furthermore, a framework developed by Ford et al [22] described how partnerships between adolescents, parents, and HCPs can improve the adolescent's health, stating that, for example, adolescents are more likely to seek support from their parents if they are well informed.

Study Aim

Views on policies regarding adolescents' and parents' ORA access are underresearched. Increasing our knowledge about adolescents who are ill and parents in caregiving roles is vital to enable the design of informed policies and education for HCPs and patient portal users, with the long-term purpose of improving adolescent health. This study aimed to investigate, both qualitatively and quantitatively, adolescents' and parents' views on the perceived benefits and risks of using the PAEHR, as well as their perspectives on the national ORA regulatory framework in Sweden. Our research questions (RQs) were as follows:

- RQ1: What benefits and risks do adolescents and parents perceive regarding access to adolescents' health records for both adolescents and parents?
- RQ2: What are adolescents' and parents' views on and awareness of the ORA regulations governing access to adolescents' health records?

Methods

Ethical Considerations

This study received ethics approval from the Regional Ethical Review Board in Uppsala, Sweden (EPN 2022/02160). Survey participants provided consent digitally, while participants recruited in the clinic provided consent in paper format. No financial incentive was offered to survey participants; however, interview participants received a gift card worth 200 SEK (approximately US $18). Data were deidentified.

Study Design

Data collection occurred from March 2022 to November 2023, after ethics approval was received. A convergent mixed methods (qualitative and quantitative) approach was adopted [23,24]. Mixed methods can be defined as the "concurrent collection of both quantitative and qualitative data" where data are integrated in the analysis [23]. The purpose of combining methods was to provide a breadth of data on an understudied topic, with interviews designed to facilitate a deeper understanding of the reasons underlying the quantitative results. The qualitative component is reported in accordance with the COREQ (Consolidated Criteria for Reporting Qualitative Research) [25] guidelines (Multimedia Appendix 1).

Participants and Setting

We recruited adolescents aged 13 to 18 years with serious health issues and parents of adolescents aged ≥13 years with serious health issues with experience in accessing their child's EHR, either having lost access or gained extended access. In this context, serious health issues refer to physical or mental health conditions that significantly affect an adolescent's well-being and require ongoing care or intervention. Study participants were recruited via social media advertisements by patient organizations and through collaboration with Uppsala University Hospital and other clinical partners (eg, during appointments, by sending surveys via mail to former patients, and by posting study information in waiting rooms). Although citizens gain access to the 1177 Journal at the age of 16 years, adolescents aged ≥13 years were eligible to participate because they can apply for early access, and the study aimed to explore views on ORA regulations. Both parents of a child were able to participate.

The national regulatory framework for patients' ORA was designed by Inera AB, the company managing the 1177 patient portal that houses the PAEHR 1177 Journal, and approved by the Swedish Association of Local Authorities and Regions. The record typically includes clinical notes, test results, and diagnoses, but information availability differs across Sweden's 21 regions and affiliated HCPs (those who have agreed to provide access). No data are concealed from parental view unless an HCP actively chooses to block information access, which can occur in cases where, for example, child abuse is suspected.

Data Collection

Survey

Two survey instruments were designed: one for adolescents and one for parents (refer to Multimedia Appendix 2 for the full surveys and Swedish translations). For this study, 9 (69%) of 13 questions were included from the adolescent survey and 13 (93%) of 14 questions from the parent survey, based on the study aim (Textbox 1). Parents' awareness of ORA was not examined. The value of including patients in research has been noted previously [26,27]. Therefore, adolescents and parents were consulted for input, which was used to revise the surveys. Questions were not mandatory, except for those on inclusion criteria and contact information (in case the participant marked interest in participating in an interview). In Sweden, study participants aged <15 years must provide written parental consent, as mandated by the Swedish Act (2003:460) concerning the ethical review of research involving humans [28]. Therefore, age was a mandatory question for adolescents, along with the provision of written parental consent for those aged 13 or 14 years. In the web-based survey, adolescents could provide parental consent digitally. For participants aged ≥15 years, consent was provided by submitting the survey. The web-based survey was conducted using REDCap (Research Electronic Data Capture; Vanderbilt University) software.

XSL•FO
RenderX

Textbox 1. Survey questions for adolescents and parents.

ADOLESCENTS

Inclusion

1. How old are you?

a. How do you want to provide guardian consent? (if younger than 15 years old)

Experience with health care

2. What types of care have you received?

Views on and awareness of online record access (ORA)

3. At what age do you think you will have (or when you received) online access to your electronic health record (EHR)?

4. Do you want to be able to read your patient-accessible EHR?

5. To what extent do you agree with the following statements? (views on ORA age limits)

6. If you have thoughts or comments to add about the EHR, please write below.

Demographics

7. You identify as...? (gender)

8. Who do you live with? (select all that apply)

9. Would you participate in an interview about this?

a. E-mail

b. Phone number

c. How would you prefer to be contacted?

PARENTS

Inclusion

1. How old is the child for whom you base your answers?

2. Did you read your child's EHR online before your child turned 13?

Experience with health care

3. What types of care has your child received?

Views on ORA

4. To what extent do you agree with the following statements? (views on ORA age limits)

5. If you have thoughts or comments to add about the EHR, please write below.

Demographics

6. You identify as...? (gender)

7. How old are you?

8. Which region do you live in?

9. In what type of area do you live?

10. What is your level of knowledge in Swedish?

11. What is your highest completed education?

12. Approximately how much is your household income before tax in a normal month?

13. Would you participate in an interview about this?

a. E-mail

b. Phone number

c. How would you prefer to be contacted?

XSL•FO
RenderX

Interviews

The first author (JH, a PhD student in health informatics with past experience of qualitative research and training) conducted the interviews with participants who registered their interest in the survey. Verbal consent for audio recording was provided before the interview. Interviews were conducted between February 2022 and November 2023 via telephone or videoconferencing software. Interview guides were created based on prior work on ORA for adolescents, children, and parents (Multimedia Appendix 3) and included similar themes as the surveys. At the start of each interview, JH introduced herself and the reasons for conducting the research. JH had no prior relationship with any of the study participants.

Data Analysis

Descriptive statistics were used to present quantitative survey data. Of the 25 interviews, 18 (72%) were transcribed by a professional company and 7 (28%) by JH. Interview analysis was conducted by JH and MH using NVivo (release 1.7.2; Lumivero). MH is a researcher in health informatics with experience of leading and conducting qualitative research. As views on ORA regulations were previously unexplored, we analyzed the interview data using thematic content analysis [29] with an inductive approach. First, JH read all transcripts to develop an understanding of participants' responses. Next, the data were categorized into codes that were grouped into categories and themes. Definitions were refined further through discussions during meetings. Discussions of the findings among all authors improved credibility. Analysis of perceived benefits and risks was inspired by previous work [7,30].

Results

Participant Demographic Characteristics

In total, 31 (74%) of 42 adolescents and 57 (81%) of 70 parents completed the survey and were included in the study. While most of the participants identified as woman in both groups, the proportion was larger among parents (47/57, 83%) than among adolescents (15/31, 48%; Table 1). Regarding gender, of the 31 adolescents, 3 (10%) selected *other* or did not want to state their gender. Of the 31 adolescents, 1 (3%) had recently turned 19 years of age.

Table 1. Survey and interview participants' demographic characteristics (n=88).

Characteristics	Adolescents (n=31)		Parents (n=57)	
	Interviewed (n=8), n (%)	Not interviewed (n=23), n (%)	Interviewed (n=17), n (%)	Not interviewed (n=40), n (%)
Gender				
Man	4 (50)	9 (39)	3 (18)	6 (15)
Woman	4 (50)	11 (48)	13 (76)	34 (85)
Other	0 (0)	1 (4)	0 (0)	0 (0)
Don't know or don't want to state	0 (0)	2 (9)	0 (0)	0 (0)
Missing	0 (0)	0 (0)	1 (6)	0 (0)
Child age (y)				
13	1 (13)	1 (4)	1 (6)	17 (42)
14	0 (0)	0 (0)	3 (18)	9 (22)
15	2 (25)	4 (17)	5 (29)	5 (12)
16	1 (13)	4 (17)	0 (0)	2 (5)
17	0 (0)	10 (44)	8 (47)	5 (12)
18	3 (38)	4 (17)	0 (0)	1 (2)
19-25	1 (13)	0 (0)	0 (0)	1 (2)
Child's diagnosis[a]				
Juvenile arthritis	2 (25)	7 (30)	4 (24)	17 (42)
Cancer	2 (25)	9 (39)	9 (53)	10 (25)
Gastrointestinal diseases (eg, irritable bowel syndrome)	2 (25)	3 (13)	0 (0)	5 (12)
Mental health issues	1 (13)	3 (13)	1 (6)	4 (10)
Diabetes	0 (0)	2 (9)	1 (6)	3 (7)
Other	3 (38)	1 (4)	3 (18)	8 (20)

[a]Participants could select all that applied; therefore, the total can exceed 100%.

XSL•FO
RenderX

Of the 31 adolescents and 57 parents who responded to the survey, 11 (36%) adolescents and 28 (49%) parents agreed to participate in an individual interview. Ultimately, of those agreeing to take part in an interview, 8 (73%) of the 11 adolescents and 17 (61%) of the 28 parents completed an interview, while 3 (27%) adolescents and 11 (39%) parents did not participate in an interview despite registering interest in the survey due to scheduling difficulties or a lack of response. Interviews lasted for a mean of 28 (range 13-40) minutes for adolescents and a mean of 42 (range 21-70) minutes for parents. Of the 17 parents, 5 (29%) reported having a medical profession. Notably, 2 (12%) of the 17 interviewees were parents of the same child, and none was a parent of a participating adolescent. All participants reported having moderate or higher levels of digital literacy.

As shown in Table 2, of the 8 adolescents, 2 (25%; aged 13 and 15 years) preferred parental ORA, whereas the remaining adolescents (n=6, 75%; aged 15 to 19 years) wanted their own access and either did not want or were indifferent to parental access, perceiving no need for it but expressing no privacy concerns. Almost all parents (16/17, 94%) desired longer access than current regulations allow (Table 3). The exception was a parent whose access was lost when their child was diagnosed with a serious health issue after the age of 13 years. Most of the parents (10/17, 59%) did not have access to their child's EHR; 2 (20%) of these 10 parents reported accessing it via the child logging in on their behalf. Additional demographic characteristics can be found in Multimedia Appendix 4.

Table 2. Adolescent participants' characteristics as reported in the interviews (n=8).

ID	Age (y)	Gender[a]	Interview setting	Child's diagnosis (age at diagnosis [y])	Current ORA[b] preference				Current ORA situation
					Adolescent	Start age (y)	Parent	End age (y)	
A27	19	Female	Telephone	Juvenile arthritis (14)	Yes, in favor	14[c]-15[c]	Okay but no need	13	Access by default
A14	18	Female	Telephone	Inflammatory bowel disease (17)	Yes, in favor	16-17[d]	No, opposed	16[c]-18[c]	Access by default
A26	18	Male	Video	Inflammatory bowel disease (14)	Yes, in favor	13[c]-14[c]	No, opposed	13	Access by default
A19	18	Female	Telephone	Juvenile arthritis (1.5)	Yes, in favor	15[c]	Okay, but no need	15[c]	Access by default
A10	16	Male	Video	Cancer (7)	Yes, in favor	13[c]	Okay, but no need	18[c]	Access by default
A29	15	Female	Video	Asthma and allergies (0), mental health (13)	Yes, in favor	12[c]-13[c]	No, opposed	12[d]-13	No access by default
A23	15	Male	Telephone	Neurological disease (5)	No need	16	Yes, in favor	16[c]	No access by default
A4	13	Male	Telephone	Cancer (2)	No need	15[c]-16	Yes, in favor	15[c]	No access by default

[a]On the basis of survey responses.

[b]ORA: online record access.

[c]Less restrictive than current regulations.

[d]More restrictive than current regulations.

XSL•FO
RenderX

Table 3. Parent participant characteristics as reported in the interviews (n=17).

ID	Age (y)	Gender[a]	Interview setting	Child's diagnosis (age at diagnosis [y])	Adolescent age (y)	Current ORA[b] preference				Current ORA situation
						Adolescent	Start age (y)	Parent	End age (y)	
P22	48	Female	Video	Cancer (13)	14	No, opposed	16	Yes, in favor	+[c]	Gained extended access
P48	50	Male	Video	Juvenile arthritis (10)	15	No, opposed	?[d]	Yes, in favor	+[c]	Gained extended access
P52	37	Female	Video	Skin disease (0)	15	Okay, but no need	13[c]	Yes, in favor	16[c] or 18[c]	Gained extended access
P8	44	Female	Video	Cancer (7)	14	Okay, but no need	15[c]	Yes, in favor	+[c]	Gained partial extended access
P15	55	Female	Video	Cancer (17)	17	Okay, but no need	18[e]	Yes, in favor	18[c]	Access to the child's EHR[f] via the child's account (with assent)
P31	48	Female	Telephone	Bone marrow disease (5)	17	Okay, but no need	16	Yes, in favor	+[c]	Access to the child's EHR via the child's account (with assent)
P1	41	Female	Video	Cancer (11)	14	Yes, in favor	14[c]-15[c]	Yes, in favor	14[c]-15[c]	Applied for but not gained extended access
P2	49	Female	Video	Cancer (4)	13	No need	16	Yes, in favor	16[c]	Applied for but not gained extended access
P54	52	Female	Video	Juvenile arthritis (3)	17	Okay, but no need	16	Yes, in favor	18[c]	Applied for but not gained extended access
P47	47	Female	Video	Juvenile arthritis (10)	15	Okay, but no need	16	Yes, in favor	+[c]	Extended access expired
P5	57	Male	Video	Cancer (2)	17	Okay, but no need	16/18[e]	Yes, in favor	18[c]	No access, unaware of extended access
P9	49	Female	Video	Cancer (4)	17	Okay, but no need	16	Yes, in favor	18[c]	No access, unaware of extended access
P12	52	Female	Telephone	Cancer (4)	17	Okay, but no need	16	Yes, in favor	?[d]	No access, unaware of extended access
P26	45	Female	Telephone	Dental surgery and orthopedic issues (7)	17	Yes, in favor	16-18[e]	No need	+[c]	No access, unaware of extended access
P38	47	Female	Video	Juvenile arthritis (10)	14	Yes, in favor	15[c]	Yes, in favor	18[c]	No access, unaware of extended access
P49	47	Female	Telephone	Juvenile arthritis (11)	15	Yes, in favor	16	Yes, in favor	16[c]	No access, unaware of extended access
P55	54	Male	Video	Diabetes (16)	17	Okay, but no need	16	No need	13	Aware of extended access

[a]On the basis of survey responses.

XSL•FO
RenderX

[b]ORA: online record access.

[c]Less restrictive than current regulations.

[d]Unable to specify.

[e]More restrictive than current regulations.

[f]EHR: electronic health record.

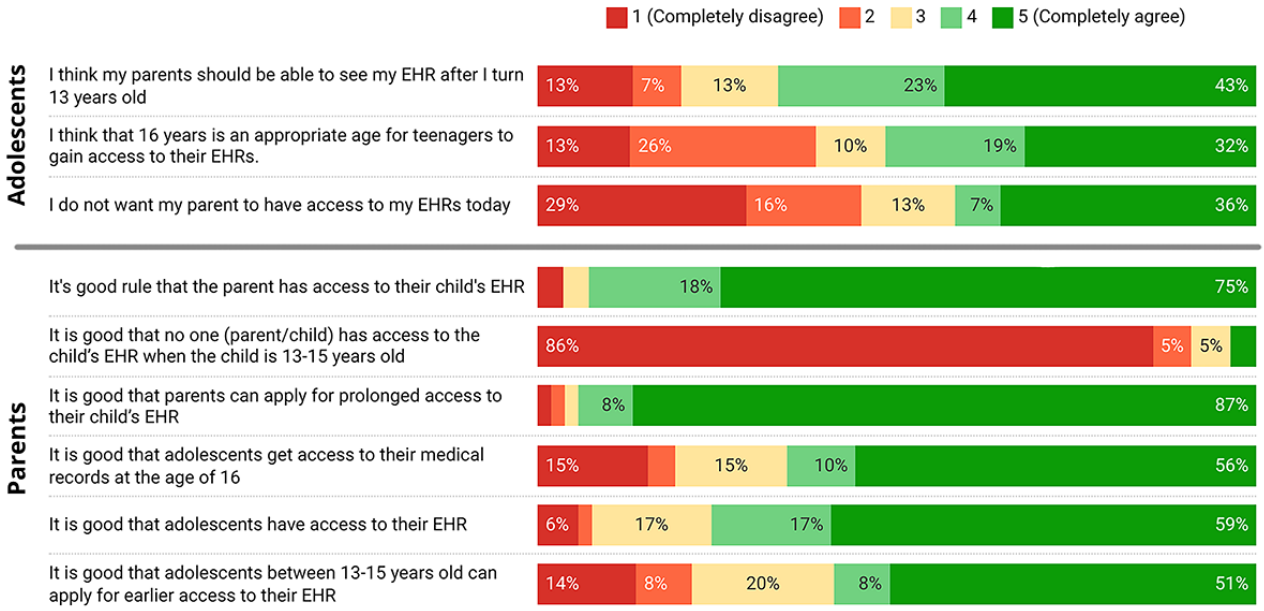
Quantitative Findings

Almost all adolescents (29/31, 94%) reported wanting access to their records. Low knowledge about the access age limit was observed: only a little more than a third (11/31, 36%) knew that the access age limit was 16 years of age, and almost as many (10/31, 32%) incorrectly guessed it to be 13 years of age. Of the respondents aged ≥16 years, 43% (10/23) claimed that they did not have current access to their records although this is the default.

Most of the adolescents (20/31, 65%) wanted their parents to be able to read their EHR after they had turned 13 years of age (Figure 1). A slight majority (16/31, 52%) agreed that 16 years of age is an appropriate age to gain access to one's health records. Most of the parents (51/55, 93%) were positive about parental ORA for children aged <13 years and negative about the gap in access from the ages of 13 to 15 years (51/56, 91%). Almost all parents (50/53, 94%) were positive about the option of applying for extended access for themselves, while more than half (30/51, 59%) were positive about adolescents applying for earlier access.

Most of the free-text comment data were reflected in the interviews. One parent responding to the survey noted that there should be a screening process for parents to access their children's records, while another referred to regulations regarding parents' rights to medication information as unclear, noting that the PAEHR is more restrictive than the information provided by pharmacies.

Figure 1. Adolescents' and parents' ratings for statements related to online record access and current regulations. EHR: electronic health record.



Qualitative Findings

Perceived Benefits of ORA

Adolescents and parents reported 6 perceived benefits of ORA: *empowering adolescents, improved emotional state, enhanced documentation accuracy, improved partnership and communication, supported parental care management,* and *better prepared for appointments* (Textbox 2).

Empowering adolescents referred to ORA helping adolescents to gradually become more involved in their care (eg, by helping them to remember appointments, track their illness, and understand their illness history). Adolescents shared that reading the notes from the beginning helped them gain a better understanding of what they had been through, providing information about events that they were too young to remember. Both adolescents and parents envisioned that this information would be helpful when meeting new HCPs. Parents were positive about their children being able to read the records "in the future," to understand their journey.

XSL•FO
RenderX

Textbox 2. Themes identified in the interviews of the perceived benefits of adolescent and parental online record access.

Empowering adolescents

- "It could be good to learn how to do things when you get older. When they might not be there." [A4, aged 13 years, diagnosed with cancer]
- "If you're 16, I believe you have the right to receive the same information that's actually written in the record." [P47, mother of child aged 15 years diagnosed with juvenile arthritis]

Improved emotional state

- "It's quite nice, well...if something happens, that I can go...I have security in that I can go back and read exactly everything, and even show that 'this is how it was.'" [A19, aged 18 years, diagnosed with juvenile arthritis]
- "As a mother I have felt that it is a security to be able to go back and read, 'what did they do now,' and it has felt good." [P15, mother of child aged 17 years diagnosed with cancer)

Enhanced documentation accuracy

- "We always have a discussion at health care meetings and such. But...they won't write down word for word what we have said...and sometimes there are misunderstandings, and then it's always good to be able to go back and check." [A26, aged 18 years, diagnosed with inflammatory bowel disease]
- "At several occasions, doctors have said, 'oh my god, how lucky you spotted that,' and such." [P22, mother of child aged 14 years diagnosed with cancer]

Improved partnership and communication

- "I have learned a lot through my parents sitting at home and reading, we have read the records together." [A23, aged 15 years, diagnosed with neurological disease]
- "[My boyfriend] has also been allowed to read a bit from the record...So that he can gain a better understanding." [A19, aged 18 years, diagnosed with juvenile arthritis]
- "You can sit together and reflect. Because otherwise it's somewhat difficult to just 'yeah, so now we're going to talk about this' and...then they want to go on some social media or something else like that. Maybe you can have a little focus on this." [P54, mother of child aged 17 years diagnosed with juvenile arthritis]
- "He clams up when doctors come to talk, then he won't speak, he won't say anything...It may be better if we talk together in advance, and he gets to ask us his questions, and we can ask the doctor." [P22, mother of child aged 14 years diagnosed with cancer]

Supported parental care management

- "You have to remember to schedule appointments and make sure to attend those appointments you've booked, so it's very, very much to manage logistically when you're sick, and it's quite nice to get help from parents when you're young." [A26, aged 18 years, diagnosed with inflammatory bowel disease)
- "It has been good to track it, because then you can also tell [the child] that 'you have to eat this vitamin because there is a deficit.' It's not as though I give her medication because it is fun." [P1, mother of child aged 14 years diagnosed with cancer]
- "Just last week, we had a situation where [my child] had got a specific medication and has been taking it, but then test results came and I saw that the levels regulated by this medication were sky high, so if we had continued taking the medication it might not have been so good. Then I could contact the physician to ask 'should we keep giving this medication or not?' And they say, 'no, don't do that.'" [P22, mother of child aged 14 years diagnosed with cancer]

Better prepared for appointments

- "I can tell [my child] that 'on Wednesday, we will see the physician, and we will talk about how to move forwards, and it might be that we will, blah blah blah,' whatever it is. And then he knows, so then when we meet the physician it won't be as dramatic." [P22, mother of child aged 14 years diagnosed with cancer]
- "We have a younger brother and live in the countryside, we have animals, and I may have to call my work and inform them I will be gone all week, so it facilitated a lot for everyone's well-being in the family that we could see for example test results on beforehand." [P52, mother of child aged 15 years diagnosed with skin disease]

Improved emotional state referred to an increased control and a sense of safety. Adolescents and parents reported that these feelings often related to having quick access to test results and being able to go back and read information. One adolescent (A26) described reading notes from childhood as fun and nostalgic. Parents reported feeling a sense of control due to increased knowledge about the illness and its terminology. Some parents stated that access to information reduced their anxiety and worry. One parent (P52) mentioned that because physicians did not always indicate that they had seen new test results, seeing that they had been active from checking the log list provided a sense of relief. Some adolescents described feeling safe when reading the EHR with their parents or merely knowing that their parents had access. One adolescent (A23) speculated that ORA provided parents with a feeling of safety, but parents

XSL•FO
RenderX

did not express this in relation to benefits of ORA for adolescents.

Enhanced documentation accuracy was reported as a benefit by both adolescents with ORA experience and parents; for example, it enabled them to ensure that HCPs had understood the information they shared during a consultation correctly and that there were no errors. Experiences of inaccuracies often involved HCPs misunderstanding details about symptoms, such as the degree of gravity or timing. One parent (P52) reported having once noted to an HCP that their child's records contained someone else's test results, apparent because the results were "too good." Another parent (P1) who had lost access to the EHR described a case involving their child where a referral had been sent for a sex change investigation because the HCP had misunderstood the adolescent's request to stop their period. The parent argued that if they had been able to review the EHR, they could have intervened earlier, preventing the adolescent's distress and avoiding unnecessary efforts.

Improved partnership and communication was reported as a benefit by both adolescents (with or without ORA experience) and parents. This referred to ORA enabling better communication among adolescents, parents, and HCPs in working together to manage the illness. Parents stated that ORA could help adolescents formulate questions beforehand, which the parents could then forward to HCPs. Many stated that parental ORA lessened the burden on the adolescent with health issues. The youngest adolescent (A4) expressed a substantial need for parental EHR access because they felt unable to manage everything alone. Older adolescents described that their perceived need for parental EHR access had decreased over time, partly because their ability to independently communicate with HCPs had increased. In addition, ORA facilitated reading the EHR together at home, allowing families to focus on the illness and providing an opportunity to ask questions in a safe environment, either in preparation for visits or as a way to debrief afterward.

Supported parental care management referred to ORA facilitating parents' provisioning of care in various ways; for example, both adolescents and parents reported that ORA facilitated parents' management of medications and appointments, improved recall of information, and enhanced parents' understanding of the child's health condition. Some parents stated that the EHRs contained more information than otherwise communicated, such as positive test results. Parents described that ORA facilitated dealing with insurance tasks and that access to test results enabled them to motivate the child to take their medications. Some parents noted that reading test results allowed them to anticipate being called to the hospital, enabling them to prepare their child mentally and emotionally in advance. Quick access to test results also enabled parents to speed up the care process and prevent unnecessary distress. One parent (P52) mentioned that test results revealed the child's actual condition, even when the adolescent claimed to feel well to avoid a hospital visit. The same parent stated that the only perceived benefit of their adolescent having ORA was that they could log in on their behalf.

Better prepared for appointments was reported as a benefit by both adolescents and parents, in that ORA facilitated the formulation of questions before appointments. Some parents described how ORA enabled preparations that were critical for their individual situation; for example, a parent (P52) living in the countryside could organize family life, animal care, and work in preparation for a hospital stay that might otherwise be sudden. Another parent (P22), whose adolescent had mild autism and struggled to process information during an appointment, described that ORA enabled her to use information from the EHR to prepare her child for what HCPs may bring up.

Perceived Risks of ORA

Participants identified 4 perceived risks of adolescent and parental ORA: *emotional distress and confusion*, *threatened confidentiality*, *increased burden*, and *low usability* (Textbox 3).

Emotional distress and confusion referred to the inability to understand information that was vague or written in clinical language, which could cause distress and lead to feelings of worry and frustration for both adolescents and parents. Confusion was also reported by an adolescent (A26) in relation to the unintuitive organization of information on the portal. Parents expressed concerns about adolescents reading concerning or negative test results while alone or learning about difficult medical events from their childhood, leading them to emphasize the importance (or necessity, for some) of having a parent present to answer questions and provide explanations. An adolescent aged 18 years diagnosed with juvenile arthritis (A26) recounted past experiences of feeling low after reading about traumatic experiences with health care in the EHR. Some adolescents and parents explained that their worry did not derive from accessing negative information in the record but from the progression of the illness itself. Two adolescents (A26 and A27) described that their close contact with HCPs reassured them that they would not receive bad news in the EHR without it being communicated in advance. Adolescents without experience of ORA did not anticipate emotional distress. While most desired an explanation from HCPs before receiving negative results, some reported prioritizing quick access to the information. Several parents recognized that other parents may worry; however, they themselves were not ones to worry.

XSL•FO
RenderX

Textbox 3. Themes identified in the interviews of the perceived risks of adolescent and parental online record access.

Emotional distress and confusion

- "It's those difficult words that one doesn't understand...And you don't really know what kind of test results you're getting back or what it means, so there's been quite a lot of Googling, consulting with mom all the time." [A10, aged 16 years, diagnosed with cancer]
- "One day it may pop up and boom, she has cancer everywhere and they can't do anything. And if you find out in her EHR. And the doctor hasn't called and explained anything. Then you get a little frustrated about it." [P2, mother of child aged 13 years diagnosed with cancer]
- "Some [parents] might say 'no, I won't read because it makes me more worried.' But in our case, I felt that nothing can... I'm already worried anyway, it's part of having a very sick child, so to speak." [P12, mother of child aged 17 years diagnosed with cancer]
- "If I read something and suddenly just feel like...oh my god, I got heart palpitations because I read something very negative or something. Then I think, for him to sit alone without anyone beside him and read this, no, I think that would just harm him, honestly. He's too young." [P22, mother of child aged 14 years diagnosed with cancer]
- "Even I, who work as a medical secretary, don't understand these terms either. I haven't worked in oncology. I don't understand everything either, so it's a bit poor of the doctors then perhaps also to dictate so that one doesn't...or the staff actually, to write and dictate so one doesn't understand." [P15, mother of child aged 17 years diagnosed with cancer]

Threatened confidentiality

- "If there's something I don't want them to know or something, they'll be able to see it or they'll be able to see all the notes that you might just...'They don't need to see this note.'" [A14, aged 18 years, diagnosed with inflammatory bowel disease]
- "If parents perhaps pressure one to log in, or something like that." [A29; aged 15 years; diagnosed with asthma, allergies, and mental health issues]
- "With honor-related violence, among other things, if you see that your child perhaps has a sexual activity and you don't believe it and so...yes, then it can get very bad...And also transgender care." [P54, mother of child aged 17 years diagnosed with juvenile arthritis]

Increased burden

- "[The teen] might have to bear too much responsibility." [P48, father of child aged 15 years diagnosed with juvenile arthritis]
- "I can understand that it could also lead to a greater workload for [HCPs], because I think that...Now, I might be a quite reasonable parent who also understands that one shouldn't reach out unnecessarily and so on. But I can imagine that there might be others who read things and maybe don't quite understand, and then they call." [P22, mother of child aged 14 years diagnosed with cancer]

Low usability

- "The website or app itself, or how one chooses to read the records, well...I can't say that it has a really great layout, and it's a bit difficult to know how everything is sorted and to find things." [A26, aged 18 years, diagnosed with inflammatory bowel disease]

Threatened confidentiality referred to the risk of sensitive information about the adolescent becoming visible to parents or others. While several adolescents mentioned that "the parent might see something one wants to hide," parents commonly specified potentially sensitive topics, such as mental or sexual health. One adolescent (A26) and many parents recognized that privacy may be a problem in families where parents seek to exercise control and may not focus on the child's best interest. Both adolescents and parents also recognized the risk that some parents might attempt to access their child's records via their account or pressure them to log in. Some adolescents and parents mentioned the risk of young adolescents sharing information with peers or on social media.

Increased burden referred to a burden placed on both adolescents and HCPs. Adolescents (only those who had not had access) and parents reported that granting adolescents access could lead to excessive responsibility for adolescents, who, especially when ill, wanted to be able to depend on their parents. Some parents imagined a burden on HCPs, such as adolescents sending numerous messages through the portal. Moreover, HCPs may feel compelled to omit sensitive information from the EHR, which would be detrimental to the child's future care. Some parents stated that patients' ORA is not a priority for HCPs, who understandably focus on providing care.

Low usability was reported as a downside or risk by an adolescent (A26), who found it challenging to locate and identify specific types of notes, such as diagnoses, clinical notes, or other documentation, due to unclear categorization and sorting. As a result, they spent more time searching for the desired information.

Views on ORA Regulations

Three themes were identified with regard to views on ORA regulations: *challenges of the access gap*, *balancing respect for autonomy and support*, and *suggested regulatory change* (Table 4). Similarities and differences between adolescents' and parents' report of themes and subthemes are visualized in Figure 2.

XSL•FO
RenderX

Table 4. Themes related to adolescents' and parents' views on online record access regulations.

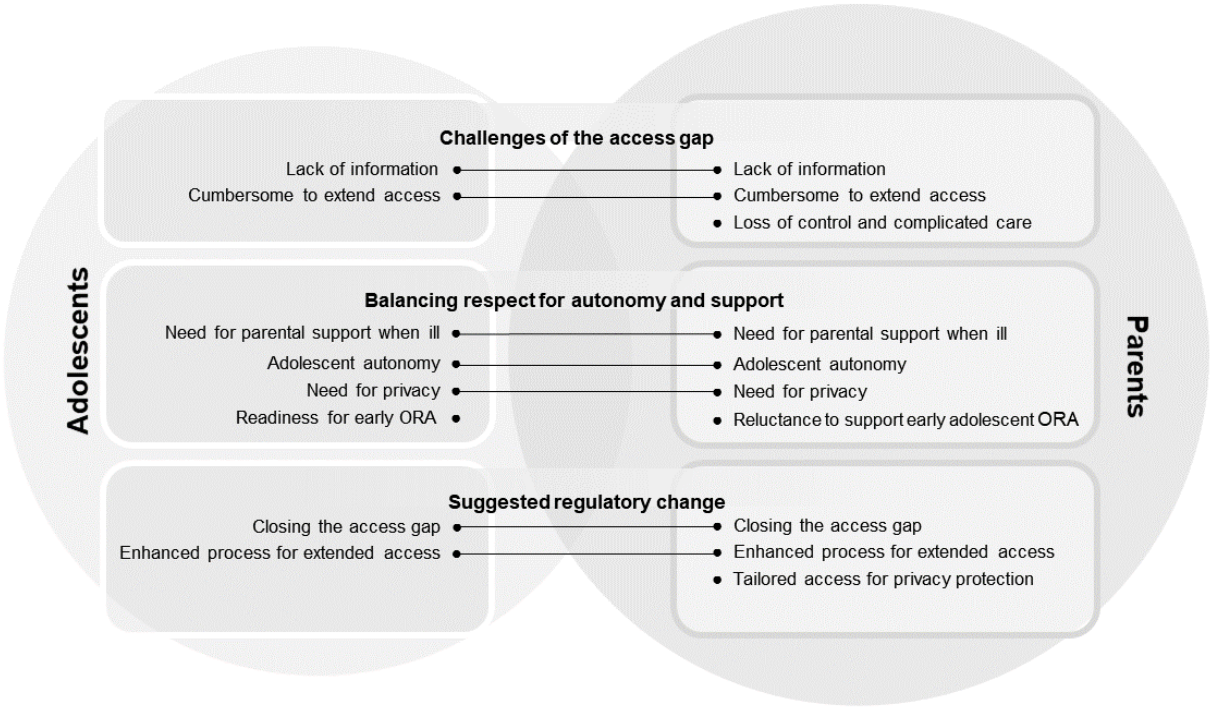
Themes and subthemes	Representative quotes
Challenges of the access gap	
Lack of information	• "Being able to access it at all, I found out just a month ago from someone at a primary care clinic, that like, you have to order it and then you'll get it on paper...but, that you can get earlier access or so, I haven't heard anything about. And it's probably because even when you ask your physician at the clinic, they don't know either." [A29; aged 15 years; diagnosed with asthma, allergies, and mental health issues] • "We knew it would come, but we still thought that 'she is sick, maybe they understand that we should have access to the record anyways.' But it...it wasn't the case." [P2, mother of child aged 13 years diagnosed with cancer]
Losing access causes a loss of control and complicates care	• "I got really angry [when losing access], as I said, because it's my child that I'm responsible for. Then she shouldn't be able to do a bunch of things without my knowledge either." [P15, mother of child aged 17 years, diagnosed with cancer] • "I felt a confusion, not being able to read the test results, if she has inflammation in her body, where does she have it or does she not, how do the liver tests look? You couldn't follow her illness in the same way when you couldn't read the EHR [electronic health record]." [P38, mother of child aged 14 years diagnosed with juvenile arthritis] • "There is extra work, both for me and physicians...or the nurse I guess, because I have to call in. And I have to match their phone hours, and then I take their time and time from those who need it better." [P1, mother of child aged 14 years diagnosed with cancer]
Cumbersome to extend access	• "It feels like a very complicated process. Especially for 13- to 15-year-olds...like, we find it easy to do something on our mobile phones, fill it out there, but if we have to first find a paper, figure out how to print it, fill it out, send it in, get it signed, get it into the system...that probably takes a few months." (A29; aged 15 years; diagnosed with asthma, allergies, and mental health issues] • "You have a thousand other things that are higher priority when you have sick children...To then submit long paper forms, find the right nurse who also doesn't know what to do...and specifically write the exact clinic on them when you go to...they send referrals here and there, I barely know what all the clinics he has been to and is going to are called." [P52, mother of child aged 15 years diagnosed with a skin disease]
Balancing respect for autonomy and support	
Need for parental support	• "It can be good, because you're darn young, and maybe you don't know how to do everything yourself and might need help." [A4, aged 13 years, diagnosed with cancer] • "It's completely different from person to person. Some might develop faster than others. And if you haven't, it might be nice for parents to be able to help." [A27, aged 19 years, diagnosed with juvenile arthritis] • "I probably wouldn't have wanted [adolescents'] access that early. There is a conflict, I'm thinking, with the child's right to know and at the same time, whether a child is emotionally equipped to see serious illnesses or prognoses, and take in the information. I think that you're young when you are...below 16, you're still young to deal with these difficult things." [P48, father of child aged 15 years diagnosed with juvenile arthritis] • "Maybe they don't need access before they're 18...I feel at least that I'm glad he can access his EHR. Otherwise, we wouldn't have seen anything. Because it's mostly me who reads it." [P15, mother of child aged 17 years diagnosed with cancer]
Adolescent autonomy	• "I think maybe you can have access slightly earlier, so that you can like, understand a little bit." [A10, aged 16 years, diagnosed with cancer] • "I live in [region], where many live in rural areas and when you're 15-16, you can move away from home. Like, into the city, and then you become more or less an adult and a bit more, 'I can take care of my record myself.'" [A29; aged 15 years; diagnosed with asthma, allergies, and mental health issues] • "I would probably wish that [my daughter] had access to see her test results. It's still her life, you know." [P38, mother of child aged 14 years diagnosed with juvenile arthritis] • "This thing about medication and making your own decisions...it's something you have to phase in. For it to work, I think you need to phase it in over a few years. It's not something you just fix with a bang on your 18th birthday. So it's still good at 16 years old that they get access and...if they are mature and willing." [P54, mother of child aged 17 years diagnosed with juvenile arthritis] • "There are some children who are more mature than their parents, I think it provides an opportunity for the children who are interested and listen during their meetings like parents...I think the opportunity should be there for them to see the whole time." [P52, mother of child aged 15 years diagnosed with a skin disease]

XSL•FO
RenderX

Themes and subthemes	Representative quotes
Need for privacy	• "It really depends, like some might start...like, if we say that one goes to BUP [child and youth mental health services] or some other place...I would say it begins at around 12-13, that one seeks help but doesn't want to tell." [A29; aged 15 years; diagnosed with asthma, allergies, and mental health issues] • "I don't think it's really about age, but more about what happens in the child's life. Because I think that there might be a difference...I'm thinking in terms of privacy. Now we have an ongoing illness process where I believe he also benefits from us being involved in and being able to help follow up. And as long as he's in that loop...I think it's very important that we have access. But after that, maybe not as much." [P22, mother of child aged 14 years diagnosed with cancer] • "There are far too many controlling guardians out there who want to control their children and all that. But I think that it must be more prevalent within certain areas, such as counseling support and youth clinics and so on. And I think we should never have access to those." [P8, mother of child aged 14 years diagnosed with cancer]
Suggested regulatory change	
Closing the access gap	• "I think maybe parents should have access until you are 13-14, and then I think it should be brought up that you can gain your own access to it." [A26, aged 18 years, diagnosed with inflammatory bowel disease] • "I think one should be able to read always, or maybe until they're 16, and from 16 they can perhaps log in themselves." [P52, mother of child aged 15 years diagnosed with skin disease]
Enhanced information on extended access	• "Could one consider sending information to the health care center, to youth...I mean, to health care centers, that parents can apply [for access extension]? Or maybe conduct some webinar?" [P49, mother of child aged 15 years diagnosed with juvenile arthritis] • "I think it should be very clear on 1177, that 'if you want to see your child's medical record, fill in here' or something like that." [P54, mother of child aged 17 years diagnosed with juvenile arthritis] • "For anything that isn't transient, like a cancer diagnosis that doesn't go away on its own, there should be a dialogue at least 6 months before the child turns 13 with the treating physician, and it should pop up in the EHR when the doctor opens it. Explaining to both children and parents, 'this is what will happen if we don't do anything, and how do you view it and what would you like access to?' and so on...Perhaps even that there can be some standard procedure, 'this is how we usually do it when it comes to cancer diseases, that you have access to blah, blah, blah...this and this.' But this you won't see. So that the wheel doesn't need to be reinvented every time." [P8, mother of child aged 14 years diagnosed with cancer]
Tailored access for privacy protection	• "Can't you block certain parts [from parents], like youth psychiatry, counseling, youth health, or something like that? I'm thinking that you could be allowed to read all the time but maybe block certain parts." [P52, mother of child aged 15 years with skin disease] • "Maybe [the adolescent] can make an agreement with the person writing in the record that 'no, but this can be kept hidden, I don't want anyone else to see this.' That there's like a toggle switch, like, private or not. You know, like when booking [setting up appointments] in Outlook, you can just be like, this is private." [P22, mother of child aged 14 years diagnosed with cancer] • "I think that if a child seeks care independently, the health care professional could perhaps ask the question 'do you not want your parent to be able to read this?' That it can be customized." [P47, mother of child aged 15 years diagnosed with juvenile arthritis]

XSL•FO
RenderX

Figure 2. Themes related to adolescents' and parents' views on online record access (ORA) regulations.



Challenges of the access gap were mentioned by both adolescents and parents. Several parents expressed strong feelings of frustration and desperation over losing their access, citing the many benefits they had experienced. Despite receiving notifications, several parents had not fully understood that they would lose access when the child turned 13 years of age and were convinced that HCPs would ensure continued ORA due to their situation. Losing access made it difficult for parents to track their child's illness because they could no longer check test results, manage appointments, or monitor medications needing refills. Instead, they had to travel to the pharmacy for medications and contact HCPs to inquire about test results during designated hours, leading them to feel that they were burdening HCPs. Most adolescents and some parents were unaware of the option to apply for extended access, especially in the case of adolescents. Of those who had applied, a majority described the application process as cumbersome: identifying the right form; submitting separate applications for each desired unit; and parents needing to frequently raise the issue with HCPs, who often lacked the necessary knowledge or information. Difficulties with the application process were both anticipated and encountered. One adolescent (A26) and several parents had given up on their efforts to apply for access due to these challenges. A few parents who had applied for extended access immediately after losing access did not regain it until 6 months later, while 1 parent (P1) was still waiting for a signature, 2 years after applying.

Adolescents and parents were *balancing respect for autonomy and support* in their appraisal of appropriate access ages. Several participants perceived that the need for adolescent and parental ORA depended on factors other than age, such as the adolescents' maturity and interest, which may not correlate with age. Adolescents and parents who advocated access earlier than the age of 16 years focused on adolescents' rights to read their records, as well as the importance of involving interested adolescents with serious health issues in their care from an early age. By contrast, having a serious health issue was often perceived as a situation necessitating parental access beyond the age of 13 years, a view supported by 5 (62%) of the 8 adolescents and almost all parents (15/17, 88%). Parents stated that parental ORA should extend into adulthood for children with severe neurocognitive impairments. Some adolescents and most parents were positive about the idea of adolescents aged 16 years gaining access, citing that younger adolescents are often less capable of managing their care and require parental support. Still, most valued the opportunity for interested and mature adolescents to become involved in their own care before adulthood. Some parents were negative about early adolescent ORA, seeing it as a burden for the adolescent or perceiving illness-related information in the EHR as harmful. One parent (P48) stated that the age of 16 years is "too young to deal with such difficult matters," and several stated that adolescents should have a parent present when reading the records.

Another source of divergent opinion was adolescents' need for confidentiality. Privacy was a priority for adolescents and 1 parent (P55) who were positive about parents losing access when their child turned 13 years of age. Many referred to a difference in the timing of adolescents beginning to seek care for sensitive matters. While most parents were understanding of the need to conceal sensitive information, they still viewed their parental responsibility as critical. Most adolescents stated that they did not feel the need to conceal information from their parents, citing a relationship of openness and their parents' prior involvement in the treatment. Nevertheless, some expressed a desire to hide nontreatment information, such as alcohol use. The exception was an adolescent aged 15 years who had

XSL•FO
RenderX

experience with mental health care and was not open to parental access, stating that any information could be sensitive for an individual. Adolescents' view of sensitive information was generally broader than that of the parents, with parents primarily focusing on mental and reproductive health. Furthermore, several parents and 1 adolescent (A26) discussed the importance of considering adolescents who may experience harm from parental ORA, such as children with controlling parents or in honor-based contexts. However, a few parents argued that such cases are rare and that the majority of adolescents benefit from parental access.

Suggested regulatory change was mentioned by both adolescents and parents. A common suggestion was to remove the existing access gap between the ages of 13 and 15 years, perhaps by finding a middle ground. Furthermore, participants proposed increasing education for adolescents, parents, and HCPs about the option of access extension and the application procedure. Parents suggested facilitating the procedure by digitizing the application to the patient portal and enabling a combined application for all units involved in treatment. Both adolescents and parents cited the need for HCPs to have more knowledge of the process. Some parents also stated that parental access should be tailored based on adolescents' preferences or technological tagging of diagnoses, allowing for the concealment of sensitive information from parental view.

Mixed Methods Comparison

Overall, the qualitative accounts of adolescents and parents largely reflected and elaborated on their ratings and views observed in the quantitative measurements. Consistent with survey findings, both adolescents and parents criticized the access gap between the ages of 13 and 15 years and expressed a desire for this gap to be closed. The qualitative findings provided insights into the perceived benefits and risks of ORA, which aided an understanding of various findings, such as parents' preference for parental ORA over that of adolescents. Moreover, extensive challenges related to access extension were revealed.

Discussion

Summary of Findings

This study found that adolescents and parents were negative about the current access gap in Sweden for adolescents aged 13 to 15 years. While adolescents were largely positive about longer parental access, parents strongly advocated it. By contrast, adolescents also preferred earlier own access, which most parents opposed. The current option to extend access beyond the default was considered complicated due to a cumbersome application process and a lack of information and HCP knowledge. Perceived benefits and risks of ORA differ, revealing tensions in the respective views, particularly concerning parents' worries about adolescents' access.

Comparison With Prior Work

While in alignment on many aspects related to ORA regulations, adolescents and parents differed mainly in their views on adolescents' access. Our findings suggest a tension between adolescents and parents similar to that between patients and HCPs [31]—adolescents appreciate having access, while parents worry about adolescents' lack of health literacy and the potential for harmful consequences. While adolescents in this study acknowledged the risk of not understanding medical terminology with ORA, they expressed minimal concern and described coping strategies to manage this challenge. However, many parents perceived a lack of interest among adolescents in reading their records, in addition to a high risk of potential harm. This is in line with previously identified parental concerns, including the possibility of adolescents misunderstanding information or reading negative test results independently [7]. These concerns are understandable, particularly during times of illness and vulnerability when parents want to ensure the best possible care for their child [32]. Nevertheless, a recent case study comparing Swedish and Finnish adolescents' ORA use indicates that earlier access may lead to increased uptake at earlier ages [12].

The tension emerging from parents' hesitance to support adolescent ORA may in part be a result of the perceived serious risks in the face of a lack of significant benefits. Notably, while several adolescents reported improved emotional states and 1 adolescent speculated that parents may feel safer with ORA, no parent envisioned that adolescents may experience more control or increased safety. Furthermore, parents reported many benefits that adolescents did not perceive, such as being able to prepare the child for medical appointments and explain medication needs. This is important because noncompliance with treatment in adolescents has been documented [33], where access to information is essential [32]. The difference in adolescents' and parents' perceived benefits indicates the difficulty in understanding another person's perspective and experiences. Given the importance of partnerships between the adolescent patient, parent, and HCPs, noted in earlier work [22], there is potential for ORA to serve as a tool for improving such partnerships; for example, we identified that the opportunity to read EHRs together at home contributed positively to adolescents' and parents' experiences. A better understanding of each other's perspectives might help mitigate concerns about harm related to a lack of health literacy and confidentiality. Both adolescents and parents recognized the benefit of adolescent access in empowering adolescents and supporting the transition into adulthood, supporting previous work [6,7].

Most of the adolescents in this study were positive about allowing parental access after the age of 13 years, recognizing that parental support lessened the burden on the child, particularly in the case of serious health issues. However, adolescents advocated a need for privacy regarding some types of information unrelated to treatment. The need for privacy regarding sensitive information was reported to increase with age and also varied depending on the type of care received. Notably, an adolescent aged 15 years with experience of mental health issues such as depression (A29) preferred restricted parental access from the age of 12 or 13 years, which was earlier than the preference expressed by adolescents with diseases such as cancer, inflammatory bowel disease, or juvenile arthritis. The adolescent also reported having moved away from home for school, which likely increased their level of independence. While most of the parents reported that they would accept not having access to sensitive information, they often referred to

XSL•FO
RenderX

sensitive topics pertaining to sexual or mental health. Meanwhile, some adolescents cited allergies and experiences of bullying as potentially sensitive. Aligned with previous findings [17], adolescents stated that what is considered sensitive information can vary from person to person, indicating a need to allow adolescents to decide what should be visible to parents in the EHR. Parents suggested enabling customization of information availability, as has been recommended in earlier work [34]. An example of a system that allows customization is found in Finland, where HCPs assess each minor's decision-making capacity and then allow those found capable to decide whether parents should have access. While such case-by-case approaches lead to a risk of increased work burden for HCPs, more research is required to explore the feasibility of customized access.

Adolescents and parents reported low knowledge about access extension, the intended solution to aid families of children with serious illness during the access gap between the ages of 13 and 15 years. It was reported that HCPs often lacked knowledge about the application process and even the possibility of extending access. Our previous research shows that <1% of adolescents aged 13-15 and their parents access the Swedish patient portal [12]. Furthermore, adolescents lacked knowledge about regulations. Adolescents have reported receiving little encouragement from HCPs to access their records [35]. Possibly, the implementation of ORA in Sweden has failed to involve and educate HCPs about the new regulations. Furthermore, given that ORA and EHR documentation are known causes for HCP job dissatisfaction and burnout [36], some HCPs may be reluctant to encourage ORA use. To improve our understanding of HCPs' perspectives, the aim of a study conducted by the authors in parallel with this study was to examine the experiences and awareness of ORA regulations among oncology HCPs in Sweden.

Implications

On the basis of the findings, we have summarized a number of implications that concern adolescents with serious health issues and their parents (Textbox 4).

Textbox 4. Implications of the findings.

Implications

- Provide health care professionals (HCPs) with information on online record access (ORA) regulations related to extended access and guidance on how to facilitate the application procedure for adolescents and parents.
- Establish a plan for families with adolescents with serious illness to retain necessary ORA through a facilitated process of applying for extended access.
- Ensure clear communication to parents and adolescents about the management of sensitive information in records on the national patient portal.
- Provide comprehensive information to adolescents regarding the age limit for gaining access and the option to receive early access on the national patient portal.
- Provide comprehensive information to parents regarding ORA regulations, loss of access, and the option to extend access on the national patient portal.
- Foster dialogue between HCPs, adolescents, and parents regarding ORA and the concealment of sensitive information.
- Implement patient portal features that enable adolescents to customize the concealment of sensitive information according to their preferences.

Limitations

This study has a number of limitations. The sample size was relatively small due to persistent recruitment difficulties, particularly in engaging adolescent participants. Future research may explore alternative recruitment strategies, such as reaching adolescents through schools or other community channels. Moreover, half of the adolescents interviewed (4/8, 50%) were aged 18 or 19 years, which likely affected their views. Among the parent participants, the majority (47/56, 84%) were women, and approximately one-third of the interview participants (5/17, 29%) had a medical background or a partner working as an HCP. Notwithstanding this limitation, unequal sample sizes are a common occurrence in mixed methods research [23]. Furthermore, our sample included adolescents with a variety of conditions; however, the focus was not on comparing experiences across groups with specific illnesses but rather on exploring broader perspectives related to ORA use. While the parents varied in education, residential area, and income, most had Swedish as their primary language (53/56, 95%). Given the role of socioeconomic factors in driving disparities in pediatric ORA adoption [37,38], future work should include minors and parents from diverse language backgrounds to capture broader perspectives. Moreover, 1 survey item included a negation ("I do not want my parents to access..."), which could have been challenging for participants to interpret and therefore to accurately respond to on a scale ranging from 1 to 5. The surveys used were designed by the authors because there are no validated questionnaires available for examining views on ORA. Finally, both adolescents who had read their records and those who had not participated in the study. As a result, some shared their expectations rather than experiences. We strove to present the findings with due consideration to this limitation because there may be differences between expectations and experiences of ORA [2]. We did not provide a demonstration for adolescents without access, which may have impeded their ability to answer anticipatory questions. However, most of the interviews (5/8, 62%) with adolescents were conducted via telephone, precluding visual demonstrations. Regarding interviews conducted via videoconferencing software, it is possible that this format influenced participants due to the potential sensitivity of the topic. In addition, technical issues such as connectivity problems or the lack of a private and secure environment could have further impacted the conversation flow. However, video

XSL•FO
RenderX

interviews offer advantages over telephone interviews by allowing for the conveyance of nonverbal cues, such as facial expressions and body language, which can help foster a sense of connection and empathy between the interviewer and participant. An interview guide was followed to improve trustworthiness, and the study was reported in accordance with the COREQ guidelines.

Conclusions

In Sweden, the regulatory framework on ORA (characterized by a default lack of access for adolescents aged 13-15 y and their parents) and a lack of available information on access extensions creates challenges for parents of adolescents with serious health issues. Both adolescents and parents desire consistent access to the EHR that considers adolescents' growing need for privacy. While there is parental reluctance to support adolescent ORA due to concerns about potential harm and low perceived need, adolescents experience benefits from ORA that parents are not aware of, and vice versa. Informing adolescents, parents, and HCPs about experienced benefits and access regulations could improve partnerships, reduce distress, and facilitate adolescent care.

Acknowledgments

The authors are grateful to all participating adolescents and parents who shared their views and experiences, making this study possible, and feel privileged to have received their insights. Furthermore, the authors would like to acknowledge Lillemor Berntsson and Linn Ullberg Anderson at Uppsala University Hospital as well as the patient organizations that helped in recruiting participants. The authors would also like to thank the young experts panel at Uppsala University Hospital and the adolescents and parents who provided their input on the study material.

Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File (Adobe PDF File), 105 KB - pediatrics_v8i1e63270_app1.pdf]

Multimedia Appendix 2
Surveys in English and Swedish.
[PDF File (Adobe PDF File), 145 KB - pediatrics_v8i1e63270_app2.pdf]

Multimedia Appendix 3
Interview guides in English and Swedish.
[PDF File (Adobe PDF File), 1318 KB - pediatrics_v8i1e63270_app3.pdf]

Multimedia Appendix 4
Demographics and detailed results.
[PDF File (Adobe PDF File), 76 KB - pediatrics_v8i1e63270_app4.pdf]

References

1. Walker J, Leveille S, Bell S, Chimowitz H, Dong Z, Elmore J, et al. OpenNotes after 7 years: patient experiences with ongoing access to their clinicians' outpatient visit notes. J Med Internet Res 2019 May 06;21(5):e13876 [FREE Full text] [doi: 10.2196/13876] [Medline: 31066717]
2. Hagström J, Blease C, Haage B, Scandurra I, Hansson S, Hägglund M. Views, use, and experiences of web-based access to pediatric electronic health records for children, adolescents, and parents: scoping review. J Med Internet Res 2022 Nov 22;24(11):e40328 [FREE Full text] [doi: 10.2196/40328] [Medline: 36413382]
3. Kujala S, Hörhammer I, Väyrynen A, Holmroos M, Nättiaho-Rönnholm M, Hägglund M, et al. Patients' experiences of web-based access to electronic health records in Finland: cross-sectional survey. J Med Internet Res 2022 Jun 06;24(6):e37438 [FREE Full text] [doi: 10.2196/37438] [Medline: 35666563]
4. Moll J, Rexhepi H, Cajander Å, Grünloh C, Huvila I, Hägglund M, et al. Patients' experiences of accessing their electronic health records: national patient survey in Sweden. J Med Internet Res 2018 Nov 01;20(11):e278 [FREE Full text] [doi: 10.2196/jmir.9492] [Medline: 30389647]
5. Benjamins J, de Vet E, Jordaan G, Haveman-Nies A. Effect of using client-accessible youth health records on experienced autonomy among parents and adolescents in preventive child healthcare and youth care: a mixed methods intervention study. J Child Health Care 2023 May 25:13674935231177782 [FREE Full text] [doi: 10.1177/13674935231177782] [Medline: 37227030]

XSL•FO
RenderX

6. Carlson JL, Goldstein R, Buhr T, Buhr N. Teenager, parent, and clinician perspectives on the electronic health record. Pediatrics 2020 Mar;145(3):e20190193 [FREE Full text] [doi: 10.1542/peds.2019-0193] [Medline: 32024749]
7. Hong MK, Wilcox L, Feustel C, Wasileski-Masker K, Olson TA, Simoneaux SF. Adolescent and caregiver use of a tethered personal health record system. AMIA Annu Symp Proc 2017 Feb 10;2016:628-637 [FREE Full text] [Medline: 28269859]
8. Bourgeois FC, DesRoches CM, Bell SK. Ethical challenges raised by OpenNotes for pediatric and adolescent patients. Pediatrics 2018 Jun;141(6):e20172745 [FREE Full text] [doi: 10.1542/peds.2017-2745] [Medline: 29776979]
9. Essén A, Scandurra I, Gerrits R, Humphrey G, Johansen MA, Kierkegaard P, et al. Patient access to electronic health records: differences across ten countries. Health Policy Technol 2018 Mar;7(1):44-56 [FREE Full text] [doi: 10.1016/j.hlpt.2017.11.003]
10. Hagström J, Scandurra I, Moll J, Blease C, Haage B, Hörhammer I, et al. Minor and parental access to electronic health records: differences across four countries. Stud Health Technol Inform 2022 May 25;294:495-499 [FREE Full text] [doi: 10.3233/SHTI220508] [Medline: 35612129]
11. Sisk BA, Antes AL, Bereitschaft C, Enloe M, Bourgeois F, DuBois J. Challenges to developing and implementing policies for adolescent online portal access. Pediatrics 2023 Jun 01;151(6):e2023061213 [FREE Full text] [doi: 10.1542/peds.2023-061213] [Medline: 37132339]
12. Hagström J, Hägglund M, Holmroos M, Lähteenmäki P, Hörhammer I. Minors' and guardian access to and use of a national patient portal: a retrospective comparative case study of Sweden and Finland. Int J Med Inform 2024 Jul;187:105465 [FREE Full text] [doi: 10.1016/j.ijmedinf.2024.105465] [Medline: 38692233]
13. Aro E. Fick inte se sin cancersjuke sons journal på nätet – regeringen lovar ändring [Article in Swedish]. Sveriges Radio. 2022 Jun 18. URL: https://sverigesradio.se/artikel/fick-inte-se-sin-cancersjuke-sons-journal-pa-natet-regeringen-lovar-andring [accessed 2023-09-20]
14. Lundgren M. Föräldrar blockade från Vilmers vårdkontakter "Besök missas" [Article in Swedish]. Sveriges Radio. 2022 Nov 2. URL: https://sverigesradio.se/artikel/foraldrar-blockade-fran-vilmers-vardkontakter-besok-missas [accessed 2023-09-20]
15. Jasik CB. Unlocking the potential of the patient portal for adolescent health. J Adolesc Health 2016 Feb;58(2):123-124 [FREE Full text] [doi: 10.1016/j.jadohealth.2015.12.003] [Medline: 26802987]
16. Sharko M, Wilcox L, Hong MK, Ancker JS. Variability in adolescent portal privacy features: how the unique privacy needs of the adolescent patient create a complex decision-making process. J Am Med Inform Assoc 2018 Aug 01;25(8):1008-1017 [FREE Full text] [doi: 10.1093/jamia/ocy042] [Medline: 29788423]
17. Hagström J, Åhlfeldt RM, Blease C, Cajander Å, Rexhepi H, Moll J, et al. Security and privacy of online record access: a survey of adolescents' views and experiences in Sweden. J Adolesc Health 2024 Nov;75(5):730-736 [FREE Full text] [doi: 10.1016/j.jadohealth.2023.12.027] [Medline: 38349307]
18. Asan O, Scanlon M, Crotty B, Holden R, Flynn K. Parental perceptions of displayed patient data in a PICU: an example of unintentional empowerment. Pediatr Crit Care Med 2019 May;20(5):435-441 [FREE Full text] [doi: 10.1097/PCC.0000000000001895] [Medline: 31058783]
19. Bell SK, Folcarelli P, Fossa A, Gerard M, Harper M, Leveille S, et al. Tackling ambulatory safety risks through patient engagement: what 10,000 patients and families say about safety-related knowledge, behaviors, and attitudes after reading visit notes. J Patient Saf 2021 Dec 01;17(8):e791-e799 [FREE Full text] [doi: 10.1097/PTS.0000000000000494] [Medline: 29781979]
20. Bergman DA, Brown NL, Wilson S. Teen use of a patient portal: a qualitative study of parent and teen attitudes. Perspect Health Inf Manag 2008;5:13 [FREE Full text] [Medline: 18923702]
21. Britto MT, Hesse EA, Kamdar OJ, Munafo JK. Parents' perceptions of a patient portal for managing their child's chronic illness. J Pediatr 2013 Jul;163(1):280-1.e1-2 [FREE Full text] [doi: 10.1016/j.jpeds.2013.02.041] [Medline: 23541773]
22. Ford CA, Davenport AF, Meier A, McRee AL. Partnerships between parents and health care professionals to improve adolescent health. J Adolesc Health 2011 Jul;49(1):53-57 [FREE Full text] [doi: 10.1016/j.jadohealth.2010.10.004] [Medline: 21700157]
23. Creswell JW, Creswell JD. Research Design: Qualitative, Quantitative, and Mixed Methods Approaches. Thousand Oaks, CA: SAGE Publications; 2018.
24. Dawadi S, Shrestha S, Giri RA. Mixed-methods research: a discussion on its types, challenges, and criticisms. J Pract Stud Educ 2021 Feb 24;2(2):25-36 [FREE Full text] [doi: 10.46809/jpse.v2i2.20]
25. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007 Dec;19(6):349-357 [FREE Full text] [doi: 10.1093/intqhc/mzm042] [Medline: 17872937]
26. Price A, Clarke M, Staniszewska S, Chu L, Tembo D, Kirkpatrick M, et al. Patient and public involvement in research: a journey to co-production. Patient Educ Couns 2022 Apr;105(4):1041-1047 [FREE Full text] [doi: 10.1016/j.pec.2021.07.021] [Medline: 34334264]
27. Riggare S. E-patients hold key to the future of healthcare. BMJ 2018 Feb 26;360:k846 [FREE Full text] [doi: 10.1136/bmj.k846] [Medline: 29483151]

XSL•FO
RenderX

28. Lag (2003:460) om etikprövning av forskning som avser människor [Article in Swedish]. Sveriges Riksdag. 2003. URL: https://tinyurl.com/3b5mcjww [accessed 2023-08-03]
29. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006;3(2):77-101 [FREE Full text] [doi: 10.1191/1478088706qp063oa]
30. Sisk BA, Bereitschaft C, Enloe M, Schulz G, Mack J, DuBois J. Oncology clinicians' perspectives on online patient portal use in pediatric and adolescent cancer. JCO Clin Cancer Inform 2023 Sep;7(7):e2300124 [FREE Full text] [doi: 10.1200/CCI.23.00124] [Medline: 37972324]
31. Hägglund M, McMillan B, Whittaker R, Blease C. Patient empowerment through online access to health records. BMJ 2022 Sep 29;378:e071531 [FREE Full text] [doi: 10.1136/bmj-2022-071531] [Medline: 36175012]
32. Breyer J. When Your Child Is Sick: A Guide to Navigating the Practical and Emotional Challenges of Caring for a Child Who is Very Ill. London, UK: John Murray Press; 2021.
33. Cromer BA, Tarnowski KJ. Noncompliance in adolescents: a review. J Dev Behav Pediatr 1989 Aug;10(4):207-215. [doi: 10.1097/00004703-198908000-00010]
34. Anoshiravani A, Gaskin GL, Groshek MR, Kuelbs C, Longhurst CA. Special requirements for electronic medical records in adolescent medicine. J Adolesc Health 2012 Nov;51(5):409-414 [FREE Full text] [doi: 10.1016/j.jadohealth.2012.08.003] [Medline: 23084160]
35. Hagström J, Blease C, Scandurra I, Moll J, Cajander Å, Rexhepi H, et al. Adolescents' reasons for accessing their health records online, perceived usefulness and experienced provider encouragement: a national survey in Sweden. BMJ Paediatr Open 2024 Mar 09;8(1):e002258 [FREE Full text] [doi: 10.1136/bmjpo-2023-002258] [Medline: 38460965]
36. Stillman M. Death by patient portal. JAMA 2023 Jul 18;330(3):223-224 [FREE Full text] [doi: 10.1001/jama.2023.11629] [Medline: 37389857]
37. Ketterer T, West DW, Sanders VP, Hossain J, Kondo MC, Sharif I. Correlates of patient portal enrollment and activation in primary care pediatrics. Acad Pediatr 2013;13(3):264-271 [FREE Full text] [doi: 10.1016/j.acap.2013.02.002] [Medline: 23680344]
38. LeLaurin JH, Nguyen OT, Thompson LA, Hall J, Bian J, Cho HD, et al. Disparities in pediatric patient portal activation and feature use. JAMIA Open 2021 Sep 29;4(3):ooab086 [FREE Full text] [doi: 10.1093/jamiaopen/ooab086] [Medline: 34604712]

Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
EHR: electronic health record
HCP: health care professional
ORA: online record access
PAEHR: patient-accessible electronic health record
REDCap: Research Electronic Data Capture
RQ: research question

Edited by S Badawy; submitted 27.06.24; peer-reviewed by L Reid-Chassiakos, G Myreteg, J Eriksen; comments to author 28.11.24; revised version received 07.12.24; accepted 24.12.24; published 27.01.25.

Please cite as:
Hagström J, Blease C, Harila A, Lähteenmäki P, Scandurra I, Hägglund M
Perspectives on Swedish Regulations for Online Record Access Among Adolescents With Serious Health Issues and Their Parents: Mixed Methods Study
JMIR Pediatr Parent 2025;8:e63270
URL: https://pediatrics.jmir.org/2025/1/e63270
doi:10.2196/63270
PMID:

©Josefin Hagström, Charlotte Blease, Arja Harila, Päivi Lähteenmäki, Isabella Scandurra, Maria Hägglund. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 27.01.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Digital Health Program to Support Family Caregivers of Children Undergoing Growth Hormone Therapy: Qualitative Feasibility Study

Alba Jiménez-Díaz[1*], MSc; Maitena Pierantonelli[1*], BA; Patricia Morte Coscolín[2,3], MD; Amaia Salinas-Uhalte[2,3], MD; Silvia Quer-Palomas[4], PhD; Octavio Rivera-Romero[5,6], PhD; Rocío Herrero[7,8], PhD; Luis Fernández-Luque[4], PhD; Rosa Baños[1,8], PhD; Ricardo C Berrios[4], BSc; Antonio de Arriba[2,3], MD, PhD

[1]Departamento de Personalidad, Evaluación y Tratamientos Psicológicos, Universitat de València, Valencia, Spain

[2]Unidad de Endocrinología Pediátrica, Hospital Universitario Miguel Servet, Zaragoza, Spain

[3]Instituto de Investigación Sanitaria de Aragón, Zaragoza, Spain

[4]Adhera Health Inc., Santa Cruz, CA, United States

[5]Instituto de Ingeniería Informática, Universidad de Sevilla, Seville, Spain

[6]Electronic Technology Department, Universidad de Sevilla, Seville, Spain

[7]Departamento de Psicología y Sociología, Universidad de Zaragoza, Teruel, Spain

[8]CIBER of Physiopathology of Obesity and Nutrition (CIBEROBN), Madrid, Spain

[*]these authors contributed equally

Corresponding Author:
Antonio de Arriba, MD, PhD
Unidad de Endocrinología Pediátrica
Hospital Universitario Miguel Servet
Paseo Isabel la Católica, 1
Zaragoza, 50009
Spain
Phone: 34 976765500
Email: adearriba@salud.aragon.es

Related Article:

This is a corrected version. See correction statement: https://pediatrics.jmir.org/2025/1/e76508

Abstract

Background: Caregivers of children with growth hormone deficiency often face emotional challenges (eg, stress) associated with their children's health conditions. This psychological burden might affect children's adherence to treatment and hinder their health-related quality of life (HrQoL). This assumption is leading to seriously considering multidimensional clinical approaches to pediatric health conditions where the emotional well-being of caregivers should be accounted for to optimize children's health outcomes. Novel mobile health (mHealth) solutions based on emotional and behavioral change techniques can play a promising role because they are increasingly used within different health areas to support adaptive psychological functioning. However, whether and how mHealth solutions of this type of emotional well-being support caregivers of children with growth-related problems is an issue that needs to be clarified.

Objective: This study aimed to gather qualitative information to better understand individualized experiences of caregiving of children undergoing growth hormone therapy (GHt) and perceived barriers or facilitators for the adoption of an mHealth solution called Adhera Caring Digital Program (ACDP).

Methods: A total of 10 family caregivers were recruited at Miguel Servet Children's Hospital, and they engaged with the ACDP for 1 month. The ACDP is a mobile-based digital intervention focused on promoting the overall well-being of family caregivers which provides access to personalized education, motivational mobile-based messages, and mental well-being exercises such as mindfulness or respiratory exercises. Subsequently, an individual semistructured interview was performed to gather qualitative user experience information.

XSL•FO
RenderX

Results: The digital intervention was well-received. The ACDP was found to be useful, easy to use, and understandable, addressing all the difficulties expressed by caregivers. It was also noted to be particularly helpful at the beginning of the treatment and, for some families, became a natural tool that strengthened the parent-child relationship.

Conclusions: The ACDP is a promising and well-accepted tool that enhances the experience of patients and caregivers. It improves the management of growth hormone deficiency and promotes the overall well-being of family caregivers.

Trial Registration: ClinicalTrials NCT04812665; https://clinicaltrials.gov/study/NCT04812665

International Registered Report Identifier (IRRID): RR2-10.1186/s12911-022-01935-1

(JMIR Pediatr Parent 2025;8:e55023) doi:10.2196/55023

KEYWORDS

growth hormone deficiency; mobile based solutions; caregivers; technology acceptance; digital health; children; therapy; feasibility study; health condition; psychological burden; quality of life; wellbeing; pediatric; mobile Health; mHealth; behavioral change; parent-child relationship

Introduction

Growth hormone deficiency (GHD) in infants is a treatable disease that causes short stature [1]. The most used growth hormone therapy (GHt) for the pediatric population is a daily injection of a recombinant human growth hormone (rhGH) [2]. The daily administration is performed out of the clinic and requires patients and caregivers to be active and engaged in the self-management of this health condition. This active self-management is of paramount importance because poor adherence to rhGH treatments can lead to reduced efficacy and increased health care costs [3]. However, as the rhGH treatment can last many years, self-management is challenging for patients and caregivers [4], and suboptimal adherence to the treatment has been constantly reported in the literature [5]. Several factors such as missed injections, poorer level of treatment understanding, discomfort with the injections, and misperceptions about the consequences of missed doses have been reported as potential causes of poor adherence [5].

Children with GHD often have to address other issues related to their short stature that impact negatively on their quality of life. As exemplified, Stephen et al [6] found that children with GHD had significantly worse quality of life and cognitive functions than children with normal stature. Varni et al [7] found that children with short stature, including those with GHD, reported statistically significantly worse fatigue than healthy children. Social withdrawal, shyness, anxiousness, and depression have also been reported as a consequence of GHD [8-15].

Caregivers play a key role in the management of the GHD. They are responsible for the treatment management and administration of GHt to children who are not autonomous enough. Furthermore, they have the responsibility of managing their children's health condition, including all children's quality of life issues. This role is not premeditated nor chosen, so caring could turn out to be burdensome and affect the caregiver both psychologically and physically [16]. For instance, stress was one of the reported consequences of caring for children living with GHD, presenting higher levels of stress among parents whose children were receiving GHt, but still had short stature [17]. This higher stress level may impact their environment, their health, and treatment adherence [16]. Therefore, caregivers are at risk of developing psychosocial problems, such as anxiety and depression, that could seriously impact the child's health management. As an example, parental stress has been associated with poorer adherence of children to medical treatment [18]. Therefore, some authors have recommended assessing routinely caregivers' stress and conducting psychosocial interventions aimed at promoting caregivers' adaptation outcomes [17].

Currently, the health care sector is being transformed to benefit from the use of information and communication technologies. Digital health enables more accessible and potentially cost-effective alternatives to deliver family-centered interventions. Few studies have reported promising results on the efficacy of mobile health (mHealth)–based interventions for caregivers of children with chronic conditions [19]. Digital solutions, especially mobile apps, supporting patients and caregivers in the management of their disease have experienced significant and rapid growth. In GHD, Fernandez-Luque et al [20] found and analyzed 76 mHealth apps related to growth monitoring and growth hormone treatment available in the Android app store (Google). Most of these apps were intended for patients and caregivers. Some of the functionalities included in these self-management apps were education about GHD, education about growth tracking, and supporting and tracking adherence. However, the quality of digital health solutions is often not high enough and issues, such as trustworthiness or data privacy, are not appropriately addressed. This fact may lead to reduced adoption and engagement rates and, therefore, impact the effectiveness of the health interventions. In addition, the acceptability of digital health solutions by targeted users (patients or caregivers) is a key factor that also impacts the effectiveness of these interventions. Patients or caregivers will be reluctant to use digital health solutions that they do not find appropriate for them. There is still a need for conducting research on understanding the factors impacting caregivers' adoption and acceptance of the use of mHealth apps supporting them in the management of pediatric diseases.

Several technology acceptance models and theories such as the Technology Acceptance Model (TAM) [21] or the Unified Theory of Acceptance and Use of Technology (UTAUT) [22] have been proposed in the literature. The UTAUT and its versions have been widely used in digital health [23-25]. The UTAUT proposes that 4 constructs play a significant role as

XSL•FO
RenderX

direct determinants of user acceptance and usage behavior—performance expectancy, effort expectancy, social influence, and facilitating conditions. Performance expectancy is defined as "the degree to which an individual believes that using the system will help him or her to attain gains in job performance." This construct is related to concepts such as perceived usefulness, extrinsic motivation, and outcome expectations. Effort expectancy is defined as "the degree of ease associated with the use of the system." This construct is related to perceived ease of use. Social influence is defined as "the degree to which an individual perceives that important others believe he or she should use the new system." This construct is related to subjective norms. Finally, facilitating conditions are defined as "the degree to which an individual believes that an organizational and technical infrastructure exists to support the use of the system." In addition, the UTAUT defines 4 moderators (gender, age, voluntariness, and experience) that influence these determinants.

This research aims to gather qualitative information to better understand the psychological burdens experienced by caregivers of children undergoing growth hormone treatment, as well as the perceived barriers and facilitators related to accepting an mHealth solution that supports the self-management of GHD.

Methods

Recruitment

A total of 10 volunteer caregivers of children with GHD being treated by the physician AA from the Pediatric Endocrinology Unit at the Miguel Servet Children's University Hospital were invited to participate during face-to-face hospital visits. The sampling was selected by convenience from June to July 2021, and none of them refused to join the study. To be included in the study, all the described criteria had to be met (Textbox 1).

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Adherence to growth hormone therapy (GHt) monitored in the last month before enrollment indicates a ratio of less than 85% (since it has been considered as an index of relatively suboptimal adherence) [26,27].
- Legal guardian of children who receive GHt in accordance with approved indications in Spain.
- Explicit agreement on data sharing regarding adherence to GHt gathered through Easypod Connect (a digital platform that monitors GHt).
- Participants must not report any limitations in the use of smartphones and smartphone apps.
- Participants must accept the terms of use and agree to install the Adhera Caring Digital Program mobile-based intervention app.
- Participants must sign the specific informed consent form for the study.

Exclusion criteria

- Candidates without an Android or Apple smartphone because the solution only works through these 2 operating systems.
- Reporting any limitation in the use of smartphone apps.
- Only 1 legal guardian per child can participate in the study.

Procedures

At baseline, participants were requested to sign the informed consent and asked about demographic data and distress assessed by the Depression, Anxiety, and Stress Scale–21 (DASS-21) in its version in Spanish. After being introduced to the mHealth solution, they were guided to download, install, and configure the app on their own mobile phone. They were granted a free month of full access to the Adhera Caring Digital Program (ACDP).

After enrolling in the ACDP for 1 month, user experience was assessed with a semistructured interview. All the research was performed in Spanish.

Ethical Considerations

The current research was approved by the Ethical Committee CEICA (Comité de Ética de la Investigación de la Comunidad de Aragón; number CP-CI PI20/494). All procedures followed were in accordance with the Helsinki Declaration of 1975, as revised in 2000. Participation in the study was voluntary and anonymous; no compensation was given. All participants gave their informed consent. Audio recordings were deleted once transcribed. All personal information was deidentified.

Measures

DASS-21 Scale

The DASS-21 is a self-reported questionnaire divided into 3 scales that measure the emotional states of depression, anxiety, and stress. Each scale has 7 items, which are graded on a Likert scale from 0 to 3 (0: did not apply to me at all, 1: applied to me to some degree or some of the time, 2: applied to me to a considerable degree or a good part of the time, and 3: applied to me very much or most of the time). The scores are calculated by measuring the result of each scale multiplied by 2. The final result is classified as normal, mild, moderate, severe, or extremely severe [26,27].

Qualitative Interview

A semistructured interview was designed in order to gather the user experience after joining the ACDP for one month.

XSL•FO
RenderX

Adhera Caring Digital Program

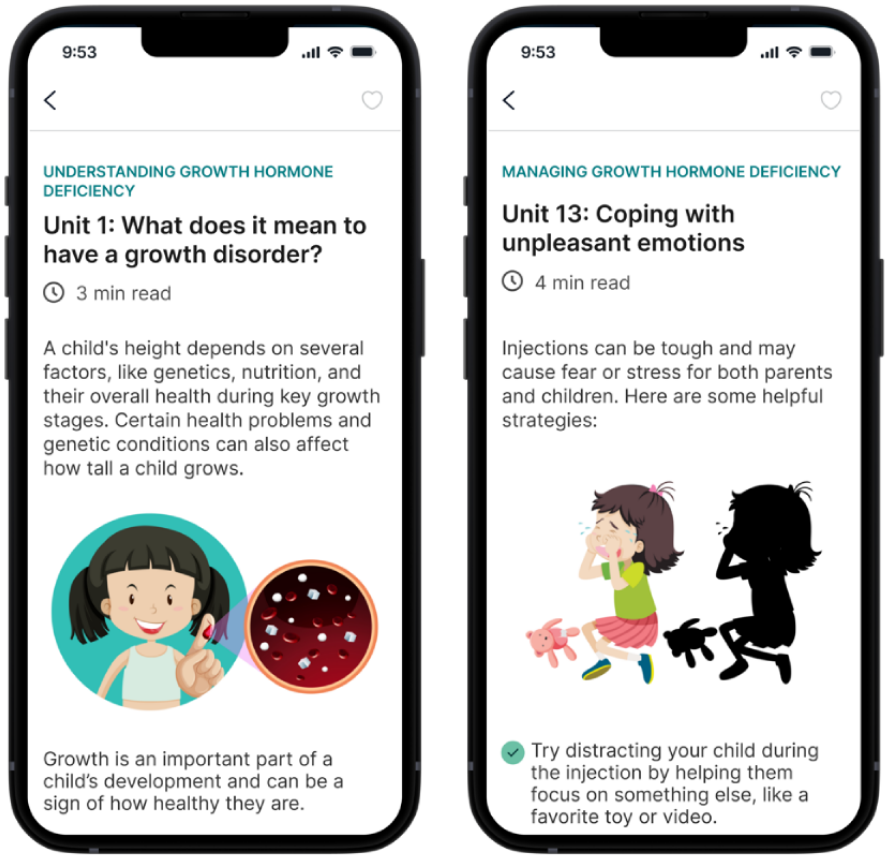
The ACDP is a mobile-based digital intervention focused on promoting the overall well-being of family caregivers which provides access to personalized education, motivational messages, and mental well-being exercises such as mindfulness or respiratory exercises. In this study, participants were invited to participate in the program for 4 weeks [28].

Psychoeducational modules provide educational content for parents or guardians of children with GHD (refer to Figure 1 for some examples). The contents include 39 units, classified into four sections: (1) managing GHD, (2) health habits to improve dealing with GHD, (3) adjusting to living with GHD, and (4) taking care of yourself to be able to take care of your child.

The program also includes a behavioral change module which complements and strengthens the knowledge of the psychoeducational module and provides lifestyle suggestions and action planning. It is done by delivering brief messages created by a multidisciplinary team of experts, including doctors and psychologists. The artificial intelligence–driven Adhera Precision Digital Companion Platform will select the tailored mobile-based messages to be sent (so the message selected will be personalized according to the patient profile, interests, and other peculiarities) [29]. This program incorporates the principles of personalized health education into a mobile platform, achieved by applying the Integrated Model of Behavioral Change [30] which is further expanded using recommender systems.

The ACDP is part of the Adhera Health Precision Digital Companion Platform, which has been developed using the best practices regarding data protection and quality management in accordance with the guidelines of ISO (International Organization for Standardization) 27001 and ISO 13465.

Figure 1. An Educational Unit within the app.



Interview Data Collection and Analysis

Participants were individually interviewed by 2 trained doctors (physicians) from the hospital. The training was provided by the sponsor's principal investigator through a workshop. The interviews were performed at the hospital or by secured video calls with caregivers or family and researchers being involved only. The mean duration of each interview was approximately 15 minutes. Individual interviews were anonymous, audio-recorded, manually transcribed, and anonymized by MP. MP and AJ-D managed and analyzed the transcripts using ATLAS.ti (Lumivero) Scientific Software Development GmbH (ATLAS.ti version 7.5.4 1993-2012 Windows). They performed an independent parallel analysis and arrived at the same conclusions regarding the themes that emerged during the interviews. Some translations of the interview can be consulted in Multimedia Appendix 1.

A data-driven inductive strategy was generally followed. However, some UTAUT model concepts [31] were considered regarding some aspects of technology acceptance, following a deductive-like approach in this specific case. The study followed the consensual qualitative research methodology [31,32]. In this approach, core ideas are identified and organized into

XSL•FO
RenderX

categories, which are embedded in broader domains. To do so, 2 reviewers (MP and AJ) independently extracted and organized the data. They then compared their findings in a series of feedback meetings to ensure objectivity and reach interrater consensus. A third reviewer (RH) was consulted in case of discrepancy.

Results

Overview

The characteristics of the sample (n=10) are described in Table 1. The majority of participants were female (80%) with a mean age of 44.9 (SD 4.41) years. Most of the caregivers were married (70%). In terms of education, the majority held a university degree (70%). The children were primarily female (70%) with a mean age of 10.6 (SD 2.5) years. The average age at the start of was 5.9 (SD 1.66) years and had been under treatment for a mean of 60.3 (SD 23.59) months. The mean adherence rate was 73.44% (SD 28.6).

Table 1. Descriptive characteristics of the sample.

Characteristic	Statistical value (N=10)
Caregiver's sex, n (%)	
Male	2 (20)
Female	8 (80)
Caregiver's age, mean (SD)	44.9 (4.41)
Caregiver's marital status, n (%)	
Married	7 (70)
Divorced	3 (30)
Education, n (%)	
High school	2 (20)
Professional training	1 (10)
University degree	7 (70)
Child's sex, n (%)	
Male	3 (30)
Female	7 (70)
Child's age, mean (SD)	10.6 (2.5)
Child's age at the start of the treatment, mean (SD)	5.9 (1.66)
Time under treatment (months), mean (SD)	60.3 (23.59)
Adherence rate to growth hormone therapy (%), mean (SD)	73.44 (28.6)

DASS-21 Scale

At baseline, DASS-21 showed that the majority of participants had no symptoms of depression (70%), anxiety (90%), or stress (70%). However, some of the participants had mild (20%) or moderate (10%) depression, severe anxiety (10%), and mild (20%) or severe (10%) stress, as described in Table 2.

XSL•FO
RenderX

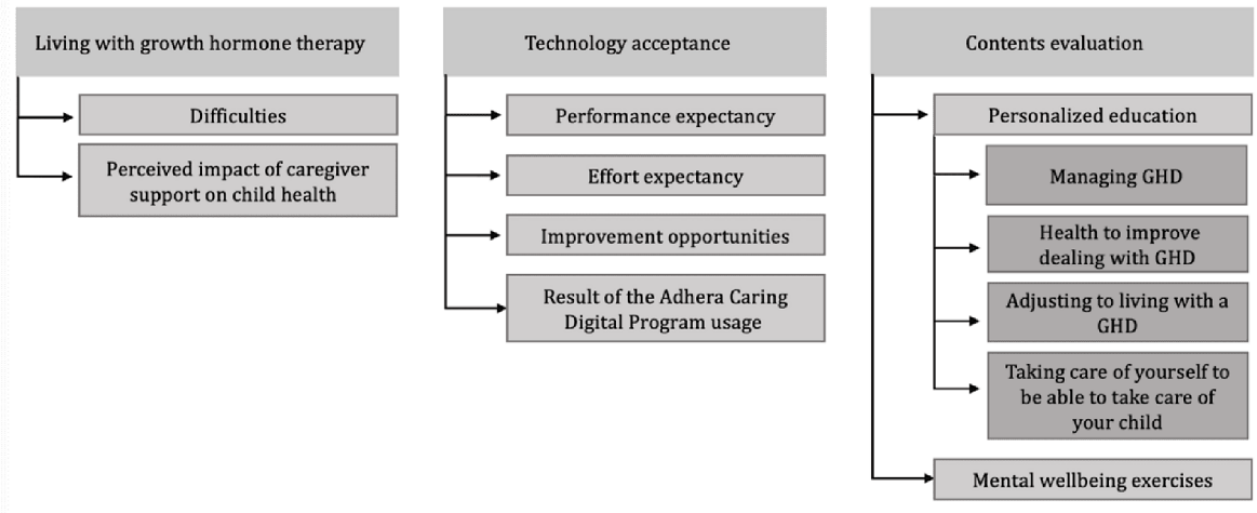
Table 2. Depression, Anxiety, and Stress Scale–21 results on baseline.

	Participants, n (%)
Depression	
Normal (0-4)	7 (70)
Mild (5-6)	2 (20)
Moderate (7-10)	1 (10)
Severe (11-13)	0 (0)
Extremely Severe (14+)	0 (0)
Anxiety	
Normal (0-3)	9 (90)
Mild (4-5)	0 (0)
Moderate (6-7)	0 (0)
Severe (8-9)	1 (10)
Extremely severe (10+)	0 (0)
Stress	
Normal (0-7)	7 (70)
Mild (8-9)	2 (20)
Moderate (10-12)	0 (0)
Severe (13-16)	1 (10)
Extremely severe (17+)	0 (0)

Interview Results

A total of 3 domains were identified as shown in Figure 2, that are living with GHt, technology acceptance, and contents evaluation, containing a total of 8 categories. Furthermore, 1 category comprehended 4 subcategories.

Figure 2. Categories or themes identified in the interviews. GHD: growth hormone deficiency.



Living With Growth Hormone Therapy

This domain encompasses the perceived impact of dealing with this condition on caregivers' everyday lives. In total, 2 categories were highlighted, difficulties and perceived impact of caregiver support on child health.

Difficulties

This category was not included as a specific question of the semistructured interview. However, caregivers expressed concern about common issues. Beyond the diagnosis, participants reported children's behavioral issues and individual characteristics that hinder the treatment administration. For instance, the child's difficulties in understanding the disease promoted their refusal of hormone treatment.

XSL•FO
RenderX

> *She is a complicated child (…) that is my main problem. I do not know if it's something to do with my daughter's character or if I do not know how to deal with it.* [Caregiver 06]

> *The child said "why do I have to do this? I do not mind. I do not mind that people do not like it."* [Caregiver 09]

Daily injections were reported to be difficult for both, children and caregivers. Participants also expressed great concern about their children's lack of autonomy toward treatment. As children get older and socialize outside the nuclear family, the lack of autonomy in treatment becomes more evident, limiting children's independence and increasing caregivers' distress.

> *She will be thirteen this summer, fourteen next summer, and that has caused me a lot of problems. I can't let her sleep anywhere, if I let her, I have to go and perform the injection. Wherever she is. This means that I can't leave her with friends. She tells me, "I want to sleep over." Well, no. If you don't inject by yourself, you can't stay. It is impossible to go camping. It is a medication that has to be in a refrigerator... that she does not inject herself. How are you going to send her? My daughter has never been to camp.*" [Caregiver 02]

Caregivers' fear of hurting their children or mismanaging treatment was also raised.

> *I don't know if there are many children who inject themselves. Maybe there are a lot, but I haven't been able to. It's impossible for him; he has needle phobia.* [Caregiver 02]

> *My mouth went dry every time I had to inject her.* [Caregiver 02]

Perceived Impact of Caregiver Support on Child Health

Participants were asked whether they felt that being supported could influence their children's health. Many participants agreed that it was important to maintain a certain level of calmness and well-being as they could be perceived as role models by the children. Consequently, it is likely that if caregivers are angry or anxious these feelings would be transmitted to their children, increasing resistance to treatment.

> *If the parents feel bad, the children will feel awful (...). If I was stressed at the beginning, I transmitted the stress to the child, and it wasn't good. The children see us as... well, "if mom says that everything is going to be fine, then it will be fine." It is very important [to know] that if we are down, we transmit fear to the children. I think it is very important.* [Caregiver 04]

The importance of achieving personal well-being in order to effectively care for others was also emphasized.

> *It would be the main subject of the twenty-second century: taking care of yourself in order to take care of others.* [Caregiver 09]

Technology Acceptance

This domain highlights that, in general, caregivers expressed a positive attitude toward the use of technology as emotional and self-management support during the growth hormone treatment.

During the analysis, four categories concerning the usefulness of the digital solution were identified, of which the first 2 were directly related to the UTAUT model: (1) performance expectancy, (2) effort expectancy, (3) improvement opportunities, and (4) result of the ACDP usage.

Performance Expectancy

According to the authors, this construct refers to the user's perception of how effectively the technology will help them achieve improvement [31]. In this study, performance expectancy refers to the caregiver's perception of the ACDP's usefulness, regarding emotional support and management of the GHt. Overall, the participants agreed with the idea that digital solutions can be a useful and positive means of supporting the role of caregivers. They often mentioned that the wide variety of resources present in the ACDP allows very different types of families enjoy appropriate support for their specific needs. For instance, some caregivers stated how the ACDP helped them normalize the GHD and explain it openly to their children while paying attention to maintaining children's self-esteem.

> *Overall, I found it very useful, not only the theoretical part but the messages that appear on your cell phone. …. It is not that I see a part that is not useful and another that is more useful. I understand that for each person there may be a part that is more useful than others... But in general, I would give it a 9… (out of 10).* [Caregiver 01]

> *I really liked it because, of course, I didn't know how to encourage my girl and how to explain to her that this is something normal.* [Caregiver 04]

In addition, the ubiquity of the resources in the ACDP, available anywhere and anytime, was also appreciated. This, together with the fact that they perceived the contents of this digital solution to be highly reliable and clinically validated, made the caregivers feel reassured.

> *It is good to include explanations because sometimes in the consultation you feel overwhelmed and end up having doubts. Then the application reminds you everything again.* [Caregiver 03]

> *Well, what I have seen is that this is the information that should be there. ... In a consultation with the doctor, he will explain the medical issues. Then, on your own, you will go to Google and you will also search for medical issues. You will find good, bad, and irrelevant information. In addition, the information might be useful for you or not, and you might rely on information unrelated to your case. That is due to how Google works and how a low-skilled person might interpret the information. Regarding the emotional side, I do consider that it would be a very good path, a very good course or training, to have it at the beginning because it has*

XSL•FO
RenderX

> *the information that needs to be there. For me, this is the starting point. From there, you can find more, but there's the information you need to have.* [Caregiver 09]

Nonetheless, one parent expressed that they preferred receiving face-to-face support rather than having a mobile app for this purpose. Also, they shared that their child did not have some of the behavioral issues mentioned in the program. Thus, the caregiver stated that they could not apply all the information received within the digital program to make the child understand the need for treatment, but they saw it as useful to support parents.

> *An application, no. A child psychologist, yes. A face-to-face, yes. I don't think the app would be useful [to make the child understand the need for treatment](...) Also, because of treatment insecurities, it would be useful for supporting parents, but through an app, I don't think it would work one hundred percent (...) I think that, apart from an application, a set [of activities] as well. A talk with parents...* [Caregiver 08]

Another person stated that one of the strategies proposed for managing the app was not suitable for their children because of their age. However, the caregiver expressed their will to continue trying other strategies suggested within the digital intervention.

> *And, in fact, I read it again and told her, "well, I'm going to try again and we're going to try to do it like this." Also, XXX is already 7 years old, so distracting her is complicated … no matter how much you form the habit: let's get her involved, let's play music, let's do it in some other way. She realizes it... You cannot fool her anymore. She knows that, in the end, [there is] an injection that she does not want. However, I will try these guidelines and ideas again.* [Caregiver 06]

Effort Expectancy

The effort expectancy concept refers to how easy the users perceive it will be to use a technology or system [31]. In this study, this construct is expressed in terms of the user experience and user interface, the structure of the information, and the degree of understandability.

The ACDP was described as easy to use by 8 participants. The adjectives "intuitive" and "beautiful" were also mentioned by some participants. It was stated that the user experience allows a peaceful state of mind which in turn facilitates the comprehension of its contents. The navigation flow was also appreciated.

> *I did not find it difficult. I found it, on the opposite side, very simple, very comfortable, very pleasant. Even the presentation of the application. Or I don't know what to call it, by folders and then more units. I find it very comfortable. I find it very nice. They are calm, it helps to make it more relaxed reading, which is what is needed for this type of information. It seems to me that you have taken great care of that.* [Caregiver 07]

However, 1 participant reported that she found the app neither pleasant nor unpleasant but contextualizing that was not important for her.

> *Neither particularly attractive nor obviously unpleasant [the application]. No, the design maybe... Because I pay little attention to those things and more to the information.* [Caregiver 01]

Most of the participants did not encounter technical issues while using the app. However, 3 users reported that they could not access a specific kind of notification related to motivational mobile-based messages. Another participant reported having issues accessing but it was smoothly solved through a password recovery process.

Regarding the understandability of the contents within the ACDP, most of the users described them as easily understandable, as the contents were described in a clear manner, using precise, direct, and natural language.

> *It seemed to me a very direct and very clear form of expression. It is very clear that anyone can understand it. That is very important. I found the information very clear. No difficult words or expressions that are difficult to understand. No, on the contrary, it seems to me that it is very well written. For easy understanding, yes. … They are like very short units that make you think. It doesn't make you read everything at once. It makes you think, and it is very good.* [Caregiver 07]

Nonetheless, a nonnative Spanish speaker reported that they would find some difficulties related to technical vocabulary related to the medical condition. These difficulties were solved by searching the words in a dictionary.

Finally, most of the users reported that the content was well-organized in diverse units, and provided brief pieces of information, with an interface similar to that of the social network platforms they are used to. This amount of information allowed for a better acquisition of knowledge and deeper reflections, compared with the relative overload of information that they felt during the diagnostic clinical visit.

> *The simplicity and clarity, the information come in very concise pills. It does not require a super long text that can make you feel tired, the information is very well dosed. … It is distributed in very chewable doses. In the open world we live in, we are more and more used to the Twitter context, with just a few characters. So, I think that this information and training is quite well dosed.* [Caregiver 01]

Improvement Opportunities

This category reflects that there is always room for improvement. The main limitation of the digital program was the moment in the patient journey when the digital program was introduced, which was mentioned by 7 participants. They declared that the digital intervention would have been especially useful right after the initial diagnosis, notwithstanding it still adds value to the GHD management at the present time.

XSL•FO
RenderX

> *I think I told you that at the beginning. I think it is a very positive, very good application. I think it will help families who are just starting out a lot, it will clarify things for them. And for families that have been using it for a long time, if it is shared with them, it will also strengthen what we have been doing for years. For those who are just starting out, it will really help them a lot more. As I was reading it I was saying "I wish I had had this when I started with this.*" [Caregiver 07]

The participants also commented on some desired additional content for the program. The parents mentioned that including techniques to involve the grandparents in the treatment (when possible) would be of interest. Also, a parent proposed including storytelling to reflect the reality of living with GHD. Thus, stories could be read before the treatment application, to help the child understand and normalize both the condition and its treatment.

> *I would look for more alternatives for the parents. It's very good to award prizes, it's very good to motivate them. But the motivation often also comes from the fact that there are alternatives for the children. I don't know [motivation] for them to start self-injecting. I don't know whether to look for other alternatives, other formulas, other... I don't know. Because I am looking for it, I told him, "be aware that if I inject you, you won't be able to stay anywhere. If I inject you, you won't be able to go camping." I don't know, look for some... some story motivating to [complete] a process, as ... the stories for children in the autism spectrum regarding how to go to a birthday, how to behave or socialize. I don't know if there is something uncomfortable like an injection, and there is some story or something that can be read to the children during nights that they can motivate themselves with. I don't know if there are any stories on the market. There surely will be.* [Caregiver 02]

Furthermore, some parents suggested that they would appreciate having a section with testimonials of other families living with GHD so that they could learn from others' experiences, or even get in touch with other families. Finally, a participant stressed the task of having a larger number of mindfulness and breathing exercises.

> *I don't think anything should be removed. Add what I was telling you, apart from those two small meditation and breathing practices. If there were any more, it would be good. I don't know if there could be some kind of sharing of experiences among people who are among parents, among children. Surely there are resources that we can use with each other... or situations how to handle them. I don't know if it is feasible in the application or not.* [Caregiver 06]

Result of the Adhera Caring Digital Program Usage

All the core ideas regarding the benefits of using the program fall within this category. Participants agreed with several benefits that the ACDP had provided them. On the one hand, it allows the normalization of their children's condition. This generates, for instance, increased self-esteem and decreased embarrassment in children. On the other hand, parents indicated that using the app leads to clarification of general concepts and knowledge about the disease, which empowers them. Finally, in the case of joint use with their children, the improvement in the relationship between caregivers and children was highlighted. The above-mentioned practical exercises have been described as "their moment together," which would be missed after the study was completed.

> *It's a perfectly normal thing, it's not like this happened to my daughter and she was born like this. It's normal. It's a disease like any other that can be cured. … she was a little embarrassed and [after] reading that with me... well, "look, I shouldn't be ashamed, that's the way it is. On the contrary, I have to say that I am brave, look. That I inject myself. And I'm going to grow up, and there's no problem." … I think I get along with her much better than before. It gives her more confidence, I don't know how to explain it. We accept it more.* [Caregiver 04]

Contents Evaluation

This domain encompasses the evaluation of the specific contents included in 2 components of the ACDP, personalized educational and mental well-being exercises.

Personalized Education

This category was organized in subcategories regarding the 4 sections of the personalized education section of the ACDP.

A. Managing GHD

In this section of the program, caregivers could obtain general information and advice on treatment management. Although it has been noted that this could be redundant as it is an explanation that the family receives when the patient is diagnosed, most participants agreed that receiving accurate and clear information resulted in a great benefit. Specifically, a sense of increased self-confidence and acceptance was highlighted in both patients and caregivers.

> *This information is missing at the beginning and creates uncertainty. Thinking about what we put in it and what effects it will have.* [Caregiver 08]

Among the most frequent core ideas were advice on how to mitigate the pain of the injection, or the reward system to promote treatment self-management.

> *(Talking about benefits of using the solution). Using ice or talking about something else... the typical advice given to mitigate the pain perception due to injections or the information given. For example, I read that sometimes it causes pain and other times it does not. It is something that we have experienced, and it is not known why. To me, it is something that catches my attention. I never knew if it was because the child was complaining because it really hurts, or because the needle is really very fine. So, I think having that knowledge regarding sometimes it hurts*

XSL•FO
RenderX

but you don't know why and sometimes it doesn't hurt is really important. [Caregiver 07]

B. Health Habits to Improve Dealing With GHD

Some units of the personalized education section were aimed at promoting healthy habits and, more specifically, enhancing healthier eating and sleeping habits. Overall, these contents were labeled as "interesting" and "important." However, 3 participants reported that they were already aware of that information since it had been provided by schools and pediatric health care providers. To them, this information was not that necessary.

Well, less useful, but not because they are not useful. Perhaps, for example, the component focused on healthy eating. It is very general information, but remembering it is important because not all families have the same opinion regarding diet or the importance of healthy eating. But maybe that's the less useful part if I have to say one. [Caregiver 07]

C. Adjusting to Living With a GHD

Considering the emotional impact of the diagnosis on the children's mental health, the program proposed the necessity of providing clear information about emotions and advice on how to strengthen the bond with the caregivers. Participants evaluated positively this content, being a topic that is rarely addressed by medical staff at diagnosis.

In my case, the first section related to the disorder. I can remember things that perhaps would have been forgotten. [Caregiver 06]

D. Taking Care of Yourself to Be Able to Take Care of Your Child

In line with the aforementioned, it is also important to consider the circular process of caring for oneself in order to care for others. Therefore, more content concerning the emotional management of caregivers was also suggested. They acknowledged the importance of their own emotional issues in the development of their children's treatment.

Mental Well-Being Exercises

These exercises included visually guided mindfulness and breathing exercises. This category gathers the users' opinions regarding mental well-being exercises. A caregiver described that practicing these exercises before applying the treatment had strengthened their relationship.

... I think I get along with her much better than before ... "mom, look what I can do." It gives her more confidence, I don't know how to explain it. ... It's our moment. She even told me the day before yesterday "when I don't do the sessions anymore it will seem strange to me, mom. That was our moment" I think it affects a lot, we talk about many things, and since we read it together (talking about the educational content) ... we commented on it. [Caregiver 04]

Some caregivers expressed their curiosity toward these practical exercises and found them appealing and enjoyable. Only 1 caregiver reported that they did not receive any benefit from these exercises, which might be related to their specific preferences as stated.

I especially liked the meditation practice. And I would tell you, I would include a little bit more. Regarding caregivers, I liked all contents focused on working as a support, as a caregiver. [Caregiver 03]

Discussion

Principal Findings

Caregivers of children undergoing GHt have reported several factors such as difficulties in understanding the disease or fear of hurting their children that may significantly impact the disease management. The role of caregivers is crucial in the management of GHD, and they have reported their well-being as a very important factor in being able to care for their children. Indeed, our results show that some caregivers have symptoms of depression, anxiety, or stress. In these circumstances, digital health enables the provision of digital services and tools supporting them in the care of their well-being and in the management of their children's disease. In this study, caregivers have expressed a positive attitude toward the use of mHealth solutions for health and well-being management. This finding is in line with those reported by other authors [32]. The results of this study support the ACDP as a feasible and potentially effective tool for caregivers of children undergoing treatment for GHD.

Caregivers' empowerment plays a key role in the effective management of GHD. Unfortunately, during routine consultations, it is not always feasible to cover all the aspects and doubts related to chronic diseases [32], especially the mental well-being of the caregiver. Digital health allows the provision of educational materials that are available just in time. Educational content must be designed not only to cover any lack of knowledge but also to encourage, empower, and optimize the caregivers' role as a manager of the GHD. In this study, caregivers realized and expressed the importance of emotional well-being as well as healthy habits and adequate control of unpleasant situations related to their child's condition. Considering that treatment adherence and the patient's health can be influenced by the caregiver's mental health [17], the ACDP can be a valuable part of the caregiver and patient journey. It is especially relevant once some participants expressed that the subcategory "family adjusting to living with a GHD" is not a common subject addressed during the diagnosis consultations. In this sense, participants in this study considered important not only the educational content but also the dispensing time of the digital health solution. Caregivers consider that the digital program is so useful that should be offered right after the diagnosis of the disease. To maximize their usefulness, digital health programs focused on helping caregivers manage their mental well-being and the day-to-day of their children's disease should be offered at the right time. Furthermore, it was suggested to include a testimonials section or a virtual space where families in the same situation can be in touch. These social features may impact user's motivation resulting in an increased adoption rate. This finding reinforces the fact that digital health can offer effective and motivational

XSL•FO
RenderX

services for caregivers' unmet needs that complement clinical practice [33,34].

Regarding the technology acceptance defined by the UTAUT theory [22-25], ACDP has been perceived positively by caregivers on performance expectancy and effort expectancy. The most important points of digital health solutions are that they can be used autonomously in the natural environment of the user, so usefulness, ease of use, and likeability are key [35,36]. The results indicate that the program seems to adjust to the core aspects of digital solutions as well as to cover all the needs and difficulties of participant caregivers of children and the user experience leads to a peaceful state of mind. Caregivers' stress levels can affect treatment adherence and the child's health [16], so giving them different tools to manage the disease seems to be a cardinal element in improving the quality of life of both. Therefore, understanding the factors that influence caregivers' adoption and acceptance of mHealth apps is essential for the development of effective digital health interventions [20]. Our study contributes to this understanding, addressing the barriers to acceptance, and adoption among caregivers managing pediatric diseases, including data security.

An interesting result is that the program has become a familiar intervention even though its target is caregivers. Some parents used mental well-being exercises together with their children, which has been reported as a great tool to improve the relationship between the caregiver and the child. Further research with higher samples will be conducted to explore deeply this promising result and analyze how this family intervention could impact caregivers' motivation, engagement, and well-being.

Limitations

This is a local study located in Zaragoza (Spain) with a small sample of 10 caregivers. Because of inclusion and exclusion criteria, people with low digital literacy were not able to participate. Interviewers were not experts but received training for the purpose of the study. Besides, although the general prevalence of GHD is higher in boys, most caregivers participating in this study were female with daughters affected with GHD, thus, parents with GHD sons might be underrepresented as well as male caregivers. Finally, the program needs further study to include recently diagnosed children.

Although there are quantitative questionnaires to measure the acceptability of digital solutions [37,38], we opted for a qualitative approach in order to get a more comprehensive understanding of the psychological burden experienced by caregivers of children undergoing growth hormone treatment, as well on the factors that influence the acceptability of the digital solution. Due to the post-positivist nature of the consensual qualitative research methodology, an interjudge reliability index is not calculated. However, trustworthiness in the qualitative analysis is guaranteed through iterative discussions between reviewers to share their independent interpretation of the qualitative data. Where consensus is not achieved, a deeper discussion is held until consensus is reached or a third independent reviewer is consulted.

Conclusions

In conclusion, the ACDP shows good acceptance results for family caregivers of children undergoing GHt. The interviews helped identify aspects for further refinement and improvement of the program, including a more intensive focus on the communication between parents and children. This study provides insights into how digital interventions can better support families of children undergoing growth hormone treatment.

Acknowledgments

OR-R has received funding from the Universidad de Sevilla, the Ministerio de Universidades of the Spanish Government under the call "Recualificación del Sistema Español de Universidades" funded by European Union–NextGenerationEU. We thank AR Conde-Moro for her assistance in editing this manuscript. We want to thank the study participants and the rest of the clinical team at HUMS (Hospital Universitario Miguel Servet) and Adhera Health.

This investigator-initiated study was financially supported by Merck Healthcare KGaA, Darmstadt Germany (CrossRef Funder ID: 10.13039/100009945). Merck reviewed the manuscript for medical accuracy only before the submission. The authors are fully responsible for the content of this manuscript, and the views and opinions described in the publication reflect solely those of the authors.

Data Availability

The datasets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

LF-L contributed to conceptualization, funding acquisition, supervision, project administration, methodology, resources, writing-original draft, and writing-review and editing. AA contributed to conceptualization, supervision, investigation, methodology, data curation, project administration, resources, writing-original draft, and writing-review and editing. RCB contributed to funding acquisition, project administration, writing-original draft, and writing-review and editing. SQ-P contributed to formal analysis, visualization, writing-original draft, and writing-review and editing. AS-U and PMC contributed to investigation. RB, AJ-D, MP,

XSL•FO
RenderX

and RH contributed to data curation, formal analysis, and visualization. OR-R contributed to validation, writing-original draft, and writing-review and edition. No artificial intelligence tools were used in any portion of the manuscript.

Conflicts of Interest

This study is about a digital solution developed and commercialized by Adhera Health. Adhera Health, AA, and OR-R have other collaborations with Merck Healthcare KGaA beyond this study.

Multimedia Appendix 1
Quotes from participants.
[DOCX File , 141 KB - pediatrics_v8i1e55023_app1.docx]

References

1. Dattani MT, Malhotra N. A review of growth hormone deficiency. Paediatrics and Child Health 2019;29(7):285-292. [doi: 10.1016/j.paed.2019.04.001]
2. Ranke MB, Wit JM. Growth hormone - past, present and future. Nat Rev Endocrinol 2018;14(5):285-300. [doi: 10.1038/nrendo.2018.22] [Medline: 29546874]
3. Cutfield WS, Derraik JGB, Gunn AJ, Reid K, Delany T, Robinson E, et al. Non-compliance with growth hormone treatment in children is common and impairs linear growth. PLoS One 2011;6(1):e16223 [FREE Full text] [doi: 10.1371/journal.pone.0016223] [Medline: 21305004]
4. Savage MO, Fernandez-Luque L, Graham S, van Dommelen P, Araujo M, de Arriba A, et al. Adherence to r-hGH therapy in pediatric growth hormone deficiency: current perspectives on how patient-generated data will transform r-hGH treatment towards integrated care. Patient Prefer Adherence 2022;16:1663-1671 [FREE Full text] [doi: 10.2147/PPA.S271453] [Medline: 35846871]
5. Fisher BG, Acerini CL. Understanding the growth hormone therapy adherence paradigm: a systematic review. Horm Res Paediatr 2013;79(4):189-196 [FREE Full text] [doi: 10.1159/000350251] [Medline: 23635797]
6. Stephen MD, Varni JW, Limbers CA, Yafi M, Heptulla RA, Renukuntla VS, et al. Health-related quality of life and cognitive functioning in pediatric short stature: comparison of growth-hormone-naïve, growth-hormone-treated, and healthy samples. Eur J Pediatr 2011;170(3):351-358. [doi: 10.1007/s00431-010-1299-z] [Medline: 20886355]
7. Varni JW, Limbers CA, Bryant WP, Wilson DP. Assessment of fatigue in pediatric patients with short stature utilizing the PedsQL™ multidimensional fatigue scale. Children's Health Care 2012;41(2):162-181. [doi: 10.1080/02739615.2012.657068]
8. Skuse D, Gilmour J, Tian CS, Hindmarsh P. Psychosocial assessment of children with short stature: a preliminary report. Acta Paediatr Suppl 1994;406:11-6; discussion 17. [doi: 10.1111/j.1651-2227.1994.tb13413.x] [Medline: 7734805]
9. Stabler B. Impact of growth hormone (GH) therapy on quality of life along the lifespan of GH-treated patients. Horm Res 2001;56 Suppl 1:55-58. [doi: 10.1159/000048136] [Medline: 11786687]
10. Stabler B, Clopper RR, Siegel PT, Stoppani C, Compton PG, Underwood LE. Academic achievement and psychological adjustment in short children. The national cooperative growth study. J Dev Behav Pediatr 1994;15(1):1-6. [doi: 10.1097/00004703-199402000-00001] [Medline: 8195431]
11. Abbott D, Rotnem D, Genel M, Cohen DJ. Cognitive and emotional functioning in hypopituitary short-statured children. Schizophr Bull 1982;8(2):310-319. [doi: 10.1093/schbul/8.2.310] [Medline: 7112044]
12. Sartorio A, Conti A, Molinari E, Riva G, Morabito F, Faglia G. Growth, growth hormone and cognitive functions. Horm Res 1996;45(1-2):23-29. [doi: 10.1159/000184754] [Medline: 8742114]
13. Wheeler PG, Bresnahan K, Shephard BA, Lau J, Balk EM. Short stature and functional impairment: a systematic review. Arch Pediatr Adolesc Med 2004;158(3):236-243. [doi: 10.1001/archpedi.158.3.236] [Medline: 14993082]
14. Sandberg DE, Bukowski WM, Fung CM, Noll RB. Height and social adjustment: are extremes a cause for concern and action? Pediatrics 2004;114(3):744-750. [doi: 10.1542/peds.2003-1169-L] [Medline: 15342848]
15. Abe S, Okumura A, Mukae T, Nakazawa T, Niijima SI, Yamashiro Y, et al. Depressive tendency in children with growth hormone deficiency. J Paediatr Child Health 2009;45(11):636-640. [doi: 10.1111/j.1440-1754.2009.01586.x] [Medline: 19845844]
16. Raina P, O'Donnell M, Schwellnus H, Rosenbaum P, King G, Brehaut J, et al. Caregiving process and caregiver burden: conceptual models to guide research and practice. BMC Pediatr 2004;4:1 [FREE Full text] [doi: 10.1186/1471-2431-4-1] [Medline: 14723791]
17. Silva N, Bullinger M, Sommer R, Rohenkohl A, Witt S, Quitmann J. Children's psychosocial functioning and parents' quality of life in paediatric short stature: the mediating role of caregiving stress. Clin Psychol Psychother 2018;25(1):e107-e118. [doi: 10.1002/cpp.2146] [Medline: 28960605]
18. Eckshtain D, Ellis DA, Kolmodin K, Naar-King S. The effects of parental depression and parenting practices on depressive symptoms and metabolic control in urban youth with insulin dependent diabetes. J Pediatr Psychol 2010;35(4):426-435 [FREE Full text] [doi: 10.1093/jpepsy/jsp068] [Medline: 19710249]

XSL•FO
RenderX

19. Mayberry LS, Berg CA, Harper KJ, Osborn CY. The design, usability, and feasibility of a family-focused diabetes self-care support mHealth intervention for diverse, low-income adults with type 2 diabetes. J Diabetes Res 2016;2016:7586385 [FREE Full text] [doi: 10.1155/2016/7586385] [Medline: 27891524]
20. Fernandez-Luque L, Labarta JI, Palmer E, Koledova E. Content analysis of apps for growth monitoring and growth hormone treatment: systematic search in the android app store. JMIR Mhealth Uhealth 2020;8(2):e16208 [FREE Full text] [doi: 10.2196/16208] [Medline: 32130162]
21. Davis FD. A Technology Acceptance Model for Empirically Testing New End-User Information Systems: Theory and Results. 1985. URL: https://dspace.mit.edu/handle/1721.1/15192 [accessed 2022-10-17]
22. Venkatesh V, Speier C, Morris MG. User acceptance enablers in individual decision making about technology: toward an integrated model. Decision Sciences 2007;33(2):297-316. [doi: 10.1111/j.1540-5915.2002.tb01646.x]
23. Adjei TK, Mohammed A, Acheampong PR, Acquah-Gyan E, Sylverken A, Twumasi-Ankrah S, et al. Determinants of a mobile phone-based Interactive Voice Response (mIVR) system for monitoring childhood illnesses in a rural district of Ghana: Empirical evidence from the UTAUT model. PLoS One 2021;16(3):e0248363 [FREE Full text] [doi: 10.1371/journal.pone.0248363] [Medline: 33705448]
24. LeRouge CM, Hah H, Deckard GJ, Jiang H. Designing for the co-use of consumer health technology in self-management of adolescent overweight and obesity: mixed methods qualitative study. JMIR Mhealth Uhealth 2020;8(6):e18391 [FREE Full text] [doi: 10.2196/18391] [Medline: 32597788]
25. Dai B, Larnyo E, Tetteh EA, Aboagye AK, Musah AAI. Factors affecting caregivers' acceptance of the use of wearable devices by patients with dementia: an extension of the unified theory of acceptance and use of technology model. Am J Alzheimers Dis Other Demen 2020;35:1533317519883493 [FREE Full text] [doi: 10.1177/1533317519883493] [Medline: 31679390]
26. Rodríguez Arnao MD, Rodríguez Sánchez A, Díez López I, Ramírez Fernández J, Bermúdez de la Vega JA, Yeste Fernández D, et al. Adherence and long-term outcomes of growth hormone therapy with easypod™ in pediatric subjects: Spanish ECOS study. Endocr Connect 2019;8(9):1240-1249 [FREE Full text] [doi: 10.1530/EC-19-0325] [Medline: 31484160]
27. de Arriba Muñoz A, Muñiz VC, Saez JJA, Beisti A, Llovet E, Aizpún JIL. Impact of adherence on growth response during the first 2 years of growth hormone treatment. Endocrine 2021;72(2):513-523. [doi: 10.1007/s12020-020-02560-6] [Medline: 33284395]
28. Lovibond S, Lovibond P. Depression Anxiety Stress Scales. NSW: Psychology Foundation of Australia; 1995.
29. Ng F, Trauer T, Dodd S, Callaly T, Campbell S, Berk M. The validity of the 21-item version of the depression anxiety stress scales as a routine clinical outcome measure. Acta Neuropsychiatr 2007;19(5):304-310. [doi: 10.1111/j.1601-5215.2007.00217.x] [Medline: 26952943]
30. Cervera-Torres S, Núñez-Benjumea FJ, de Arriba Muñoz A, Chicchi Giglioli IA, Fernández-Luque L. Digital health for emotional and self-management support of caregivers of children receiving growth hormone treatment: a feasibility study protocol. BMC Med Inform Decis Mak 2022;22(1):215 [FREE Full text] [doi: 10.1186/s12911-022-01935-1] [Medline: 35964116]
31. de Vries H. An integrated approach for understanding health behavior; the I-change model as an example. PBSIJ 2017;2(2). [doi: 10.19080/PBSIJ.2017.02.555585]
32. Venkatesh V, Morris MG, Davis GB, Davis FD. User Acceptance of Information Technology: Toward a Unified View. MIS Quarterly 2003;27(3):425-478. [doi: 10.2307/30036540]
33. Hill CE, Knox S, Thompson BJ, Williams EN, Hess SA, Ladany N. Consensual qualitative research: An update. Journal of Counseling Psychology 2005;52(2):196-205. [doi: 10.1037/0022-0167.52.2.196]
34. Hill CE, Knox S. Conceptual foundations of consensual qualitative research. Essentials of consensual qualitative research 2021:3-10. [doi: 10.1037/0000215-001]
35. Rodríguez Torres A, Jarillo Soto EC, Casas Patiño D. Medical consultation, time and duration. Medwave 2018;18(5):e7266. [doi: 10.5867/medwave.2018.05.7264] [Medline: 30312289]
36. Xu X, Griva K, Koh M, Lum E, Tan WS, Thng S, et al. Creating a smartphone app for caregivers of children with atopic dermatitis with caregivers, health care professionals, and digital health experts: participatory co-design. JMIR Mhealth Uhealth 2020;8(10):e16898 [FREE Full text] [doi: 10.2196/16898] [Medline: 33118949]
37. Miguel Cruz A, Lopez Portillo HP, Daum C, Rutledge E, King S, Liu L. Technology acceptance and usability of a mobile app to support the workflow of health care aides who provide services to older adults: pilot mixed methods study. JMIR Aging 2022;5(2):e37521 [FREE Full text] [doi: 10.2196/37521] [Medline: 35583930]
38. Fitrianie S, Horsch C, Beun RJ, Griffioen-Both F, Brinkman WP. Factors affecting user's behavioral intention and use of a mobile-phone-delivered cognitive behavioral therapy for insomnia: a small-scale UTAUT analysis. J Med Syst 2021;45(12):110 [FREE Full text] [doi: 10.1007/s10916-021-01785-w] [Medline: 34767084]

Abbreviations

ACDP: Adhera Caring Digital Program
DASS-21: Depression, Anxiety and Stress Scale–21

XSL•FO
RenderX

GHD: growth hormone deficiency
GHt: growth hormone therapy
HrQoL: health-related quality of life
ISO: International Organization for Standardization
mHealth: mobile health
rhGH: recombinant human growth hormone
TAM: Technology Acceptance Model
UTAUT: Unified Theory of Acceptance and Use of Technology

Edited by S Badawy; submitted 30.11.23; peer-reviewed by G Engvall, S C. Torres, P Codyre, N Chambers; comments to author 16.05.24; revised version received 16.09.24; accepted 26.10.24; published 05.02.25.

Please cite as:
Jiménez-Díaz A, Pierantonelli M, Morte Coscolín P, Salinas-Uhalte A, Quer-Palomas S, Rivera-Romero O, Herrero R, Fernández-Luque L, Baños R, Berrios RC, de Arriba A
Digital Health Program to Support Family Caregivers of Children Undergoing Growth Hormone Therapy: Qualitative Feasibility Study
JMIR Pediatr Parent 2025;8:e55023
URL: https://pediatrics.jmir.org/2025/1/e55023
doi:10.2196/55023
PMID:39908086

©Alba Jiménez-Díaz, Maitena Pierantonelli, Patricia Morte Coscolín, Amaia Salinas-Uhalte, Silvia Quer-Palomas, Octavio Rivera-Romero, Rocío Herrero, Luis Fernández-Luque, Rosa Baños, Ricardo C Berrios, Antonio de Arriba. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 05.02.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Community Caregivers' Perspectives on Health IT Use for Children With Medical Complexity: Qualitative Interview Study

Farah Elkourdi[1], MS; Onur Asan[1], PhD

Department of Systems and Enterprises, Stevens Institute of Technology, Hoboken, NJ, United States

Corresponding Author:
Onur Asan, PhD
Department of Systems and Enterprises
Stevens Institute of Technology
1 Castle Point Terrace
Hoboken, NJ, 07030
United States
Phone: 1 2012165514
Email: oasan@stevens.edu

Abstract

Background: Children with medical complexity represent a unique pediatric population requiring extensive health care needs and care coordination. Children with medical complexities have multiple significant chronic health problems that affect multiple organ systems and result in functional limitations and high health care needs or use. Often, there is a need for medical technology and total care for activities of daily living, much of which is provided at home by family and caregivers. Health IT (HIT) is a broad term that includes various technologies, such as patient portals, telemedicine, and mobile health apps. These tools can improve the care of children with medical complexity by enhancing communication, information exchange, medical safety, care coordination, and shared decision-making. In this study, we identified children with medical complexity as children aged <21 years who have >3 chronic health conditions. Community caregivers contribute to the care management of children with medical complexity, serving as advocates and coordinators, primary sources of information about children's needs, and facilitators of access to care. They are often the first point of contact for the families of children with medical complexity, particularly in vulnerable communities, including families in rural areas, low-income households, and non–English-speaking immigrant populations.

Objective: This study aims to introduce the HIT needs and preferences for children with medical complexity from the perspective of community caregivers. By including their perspective on HIT development, we can better appreciate the challenges they face, the insights they offer, and the ways in which they bridge gaps in care, support, and resources.

Methods: We conducted semistructured interviews (n=12) with formal community caregivers of children with medical complexity populations from a parent advocacy network on the US East Coast. Interviews were audio recorded via Zoom and then transcribed. An inductive thematic analysis was conducted to reveal HIT challenges and preferences for improving the care of children with medical complexity.

Results: We categorized the interview results into themes and subthemes. There are four main themes: (1) telehealth transforming care for children with medical complexity during the COVID-19 pandemic, (2) suggested tools and technologies for care for children with medical complexity, (3) HIT feature preferences, and (4) transition to adult care. Each theme had multiple subthemes capturing all details related to design features of needed technologies.

Conclusions: The study emphasizes the need to develop and enhance HIT for the care of children with medical complexity. The identified themes can serve as design guidelines for designers by establishing a foundation for user-centered HIT tools to effectively support children with medical complexity and their families. Telehealth and mobile health apps could improve care management and quality of life for children with medical complexity.

(JMIR Pediatr Parent 2025;8:e67289) doi:10.2196/67289

KEYWORDS

pediatric care; children with medical complexity; family-centered care; health information technology; health care software solutions; mobile phone; artificial intelligence

XSL•FO
RenderX

Introduction

Background

Children with medical complexity are a unique group within the pediatric population, characterized by diverse and significant medical needs. Though they represent <1% of children in the United States, children with medical complexities face chronic health conditions that are severe and enduring [1]. These children, all aged <21 years, often have congenital or acquired multisystem diseases or severe neurological conditions that lead to substantial functional impairments [2]. Although there is no universal definition, we used the most common criteria in our study for children with medical complexity as children aged <21 years who have >3 chronic health conditions [2].

Caring for children with medical complexity requires collaboration among stakeholders, including parents, health care providers in hospitals and clinics, school and home nurses, and community caregivers. Despite efforts, the challenges in coordinating care for these children persist, remaining largely unresolved [3]. These challenges include barriers to technology systems, inadequate access to health information, and a lack of partnership in care [4]. The burden of managing these complex medical needs falls heavily on parents, who often experience a significant caregiver burden [5].

Various technologies have been used in health care to improve the quality-of-care process. Health IT (HIT), including patient portals, telemedicine, and mobile health apps, has the potential to help with data management, sharing, and care coordination [6]. These HITs can positively impact medical outcomes, including physical, psychological, and continuity of care [7], minimize medication errors, and provide safer care [8]. For instance, telehealth emerged as a primary technology to provide safer care to children with medical complexity during the COVID-19 pandemic. Children with medical complexity is a vulnerable population that can benefit from technological interventions to improve care management, including information exchange, shared decision-making, and follow-up [9]. However, there is a need for studies to evaluate the effectiveness of HIT in caring for the children with medical complexity population and to identify the challenges and limitations associated with it. It is also critical to explore strategies for safely and effectively integrating HIT into the overall care management of children with medical complexity [10-12].

While parents are responsible for the day-to-day care of their children, community caregivers play a broader role by helping parents navigate complex health care systems. In addition, they ensure that children with medical complexities become fully participating and contributing members of their communities [13]. Community caregivers contribute to the care management of children with medical complexity, serving as advocates, coordinators, primary sources of information about children's needs, and facilitators of access to care [13]. In addition, they support families in vulnerable communities who have a child with a medical complexity, including families in rural areas, low-income households, and non–English-speaking immigrant populations [13,14]. Their experience navigating health care systems and HIT enables them to identify gaps in care and areas for improvement. Understanding their feedback and perspective on the use of technology in care for children with medical complexity is essential.

Objective

This study aimed to fill this gap by exploring how current tools and technologies are used and how they can be further optimized to meet the specific needs of children with medical complexity from the viewpoint of community caregivers. By gathering their insights, challenges, and recommendations, this study seeks to guide the development of technological solutions that enhance communication among stakeholders and improve the quality of life for children with medical complexity and their families. To our knowledge, this is the first study to specifically address technology suggestions from the perspective of formal community caregivers.

Methods

Study Design and Data Collection

We recruited formal community caregivers of children with medical complexity populations from the Parent Advocacy Network organization based in New Jersey in the United States, which was founded by the parents of children with special needs in 1987 to provide support to the families of patients with special needs [13]. The staff have supported >500 families of children with medical complexity in New Jersey for many years. We disseminated an informative recruitment email to all the staff members to participate in our study. Most of the staff are also parents of patients with special needs. We used a theoretical data saturation approach in recruitment. The saturation level was determined as the stage where adding more interviews would no longer enrich the conceptual depth of existing themes or reveal additional themes [15]. We ended up with 12 in-depth, semistructured interviews conducted from April 2023 to August 2023. Most (11/12, 92%) participants were female, and (1/12, 8%) participants were male. This study has an exploratory nature to identify various suggestions and needs in HIT design requirements for care for children with medical complexity. The exploratory nature of a qualitative approach generates very rich data and allows us to capture the caregivers' detailed experiences in the matter.

We conducted audio interviews over Zoom (Zoom Video Communications) and recorded all the interviews to be transcribed verbatim for the analysis. The interview guide included questions on the pros and cons of technologies used in care for children with medical complexity, user preferences and needs, suggestions for improving current technologies, telehealth experiences during the COVID-19 pandemic, and design recommendations for new technologies. We did ask probes when necessary to capture more details in unbiased ways. The audio interview was over Zoom per institutional review board requirement, so we did not record the video or observe any nonverbal cues. Each interview lasted from 45 to 60 minutes, and the participants' comfort level determined the duration in continuing to disclose their perceptions and share their experiences.

XSL•FO
RenderX

Data Analysis

The interviews were recorded, transcribed, and analyzed using inductive thematic analysis. The raw data were initially labeled into themes to capture essential data. The themes emerged upon comparing experiences views, situations, and contexts from the same and different participants, and we gradually refined the coding schema. We emerged themes by comparing experiences, views, situations, and contexts from the same and different participants and gradually refined the coding schema. The first author (FE) coded the data and created the themes and a codebook, which the second researcher (OA) validated and refined. Both authors performed the coding using Excel (Microsoft Corp).

During the data analysis process, the authors used an inductive approach to identify themes and understand technological needs, preferences, available options, challenges, and suggestions for improvements. The inductive approach is characterized by a search for patterns [16]. We identified 4 primary themes with their codes. After coding the data, both authors collaborated to categorize the data within each theme into subthemes. Subthemes define common dimensions within the main theme [17]. The objective was to explore the data beyond identifying common or dominant themes to uncover unique insights [18].

Ethical Considerations

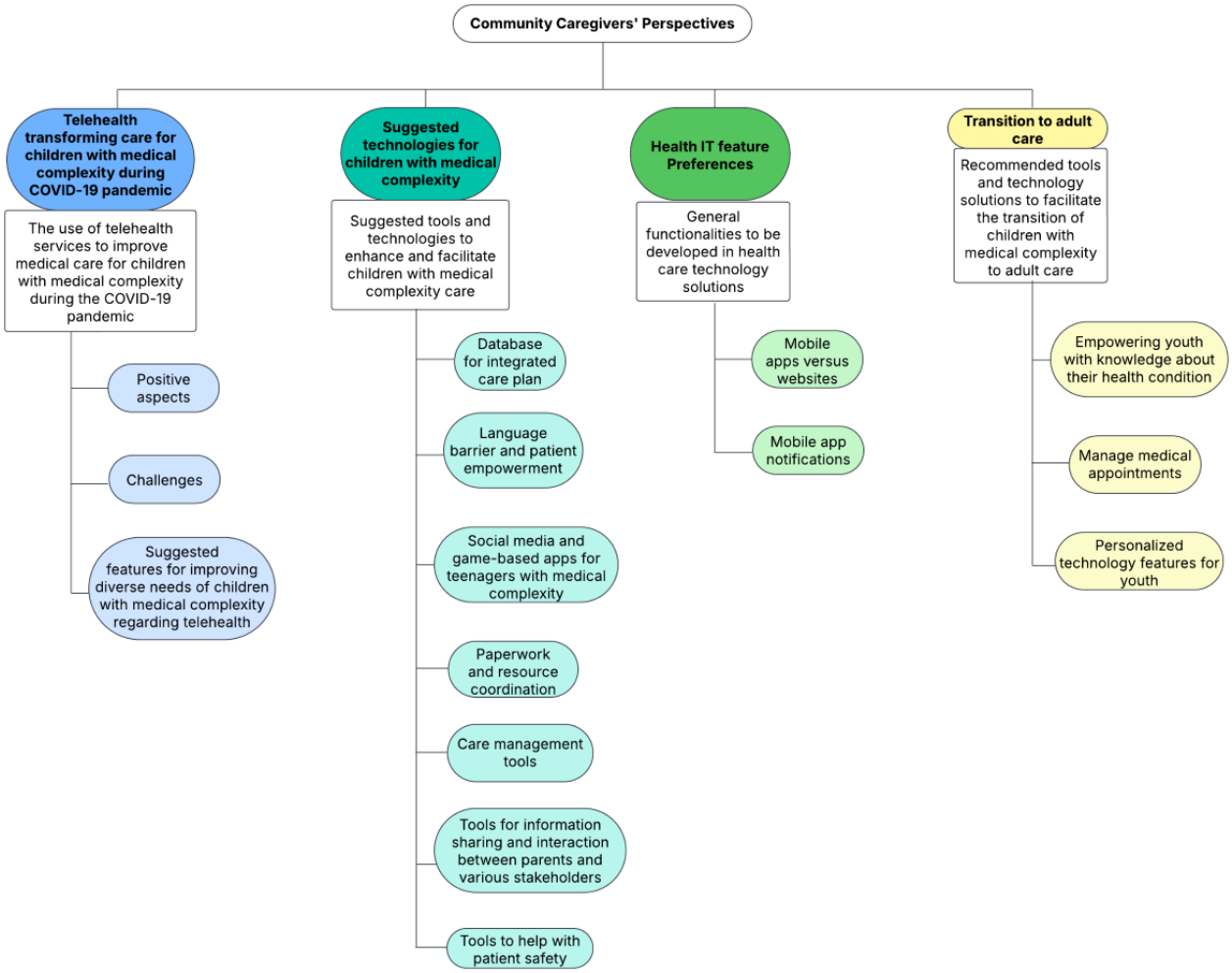
This qualitative study used semi-structured interviews to collect data after obtaining ethics approval (ID 2023-006 (N)) from the Stevens Institute of Technology. The data was de-identified and does not include any identifier. Participants were paid 30 dollars compensation upon completion of the interviews.

Results

Overview

The inductive analysis resulted in four major themes: (1) telehealth transforming care for children with medical complexity during the COVID-19 pandemic, (2) suggested tools and technologies for care for children with medical complexity, (3) HIT feature preferences, and (4) transition to adult care. Figure 1 shows the 4 major themes and associated subthemes.

Figure 1. Identified major themes and subthemes.



XSL•FO
RenderX

Theme 1: Telehealth Transforming Care for Children With Medical Complexity During the COVID-19 Pandemic

The first primary theme identified from the thematic analysis was telehealth use, which is defined as using telehealth services to improve medical care for children with medical complexity health needs during the COVID-19 pandemic. We also developed several subthemes for positive and negative perceptions regarding telehealth use in care for children with medical complexity and suggestions to improve telehealth technologies for care for children with medical complexity from caregivers' perspectives.

The diverse needs of children with medical complexity result in varying health outcomes from telehealth services, depending on the child's medical condition during the COVID-19 pandemic. For example, participant 9 reported improvements in the child's health through telehealth visits, while participant 10 expressed dissatisfaction with the health outcomes achieved through telehealth therapy sessions:

> *They are all so different. I have one parent that I know when they went virtual, it worked beautifully with her daughter, who has limited speech. It helped so much because she was able to navigate everything. She had clear expectations. She is very visual. So it actually helped a lot.* [Participant 9]

> *Occupational therapy, or the physical therapy or speech therapy, even some of these therapy sessions cannot be offered for children who have very limited understanding or limited functional skills so having those virtual sessions were not beneficial for them, or meaningful for them. For example, if the child cannot follow a direction because of their cognitive ability, or because of that developmental status, then the virtual therapy is not meaningful for them. If the physical therapist is giving the child this direction but then the child cannot move, so the parent has to be right next to the child so that they can either assist the child or they can model that to the child. So then it is a barrier. If the parents are busy with their work, or if they have other commitments then the child is not getting the meaningful therapy sessions.* [Participant 10]

However, the participants who are the community caregivers shared common points regarding positive aspects, challenges they observed children with medical complexity parents experiencing, and ideas for improving telehealth services. Multimedia Appendix 1 presents subthemes of the positive aspects of telehealth as perceived by participants, alongside the challenges and limitations they experienced. It also includes suggestions for improving telehealth services to address the diverse needs of children with medical complexity. We reported at least 1 sample quote for each identified subtheme. Positive aspects include just-in-time access to care services (telehealth provides easier access to a variety of needed health care providers), facilitating physician-patient or parent interaction (telehealth facilitates interaction and communication between parents and providers during the COVID-19 pandemic), and overcoming geographical barriers (mitigating the barriers in health care services resulting from physical distance). However, participants also identified several challenges, including technical difficulties (the challenges and issues related to the technology used for telehealth appointments that impact the accessibility of services), a lack of communication while transitioning to telehealth during COVID-19 pandemic (the difficulties experienced due to unclear communication while shifting to telehealth services during the COVID-19 pandemic), and simplicity for non–tech-savvy parents (the need for technology that is easy to use and navigate, especially for parents who are not comfortable using various digital tools). In addition, participants suggested several features to improve telehealth for children with medical complexity, including visual graphics (using visual elements to enhance communication and engagement during the telehealth session), educational components (enhancing users' understanding of telehealth), video and audio support (the critical need for high-quality video and audio technology in telehealth to facilitate effective and accurate communication between health care providers and patients), questionnaire addition (the integration of questionnaires into telehealth services), and providing variety of ways to communicate (offering diverse methods to facilitate communication for patients who may find it challenging to express themselves).

Theme 2: Suggested Tools and Technologies for Care for Children With Medical Complexity

This theme covers suggestions for developing tools and technologies to enhance and facilitate care for children with medical complexity. Participants suggested developing various tools and technologies to support themselves or the parents of children with medical complexity, along with the features to be added to existing technology, as shown in Multimedia Appendix 2. One suggestion was the creation of a database for integrated care plans, a comprehensive system to help families manage and coordinate all aspects of their child's health care. This would serve as a centralized database to provide a clear and organized record of their child's information:

> *The parents need to keep records and, when anything changes, be ready and clear on what needs to happen. Even if a home nurse is coming to assist the parents, the parents are still, as I like to refer to them, the captain of the ship. They are the ones who need to know everything there is to know about their child's health.* [Participant 12]

Participants also recommended tools to address language barriers and empower patients, aiming to overcome communication challenges between parents and health care providers arising from differences in languages or communication styles:

> *It becomes even more complex for my underserved families. For example, if the nurse needs to talk to the child's doctors because the parent does not speak English, the parent should still be included in all of those conversations.* [Participant 5]

> *Some of the medical terminology is very difficult to translate into the parents' native language. Although we have the technology in place, certain medical*

XSL•FO
RenderX

> *terms cannot be translated or interpreted in a way that parents can understand.* [Participant 7]

To enhance social development for teenagers with medical complexity, suggestions included social media and game-based apps designed to improve social skills and provide relevant health care information in engaging formats:

> *When things are developed in a very controlled setting, they work fabulously. However, as they trickle down into real life and society, and real people use them, often the system itself does not work as it should. For example, a system that allows communication without speech by exchanging pictures might help children, but instead of encouraging language development, it may lead to them becoming too comfortable using pictures. When applied in real time, this is very challenging for them, and they are not motivated to become verbal. I have heard many parents complain about this. These should be considered social skill lessons. If a game or solution could be developed and applied to real life, that would be great.* [Participant 11]

Paperwork and resource coordination tools were also highlighted to help families organize and track paperwork and resources associated with their child's care:

> *Sometimes families are not always that organized. One of the things we always advise families is to write down information when they go to the doctor's office, whether in person or virtually. We encourage them to learn how to communicate effectively with doctors and schools and to centralize their paperwork in one place. Managing all the documents, doctor's notes, and medication records can be overwhelming, so it is important to teach families how to keep everything organized.* [Participant 3]

Regarding care management tools, participants suggested tools to assist parents with scheduling, tracking appointments, and managing medications:

> *Medications themselves can be particularly difficult to manage. Understanding and managing prescriptions, including knowing when to refill medications. There are complex instructions like "do not give this one with that one," "take this one with food," "this one needs to be refrigerated," and "this one is an intramuscular injection." With so many different medications and dosages, it can be overwhelming. For example, the same medication might require two pills in the morning and only one at night, which can change on the same day.* [Participant 3]

In addition, suggestions were made for tools to facilitate the exchange of information between parents, medical providers, and other care providers. Effective communication is essential for informed care coordination and comprehensive childcare:

> *Text-like feature that allows parents to choose who they want to include in a conversation. Parents do not necessarily want the school involved when it comes to medical matters. But it could have that option where the parent can choose to include people. It should have easy access to sharing and being able to pick and choose what you share and with whom. Making sure that the parent has control and is aware of who is getting what information.* [Participant 9]

Finally, the participants suggested tools to minimize risks and prevent errors in the care of children with medical complexity:

> *I think there is a need for tools and features that support children with medical complexity care to minimize risks. Unfortunately, families are sometimes the care managers. So, for example, if a child needs a diet for a gastrointestinal condition, yet also has kidney disease. They would need to consult with the medical team before they could give that diet and often that does not happen. The family has to say that this child has this medical condition and has to coordinate care between different teams, and it should not be that way, particularly with the availability of electronic health records. But unfortunately, they do not necessarily read the charts, or they are so siloed that they are only focused on their specific specialty.* [Participant 5]

Theme 3: HIT Feature Preferences

The analysis showed another major theme around general recommendations preferred in HIT. This theme may assist system and software engineers in developing effective platforms that meet the needs of parents and supporters of children with medical complexity. Understanding these shared preferences is essential for designing technology that provides meaningful support and enhances engagement. The participants expressed their preferences for mobile apps and websites. They valued the convenience of mobile apps for quick access. In addition, mobile apps are beneficial for caregivers or patients with disabilities. However, they recognized that older adults caring for grandchildren with medical complexity prefer websites for their ability to display information on larger screens, such as laptops. The participants also emphasized the importance of mobile app notifications in coordinating care by providing timely reminders for caregivers. Table 1 presents the participants' perspectives on mobile apps and websites.

XSL•FO
RenderX

Table 1. Perspectives on mobile apps and websites.

Subthemes and definitions	Quotes
Mobile apps versus websites (the comparison between mobile apps and websites in terms of preferences)	• "Mobile access provides much more freedom. You do not need to have your laptop with you; if you are outside, you can still access data through your mobile device. However, many grandparents who take care of their grandchildren might not be able to have or use mobile apps." [Participant 10] • "I think it is important to have something that is not so cumbersome, something they can pull out and use, which is a phone. The invention of the smartphone might have so many capabilities for individuals with disabilities." [Participant 12]
Mobile app notifications (the importance of mobile app notification feature for caregivers)	• "I would like an app to coordinate everything and also send reminders or share reminders of what is coming up next. For instance, in terms of care coordination, I am adding information to the app, perhaps that my child visited a specialist on this date, then maybe the app can add reminders in additional ways about an upcoming appointment. Or maybe, if I say in my notes that I met with this specialist and need to schedule a follow-up appointment with so and so. Maybe the app can understand the action items from those notes and say you mentioned this, and you need to schedule a follow-up appointment with this specialist." [Participant 1]

Theme 4: Transition to Adult Care

The last primary theme focuses on a sensitive period in the continuum of care of children with medical complexity. At the age of 21 years, children with medical complexity experience the transition or transfer of care from pediatric settings to an adult setting, findings showed suggestions for technologies specifically for this transition period. The community caregivers highlighted several features of these technologies, especially those related to enabling self-care and management for the patients. The theme emphasized the necessity of designing technology to empower the youth with the necessary knowledge during this transition to adulthood. In addition, given the shortage of resources and skillsets in adult settings compared to pediatric settings for the children with medical complexity population, they highlighted the various needs children with medical complexity teenagers or young adults with medical complexity might have during and after the transition; therefore, a personalized technology, specifically addressing their needs, would be beneficial. Table 2 presents the subthemes related to various suggestions for using technology to facilitate the transition to adult care.

Table 2. Suggested technology to support the transition to adult care.

Subthemes and definitions	Quotes
Empowering youth with knowledge about their health condition (providing youth with the necessary knowledge to understand and manage their own health issues)	"A youth app would be so important to support health care transition. It is supposed to start at 12 because our kids are going to grow up. Youth are going to go to college, and they are going to have a new provider who is a specialist. Mom is not going to be there with them. So, I believe it is important to provide them with resources about their disability, what it is, and their medications." [Participant 5]
Manage medical appointments (teaching youth with medical complexities how to schedule and organize their own health care visits)	"I think of an app that would help the child to make appointments such as a scheduler. As a mother of a child with medical complexity, we do everything. The truth is that they are going to grow up, and the first steps might even be just having your child sign their name when they come into a doctor's office or calling to make an appointment. The app should be integrated with text to talk for youth with medical complexity." [Participant 5]
Personalized technology features for youth (technology solutions that meet the unique needs and abilities of children with medical complexity)	"An app should be able to assess whether users can read well; based on this assessment, we would use either tenth or twelfth-grade English. If users have receptive issues or dyslexia, we will avoid using this font and instead use one without unusual markings. For example, consider a twelfth-grader who reads at a third-grade level but is transitioning to adulthood. Currently, there are no resources for this, so the child will often rely on information from his parents. This can be a real struggle because, although the content is intended for him, he does not have access to it." [Participant 10]

Discussion

Principal Findings

This qualitative study explores formal community caregivers' perspectives on integrating HIT in the care of children with medical complexity. Community caregivers are an essential part of the care model for children with medical complexity from underserved populations [13,14]. Our findings showed the critical benefits of telehealth for this population, especially during the COVID-19 pandemic, though some negative experiences and improvement suggestions are also noted. We also identified various specific needs that can promote future technology design to address the specific needs of children with medical complexity in care management as well as the interaction between the parents of children with medical complexity and care providers. Finally, our findings address the need for technologies that support the transition from pediatric to adult care for the children with medical complexity population. To our knowledge, this is the first study capturing children with medical complexity community caregivers' perception of the role and needs of HIT in an effective care for children with medical complexity model.

XSL•FO
RenderX

Shifting From In-Person Visits to Telehealth

The COVID-19 pandemic has accelerated the adoption of telehealth into the American health care systems, providing safe access to medical care [19,20]. The data reveal that telehealth provided alternatives and safer options to the children with medical complexity population during the peak time of the COVID-19 pandemic as a cost-effective solution that can potentially improve health outcomes for children with medical complexity, facilitate physician-caregiver interaction, and increase caregiver satisfaction, as reported in other studies [21-23]. Community caregivers emphasize that telehealth eases the burden on parents, especially those from underserved populations, by reducing the time they need to take off work and travel long distances, as discussed by other studies [24,25]. During the COVID-19 pandemic, telehealth was the safest method to maintain physical distance while ensuring timely and affordable care [26]. Telehealth facilitated follow-up care, reducing the burden on care teams and decreasing exposure risks for both patients and health care providers [27]. However, the findings also showed that there are certain tasks, especially in inpatient settings, which cannot be done using telehealth. Clear communication between parents and health care providers is needed to ensure timely and reliable care [28]. Our study also revealed that community caregivers advocate for the continuity of telehealth services after the COVID-19 pandemic, driven by the factors mentioned earlier. Despite its advantages, our analysis also showed several challenges related to telehealth use in the care of children with medical complexity. These challenges include technical difficulties, connection issues, a user-unfriendly interface, and a lack of clear instructions for parents to connect to the system [29-31]. These challenges should be addressed and enhanced for better use of telehealth in care for children with medical complexity.

A previous study focused on providing recommendations to enhance telehealth functionalities and support diverse communication needs from the perspective of children, which aligns with our findings [32]. Our participants reported that children with medical complexity often struggle to sit still, listen, and engage throughout a long telehealth session. They suggested that for children with medical complexity, particularly those with developmental disabilities, integrating fun graphics with timers into telehealth can transform their experience. This approach allows families to create a structured environment that actively engages children and leads to more productive telehealth sessions. Moreover, our participants suggest accommodating diverse communication preferences during telehealth sessions, as some children might feel more comfortable expressing themselves through text. Integrating features such as fill-in-the-blank sentences, text-to-voice options, and voice-to-text options can significantly enhance accessibility. In addition, allowing children to choose their voice gender and use emojis to convey their pain levels or express agreement and disagreement can facilitate more effective communication. These adaptations can help create a more inclusive and supportive telehealth experience.

In addition, health care providers must listen to parents' concerns and answer their questions, as it will assist them in coping with difficult situations [33]. Our participants recommend that preappointment questionnaires may enhance communication between parents and health care providers. This approach will help parents in addressing their concerns in advance, which will be discussed during the session. In addition, integrating an educational component into telehealth will enhance parents' understanding of the medical information presented during the session.

Technologies for Improving Outcomes of Care for Children With Medical Complexity

Community caregivers suggested tools to address various needs of this population, including parent or patient empowerment, information management, care coordination, communication, and patient safety. Visiting the physician's office can be stressful for this vulnerable group due to the unfamiliar environment [34,35]. Our study revealed that games and social media platforms could improve the social skills of children with medical complexity, such as interacting with the health care staff. Participants suggested gamified learning apps that focus on teaching what is socially appropriate and inappropriate. In addition, social media platforms, such as TikTok, Snapchat, and Instagram, provide short videos that capture children's attention. This feature can help children with medical complexities learn how to interact in a physician's office and encourage them to participate actively in their health management.

Several subthemes emerged from the analysis, showing various management tools to help the parents of children with medical complexity at different levels of care for children with medical complexity, not only in hospitals but mostly in home settings. The data clearly show the increasing interest among caregivers in integrating various HIT tools into the care for children with medical complexity journey to improve the quality of care. As this interest expands, concerns arise regarding validating these technologies, as many lack regulatory approval. In addition, improving patient safety in complex pediatric health care requires providing families with tools that help them with decision-making and communication. Successful communication requires timely information exchange between primary care, specialty care, and families to enhance medical outcomes for children with medical complexity [36]. Our participants indicated that parents often felt responsible for sharing information, as they are the primary drivers of their children's care. Miscommunication and the use of multiple medications in complex medical conditions increase opportunities for error, particularly as children transition between health care settings and practitioners [37]. Communication barriers often prevent parents from properly filling prescriptions or adjusting dosages, resulting in frequent errors and increased risks to patient safety [38]. In addition, parents need to find the right channels and have a road map to assist in understanding and managing the complicated situations or challenges they will encounter in the future [39]. Therefore, community caregivers ask for effective technologies and tools to be developed to address these critical needs of the parents of children with medical complexity.

Another subtheme highlighted the need to address language barriers and empower parents and patients, especially those from underserved populations with low education levels. Parents

XSL•FO
RenderX

with limited English proficiency encounter communication challenges that negatively affect access to and quality of health services for children with medical complexity [40]. Language barriers and health literacy limitations could be associated with parents' less understanding of diagnoses, treatment options, care plans, and follow-up recommendations [41]. In addition, language barriers include a limited understanding of medical terminology while explaining the child's diagnosis and treatment plan [42]. The parents want clear instructions, simplified medical terms, and concrete medication directions [43]. A well-designed tool can help these parents mitigate these barriers and become empowered in the care of their own children with medical complexity.

Preferences and Specifications for User-Centric Design

The data showed some discussions on preferences on the type of technology platforms discussed by community caregivers. The participants discussed their preferences for mobile apps and websites, focusing on how these platforms can meet diverse needs. Smartphones allow users to access information and services anytime and anywhere [44]. However, older adults caring for children or grandchildren with medical complexity might prefer using desktops and laptops, as larger screens provide a more accessible information display.

The participants also emphasized the importance of reminders and notifications in managing their caregiving responsibilities effectively. Reminders are an important feature in mobile apps, helping users manage medication, appointments, and adherence to medical conditions [45]. For instance, the participants in our study mentioned that writing notes is a common practice to keep track of important tasks and appointments; however, this can often lead to information overload and disorganization. It was suggested that an app could analyze these notes and identify action items. Then, the mobile app could send reminders on upcoming appointments and other important tasks. This could be achieved using an artificial intelligence (AI)–powered mobile app that uses natural language processing to analyze the text notes. AI-assisted mobile apps could be designed to provide personalized experiences for parents and offer insights that drive better decision-making [46]. In addition, AI-assisted apps could be extended to assist parents in enhancing medication adherence by recognizing medications and verifying their ingestion [47].

The Role of Technology in Supporting Transitions to Adult Health Care

Our data revealed an interesting theme focusing on the care transition or transfer of this vulnerable population from pediatrics to adult care and how to make this transition better by using various technologies and tools. These tools should educate youth about their complex medical conditions, medications, and overall health management [48]. Children with medical complexity will inevitably grow up, and they will need to navigate independent adult life and responsibilities. Managing multiple medical appointments and follow-ups becomes a significant skill while transitioning to adult care. Our participants suggested an app that includes features such as appointment scheduling and text-to-speech integration, which could help youth with medical complexity learn to navigate this aspect of their care independently. Furthermore, personalized technology solutions that adapt to individual reading levels and cognitive abilities are essential [49]. As suggested by Statewide Parent Advocacy Network participants, an app that provides content accommodating varying reading skills can ensure that children with medical complexity with different learning needs can equally engage with and access adult transition resources.

As shown in the literature, this transition period is risky, and adult settings are significantly less prepared compared to pediatric settings to care for this vulnerable population [50]. Transitioning from pediatric to adult health care is unique to each child and ideally occurs between the ages of 18 and 21 [51]. The negative impact of poorly managed care transition contributes to family burden and distress [52,53]. Families face significant challenges in motivating their children and often lack clarity about the steps needed for the adult care transition phase [53]. There is growing interest in leveraging HIT to facilitate the transition from pediatric to adult care [54,55]. Health care providers and parents support youth in developing autonomy, decision-making skills, and self-management by creating tailored plans that address their abilities and complexities [49]. This process can be further empowered by leveraging HIT, which can provide tools and resources to enhance personalized care and support this transitioning phase, as highlighted by the participants in our study.

Limitations

A limitation of this study is that the interviews were conducted with members of only one organization. In addition, we only collected gender as demographic information about participants. Our participants were predominantly female, so future studies could balance the insights by adding more male community caregivers.

Conclusions

This study explored and analyzed the needs of children with medical complexities and their caregivers throughout their care journey from community caregivers' perspectives. We identified several areas where HIT could enhance care for children with medical complexity conditions. There is a need for improvement in telehealth and the development of mobile health apps across various areas of care for children with medical complexity, such as data management, educational resources, care coordination, and transition to adult care. By addressing these areas, technology designers can contribute to more effective, coordinated, and personalized care for children with medical complexity. This improvement will potentially lead to better health outcomes and a higher quality of life for children with medical complexity.

XSL•FO
RenderX

Acknowledgments

The research reported in this paper was supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development of the National Institutes of Health (R15HD109791). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The authors are also grateful for the Statewide Parent Advocacy Network (SPAN) workers who have supported this study. The authors also thank Deepa Srinivasavaradan, the director of early childhood initiatives at SPAN, for her assistance with data collection.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Telehealth subthemes, definitions, and sample quotes.
[DOCX File , 20 KB - pediatrics_v8i1e67289_app1.docx]

Multimedia Appendix 2
Suggested tools and technologies to be developed for children with medical complexity care.
[DOCX File , 19 KB - pediatrics_v8i1e67289_app2.docx]

References

1. Murphy NA, Alvey J, Valentine KJ, Mann K, Wilkes J, Clark EB. Children with medical complexity: the 10-year experience of a single center. Hosp Pediatr 2020 Aug;10(8):702-708. [doi: 10.1542/hpeds.2020-0085] [Medline: 32699000]
2. Cohen E, Kuo DZ, Agrawal R, Berry JG, Bhagat SK, Simon TD, et al. Children with medical complexity: an emerging population for clinical and research initiatives. Pediatrics 2011 Mar;127(3):529-538 [FREE Full text] [doi: 10.1542/peds.2010-0910] [Medline: 21339266]
3. Pérez-Ardanaz B, Gutiérrez-Rodríguez L, Pelaez-Cantero MJ, Morales-Asencio JM, Gómez-González A, García-Piñero JM, et al. Healthcare service use for children with chronic complex diseases: a longitudinal six-year follow-up study. J Pediatr Nurs 2024 Jul;77:e132-e138 [FREE Full text] [doi: 10.1016/j.pedn.2024.04.001] [Medline: 38594165]
4. Adams S, Beatty M, Moore C, Desai A, Bartlett L, Culbert E, et al. Perspectives on team communication challenges in caring for children with medical complexity. BMC Health Serv Res 2021 Apr 01;21(1):300 [FREE Full text] [doi: 10.1186/s12913-021-06304-8] [Medline: 33794885]
5. Geyer D, Vessey JA. Caring for children with medical complexity at home: an integrative review. J Pediatr Nurs 2024 May;76:167-175. [doi: 10.1016/j.pedn.2024.02.018] [Medline: 38412708]
6. Health information privacy. U.S. Department of Health and Human Services. URL: https://www.hhs.gov/hipaa/for-professionals/special-topics/health-information-technology/index.html [accessed 2024-07-22]
7. Kruse CS, Beane A. Health information technology continues to show positive effect on medical outcomes: systematic review. J Med Internet Res 2018 Feb 05;20(2):e41 [FREE Full text] [doi: 10.2196/jmir.8793] [Medline: 29402759]
8. Alotaibi YK, Federico F. The impact of health information technology on patient safety. Saudi Med J 2017 Dec 03;38(12):1173-1180 [FREE Full text] [doi: 10.15537/smj.2017.12.20631] [Medline: 29209664]
9. Asan O, Elkefi S, Clouser KN, Percy S. Using health information technology to support the needs of children with medical complexity: mapping review of consumer informatics applications. Front Digit Health 2022 Dec 23;4:992838 [FREE Full text] [doi: 10.3389/fdgth.2022.992838] [Medline: 36620184]
10. Parks R, Doutcheva N, Umachandran D, Singhe N, Noejovich S, Ehlenbach M, et al. Identifying tools and technology barriers to in-home care for children with medical complexity. Proc Hum Factors Ergon Soc Annu Meet 2021 Nov 12;65(1):510-514. [doi: 10.1177/1071181321651214]
11. Lin JL, Huber B, Amir O, Gehrmann S, Ramirez KS, Ochoa KM, et al. Barriers and facilitators to the implementation of family-centered technology in complex care: feasibility study. J Med Internet Res 2022 Aug 23;24(8):e30902 [FREE Full text] [doi: 10.2196/30902] [Medline: 35998021]
12. Elkourdi F, Asan O, Mansouri M. The unintended effects of medical software on clinical decisions and patient safety: a system viewpoint. In: Proceedings of the The Eighteenth International Conference on Systems. 2023 Presented at: ICONS 2023; April 24-28, 2023; Venice, Italy.
13. SPAN's history and mission. SPAN. URL: https://spanadvocacy.org/about/ [accessed 2024-05-28]
14. Muriuki AM, Andoh SY, Newth H, Blackett-Dibinga K, Biti D. The impact of community caregivers in Côte d'Ivoire. Save the Children. 2024. URL: https://socialserviceworkforce.org/wp-content/uploads/2024/03/The-Impact-of-Community-Caregivers-in-Cote-dIvoire.pdf [accessed 2025-01-27]
15. Nelson J. Using conceptual depth criteria: addressing the challenge of reaching saturation in qualitative research. Qual Res 2016 Dec 14;17(5):554-570. [doi: 10.1177/1468794116679873]

XSL•FO
RenderX

16. Graneheim UH, Lindgren BM, Lundman B. Methodological challenges in qualitative content analysis: a discussion paper. Nurse Educ Today 2017 Sep;56:29-34. [doi: 10.1016/j.nedt.2017.06.002] [Medline: 28651100]
17. Bradley EH, Curry LA, Devers KJ. Qualitative data analysis for health services research: developing taxonomy, themes, and theory. Health Serv Res 2007 Aug;42(4):1758-1772 [FREE Full text] [doi: 10.1111/j.1475-6773.2006.00684.x] [Medline: 17286625]
18. Dew K. A health researcher's guide to qualitative methodologies. Aust N Z J Public Health 2007 Oct;31(5):433-437 [FREE Full text] [doi: 10.1111/j.1753-6405.2007.00114.x] [Medline: 17931290]
19. Hirko KA, Kerver JM, Ford S, Szafranski C, Beckett J, Kitchen C, et al. Telehealth in response to the COVID-19 pandemic: implications for rural health disparities. J Am Med Inform Assoc 2020 Nov 01;27(11):1816-1818 [FREE Full text] [doi: 10.1093/jamia/ocaa156] [Medline: 32589735]
20. Wosik J, Fudim M, Cameron B, Gellad ZF, Cho A, Phinney D, et al. Telehealth transformation: COVID-19 and the rise of virtual care. J Am Med Inform Assoc 2020 Jun 01;27(6):957-962 [FREE Full text] [doi: 10.1093/jamia/ocaa067] [Medline: 32311034]
21. Van Orne J, McClure A. Telehealth and children with medical complexity: an integrative literature review. Journal of Informatics Nursing 2024;9(2).
22. Ferro F, Tozzi AE, Erba I, Dall'Oglio I, Campana A, Cecchetti C, et al. Impact of telemedicine on health outcomes in children with medical complexity: an integrative review. Eur J Pediatr 2021 Aug 01;180(8):2389-2400 [FREE Full text] [doi: 10.1007/s00431-021-04164-2] [Medline: 34196791]
23. Bouabida K, Lebouché B, Pomey MP. Telehealth and COVID-19 pandemic: an overview of the telehealth use, advantages, challenges, and opportunities during COVID-19 pandemic. Healthcare (Basel) 2022 Nov 16;10(11):2293 [FREE Full text] [doi: 10.3390/healthcare10112293] [Medline: 36421617]
24. Menon DU, Belcher HM. COVID-19 pandemic health disparities and pediatric health care-the promise of telehealth. JAMA Pediatr 2021 Apr 01;175(4):345-346. [doi: 10.1001/jamapediatrics.2020.5097] [Medline: 33284346]
25. Kolluri S, Stead TS, Mangal RK, Coffee RL, Littell J, Ganti L. Telehealth in response to the rural health disparity. Health Psychol Res 2022;10(3):37445 [FREE Full text] [doi: 10.52965/001c.37445] [Medline: 35999970]
26. Ganjali R, Jajroudi M, Kheirdoust A, Darroudi A, Alnattah A. Telemedicine solutions for clinical care delivery during COVID-19 pandemic: a scoping review. Front Public Health 2022 Jul 22;10:937207 [FREE Full text] [doi: 10.3389/fpubh.2022.937207] [Medline: 35937265]
27. Binder AF, Handley NR, Wilde L, Palmisiano N, Lopez AM. Treating hematologic malignancies during a pandemic: utilizing telehealth and digital technology to optimize care. Front Oncol 2020 Jun 26;10:1183 [FREE Full text] [doi: 10.3389/fonc.2020.01183] [Medline: 32676459]
28. Haleem A, Javaid M, Singh RP, Suman R. Telemedicine for healthcare: capabilities, features, barriers, and applications. Sens Int 2021;2:100117 [FREE Full text] [doi: 10.1016/j.sintl.2021.100117] [Medline: 34806053]
29. Gajarawala SN, Pelkowski JN. Telehealth benefits and barriers. J Nurse Pract 2021 Feb;17(2):218-221 [FREE Full text] [doi: 10.1016/j.nurpra.2020.09.013] [Medline: 33106751]
30. Tabibzadeh M, Tran H. Improving quality of care and patient safety in virtual visits: investigating barriers of telehealth implementation. Proc Hum Factors Ergon Soc Annu Meet 2022 Oct 27;66(1):1564-1568. [doi: 10.1177/1071181322661110]
31. Blandford A, Wesson J, Amalberti R, AlHazme R, Allwihan R. Opportunities and challenges for telehealth within, and beyond, a pandemic. Lancet Glob Health 2020 Nov;8(11):e1364-e1365 [FREE Full text] [doi: 10.1016/S2214-109X(20)30362-4] [Medline: 32791119]
32. Beneteau E, Paradiso A, Pratt W. Children's designs for the future of telehealth. AMIA Annu Symp Proc 2021;2021:207-216 [FREE Full text] [Medline: 35308905]
33. Bry A, Wigert H, Bry K. Need and benefit of communication training for NICU nurses. PEC Innov 2023 Dec;2:100137. [doi: 10.1016/j.pecinn.2023.100137] [Medline: 37214501]
34. Lerwick JL. Minimizing pediatric healthcare-induced anxiety and trauma. World J Clin Pediatr 2016 May 08;5(2):143-150 [FREE Full text] [doi: 10.5409/wjcp.v5.i2.143] [Medline: 27170924]
35. Gripko M, Joseph A, MohammadiGorji S. Effects of the physical environment on children and families in hospital-based emergency departments: a systematic literature review. J Environ Psychol 2023 Mar;86:101970 [FREE Full text] [doi: 10.1016/j.jenvp.2023.101970] [Medline: 37366532]
36. Stille CJ, Honigfeld L, Heitlinger LA, Kuo DZ, Werner EJ. The pediatric primary care-specialist interface: a call for action. J Pediatr 2017 Aug;187:303-308. [doi: 10.1016/j.jpeds.2017.04.054] [Medline: 28595768]
37. Huth K, Vandecruys P, Orkin J, Patel H. Medication safety for children with medical complexity. Paediatr Child Health 2020 Nov;25(7):473-474 [FREE Full text] [doi: 10.1093/pch/pxaa105] [Medline: 33178368]
38. Neuspiel DR, Taylor MM. Reducing the risk of harm from medication errors in children. Health Serv Insights 2013 Jun 30;6. [doi: 10.4137/hsi.s10454]
39. Cady RG, Belew JL. Parent perspective on care coordination services for their child with medical complexity. Children (Basel) 2017 Jun 06;4(6):45 [FREE Full text] [doi: 10.3390/children4060045] [Medline: 28587274]

XSL•FO
RenderX

40. Nageswaran S, Ellis MB, Beveridge MS. Communication challenges faced by Spanish-speaking caregivers of children with medical complexity: a qualitative study. J Racial Ethn Health Disparities 2022 Dec 30;9(6):2218-2226 [FREE Full text] [doi: 10.1007/s40615-021-01161-x] [Medline: 34595676]
41. Khan A, Yin HS, Brach C, Graham DA, Ramotar MW, Williams DN, et al. Association between parent comfort with English and adverse events among hospitalized children. JAMA Pediatr 2020 Dec 01;174(12):e203215 [FREE Full text] [doi: 10.1001/jamapediatrics.2020.3215] [Medline: 33074313]
42. Zamor RL, Vaughn LM, McCann E, Sanchez L, Page EM, Mahabee-Gittens EM. Perceptions and experiences of Latinx parents with language barriers in a pediatric emergency department: a qualitative study. BMC Health Serv Res 2022 Dec 01;22(1):1463 [FREE Full text] [doi: 10.1186/s12913-022-08839-w] [Medline: 36457015]
43. Rungvivatjarus T, Huang MZ, Winckler B, Chen S, Fisher ES, Rhee KE. Parental factors affecting pediatric medication management in underserved communities. Acad Pediatr 2023 Jan;23(1):155-164 [FREE Full text] [doi: 10.1016/j.acap.2022.09.001] [Medline: 36100181]
44. Okuboyejo S, Eyesan O. mHealth: using mobile technology to support healthcare. Online J Public Health Inform 2014 Feb 05;5(3):233 [FREE Full text] [doi: 10.5210/ojphi.v5i3.4865] [Medline: 24678384]
45. Salari R, Niakan Kalhori SR, Fatehi F, Ghazisaeedi M, Nazari M. Determining minimum set of features for diabetes mobile apps. J Diabetes Metab Disord 2019 Dec 27;18(2):333-340 [FREE Full text] [doi: 10.1007/s40200-019-00417-y] [Medline: 31890658]
46. Asan O, Choi E, Wang X. Artificial intelligence-based consumer health informatics application: scoping review. J Med Internet Res 2023 Aug 30;25:e47260 [FREE Full text] [doi: 10.2196/47260] [Medline: 37647122]
47. Chen HH, Hsu HT, Lin PC, Chen CY, Hsieh HF, Ko CH. Efficacy of a smartphone app in enhancing medication adherence and accuracy in individuals with schizophrenia during the COVID-19 pandemic: randomized controlled trial. JMIR Ment Health 2023 Dec 14;10:e50806 [FREE Full text] [doi: 10.2196/50806] [Medline: 38096017]
48. Teed M, Bekx A, Paul M, Younker L. Health care transition for children with medical complexity: challenges and lessons learned. J Pediatr Nurs 2021 Nov;61:275-279. [doi: 10.1016/j.pedn.2021.07.022] [Medline: 34365163]
49. Li L, Polanski A, Lim A, Strachan PH. Transition to adult care for youth with medical complexity: assessing needs and setting priorities for a health care improvement initiative. J Pediatr Nurs 2022 Jan;62:144-154. [doi: 10.1016/j.pedn.2021.08.006] [Medline: 34404554]
50. White PH, Cooley WC, Transitions Clinical Report Authoring Group, American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians. Supporting the health care transition from adolescence to adulthood in the medical home. Pediatrics 2018 Nov;142(5):e20182587. [doi: 10.1542/peds.2018-2587] [Medline: 30348754]
51. American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians, Transitions Clinical Report Authoring Group, Cooley WC, Sagerman PJ. Supporting the health care transition from adolescence to adulthood in the medical home. Pediatrics 2011 Jul;128(1):182-200. [doi: 10.1542/peds.2011-0969] [Medline: 21708806]
52. Tomette A, Henderson JN, Hass A, Carson LD, King K. Parental stress as a child with diabetes transitions from adolescence to emerging adulthood. J Patient Exp 2020 Jun 02;7(3):365-371 [FREE Full text] [doi: 10.1177/2374373519842963] [Medline: 32821796]
53. Cheak-Zamora NC, Teti M, First J. 'Transitions are scary for our kids, and they're scary for us': family member and youth perspectives on the challenges of transitioning to adulthood with autism. J Appl Res Intellect Disabil 2015 Nov 05;28(6):548-560. [doi: 10.1111/jar.12150] [Medline: 25753589]
54. Lopez KN, O'Connor M, King J, Alexander J, Challman M, Lovick DK, et al. Improving transitions of care for young adults with congenital heart disease: mobile app development using formative research. JMIR Form Res 2018 Sep 11;2(2):e16 [FREE Full text] [doi: 10.2196/formative.9963] [Medline: 30574573]
55. Miller C. Using technology to bridge the transition from pediatric to adult health care. J Am Assoc Nurse Pract 2022 Jun 01;34(6):850-858. [doi: 10.1097/JXX.0000000000000700] [Medline: 35383652]

Abbreviations

AI: artificial intelligence
HIT: health IT

XSL•FO
RenderX

Edited by S Badawy; submitted 07.10.24; peer-reviewed by Y Luo, A Ren; comments to author 19.10.24; revised version received 23.11.24; accepted 27.12.24; published 10.02.25.

Please cite as:
Elkourdi F, Asan O
Community Caregivers' Perspectives on Health IT Use for Children With Medical Complexity: Qualitative Interview Study
JMIR Pediatr Parent 2025;8:e67289
URL: https://pediatrics.jmir.org/2025/1/e67289
doi:10.2196/67289
PMID:

©Farah Elkourdi, Onur Asan. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 10.02.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Content Development for a Multilevel Intervention to Operationalize Behavior Change Theory and Improve Parenting Behaviors for Physical Activity: Descriptive Study

Breanne C Wilhite[1], MPH, PhD; Erin Hennessy[1], MPH, PhD; Christina Economos[1], PhD; Jennifer Sacheck[2], MS, PhD; Rachel Zive[3], MPH; Christine Odalen[3], MS; Stephanie Herrick[3], MS; Daniel P Hatfield[1,4], PhD

[1]The Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy, Tufts University, 150 Harrison Ave, Boston, MA, United States

[2]Department of Behavioral and Social Sciences, School of Public Health, Brown University, Providence, RI, United States

[3]Rising New York Road Runners, New York Road Runners, New York, NY, United States

[4]FHI 360, Washington, DC, United States

Corresponding Author:
Erin Hennessy, MPH, PhD
The Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy, Tufts University, 150 Harrison Ave, Boston, MA, United States

Abstract

Background: Theory-informed strategies for engaging parents in children's physical activity (PA) promotion show promise. However, behavior-change interventions must become more rigorous in both their application of theory and the reporting of its use to continue to advance the field.

Objective: This study aims to elucidate how 2 behavior change theories were used to develop parent communication materials in a 20-week communications campaign, nested within a multilevel (school-home) intervention to promote children's PA. The innovation described in this study is derived from the Supporting Physical Literacy at School and Home (SPLASH) feasibility study (2021 - 2022).

Methods: A team of 7 experts, including graduate students, researchers, faculty, and child PA specialists, collaboratively designed the process used to develop the intervention content. With experience in theory-informed interventions and health-related communication campaigns, they held recurring meetings to refine the approach.

Results: A four-step process was used to develop the theory-informed parent communication materials: (1) establish a theoretical foundation for communication materials (ie, social cognitive theory and self-determination theory) and conduct focus groups with the priority population; (2) identify and select PA parenting behaviors aligned with evidence and behavioral theories to form PA parenting objectives that advance children's PA; (3) identify theoretical determinants of parent behavior change and outline methods for applying determinants to address PA parenting objectives; (4) operationalize theory-informed strategy and draft, review, and finalize materials. Parent communications were delivered through print materials and electronic channels, including email, text messages, Facebook (Meta Platforms, Inc), and activity videos.

Conclusions: This descriptive study advances progress in the development of school-based PA promotion efforts seeking to incorporate parent engagement strategies by detailing how behavior-change theories can be operationalized to improve PA parenting behaviors. This methodology is valuable for others seeking to translate theoretical constructs into behavior-change communication messages.

Trial Registration: ClinicalTrials.gov NCT05887583; https://clinicaltrials.gov/study/NCT05887583

(JMIR Pediatr Parent 2025;8:e73510) doi:10.2196/73510

KEYWORDS

school-based physical activity; multilevel intervention; behavior change theory; physical activity parenting; communication material design; theory-informed design

Introduction

Participating in regular and sufficient physical activity (PA) is an essential contributor to optimal growth and development in childhood and favorable physical and mental health throughout the life course [1,2]. In the United States, changes in lifestyle factors, the built environment, and opportunities for PA have resulted in declines in children's PA, with disparities by gender, race, ethnicity, and family income becoming increasingly

XSL•FO
RenderX

pervasive [3-6]. The development of strategies that can improve and maintain children's PA is therefore a growing priority.

Based on the substantial amount of time school-aged children spend at school, the availability and accessibility of PA opportunities at school can have a significant impact on promoting children's PA [7,8]. Reviews of school-based PA interventions have shown promise for improving children's PA levels [9,10], with multicomponent, comprehensive school PA programs (ie, integration of multiple strategies during and outside school hours) potentially having the greatest impact on daily activity levels [11,12]. In addition, there is widespread belief that parent or caregiver (herein referred to as "parents," which includes biological parents, other biological relatives who may act as caretakers, and nonbiological parents such as adoptive, foster, or stepparents) engagement in school-based PA promotion efforts is essential for providing the consistent opportunities and support children need to be physically active [10,13-17]. As such, developing school-based PA interventions that involve parents has become an area of growing attention.

Some commonly used parent engagement strategies in school-based interventions include establishing clear communication channels between school and home, providing opportunities for parents to build their knowledge, skills, and confidence for supporting their children's behaviors, and engaging parents in activities at home to reinforce messages and practices taught at school [18]. However, the independent contribution that parent engagement strategies have on school-based intervention effectiveness, including child PA outcomes, is inconclusive [14,15,19,20]. A review by O'Connor et al [21] of school-based PA interventions with parental components found that inadequate and inconsistent reporting has made it difficult to interpret outcomes and draw conclusions on the most effective parent engagement strategies. Theory-based, empirically verified procedures are warranted to allow for a more systematic evaluation of such interventions' impact on both parent and child behaviors and for their eventual widespread dissemination.

There has been progress in the broader behavior-change science field to develop systematic methods such as ontologies [22-24], taxonomies [25-27], methods for mapping interventions [28-30], and a theory coding scheme [31] that can be widely applied across the design, implementation, and evaluation phases of theory-based health behavior interventions [32,33]. However, continued inconsistencies in theory application and poor reporting of theory use make it difficult to ascertain and disseminate effective methods, limiting both the advancement and practical application of behavior-change strategies [34,35]. Furthermore, these systematic methods provide frameworks for intervention planning and design broadly, with none focusing on the operationalization of theory into intervention content, such as communication materials. This may help explain why studies of communication interventions seldom provide descriptions of how theory was applied to messaging and materials design, making it difficult to interpret study results, draw broader conclusions about whether given theories are useful and replicate methods.

This descriptive study aims to address these gaps in school-based intervention design by detailing the development of theory-informed communication materials intended to engage parents in children's PA promotion efforts. More specifically, our work recounts how two behavior change theories were used to inform a 20-week multichannel communications campaign seeking to engage parents, nested within a school-based PA intervention (herein referred to as the "multilevel intervention"). This innovative descriptive study provides an example for operationalizing theory in communication messages for multilevel behavior change. These methods are of value to others seeking to be more rigorous in the application and reporting of theory use when designing parent engagement strategies to promote children's PA.

Methods

The Supporting Physical Literacy at School and Home Study

This work was conducted in partnership with New York Road Runners (NYRR). NYRR is the world's premier community running organization with a mission to help and inspire people through running. They have disseminated youth running and PA programming since 1999. In 2017, NYRR released a new running-based youth program, Rising New York Road Runners (RNYRR), that can be incorporated into before-, during-, and after-school PA opportunities. RNYRR programming focuses on enjoyable, inclusive, developmentally appropriate games and activities that sequentially build motor skills in one or more domains (eg, locomotion, balance, and object control) to improve children's physical literacy (PL), defined as their confidence, competence, and motivation to be physically active for life [36,37].

The innovation described in this descriptive study is derived from the multilevel intervention, the Supporting Physical Literacy at School and Home (SPLASH) feasibility study (NCT05887583). Implemented during the 2021 - 2022 school year, SPLASH was designed to support RNYRR's existing school-based PA program by developing and delivering strategies to engage families in children's PA beyond school as well.

The aims of the SPLASH study included: (1) the development of a theory-informed home-based communications component, and (2) an assessment of implementation feasibility and acceptability in the target population. Aim 1 is the focus of this descriptive study, and results from aim 2 are forthcoming.

Key Programmatic Elements

A 4-step process was used to develop the theory-informed parent communications. Each step in the process included several activities that were informed by theory and existing evidence. The outputs generated from the activities were then integrated into the subsequent step. The entire 4-step process serves as an example of designing theory-informed communication materials intended to engage parents in children's PA. Table 1 outlines the steps, activities, and outputs.

XSL•FO
RenderX

Table . Development process of theory-informed communication materials.

Step	Activity	Output
Step 1: formative research		
Theoretical foundations	Aligned theoretical foundations for communication materials with overall multilevel intervention aims.	Theoretical basis established for communication materials.
Focus groups	Conducted focus groups with the priority population.	Summarized findings to tailor communication content.
Step 2: behavior change objectives	Conducted a literature review to identify and select PA parenting behaviors aligned with existing evidence and theoretical basis.	Parenting objectives are formed to advance children's PA[a].
Step 3: theory-informed strategy	Identified theoretical determinants of parental behavior change and outlined the application of determinants.	A strategy created to address PA parenting objectives.
Step 4: operationalization	Selected communication channels and drafted, reviewed, and edited materials to operationalize the theory-informed strategy.	Communication materials finalized.

[a]PA: physical activity.

Step 1 (formative research) took place during the grant proposal design phase in 2018 - 2019. Steps 2 - 4 took place from fall 2019 to spring 2021, with implementation of the multilevel intervention beginning in fall 2021.

The process included a planning and design team of 7 members, consisting of graduate students, research managers, research scientists, and faculty members from leading universities in nutrition, PA, and behavior change, and child PA specialists from RNYRR. The process was collaborative and iterative, consisting of recurring team meetings to review and discuss progress. Many team members had previously worked together on similar school- and community-based projects, including studies testing theory-informed approaches to promote child PA and improve health-related parenting practices [16,38-41]. Collectively, our team consisted of PA experts with experience in applying behavior change theories to intervention design and in developing and implementing communication campaigns to improve children's health behaviors.

Ethical Considerations

This study was reviewed and approved by the Social, Behavioral, and Educational Research Institutional Review Board at Tufts University (approval no 1812027; January 2019). All procedures were conducted following the ethical standards of the institutional research committee and the Declaration of Helsinki and later amendments. Informed consent was obtained from all participants before data collection. All data was deidentified and participants recieved a $50 Visa prepaid debit card for their time.

Results

Step 1: Formative Research

Theoretical Foundations

The theoretical basis for the communications campaign was selected during the grant proposal design phase in 2018. The National Institutes of Health Funding Opportunity Announcement (PAR-14 - 321) encouraged applications for "Phased Innovation (R21/R33) grant awards to support highly innovative research aimed at developing multilevel interventions that will increase health-enhancing PA: (1) in persons or groups who can benefit from such activity, and (2) that can be made scalable and sustainable for broad use across the nation." In response to this funding announcement, the authors partnered with NYRR to expand upon RNYRR's school-based PA program. We proposed developing strategies that would engage families in children's PA learning outside of school time to complement and reinforce the in-school programming. As the RNYRR school curriculum was developed with a focus on increasing children's PL, we sought to draw upon theoretical frameworks that would complement PL tenets when designing the family communication materials.

The concept of PL has been defined in several ways; for the multilevel intervention, we adopted the definition from the Aspen Institute's landmark 2015 report: "physical literacy is the ability (competence), confidence, and desire (motivation) to be physically active for life [42]." According to that report, ability or competence includes fundamental movement skills, which provide the foundation for a range of PA; confidence is one's belief in their ability to participate in sports or other physical activities; and desire or motivation includes intrinsic enthusiasm for PA.

Social cognitive theory (SCT) and self-determination theory (SDT) are two theoretical frameworks that complement PL concepts. For example, SCT constructs of self-efficacy and behavioral skills are similar to the confidence and competence components of PL [43], and SDT centers on motivational states and therefore aligns with the motivational dimension of PL [44]. Furthermore, SCT and SDT are commonly used in the design of interventions to target the determinants of children's PA, aiming to improve the promotion and maintenance of PA across the lifecycle [43,45-47]; PL-based approaches focus on not just eliciting near-term PA but also enabling children to be "active for life [42]." Given the theoretical and empirical evidence for SCT- and SDT-based strategies in promoting children's PA, the alignment between these theories and PL concepts, and the

XSL•FO
RenderX

study team members' prior experience with the application of both theories, we selected SCT and SDT as the theoretical basis for our communication materials. Table 2 summarizes the relevant literature for SCT and SDT in children's PA behavior change.

Table . Summary of social cognitive theory and self-determination theory supporting evidence for children's physical activity (PA) behavior change.

Overview of theory	Behavior change mechanisms	Evidence for children's PA	Long-term maintenance of behavior changes	Application to intervention design
Social cognitive theory (SCT)				
Learning occurs in a social context through dynamic, reciprocal interactions between cognitive, behavioral, and environmental factors [48].	Behavior change is bidirectional and shaped by interactions between individuals and their environment, including others [49].	Observational learning, goal setting, and reinforcement are key to effective family-based interventions for increasing children's PA [50].	For long-term maintenance of behavior, SCT emphasizes the importance of a supportive environment [45].	SCT effectively supports school-based interventions by engaging parents and extending children's PA support across school and home environments.
Self-determination theory (SDT)				
Three innate and universal human needs underlie growth: autonomy, competence, and relatedness [51].	Behavior change relies on motivation and occurs when an individual's psychological and physiological needs are met [51].	A motivational climate that fosters effort, personal growth, and decision-making opportunities significantly improves children's PA outcomes [47].	For long-term maintenance of behavior, SDT emphasizes the importance of sustained intrinsic motivation for the behavior [45].	SDT is ideal for PA interventions that enhance children's intrinsic motivation by fostering enjoyment and interest [52].

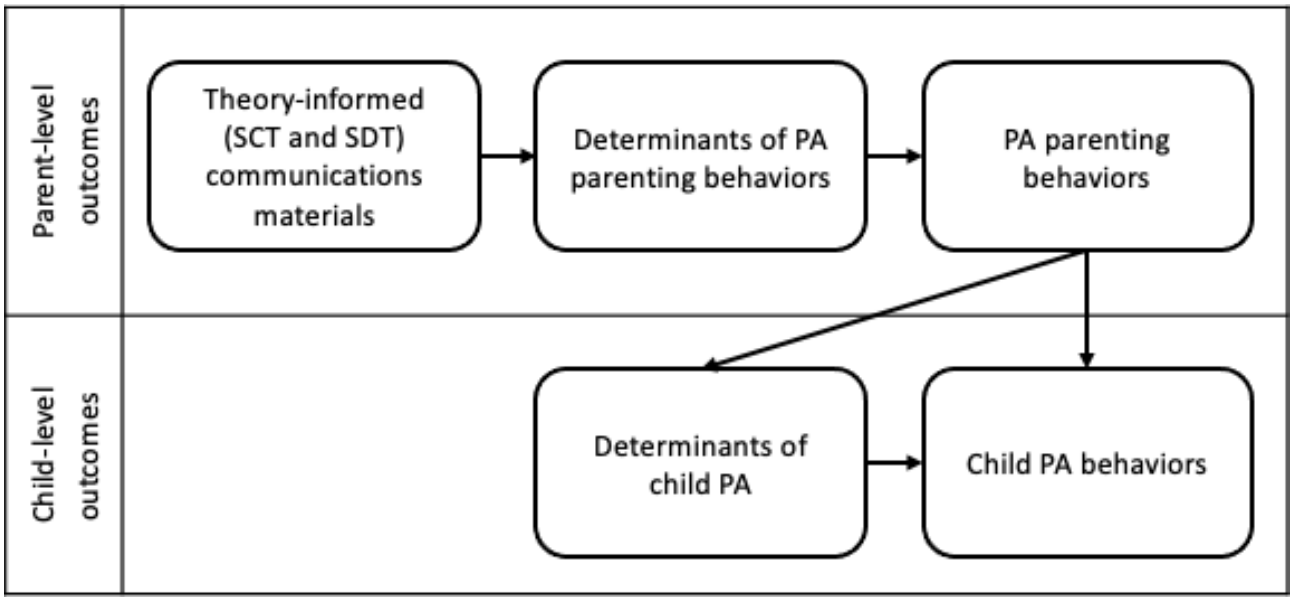
Though both theories help to explain the determinants of and conditions necessary for promotion and maintenance of a behavior, integrating components of the two may provide a more comprehensive understanding and improve the overall effectiveness of an intervention [9]. The integration of SCT and SDT has been a promising area of interest in designing and implementing school-based PA interventions [53,54]. Underlying these studies is the concept that the three basic human needs outlined in SDT (ie, autonomy, competence, and relatedness) can be satisfied or inhibited by the cognitive, behavioral, and environmental factors outlined in the SCT [55]. For example, social environmental factors, such as support for PA (ie, encouraging children's choices, options, and opportunities to participate in PA) from multiple sources, may positively influence students' motivation for and long-term engagement in PA [56,57]. Conversely, autonomous motivation for PA can positively influence factors such as attitudes toward PA, thereby influencing PA intention [58].

While the overall behavioral objective of the multilevel intervention was to promote children's PA, the intention of our theory-informed communication materials was to engage parents and improve their PA parenting behaviors. By operationalizing theoretical constructs into the materials, we hoped to target the SCT and SDT determinants of PA parenting behaviors, thereby influencing the PA parenting behaviors. The improvement in PA parenting behaviors could then enhance the SCT and SDT determinants of their children's PA and promote their children's PA behaviors.

Figure 1 depicts the relationship between the theory-informed (ie, SCT and SDT) communication materials and parental- and child-level behavioral outcomes. By operationalizing theoretical constructs into the materials, we aimed to target the SCT and SDT determinants of PA parenting behaviors, thereby influencing the PA parenting behaviors. Improvement in PA parenting behaviors could then enhance the SCT and SDT determinants of children's PA and promote their PA behaviors.

XSL•FO
RenderX

Figure 1. Promoting children's PA through theory-informed communication materials targeting PA parenting behaviors. PA: physical activity; SCT: social cognitive theory; SDT: self-determination theory.



Focus Groups

Focus groups were conducted with parents from the priority population to inform the overall development of the theory-informed parent communications. These focus groups explored parental knowledge and attitudes around child PA, parental perceptions of their children's PA engagement, perceived barriers and facilitators to supporting their children's PA, and current or preferred school-family communication channels.

Eight focus groups were conducted with parents of children in grades 3 - 5 in both the NYC and Boston areas between April and June 2019. Of the parents who participated in a focus group (n=69), 30% and 48% identified as non-Hispanic Black and Hispanic, respectively, and 89% identified as mothers. Results were coded by 3 study team members and organized by major themes. Primary results used in developing the materials include the following: (1) parents saw their children as lacking sufficient PA and viewed themselves as primary motivators, facilitators, and role models. Ensuring adequate PA for their children was a priority for them, (2) parents valued PE for teaching their children PA skills but wanted more school communication and involvement in PA opportunities. They preferred diverse communication methods with no single preferred frequency, and (3) parents wanted to engage in family PA but faced barriers such as time, energy, motivation, and space. They sought activity ideas aligned with PE lessons, adaptable for the whole family, and feasible in a limited space.

These findings contributed to a clearer understanding of the challenges faced by parents in our priority population to support or engage in PA with their children and highlighted potential opportunities to better connect families with schools. These findings were incorporated throughout the communication design process to ensure the final materials were responsive to the needs and preferences of the priority population.

Step 2: Behavior Change Objectives

To engage parents to promote children's PA, we needed to first identify priority PA parenting behaviors and the determinants of those PA parenting behaviors within the context of our theoretical basis. Reviewing the literature through the lens of SCT and SDT allowed us to understand how parents could both serve as an important socioenvironmental influence in the context of SCT and help satisfy needs in the context of SDT [59-61]. Our goal in step 2 was to (1) categorize the most influential parenting behaviors for promoting children's PA based on our literature review of existing evidence and (2) ensure the PA parenting behaviors aligned with the formative research conducted in Steps 1a and 1b. Collectively, step 2 details how our PA parenting objectives relate to the theoretical determinants of children's PA.

Our review of the parenting literature was conducted in the summer of 2019 by 3 study team members and supported by a Tufts University librarian. Web of Science, PubMed, and Ovid databases were used with a broad search strategy across all years of publication. Example search terms, informed by similar reviews, included terms related to parents (parent* OR famil* OR caregiver* OR family carer*), children (pediatric* OR child* OR kid* OR adolescen*), parent engagement (involv* OR participat* OR engage* OR outreach OR recruit* OR retain* OR retention*), intervention type (community-linked OR community-based OR school* OR teacher* OR student* OR classroom*), and child behavioral outcomes (exercis* OR recreation* OR fitness* OR physical activit*).

After reviewing 423 abstracts and 27 full-text papers, 3 categories of parental behaviors emerged as being supportive of children's PA behavior change: modeling of PA, parental support of child PA, and parental encouragement for child PA [50,62-64]. Termed collectively as "PA parenting practices," these behaviors are influenced by parents' own PA attributes and perceptions. For example, parents with a positive perception of PA, who engage in, value, and enjoy PA, tend to have a high self-efficacy to promote their child's PA. In addition, parents

XSL•FO
RenderX

who perceive that their child enjoys and is competent in PA are more likely to adopt responsive and structured PA parenting practices [65,66]. Responsive and structured PA parenting practices can, in turn, indirectly influence children's PA by enhancing children's modifiable PA attributes, such as their perceived competence, self-efficacy, and motivation for PA [66-68]. Some PA parenting practices, such as supportive behaviors, are associated with a direct increase in children's PA levels [50,64]. Therefore, by aiming to improve PA parenting practices through our materials, our intervention aimed to target parents as potential mediators of their child's PA behaviors [16,17].

The final parental behavior change objectives, with a brief description of specific behaviors, for our communications campaign were as follows. First, parents will serve as role models for their children's PA. Parents will model enjoyable and relevant PA behaviors individually and with their children. Second, parents will provide instrumental and informational support, including the provision of choices, for their children's PA. Specifically, (2a) parents will provide choices and descriptions of activities for their children to select from, and (2b) parents will promote a sense of familial connection around PA. Third, parents will provide praise and encouragement for their children's PA. This includes (3a) giving frequent, direct, specific, and positive feedback and encouragement regarding some aspect of their children's performance, and (3b) encouraging the use of process goals that allow for success and are achievable.

Table 3 exemplifies the relationships between the 3 parental behavior change objectives and the previously established theoretical basis for children's PA behavior change.

Table . Relationships between physical activity (PA) parenting objectives and theoretical constructs of children's PA.

PA parenting behavioral objective	• Theoretical basis for children's behavior change (related theory)
Parents serve as role models for their children's PA	• Observing parents (as influential role models) successfully performing the behavior can improve children's self-efficacy (SCT[a]) and promote feelings of relatedness (SDT[b]) and competence (SDT), while shifting outcome expectations (SCT).
Parents will provide instrumental and informational support, including provision of choices, for their children's PA	• Providing activity choices and a rationale for all prescribed activities supports the development of autonomy (SDT) and knowledge (SCT) of engaging in PA for the children. • Development of familial support (SCT) for the children can encourage feelings of relatedness (SDT).
Parents will provide praise and encouragement for their children's PA	• Positive feedback from parents supports the development of self-efficacy (SCT) and perceptions of competence (SDT) in the children. • Process goals that are moderate and focus attention on the task (rather than performance relative to others) support autonomy (SDT), perceived competence (SDT), and self-efficacy (SCT).

[a]SCT: social cognitive theory.

[b]SDT: self-determination theory.

Step 3: Theory-Informed Strategy

To target the parental objectives in our communication materials, we needed to (1) identify the theoretical determinants of the PA parenting behaviors we wished to change and (2) outline the methods for addressing the determinants in a communication campaign. Collectively, step 3 can be thought of as the theory-informed strategy for advancing our PA parenting objectives. Here, our definition of "theory-informed" is that the strategy for operationalization is informed by behavioral and social science theories [28]. Our theoretical basis provides evidence for why we anticipate our strategy will result in the desired parental behavior change.

Within the theoretical basis, we identified the determinants of the PA parenting behaviors we aimed to influence in our communications campaign. This process included a combination of literature and expert review from our team. After identifying the SCT or SDT constructs indicative of the parenting behavior, we then described the role of the theoretical determinant in advancing the behavioral objective. All constructs were contextualized based on their reciprocal relationships with one another. After determining the constructs predictive of the desired behavior change, we sought to outline the application of the constructs, or the methods for operationalizing the determinants into the communication messages. Outlining the methods for operationalizing the theoretical constructs required careful consideration for how to address the determinants through communication messages.

Table 4 shows how the PA parenting objectives were linked to methods via the behavioral determinants. The methods were applied by operationalizing the theoretical constructs into the communication materials in step 4.

XSL•FO
RenderX

Table . Theory-informed strategy for achieving physical activity (PA) parenting behavioral objectives.

Objective	Theoretical determinants of parent behavior change	Methods for addressing determinants
Parents will serve as role models for their children's PA	1. Improving knowledge (SCT[a]) about the role parents play in children's PA can influence realistic outcome expectations (SCT) for parents and encourage them to be role models.2. Giving families opportunities (SCT) for observational learning (SCT) can enhance parents' behavioral skills (SCT) for role modeling behaviors.3. Providing enactive mastery experiences can enhance parents' self-efficacy (SCT) and perceived competence (SDT[b]) for role modeling behaviors.	1. Parents receive information on the importance of their role in their children's PA.2. Parents are given instructions and ideas for how to model activities with their children.3. Parents are encouraged to lead their children's PA by modeling activities with supportive and accessible prompts.
Support for their children's PA	1. Sharing new and enjoyable opportunities (SCT) for family activities can enhance parents' autonomy (SDT) for providing instrumental support for their children's PA.2. Giving parents suggestions for how to reduce barriers (SCT) to PA can enhance parents' self-efficacy (SCT) for providing informational support and provision of choices for their children's PA.	1. Parents are given activity choices, with a clear description of each, and prompted to do the activities with their children.2. Parents are provided with guidance on how to overcome common barriers to engaging in PA with their children, such as space or time constraints.
Parents will provide praise and encouragement for their children's PA	1. Providing information and examples about the role of encouragement and praise in their children's PA can improve parents' knowledge (SCT) and self-efficacy (SCT) for encouraging and praising their children's PA.2. The act of self-monitoring and setting goals (SCT) or intentions (SCT) as a family and reinforcing (SCT) them every week throughout the program can improve parents' perceived competence (SDT) for encouraging and praising their children's PA.	1. Parents receive background information and user-friendly prompts to give frequent, specific, and positive praise for their children's PA behaviors.2. Materials reference and discuss the use of process goals for parents to use to encourage their children's PA.

[a]SCT: social cognitive theory.

[b]SDT: self-determination theory.

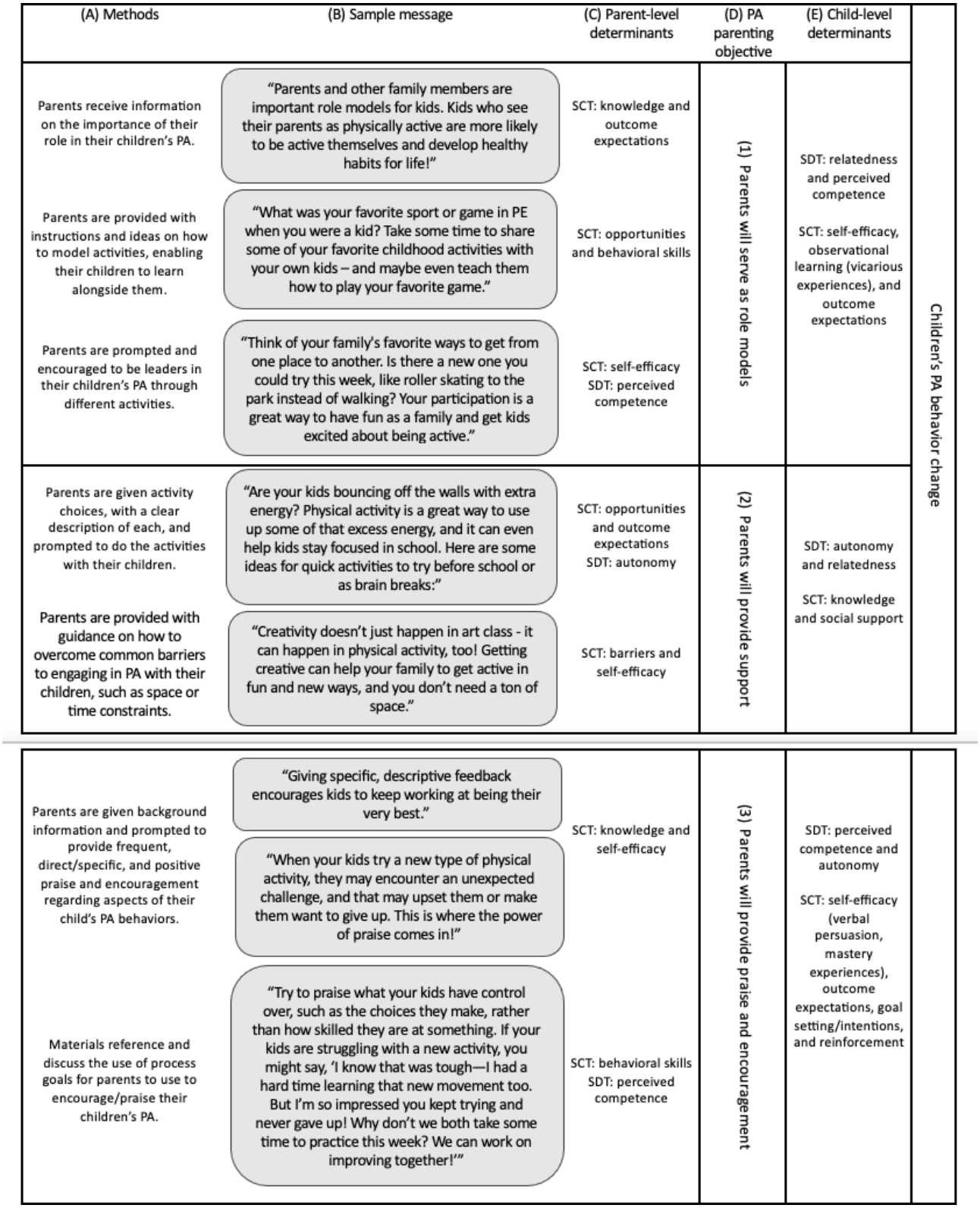
Step 4: Operationalization

In the final design step, the theory-informed messages were written and fully integrated into communication materials. Communication channels included emails, text messages, Facebook posts, and newsletters. The process for drafting and editing the messages was iterative and involved the entire research team.

Figure 2 includes sample messages exemplifying how we operationalized our strategy to achieve our PA parenting behavioral objectives. Each sample message is a manifestation of one or more methods (Figure 2A). In operationalizing our strategy, we can target key parent-level determinants (Figure 2C) that influence our PA parenting behaviors (Figure 2D). The PA parenting objectives are linked to changes in children's PA behavior via the child-level determinants (Figure 2E).

XSL•FO
RenderX

Figure 2. Operationalization of theory-informed strategy for achieving physical activity (PA) parenting behavioral objectives. SCT: social cognitive theory; SDT: self-determination theory; PA: physical activity.



Two study team members worked together to write the first draft of the family communication messages. One Tufts team member served as the behavior change expert, ensuring the theoretical constructs, methods, and parameters identified in step 3 were incorporated into the content; the other RNYRR team member served as the curriculum expert, ensuring the school-based curriculum was aligned with the family content. Both team members carefully deconstructed each message and mapped theoretical constructs to the messages. A grid was created to keep track of construct operationalization, ensuring intentionality. Input was obtained from other team members over multiple rounds and edits. Careful consideration was taken to ensure the content was appropriate for the target audience's sociodemographic, cultural, and educational backgrounds.

XSL•FO
RenderX

Messages were refined and final edits were presented to and agreed upon by all team members. Final materials were translated into Spanish for the study's target audience.

Email served as the primary communication channel, with the other modes of communication written to reinforce that channel. All materials were aligned with the program theme, Rising Together, emphasizing the importance of being active as a family. Final material design was overseen by RNYRR to ensure consistency in appearance. When families signed up to receive the materials, they had the option to sign up for emails only, text messages only, or both emails and texts. To achieve equity in access to materials, all email communications were printed and delivered to participating schools to be placed into children's backpacks on a weekly basis. Print-based emails contained QR codes that could be scanned to access the electronic content. The 20-week communications campaign and multilevel program were pilot tested in 6 NYC elementary schools during the 2021 - 2022 school year.

Discussion

Principal Findings

This descriptive study details a 4-step process used to operationalize behavior change theory in a multichannel communications campaign, nested within a multilevel PA intervention. We describe systematic procedures that can be used in designing behavior change communication messages seeking to improve PA parenting behaviors and promote children's PA.

The ability of parent engagement strategies to effectively engage parents and promote children's PA in school-based interventions remains inconclusive [18]. We provide a practical 4-step process using commonly cited strategies that can be applied and empirically evaluated for their independent impact on school-based intervention effectiveness [14,50]. As Bandura [69] noted, public health campaigns are important for getting people to adopt health behaviors. However, health communications foster adoption of health behaviors to the extent that they raise individuals' self-efficacy. Health communications must therefore be designed to enable people to build the necessary skills and self-beliefs needed to change their behaviors. Given the intentionality and feasibility of our communications to engage parents and impact parental-level determinants and behaviors, future applications of our methods can begin to advance understanding of the isolated impact of parent engagement strategies on child-level outcomes.

Comparison With Prior Work

To our knowledge, this 4-step design process is innovative within multilevel behavior change interventions. Similar strategies have been used in designing interventions for various behaviors, including medication adherence [70], hand hygiene compliance [71], and occupational sedentary behavior [33], and in various contexts, including tailored feedback during a weight loss intervention [72] and a garden-enhanced nutrition curriculum [73]. However, only one of these interventions [74] addresses the complexity of promoting behavior change through an additional level of influence, as we aim to do in influencing PA parenting practices to promote children's PA. This additional level of behavior change makes our approach valuable for others seeking translatable methods for applying theory-informed strategies to multilevel behavior change, such as in efforts to promote children's PA.

Current frameworks for theory application do not include specific methods for designing health communications as part of intervention design [29,30,75]. While the theoretical evidence includes guides for translating theory-based methods into practical applications, these frameworks fall short of providing advice for operationalizing theoretical determinants into behavior change communication messages. Furthermore, while the empirical evidence provides examples of how theoretical constructs were translated into behavior change methods [70] or intervention activities and components [33,73,74], none have been specific to the translation of theory for the content of communications. This descriptive study addresses gaps in current intervention design frameworks and studies and complements their use by providing practical advice and examples for operationalizing theory into communication messages. The methods used in this descriptive study may, therefore, be used by interventionists in congruence with current frameworks to create communications that can be incorporated into multilevel behavior change interventions, which have been recommended for increasing children's PA [13].

While there are many functions and benefits of theory application during the design, implementation, and evaluation stages of interventions [49,75-77], increased effectiveness is often cited as the primary reason for the use of theory in behavior change intervention design [78]. This argument may hold for theory-informed approaches to promote children's PA [46,49,50], despite inconsistent conclusions on whether the use of theory improves intervention effectiveness [15]. Prior studies have noted that the variable findings on the effectiveness of behavior change interventions, including those for children's PA, could be explained by "methodological and reporting issues at study and review level," including issues with how theory is applied during the intervention design process [78]. Michie and Prestwich [31], for example, point out that "where a theoretical base for an intervention is stated, there is seldom reference to a method describing how the theory informed the design of the intervention." By providing a detailed example and replicable methods for applying theory to communication materials, one of the crucial steps in the intervention life cycle, we believe our study to be of benefit to others attempting to be more rigorous in both their application of theory and reporting of its use in PA interventions.

This descriptive study's description of the operationalization of theory in our communication materials will provide important contextual information for interpreting future results of the communications campaign. The feasibility of implementing the communications campaign and the acceptability of the materials for the target population will also be considered in a pilot study, and adjustments to the materials will be made. The adapted communications will be implemented in a randomized controlled trial. Findings from the trial will be used to understand if our theory-informed communications effectively engage parents, thereby influencing their determinants of PA and PA parenting

XSL•FO
RenderX

behaviors, while examining the overall impact of the intervention on children's PA determinants and PA behaviors. After a second phase of adjustment, including any adjustments to the methods outlined in this study, the communications may be considered for dissemination across the NYRR network of schools. Given the diversity and reach of the schools and the continuous feedback solicited by the program, the materials may continue to be adapted to fit local contexts and populations. The present descriptive study, together with future research plans, will therefore jointly advance the broader field of childhood PA research and practice.

Limitations

Given the lack of examples in the literature, our descriptive study is not without constraints. For example, when operationalizing the theory-informed strategy from step 3 into communication messages in step 4, we lacked explicit guidance on any methodological parameters that should be considered. As previously discussed by Kok et al [30], the effectiveness of a behavior change method will depend on whether the parameters for the method are satisfied. In other words, a theory-informed strategy requires more than outlining what constructs to target and what methods to use to operationalize the constructs; it requires a consideration for the "theoretical parameters under which the theoretical process is effective or not" [30,79]. An example in the context of our descriptive study would be that improving parental self-efficacy requires a series of reinforcing messages, as opposed to a single message [49]. Parameters for operationalizing theory are not clearly defined for the application of parenting behavior change. Empirical evidence of what conditions were used when operationalizing theory for parenting behaviors will be required to determine the relevant parameters for effectiveness.

Participation of the target population is important for establishing the most relevant theoretical determinants of a behavior or for understanding how theory-informed strategies should be applied in the design process [29]. Our formative research with the priority population, including focus groups with parents, focused on topics such as communication channel preference and the feasibility of engaging parents through communication materials but did not include an explicit theoretical focus. Additional formative research informed by SCT and SDT may have enabled further tailoring in how we operationalized theory in our communication messages.

Conclusions

This descriptive study advances progress in the development of school-based PA promotion efforts seeking to incorporate parent engagement strategies by detailing the operationalization of theory into communication messages. Future application of our 4-step process can be used to develop theory-informed communication materials that aim to target PA parenting behaviors.

The methodology detailed in this descriptive study is valuable for others seeking to translate theoretical constructs into behavior-change communication messages. This work provides an example and draws attention to the role of rigorous theory application and reporting in developing communications that support children's PA behavior change as part of overall behavior-change intervention design.

Acknowledgments

BCW was supported by the National Needs Fellowship (grant 2019-38420-29021) from the United States Department of Agriculture (USDA) National Institute of Food and Agriculture. The Rising New York Road Runners (RNYRR) study was supported by a grant from the National Cancer Institute, National Institutes of Health (R21/R33-CA226829).

Conflicts of Interest

None declared.

References

1. Janssen I, Leblanc AG. Systematic review of the health benefits of physical activity and fitness in school-aged children and youth. Int J Behav Nutr Phys Act 2010 May 11;7:40-40. [doi: 10.1186/1479-5868-7-40] [Medline: 20459784]
2. Eime RM, Young JA, Harvey JT, Charity MJ, Payne WR. A systematic review of the psychological and social benefits of participation in sport for adults: informing development of a conceptual model of health through sport. Int J Behav Nutr Phys Act 2013 Dec 7;10:135-135. [doi: 10.1186/1479-5868-10-135] [Medline: 24313992]
3. Whitt-Glover MC, Taylor WC, Floyd MF, Yore MM, Yancey AK, Matthews CE. Disparities in physical activity and sedentary behaviors among US children and adolescents: prevalence, correlates, and intervention implications. J Public Health Policy 2009;30 Suppl 1:S309-S334. [doi: 10.1057/jphp.2008.46] [Medline: 19190581]
4. Troiano RP, Berrigan D, Dodd KW, Mâsse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. Med Sci Sports Exerc 2008 Jan;40(1):181-188. [doi: 10.1249/mss.0b013e31815a51b3] [Medline: 18091006]
5. Belcher BR, Berrigan D, Dodd KW, Emken BA, Chou CP, Spruijt-Metz D. Physical activity in US youth: effect of race/ethnicity, age, gender, and weight status. Med Sci Sports Exerc 2010 Dec;42(12):2211-2221. [doi: 10.1249/MSS.0b013e3181e1fba9] [Medline: 21084930]
6. Hubbard K, Economos CD, Bakun P, et al. Disparities in moderate-to-vigorous physical activity among girls and overweight and obese schoolchildren during school- and out-of-school time. Int J Behav Nutr Phys Act 2016 Mar 22;13:39. [doi: 10.1186/s12966-016-0358-x] [Medline: 27000400]

XSL•FO
RenderX

7. Piercy KL, Troiano RP, Ballard RM, et al. The Physical Activity Guidelines for Americans. JAMA 2018 Nov 20;320(19):2020-2028. [doi: 10.1001/jama.2018.14854] [Medline: 30418471]
8. Seabra A, Mendonça D, Maia J, et al. Gender, weight status and socioeconomic differences in psychosocial correlates of physical activity in schoolchildren. J Sci Med Sport 2013 Jul;16(4):320-326. [doi: 10.1016/j.jsams.2012.07.008] [Medline: 23085528]
9. Lonsdale C, Rosenkranz RR, Peralta LR, Bennie A, Fahey P, Lubans DR. A systematic review and meta-analysis of interventions designed to increase moderate-to-vigorous physical activity in school physical education lessons. Prev Med 2013 Feb;56(2):152-161. [doi: 10.1016/j.ypmed.2012.12.004]
10. Neil-Sztramko SE, Caldwell H, Dobbins M. School-based physical activity programs for promoting physical activity and fitness in children and adolescents aged 6 to 18. Cochrane Database Syst Rev 2021 Sep 23;9(9):CD007651. [doi: 10.1002/14651858.CD007651.pub3] [Medline: 34555181]
11. Carlson JA, Sallis JF, Norman GJ, et al. Elementary school practices and children's objectively measured physical activity during school. Prev Med 2013 Nov;57(5):591-595. [doi: 10.1016/j.ypmed.2013.08.003]
12. Hills AP, Dengel DR, Lubans DR. Supporting public health priorities: recommendations for physical education and physical activity promotion in schools. Prog Cardiovasc Dis 2015;57(4):368-374. [doi: 10.1016/j.pcad.2014.09.010] [Medline: 25269062]
13. van Sluijs EMF, McMinn AM, Griffin SJ. Effectiveness of interventions to promote physical activity in children and adolescents: systematic review of controlled trials. BMJ 2007 Oct 6;335(7622):703. [doi: 10.1136/bmj.39320.843947.BE] [Medline: 17884863]
14. Golley RK, Hendrie GA, Slater A, Corsini N. Interventions that involve parents to improve children's weight-related nutrition intake and activity patterns - what nutrition and activity targets and behaviour change techniques are associated with intervention effectiveness? Obes Rev 2011 Feb;12(2):114-130. [doi: 10.1111/j.1467-789X.2010.00745.x] [Medline: 20406416]
15. Van Lippevelde W, Verloigne M, De Bourdeaudhuij I, et al. Does parental involvement make a difference in school-based nutrition and physical activity interventions? A systematic review of randomized controlled trials. Int J Public Health 2012 Aug;57(4):673-678. [doi: 10.1007/s00038-012-0335-3] [Medline: 22301709]
16. Hatfield DP, Chomitz VR, Chui KKH, Sacheck JM, Economos CD. Demographic, physiologic, and psychosocial correlates of physical activity in structured exercise and sports among low-income, overweight children. J Nutr Educ Behav 2015;47(5):452-458. [doi: 10.1016/j.jneb.2015.05.008] [Medline: 26145759]
17. Trost SG, Loprinzi PD. Parental influences on physical activity behavior in children and adolescents: a brief review. Am J Lifestyle Med 2011 Mar;5(2):171-181. [doi: 10.1177/1559827610387236]
18. Michael SL, Barnes SP, Wilkins NJ. Scoping review of family and community engagement strategies used in school-based interventions to promote healthy behaviors. J Sch Health 2023 Sep;93(9):828-841. [doi: 10.1111/josh.13367] [Medline: 37670597]
19. Van Lippevelde W, Verloigne M, De Bourdeaudhuij I, et al. What do parents think about parental participation in school-based interventions on energy balance-related behaviours? A qualitative study in 4 countries. BMC Public Health 2011 Nov 23;11(1):881-881. [doi: 10.1186/1471-2458-11-881] [Medline: 22112159]
20. Hnatiuk JA, Brown HE, Downing KL, Hinkley T, Salmon J, Hesketh KD. Interventions to increase physical activity in children 0-5 years old: a systematic review, meta-analysis and realist synthesis. Obes Rev 2019 Jan;20(1):75-87. [doi: 10.1111/obr.12763] [Medline: 30257277]
21. O'Connor TM, Jago R, Baranowski T. Engaging parents to increase youth physical activity a systematic review. Am J Prev Med 2009 Aug;37(2):141-149. [doi: 10.1016/j.amepre.2009.04.020] [Medline: 19589450]
22. Hale J, Hastings J, West R, et al. An ontology-based modelling system (OBMS) for representing behaviour change theories applied to 76 theories. Wellcome Open Res 2020;5:177. [doi: 10.12688/wellcomeopenres.16121.1] [Medline: 33215048]
23. Wright AJ, Norris E, Finnerty AN, et al. Ontologies relevant to behaviour change interventions: a method for their development. Wellcome Open Res 2020;5:126. [doi: 10.12688/wellcomeopenres.15908.3] [Medline: 33447665]
24. Hastings J, Michie S, Johnston M. Theory and ontology in behavioural science. Nat Hum Behav 2020 Mar;4(3):226. [doi: 10.1038/s41562-020-0826-9] [Medline: 32066979]
25. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013 Aug;46(1):81-95. [doi: 10.1007/s12160-013-9486-6] [Medline: 23512568]
26. Michie S, Ashford S, Sniehotta FF, Dombrowski SU, Bishop A, French DP. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: the CALO-RE taxonomy. Psychol Health 2011 Nov;26(11):1479-1498. [doi: 10.1080/08870446.2010.540664] [Medline: 21678185]
27. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. Health Psychol 2008 May;27(3):379-387. [doi: 10.1037/0278-6133.27.3.379] [Medline: 18624603]
28. Bartholomew LK, Parcel GS, Kok G. Intervention mapping: a process for developing theory- and evidence-based health education programs. Health Educ Behav 1998 Oct;25(5):545-563. [doi: 10.1177/109019819802500502] [Medline: 9768376]

XSL•FO
RenderX

29. Kok G. A practical guide to effective behavior change: how to apply theory- and evidence-based behavior change methods in an intervention. Eur Health Psychol 2014;16(5):156-170 [FREE Full text]
30. Kok G, Gottlieb NH, Peters GJY, et al. A taxonomy of behaviour change methods: an Intervention mapping approach. Health Psychol Rev 2016 Sep;10(3):297-312. [doi: 10.1080/17437199.2015.1077155] [Medline: 26262912]
31. Michie S, Prestwich A. Are interventions theory-based? Development of a theory coding scheme. Health Psychol 2010 Jan;29(1):1-8. [doi: 10.1037/a0016939] [Medline: 20063930]
32. Teixeira PJ, Marques MM, Silva MN, et al. A classification of motivation and behavior change techniques used in self-determination theory-based interventions in health contexts. Motiv Sci 2020;6(4):438-455. [doi: 10.1037/mot0000172]
33. Stephenson A, Garcia-Constantino M, McDonough SM, Murphy MH, Nugent CD, Mair JL. Iterative four-phase development of a theory-based digital behaviour change intervention to reduce occupational sedentary behaviour. Digit HEALTH 2020;6:2055207620913410. [doi: 10.1177/2055207620913410] [Medline: 32257366]
34. Willmott T, Rundle-Thiele S. Are we speaking the same language? Call for action to improve theory application and reporting in behaviour change research. BMC Public Health 2021 Mar 10;21(1):479. [doi: 10.1186/s12889-021-10541-1] [Medline: 33691658]
35. Michie S, Abraham C. Interventions to change health behaviours: evidence-based or evidence-inspired? Psychol Health 2004 Feb;19(1):29-49. [doi: 10.1080/0887044031000141199]
36. The essential components of physical education. SHAPE America – Society of Health and Physical Educators. 2015. URL: https://www.shapeamerica.org/Common/Uploaded%20files/uploads/pdfs/TheEssentialComponentsOfPhysicalEducation.pdf
37. Physical literacy. Sport for Life. URL: https://sportforlife.ca/physical-literacy/ [accessed 2025-07-24]
38. Hatfield DP, Chomitz VR, Chui KKH, Sacheck JM, Brown AA, Economos CD. Impact of a community-based physical activity program on fitness and adiposity among overweight and obese children. Health Promot Pract 2017 Jan;18(1):75-83. [doi: 10.1177/1524839916642714] [Medline: 27199149]
39. Wright CM, Duquesnay PJ, Anzman-Frasca S, et al. Study protocol: the Fueling Learning through Exercise (FLEX) study - a randomized controlled trial of the impact of school-based physical activity programs on children's physical activity, cognitive function, and academic achievement. BMC Public Health 2016 Oct 13;16(1):1078. [doi: 10.1186/s12889-016-3719-0] [Medline: 27737676]
40. Hennessy E, Hughes SO, Goldberg JP, Hyatt RR, Economos CD. Parent-child interactions and objectively measured child physical activity: a cross-sectional study. Int J Behav Nutr Phys Act 2010 Oct 7;7:71. [doi: 10.1186/1479-5868-7-71] [Medline: 20929570]
41. Lynskey VM, Shonkoff ET, Matthews E, et al. Using a marketing evaluation tool to optimize a social marketing campaign: insights from a copy test of a you're the mom campaign ad. J Nutr Educ Behav 2018 Oct;50(9):937-946. [doi: 10.1016/j.jneb.2018.05.009] [Medline: 30166256]
42. Physical literacy in the united states: a model, strategic plan, and call to action. The Aspen Institute. 2015. URL: https://static1.squarespace.com/static/595ea7d6e58c62dce01d1625/t/5a58ff530d9297816e8e6ff8/1515781978376/PhysicalLiteracy_AspenInstitute+%28Full+report%29.pdf [accessed 2025-07-26]
43. Young MD, Plotnikoff RC, Collins CE, Callister R, Morgan PJ. Social cognitive theory and physical activity: a systematic review and meta-analysis. Obes Rev 2014 Dec;15(12):983-995. [doi: 10.1111/obr.12225] [Medline: 25428600]
44. Chen A. Operationalizing physical literacy for learners: embodying the motivation to move. J Sport Health Sci 2015 Jun;4(2):125-131. [doi: 10.1016/j.jshs.2015.03.005]
45. Kwasnicka D, Dombrowski SU, White M, Sniehotta F. Theoretical explanations for maintenance of behaviour change: a systematic review of behaviour theories. Health Psychol Rev 2016 Sep;10(3):277-296. [doi: 10.1080/17437199.2016.1151372] [Medline: 26854092]
46. Lubans DR, Foster C, Biddle SJH. A review of mediators of behavior in interventions to promote physical activity among children and adolescents. Prev Med 2008 Nov;47(5):463-470. [doi: 10.1016/j.ypmed.2008.07.011]
47. Taylor IM, Lonsdale C. Cultural differences in the relationships among autonomy support, psychological need satisfaction, subjective vitality, and effort in British and Chinese physical education. J Sport Exerc Psychol 2010 Oct;32(5):655-673. [doi: 10.1123/jsep.32.5.655] [Medline: 20980709]
48. Bandura A, National Institution of Mental Health. Social Foundations of Thought and Action: A Social Cognitive Theory: Prentice-Hall; 1986.
49. Glanz K, Bishop DB. The role of behavioral science theory in development and implementation of public health interventions. Annu Rev Public Health 2010;31:399-418. [doi: 10.1146/annurev.publhealth.012809.103604] [Medline: 20070207]
50. Brown HE, Atkin AJ, Panter J, Wong G, Chinapaw MJM, van Sluijs EMF. Family-based interventions to increase physical activity in children: a systematic review, meta-analysis and realist synthesis. Obes Rev 2017 Apr;18(4):491-494. [doi: 10.1111/obr.12493] [Medline: 28260230]
51. Deci EL, Ryan RM. Intrinsic Motivation and Self-Determination in Human Behavior: Springer; 1985. URL: https://link.springer.com/book/10.1007/978-1-4899-2271-7 [accessed 2025-08-14]
52. Fortier MS, Duda JL, Guerin E, Teixeira PJ. Promoting physical activity: development and testing of self-determination theory-based interventions. Int J Behav Nutr Phys Act 2012 Mar 2;9:20. [doi: 10.1186/1479-5868-9-20] [Medline: 22385751]

XSL•FO
RenderX

53. Zhang T, Solmon M. Integrating self-determination theory with the social ecological model to understand students' physical activity behaviors. Int Rev Sport Exerc Psychol 2013 Sep;6(1):54-76. [doi: 10.1080/1750984X.2012.723727]
54. Hagger MS, Chatzisarantis NLD. The trans-contextual model of autonomous motivation in education: conceptual and empirical issues and meta-analysis. Rev Educ Res 2016 Jun;86(2):360-407. [doi: 10.3102/0034654315585005] [Medline: 27274585]
55. Sevil-Serrano J, Aibar A, Abós Á, Generelo E, García-González L. Improving motivation for physical activity and physical education through a school-based intervention. The Journal of Experimental Education 2022 Apr 3;90(2):383-403. [doi: 10.1080/00220973.2020.1764466]
56. Sevil J, García-González L, Abós Á, Generelo Lanaspa E, Aibar Solana A. Which school community agents influence adolescents' motivational outcomes and physical activity? Are more autonomy-supportive relationships necessarily better? Int J Environ Res Public Health 2018 Aug 30;15(9):1875. [doi: 10.3390/ijerph15091875] [Medline: 30200200]
57. Gillison FB, Rouse P, Standage M, Sebire SJ, Ryan RM. A meta-analysis of techniques to promote motivation for health behaviour change from a self-determination theory perspective. Health Psychol Rev 2019 Mar;13(1):110-130. [doi: 10.1080/17437199.2018.1534071] [Medline: 30295176]
58. González‐Cutre D, Sicilia Á, Beas‐Jiménez M, Hagger MS. Broadening the trans‐contextual model of motivation: a study with Spanish adolescents. Scandinavian Med Sci Sports 2014 Aug;24(4):e306-e319. [doi: 10.1111/sms.12142]
59. McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. Health Educ Q 1988;15(4):351-377. [doi: 10.1177/109019818801500401] [Medline: 3068205]
60. Zhang T, Thomas K, Weiller K. Predicting physical activity in 10-12 year old children: a social ecological approach. J Teach Phys Educ 2015;34(3):517-536. [doi: 10.1123/jtpe.2013-0195]
61. Abdelghaffar EA, Hicham EK, Siham B, Samira EF, Youness EA. Perspectives of adolescents, parents, and teachers on barriers and facilitators of physical activity among school-age adolescents: a qualitative analysis. Environ Health Prev Med 2019 Apr 9;24(1):21. [doi: 10.1186/s12199-019-0775-y] [Medline: 30961543]
62. Yao CA, Rhodes RE. Parental correlates in child and adolescent physical activity: a meta-analysis. Int J Behav Nutr Phys Act 2015 Feb 11;12:10. [doi: 10.1186/s12966-015-0163-y] [Medline: 25890040]
63. Biddle SJH, Atkin AJ, Cavill N, Foster C. Correlates of physical activity in youth: a review of quantitative systematic reviews. Int Rev Sport Exerc Psychol 2011 Mar;4(1):25-49. [doi: 10.1080/1750984X.2010.548528]
64. Davison KK, Mâsse LC, Timperio A, et al. Physical activity parenting measurement and research: challenges, explanations, and solutions. Child Obes 2013 Aug;9 Suppl(Suppl 1):S103-S109. [doi: 10.1089/chi.2013.0037] [Medline: 23944918]
65. Loprinzi PD, Trost SG. Parental influences on physical activity behavior in preschool children. Prev Med 2010 Mar;50(3):129-133. [doi: 10.1016/j.ypmed.2009.11.010]
66. Dowda M, Pfeiffer KA, Brown WH, Mitchell JA, Byun W, Pate RR. Parental and environmental correlates of physical activity of children attending preschool. Arch Pediatr Adolesc Med 2011 Oct;165(10):939-944. [doi: 10.1001/archpediatrics.2011.84] [Medline: 21646573]
67. Trost SG, Sallis JF, Pate RR, Freedson PS, Taylor WC, Dowda M. Evaluating a model of parental influence on youth physical activity. Am J Prev Med 2003 Nov;25(4):277-282. [doi: 10.1016/s0749-3797(03)00217-4] [Medline: 14580627]
68. Seabra AC, Maia J, Seabra AF, Welk G, Brustad R, Fonseca AM. Evaluating the youth physical activity promotion model among Portuguese elementary school children. J Phys Act Health 2013 Nov;10(8):1159-1165. [doi: 10.1123/jpah.10.8.1159] [Medline: 23220890]
69. Bandura A. Health promotion by social cognitive means. Health Educ Behav 2004 Apr;31(2):143-164. [doi: 10.1177/1090198104263660] [Medline: 15090118]
70. Patton DE, Ryan C, Hughes CM. Development of a complex community pharmacy intervention package using theory-based behaviour change techniques to improve older adults' medication adherence. BMC Health Serv Res 2020 May 13;20(1):418. [doi: 10.1186/s12913-020-05282-7] [Medline: 32404090]
71. Sands M, Aunger R. Development of a behaviour change intervention using a theory-based approach, Behaviour Centred Design, to increase nurses' hand hygiene compliance in the US hospitals. Implement Sci Commun 2021 Feb 18;2(1):23. [doi: 10.1186/s43058-021-00124-x] [Medline: 33602328]
72. Ryan K, Murphy LE, Linehan C, Dockray S. Theory in practice: identifying theory-based techniques in health coaches' tailored feedback during a weight loss intervention. Psychol Health 2020 Nov 1;35(11):1384-1406. [doi: 10.1080/08870446.2020.1748629]
73. Linnell JD, Zidenberg-Cherr S, Briggs M, et al. Using a systematic approach and theoretical framework to design a curriculum for the Shaping Healthy Choices Program. J Nutr Educ Behav 2016 Jan;48(1):60-69. [doi: 10.1016/j.jneb.2015.09.010]
74. Bestle SMS, Christensen BJ, Trolle E, et al. Reducing young school children's intake of sugar-rich food and drinks: study protocol and intervention design for "Are You Too Sweet?" A multicomponent 3.5-month cluster randomised family-based intervention study. Int J Environ Res Public Health 2020 Dec 21;17(24):9580. [doi: 10.3390/ijerph17249580] [Medline: 33561071]
75. Bartholomew LK, Mullen PD. Five roles for using theory and evidence in the design and testing of behavior change interventions. J Public Health Dent 2011;71 Suppl 1:S20-S33. [doi: 10.1111/j.1752-7325.2011.00223.x] [Medline: 21656946]

XSL•FO
RenderX

76. Damschroder LJ. Clarity out of chaos: Use of theory in implementation research. Psychiatry Res 2020 Jan;283:112461. [doi: 10.1016/j.psychres.2019.06.036] [Medline: 31257020]
77. Davidoff F, Dixon-Woods M, Leviton L, Michie S. Demystifying theory and its use in improvement. BMJ Qual Saf 2015 Mar;24(3):228-238. [doi: 10.1136/bmjqs-2014-003627] [Medline: 25616279]
78. Dalgetty R, Miller CB, Dombrowski SU. Examining the theory-effectiveness hypothesis: a systematic review of systematic reviews. Br J Health Psychol 2019 May;24(2):334-356. [doi: 10.1111/bjhp.12356] [Medline: 30793445]
79. Kok G, Gottlieb NH, Panne R, Smerecnik C. Methods for environmental change; an exploratory study. BMC Public Health 2012 Nov 28;12:1037-1037. [doi: 10.1186/1471-2458-12-1037] [Medline: 23190712]

Abbreviations

NYRR: New York Road Runners
PA: physical activity
PL: physical literacy
RNYRR: Rising New York Road Runners
SCT: social cognitive theory
SDT: self-determination theory
SPLASH: Supporting Physical Literacy at School and Home

Edited by A Serlachius; submitted 05.03.25; peer-reviewed by H Tilga, L Columna; revised version received 23.06.25; accepted 06.07.25; published 26.08.25.

Please cite as:
Wilhite BC, Hennessy E, Economos C, Sacheck J, Zive R, Odalen C, Herrick S, Hatfield DP
Content Development for a Multilevel Intervention to Operationalize Behavior Change Theory and Improve Parenting Behaviors for Physical Activity: Descriptive Study
JMIR Pediatr Parent 2025;8:e73510
URL: https://pediatrics.jmir.org/2025/1/e73510
doi:10.2196/73510

©Breanne C Wilhite, Erin Hennessy, Christina Economos, Jennifer Sacheck, Rachel Zive, Christine Odalen, Stephanie Herrick, Daniel P Hatfield. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 26.8.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Moderators of a mHealth Intervention for Adolescent Physical Activity: Intervention Refinement Study

Christopher C Cushing[1], PhD; Adrian Ortega[2,3], PhD; David A Fedele[4], PhD; Calissa J Leslie-Miller[1], MS; Jordan A Carlson[5], PhD; Ann M Davis[6], PhD; Joshua M Smyth[7], PhD

[1]Department of Clinical Child Psychology and Life Span Institute, University of Kansas, 1000 Sunnyside Avenue, Lawrence, KS, United States

[2]Division of Developmental and Behavioral Health and Center for Children's Healthy Lifestyle & Nutrition, Children's Mercy, Kansas City, MO, United States

[3]Department of Pediatrics, University of Missouri-Kansas City School of Medicine, Kansas City, MO, United States

[4]Nemours Children's Health, Jacksonville, FL, United States

[5]Center for Children's Healthy Lifestyles & Nutrition, Children's Mercy, Kansas City, MO, United States

[6]Department of Pediatrics, Division of Developmental and Behavioral Pediatrics, Center for Children's Healthy Lifestyles & Nutrition, University of Kansas Medical Center, Kansas City, KS, United States

[7]Department of Psychology, The Ohio State University, Columbus, OH, United States

Corresponding Author:
Christopher C Cushing, PhD
Department of Clinical Child Psychology and Life Span Institute, University of Kansas, 1000 Sunnyside Avenue, Lawrence, KS, United States

Abstract

Background: An adaptive text messaging intervention to promote adolescent physical activity has demonstrated feasibility, acceptability, and preliminary efficacy in a recent proof-of-concept study. To inform future intervention development, a secondary analysis of the data examined how physical activity is influenced by mood, environment, and physical feelings of energy and fatigue.

Objective: This study aims to understand how both macro- and microtemporal variables (eg, psychological and environmental variables at both levels) influence the efficacy of a brief mobile health intervention (ie, NUDGE) for physical activity.

Methods: Using a matched control design, we evaluated the effect of daily positive and negative affect, perceptions of the weather, energy, and fatigue as moderators of the effect of the intervention on 21 intervention participants and 21 matched controls.

Results: Consistent with study hypotheses, macrotemporal (levels of the variable on a 3-week timescale) moderators of intervention effectiveness were observed for positive affect (P<.001), negative affect (P=.03), energy (P<.001), fatigue (P<.001), and perceived weather barriers (P<.001) for moderate-to-vigorous physical activity. These effects were observed more consistently for moderate-to-vigorous physical activity than for sedentary behavior, which was only significant for energy (P<.001). No effects for microtemporal variables (at the day level) were observed.

Conclusions: There appears to be an optimization opportunity for mobile health physical activity interventions that can be achieved by personalizing intervention features and content based on approximately monthly assessments of affect, physical feeling states, and perceived weather barriers.

(JMIR Pediatr Parent 2025;8:e59334) doi:10.2196/59334

KEYWORDS

mHealth; mobile health; adolescent well-being; physical activity; personalized; adaptive intervention; optimization; adolescent; teen; teenager; youth; exercise; text message; text messaging; nudge; feasibility; acceptability; mood; energy; fatigue

Introduction

Physical inactivity is a significant public health concern, with recent data showing less than 25% of youth meet the recommended 60 minutes of moderate-to-vigorous physical activity (MVPA) per day [1,2]. Consequences of low MVPA and high sedentary time over the lifespan have significant well-established links to cardiovascular disease, diabetes, poor respiratory health, and cancer [2]. Levels of MVPA decrease as children transition into adolescence, with the majority of individuals failing to meet physical activity guidelines by the age of 13 years [3]. Therefore, interventions targeting increases in MVPA and decreases in sedentary time are critical for

XSL•FO
RenderX

adolescents, with long-term benefits that may accrue through adulthood.

Effect sizes for pediatric physical activity interventions are small, producing an increase in objectively measured MVPA that is less than 5 minutes per day on average [4,5]. To improve the efficacy of physical activity interventions, behavioral scientists are leveraging digital technologies to gain insight into key determinants of adolescent physical activity. An innovative perspective involves examining how macrotemporal factors (ie, slow-changing variables over weeks or months) interact with dynamic, microtemporal factors (ie, fast-changing variables over minutes, hours, or days) to influence adolescent physical activity behaviors [6]. Studying physical activity behavior in this manner may increase the understanding of how fast-changing, microtemporal (eg, daily, within-day) and slow-changing, macrotemporal (eg, long-term) variables affect physical activity engagement and could subsequently inform adaptive intervention technologies that are individually tailored to accommodate these microtemporal and macrotemporal variables.

Studies demonstrate that contextual factors, such as the availability of sidewalks and playgrounds, are related to engagement in physical activity [7]. Other macrotemporal variables related to physical activity include person-specific motivational factors, such as self-efficacy for exercise and perceived behavioral control [8-10]. In addition, Cushing et al [11], as well as Dunton et al [12], demonstrated that microtemporal variability in affect (ie, positive and negative affect), physical feeling states (ie, energy and fatigue), and external context (eg, being at home, rainy weather conditions, or time of day) [13] is related to MVPA and sedentary time, and these findings have been extended to adults as well [14]. The field has successfully established broadly that MVPA interventions work; therefore, the critical next phase of intervention optimization is understanding for whom these interventions work and in what context [15].

Framed within the ORBIT (Obesity Relation Behavioral Intervention Trials) model of intervention development [16], we [17] developed and evaluated the NUDGE (Network Underwritten Dynamic Goals Engine) as an unrandomized proof-of-concept study. NUDGE is a mobile health (mHealth) intervention that uses an automated text-message platform to promote adolescent physical activity by prompting users to self-monitor and set daily goals for minutes of MVPA, which was informed by Carver and Scheier's [18] Cybernetic Control Theory. NUDGE demonstrated feasibility and preliminary efficacy for improving adolescent MVPA (Cohen d=0.83) and sedentary time (d=0.40). Evaluating macro- and microtemporal variables and their influence on NUDGE could be especially informative and provide insight into individual determinants of physical activity engagement for intervention development.

This study is a secondary analysis of NUDGE to guide future intervention development within the "refine phase" of the ORBIT model. Briefly, this phase uses available data or literature to iteratively make changes to a program before conducting a fully powered randomized controlled trial. The goal is to understand how both macro- and microtemporal variables (eg., psychological and environmental variables at both levels) influence the efficacy of a brief mHealth intervention (ie, NUDGE) for physical activity. We expected that both macro- and microtemporal positive affect and energy would be related to larger intervention effects (ie, more MVPA and less sedentary time), whereas negative affect, fatigue, and perception of poor weather would be related to a diminished intervention effect.

Methods

Participants and Procedures

We combined participants from 2 separate studies with identical procedures, ecological momentary assessment (EMA) protocols, and objective monitoring of physical activity. The primary difference between study protocols was that one study involved the delivery of the NUDGE program to the intervention group (detailed below), whereas the other study involved an attention control group. The research team recruited participants in the NUDGE group in 2017 and the attention-control group from 2015 to 2016. Recruitment occurred across all 4 seasons of the year. Recruitment methods included flyers, information letters, and social media postings. We excluded adolescents from participating if they had vision loss or low vision, could not read English, or had a medical condition that would limit their physical activity.

We conducted phone screenings with adolescents 13 - 18 years of age and their caregivers to determine their eligibility for the study and scheduled eligible adolescents for a baseline visit. At that visit, we obtained informed consent and assent for caregivers and adolescents, respectively. We provided participants with an accelerometer to wear on their nondominant wrist for the 20-day study period and trained them on how to respond to the EMA surveys via a study smartphone. To maximize adherence to the protocol [19], we allowed participants to select 4 times per day (2 morning and 2 afternoon and evening) to receive EMA surveys, with each survey delivered at least 2 hours apart. Participants in the NUDGE intervention chose an additional time in the evening to receive text messages to set physical activity goals and a time in the morning to receive a goal reminder text message. Participants received up to US $40 for completing study procedures.

NUDGE Intervention

As described elsewhere [17], the NUDGE intervention is an automated chatbot. Users are asked to set a daily physical activity goal in minutes of MVPA, which is stored by the system. Next, users are prompted to self-monitor their MVPA at the end of the day and are provided with feedback based on their goal attainment. This process repeats daily for the 20-day study period. A goal is set based on a user's self-reported exercise from the prior day. Users are allowed to set slightly more or less ambitious goals depending on their preference, but overall, the system encourages increasingly strenuous goals until users achieve 60 minutes of MVPA in a single day.

Matched Attention Control Condition

We drew a matched sample of 21 participants from a 100-person dataset of individuals who did not complete the intervention to

XSL•FO
RenderX

create the matched attention control. Attention control participants were matched to NUDGE participants on sex, age, and race and ethnicity, with priority given in the order the variables are listed. Participants who did not receive the NUDGE intervention were given the same study experience. They wore an accelerometer on their nondominant wrist, answered EMA surveys at 4 self-selected times per day for 20 days, and completed the same baseline and exit questionnaires. Research staff explained that the study was an assessment of physical activity and psychological variables, and the reimbursement structure was the same as the NUDGE group.

Measures

Demographics

Adolescents completed self-reported measures of demographic variables (eg, sex as a biological variable and race and ethnicity) during the baseline visit.

Physical Activity and Sedentary Time

We used wrist-worn ActiGraph GT3X-BT accelerometers (ActiGraph LLC) to measure physical activity across 20 consecutive intervention days. We initialized accelerometers to detect movements at 30 Hz. We processed the accelerometer data in Actigraph Actilife software v6.10.2 and converted raw measurements into 60-second epochs. We removed sleep and nonwear periods using the Sadeh et al [20] and Troiano et al [21] algorithms, respectively. We used the Chandler algorithm [22], a validated algorithm for measuring MVPA in youth using wrist-worn accelerometers, to define cut points for sedentary behavior, light physical activity, and MVPA.

Positive and Negative Affect

We measured positive and negative affect 4 times per day via EMA using the Positive and Negative Affect Schedule for Children (PANAS-C; [23,24]). The PANAS-C has strong psychometric properties for describing positive and negative affect and also demonstrates good test-retest reliability and convergent and discriminant validity [24,25]. Previous studies show delivering the PANAS-C on a mobile phone is feasible, reliable, and successful in gathering EMA responses to measure affect in real time [11,12,26,27]. The positive affective domain included the following mood states: joyful, cheerful, happy, lively, and proud. The negative affective domain included the following mood states: miserable, mad, afraid, scared, and sad. Participants rated the extent to which they experienced each mood state on a 5-point Likert scale from 1, “not at all,” to 5, “extremely.” We summed item responses for the positive and negative affective domains for each survey completion. We then mean-centered these values so that all regression weights were relative to no positive or negative affect. Finally, we averaged these values across the day to produce estimates of positive and negative affect for each study day.

Energy and Fatigue

Energy and fatigue were measured using questions from the Profile of Mood States (POMS; [28]) 4 times a day via EMA survey. For energy, 3 items with the highest factor loading from the vigor-activity subscale were used (ie, energetic, full of pep, and vigorous). For fatigue, 3 items with the highest factor loading from the fatigue-inertia subscale were used (ie, fatigued, exhausted, and worn out). Participants rated the extent to which they experienced each mood state on a 5-point Likert scale from 1, “not at all,” to 5, “extremely.” We summed item responses for the energy and fatigue scales for each survey completion. We also mean-centered these values so that all regression weights were relative to no energy or fatigue. We then averaged these values across the day to produce daily estimates of energy and fatigue.

Perceived Weather Barriers

We additionally measured participants’ perception of weather during EMA surveys with one item 4 times per day: “What is the weather like outside?” In this variable, the intent is to capture high or low perceptions of weather as a barrier and not actual weather conditions. Participants rated their perception of weather as 1, “too hot,” 2, “too cold,” 3, “just right,” 4, “too rainy,” or 5, “too windy.” Our app was limited and only allowed a single response to this prompt (eg, participants could not say it was both too hot and too windy). For this reason, we recoded responses to indicate endorsements of perceived optimal weather and perceived weather barriers (eg, 0=“just right” and 1=all other responses, respectively). Finally, a daily weather barrier score was generated to capture each of the 4 EMA responses by summing these responses across the day, where lower scores represented fewer perceived weather barriers to MVPA. The final daily weather barrier variable ranged from 0 to 4, where 0 represents a response of just right at each EMA survey and 4 represents an endorsement of a perceived weather barrier at each EMA survey. Higher scores indicate more cumulative perceived weather barriers within a day.

Data Analysis Plan

We first divided each hypothesized moderator (eg, positive and negative affect, energy, fatigue, and perceived weather) into between-person and within-person components. The 4 daily assessments were averaged into day-level variables, and then person-mean centering was used to calculate the within-person value [29]. For example, each participant received a personal between-person value of their positive affect, indicating their average level of positive affect during the study, as well as a within-person value of positive affect for each of the 20 days, indicating their daily positive affect relative to their average. Because within-day scores are aggregated at the day level, the within-person effects can be interpreted as day-to-day fluctuations.

Using SAS (SAS Institute) PROC MIXED, we used first-order autoregressive (AR1) multilevel models for the day-level physical activity and sedentary behavior dependent variables. Hypothesized moderators were specified as interactions with group participation (ie, NUDGE intervention vs attention control) on MVPA and sedentary time. All models were estimated using the full information maximum likelihood estimation [29], and separate models were run for each hypothesized moderator. Based on our prior work, we used a random linear model for time at the day level (with the first day of the study coded 0) in the current analyses [17]. For models with significant interactions, we conducted post hoc probing at the mean, as well as ±1 SD above or below the mean of the

XSL•FO
RenderX

moderator to determine simple slopes and regions of significance. Each model is conditioned such that regression coefficients can be interpreted as minutes of MVPA or sedentary time per day.

Ethical Considerations

All study procedures were approved by the local institutional review board at the University of Kansas (STUDY00140405). Informed consent and assent were obtained for data collected in this project and the study team has followed institutional policies for maintaining privacy and confidentiality. Data in the current manuscript are deidentified.

Results

Descriptive Statistics

The final sample consists of 42 adolescents aged 13 - 18 years (mean 15.14, SD 1.72) in a matched comparison design (ie, NUDGE vs attention control), based on age and sex (n=21 per group). Participants were predominantly female and Caucasian (32/42, 76.2% female and 28/42, 66.7% Caucasian). Detailed sample demographics are shown in Table 1. Over the course of the assessment period, participants in the intervention group engaged in an average of 46 (SD 42) minutes of MVPA and 649 (SD 174) minutes of sedentary time per day. The attention control group obtained an average of 24 (SD 27) minutes of MVPA and 733 (SD 220) minutes of sedentary time per day.

Table . Adolescent and caregiver demographic characteristics.

Characteristics	Both groups (N=42)	NUDGE group (n=21)	Attention control group (n=21)
Adolescent age, mean (SD)	15.24 (2)	15.14 (2)	15.14 (2)
Adolescent sex, n (%)			
Male	10 (24)	5 (24)	5 (24)
Female	32 (76)	16 (76)	16 (76)
Race and ethnicity, n (%)			
Caucasian	28 (67)	16 (76)	12 (57)
Latino or Latina	4 (10)	2 (10)	2 (10)
African American	3 (7)	2 (10)	1 (5)
Asian	4 (10)	1 (5)	3 (14)
Other	2 (5)	0	2 (10)
Missing	1 (2)	0	1 (5)
Caregiver's marital status, n (%)			
Married	29 (69)	14 (67)	15 (71)
Divorced	7 (17)	5 (24)	2 (10)
Never married	4 (10)	2 (10)	2 (10)
Separated	2 (5)	0	2 (10)
Approximate family income, n (%)			
≤$60,000	13 (31)	4 (19)	9 (43)
>$60,000	28 (67)	16 (76)	12 (57)
Missing	1 (2)	1 (5)	—[a]

[a]Not applicable.

Model Building

MVPA Models

Overview

An empty model revealed that the intraclass correlation coefficient for MVPA was 0.43, indicating that 43% of the variance was day-level within-person (level 1) variability plus error and 57% was between-person (level 2). As noted above, all final models included a random intercept for the dependent variable and a random linear slope for time coded as day in the study starting at day 0. All models had a significant main effect for group (P=.03), and that parameter was included in all final models. All model effects are relations to MVPA at the day level, and β-weights are unstandardized beta coefficients and represent more or less daily activity relative to the control.

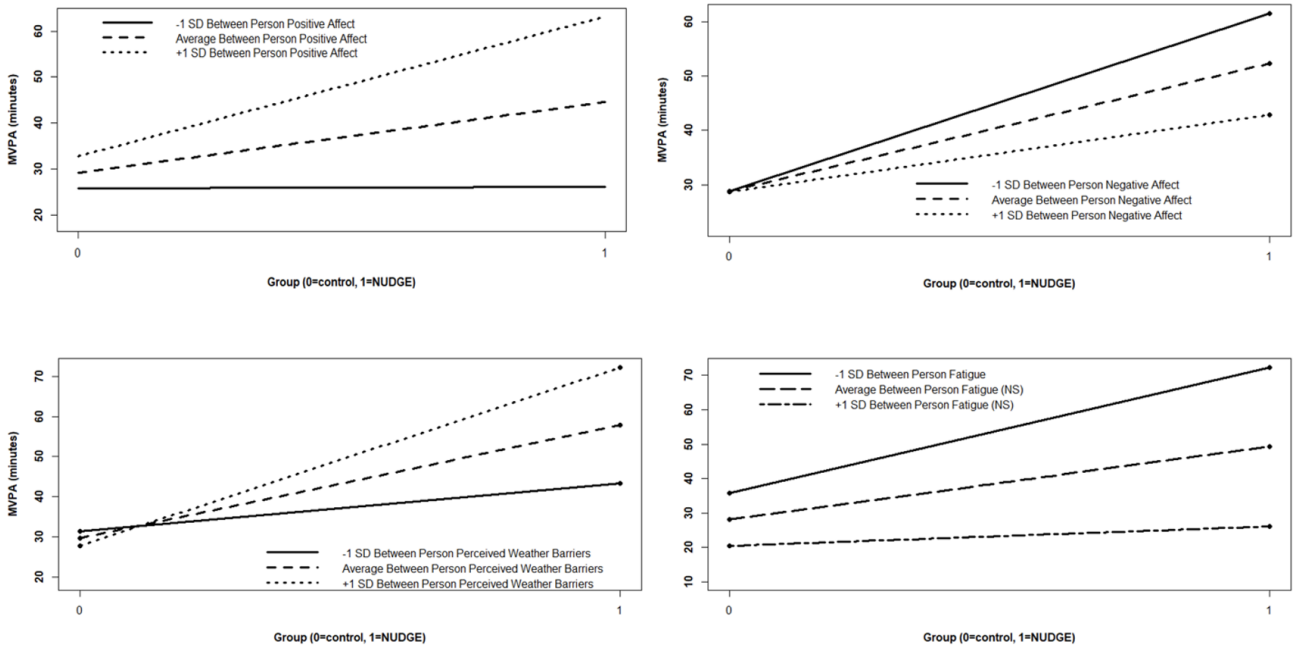
Positive Affect

There was a significant interaction of between-person positive affect and group (P<.001), such that being in the NUDGE intervention (vs control) was related to 30.42 additional minutes/day of MVPA (P<.001 from post hoc probing) among

XSL•FO
RenderX

individuals with levels of between-person positive affect +1 SD above the mean, but with a nonsignificant simple slope at −1 SD below the mean (See Figure 1A). The interaction between within-person positive affect and group was nonsignificant.

Figure 1. Interaction effects for affect and environmental moderators of the intervention effect. Note: Significant simple slopes, based on post hoc probing, are graphed for interactions where 2 or more levels of the moderator are significant. Nonsignificant slopes are not displayed. The model for fatigue moderating the intervention effect on MVPA did have 1 significant simple slope, but the single line is not displayed. MVPA: moderate-to-vigorous physical activity; NS: nonsignificant; NUDGE: Network Underwritten Dynamic Goals Engine.



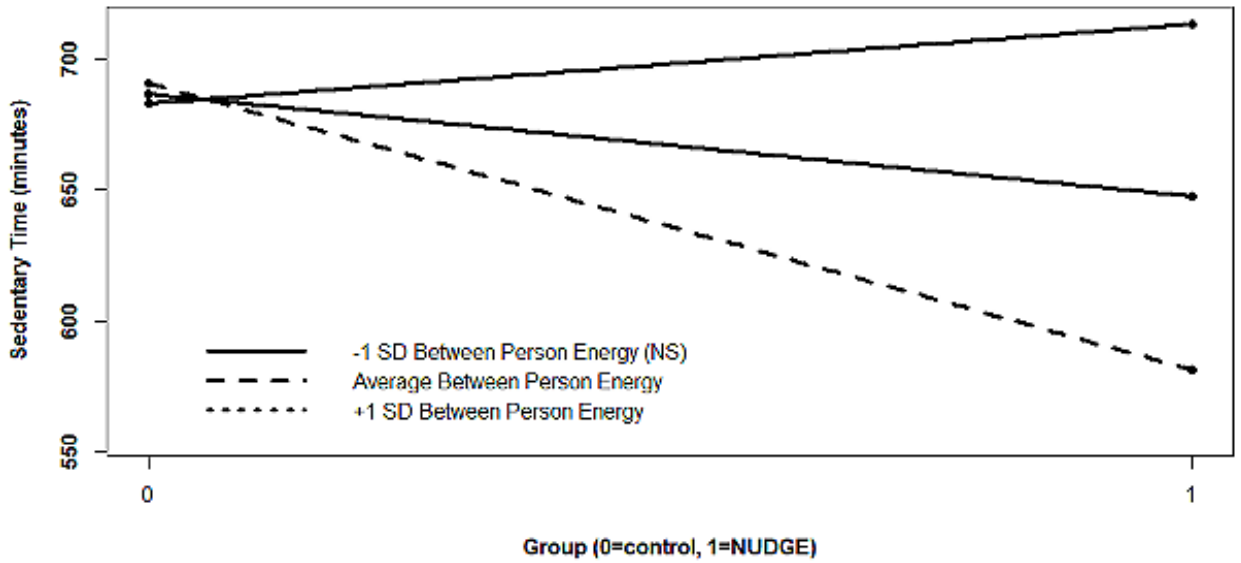
Negative Affect

The final model for negative affect indicated a significant interaction between group and between-person negative affect (P=.03). Simple slopes indicated that individuals with between-person negative affect +1 SD above the mean obtained 14.08 more minutes/day of MVPA than the control, with those −1 SD below the mean obtaining 32.71 more minutes/day. Generally, participants with less negative affect experienced a greater beneficial effect of the NUDGE on MVPA. The interaction of group and within-person negative affect was nonsignificant.

Energy

The final model for energy predicting MVPA had a significant main effect of group (P<.001) and included a significant interaction between group and between-person energy (P<.001; Figure 2). However, post hoc probing indicated no significant slopes or regions of significance for this moderator. Within-person energy did not moderate the effect of NUDGE on MVPA.

Figure 2. Energy moderating the effect of Network Underwritten Dynamic Goals Engine on sedentary time. Note: Simple slopes, based on post-hoc probing, are graphed for with significant omnibus interactions; NS: nonsignificant; NUDGE: Network Underwritten Dynamic Goals Engine.



XSL•FO
RenderX

Fatigue

Individuals with lower levels of between-person fatigue (eg, −1 SD below the mean) in the NUDGE condition obtained more MVPA each day relative to their counterparts in the control condition (β=36.54; *P*<.001). Simple slopes were not significant for those with +1 SD above the mean levels of between-person fatigue. The interaction between within-person fatigue and group was not statistically significant.

Perceived Weather Barriers

The interaction term was again significant for perceived weather barriers, with those who perceived +1 SD more barriers than the mean obtaining 44.53 more minutes of MVPA each day in the NUDGE group than the control, and those with −1 SD below the mean obtaining only 11.99 additional minutes per day. Interestingly, those with higher levels of between-person who perceived weather barriers in the NUDGE condition obtained more MVPA compared to those with lower perceived weather barriers. Within-person–perceived weather barriers did not moderate the effect of NUDGE on MVPA.

Sedentary Time Models

Overview

An empty model revealed that the Intraclass Correlation Coefficient for sedentary time was 0.37, indicating that 37% of the variance was day-level within-person (level 1) variability plus error and 63% was between-person (level 2). As noted above, all final models included a random intercept for the dependent variable and a random linear slope for time coded as day in the study starting at day 0. All model effects are relations to sedentary time at the day level, and β-weights represent more or less daily activity relative to the control.

Positive Affect

The final model for positive affect predicting sedentary time included a significant main effect of group (β=−39.56, *P*=.02) and between-person positive affect (β=−6.39, *P*<.001). Neither between-person nor within-person positive affect moderated the effect of NUDGE on sedentary time.

Negative Affect

The final model for negative affect predicting sedentary time included a significant main effect of group (β=−58.05; *P*=.001) and between-person negative affect (B=10.00; *P*=.049). Neither between-person nor within-person negative affect moderated the effect of NUDGE on sedentary time.

Energy

The final model for energy predicting sedentary time had a significant main effect of group (*P*<.001) and included a significant interaction between group and between-person energy (*P*<.001). Individuals with +1 SD between-person energy above the mean (β=−109.21, *P*<.001) in the NUDGE group accumulated less sedentary time each day relative to their counterparts in the control condition. The simple slope was not significant at −1 SD below the mean. Within-person energy did not moderate the effect of NUDGE on sedentary time.

Fatigue

The final model for fatigue predicting sedentary time had a significant main effect of group (*P*<.001) and included a significant main effect of group (β=−50.33; *P*=.003) and between-person fatigue (β=16.29, *P*<.001). Interactions of between-person and within-person fatigue and the group were not statistically significant.

Perceived Weather Barriers

There were no significant main effects of group, between-person or within-person perceived weather barriers, or interactions between these variables predicting sedentary time.

Discussion

Principal Findings

This study aimed to determine how macro- and microtemporal variables influence the effects of our mHealth intervention targeting adolescent physical activity. All of the macrotemporal study variables moderated the effect of NUDGE on MVPA, but only macrotemporal energy moderated the effect of NUDGE on sedentary time. With the exception of macrotemporal perceived weather barriers on MVPA, all of our significant interactions were in the hypothesized direction. In other words, adolescents with higher levels of macrotemporal positive affect and energy experienced larger intervention effects (ie, more MVPA and less sedentary time). Similarly, those with lower levels of negative affect and fatigue experienced larger intervention effects. Microtemporal associations with MVPA identified in other studies were not as important in this study as might have been indicated by other associational work [10,12,30]. This study indicates that while microtemporal findings do likely hold potential for personalization, the most immediate opportunity may be at the macrotemporal level. Momentary affect is difficult to capture using passive monitoring; therefore, fortunately, macrotemporal assessment is both easier and more suitable [31,32].

The literature indicates that mHealth interventions produce significant positive health outcomes in youth. The majority of these interventions have used standardized protocols to deliver the same intervention content to users, usually in the form of text messages [33,34]. However, recent developments in mHealth technologies show that mHealth interventions can leverage personalization to promote behavior change [10,35]. In the next iteration of the NUDGE protocol, it may be possible to use baseline information on macrotemporal factors to optimize the intervention for each participant. For instance, participants with low levels of positive affect or high levels of fatigue at baseline may need a preliminary intervention that is more complex than simple text message prompts to set and keep track of their physical activity goals. In both instances, a brief behavioral activation intervention might be warranted to help adolescents acknowledge the importance of setting and meeting goals, even when mood or fatigue are barriers [36].

There are other tailoring opportunities based on how NUDGE interacts with macrotemporal variables assessed at baseline. For example, NUDGE produced a desirable effect for all participants regardless of macrotemporal negative affect or perceived

XSL•FO
RenderX

weather. However, it was more effective for those with lower negative affect. For individuals experiencing high negative affect, it may make sense to address this barrier first before enrolling participants in the NUDGE intervention or to use MVPA promotion strategies that are unlikely to be affected by affect (eg, scheduled family exercise). Similarly, the intervention was particularly effective for participants who demonstrated higher than average positive affect. For this group, additional prompts might be wasted contacts that could decrease engagement or lead to habituation [37]. Our results on fatigue suggest that those with higher-than-average fatigue may need a sequencing approach to improve their fatigue before starting on the activity intervention. Finally, the relationship with weather demonstrates that those who perceive more weather barriers derive more benefit from NUDGE, which may indicate the importance of goal-setting and review even in the face of environmental barriers. All of the intervention strategies discussed above fit nicely in phase 2 of the ORBIT model for refining behavioral interventions before proceeding to fully randomized control trials [16].

Within the ORBIT model, NUDGE was tested in a nonrandomized, proof-of-concept study. Initial findings were promising and indicate randomized pilot testing is warranted. However, the ORBIT model encourages behavioral scientists to consider how an intervention can be optimized and refined to deliver more efficient interventions. Rather than making clinical judgments or relying on anecdotal evidence to guide intervention refinement, we can use data from this study to inform the development of future versions of NUDGE. One iteration might use responsive, context-dependent intervention support while another might test tailored decision points for goal setting based on trait-level characteristics (eg, high negative affect and fatigue). This process of using empirical evidence for optimization represents a step forward in the development and refinement of technology-based behavioral interventions [38].

Limitations and Future Directions

Results from this study should be considered in light of several limitations. Most importantly, participants were not randomized. In addition, the sample was relatively small, participants were predominantly female and Caucasian, and only adolescents from a specific geographic location were included. Future studies should recruit a larger sample of youth to test the generalizability of effects found in this study and provide opportunities for fully powered analyses. In addition, a larger study may be able to identify microtemporal moderators that were not present in this study. While not a major contributor in this study, there is a growing body of literature establishing that microtemporal relationships do affect the health behavior of children and adolescents [30]. Another limitation of this study was our methodology for measuring psychological feeling states. While EMA allowed us to measure daily fluctuations in these states, our protocol instructed adolescents to answer several survey questions 4 times throughout the day for almost 3 weeks. Future studies may benefit from using smart devices (eg, smartwatches) to reduce participant burden by making survey prompts easier to complete and to capture physiological data related to energy and mood (eg, heart rate and skin conductance; [39]).

Findings from this study add further support for the effects of psychological variables and perceived weather barriers on adolescent MVPA and sedentary time. Results highlight the importance of assessing macrotemporal factors (eg, positive and negative affect, energy, fatigue, and perceived weather barriers) in the context of a physical activity intervention for adolescents. While our initial examination of NUDGE showed an overall increase in MVPA, the results from this study indicate that adolescents may respond differently to the NUDGE intervention based on their macrotemporal characteristics, such as positive and negative affect, energy, fatigue, and perceived weather barriers. Future mHealth intervention trials should test the impact of tailored content on adolescents' MVPA and sedentary time to further refine adaptive physical activity interventions.

Conclusion

Our secondary data analysis of the NUDGE intervention suggests that patterns of variables, such as affect, energy, fatigue, and weather may moderate the effectiveness of text-message interventions for physical activity. Future iterations of NUDGE may benefit from using tailoring variables to modify the intervention experience of each participant depending on their level of the variables explored in this paper.

Conflicts of Interest

CCC has received consulting fees from PepsiCo and speaker/consulting fees from Cincinnati Children's Hospital Medical Center.

References

1. Katzmarzyk PT, Denstel KD, Beals K, et al. Results from the United States 2018 report card on physical activity for children and youth. J Phys Act Health 2018 Nov 1;15(S2):S422-S424. [doi: 10.1123/jpah.2018-0476] [Medline: 30475143]
2. 2018 physical activity guidelines advisory committee scientific report. : US Department of Health and Human Services; 2018 URL: https://odphp.health.gov/sites/default/files/2019-09/PAG_Advisory_Committee_Report.pdf
3. Nader PR, Bradley RH, Houts RM, McRitchie SL, O'Brien M. Moderate-to-vigorous physical activity from ages 9 to 15 years. JAMA 2008 Jul 16;300(3):295-305. [doi: 10.1001/jama.300.3.295] [Medline: 18632544]
4. Cushing CC, Brannon EE, Suorsa KI, Wilson DK. Systematic review and meta-analysis of health promotion interventions for children and adolescents using an ecological framework. J Pediatr Psychol 2014 Sep;39(8):949-962. [doi: 10.1093/jpepsy/jsu042] [Medline: 24934246]

XSL•FO
RenderX

5. Metcalf B, Henley W, Wilkin T. Effectiveness of intervention on physical activity of children: systematic review and meta-analysis of controlled trials with objectively measured outcomes (EarlyBird 54). BMJ 2012 Sep 27;345:e5888. [doi: 10.1136/bmj.e5888] [Medline: 23044984]
6. Dunton GF. Sustaining health-protective behaviors such as physical activity and healthy eating. JAMA 2018 Aug 21;320(7):639-640. [doi: 10.1001/jama.2018.6621] [Medline: 29852046]
7. Sallis JF, Owen N, Fisher E. Ecological models of health behavior. In: Health Behavior: Theory, Research, and Practice: Jossey-Bass; 2015, Vol. 05:43-64.
8. Craggs C, Corder K, van Sluijs EMF, Griffin SJ. Determinants of change in physical activity in children and adolescents: a systematic review. Am J Prev Med 2011 Jun;40(6):645-658. [doi: 10.1016/j.amepre.2011.02.025] [Medline: 21565658]
9. B. Owen K, Smith J, Lubans DR, Ng JYY, Lonsdale C. Self-determined motivation and physical activity in children and adolescents: a systematic review and meta-analysis. Prev Med 2014 Oct;67:270-279. [doi: 10.1016/j.ypmed.2014.07.033]
10. Cushing CC, Monzon A, Ortega A, Bejarano CM, Carlson JA. Commentary: identifying opportunities for pediatric ehealth and mhealth studies: physical activity as a case example. J Pediatr Psychol 2019 Apr 1;44(3):269-274. [doi: 10.1093/jpepsy/jsz005] [Medline: 30835782]
11. Cushing CC, Mitchell TB, Bejarano CM, Walters RW, Crick CJ, Noser AE. Bidirectional associations between psychological states and physical activity in adolescents: a mHealth pilot study. J Pediatr Psychol 2017 Jun 1;42(5):559-568. [doi: 10.1093/jpepsy/jsw099] [Medline: 28131985]
12. Dunton GF, Huh J, Leventhal AM, et al. Momentary assessment of affect, physical feeling states, and physical activity in children. Health Psychol 2014 Mar;33(3):255-263. [doi: 10.1037/a0032640] [Medline: 23668846]
13. Bejarano CM, Cushing CC, Crick CJ. Does context predict psychological states and activity? An ecological momentary assessment pilot study of adolescents. Psychol Sport Exerc 2019 Mar;41:146-152. [doi: 10.1016/j.psychsport.2018.05.008]
14. Kim J, Conroy DE, Smyth JM. Bidirectional associations of momentary affect with physical activity and sedentary behaviors in working adults. Ann Behav Med 2020 Mar 24;54(4):268-279. [doi: 10.1093/abm/kaz045] [Medline: 31613961]
15. Hekler E, Tiro JA, Hunter CM, Nebeker C. Precision health: the role of the social and behavioral sciences in advancing the vision. Ann Behav Med 2020 Nov 1;54(11):805-826. [doi: 10.1093/abm/kaaa018] [Medline: 32338719]
16. Czajkowski SM, Powell LH, Adler N, et al. From ideas to efficacy: the ORBIT model for developing behavioral treatments for chronic diseases. Health Psychol 2015 Oct;34(10):971-982. [doi: 10.1037/hea0000161] [Medline: 25642841]
17. Cushing CC, Bejarano CM, Ortega A, Sayre N, Fedele DA, Smyth JM. Adaptive mHealth intervention for adolescent physical activity promotion. J Pediatr Psychol 2021 Jun 3;46(5):536-546. [doi: 10.1093/jpepsy/jsaa125] [Medline: 33484137]
18. Carver CS, Scheier MF. Control theory: a useful conceptual framework for personality-social, clinical, and health psychology. Psychol Bull 1982 Jul;92(1):111-135. [doi: 10.1037/0033-2909.92.1.111] [Medline: 7134324]
19. Heron KE, Everhart RS, McHale SM, Smyth JM. Using mobile-technology-based ecological momentary assessment (EMA) methods with youth: a systematic review and recommendations. J Pediatr Psychol 2017 Nov 1;42(10):1087-1107. [doi: 10.1093/jpepsy/jsx078] [Medline: 28475765]
20. Sadeh A, Sharkey KM, Carskadon MA. Activity-based sleep-wake identification: an empirical test of methodological issues. Sleep 1994 Apr;17(3):201-207. [doi: 10.1093/sleep/17.3.201] [Medline: 7939118]
21. Troiano RP, Berrigan D, Dodd KW, Mâsse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. Med Sci Sports Exerc 2008 Jan;40(1):181-188. [doi: 10.1249/mss.0b013e31815a51b3] [Medline: 18091006]
22. Chandler JL, Brazendale K, Beets MW, Mealing BA. Classification of physical activity intensities using a wrist-worn accelerometer in 8-12-year-old children. Pediatr Obes 2016 Apr;11(2):120-127. [doi: 10.1111/ijpo.12033] [Medline: 25893950]
23. Ebesutani C, Regan J, Smith A, Reise S, Higa-McMillan C, Chorpita BF. The 10-item positive and negative affect schedule for children, child and parent shortened versions: application of item response theory for more efficient assessment. J Psychopathol Behav Assess 2012 Jun;34(2):191-203. [doi: 10.1007/s10862-011-9273-2]
24. Laurent J, Catanzaro SJ, Joiner TE, et al. A measure of positive and negative affect for children: scale development and preliminary validation. Psychol Assess 1999;11(3):326-338. [doi: 10.1037/1040-3590.11.3.326]
25. Crook K, Beaver BR, Bell M. Anxiety and depression in children: a preliminary examination of the utility of the PANAS-C. J Psychopathol Behav Assess 1998 Dec;20(4):333-350. [doi: 10.1023/A:1021967623139]
26. Cushing CC, Bejarano CM, Mitchell TB, Noser AE, Crick CJ. Individual differences in negative affectivity and physical activity in adolescents: an ecological momentary assessment study. J Child Fam Stud 2018 Sep;27(9):2772-2779. [doi: 10.1007/s10826-018-1128-y]
27. Dunton GF, Liao Y, Intille S, Wolch J, Pentz MA. Physical and social contextual influences on children's leisure-time physical activity: an ecological momentary assessment study. J Phys Act Health 2011 Jan;8(1):S103-S108. [doi: 10.1123/jpah.8.s1.s103] [Medline: 21350250]
28. McNair DM, Lorr M, Droppleman LF. Profile of Mood State Manual: Educational and Industrial Testing Service; 1971.
29. Enders CK. The performance of the full information maximum likelihood estimator in multiple regression models with missing data. Educ Psychol Meas 2001 Oct 1;61(5):713-740. [doi: 10.1177/00131640121971482]
30. Liao Y, Shonkoff ET, Dunton GF. The acute relationships between affect, physical feeling states, and physical activity in daily life: a review of current evidence. Front Psychol 1975;6. [doi: 10.3389/fpsyg.2015.01975]

XSL•FO
RenderX

31. Fedele DA, Cushing CC, Koskela-Staples N, et al. Adaptive mobile health intervention for adolescents with asthma: Iterative user-centered development. JMIR Mhealth Uhealth 2020 May 6;8(5):e18400. [doi: 10.2196/18400] [Medline: 32374273]
32. Cushing CC, Fedele DA, Patton SR, et al. Responsive Asthma Care for Teens (ReACT): development protocol for an adaptive mobile health intervention for adolescents with asthma. BMJ Open 2019 Aug 20;9(8):e030029. [doi: 10.1136/bmjopen-2019-030029] [Medline: 31434777]
33. Fedele DA, Cushing CC, Fritz A, Amaro CM, Ortega A. Mobile health interventions for improving health outcomes in youth: a meta-analysis. JAMA Pediatr 2017 May 1;171(5):461-469. [doi: 10.1001/jamapediatrics.2017.0042] [Medline: 28319239]
34. Ludwig K, Arthur R, Sculthorpe N, Fountain H, Buchan DS. Text messaging interventions for improvement in physical activity and sedentary behavior in youth: systematic review. JMIR Mhealth Uhealth 2018 Sep 17;6(9):e10799. [doi: 10.2196/10799] [Medline: 30224335]
35. Mohr DC, Schueller SM, Tomasino KN, et al. Comparison of the effects of coaching and receipt of app recommendations on depression, anxiety, and engagement in the IntelliCare platform: factorial randomized controlled trial. J Med Internet Res 2019 Aug 28;21(8):e13609. [doi: 10.2196/13609] [Medline: 31464192]
36. Martin F, Oliver T. Behavioral activation for children and adolescents: a systematic review of progress and promise. Eur Child Adolesc Psychiatry 2019 Apr;28(4):427-441. [doi: 10.1007/s00787-018-1126-z] [Medline: 29476253]
37. Schueller SM, Muñoz RF, Mohr DC. Realizing the potential of behavioral intervention technologies. Curr Dir Psychol Sci 2013 Dec;22(6):478-483. [doi: 10.1177/0963721413495872]
38. Riley WT. Theoretical models to inform technology-based health behavior interventions. In: Marsch J, Lord S, Dallery J, editors. Behavioral Health Care and Technology: Oxford Academic; 2014:13-24. [doi: 10.1093/med/9780199314027.003.0002]
39. Ponnada A, Thapa-Chhetry B, Manjourides J, Intille S. Measuring criterion validity of microinteraction ecological momentary assessment (micro-ema): Exploratory pilot study with physical activity measurement. JMIR Mhealth Uhealth 2021 Mar 10;9(3):e23391. [doi: 10.2196/23391] [Medline: 33688843]

Abbreviations

EMA: ecological momentary assessment
mHealth: mobile health
MVPA: moderate-to-vigorous physical activity
NUDGE : Network Underwritten Dynamic Goals Engine
ORBIT: Obesity Relation Behavioral Intervention Trials
PANAS-C: Positive and Negative Affect Schedule for Children
POMS: Profile of Mood States

Edited by S Badawy; submitted 09.04.24; peer-reviewed by A Willms, R Marshall; revised version received 19.05.25; accepted 20.05.25; published 05.12.25.

Please cite as:
Cushing CC, Ortega A, Fedele DA, Leslie-Miller CJ, Carlson JA, Davis AM, Smyth JM
Moderators of a mHealth Intervention for Adolescent Physical Activity: Intervention Refinement Study
JMIR Pediatr Parent 2025;8:e59334
URL: https://pediatrics.jmir.org/2025/1/e59334
doi:10.2196/59334

© Christopher C Cushing, Adrian Ortega, David A Fedele, Calissa J Leslie-Miller, Jordan A Carlson, Ann M Davis, Joshua M Smyth. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 5.12.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Using a Consumer Wearable Activity Monitoring Device to Study Physical Activity and Sleep Among Adolescents in Project Viva: Cohort Study

Yutong Zhang[1], MS; Nicole Bornkamp[1], BA, MPH; Marie-France Hivert[1,2,3], MMSc, MD; Emily Oken[1,3,4], MPH, MD; Peter James[1,3,5,6], MHS, ScD

[1]Department of Population Medicine, Harvard Pilgrim Health Care Institute, Boston, MA, United States

[2]Diabetes Unit, Massachusetts General Hospital, Harvard Medical School, Boston, MA, United States

[3]Harvard Medical School, Harvard University, Cambridge, MA, United States

[4]Department of Nutrition, Harvard T.H. Chan School of Public Health, Harvard University, Boston, MA, United States

[5]Department of Environmental Health, Harvard T.H. Chan School of Public Health, Harvard University, Boston, MA, United States

[6]Division of Environmental and Occupational Health, Department of Public Health Sciences, University of California, Davis School of Medicine, Davis, CA, United States

Corresponding Author:
Yutong Zhang, MS
Department of Population Medicine, Harvard Pilgrim Health Care Institute, Boston, MA, United States

Abstract

Background: The increasing prevalence of physical inactivity and insufficient sleep in adolescents likely contribute to worsening cardiometabolic and mental health. However, obtaining accurate behavioral measures is a challenge. Consumer wearable devices offer a user-friendly method to assess physical activity and sleep.

Objective: This study aimed to describe the process and the preliminary results of physical activity and sleep collected using a consumer wearable Fitbit device in an adolescent cohort.

Methods: We provided Fitbit Charge 2 or Charge 3 wrist-worn activity monitors to adolescent participants in Project Viva, a Boston, Massachusetts area cohort, from 2017 to 2022. We invited participants to wear the devices for ≥7 days for 24 hours a day to measure their physical activity, heart rate, and sleep, and allowed them to keep the device as a participation incentive.

Results: We collected over 7 million minutes of physical activity, heart rate, and sleep data from 677 participants, 53% (356/677) of whom were female. The mean (SD) age of participants was 17.7 (0.7) years. Among the 677 participants, 65% (n=439) were non-Hispanic White, 14% (n=947) were non-Hispanic Black, 10% (n=69) were Hispanic, 3.2% (n=22) were non-Hispanic Asian, and 7.8% (n=53) belonged to other races. Participants demonstrated a high adherence to the research protocol, with the mean (SD) wear duration of 7.5 (1.1) days, and 90% of participants (612/677) had 5 or more days wearing the device for >600 minutes/day. The mean (SD) number of steps was 8883 (3455) steps/day and the mean (SD) awake sedentary time was 564 (138) minutes/day. Male participants were more often engaged in very active (27 minutes/day) and moderately active physical activity (29 minutes/day) compared with female participants (15 and 17 minutes/day, respectively). Over 87% (588/677) of participants had sleep data available for 5 or more days, among whom the average nightly sleep duration was 7.9 (SD 0.9) hours.

Conclusions: This study demonstrated the feasibility of using consumer wearable devices to measure physical activity and sleep in a cohort of US adolescents. The high compliance rates provide valuable insights into adolescent behavior patterns and their influence on chronic disease development and mental health outcomes.

(JMIR Pediatr Parent 2025;8:e59159) doi:10.2196/59159

KEYWORDS

wearable device; Fitbit; physical activity; sleep; adolescents; behavior risk; mobile phone

Introduction

The prevalence of physical inactivity and insufficient sleep in adolescents has become a major health concern worldwide. In the United States, approximately 76% of children aged 6 - 17 years engage in less than the recommended 60 minutes of moderate-to-vigorous physical activity per day [1]. Similarly, almost a quarter of US children aged 6 - 17 years have less than the recommended 8 hours of sleep per day [2]. Adolescence is a vulnerable period for the development of both psychiatric and chronic medical illnesses [3]. A lack of moderate-to-vigorous physical activity is linked to a higher risk of excessive calorie

XSL•FO
RenderX

intake, obesity [4,5], and cardiometabolic diseases [6-8]; higher risk of depression and anxiety [9-11]; and lower cognitive and school performance [12,13]. In addition, insufficient sleep has been associated with unhealthy dietary behavior [14,15], being overweight [14,16,17], poor school performance, and depression [18-20]. Given the health concerns related to physical inactivity and insufficient sleep among adolescents, a better understanding of these health behaviors through accurate, large-scale data among representative populations is crucial.

Consumer-based wearable devices such as Fitbit (Google) have become popular for objectively measuring physical activity and sleep due to the advancements in microtechnology, wireless communication, battery capacity, and multidimension measurements. In addition, Fitbit devices use Bluetooth for easy data transfer to Fitbit servers through a smartphone or tablet, allowing for synchronization of real-time data. This helps avoid the burden of mailing devices back to researchers and potential data loss that may occur with actigraphs meant solely for research. Fitbits have been validated for collecting real-time behavior data on free-living subjects [21-25]. Although Fitbits have been used to collect real-time behavior data, researchers have not described real-world methods to operationalize consumer-based wearable devices to collect health behavior data in adolescent cohorts. Detailing the operational methods for these devices in real-world setting can enable researchers to examine this novel approach in depth and understand the measurement values.

In this study, we used commercially available Fitbit devices to gather physical activity and sleep data in adolescents. We describe our data collection and cleaning process, and present participants' wear-time results. The collected data will be used to study associations of physical activity and sleep with many aspects of adolescent and young adult health, including cardiometabolic, experiential, and mental health, in future research.

Methods

Project Viva Cohort

Project Viva is an ongoing prospective cohort focused on maternal and child health. We recruited pregnant women between 1999 and 2002 in eastern Massachusetts who received prenatal care at Atrius Harvard Vanguard Medical Associates. Detailed recruitment, eligibility, and cohort information have been previously reported [26]. We collected comprehensive information from mothers and their children at various life stages, and attempted to follow all willing participants after birth. Of the 2128 mother-child pairs enrolled at birth, 1576 pairs had not previously disenrolled and thus were eligible for the Mid-Teen visit.

Data Collection

We contacted participants from July 1, 2017, to August 30, 2021. We invited participants as mother-child pairs by mail or email to participate in the Mid-Teen visit when the child turned 16.5 years old. If the child had sibling(s) who were also enrolled in Project Viva, the sibling(s) also attended the visit regardless of the age.

We collected data on the demographic variables at several life stages. At recruitment, we collected data about the maternal education. We obtained the child sex at birth and birth date from hospital medical records. During the Mid-Teen visit, trained research assistants measured weight using a calibrated Tanita scale (model TBF-300A; Tanita Corporation of America) and weight using a calibrated stadiometer (Shorr Productions). We calculated the BMI using weight (kg)/ square of height (m^2). Race, ethnicity, and household income were collected through a questionnaire.

Wearable Device

We invited all adolescent participants to provide data on physical activity, heart rate, and sleep for 1 week to align with traditional actigraphy study and avoid over burdening participants. Participants had to consent to wear a Fitbit Charge 2 (before 2018) or Fitbit Charge 3 (after 2018) wearable device, depending on the year of the research visit. Both devices have the same core measurement technique, MEMS 3-axis accelerometer and optical heart-rate tracker and are able to track physical activity, heart rate, and sleep on free-living subjects [27,28]. Trained study staff instructed participants to download the Fitbit app on their smartphone and to register a Fitbit account. Study staff then linked their account ID to Fitabase [29], a data management platform to support research projects using Fitbit devices. Participants were asked to wear the device on the nondominant wrist and to synchronize their Fitbit with the app at least once daily. Once synced, study staff were able to access participant data through Fitabase. During the data collection period, research staff checked the platform 2 times a week. For those who did not provide the requested 5 days of data, we sent up to 10 reminders to participants to initiate or continue wearing the device and to sync their data on the app.

The Fitbit device measures physical activity, heart rate, and sleep stages. Physical activity is measured through miniaturized accelerometers. Fitbit uses a proprietary algorithm to calculate steps and categorizes activity intensity into 4 levels—very active, moderately active, lightly active, and sedentary, at the minute level [30,31]. The heart rate is measured through photoplethysmography, an optical technique that uses a light sensor to detect blood volume changes in the capillaries above the wrist [32]. Fitbit uses this measurement to run through a proprietary algorithm to get the beats per minute (bpm). Then, Fitbit combines the accelerometers and heart-rate pattern under a proprietary sleep algorithm to estimate sleep stages. Although some studies have implied that Fitbit may overestimate or underestimate the physical activity and sleep in certain situations, the algorithm has been validated in the contexts of measuring steps and 2-stage wake and sleep classification, with the accuracy mostly being between 80% and 90% when compared with research-grade devices [21-25,33-35].

Data Cleaning and Analysis

We downloaded minute-level Fitbit data on August 29, 2022. The data contained information on activity intensities, steps, heart rate, and sleep every minute. We used heart rate as a proxy to determine wear time. If participants did not have heart rate observed in a given minute, we considered it as nonwear time. We used 2 cutoffs to define participants' valid data, (1)

XSL•FO
RenderX

participants with heart rate data for at least 600 minutes (10 h)/day for 5-9 days and (2) participants with heart rate data for at least 1200 minutes (20 h)/day for 5-9 days. The first cutoff is commonly used in actigraphy studies [36], while the second cutoff allows us to evaluate participants who had high compliance in a full 24-hour period [37].

We used the minute-level data to calculate the results at the daily and participant levels for valid participants. For the daily value of physical activity, we calculated the average steps/hour (during wear time), total steps per day, awake sedentary minutes, lightly active minutes, moderately active minutes, and very active minutes. The awake sedentary time was defined based on the Fitbit algorithm and excluded sleep. We then used the daily value to calculate the physical activity at the participant level.

For sleep data, we selected participants who had sleep data for 5-9 days from the 600 minutes/day cutoff described above. Fitbit assigns 3 values to indicate sleep stages for each minute during sleep periods, “1” indicates being asleep; “2” indicates being in a restless state, which may indicate restlessness during sleep or wakefulness; and “3” indicates being awake during the sleep period. Otherwise, sleep is categorized as “NA,” which indicates being fully awake (ie, not part of a sleep period) [38]. We defined a series of sleep metrics based on previous studies [39-41]. We defined sleep cycle as a series of distinct stages of sleep that a person can go through from being asleep to being awake. We defined sleep period as a specific time interval between sleep onset and the end of sleep, where multiple sleep cycles can occur in 1 sleep period. To determine the main sleep period, we manually examined participants’ sleep cycles and merged sleep cycles if multiple cycles occurred between 6 PM and 6 AM. If no sleep was found between 6 PM and 6 AM, we then examined the post 6 AM sleep onset time and manually identified the sleep period based on all available Fitbit sleep records for the participant. For the calculation of sleep duration, we focused on the main sleep period, excluding any nap times that occurred after the main sleep period.

Next, we classified the total time spent awake between the sleep onset time and sleep wake up time as wakefulness after sleep onset (WASO). We used the total asleep time between the sleep onset and wake up time divided by the total sleep duration to calculate sleep efficiency. We also calculated the sleep midpoint, which is the middle time between the sleep onset time and final wake up time. We then used the sleep midpoint to determine social jet lag, which measures the difference in sleep midpoint time between week nights (Sunday-Thursday) and weekend nights (Friday and Saturday).

We obtained the demographic characteristics for all participants who had Fitbit data available and for the subset of participants with adequate wear time based on 600 minutes/day and 1200 minutes/day cutoffs. We determined the mean (SD) for average wear days, daily wear time, total steps/hour, and total steps/day using each minimal cutoff. We then compared the wear time by sex into 4 physical activity categories: very active, moderately active, lightly active, and awake sedentary in participants who met our 600 minutes/day cutoff. Finally, we showed sleep results for all valid participants and classified participants who had average sleep onset times before and after midnight, respectively. All the data preparation and analyses were conducted using R (R Foundation for Statistical Computing).

Ethical Considerations

The Institutional Review Board at Harvard Pilgrim Health Care approved this study protocol (235301). All participants provided written informed consent (if aged over 18 years) and assent in combination with parent or guardian informed consent (if under the age of 18 years).

Results

Overall

Out of the 901 invited participants, 809 consented to the Mid-Teen visit and 702 agreed to participate in the Fitbit substudy (Figure 1 shows the participant eligibility flow chart). We ultimately obtained Fitbit data from 677/702 participants (96% of those who consented to the Fitbit substudy). We found similar demographic characteristics between participants who consented to the Mid-Teen visit but did not consent to the Fitbit substudy and those who consented to the Fitbit substudy (Table 1). The raw dataset comprised over 7 million minutes of physical activity and 6 million minutes of sleep data from 677 participants. After data cleaning, the percentage of valid participants remained high (612/677, 90%, using the 600 minutes/day for 5-9 days as the cutoff, and 538/677, 79%, using 1200 minutes/day for 5-9 days as the cutoff).

XSL•FO
RenderX

Figure 1. Diagram of participant flowchart showing the number of participants at different stages of the Mid-Teen (MT) visit.

XSL•FO
RenderX

Table . Demographic and socioeconomic characteristics of participants who consented to the Mid-Teen visit, participants who received a Fitbit device, and participants with valid data based on 600 minutes/day and 1200 minutes/day cutoffs.

Characteristic	Participants who consented to the Mid-Teen visit (n=809)	Participants who consented to the Mid-Teen visit but did not provide Fitbit data (n=132)	Participants who received the Fitbit device (n=677)	Participants with valid data considering the cutoff of 600 minutes/day for 5 - 9 days (n=612)	Participants with valid data considering the cutoff of 1200 minutes/day for 5 - 9 days (n=538)
Age (years), mean (SD)	17.4 (0.7)	18.3 (0.8)	17.7 (0.7)	17.7 (0.7)	17.7 (0.7)
Sex at birth, n (%)					
Female	423 (52)	67 (51)	356 (53)	332 (54)	295 (55)
Male	386 (48)	65 (49)	321 (47)	280 (46)	243 (45)
Race and ethnicity, n (%)					
Non-Hispanic White	528 (65)	89 (67)	439 (65)	395 (65)	346 (64)
Non-Hispanic Black	121 (15)	27 (20)	94 (14)	85 (14)	76 (14)
Hispanic	78 (9.6)	9 (6.8)	69 (10)	60 (9.8)	50 (9.3)
Non-Hispanic Asian	26 (3.2)	4 (3)	22 (3.2)	22 (3.6)	22 (4.1)
Other	56 (6.9)	3 (2.3)	53 (7.8)	50 (8.2)	44 (8.2)
BMI (kg/m^2), mean (SD)	23.96 (5.2)	22.65 (2.8)	24.01 (5.3)	23.94 (5.2)	24.03 (5.3)
Unknown, n (%)	114 (14.1)	104 (79)	10 (1.5)	9 (1.5)	9 (1.7)
Household income, n (%)					
<$40,000	51 (6.3)	10 (7.6)	41 (6.1)	34 (5.6)	33 (6.1)
$40,000-$70,000	79 (9.8)	15 (11)	64 (9.5)	54 (8.8)	45 (8.4)
>$70,000	597 (74)	72 (55)	525 (78)	482 (79)	423 (79)
Unknown	82 (10)	35 (27)	47 (6.9)	42 (6.9)	37 (6.9)
Maternal college education, n (%)	598 (74)	103 (78)	495 (73)	453 (74)	400 (75)

Participant Compliance

Among all participants with valid data considering the cutoff of at least 600 minutes/day (on every day worn), participants tended to wear the device for more than 10 hours per day and for more days than requested (Figure S1 in Multimedia Appendix 1). Furthermore, the pattern of wearing the device for more than 10 hours per day persisted when comparing the first recording day with the last recording day (Table S1 in Multimedia Appendix 1). When comparing the wear time between the two cutoffs, the average number of wear days and daily wear time were similar between the 600 minutes/day cutoff group and the 1200 minutes/day cutoff group (wear days: 7.5 days, SD 1.1 days vs 7.7 days, SD 0.9 days; wear time: 1323 minutes, SD 100 minutes vs 1350 minutes, SD 61 minutes). Similarly, the average values for steps/hour were similar between the groups defined by the two different cutoffs (Table 2).

XSL•FO
RenderX

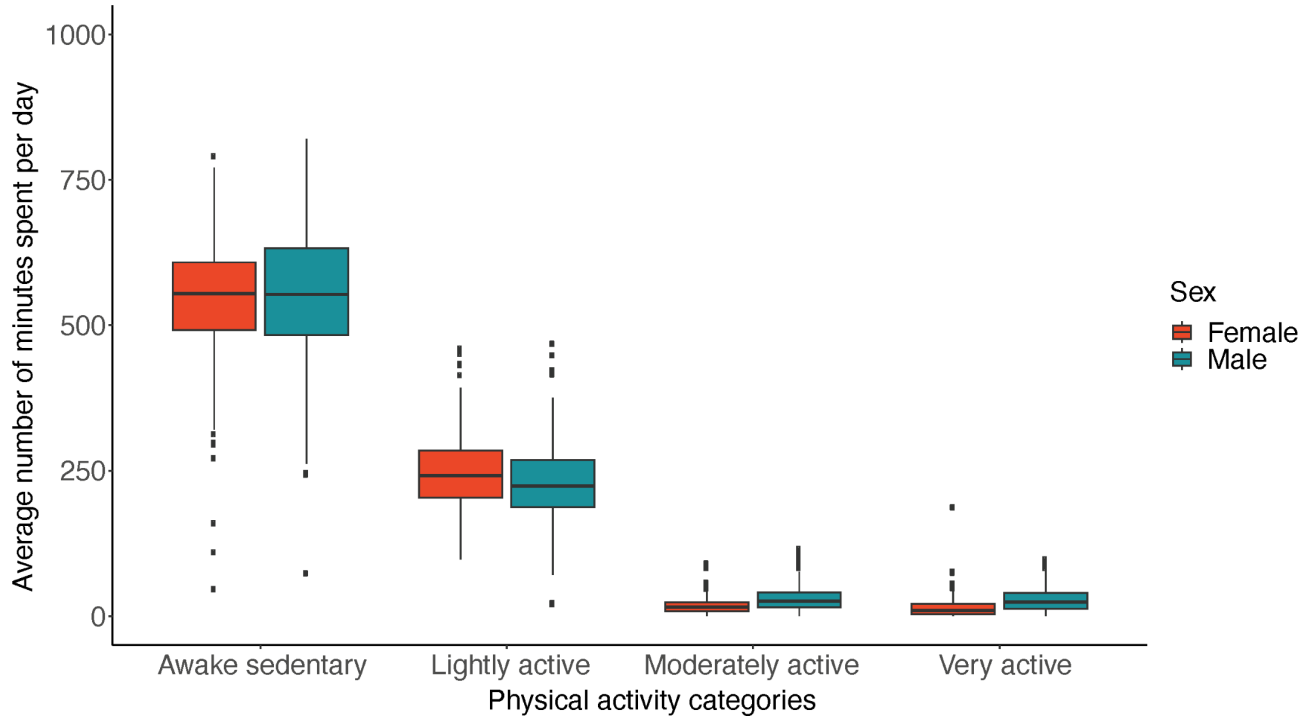
Table . Participants' physical activity results based on 600 minutes/day and 1200 minutes/day cutoffs.

Variable	Participants with valid data considering the cutoff of 600 min/d wear time for 5 - 9 days (n=612), mean (SD)	Participants with valid data considering the cutoff of 1200 min/d wear time for 5 - 9 days (n=538), mean (SD)
Total wear time (d)	7.5 (1.1)	7.7 (0.9)
Daily wear time (min)	1323 (100)	1350 (61)
Total steps per hour (steps/h)	399 (157)	400 (150)
Total steps per day (steps)	8883 (3455)	9041 (3414)
Physical activity level		
Very active (min/d)	20 (20)	21 (20)
Moderately active (min/d)	23 (18)	23 (18)
Lightly active (min/d)	235 (70)	239 (67)
Awake sedentary (min/d)	564 (138)	568 (121)

Physical Activity Results

Among the 4 physical activity categories (awake sedentary, lightly active, moderately active, and very active), we found that of the total awake wear time, the longest duration was spent in sedentary activity for both the 600 minutes/day cutoff group (mean 564 min/d, SD 138 min/d) and the 1200 min/d cutoff group (mean 568 min/d, SD 121 min/d; Table 2). The average wear time spent in the physical activity categories of very active and moderately active was less than 25 minutes per day for both cutoffs. Male participants spent a slightly higher wear time in the physical activity categories of very active and moderately active compared with female participants (very active: 27 min/d vs 15 min/d, moderately active: 29 min/d vs 17 min/d; Figure 2). On the other hand, female participants spent slightly more time in light activity compared with male participants (245 min/d vs 222 min/d).

Figure 2. Average time spent per day in each of the 4 activity levels: awake sedentary, lightly active, moderately active, and very active. Orange represents female participants and teal represents male participants. The vertical axis indicates the wearing time spent in each activity. Participants were selected using the minimal cutoff for wear time of at least 600 minutes/day for 5 - 9 days.



Sleep Results

Out of the 612 participants who wore the Fitbit for at least 600 minutes/day, 588 participants had sleep data available (Table 3). In these participants, the average number of days with sleep data available was 6.9 (SD 1.2) days with a mean sleep duration of 7.9 (SD 0.9) hours and average sleep onset time of 00:16 AM (SD 1.5 h). When stratified by weekends and weekdays, participants exhibited longer sleep duration during weekends compared with weekdays (mean 8.4 hours, SD 1.4 hours vs 7.8

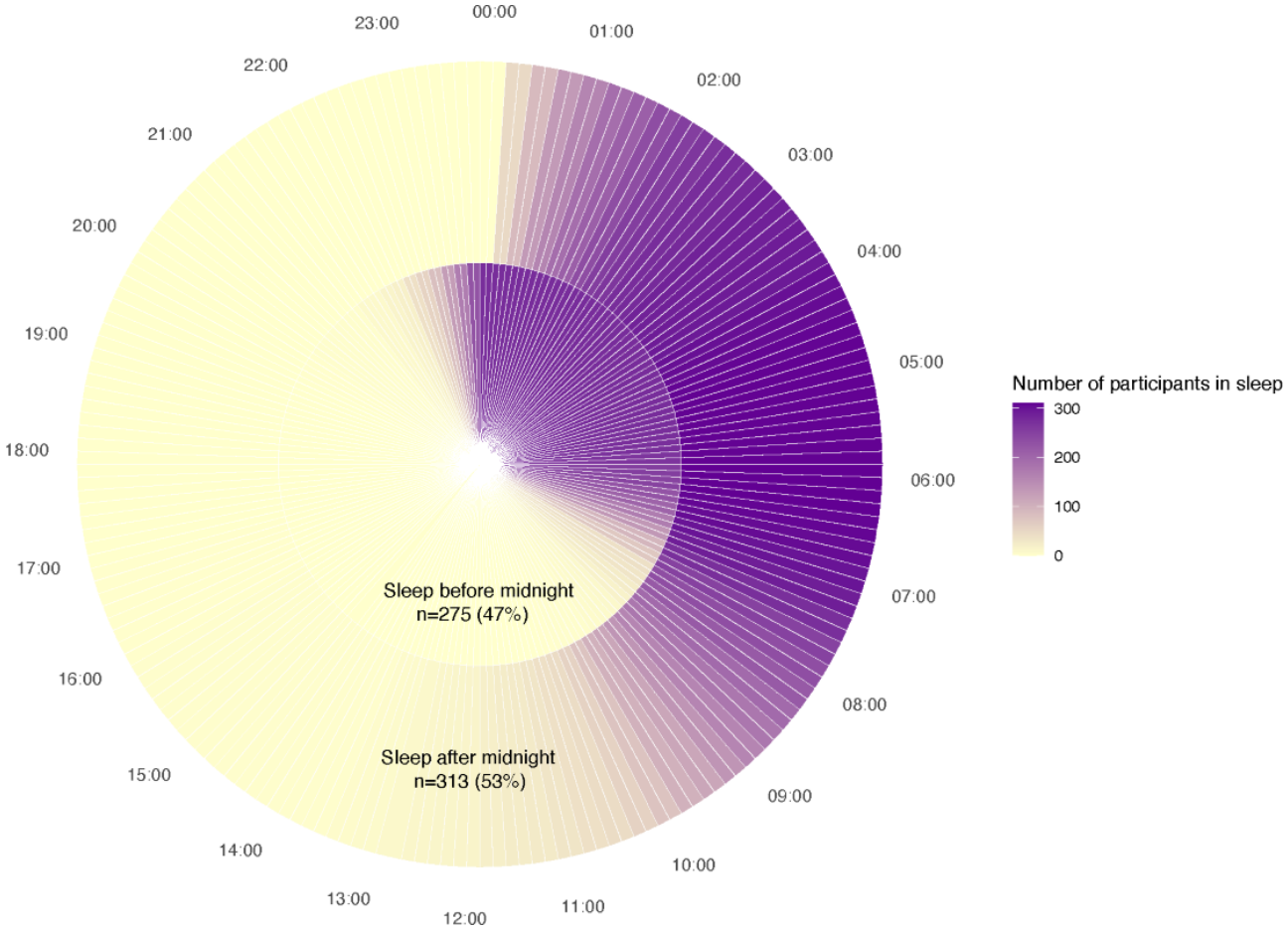
XSL•FO
RenderX

hours, SD 1.1 hours), while the sleep efficiency and WASO stayed consistent (Table S2 in Multimedia Appendix 1). In addition, we classified participants into 2 groups (average sleep onset time before midnight vs average sleep onset time after midnight). The sleep efficiency and WASO were minimally different between the two groups. However, the group with the average sleep onset time before midnight had a longer sleep duration, more social jet lag, and earlier wake up time compared with the second group (sleep duration: 8.1 hours, SD 0.8 hours vs 7.8 hours, SD 0.95 hours; social jet lag: 1.0 hour, SD 1.2 hours vs 0.6 hours, SD 1.9 hours; and wakeup time: 07:16 AM, SD 0.9 h vs 09:09 AM, SD 1.6 h). Furthermore, Figure 3 shows that participants with sleep onset after midnight have a wider wake window (a larger SD) compared with participants with sleep onset before midnight.

Table . Sleep results for participants who have valid data for 5 - 9 days of sleep considering 600 minutes/day, and separated by sleep onset before midnight and sleep onset after midnight.

Sleep measure	Overall participants (n=588), mean (SD)	Participants with average sleep onset before midnight (n=275), mean (SD)	Participants with average sleep onset after midnight (n=313), mean (SD)
Number of days with available data	6.9 (1.2)	6.9 (1.3)	6.9 (1.2)
Sleep duration (h)	7.9 (0.9)	8.1 (0.8)	7.8 (0.95)
Sleep efficiency (%)	93 (5)	93 (6)	93 (5)
Wakefulness after sleep onset (h)	0.6 (0.4)	0.6 (0.5)	0.6 (0.4)
Social jet lag (h)	0.8 (1.6)	1.0 (1.2)	0.6 (1.9)
Sleep onset time	00:16 AM (1.5 h)	23:11 PM (0.6 h)	01:17 AM (1.2 h)
Wake-up time	08:17 AM (1.6 h)	07:17 AM (0.9 h)	09:09 AM (1.6 h)

Figure 3. Sleep patterns for participants with average sleep onset before or after midnight (N=588). The inner circle includes participants whose average sleep onset time occurred before midnight (275/588, 47%) and the outer circle includes participants whose average sleep onset time occurred after midnight (313/588, 53%). The clock is based on 24-hour clock with 15 minute intervals. The gradient represents the number of participants in sleep in that given interval, where more purple color indicates more participants in sleep.



XSL•FO
RenderX

Discussion

Principal Findings

Physical activity and sleep are major behavioral factors associated with various domains of health in adolescents. Consumer-based accelerometry devices, such as Fitbit, have enabled researchers to examine these behaviors efficiently at scale. For our Mid-Teen visit (aged ~17 years old), we invited Project Viva participants to use a Fitbit wearable device to collect physical activity and sleep data. We found participants were likely to consent and to wear the devices for the requested time. We observed that adolescents were spending the majority of their awake time in sedentary activities, with very little time participating in the physical activity categories of very active and moderately active. In the sleep data, we noticed that sleep onset time minimally impacted average sleep duration, sleep efficiency, and WASO; however, participants with a sleep onset after midnight tended to have much wider wakeup time window and less social jet lag.

The rising popularity of wearable devices has introduced a new method of data collection for assessing physical activity and sleep for epidemiology research [42]. This study illustrated the feasibility of using consumer-based wearable devices to collect human-behavior data, such as physical activity, sleep duration, and other sleep metrics, in free-living conditions. In addition, the high granularity of this data enabled us to examine physical activity and sleep at multiple levels: minute level, daily level, and the participant level. The objective data collection method avoided measurement errors resulting from recall or social desirability bias [43,44]. The device being used, unlike many research-based devices, does not need to be mailed back by participants, which avoided additional communication and shipping costs for the researchers, and participant burden of shipping back devices. We additionally avoided the potential of device and data loss during shipping. Furthermore, in the initial communications for the Mid-Teen visit, study staff informed participants that they could keep the device after the study period, and many participants felt it was a nice incentive to participate.

Project Viva has collected sleep and cardiometabolic health information across multiple visits in childhood and adolescence, and plans to continue health assessments in many domains in young adulthood. Our physical activity findings align with existing research, emphasizing the prevalence of sedentary lifestyle among adolescents [45,46]. Notably, we observed a delayed sleep onsite time and longer sleep duration on weekends, similar to previous studies [47,48]. For our future studies, we plan to examine associations of sleep and physical activity behaviors with cardiometabolic health data already collected at the midadolescence visit, such as weight, body composition, blood pressure, and blood biomarkers of cardiovascular health. Furthermore, we plan to use the Fitbit results as a calibration tool to enhance the accuracy and reliability of the self-reported physical activity and sleep data for participants who did not participate in the Fitbit substudy. These Fitbit data offer a unique way to examine health behavior and provide valuable insights into the relationship between behavioral factors and chronic disease development with opportunities for potential interventions. In addition, we have minute level and daily level dataset on objective health behaviors available for more detailed analyses.

Limitations and Challenges

While this study provides insights in using wearable devices to collect adolescent behavior data, there are some limitations to the inferences we can make. First, unlike other actigraphy studies that require participants to complete sleep diaries to self-report sleep onset and wake up times while wearing the device, our study did not request participants to fill out sleep diaries. This made it more difficult to clean the sleep data, especially for participants whose sleep period was less consistent, requiring us to make judgments based on their recorded sleep patterns and manually assign “sleep periods.” Second, despite instructing participants to wear the device on the nondominant wrist, we were unable to actively track the wearing status of the device. The wear habits might have influenced the accuracy of step counts and sleep stage recording [49-51]. The third limitation is the proprietary algorithm used by Fitbit. Although previous validation studies have shown 80% - 90% of accuracy for Fitbit devices in adolescents and adults when comparing both physical activity and sleep using research-grade accelerometry[21-25,50-52], the lack of accessibility to Fitbit’s underlying algorithms poses challenges in understanding the logic behind the algorithms for each device type and age populations. Finally, Project Viva is composed of adolescents from families with generally high median incomes and higher educational background, which could restrict the ability to generalize the findings to other populations. However, the high granularity data captures individual differences and can be used for comparative analyses as well as integrating with other cohort to extend the findings to a diverse population.

Conclusion

This study provided valuable insights into using consumer-based wearable devices to collect human behavior data. These data on physical activity and sleep characteristics are important for researchers seeking to understand their influence on chronic disease development and mental health outcomes. For future research, consumer wearable devices hold great potential for researchers to apply across different adolescent populations. Their use allows us to gain greater understanding of how lifestyle factors impact long-term health outcomes in diverse populations. These data may shed light on future policies or interventions aiming at increasing physical activity and improving sleep health, ultimately leading to improvements in physical and mental health.

Acknowledgments

Project Viva is supported by all the listed grants: R01HD034568, UH3OD023286, and R24ES030894.

XSL•FO
RenderX

Data Availability

The datasets analyzed during this study are not publicly available due to Project Viva's data use and sharing policy but are available upon reasonable request at project_viva@hphci.harvard.edu.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Basic statistical results.
[DOCX File, 78 KB - pediatrics_v8i1e59159_app1.docx]

References

1. Physical activity facts. Healthy Schools.: CDC; 2022. URL: https://www.cdc.gov/healthyschools/physicalactivity/facts.htm
2. Wheaton AG, Jones SE, Cooper AC, Croft JB. Short sleep duration among middle school and high school students - United States, 2015. MMWR Morb Mortal Wkly Rep 2018 Jan 26;67(3):85-90. [doi: 10.15585/mmwr.mm6703a1] [Medline: 29370154]
3. Brand S, Kirov R. Sleep and its importance in adolescence and in common adolescent somatic and psychiatric conditions. Int J Gen Med 2011;4:425-442. [doi: 10.2147/IJGM.S11557] [Medline: 21731894]
4. McManus AM, Mellecker RR. Physical activity and obese children. J Sport Health Sci 2012 Dec;1(3):141-148. [doi: 10.1016/j.jshs.2012.09.004]
5. Głąbska D, Guzek D, Mellová B, Zadka K, Żywczyk K, Gutkowska K. The national after-school athletics program participation as a tool to reduce the risk of obesity in adolescents after one year of intervention: a nationwide study. Int J Environ Res Public Health 2019 Jan 31;16(3):405. [doi: 10.3390/ijerph16030405] [Medline: 30708984]
6. Henriksson H, Henriksson P, Tynelius P, et al. Cardiorespiratory fitness, muscular strength, and obesity in adolescence and later chronic disability due to cardiovascular disease: a cohort study of 1 million men. Eur Heart J 2020 Apr 14;41(15):1503-1510. [doi: 10.1093/eurheartj/ehz774] [Medline: 31710669]
7. Ekelund U, Luan J, Sherar LB, et al. Moderate to vigorous physical activity and sedentary time and cardiometabolic risk factors in children and adolescents. JAMA 2012 Feb 15;307(7):704-712. [doi: 10.1001/jama.2012.156] [Medline: 22337681]
8. Saunders TJ, Chaput JP, Tremblay MS. Sedentary behaviour as an emerging risk factor for cardiometabolic diseases in children and youth. Can J Diabetes 2014 Feb;38(1):53-61. [doi: 10.1016/j.jcjd.2013.08.266] [Medline: 24485214]
9. Hu S, Li X, Yang L. Effects of physical activity in child and adolescent depression and anxiety: role of inflammatory cytokines and stress-related peptide hormones. Front Neurosci 2023;17:1234409. [doi: 10.3389/fnins.2023.1234409] [Medline: 37700748]
10. Wang X, Cai ZD, Jiang WT, Fang YY, Sun WX, Wang X. Systematic review and meta-analysis of the effects of exercise on depression in adolescents. Child Adolesc Psychiatry Ment Health 2022;16(1):16. [doi: 10.1186/s13034-022-00453-2]
11. Korczak DJ, Madigan S, Colasanto M. Children's physical activity and depression: a meta-analysis. Pediatrics 2017 Apr;139(4):e20162266. [doi: 10.1542/peds.2016-2266] [Medline: 28314824]
12. Haverkamp BF, Wiersma R, Vertessen K, van Ewijk H, Oosterlaan J, Hartman E. Effects of physical activity interventions on cognitive outcomes and academic performance in adolescents and young adults: a meta-analysis. J Sports Sci 2020 Dec;38(23):2637-2660. [doi: 10.1080/02640414.2020.1794763] [Medline: 32783695]
13. Bidzan-Bluma I, Lipowska M. Physical activity and cognitive functioning of children: a systematic review. Int J Environ Res Public Health 2018 Apr 19;15(4):800. [doi: 10.3390/ijerph15040800] [Medline: 29671803]
14. Chen MY, Wang EK, Jeng YJ. Adequate sleep among adolescents is positively associated with health status and health-related behaviors. BMC Public Health 2006 Mar 8;6(1):59-59. [doi: 10.1186/1471-2458-6-59] [Medline: 16524482]
15. Weiss A, Xu F, Storfer-Isser A, Thomas A, Ievers-Landis CE, Redline S. The association of sleep duration with adolescents' fat and carbohydrate consumption. Sleep 2010 Sep;33(9):1201-1209. [doi: 10.1093/sleep/33.9.1201] [Medline: 20857867]
16. Gupta NK, Mueller WH, Chan W, Meininger JC. Is obesity associated with poor sleep quality in adolescents? Am J Hum Biol 2002;14(6):762-768. [doi: 10.1002/ajhb.10093] [Medline: 12400037]
17. Hayes JF, Balantekin KN, Altman M, Wilfley DE, Taylor CB, Williams J. Sleep patterns and quality are associated with severity of obesity and weight-related behaviors in adolescents with overweight and obesity. Child Obes 2018 Jan;14(1):11-17. [doi: 10.1089/chi.2017.0148] [Medline: 28850274]
18. Foti KE, Eaton DK, Lowry R, McKnight-Ely LR. Sufficient sleep, physical activity, and sedentary behaviors. Am J Prev Med 2011 Dec;41(6):596-602. [doi: 10.1016/j.amepre.2011.08.009] [Medline: 22099236]
19. Shochat T, Cohen-Zion M, Tzischinsky O. Functional consequences of inadequate sleep in adolescents: A systematic review. Sleep Med Rev 2014 Feb;18(1):75-87. [doi: 10.1016/j.smrv.2013.03.005] [Medline: 23806891]
20. Zhang J, Paksarian D, Lamers F, Hickie IB, He J, Merikangas KR. Sleep patterns and mental health correlates in US adolescents. J Pediatr 2017 Mar;182:137-143. [doi: 10.1016/j.jpeds.2016.11.007] [Medline: 27939122]

XSL•FO
RenderX

21. Vooijs M, Alpay LL, Snoeck-Stroband JB, et al. Validity and usability of low-cost accelerometers for internet-based self-monitoring of physical activity in patients with chronic obstructive pulmonary disease. Interact J Med Res 2014 Oct 27;3(4). [doi: 10.2196/ijmr.3056] [Medline: 25347989]
22. Adam Noah J, Spierer DK, Gu J, Bronner S. Comparison of steps and energy expenditure assessment in adults of Fitbit Tracker and Ultra to the Actical and indirect calorimetry. J Med Eng Technol 2013 Oct;37(7):456-462. [doi: 10.3109/03091902.2013.831135]
23. Diaz KM, Krupka DJ, Chang MJ, et al. Fitbit®: An accurate and reliable device for wireless physical activity tracking. Int J Cardiol 2015 Apr 15;185:138-140. [doi: 10.1016/j.ijcard.2015.03.038] [Medline: 25795203]
24. Haghayegh S, Khoshnevis S, Smolensky MH, Diller KR, Castriotta RJ. Accuracy of wristband Fitbit models in assessing sleep: systematic review and meta-analysis. J Med Internet Res 2019 Nov 28;21(11):e16273. [doi: 10.2196/16273] [Medline: 31778122]
25. Nelson MB, Kaminsky LA, Dickin DC, Montoye AHK. Validity of consumer-based physical activity monitors for specific activity types. Med Sci Sports Exerc 2016;48(8):1619-1628. [doi: 10.1249/MSS.0000000000000933]
26. Oken E, Baccarelli AA, Gold DR, et al. Cohort profile: project viva. Int J Epidemiol 2015 Feb;44(1):37-48. [doi: 10.1093/ije/dyu008] [Medline: 24639442]
27. Fitbit. Fitbit Charge 2TM user manual. 2016. URL: https://staticcs.fitbit.com/content/assets/help/manuals/manual_charge_2_en_US.pdf [accessed 2025-01-24]
28. Fitbit. Fitbit Charge 3TM user manual. 2018. URL: https://staticcs.fitbit.com/content/assets/help/manuals/manual_charge_3_en_US.pdf [accessed 2025-01-24]
29. Fitabase. URL: www.fitabase.com [accessed 2025-01-22]
30. Haghayegh S, Khoshnevis S, Smolensky MH, Diller KR, Castriotta RJ. Performance assessment of new-generation Fitbit technology in deriving sleep parameters and stages. Chronobiol Int 2020 Jan;37(1):47-59. [doi: 10.1080/07420528.2019.1682006] [Medline: 31718308]
31. Lee JM, Kim Y, Welk GJ. Validity of consumer-based physical activity monitors. Med Sci Sports Exerc 2014 Sep;46(9):1840-1848. [doi: 10.1249/MSS.0000000000000287] [Medline: 24777201]
32. Haghayegh S, Khoshnevis S, Smolensky MH, Diller KR. Accuracy of PurePulse photoplethysmography technology of Fitbit Charge 2 for assessment of heart rate during sleep. Chronobiol Int 2019 Jul;36(7):927-933. [Medline: 30990098]
33. Benedetto S, Caldato C, Bazzan E, Greenwood DC, Pensabene V, Actis P. Assessment of the Fitbit Charge 2 for monitoring heart rate. PLoS ONE 2018;13(2):e0192691. [doi: 10.1371/journal.pone.0192691] [Medline: 29489850]
34. Mantua J, Gravel N, Spencer RMC. Reliability of sleep measures from four personal health monitoring devices compared to research-based actigraphy and polysomnography. Sensors (Basel) 2016;16:646. [doi: 10.3390/s16050646]
35. Evenson KR, Goto MM, Furberg RD. Systematic review of the validity and reliability of consumer-wearable activity trackers. Int J Behav Nutr Phys Act 2015 Dec 18;12(161):159. [doi: 10.1186/s12966-015-0314-1] [Medline: 26684758]
36. Mitchell JA, Godbole S, Moran K, et al. No evidence of reciprocal associations between daily sleep and physical activity. Med Sci Sports Exerc 2016 Oct;48(10):1950-1956. [doi: 10.1249/MSS.0000000000001000] [Medline: 27285490]
37. Fore R, Hart JE, Choirat C, et al. Embedding mobile health technology into the nurses' health study 3 to study behavioral risk factors for cancer. Cancer Epidemiol Biomarkers Prev 2020 Apr 1;29(4):736-743. [doi: 10.1158/1055-9965.EPI-19-1386]
38. Fitbit. Fitabase data dictionary. 2018.
39. Actigraphy-based assessment of sleep parameters—PMC. URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7191872/ [accessed 2024-07-23]
40. Reliability of actigraphy and subjective sleep measurements in adults: the design of sleep assessments. URL: https://doi.org/10.5664/jcsm.6384
41. Thompson MJ, Gillis BT, Hinnant JB, Erath SA, Buckhalt JA, El-Sheikh M. Trajectories of actigraphy-derived sleep duration, quality, and variability from childhood to adolescence: downstream effects on mental health. SLEEP 2024 Aug 14;47(8):zsae112. [doi: 10.1093/sleep/zsae112] [Medline: 38758702]
42. de Zambotti M, Baker FC, Willoughby AR, et al. Measures of sleep and cardiac functioning during sleep using a multi-sensory commercially-available wristband in adolescents. Physiol Behav 2016 May 1;158:143-149. [doi: 10.1016/j.physbeh.2016.03.006] [Medline: 26969518]
43. Mahmood A, Kim H, Kedia S, Dillon P. Wearable activity tracker use and physical activity among informal caregivers in the United States: quantitative study. JMIR Mhealth Uhealth 2022 Nov 24;10(11):e40391. [doi: 10.2196/40391] [Medline: 36422886]
44. Lang C, Kalak N, Brand S, Holsboer-Trachsler E, Pühse U, Gerber M. The relationship between physical activity and sleep from mid adolescence to early adulthood. A systematic review of methodological approaches and meta-analysis. Sleep Med Rev 2016 Aug;28:32-45. [doi: 10.1016/j.smrv.2015.07.004] [Medline: 26447947]
45. Guthold R, Stevens GA, Riley LM, Bull FC. Global trends in insufficient physical activity among adolescents: A pooled analysis of 298 population-based surveys with 1·6 million participants. Lancet Child Adolesc Health 2020 Jan;4(1):23-35. [doi: 10.1016/S2352-4642(19)30323-2] [Medline: 31761562]
46. Hallal PC, Andersen LB, Bull FC, et al. Global physical activity levels: surveillance progress, pitfalls, and prospects. Lancet 2012 Jul 21;380(9838):247-257. [doi: 10.1016/S0140-6736(12)60646-1] [Medline: 22818937]

XSL•FO
RenderX

47. Gradisar M, Gardner G, Dohnt H. Recent worldwide sleep patterns and problems during adolescence: A review and meta-analysis of age, region, and sleep. Sleep Med 2011 Feb;12(2):110-118. [doi: 10.1016/j.sleep.2010.11.008] [Medline: 21257344]
48. Hysing M, Pallesen S, Stormark KM, Lundervold AJ, Sivertsen B. Sleep patterns and insomnia among adolescents: A population-based study. J Sleep Res 2013 Oct;22(5):549-556. [doi: 10.1111/jsr.12055] [Medline: 23611716]
49. Tully MA, McBride C, Heron L, Hunter RF. The validation of Fitbit ZipTM physical activity monitor as a measure of free-living physical activity. BMC Res Notes 2014 Dec 23;7(1):952. [doi: 10.1186/1756-0500-7-952] [Medline: 25539733]
50. Feehan LM, Geldman J, Sayre EC, et al. Accuracy of Fitbit devices: systematic review and narrative syntheses of quantitative data. JMIR Mhealth Uhealth 2018 Aug 9;6(8):e10527. [doi: 10.2196/10527] [Medline: 30093371]
51. Godino JG, Wing D, de Zambotti M, et al. Performance of a commercial multi-sensor wearable (Fitbit Charge HR) in measuring physical activity and sleep in healthy children. PLoS ONE 2020;15(9):e0237719. [doi: 10.1371/journal.pone.0237719] [Medline: 32886714]
52. Stahl SE, An HS, Dinkel DM, Noble JM, Lee JM. How accurate are the wrist-based heart rate monitors during walking and running activities? Are they accurate enough? BMJ Open Sport Exerc Med 2016 Apr;2(1):e000106. [doi: 10.1136/bmjsem-2015-000106]

Abbreviation

BPM: beats per minute
WASO: wakefulness after sleep onset

Edited by S Badawy; submitted 03.04.24; peer-reviewed by HA Golkashani, S Alomairah; revised version received 02.12.24; accepted 18.12.24; published 04.02.25.

Please cite as:
Zhang Y, Bornkamp N, Hivert MF, Oken E, James P
Using a Consumer Wearable Activity Monitoring Device to Study Physical Activity and Sleep Among Adolescents in Project Viva: Cohort Study
JMIR Pediatr Parent 2025;8:e59159
URL: https://pediatrics.jmir.org/2025/1/e59159
doi:10.2196/59159

© Yutong Zhang, Nicole Bornkamp, Marie-France Hivert, Emily Oken, Peter James. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 4.2.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Parental Perceptions of Priorities and Features for a Mobile App to Promote Healthy Lifestyle Behaviors in Preschool Children: Mixed Methods Evaluation

Jessica R Thompson[1,2*], PhD, MEd; Summer J Weber[2,3*], PhD, RD; Shelagh A Mulvaney[4], PhD; Susanna Goggans[2], BS; Madeline Brown[2], MPH; Anthony Faiola[5], PhD; Lynn Maamari[2], MS; Pamela C Hull[2,6], PhD

[1]Department of Health Policy and Administration, The Pennsylvania State University, University Park, PA, United States

[2]Community Impact Office, University of Kentucky Markey Cancer Center, University of Kentucky, Lexington, KY, United States

[3]Evidence Analysis and Regulatory Affairs, Food and Nutrition Service, United States Department of Agriculture, Alexandria, VA, United States

[4]School of Nursing, Vanderbilt University, Nashville, TN, United States

[5]Department of Population Health, College of Nursing, University of Cincinnati, Cincinnati, OH, United States

[6]Department of Behavioral Science, University of Kentucky, Lexington, KY, United States

[*]these authors contributed equally

Corresponding Author:
Jessica R Thompson, PhD, MEd
Department of Health Policy and Administration
The Pennsylvania State University
601E Ford Building
University Park, PA, 16802-1503
United States
Phone: 1 8148638129
Email: jrthompson@psu.edu

Abstract

Background: Parents of preschool-aged children are a key focus for interventions to shape healthy lifestyle behaviors and support risk reduction for obesity from an early age. In light of limited existing evidence on the use of mobile technology to promote healthy lifestyle behaviors among young children, we sought to gather parental priorities regarding a mobile app focused on guided goal setting across the domains of diet, physical activity, media use, and sleep.

Objective: The purpose of this study was to explore the priorities and needs of parents of 2- to 5-year-old children to guide developing the content and features of a mobile app aimed at promoting healthy lifestyle behaviors using a novel convergent mixed methods approach.

Methods: From November to December 2021, we invited parents or guardians in Kentucky to complete a series of web-based concept mapping activities and semistructured interviews (total N=30). Using 2 lists of items focused on (1) parental priorities (content areas) and (2) application features, we asked participants to conduct concept mapping procedures for each list: a web-based sorting activity, where participants grouped items together into thematic piles that made sense to them, and a rating activity, where participants rated each item on a 5-point Likert-type scale. The qualitative interviews were transcribed verbatim, coded, and then analyzed by constant comparative analysis to identify themes. We used the quantitative findings from the concept mapping process to triangulate the resulting themes from the qualitative interviews and generate possible app content areas and features.

Results: The concept mapping results resulted in two 3-cluster concept maps. For parental priorities, participants identified the clusters Creating Healthy Eating Habits, Forming Boundaries, and Building Good Relationships; for app features, participant clusters included Eating Healthy, Using the App, and Setting Goals. The interview themes also represented those 2 domains. Overall, the participants indicated that the top priorities were general health and wellbeing, routine and setting boundaries, and food and healthy eating when it comes to building healthy behaviors among their preschool-aged children. Parents indicated that quick, easy, and child-friendly recipes, goal tracking, and the use of tips and notifications were the features they valued most.

Conclusions: This study contributes to the understanding of what parents or caregivers of young children want from mobile apps, in both content and features, to support building healthy behaviors and routines. The findings can inform future research

XSL•FO
RenderX

on the development and evaluation of existing or new mobile apps. Specific app features identified to meet family needs should be designed closely with a diverse set of families and tested using rigorous designs to identify the mechanisms of action that mobile apps may use for efficacious healthy parenting outcomes.

(JMIR Pediatr Parent 2025;8:e65451) doi:10.2196/65451

KEYWORDS

mHealth; childhood obesity; mixed methods; pediatric; healthy lifestyle behaviors; preschool children; mobile application; diet; physical activity; exercise; media use; sleep; development; semi-structured interviews; healthy eating; parents; caregivers

Introduction

Healthy lifestyle behaviors remain an essential focus for health care efforts in the United States. As of 2017-2020, the US obesity prevalence rate was 41.9%, with obesity being the leading cause of preventable death across major outcomes, such as heart disease, stroke, type II diabetes, and several forms of cancer [1]. Likewise, childhood obesity rates continue to be a concern in the United States, including a prevalence rate of 12.7% among 2- to 5-year-old children in 2017-2020, resulting in conditions such as high blood pressure, high cholesterol, asthma, sleep apnea, and joint problems at an early age [2]. Additionally, childhood obesity disproportionately affects children of lower socioeconomic status and minority groups [3-5], exacerbating and contributing to this vast array of secondary consequences [6,7]. The state of Kentucky currently ranks second in the nation for both adult and childhood obesity rates, with significantly high rates of obesity among rural Appalachian and urban minority residents [1,2,8]. Parents of preschool-aged children remain a key focus for interventions supporting communities with disproportionately high obesity rates in an attempt to curtail these rates from an early age [9].

Recent research on healthy lifestyle behaviors among preschool-aged children has identified relevant determinants and behaviors. For example, Townsend et al [10,11] describe 12 dietary and behavioral determinants for childhood obesity risk reduction: fat, dietary fiber, fruit or vegetables, calcium or dairy, sweetened beverages, restaurant-prepared food, breakfast, energy density of eaten foods, physical activity, TV-viewing, sleep duration, and parenting. A recent systematic review of family-based childhood obesity prevention interventions indicates that interventions tend to focus on the domains of diet, physical activity, media use, and sleep; however, less than half of the included studies targeted a behavioral domain beyond diet and physical activity, and only 16% targeted all 4 behavioral domains [12]. Likewise, few studies exist that focus on goal-setting interventions among children and adolescents [13], even though guided goal setting represents a feasible strategy for parents to improve health behaviors for obesity risk reduction among children [14]. Additionally, a recent meta-analysis indicated that obesity prevention interventions in youth with low socioeconomic status are more successful when several behavior change strategies are integrated, rather than relying solely on one strategy [15].

Thousands of mobile apps exist that focus on nutrition and physical exercise but are primarily geared toward adults [16]. In our recent review, we found only 3 preexisting reviews of multiple mobile health (mHealth) apps designed for children and parents between 2015 and 2022 [17]. Of the 3 reviews, only one provided a list of specific app names, focusing on nutrition as a behavioral intervention for child obesity [18]. The authors of this review concluded that most apps, although free or relatively inexpensive (making them highly attractive to parents), contained content of low quality, were poorly designed, or were not grounded in credible dietary guidelines due to a lack of involvement of nutrition or scientific professionals in the design process [18]. In this review, the most common nutrition features in such apps included promotion of energy balance and guidance on appropriate portion size, and the most common behavioral change feature involved goal setting. Our review identified only 9 apps that use goal setting to change the health behaviors of children.

In light of limited existing evidence, we sought to design a mobile app geared toward parents of preschool-aged (2- to 5-year-old) children, integrating guided goal setting across the domains of diet, physical activity, media use, and sleep. During the formative stage of app development, we sought to integrate feedback from parents with children in our target age range in order to assess major areas of interest and ways the app could best meet their needs. Using a novel mixed methods approach, we combined concept mapping activities and qualitative interviews to capture the perceptions of parents on app content and features. Concept mapping is a useful formative design research tool that uses a structured process to create a visual representation or cognitive map of ideas and concepts [19]. This method has been widely used in a range of formative research topics including mHealth app evaluation [20] and in the development of apps focused on reducing school absences [21]. To our knowledge, this is the first application of concept mapping combined with interviews in the formative design and development of a health-focused app for parents of preschool-aged children. Specifically, the purpose of this study was to use this novel convergent mixed methods approach to explore the needs and desires of parents of 2- to 5-year-old children for the content and features of a health-based mobile app designed to promote healthy behaviors to reduce future obesity risk.

Methods

Recruitment

Study inclusion criteria include the following: primary caregiver of a 2- to 5-year-old child, 18 years or older, and use a smartphone or mobile phone and smartphone apps. Participants were recruited via printed flyers placed at various community-based organizations and distributed via community outreach activities as well as email listservs and social media

XSL•FO
RenderX

channels managed by the university. Recruitment advertisements invited parents to participate in a study to help design a smartphone app for families. Those interested in the study could connect with the study team via an internet link, email, or telephone. The study team employed eligibility prescreening via a REDCap (Research Electronic Data Capture; Vanderbilt University) survey [22]. Participants had the option to complete the eligibility survey online or over the phone.

Ethical Considerations

A waiver of documentation of consent was granted by the University of Kentucky Medical Institutional Review Board (61563). The survey included a web-based process with consent indicated by selecting the "submit" button. If administered by phone, the staff read the consent information and asked participants to consent verbally. Eligible participants were contacted by study staff to schedule an interview and sent a link and log-in information for concept mapping activities.

Study Procedures

From November to December 2021, we conducted 60-minute qualitative interviews (N=30). Interviews were facilitated by staff with a background in public health nutrition and qualitative methodology and conducted via Zoom (Zoom Video Communications) [23]. Interviews were recorded with participant permission. The interview protocol was developed based on a multilevel model of behavioral factors related to pediatric overweight (eg, dietary intake, physical activity, sedentary behavior, sleep, family meals, parenting styles, and feeding practices) [10,11] and research on the importance of goal setting in behavior change [24,25]. In addition, questions were informed by our formative research that demonstrated interest in health-focused apps designed among parents with preschool aged children [26,27] and a review of the content and features of existing apps for parents related to goal setting and tracking [17]. Based on this literature, we developed a semistructured discussion guide (Table S1 in Multimedia Appendix 1) in which we intentionally grouped questions in three logically progressing areas: (1) overall parenting routines and challenges, (2) health and wellness for their preschool-aged child with probes in specific domains from the literature (eg, mealtime, sleep, and active play), and (3) current mobile app use and desired features.

Using a convergent mixed methods design [28], interview participants were simultaneously asked to join in web-based concept mapping activities. Concept mapping is a participatory mixed method that incorporates quantitative elements with qualitative data collection to build consensus around a topic of interest [19,29]. To begin, the study team developed 2 sets of items based on formative research [26,27], which responded to two focal questions: (1) What are health and wellness priorities of your 2- to 5-year-old child? (23 items) and (2) What are the features you would like to have on an app on your phone that could help you set goals and work on goals for taking care of the health and wellness of your 2- to 5-year-old child (31 items)? The first question sought to gather perspectives on app content while the second served to capture desires for app features. We asked participants to complete 2 procedures: a virtual sorting activity, where participants grouped items into thematic piles that made sense to them, and a rating activity, where participants rated each item on a 5-point Likert-type scale. For the 23 health and wellness priority items, this rating question was as follows: How important is this item to you as a priority for your child's health (from not at all important [1] to extremely important [5])? For the 31 app feature items, we asked the following question: How often would you use this feature in an app on your phone (from never [1] to all the time [5])? In addition, we asked demographic questions, including race, ethnicity, marital status, number of children, employment status, education, income, and receipt of assistance programs. All concept mapping data were collected using Groupwisdom (Concept Systems, Inc), a web-based concept mapping software [30].

Analysis

The qualitative interviews were transcribed verbatim and analyzed through a combination of a deductive approach and grounded theory to identify themes [31,32] using the ATLAS.ti qualitative data analysis software (version 8.0) [33]. The initial identification of overarching thematic codes used a deductive strategy based on the interview questions, which was informed by previous research on behavioral determinants related to childhood obesity risk reduction, mealtime and child feeding practices, and guided goal setting among parents of preschool-aged children [10,11]. This initial deductive analysis also focused on overarching thematic codes related to potential app features and tools for families of preschool-aged children [17]. Additionally, we used a line-by-line analysis approach to generate a list of emergent, more granular subcodes within the larger coding schematic. In total, 3 coders with backgrounds in public health were trained to allocate codes to quotations. Interrater reliability was determined according to the procedures of Gough and Conner [34], which resulted in a high level of correspondence (93% agreement). The criteria of Lincoln and Guba [35] for trustworthiness of qualitative research were applied to ensure credibility of the findings.

We analyzed the sorting data from each set of concept mapping items in the Groupwisdom software. Specifically, we used similarity matrices and multi-dimensional scaling to generate 2-point maps, which reflect group consensus on the similarity of items. Next, we performed hierarchical cluster analysis for each set of sorting data to group the sets of items into common thematic clusters, resulting in 2 cluster maps. We combined the point and cluster maps for each focus area (parental priorities and app features) to depict items within their thematic areas. As a part of the recommended concept mapping methodology, we also analyzed average item ratings for the Likert-type rating scales to determine which items participants believed were the most important priorities for the health and wellness of their child and which app features were most likely to be used [19].

Finally, we used the interview themes to triangulate the concept mapping findings. Specifically, we synthesized the parental priorities and desired app features results to derive possible content and features of a novel mobile app to improve health behaviors among preschool-aged children.

XSL•FO
RenderX

Results

Participant Characteristics

Table 1 shows the characteristics of those who participated in at least one activity (N=30): qualitative interviews only (n=2), concept mapping only (n=4), or both (n=24). Overall, the majority of participants identified as non-Hispanic White (93.3%), married (70.0%), having 1 or 2 children (80.0%; range 1 to ≥4), and being employed either part- or full-time (63.4%). A significant portion of the sample (36.6%) had a monthly income of US $2999 or less and 40.0% had not obtained a Bachelor's degree. For families using public assistance, most participated in a combination of WIC (Special Supplemental Nutrition Program for Women, Infants, and Children), SNAP (Supplemental Nutrition Assistance Program), and Medicare or Medicaid.

XSL•FO
RenderX

Table 1. Characteristics for interview or concept mapping participants (N=30).

Demographic variables	Frequency, n (%)
Race or ethnicity	
Non-Hispanic White or Caucasian	28 (93.3)
Hispanic, Latino, or Spanish origin	2 (6.7)
Marital status	
Married	21 (70.0)
Single—divorced	2 (6.7)
Single—never married	6 (20.0)
Did not respond	1 (3.3)
Children	
1	14 (46.7)
2	10 (33.3)
3	3 (10.0)
4 or more	3 (10.0)
Employment	
Full-time	17 (56.7)
Part-time	2 (6.7)
Not employed	11 (36.7)
Education	
High school or GED (General Educational Development high school equivalency diploma)	3 (10.0)
Some college or technical degree	9 (30.0)
Bachelor's degree	5 (16.7)
Graduate degree	9 (30.0)
Did not respond	4 (13.3)
Monthly income	
<US $1000	4 (13.3)
US $1000-US $1999	3 (10.0)
US $2000-US $2999	4 (13.3)
US $3000-US $3999	1 (3.3)
US $4000-US $4999	5 (16.7)
US $5000+	7 (23.3)
Did not respond or don't know	6 (20.0)
Types of assistance	
WIC (Special Supplemental Nutrition Program for Women, Infants, and Children)	8 (26.7)
Head start	2 (6.7)
SNAP (Supplemental Nutrition Assistance Program)	7 (23.3)
TANF (Temporary Assistance for Needy Families)	0 (0.0)
Medicare or Medicaid	6 (20.0)

Concept Mapping and Interview Results

The concept mapping results reflected both app content and features: parental priorities and app features. The in-depth interviews resulted in thematic areas containing 257 individual total codes which also fell into these areas. The parental priority themes included the following: desired areas for improvement, routine, mealtime or child feeding behaviors, active play or physical activity, and sleep. The app features' themes included recipes, goal tracking, grocery shopping or meal planning, and tips and notifications. Representative quotes from the identified themes are shared in Table 2.

XSL•FO
RenderX

Table 2. Representative quotes from the in-depth interviews by thematic areas.

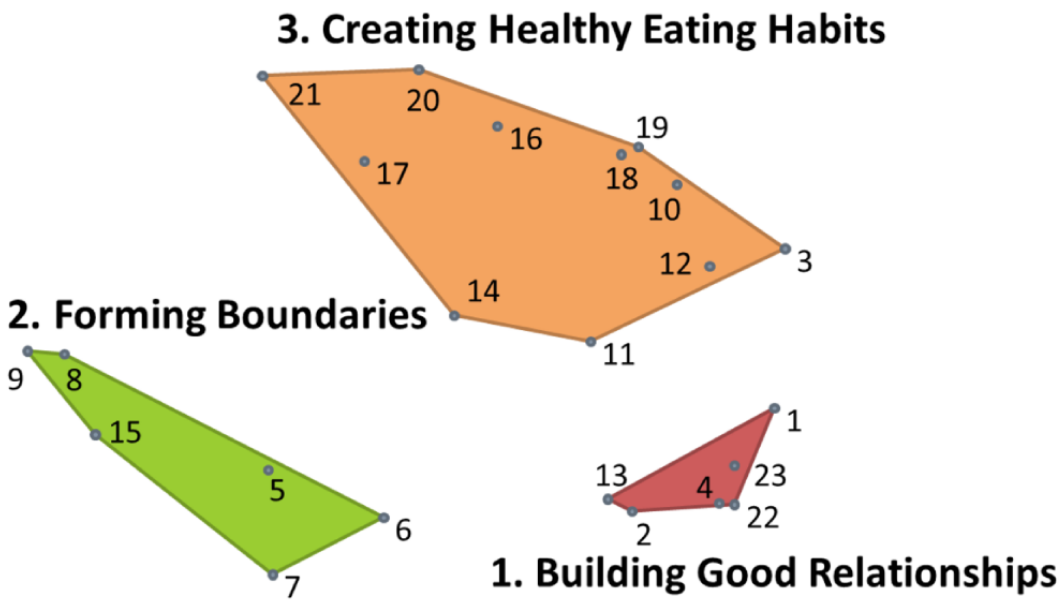
Themes	Quotes
Desired areas of improvement	• I care about, of course, my children and their well-being. That they stay happy and healthy; mentally, physically, emotionally. (Mother of 2 boys ages 3 and 6 years old) • I'm always up for changes, improvements, anything that I can do that'll make anything easier or more efficient because a lot of times I'll do things the hard way instead of an easier way. I don't know why. My dad always said that I do everything the hard way. (Mother of a 4-year-old boy and a 1-year-old girl)
Routine	• We do try to follow [a routine] just because it tends to let our girls have a better, you know, day, especially when they're on their routine- and if they're not in routine, they tend to act out more. So, we do try to... but we don't always follow it, and sometimes it bites us in the [expletive] so on those days it's a little more difficult. (Mother of 2 girls 7 and 2 years old)
Mealtime and child feeding behaviors	• She's very picky. And I have a lot of issues with my weight and I'm afraid that she's going to too. So, I try to like- "Oh well here, I'm eating broccoli. Do you want to eat this? Because dinosaurs eat broccoli" because she likes dinosaurs so she's like, "No it's OK- I'm a dinosaur that doesn't like broccoli." (Mother of 2 girls ages 6 and 4 years old)
Planning grocery shopping	• I do better if I have a list. Sometimes we'll make a list on my phone before I go into the store, so I have something to make sure I get everything. And then a lot of times we'll use Click List, which makes it a lot easier because then everything that we need is all right there, like we have to order it that way, so that makes it a lot easier[…] Sometimes I'm still a pencil paper person too. I kind of do all of it. (Mother of a 4-year-old boy and a 1-year-old girl)
Active play or physical activity	• Then I know at school, right now they only get to go outside if it's warm enough so he hasn't been outside much, and I can tell on the days when he's been able to play outside at school versus when he hasn't. (Mother of a 3-year-old boy)
Sleep	• They report his behavior at school because sometimes he does not get good reports and his behavior at school- and I've told them it is directly related to sleep. […] That's one of the biggest factors like nights where I know that he's not slept as much, or if they've said he's took a nap or not. It's most directly related to his bad behavior, a lot of times at school, it'll be one the number one thing. So that is important. (Female caregiver to a 4-year-old boy)
App features	
Recipes	• The recipes that get more attention for me are ones I might actually use instead of just browsing would be the ones that's catered for the kids. Or to make it better for them or like a kid twist on something you know, that would be what I would want. (Caregiver to a 4-year-old boy)
Goal tracking	• I know at home sometimes we'll set goals for him. If there's an area that we see, an area of concern, then we'll do like a sticker chart like that I would use in school with a student to meet a certain goal, and we'll talk about that you have to do these three out of the five times. And so, I think if there was an app that would probably be easier than creating sticker charts all the time. (Mother of a 5-year-old boy)
Grocery shopping and meal planning	• I would be interested in it [a shopping list feature] if it was kid friendly and simple. Like if it would be probably like the simplest and quickest kind of interface. Some have gotten to cluttered and have to many things going on, to many things to edit, so, simple is best. (Caregiver to a 4-year-old boy)
Tips and notifications	• I would just say simple. As a parent with everything else on my plate, simplicity is the easiest way[…] if I'm looking for something in particular, I want to be able to find it as quickly as I can. (Mother of 2 boys ages 2 and 4 years old)

XSL•FO
RenderX

Parental Priorities

Figure 1 displays the combined point and cluster map for the parental priorities area, which shows each of the 23 items in relative positions based on similarity (ie, items close together were often sorted together by participants) and grouped into thematic clusters, providing understanding of perceived commonality. The resulting clusters were as follows: (1) Building Good Relationships, (2) Forming Boundaries, and (3) Creating Healthy Eating Habits. These cluster names were developed from pile names participants created in the sorting process and reflect the major desired areas for app content. Table 3 includes all of the concept mapping items grouped by cluster and sorted by the average rating for each item; the highest rated items for each cluster are shown in italics.

Figure 1. Parental priorities combined point and cluster concept map.



XSL•FO
RenderX

Table 3. Concept mapping items grouped by cluster with average item ratings (highest rated for each cluster in italics).

Cluster and item	Statement	Average rating (Importance: 1=not at all to 5=extremely)
Parental properties		
1. Building good relationships		
1	*Taking care of my child's health*	*4.96*
22	*Being a good parent*	*4.92*
2	Talking and listening to my child	4.88
23	Helping my child feel good about their body as they grow up	4.88
4	Spending quality time with my child	4.79
13	Playing with my child	4.67
2. Forming boundaries		
6	*Setting and sticking to boundaries that are clear*	*4.50*
5	*Establishing and sticking to a daily routine*	*4.17*
7	How to reward my child for good behavior	4.08
8	Limiting my child's time using a phone or tablet	4.00
15	Getting my child to bed on-time	4.00
9	Limiting my child's time watching TV	3.67
3. Creating healthy eating habits		
3	*Having a variety of healthy food choices at home*	*4.63*
12	*Being a good role model for my child by eating healthy*	*4.42*
19	Getting my child to eat vegetables	4.38
18	Getting my child to eat healthy food	4.29
11	Encouraging exercise or physical activity for my child	4.25
10	Making sure my child doesn't drink too much sugar	4.13
14	Being a good role model for my child by exercising	4.04
16	Preparing more meals at home	3.92
17	Cooking with my child	3.67
21	Ways to address my child's picky eating	3.58
20	Quick and easy recipes for my family	3.50
App features		
1. Eating healthy		
1	*Healthy recipes*	*4.42*
4	*Easy recipes*	*4.29*
5	*Quick recipes*	*4.29*
3	Recipes for kids	4.17
11	Add recipes to a meal plan	4.08
8	Recipe tips	4.04
6	Search and filter recipes	3.92
7	View recipe nutrition facts	3.88

XSL•FO
RenderX

Cluster and item	Statement	Average rating (Importance: 1=not at all to 5=extremely)
10	Make a meal plan	3.83
12	Tips about child health and nutrition	3.79
9	Make a grocery list	3.71
2	Recipes that can fit my family's dietary needs (eg, vegetarian, gluten free, no dairy, allergies, etc.)	3.50
2. Using the app		
13	*App alerts to view tips about child health and nutrition*	*3.50*
31	*Links to videos about child health and nutrition*	*3.50*
23	*Configure app preferences*	*3.25*
22	Setup my family profile—selecting a photo or avatar	2.88
28	Using the app with other family members	2.54
26	Sharing my goal progress with friends and family	2.08
25	Sharing my goal progress with other app users	2.04
27	Sharing my goal progress on social media	1.83
3. Setting goals		
20	*Set and track goals about making food more child friendly*	*3.88*
30	*Rewards or points for reaching my goals*	*3.79*
14	Quizzes to assess my child's health and well being	3.63
29	Getting feedback on how to improve on my goals	3.50
15	Set and track goals about my child's health and well being	3.42
24	Set and track goals about what my child eats and drinks	3.42
16	Set and track goals about my child's physical activity	3.33
18	Set and track goals about my child's mealtime routine	3.33
21	Reminder alerts to track goals for my child daily	3.29
19	Set and track goals about eating together as a family	3.21
17	Set and track goals about my child's bedtime	3.13

Building Good Relationships

Items in the Building Good Relationships cluster with the overall highest importance ratings included: "1. Taking care of my child's health" (4.96 out of 5) and "22. Being a good parent" (4.92 out of 5), which highlights the importance of overall child well-being. To begin the interviews, we asked about what is most important as a parent or caregiver of your 2- to 5-year-old child or children. Several parents mentioned child happiness or child emotional or mental health as a main priority. Parents also mentioned spending time with their child, active listening, and communication with their child as important aspects of their parenting style. Many parents stated their child's health in general was most important, while other parents mentioned specific areas of child health such as healthy eating and physical activity. Other areas of priority included building and sticking to a routine, school readiness, and participation in religion.

XSL•FO
RenderX

Forming Boundaries

The Forming Boundaries cluster spoke to the participant-identified need for routine and time management. Items "6. Setting and sticking to boundaries that are clear" (4.50 out of 5) and "5. Establishing a daily routine" (4.17 out of 5) had the highest importance ratings in the cluster. Caregivers described a routine or schedule to establish consistency and reliability for their children. The morning routine, although often the most stressful or hectic, was integral to several families, especially those with a strict morning schedule. Evening routines were often described as a way to establish togetherness and connection with their children, whether through mealtime, playtime, or screen time. Bedtime routines varied for families but were the most commonly described area of routine. Caregivers described that their schedules were highly dependent on a variety of factors such as non-autonomous work schedules, unemployment, appointments, busy lifestyles, child health, and their child's mood or behavior.

Many of those who said that their routine was important or somewhat important emphasized that "life is easier with routine, more difficult without," and that their children were motivated by or thrived on routine. However, not all caregivers identified as planners; ie, several caregivers explicitly mentioned they do not adhere to a routine or *play it mostly by ear.* Whether parents viewed routine as important or not, they were able to describe scenarios where lack of structure was linked to child behavior issues.

Appropriately, the screen time–related items fell in this cluster, including items "8. Limiting my child's time using a phone or tablet" and "9. Limiting my child's time watching TV." Interestingly, the phone or tablet item had a higher importance rating than watching TV (4.00 compared to 3.67 out of 6), suggesting phones and tablets may be a particular area of focus for screen time strategies. Tips for screen time reduction were desirable among interview participants. Barriers included: apartment living or not having a yard, child injuries, busy schedules, younger children (eg, infants) in the household, child health issues, and caregiver being unconcerned about screen time.

Similarly, the only sleep-related item, "15. Getting my child to bed on time," fell into this cluster. Most interview participants described a bedtime routine for their young children and stated that their child had a set bedtime. Participants who stuck to a routine described their child's sleep and sleep compliancy as easy, with good quality and quantity. Alternatively, some caregivers described children who had difficulty falling asleep, resisted sleep, or had issues with waking regularly in the night. Several sleep improvement strategies included having a light, night light, or red light in the room; reading to children before bed; use of supplemental melatonin; soft music; and limits on screen time. Participants also described barriers, such as the use of screens, continuation of breastfeeding, and co-sleeping.

Creating Healthy Eating Habits

The food and nutrition items grouped together as its own cluster (Creating Healthy Eating Habits), including a variety of eating and meal planning or preparation items. The most highly rated were as follows: "3. Having a variety of healthy food choices at home" (4.63 out of 5), followed by "12. Being a good role model for my child by eating healthy" (4.42 out of 5) and "19. Getting my child to eat vegetables" (4.38 out of 5). Mealtime and child feeding were major themes of the interviews. Participant responses were mixed if planning healthy meals was easy, difficult, or somewhere in-between. Many participants stated they actively try to prepare and provide healthy meals for themselves and their children. However, barriers to planning healthy meals included busy schedules or time, finances, food allergies or intolerances in the household, caregivers identifying as poor cooks, and having to tend to more than one young child. Convenience food and eating out were mentioned by parents as a strategy to address busy schedules.

Barriers to desirable child feeding included the child wanting to eat different foods than those prepared, frequent snacking, and wanting to eat close to bedtime. Picky eating was the most frequently raised barrier; only 5 caregivers stated their child was not a picky eater. Successful strategies to combat picky eating included eating meals with children or modeling healthy eating, cooking or preparing food with children, making food child-friendly, and keeping foods separated or compartmentalized on the plate or during serving. Unsuccessful strategies included food coloring or telling the child that a favorite character or animal eats the food. Many parents also stated encouraging vegetable eating was an important part of child feeding. Notably, item "21. Ways to address picky eating" had the second-lowest importance rating in the cluster (3.50 out of 5); this rating may indicate participant preferences toward broadly increasing positive strategies and healthy choices rather than a focus on specific strategies geared toward picky eating.

Some parents practiced strict restriction of what they considered unhealthy or junk foods, while others allowed children to have unimpeded access to snacks high in sugar, fat, and excess calories. A few caregivers expressed concern over their own weight and how this extended to their concern about child overweight or obesity. Although located in the Building Good Relationships cluster, participants highly rated item "23. Helping my child feel good about their body as they grow up" (4.88 out of 5), further emphasizing participant concerns about weight and body image as it relates to food choices.

The diversity of thought around meal planning and grocery shopping may be reflected by the lack of highly rated items. For example, items such as "16. Preparing meals at home," "17. Cooking with my child," and "20. Quick and easy recipes for my child" that correspond to planning and preparing meals fell at the bottom of the ratings for the Creating Healthy Eating Habits cluster (3.92, 3.58, and 3.50 out of 5, respectively). The relatively lower ratings of these items may be due to the wide range of opinions and strategies used by study participants. Participants who identified as meal planners described their motivations and strategies, including budgeting, shopping for staples, or sticking to the list. Some parents found it easier to buy only a few items at a time, while others found it easier to shop in bulk—using storage capacities of their pantries and freezers. Key facilitators included proximity to the grocery store, sharing tasks with another parent or caregiver, and allowing children to choose items at the store. Barriers included busy

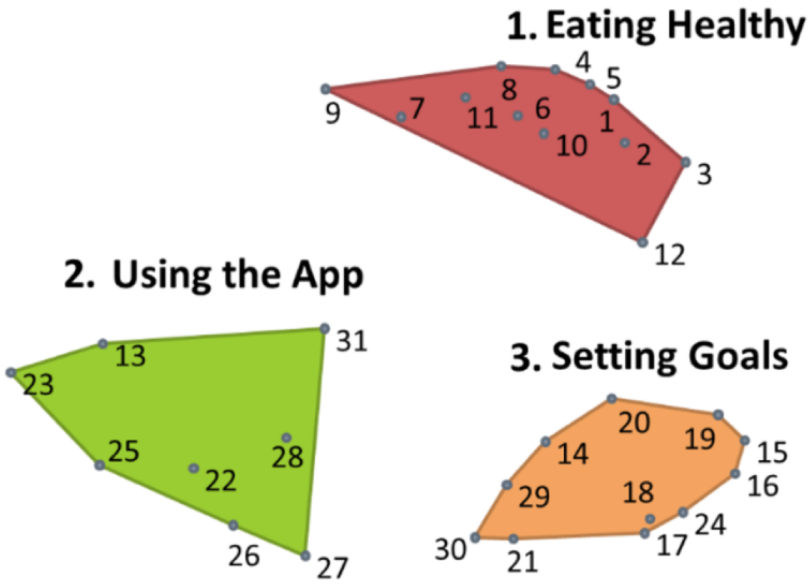
XSL•FO
RenderX

schedules, lack of time, finances, child misbehavior, and shopping with children present.

App Features

Figure 2 shows the combined point and cluster map for the App Features area. The App Features map included the following clusters: (1) Eating Healthy, (2) Using the App, and (3) Setting Goals; likewise, these cluster names were developed from participant pile names in the sorting activity. In the interviews, participants were asked about their current use of apps, especially those that helped with parenting. The type of apps most frequently used by participants to help with parenting were social media (eg, Facebook, Instagram, Snapchat), which caregivers used to follow nutrition-related content, such as recipes, and for parenting advice or finding childcare. Many parents said they used apps to search for and view recipes, including through social media pages, Pinterest, YouTube, and WIC apps. Other participants preferred to use general search engines to find recipes.

Figure 2. Application features combined point and cluster concept map.



Eating Healthy

The concept mapping results support a high interest level in recipes. Items “1. Healthy recipes” (4.42 out of 5), “4. Easy recipes” (4.29 out of 5), and “5. Quick recipes” (4.29 out of 5) had the highest ratings in the Eating Healthy cluster, indicating participants are likely to use these features often or all the time. Recipe viewing was among the most popular desired app features in the interviews; however, some participants did mention they either do not use recipes or are not interested in looking up recipes in an app feature. Participants expressed interest in recipes for the entire family, which could include kid-friendly options, rather than child-specific recipes. Caregivers’ desire for planning features like a grocery list maker and meal planning tools was also desired; however, in the concept mapping results, items around meal planning and grocery lists were not as highly rated as those related to recipes. When discussing this as an app feature, participants explained how meal or grocery shopping features may be more likely to be used if they are kept simple.

Setting Goals

The concept mapping findings also support the popularity of goal-tracking features. Item “20. Set and track goals about making food more child-friendly” (3.88 out of 5) had the highest rating for potential use among a variety of goal-tracking items in the Setting Goals cluster. Tracking features, especially goal tracking (eg, healthy eating, sticking to a routine, sleep, etc.) were also among the most desirable features among interview participants. Alternatively, some caregivers mentioned that, due to a lack of time or disinterest, they do not wish to log items or meticulously keep track of child-related goals on their phone. Some parents said this type of activity is already intuitive for them, so the feature would be unnecessary. Other participants said they already use a form of goal tracking that the app would allow them to simplify.

Using the App

Items “13. App alerts to view tips about child health and nutrition” (3.50 out of 5) and “31. Links to views about child health and nutrition” (3.50 out of 5) had the highest ratings among the Using the App cluster, supporting participants’ desire for helpful tips and notifications. The next highest rated item was “23. Configure app preferences,” suggesting that participants would like to tailor the app settings to their preferences. In the interviews, helpful tips and notifications were welcomed by caregivers; however, many wanted to be clear about the desired frequency at which they wished to be

XSL•FO
RenderX

notified on their phone. Developmental milestone tracking, general parenting tips, and the desire for everything to be in one place were desirable app features. Resoundingly, caregivers also voiced that simplicity and efficiency were important to them in an app.

Synthesis of Parental Priorities and App Features

Table 4 presents a list of possible content and features for a novel mobile app to improve health behaviors among preschool-aged children, based on the combined interview and concept mapping results. The first column depicts the topic areas of the overarching interview codes, the second column lists possible app content areas based on interview subcodes for parental priorities, and the third column lists possible app features based on interview subcodes along with the features rated as most desired in the concept mapping data, which are indicated in bold italics. By first understanding parental priorities, we ensured our resulting app content will be grounded in user-centered needs. In particular, parental feedback pointed to the need for a holistic app with a variety of health topics in one place, including a strong focus on food and nutrition, routines and time management, along with general parenting tips, each of which correspond to the clusters from the concept mapping process (Creating Healthy Eating Habits, Forming Boundaries, and Building Good Relationships). Informed by the concept mapping rating data, we gained information on ways to focus the development of our novel mobile app through the inclusion of quick, easy, and child-friendly recipes; grocery list or meal planning tools; goal tracking; helpful parenting tips; and the ability to control settings, such as notifications and recipe filters, to customize the experience for individual users. As a whole, exploring parental priorities and mobile app features in combination ensured our app development will be informed by both the desired content and functions that target users (parents with preschool children) would like to have.

Table 4. Summary of possible app content and features based on interview and concept mapping results (most desired features in italics).

Interview topic	Parental priorities: possible app content	Parental interests: possible app features

Food and nutrition	• Mealtime or eating behavior (eg, picky eating)
	• Making/planning healthy meals
		• *Quick, easy recipes*:
		  • Kid-friendly; cooking with kids
		  • Sort or filter ingredients; allergies
		• Grocery list or meal planning
		• Picky eating and child nutrition tips

Other health-related	• Limiting screen time • Dental health • Activities for children	• *Desire for multiple health topics in one place (holistic)* • Active play and activities for children tips • Features for parent and child
Routine and time management	• Time management/planning • Managing work responsibilities and parenting	• *Goal tracking* • *Ability to control settings* • Sleep (bedtime/nap) tracking • Ability to share success
Behavioral issues	• Discipline and rule setting • Sticking to boundaries • Reacting mindfully to behavior and patience • Influencing your child	• *General parenting tips* • Interaction with other parents or users • Account for other family members or parent
Developmental milestones	• Potty training • Improving speech • Socialization and interacting with others • Improving sensory development	• Developmental milestone tracking • Communication with health care provider

Discussion

Principal Results and Comparison With Prior Work

Concept mapping has been used on projects focused on childhood obesity prevention programs for adolescents [36] or for the development of culturally appropriate interventions [37], as well as for areas such as sugary drink consumption among children [38], food parenting practices [39], and overall childhood thriving [40]. To our knowledge, however, our study is the first application of the method to guide the development of a health behaviors app for parents of preschool-aged children. In this study, we used a novel, convergent mixed methods approach to identify parental child health priorities and mobile app features that parents or caregivers would prefer to use. Through the use of qualitative interviews, we were able to describe the breadth of parenting challenges and experiences the participants faced. With the addition of concept mapping activities, we were able to identify converging themes and assess priorities among the provided information.

Overall, the participants in this study indicated psychosocial health and general wellbeing, rather than specific behaviors, as their primary focus when expressing their interest in improving health among their preschool-aged children for mobile app content. Using previous research, 12 behavioral factors were identified related to childhood overweight and obesity that

XSL•FO
RenderX

parents identified when thinking about the health of their child [10,11]. Parent and caregiver responses in this study suggest the importance of establishing a routine and setting boundaries, particularly in areas such as screen time and sleep behaviors. Although healthy eating arose as the most desired topic for resources for young children, participants described a wide variety of preferences around meal planning, grocery shopping, and ways to improve food-related behaviors. Notably, our participants described the importance of all of the related areas identified in the previous literature as important app content to building healthy behaviors for preschool-aged children, including nutrition, physical activity, media use, and sleep.

For specific app features, parents indicated their top choices as (1) quick, easy, and child-friendly recipes; (2) goal-tracking features; and (3) the use of tips and notifications. Goal-setting has been a common behavior change feature used in mobile health applications for children in previous studies with techniques used such as rewards for making progress [18,41,42]. However, there has been a significant gap in that many of the mobile health applications do not feature the involvement of health professionals [18], and few apps exist with the intention of parents using them to modify their children's health behaviors [16,17,43]. In the recent review on goal-setting applications for parents and children, 9 applications were identified that allowed goal-tracking in the setting of health-related behaviors of children, with 6 focused on nutrition or mealtime, 5 focused on physical activity or screen time, 7 focused on sleep, and 6 focused on personal hygiene. None of the apps allowed a parent to specifically recommend goals for each child [17]. Furthermore, matching the divergent views about healthy eating strategies, our participants expressed diversity of thought on their potential use of meal planning or grocery shopping features, though many indicated they would use such features in an app. Additionally, participants expressed interest in tailoring the tips or notifications to a variety of use preferences. As with the health behaviors, our participants described a desire to have everything in one place, so they can find what they need quickly and easily depending on specific needs for their child.

Nutrition and facilitating family mealtimes and daily routines were clearly identified as priorities for this sample of parents and caregivers. The implications of the diverse needs, preferences, and priorities for child health described here may indicate that utility and engagement with mobile tools rest in the balance of simplicity with a choice of multiple features and content foci. Shopping, recipes, and cooking were central to the concerns expressed by these individuals. App features focused on recipes may be designed to incorporate multiple needs and priorities. For example, in order to support the "ease" of healthy meal preparation, provide a recipe feature that allows filtering by time to prepare, provide recipes that address different dietary requirements based on allergies or cultural preferences, or make a shopping list easy to create based on items needed for recipes. Given the preference for a one-stop mobile app, we anticipate that parents will be more engaged with apps that incorporate the whole child and provide behavioral, social, and psychological wellness resources as well.

Limitations

The study sample is representative of relatively lower income families who use public assistance programs; however, the sample included primarily non-Hispanic white and married participants whose perspectives may not represent those of other ethnicities or demographic groups. Future studies in this area should recruit and stratify participants of diverse backgrounds, including single parents and non-traditional family structures, to uncover differences in needs or desires. In addition, individuals choosing to participate in this type of study may be more engaged with parenting practices and improving their child's health than the general population, resulting in selection bias. The use of technology, such as Zoom, can also be a concern among this population; as such, we provided one-on-one assistance to ensure participants felt comfortable using the platform. Additionally, the study had a relatively small sample size, although appropriate for a qualitative approach. Likewise, the purpose of concept mapping is to identify consensus but is dependent upon the composition of the participant sample. Within the concept mapping data, high importance ratings with low variability are often seen, as items are included in the brainstorming list based on their potential importance; we experienced this issue in our data. However, by using multiple methods to triangulate our findings, we feel confident in the ability of our results to accurately capture the perceptions of parents of young children.

Conclusions

For our team, this formative research provided the groundwork for the development of a novel mobile app, including both content and features, for parents and caregivers of preschool-aged children focused on guided goal setting across the domains of diet, physical activity, media use, and sleep. A convergent mixed methods approach provided high-quality data on diverse parental perceptions and challenges and needs for families. Specific app features identified to meet family needs should be designed closely with a diverse set of families and tested using rigorous designs to identify the mechanisms of action that mobile apps may use for efficacious healthy parenting outcomes. This study makes important contributions to the mHealth field for understanding what parents or caregivers of young children want from mobile apps to support building healthy behaviors and routines. The findings can inform future research on the development and evaluation of existing or new mobile apps.

Acknowledgments

The authors would like to thank Caree McAfee and Jane Morgan for operational support of study implementation and thank Kentucky Cancer Program staff for distributing study advertisements in the community to promote the study (Angela Combs, Amy Oliver-Steinkhul, Wynona Padgett, Tonya Pauley, Mindy Rogers, Jeff Russell, Mary Jo Schneider, Ashley Teague, and

XSL•FO
RenderX

Khadijah Wallace, Jennifer Wilson). This research was supported by United States Department of Agriculture (grant #2017-68001-34846) and National Institutes of Health (NIH) Clinical and Translational Science Awards (grant #UL1TR001998).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Semistructured discussion guide for interview questions.
[PNG File , 547 KB - pediatrics_v8i1e65451_app1.png]

References

1. Adult Obesity Facts. Centers for Disease Control and Prevention. 2020. URL: https://www.cdc.gov/obesity/data/adult.html [accessed 2025-01-25]
2. Childhood Obesity Facts. Centers for Disease Control and Prevention. URL: https://www.cdc.gov/obesity/data/childhood.html [accessed 2025-01-25]
3. Fradkin C, Wallander JL, Elliott MN, Tortolero S, Cuccaro P, Schuster MA. Associations between socioeconomic status and obesity in diverse, young adolescents: variation across race/ethnicity and gender. Health Psychol 2015;34(1):1-9 [FREE Full text] [doi: 10.1037/hea0000099] [Medline: 25133824]
4. Ogden CL, Lamb MM, Carroll MD, Flegal KM. Obesity and socioeconomic status in children and adolescents: United States, 2005-2008. NCHS Data Brief 2010(51):1-8 [FREE Full text] [Medline: 21211166]
5. Taveras EM, Gillman MW, Kleinman KP, Rich-Edwards JW, Rifas-Shiman SL. Reducing racial/ethnic disparities in childhood obesity: the role of early life risk factors. JAMA Pediatr 2013;167(8):731-738 [FREE Full text] [doi: 10.1001/jamapediatrics.2013.85] [Medline: 23733179]
6. May AL, Kuklina EV, Yoon PW. Prevalence of cardiovascular disease risk factors among US adolescents, 1999-2008. Pediatrics 2012;129(6):1035-1041. [doi: 10.1542/peds.2011-1082] [Medline: 22614778]
7. Llewellyn A, Simmonds M, Owen CG, Woolacott N. Childhood obesity as a predictor of morbidity in adulthood: a systematic review and meta-analysis. Obes Rev 2016;17(1):56-67. [doi: 10.1111/obr.12316] [Medline: 26440472]
8. Robert Wood Johnson Foundation. 2023. URL: https://www.countyhealthrankings.org/explore-health-rankings/kentucky?year=2023 [accessed 2025-01-25]
9. Mehdizadeh A, Nematy M, Vatanparast H, Khadem-Rezaiyan M, Emadzadeh M. Impact of parent engagement in childhood obesity prevention interventions on anthropometric indices among preschool children: a systematic review. Child Obes 2020;16(1):3-19. [doi: 10.1089/chi.2019.0103] [Medline: 31479311]
10. Townsend M, Ontai L, Ritchie L, Williams S, Young T. Guiding family-based obesity prevention efforts in low-income children in the US, Part 2: what behaviors do we measure? Int J Child Adolesc Health 2022;2(1):31-47.
11. Townsend M, Ontai L, Young T, Ritchie L, Williams S. Guiding family-based obesity prevention efforts in low-income children in the US, Part 1: What determinants do we target? Int J Child Adolesc Health 2021;2(1):19-30.
12. Ash T, Agaronov A, Young T, Aftosmes-Tobio A, Davison KK. Family-based childhood obesity prevention interventions: a systematic review and quantitative content analysis. Int J Behav Nutr Phys Act 2017;14(1):113 [FREE Full text] [doi: 10.1186/s12966-017-0571-2] [Medline: 28836983]
13. Shilts MK, Horowitz M, Townsend MS. Goal setting as a strategy for dietary and physical activity behavior change: a review of the literature. Am J Health Promot 2004;19(2):81-93. [doi: 10.4278/0890-1171-19.2.81] [Medline: 15559708]
14. Shilts MK, Sitnic SL, Ontai L, Townsend MS. Guided goal setting: a feasible obesity prevention behavior change strategy for low-income parents with young children. J Hum Sci Ext 2018;6(3):11. [doi: 10.54718/skql2392]
15. Harakeh Z, Preuhs K, Eekhout I, Lanting C, Klein Velderman M, van Empelen P. Behavior change techniques that prevent or decrease obesity in youth with a low socioeconomic status: a systematic review and meta-analysis. Child Obes 2024;20(2):128-140. [doi: 10.1089/chi.2022.0172] [Medline: 37204322]
16. Krebs P, Duncan DT. Health app use among us mobile phone owners: a national survey. JMIR Mhealth Uhealth 2015;3(4):e101 [FREE Full text] [doi: 10.2196/mhealth.4924] [Medline: 26537656]
17. Weber SJ, Mulvaney SA, Faiola A, Brown M, Koyama T, Sun L, et al. Commercially available mobile apps with family behavioral goal setting and tracking for parents: review and quality evaluation. JMIR Pediatr Parent 2023;6:e41779 [FREE Full text] [doi: 10.2196/41779] [Medline: 37831486]
18. Burrows TL, Khambalia AZ, Perry R, Carty D, Hendrie GA, Allman‐Farinelli MA, et al. Great 'app‐eal' but not there yet: a review of iPhone nutrition applications relevant to child weight management. Nutr Diet 2015;72(4):363-367. [doi: 10.1111/1747-0080.12184]
19. Kane M, Trochin WM. In: Bickman L, Rog D, editors. Concept Mapping for Planning and Evaluation. Thousand Oaks, CA: Sage Publications, Ltd; 2007.

XSL•FO
RenderX

20. Bonten TN, Rauwerdink A, Wyatt JC, Kasteleyn MJ, Witkamp L, Riper H, EHealth Evaluation Research Group. Online guide for electronic health evaluation approaches: systematic scoping review and concept mapping study. J Med Internet Res 2020;22(8):e17774 [FREE Full text] [doi: 10.2196/17774] [Medline: 32784173]
21. Hoogsteder MHH, Douma LN, Eskens CGA, Berendsen RL, Vanneste YTM, Schaafsma FG. Professionals' and students' perceived needs for an online supportive application for reducing school absence and stimulating reintegration: concept mapping study. JMIR Form Res 2021;5(6):e24659 [FREE Full text] [doi: 10.2196/24659] [Medline: 34152275]
22. Vanderbilt U. Research Electronic Data Capture (REDCap). Vanderbilt University. 2022. URL: https://projectredcap.org/about/ [accessed 2022-08-11]
23. Zoom. Zoom Video Communications Inc. 2022. URL: https://zoom.us/ [accessed 2025-01-25]
24. Berkman ET. The neuroscience of goals and behavior change. Consult Psychol J 2018;70(1):28-44 [FREE Full text] [doi: 10.1037/cpb0000094] [Medline: 29551879]
25. Perdew M, Liu S, Naylor P. Family-based nutrition interventions for obesity prevention among school-aged children: a systematic review. Transl Behav Med 2021;11(3):709-723. [doi: 10.1093/tbm/ibaa082] [Medline: 32893869]
26. Hull P, Emerson JS, Quirk ME, Canedo JR, Jones JL, Vylegzhanina V, et al. A smartphone app for families with preschool-aged children in a public nutrition program: prototype development and beta-testing. JMIR Mhealth Uhealth 2017;5(8):e102 [FREE Full text] [doi: 10.2196/mhealth.7477] [Medline: 28768611]
27. Hull P, Shearer E, Weber SJ, Schmidt D, Jones J, Harris C, et al. CHEW 2.0: user testing of the Children Eating Well (CHEW) smartphone application for WIC families. J Nutr Educ Behav 2018;50(7):S111. [doi: 10.1016/j.jneb.2018.04.246]
28. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. Health Serv Res 2013;48(6 Pt 2):2134-2156 [FREE Full text] [doi: 10.1111/1475-6773.12117] [Medline: 24279835]
29. Thompson JR, Burke JG. Increasing community participation in public health research: applications for concept mapping methodology. Prog Community Health Partnersh 2020;14(2):243-250. [doi: 10.1353/cpr.2020.0025] [Medline: 33416645]
30. GroupWisdom. Concept Systems Incorporated. 2022. URL: https://groupwisdom.com/ [accessed 2025-01-25]
31. Corbin J, Strauss A. Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory. Thousand Oaks, CA: SAGE Publications, Inc; 2014.
32. Gilgun J. Deductive qualitative analysis and grounded theorynsitizing concepts and hypothesis-testing. In: The SAGE Handbook of Current Developments in Grounded Theory. Washington, DC: Sage; 2019:107-122.
33. ATLAS.ti 22 Qualitative Data Analysis. ATLAS.ti. 2022. URL: https://atlasti.com/ [accessed 2025-01-25]
34. Gough B, Conner MT. Barriers to healthy eating amongst men: a qualitative analysis. Soc Sci Med 2006;62(2):387-395. [doi: 10.1016/j.socscimed.2005.05.032] [Medline: 16011867]
35. Lincoln YS, Guba EG. Naturalistic Inquiry. Los Angeles, Washington, DC: SAGE Publications; 1985:416.
36. Kornet-van der Aa DA, van Randeraad-van der Zee CH, Mayer J, Borys JM, Chinapaw MJM. Recommendations for obesity prevention among adolescents from disadvantaged backgrounds: a concept mapping study among scientific and professional experts. Pediatr Obes 2018;13(6):389-392 [FREE Full text] [doi: 10.1111/ijpo.12239] [Medline: 28921882]
37. Keita AD, Whittaker S, Wynter J, Kidanu TW, Chhay C, Cardel M, et al. Applying concept mapping methodology to identify the perceptions of risk and protective factors for childhood obesity among southeast Asian refugees. J Health Care Poor Underserved 2016;27(4):1909-1933. [doi: 10.1353/hpu.2016.0171] [Medline: 27818447]
38. Halberg SE, Visek AJ, Blake EF, Essel KD, Sacheck J, Sylvetsky AC. SODA MAPS: a framework for understanding caffeinated sugary drink consumption among children. Front Nutr 2021;8:640531 [FREE Full text] [doi: 10.3389/fnut.2021.640531] [Medline: 33777993]
39. O'Connor TM, Mâsse LC, Tu AW, Watts AW, Hughes SO, Beauchamp MR, et al. Food parenting practices for 5 to 12 year old children: a concept map analysis of parenting and nutrition experts input. Int J Behav Nutr Phys Act 2017;14(1):122 [FREE Full text] [doi: 10.1186/s12966-017-0572-1] [Medline: 28893273]
40. Ettinger AK, Ray KN, Burke JG, Thompson J, Navratil J, Chavis V, et al. A community partnered approach for defining child and youth thriving. Acad Pediatr 2021;21(1):53-62. [doi: 10.1016/j.acap.2020.04.011] [Medline: 32445827]
41. Brown JM, Franco-Arellano B, Froome H, Siddiqi A, Mahmood A, Arcand J. The content, quality, and behavior change techniques in nutrition-themed mobile apps for children in Canada: app review and evaluation study. JMIR Mhealth Uhealth 2022;10(2):e31537 [FREE Full text] [doi: 10.2196/31537] [Medline: 35171100]
42. Schoeppe S, Alley S, Rebar AL, Hayman M, Bray NA, Van Lippevelde W, et al. Apps to improve diet, physical activity and sedentary behaviour in children and adolescents: a review of quality, features and behaviour change techniques. Int J Behav Nutr Phys Act 2017;14(1):83 [FREE Full text] [doi: 10.1186/s12966-017-0538-3] [Medline: 28646889]
43. Bardus M, van Beurden SB, Smith JR, Abraham C. A review and content analysis of engagement, functionality, aesthetics, information quality, and change techniques in the most popular commercial apps for weight management. Int J Behav Nutr Phys Act 2016;13:35 [FREE Full text] [doi: 10.1186/s12966-016-0359-9] [Medline: 26964880]

Abbreviations

mHealth: mobile health
REDCap: Research Electronic Data Capture

XSL•FO
RenderX

SNAP: Supplemental Nutrition Assistance Program
WIC: Special Supplemental Nutrition Program for Women, Infants, and Children

Edited by S Badawy; submitted 15.08.24; peer-reviewed by G Almquist-Tangen, N Neuman, S Nilsson; comments to author 11.09.24; revised version received 03.12.24; accepted 23.12.24; published 19.02.25.

Please cite as:
Thompson JR, Weber SJ, Mulvaney SA, Goggans S, Brown M, Faiola A, Maamari L, Hull PC
Parental Perceptions of Priorities and Features for a Mobile App to Promote Healthy Lifestyle Behaviors in Preschool Children: Mixed Methods Evaluation
JMIR Pediatr Parent 2025;8:e65451
URL: https://pediatrics.jmir.org/2025/1/e65451
doi:10.2196/65451
PMID:

©Jessica R Thompson, Summer J Weber, Shelagh A Mulvaney, Susanna Goggans, Madeline Brown, Anthony Faiola, Lynn Maamari, Pamela C Hull. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 19.02.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

The Role of Early Engagement in a Self-Directed, Digital Mental Health Intervention for Adolescent Anxiety: Moderated Regression Analysis

Emma-Leigh Senyard[1,2], BPsychSci (Hons), MClinPsych; Arlen Rowe[2], BPsych (Hons), PhD; Govind Krishnamoorthy[1,2,3], BBSc, BPsych (Hons), MPsych, PhD; Susan H Spence[4,5], BSc (Hons), MBA, PhD; Caroline Donovan[5,6], BA (Hons), PhD; Sonja March[1,2,3], BA, BPsych (Hons), PhD

[1]School of Psychology and Wellbeing, University of Southern Queensland, Ipswich, Australia

[2]Centre for Health Research, University of Southern Queensland, 37 Sinnathamby Boulevard, Springfield Central, Australia

[3]Manna Institute, Springfield Central, Australia

[4]Australian Institute for Suicide Research and Prevention, Griffith University, Mount Gravatt, Australia

[5]School of Applied Psychology, Griffith University, Mount Gravatt, Australia

[6]Griffith Centre for Mental Health, Griffith University, Mount Gravatt, Australia

Corresponding Author:
Emma-Leigh Senyard, BPsychSci (Hons), MClinPsych
School of Psychology and Wellbeing, University of Southern Queensland, Ipswich, Australia

Abstract

Background: Digital mental health (dMH) interventions offer the ability to reach many more adolescents with anxiety than face-to-face therapy. While efficacious dMH interventions are available for adolescents, premature dropout and low engagement are common, especially if delivered on a self-help basis without any form of therapist guidance. This is concerning, given that higher engagement, in terms of the number of sessions completed, has been repeatedly associated with improved clinical outcomes. The reasons for poor adolescent engagement in dMH programs are unclear. A clear understanding of when and why disengagement occurs is important in order to seek to improve engagement rates. Contemporary models consider engagement as multifaceted, comprising both “use” (eg, amount of content completed, frequency of use, duration spent logged into the dMH program, and depth of use, such as word or character count) and “user experience” (eg, interest and satisfaction in the program and affect and attention whilst engaging in the program).

Objective: This study investigated the role of demographic and early engagement (EE) factors, specifically program use, in predicting overall program engagement and continued engagement, respectively, in a self-directed, internet-based cognitive behavioral therapy program for adolescent anxiety, namely, BRAVE Self-Help. It examined multiple measures of program use, including task completion, homework completion, and depth of response (character count of responses typed into program tasks). It also examined the moderating role of baseline anxiety severity.

Methods: Data collected between July 2014 and May 2020 from 2850 adolescents aged 12 to 18 years who participated in BRAVE Self-Help were analyzed via a series of moderated regressions.

Results: Results showed that EE (in terms of program use) was associated with continued engagement, demonstrated by early tasks (tasks completed in the first two sessions; R^2=0.035; P<.001) and early depth (characters written in the first two sessions; R^2=0.08; P<.001) predicting continued depth of program response (total character count of responses typed into all program tasks from sessions 3 to 10). Demographic factors and anxiety severity did not directly impact adolescents’ engagement in BRAVE Self-Help.

Conclusions: These findings highlight the need to investigate ways to (1) enhance EE and (2) better understand how to measure and capture all aspects of program engagement.

(JMIR Pediatr Parent 2025;8:e60523) doi:10.2196/60523

KEYWORDS

youth; adolescent; teen; teenager; anxiety; eHealth; internet; engagement; mental health; participation; cognitive behavioral therapy; CBT; psychotherapy; self-help; self-guided; retention; attrition; dropout; digital mental health; web-based

XSL•FO
RenderX

Introduction

Background

Approximately 6.5% of adolescents internationally experience anxiety [1]. Anxiety can become entrenched, lead to a lifelong struggle, and is linked to numerous other problems, such as reduced academic performance, poor self-esteem, social problems, substance abuse, depression, and attention and concentration difficulties [2,3]. Digital mental health (dMH) interventions are an effective treatment of choice for many adolescents with anxiety [4-6]. These digital interventions are highly accessible, flexible, affordable, require no waitlists, and reduce concerns about stigma [6].

While dMH interventions are highly accessible and efficacious, it is a concern that, when delivered on a self-directed basis without therapist support, many adolescents cease the program early or neglect to complete program activities [4]. For example, in a study on the dMH program, youthCOACH, which targets chronic medical conditions in youth aged 12 and 21 years using cognitive behavioral therapy (CBT), only 40% of adolescents adhered to the intervention (completed at least 80% of the seven modules) [7]. In another study on the BRAVE Self-Help program, an open-access CBT dMH program for child and adolescent anxiety, only 30% of the 4425 children and adolescents completed more than three sessions, with the greatest clinical improvements made by those users completing at least 6 of 10 sessions [4]. These findings are consistent with those of a recent systematic review and meta-analysis of 35 predominantly adult dMH interventions (both therapist-supported and self-help), which found that greater engagement was associated with stronger treatment gains [8]. Thus, those with lower engagement potentially fail to obtain the greatest clinical benefit.

Engagement in dMH Interventions

Gan et al [8] suggested that variability in the operationalization of engagement is a limitation of the dMH field, and defined engagement as any objective indicator of intervention use (eg, sessions completed, time spent, or number of logins). Indeed, a broader inspection of the literature reveals that dMH researchers have not applied a universal definition of the construct of engagement, and the term is frequently used interchangeably with “adherence,” “compliance,” and “use” [9,10]. To date, the majority of research has focused on the amount of the intervention completed, such as the number of completed treatment sessions or activities (eg, March et al [4], Calear et al [11], and Fleming et al [12]) to capture the use of dMH interventions. However, it is now widely acknowledged that engagement is multifaceted and incorporates more than just the number of sessions completed [4,13,14]. Two key reviews by Yardley et al [14] and Perski et al [15] suggest that engagement should be conceptualized as including both use and user experience. Use refers to the amount of intervention content completed (ie, completed sessions and activities), frequency of session completion, duration spent on intervention, and depth of responses (ie, character or word count). In contrast, user experience refers to subjective, self-reported experiences (ie, attention, interest, and satisfaction with the program), and affect experienced during the program [14,15]. The clinical validity and reliability of these constructs are not yet known; however, the frameworks proposed by Yardley et al [14] and Perski et al [15] provide a useful and comprehensive structure to guide research and advance our understanding and measurement of the numerous potential facets of engagement in dMH interventions.

Early Engagement

Given that higher program use (at least in terms of the number of sessions completed) has consistently been shown to be positively associated with treatment outcomes, but that many participants do not progress beyond a few sessions of dMH programs [8,16], it appears that understanding early engagement (EE) in the first few sessions could offer valuable insight and assist in identifying ways to enhance overall program completion. In a blended-care CBT intervention (combination of videoconference therapy sessions and personalized dMH activities), Wu et al [17] examined the predictors of program retention and found that engagement was poor if participants did not complete their assigned web-based activities early in treatment. Here, engagement was defined as the completion of both the first telehealth therapy session and assigned dMH activities after the session. In relation to self-help dMH programs, there is some research that has identified early “use” in dMH programs is related to program engagement, however, evidence is limited to engagement conceptualized as word count of activity responses [18]. For example, Wallert et al [18] found that writing more words in early dMH activities was related to higher rates of overall program adherence (completing three or more homework tasks). It is possible that greater effort or more in-depth use of content and tasks early in the program (better engagement) may facilitate interest, trigger symptom improvements, and sustained engagement over time. Given that more recent frameworks propose the conceptualization of engagement beyond the number of program sessions completed, there is a need to examine additional facets of engagement and determine whether different types of EE (eg, early completion of in-session and homework tasks, character count, subjective self-report measures, and affect experienced during the program) are important in facilitating program engagement in dMH interventions. This study focuses specifically on the program use component of engagement as it is typically routinely collected and operationalizes multiple measures of program use. It also focuses primarily on the role of EE as described above, and its relationship to overall engagement.

Factors Influencing dMH Engagement

Much of the existing literature has examined factors associated with dMH engagement in adult populations. In a review of 83 adult dMH programs, Liverpool et al [19] found that both intervention-specific influences (such as program suitability, usability, and acceptability) and person-specific influences (such as motivation, opportunity and time availability, family support, and capability) influenced user engagement. Borghouts et al [20] further highlighted that social connectedness, participants feeling “in control” of their health, and having insight into their concerns, were also facilitators of dMH program engagement. With respect to adolescent programs, a review of dMH programs

XSL•FO
RenderX

by Lehtimaki et al [21] found that female, those with lower baseline anxiety, and those with a longer history of mental health conditions were more likely to complete dMH interventions [21]. Similarly, March et al [4,16] found that male, those with higher baseline anxiety severity, and those living in nonmetropolitan regions showed lower levels of engagement (operationalized as the number of sessions completed) in a dMH program for anxiety. However, to date, there is very limited research specifically examining the individual facets of engagement (as suggested in the frameworks by Perski et al [15] and Yardley et al [14]) that predict program engagement with dMH interventions by adolescents.

Aims of This Research

This study examined the factors influencing program engagement, specifically, program use, in a dMH intervention for adolescent anxiety (BRAVE Self-Help). Extending on previous literature, engagement was conceptualized as being multifaceted. The first aim was to examine the effect of person-specific demographic factors (including gender, age, and residential location) on program engagement (sessions completed, in-session and homework tasks completed, depth (total character count), and average frequency (days) between sessions). The second aim was to examine the impact of EE on continued program engagement. EE was examined specifically in relation to program use, and conceptualized as the number of in-session tasks completed, homework tasks completed, and character count (depth of use), within the first two sessions of the program. In addition, previous research has found that participants completing a greater number of BRAVE sessions showed lower baseline anxiety severity [4] and were less likely to be classed in the high anxiety severity group when examining trajectories of change [16], suggesting that anxiety severity may be a relevant factor to consider. Therefore, this study further examined whether baseline anxiety severity moderated the relationship between demographic and EE factors and program engagement.

Methods

Participants and Procedure

Participants were 2850 adolescents aged between 12 and 17 years who had registered for the BRAVE Self-Help program between July 2014 and May 2020. In line with the intended audience of BRAVE Self-Help, only participants demonstrating baseline anxiety severity at an elevated or clinical level on the Children's Anxiety Scale 8-item (CAS-8; see below for details) [22] were included in this study. This study was restricted to adolescents who had completed at least 2 sessions of the program. This was in line with our conceptualization of EE in this study. To ensure adequate measurement of EE, data were required relating to in-session tasks completed (sessions 1 and 2), and between-session tasks (homework allocated in session 1 that was subsequently reported on in session 2). Thus, to provide a comprehensive indication of EE, we required data collected in sessions 1 and 2. Further, as per calls for research to more comprehensively examine engagement through multiple components (eg, Yardley et al [14] and Perski et al [15]), it was important to include 2 sessions in our definition of EE as many dMH programs focus only on introductory and education-based content in the first session (eg, March et al [16]) without the inclusion of many interactive activities. Therefore, examining only responses to session 1 would not allow sufficient examination of program use in the form of completed activities or use depth. Participants were excluded from the study if they were completing the program as part of a school curriculum or school-based intervention, in order to mitigate any other engagement strategies delivered to these participants (eg, mandatory attendance and homework completion and support or facilitation by a school professional).

Ethical Considerations

Participants were self-referred or referred by others (eg, general practitioners, school counselors, and other mental health practitioners) to the open-access BRAVE Self-Help program. No incentives were provided for participating in the program. Participants provided informed consent prior to commencing the program, and parental consent was also obtained if the adolescent was younger than 16 years of age. Informed consent was also provided for their data to be used in future research. All data analyzed were deidentified. During the registration process, participants provided demographic information (see below) and completed the CAS-8 [22]. This study was part of a larger, ongoing effectiveness study of BRAVE Self-Help (human research ethics approval: ETH2023-0832; University of Southern Queensland; 2020/581; Griffith University).

Intervention

This study used data extracted from BRAVE Self-Help for teenagers (aged 12 to 17 years), a dMH intervention for adolescents with anxiety [4]. BRAVE Self-Help is delivered in 10 web-based, interactive, weekly sessions of 30 to 60 minutes duration and includes cognitive-behavioral strategies such as psychoeducation, cognitive restructuring, physiological awareness, relaxation, graded exposure, problem-solving strategies, positive reinforcement, and guided imagery [23]. Homework tasks are allocated each week to consolidate and enhance learning from each session. Reminders to complete sessions are sent to participants via automated email. BRAVE Self-Help is completed without therapist support, and sessions can be completed at any time but must be completed in order. For a detailed description of the program, refer to March et al [4].

Measures

Demographics

Demographic information was measured at program registration and included age (years), gender, and location (postcode). Participants selected their gender from male, female, transgender, transsexual, transgender or transsexual, genderqueer, androgynous, or other. For analytic purposes, gender was recoded into male, female, and other. Those who identified their gender as "other" were excluded from analyses due to the small number of participants in this category (n=3). Location was coded according to the Australian Statistical Geography Standard [24] with participants categorized into: Major Cities, Inner Regional, Outer Regional, Remote, and Very Remote locations. For analytic purposes and due to the

XSL•FO
RenderX

small number of participants in Outer Regional, Remote, and Very Remote categories, the location was recoded into three categories: (1) Major Cities, (2) Inner Regional, and (3) Outer Regional and Remote.

Anxiety Severity

Anxiety symptom severity was measured at program registration through CAS-8 [22]. Respondents are required to rate on a 4-point scale from 0=Never to 3=Always, the frequency with which each item applies to them. Item responses are summed to produce a total anxiety symptom severity score between 0 and 24, with higher scores indicating greater anxiety symptom severity. CAS-8 scores above the 84th percentile (≥10 for male and ≥12 for female) were categorized as elevated, whilst scores above the 94th percentile (≥13 for male and ≥16 for female) were categorized as Clinical [22]. The CAS-8 has been shown to demonstrate high internal consistency (Cronbach α=0.89) [22]. The internal consistency of the CAS-8 in this study was good (Cronbach α=0.87).

Engagement

This study focused on engagement in terms of program use. A summary of all engagement measures and their operationalizations is provided in Table 1.

XSL•FO
RenderX

Table . Operationalizations of EE[a] and OE[b].

Variable	Definition	Method of measurement
EE		
Completed tasks in sessions 1 and 2 (early tasks)	Completed tasks were defined consistent with completed tasks for program engagement.	The total of the number of tasks completed in sessions 1 and 2, operationalized consistent with the program engagement definition for completed tasks, but for sessions 1 and 2 only.
Session 1 homework tasks completed (early homework)	Completed homework tasks were defined consistent with completed homework tasks for program engagement.	The number of session 1 homework tasks completed was measured, consistent with the definition for program engagement for homework tasks, but for sessions 1 and 2 only.
Depth of early responses (early depth)	Early depth was defined as the number of characters typed into free-text boxes in response to program activities.	The total number of characters included in free-text response boxes in sessions 1 and 2 was calculated. Homework tasks were not included.
OE		
Number of completed sessions (completed sessions)[c]	Adherence to prescribed program sessions.	The number of sessions completed.
Tasks completed (total tasks)[c]	Tasks were defined as an in-session activity or task embedded within the program, which required the participant to type in a textbox or respond to a question asked.	Total number of tasks completed throughout program. Each separate textbox or response activity was counted as one activity. Activities were defined as completed if the written response by the participant had a minimum of three characters. This was to reduce the probability of a participant filling in the textbox but not having engaged in the activity (ie, responding with an "x" or writing short answers). Each individual completed task was then computed to obtain the total number of tasks completed.
Overall homework tasks completed (total homework)[c]	Homework task completion was defined as a task embedded in the homework section of the session (as the start of the session), which required the participant to type in a textbox or respond to a question asked. Homework tasks were prescribed in the previous session and reported on in the following session.	The total number of homework tasks completed. Each separate textbox or response activity was counted as one activity. As with tasks completed, activities were defined as completed if the written response by the participant had a minimum of three characters.
Session frequency (frequency)[c]	Frequency was defined as how often a participant engages with the intervention.	The average number of days between each completed session.
Depth of responses (program depth)[c]	Program depth was defined as character count within program activities that required a written response. That is, the number of characters typed into free-text boxes.	Total number of characters typed into program activities. Homework tasks were not included. Character count was chosen (over word count) to minimize issues such as typing errors, and missing or additional spaces [25]. To compute the depth of responses, the total characters for each session was computed before averaging the total number of characters across completed sessions.

[a]EE: early engagement.

[b]OE: overall program engagement.

[c]These variables were measured across 10 sessions when demographic variables were the predictor of OE, but across sessions 3 to 10 when EE variables were the predictor of continued engagement.

Early Engagement

EE was defined as engagement within the first 2 sessions of the program. Similar to the operationalization of engagement by Wu et al [17] , EE in this study was defined as the number of tasks completed in sessions 1 and 2, the number of session 1 homework tasks completed (data collected in session 2), and depth of responses (character count) in sessions 1 and 2. Because homework tasks allocated in session 1 are completed between sessions and reported in session 2, it was essential that this study included session 2 in its conceptualization of EE.

Program Engagement

Program engagement was operationalized as both overall program engagement (OE) and continued engagement (CE). OE was measured through the total number of program sessions completed, total number of program tasks completed, total number of homework tasks completed, total engagement depth

XSL•FO
RenderX

(character count of responses typed into any program tasks), and average frequency of sessions (average days between sessions). CE was defined as engagement after session 2 (ie, the number of in-session and homework tasks, sessions completed, and depth of engagement from sessions 3 to 10 only). The number of prescribed tasks and homework tasks per session is detailed in Multimedia Appendix 1.

Analytic Strategy

Data were analyzed using SPSS Statistics (version 27; IBM Corp). EE and OE were computed from raw program output data and are described in Table 1 and reported in Table 2 for the total sample, elevated, and clinical subgroups. Differences between the elevated and clinical groups for overall and early program engagement were analyzed using Cohen *d*.

Table . Summary of participant demographic and clinical factors across baseline anxiety status.

Variable	Elevated anxiety (n=915, 32.11%)	Clinical anxiety (n=1935, 67.89%)	Total participants (n=2850)	*t* test (*df*)[a]	Cohen *d*[a]	Chi-square (*df*)[a]	*P* value[a]
Demographic factors							
Age (years), mean (SD)	13.84 (1.99)	14.32 (1.76)	14.17 (1.85)	6.513 (2848)	0.26	—[b]	<.001
Sex, n (%)				—	—	1.26 (1)	.26
Male	243 (26.55)	553 (27.55)	796 (27.92)				
Female	672 (73.44)	1382 (71.42)	2054 (72.07)				
Location, n (%)				—	—	0.73 (1)	.87
Major Cities	473 (51.69)	976 (50.44)	1449 (57.54)				
Inner Regional	214 (23.39)	471 (24.34)	685 (24.03)				
Outer Regional and Remote	119 (13.01)	265 (13.70)	384 (13.47)				
Missing[c]	109 (11.91)	223 (11.52)	332 (11.65)				
Aboriginal and Torres Strait Islander, n (%)				—	—	57.29 (1)	<.001
Yes	4 (0.01)	10 (0.01)	14 (0.01)				
No	199 (21.75)	214 (11.06)	413 (14.49)				
Missing[d]	712 (77.81)	1711 (88.42)	2423 (85.02)				
Clinical factors							
CAS-8[e] score at baseline, mean (SD)	14.26 (4.41)	15.96 (6.54)	15.41 (5.99)	7.133 (2848)	0.30	—	<.001

[a]Ratio of difference, effect size (Cohen *d* and chi-square), degrees of freedom, and significance between the elevated and clinical group at baseline.

[b]Not applicable.

[c]332 participants did not disclose their residing location.

[d]Aboriginal and Torres Strait Islander data were not collected until August 27, 2018.

[e]Children's Anxiety Scale 8-item.

For the first research question, 15 separate moderated regression analyses were conducted to examine whether baseline demographic factors predicted OE (one moderated regression per predictor and dependent variable) and whether baseline anxiety severity moderated these relationships. Demographic factors (age, gender, and location) acted as the independent variables, whilst total completed sessions, total tasks completed, total homework tasks completed, depth of responses, and frequency of session completion acted as the (OE) dependent variables.

For the second research question, 15 separate moderated regression analyses were conducted to examine whether EE factors predicted CE (one moderated regression per predictor and dependent variable), and whether baseline anxiety severity moderated these relationships. Early tasks, early depth, and early homework acted as the independent variables. The dependent CE variables were completed sessions, total tasks completed, total homework tasks completed, depth of responses, and frequency of session completion.

Anxiety severity acted as the moderator variable, with participants categorized as either elevated or clinical. Regression

XSL•FO
RenderX

analyses were conducted separately for each predictor, given that previous research has shown certain demographic factors may contribute more to overall engagement than others [4,21] and models suggest that the multifaceted nature of engagement needs to be further understood [14,15]. As we were interested in understanding which EE factors had the strongest effects in predicting CE, we conducted separate rather than multivariate regression analyses. Given the large number of regression analyses conducted, a conservative Bonferroni correction of $P<.001$ was applied for all analyses.

Results

Demographic and Clinical Characteristics of Participants

A summary of participant baseline demographic and clinical characteristics across anxiety status is provided in Table 2.

EE, CE, and OE Characteristics

As seen in Table 3, adolescents in the elevated group demonstrated significantly greater OE than those in the clinical group, as measured by total homework, program depth, and early depth. Adolescents in the elevated group also had a significantly higher frequency (days between sessions) than those in the clinical group, which may suggest that these adolescents may be completing the program more in line with program frequency recommendations (sessions should be 5 to 7 days apart).

Table . Summary of OE[a], CE[b], and EE[c] characteristics.

	Elevated group (n=915), mean (SD)	Clinical group (n=1935), mean (SD)	Total participants (n=2850), mean (SD)	Cohen *d*[d]	*P* value[d]
OE[e]					
Completed sessions (OE)	4.14 (2.60)	3.96 (2.52)	4.02 (2.55)	0.07	.08
Total tasks (OE)[f]	71.48 (40.67)	68.40 (39.66)	69.39 (40.01)	0.08	.06
Total homework[f] (OE)	51.31 (30.93)	48.86 (29.85)	49.64 (30.22)	0.08	.04
Program depth (OE)	73.43 (52.10)	68.17 (49.90)	69.86 (50.67)	0.10	.01
Frequency (OE)	5.62 (8.25)	4.66 (8.31)	4.97 (8.30)	0.12	.004
CE[g]					
Completed sessions (CE)	5.17 (2.36)	5.11 (2.29)	5.13 (2.32)	0.03	.52
Total tasks (CE)[f]	119.07 (24.48)	116.77 (24.84)	117.63 (24.66)	0.09	.02
Total homework (CE)[f]	86.68 (24.59)	82.60 (25.77)	84.15 (25.33)	0.16	<.001
Program depth (CE)	767.10 (862.73)	673.67 (795.40)	703.67 (818.63)	0.11	.004
Frequency (CE)	6.43 (9.70)	4.82 (8.81)	5.33 (9.12)	0.17	<.001
EE[h]					
Early tasks (EE)[f]	16.97 (3.51)	16.98 (3.73)	16.98 (3.66)	0.00	.95
Early homework (EE)[f]	2.00 (2.00)	2.08 (2.00)	2.06 (2.00)	0.04	.32
Early depth (EE)	13.10 (7.07)	12.54 (6.94)	12.72 (6.99)	0.08	.05

[a]OE: overall program engagement.

[b]CE: continued engagement.

[c]EE: early engagement.

[d]Mean (SD), effect size, degrees of freedom, and significance between the elevated and clinical group at baseline.

[e]OE statistics across all 10 sessions of the program.

[f]The number of prescribed tasks and homework tasks per session is detailed in Multimedia Appendix 1.

[g]CE statistics (3 to 10 sessions only).

[h]EE statistics (session 1 and 2 only).

XSL•FO
RenderX

Correlations Among Demographic Factors, OE, CE, and EE

Before completing moderated regressions, correlations were analyzed between all predictor and outcome variables, which are presented in Multimedia Appendix 2. Of the relationships of interest, greater age was significantly correlated with higher completed sessions, frequency, total homework, total tasks, and severity. Female gender was strongly associated with greater completed sessions and program depth. In relation to EE predictors, there was a significant correlation between higher early tasks and greater program depth, total homework, frequency, and total tasks. Greater early depth was also significantly positively associated with total homework, completed sessions, total tasks, and average frequency. Higher early homework was significantly and positively associated with program depth, total homework, total tasks, and frequency. Finally, lower anxiety severity was significantly correlated with greater program depth (CE), average frequency (CE), and program depth (OE).

Demographic Factors Associated With OE

Overview

The results of the moderated regression analyses examining whether demographic variables predicted OE, and if these relationships were moderated by anxiety severity, are presented in Tables S1-S5 in Multimedia Appendix 3.

Completed Sessions (OE)

The overall regression models were significant for gender (R^2=0.006; P<.001), but not for age (R^2=0.004; P=.01), and location (R^2=0.010; P=.01). Despite the overall model being significant, as shown in Table S1 in Multimedia Appendix 3, there were no significant unique effects for gender or interaction effects in predicting completed sessions (overall).

Total Tasks (OE)

The overall regression models were significant for age (R^2=0.007; P<.001), but not for gender (R^2=0.002; P=.*12*) or location (R^2=0.007; P=.05). There were no significant unique effects for age or interaction effects (Table S2 in Multimedia Appendix 3).

Program Depth (OE)

The overall regression models for age (R^2=0.003; P=.20), gender (R^2=0.000; P=.60), and location (R^2=0.004; P=.32) were not significant in predicting program depth (overall), nor were there any significant interactions (Table S3 in Multimedia Appendix 3).

Frequency (OE)

The overall regression models were significant for age (R^2=0.079; P<.001), but not for gender (R^2=0.003; P=.02) or location (R^2=0.005; P=.02). There was no significant unique effect for age and no significant interaction effects observed (Table S4 in Multimedia Appendix 3). Whilst not significant at the Bonferroni level, there was a trend observed for the effect of severity in the regression model testing gender as the independent variable. There was a negative relationship between severity and frequency (overall), r_{2188}=–0.082; P<.001, with higher levels of anxiety related to fewer days between sessions.

Total Homework (OE)

The overall models were not significant for age (R^2=0.004; P=.11), gender (R^2=0.002; P=.15), or location (R^2=0.004; P=.23), nor were there any significant interaction effects (Table S5 in Multimedia Appendix 3).

EE Factors Associated With CE

Outcomes from moderated regressions were conducted to determine whether EE variables predicted CE, and if these relationships were moderated by anxiety severity.

Completed Sessions (CE)

The overall regression models were significant for early depth (R^2=0.011; P<.001), but not for early tasks (R^2=0.004; P=.10) or early homework (R^2=0.004; P=.09). Despite the overall model being significant (Table S1 in Multimedia Appendix 4), there were no unique effects for early depth and no significant interaction effects across any of the regression models.

Total Tasks (CE)

The overall regression models were significant for early homework (R^2=0.236; P<.001), early tasks (R^2=0.310; P<.001), and early depth (R^2=0.166; P<.001) in predicting total tasks (CE). However, there were no significant unique effects or interactions at the conservative Bonferroni level, as shown in Table 4, though there were effects evident using a traditional P<.05 cut-off. Specifically, a trend was evident (P<.05) for a positive relationship between early homework and CE total tasks (r_{2850}=0.481; P<.001), with greater homework tasks completed in sessions 1 and 2 related to greater overall task completion. This was also the case for early tasks and CE total tasks (r_{2850}=0.555; P<.001), where greater tasks in the first 2 sessions were associated with greater CE tasks completed and between early depth and CE total tasks (r_{2850}=0.405; P<.001), with more characters written in the first two sessions being associated with more total CE tasks completed.

XSL•FO
RenderX

Table . Linear model of EE[a] variables predicting program tasks (CE[b]) as a function of anxiety severity.

EE predictors	β	Standard β coefficient	Individual regression coefficient (t)	*P* value	95% CI
Early tasks					
Constant	53.68	25.40	2.11	.04	3.57 to 103.80
Early tasks	1.77	0.70	2.53	.01	0.39 to 3.15
Severity	6.19	14.07	.44	.66	–21.56 to 33.94
Early tasks severity[c]	–.12	0.39	–0.30	.78	–0.89 to 0.66
Early homework					
Constant	55.15	24.03	2.30	.02	7.74 to 102.55
Early homework	2.73	1.03	2.65	.01	0.70 to 4.76
Severity	13.46	13.12	1.03	.31	–12.44 to 39.35
Early homework severity[c]	–.52	.57	–0.92	.36	–1.65 to 0.60
Early depth					
Constant	96.20	12.18	7.90	<.001	72.16 to 120.23
Early depth	.05	0.02	2.23	.03	0.01 to 0.09
Severity	2.50	7.04	0.37	.72	–11.40 to 16.40
Early depth severity[c]	–.01	0.01	–0.60	.56	–0.04 to 02

[a]EE: early engagement.

[b]CE: continued engagement.

[c]Severity refers to baseline anxiety severity.

Program Depth (CE)

The overall regression models were significant for early tasks (R^2=0.035; P<.001), early homework (R^2=0.03; P<.001), and early depth (R^2=0.08; P<.001) in predicting program depth CE. As shown in Table 5, there was a significant unique positive effect for early tasks and early depth. CE program depth increased by 24.84 characters with each early task completed, explaining 3.5% of the variance in CE program depth. CE program depth also increased by 0.85 characters for each early depth increase of one character, accounting for 7.9% of the variance in CE program depth. Whilst not significant at the conservative Bonferroni significance level, there was a positive trend (P<.05) evident between early homework and CE program depth, r_{2850}=0.154; P<.001, with CE program depth increasing as early homework tasks increased. No significant interactions were found in any of the regression models predicting CE program depth.

XSL•FO
RenderX

Table . Linear model of EE[a] variables predicting program depth (CE[b]) as a function of anxiety severity.

EE predictors	β	Standard β coefficient	Individual regression coefficient (t)	*P* value	95% CI
Early tasks					
Constant	14.11	276.45	0.05	.96	–527.96 to 556.17
Early tasks	24.94	7.97	3.13	<.001	9.31 to 40.57
Severity	6.08	156.73	0.04	.97	–301.24 to 313.39
Early tasks severity[c]	–2.94	4.52	–0.65	.52	–11.80 to 5.92
Early homework					
Constant	264.36	216.70	1.22	.22	–160.53 to 689.25
Early homework	27.52	9.62	2.86	<.001	8.65 to 46.30
Severity	–11.54	123.25	–0.09	.93	–253.22 to 230.14
Early homework severity[c]	–3.85	5.47	–0.70	.48	–14.57 to 6.87
Early depth					
Constant	356.40	111.55	3.20	<.001	10.80 to 12.62
Early depth	.85	0.17	5.00	<.001	0.52 to 1.18
Severity	–28	63.80	–0.44	.66	–153.11 to 97.11
Early depth severity[c]	–.08	0.10	–0.87	.39	–0.277 to 0.108

[a]EE: early engagement.

[b]CE: continued engagement.

[c]Severity refers to baseline anxiety severity.

Frequency (CE)

The overall models were significant for early tasks (R^2=0.014; P<.001), early homework (R^2=0.013; P<.001), and early depth (R^2=0.015; P<.001) predicting CE frequency. However, no significant unique effects for early tasks, early homework, or early depth were found at the Bonferroni-adjusted level, nor were there any interaction effects (Table S2 in Multimedia Appendix 4). Although, in the regression model for early depth predicting CE frequency, there was a trend for a negative relationship between anxiety severity and CE frequency (r_{2188}=–0.082; P<.001), with days between sessions being fewer for those with higher baseline levels of anxiety.

Total Homework (CE)

The overall regression models were significant for early homework (R^2=0.215; P<.001), early tasks (R^2=0.244; P<.001), and early depth (R^2=0.094; P=.001) in predicting CE total homework. However, there were no significant unique or interaction effects in any of the models (Table S3 in Multimedia Appendix 4).

Discussion

Principal Findings

This study analyzed the relationship between demographic and EE factors, and OE and CE, respectively, and assessed whether such relationships were moderated by baseline anxiety severity in a dMH self-help intervention for adolescent anxiety, BRAVE Self-Help. Importantly, this study examined the utility of conceptualizing engagement, specifically, program use, in multiple ways to better understand engagement in dMH interventions. Overall, the results highlighted that a higher level of EE in the first two sessions was associated with greater CE (intervention-specific factor). This was evident specifically when predicting CE program depth (characters written), but a trend was also observed for CE tasks completed. That is, early depth of program use (characters written in the first two sessions) and early tasks completed in the first two sessions were associated with greater CE in terms of program tasks and depth of responses. In addition, there were bivariate associations between multiple EE and CE variables, suggesting a clear relationship.

Additionally, contrary to expectations, the study failed to demonstrate that anxiety severity impacts engagement either directly or indirectly for most indicators of engagement, although a higher baseline level of anxiety was associated with fewer average days between sessions (frequency). This may suggest that adolescents with more severe anxiety are eager to seek further assistance and see improvements in their anxiety. Although the impact of anxiety severity on engagement was inconsistent in this study, previous research has found that higher anxiety severity is related to poorer program engagement for adolescents in dMH programs [4,16,20,21]. Variations in the way in which engagement has been measured across studies may account for the difference in findings in this study.

XSL•FO
RenderX

Importantly, person-specific demographic factors (age, gender, and location) showed little relevance in predicting program engagement in this study. Previous studies have reported mixed findings with respect to the impact of demographic variables on engagement in dMH programs [4,16,21]. Further research in relation to the relevance of person-specific factors in predicting program engagement should be undertaken once engagement can be measured more holistically.

EE Appears Important

The intervention-specific finding that EE was generally associated with CE is not surprising, yet an important research finding. Whilst previous research has identified that program engagement is associated with positive clinical outcomes [4,8], this study shows that engaging well early in the program, specifically early program use, is specifically associated with greater CE. Although the effects were small, our findings highlight that there is a need to identify ways to meaningfully engage adolescents in both in-session and homework tasks in the first two sessions of the program, to increase program engagement, and ultimately, the benefits obtained from dMH interventions.

There are few studies that have identified that EE, in terms of use, is important in predicting program engagement, but these studies did not capture the full breadth of engagement (ie, as proposed by Perski et al [15]) and were blended-care or therapist-supported interventions, rather than self-help. In a blended-care CBT intervention for adults with anxiety and depression, where participants had both face-to-face video therapy and digital activities (eg, thought monitoring and mood diaries), participants were around 10 times more likely to withdraw from the intervention if they had not completed the assigned dMH activities after the first session [17]. However, unlike this study, Wu et al [17] defined engagement purely as the number of sessions and web-based activities completed. Another study by Wallert et al [18] demonstrated the importance of early use factors in a therapist-supported dMH program, however, that was limited to early word count and homework tasks only. The study by Wu et al [17] found that higher word count in the first homework tasks was associated with greater adherence (measured in terms of completed homework activities). Interestingly, EE factors included in this study were not associated with completed sessions, but rather, what adolescents did in the program (ie, the amount of in-session and homework activities and character count). This may reflect that participants get what they want or need, without having to complete the entire program (ie, symptom relief or education about anxiety). Alternatively, these findings may suggest that we have not adequately measured all aspects of engagement that relate to treatment outcomes. These results are consistent with findings by both Alberts et al [26] and Yardley et al [14] who found that program engagement may not necessarily predict clinical outcomes. Overall, this study's findings emphasize the importance of understanding more about EE, its relationship to program completion and outcomes, and the strategies to enhance it.

Defining Engagement

Contemporary models of engagement highlight the need to consider both user experience and use [14,15]. This study, whilst meaningful in highlighting the importance of EE (program use) in dMH programs for adolescents, did not capture all facets of engagement (eg, user experience), which may explain the small effect sizes found. There is a large variation in the way in which engagement is defined and measured across dMH programs [12], and engagement has not often been measured holistically. This study primarily focused on the use aspects of engagement rather than the experiential or affective elements. The assessment of user experience would allow the opportunity for a more nuanced understanding of engagement, where participants' own subjective experience of the program is measured [14,15]. For example, this could include self-report questionnaires or interviews on engagement and experience with the program, or examination of the content and quality of activity responses rather than just character count [15], which may allow a richer understanding of the factors predicting OE, reasons for disengagement, and inform the development or refinement of dMH programs to achieve higher levels of engagement.

Strengths and Limitations

This study holds several strengths. First, the study had a large sample size of adolescents taking part in a real-world effectiveness study. The study further explored novel predictive factors of engagement in dMH programs, filling a significant gap in the literature regarding our understanding of adolescent engagement, particularly adolescent use, in these programs. The results were also analyzed using both a conservative and traditional significance level, adding merit to our findings. Despite its strengths, there were some limitations inherent to the study. First, this study did not consider the predictors of people who fail to take up BRAVE Self-Help, for example, factors at registration, or in the first session, such as participant perceptions of the content being valuable and helpful, time available to complete the program, and beliefs about the need for treatment. These were not the focus of this study; however, they should be the focus of future research, with specific adaptations to collect data of this nature. Furthermore, while this study considered engagement as multifaceted, the components of engagement analyzed in this study were limited to the available data that has been routinely collected within the BRAVE Self-Help platform, and thus, not all components of engagement as suggested in the engagement models of Perski et al [15] and Yardley et al [14] could be examined. Specifically, this study focused on understanding multiple measures of program use, but did not address user experience, which should be analyzed in future research. Further, whilst this study did examine the role of anxiety severity in influencing engagement, it did not examine whether changes in anxiety experienced beyond EE and over the course of treatment, had additional influence on OE. It is possible that as anxiety symptoms reduce, participants would be more or less likely to continue to engage in the program, and this should be examined in future research. Finally, whilst not possible to include all potential psychosocial factors in this study and analysis, engagement may have been influenced by other factors, such as satisfaction with the

XSL•FO
RenderX

program, personality, socioeconomic status, and previous exposure to treatment.

Future Directions

This study highlights the need to better understand how to measure the construct of engagement and investigate the role of EE in supporting OE. It is recognized that facets of engagement may overlap and be interrelated (eg, completed tasks and completed sessions), and therefore, conducting a factor analysis may be useful in identifying whether these variables are discrete, and may assist in the empirical validation of proposed engagement models such as that of Perski et al [15] and Yardley et al [14]. Additionally, analysis of predictors of further potential facets of engagement, such as user experience as proposed by Perski et al [15] (including interest in the program and attention sustained within the program, affect, and satisfaction) will be useful in more broadly understanding the construct of engagement and its relationship to EE, anxiety severity, and outcome. Subsequent studies may also consider the use of digital linguistic tools, which may be useful in providing more information about whether sentiment and affect relate to engagement. Future research should also seek to understand how to enhance EE. This could be achieved through qualitative research with adolescents themselves, to better understand the unique needs of the user, and gain a detailed, nuanced account of how to enhance EE. Adding to our understanding will allow for dMH programs to be refined, tailored, and developed with such findings in mind. Taken together, the application of the findings of this study could improve engagement, and ultimately, potential clinical outcomes for adolescents with anxiety.

Conclusions

To date, there has been little research investigating the factors influencing engagement in dMH interventions for adolescents. The intervention-specific factor of poor EE, in terms of early program use, was found to be a barrier to CE in this study. Understanding how to better operationalize and measure engagement, along with identifying areas of focus to enhance EE, will help refine adolescent dMH interventions and aid in the design and development of future interventions. By doing so, user engagement can be enhanced and the benefit to the user of the program can be maximized.

Acknowledgments

The authors acknowledge funding provided by the Medical Research Future Fund through the Department of Health (APP1179490).

Conflicts of Interest

SM, SHS, and CD acknowledge that although intellectual property for BRAVE-ONLINE is owned by UniQuest/the University of Queensland, they may potentially benefit from future royalties related to the program.

Multimedia Appendix 1
Prescribed tasks and homework tasks across sessions.
[DOCX File, 13 KB - pediatrics_v8i1e60523_app1.docx]

Multimedia Appendix 2
Correlations between demographic, overall program engagement, continued engagement, and early engagement variables.
[DOCX File, 20 KB - pediatrics_v8i1e60523_app2.docx]

Multimedia Appendix 3
Moderated regression results of the relationship between demographic variables and OE, and whether these relationships were moderated by anxiety severity.
[DOCX File, 28 KB - pediatrics_v8i1e60523_app3.docx]

Multimedia Appendix 4
Moderated regression results of the relationship between early engagement and continued engagement, and whether these relationships were moderated by anxiety severity.
[DOCX File, 27 KB - pediatrics_v8i1e60523_app4.docx]

References

1. Polanczyk GV, Salum GA, Sugaya LS, Caye A, Rohde LA. Annual research review: a meta‐analysis of the worldwide prevalence of mental disorders in children and adolescents. Child Psychol Psychiatry 2015 Mar;56(3):345-365. [doi: 10.1111/jcpp.12381]
2. de Lijster JM, van den Dries MA, van der Ende J, et al. Developmental trajectories of anxiety and depression symptoms from early to middle childhood: a population-based cohort study in the Netherlands. J Abnorm Child Psychol 2019 Nov;47(11):1785-1798. [doi: 10.1007/s10802-019-00550-5] [Medline: 31069583]

XSL•FO
RenderX

3. Lyneham HJ, Rapee RM. Agreement between telephone and in-person delivery of a structured interview for anxiety disorders in children. J Am Acad Child Adolesc Psychiatry 2005 Mar;44(3):274-282. [doi: 10.1097/00004583-200503000-00012] [Medline: 15725972]
4. March S, Spence SH, Donovan CL, Kenardy JA. Large-scale dissemination of internet-based cognitive behavioral therapy for youth anxiety: feasibility and acceptability study. J Med Internet Res 2018 Jul 4;20(7):e234. [doi: 10.2196/jmir.9211] [Medline: 29973338]
5. Podina IR, Mogoase C, David D, Szentagotai A, Dobrean A. A meta-analysis on the efficacy of technology mediated CBT for anxious children and adolescents. J Rat-Emo Cognitive-Behav Ther 2016 Mar;34(1):31-50. [doi: 10.1007/s10942-015-0228-5]
6. Sweeney GM, Donovan CL, March S, Forbes Y. Logging into therapy: adolescent perceptions of online therapies for mental health problems. Internet Interventions 2019 Mar;15:93-99. [doi: 10.1016/j.invent.2016.12.001] [Medline: 30792959]
7. Geirhos A, Domhardt M, Lunkenheimer F, et al. Feasibility and potential efficacy of a guided internet- and mobile-based CBT for adolescents and young adults with chronic medical conditions and comorbid depression or anxiety symptoms (youthCOACHCD): a randomized controlled pilot trial. BMC Pediatr 2022 Jan 29;22(1):69. [doi: 10.1186/s12887-022-03134-3] [Medline: 35093047]
8. Gan DZQ, McGillivray L, Han J, Christensen H, Torok M. Effect of engagement with digital interventions on mental health outcomes: a systematic review and meta-analysis. Front Digital Health 2021;3:764079. [doi: 10.3389/fdgth.2021.764079] [Medline: 34806079]
9. Newton AS, March S, Gehring ND, Rowe AK, Radomski AD. Establishing a working definition of user experience for eHealth interventions of self-reported user experience measures with eHealth researchers and adolescents: scoping review. J Med Internet Res 2021 Dec 2;23(12):e25012. [doi: 10.2196/25012] [Medline: 34860671]
10. Sieverink F, Kelders SM, van Gemert-Pijnen JE. Clarifying the concept of adherence to eHealth technology: systematic review on when usage becomes adherence. J Med Internet Res 2017 Dec 6;19(12):e402. [doi: 10.2196/jmir.8578] [Medline: 29212630]
11. Calear AL, Christensen H, Mackinnon A, Griffiths KM. Adherence to the MOODGYM program: outcomes and predictors for an adolescent school-based population. J Affect Disord 2013 May;147(1-3):338-344. [doi: 10.1016/j.jad.2012.11.036] [Medline: 23245469]
12. Fleming T, Bavin L, Lucassen M, Stasiak K, Hopkins S, Merry S. Beyond the trial: systematic review of real-world uptake and engagement with digital self-help interventions for depression, low mood, or anxiety. J Med Internet Res 2018 Jun 6;20(6):e199. [doi: 10.2196/jmir.9275] [Medline: 29875089]
13. Short CE, DeSmet A, Woods C, et al. Measuring engagement in eHealth and mHealth behavior change interventions: viewpoint of methodologies. J Med Internet Res 2018 Nov 16;20(11):e292. [doi: 10.2196/jmir.9397] [Medline: 30446482]
14. Yardley L, Spring BJ, Riper H, et al. Understanding and promoting effective engagement with digital behavior change interventions. Am J Prev Med 2016 Nov;51(5):833-842. [doi: 10.1016/j.amepre.2016.06.015] [Medline: 27745683]
15. Perski O, Blandford A, West R, Michie S. Conceptualising engagement with digital behaviour change interventions: a systematic review using principles from critical interpretive synthesis. Transl Behav Med 2017 Jun;7(2):254-267. [doi: 10.1007/s13142-016-0453-1] [Medline: 27966189]
16. March S, Batterham PJ, Rowe A, Donovan C, Calear AL, Spence SH. Trajectories of change in an open-access internet-based cognitive behavior program for childhood and adolescent anxiety: open trial. JMIR Ment Health 2021 Jun 18;8(6):e27981. [doi: 10.2196/27981] [Medline: 34142971]
17. Wu MS, Chen SY, Wickham RE, et al. Predicting non-initiation of care and dropout in a blended care CBT intervention: Impact of early digital engagement, sociodemographic, and clinical factors. Digital Health 2022;8:20552076221133760. [doi: 10.1177/20552076221133760] [Medline: 36312847]
18. Wallert J, Gustafson E, Held C, et al. Predicting adherence to internet-delivered psychotherapy for symptoms of depression and anxiety after myocardial infarction: machine learning insights from the U-CARE heart randomized controlled trial. J Med Internet Res 2018 Oct 10;20(10):e10754. [doi: 10.2196/10754] [Medline: 30305255]
19. Liverpool S, Mota CP, Sales CMD, et al. Engaging children and young people in digital mental health interventions: systematic review of modes of delivery, facilitators, and barriers. J Med Internet Res 2020 Jun 23;22(6):e16317. [doi: 10.2196/16317] [Medline: 32442160]
20. Borghouts J, Eikey E, Mark G, et al. Barriers to and facilitators of user engagement with digital mental health interventions: systematic review. J Med Internet Res 2021 Mar 24;23(3):e24387. [doi: 10.2196/24387] [Medline: 33759801]
21. Lehtimaki S, Martic J, Wahl B, Foster KT, Schwalbe N. Evidence on digital mental health interventions for adolescents and young people: systematic overview. JMIR Ment Health 2021 Apr 29;8(4):e25847. [doi: 10.2196/25847] [Medline: 33913817]
22. Spence SH, Sawyer MG, Sheffield J, et al. Does the absence of a supportive family environment influence the outcome of a universal intervention for the prevention of depression? Int J Environ Res Public Health 2014 May 13;11(5):5113-5132. [doi: 10.3390/ijerph110505113] [Medline: 24828082]
23. Spence SH, Donovan CL, March S, et al. A randomized controlled trial of online versus clinic-based CBT for adolescent anxiety. J Consult Clin Psychol 2011 Oct;79(5):629-642. [doi: 10.1037/a0024512] [Medline: 21744945]

XSL•FO
RenderX

24. Remoteness Areas, Australian Statistical Geography Standard (ASGS), Edition 3. Australian Bureau of Statistics. 2023. URL: https://www.abs.gov.au/statistics/standards/australian-statistical-geography-standard-asgs-edition-3/jul2021-jun2026/remoteness-structure/remoteness-areas [accessed 2023-03-06]
25. Sindahl TN, van Dolen W. Texting at a child helpline: how text volume, session length and duration, response latency, and waiting time are associated with counseling impact. Cyberpsychol Behav Soc Netw 2020 Apr;23(4):210-217. [doi: 10.1089/cyber.2019.0100] [Medline: 31990599]
26. Alberts NM, Law EF, Chen AT, Ritterband LM, Palermo TM. Treatment engagement in an internet-delivered cognitive behavioral program for pediatric chronic pain. Internet Interventions 2018 Sep;13:67-72. [doi: 10.1016/j.invent.2018.07.005] [Medline: 30206521]

Abbreviations

CAS-8: Children's Anxiety Scale 8-item
CBT: cognitive behavioral therapy
CE: continued engagement
dMH: digital mental health
EE: early engagement
OE: overall program engagement

Edited by A Serlachius; submitted 14.05.24; peer-reviewed by Y Zang; revised version received 20.03.25; accepted 09.04.25; published 02.06.25.

Please cite as:
Senyard EL, Rowe A, Krishnamoorthy G, Spence SH, Donovan C, March S
The Role of Early Engagement in a Self-Directed, Digital Mental Health Intervention for Adolescent Anxiety: Moderated Regression Analysis
JMIR Pediatr Parent 2025;8:e60523
URL: https://pediatrics.jmir.org/2025/1/e60523
doi:10.2196/60523

© Emma-Leigh Senyard, Arlen Rowe, Govind Krishnamoorthy, Susan H Spence, Caroline Donovan, Sonja March. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 2.6.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Sex Differences in the Joint Trajectories of Depressive Symptoms and Body Mass Index From Adolescence to Early Adulthood: Longitudinal Observational Study

Jing Chen[1], PhD; Rui Shan[1], MD; Wen Yuan[2], PhD; Qiong Wu[3], PhD; Yang Yang[1], MD; Yi-Hang Yang[1], MD; Jing-Yao Liu[1], MD; Wu-Cai Xiao[1], MD; Shanghang Zhang[4], PhD; Li-Ming Wen[5], PhD; Xiao-Rui Zhang[6*], PhD; Zheng Liu[1*], PhD; Yi Song[2], PhD

[1]Department of Maternal and Child Health, School of Public Health, Peking University, 38 Xueyuan Road, Haidian District, Beijing, China

[2]Institute of Child and Adolescent Health, School of Public Health, Peking University, Beijing, China

[3]Institute of Social Science Survey, Peking University, Beijing, China

[4]The School of Computer Science, Peking University, Beijing, China

[5]School of Public Health, The Faculty of Medicine and Health, University of Sydney, Sydney, Australia

[6]Department of Pediatrics, Peking University People's Hospital, Beijing, China

[*]these authors contributed equally

Corresponding Author:
Zheng Liu, PhD
Department of Maternal and Child Health, School of Public Health, Peking University, 38 Xueyuan Road, Haidian District, Beijing, China

Related Article:

This is a corrected version. See correction statement: https://pediatrics.jmir.org/2025/1/e84632

Abstract

Background: Adolescence is a critical transitional period between childhood and adulthood, marked by dramatic changes in physical and psychosocial health. Adolescents are vulnerable to both depression and adiposity, but how these conditions evolve over time from adolescence to early adulthood and whether sex differences exist remains unclear.

Objective: This study aims to first identify the population heterogeneity in the joint trajectories of depressive symptoms and BMI from adolescence to early adulthood and then explore the sex differences in the joint trajectories.

Methods: In this study, we adopt the latent class trajectory modeling to identify the combined trajectories of depressive symptoms and BMI from adolescence at baseline to early adulthood at follow-ups using a longitudinal study (2010-2020). We used the multinomial logistic regressions to examine the sex-specific associations with the trajectory classifications.

Results: Our results found that individuals' depressive symptoms and BMI might not always change parallelly from adolescence to early adulthood. Instead, some individuals appeared to be prone to depressive symptoms or elevated BMI, while others were multimorbid with both of them. Moreover, our study identified a clear sex-specific pattern in the joint trajectories of depressive symptoms and BMI: the females were at a higher risk of developing depressive symptoms but remained relatively stable weight status over time (odds ratio [OR] 0.68, 95% CI 0.52-0.89), while the males were at a lower risk of developing depressive symptoms but with an increasing risk of developing adiposity over time (OR 1.83, 95% CI 1.35-2.49).

Conclusions: Depressive symptoms and BMI might not always change in parallel from adolescence to early adulthood, and there is a clear sex-specific pattern in the joint trajectories of depressive symptoms and BMI. This will inform the design of future sex-specific interventions that match the distinguished profiles in male and female participants during the period of adolescence and early adulthood, respectively, thus maximizing the intervention effects in preventing both depression and adiposity in early life.

(JMIR Pediatr Parent 2025;8:e72722) doi:10.2196/72722

KEYWORDS

heterogeneity; trajectory; depressive symptoms; body mass index; sex

XSL•FO
RenderX

Introduction

Adolescence and early adulthood are critical periods transforming from childhood to adulthood with dramatic changes in physical and psychosocial health [1,2]. The health condition during adolescence and early adulthood not only lays a solid healthy foundation for the following life course but also sustains long-term health effects to the next life cycle (ie, intergenerational transmission). Indeed, many adult-prevalent, noncommunicable diseases, such as depression [3] and adiposity [4], start in adolescence or early adulthood. Globally, the prevalence of elevated depressive symptoms and obesity among adolescents has risen rapidly in recent decades [5,6] from 24% to 37% [7] and from 0.7% to 5.6% [8], respectively. Early adulthood is also crucial for both brain development and obesity prevention [9,10].

Multimorbidity refers to the coexistence of 2 or more long-term health conditions or diseases in an individual. Focusing on multimorbidity is critical, as targeting each health condition or disease in isolation can be ineffective and inefficient. To illustrate, if an intervention only focused on obesity by providing behavior change techniques to improve diet or physical activity behaviors, it would have neglected to provide emotional support for the vulnerable individuals, leaving them exposed to the potential adverse intervention effects such as body image dissatisfaction, low self-esteem, or even eating disorders [11]; by contrast, if an intervention targeted both depression and comorbid adiposity, it could combine elements of psychotherapy (eg, cognitive behavioral interventions) with healthy lifestyle enhancement, comprehensively covering both the physical and psychological health of intervention recipients [12].

To locate the time window when the multimorbidity interventions come in, it is important to clarify the longitudinal trends in depression and adiposity over time. For example, individuals with obesity at both age 13 and afterward had significantly higher risks of developing diabetes mellitus in adulthood, compared to those with obesity only at age 13 [13]. Another study pointed out that the trajectory of depressive symptoms over 10 years, rather than the one time point, had important health effects [14]. However, most existing studies typically assessed depression and adiposity cross-sectionally at one time point [15,16] but failed to capture their changes over time.

Researchers have called for breaking through the bottleneck of the “one-size-fits-all” intervention approach. One way to develop targeted interventions is to explore the sex-specific patterns of the coexistence of depression and adiposity [17]. Indeed, epidemiological studies have shown a higher risk of depression in females than males [18-21], while a higher risk of adiposity in males than females [22,23]. These findings might be attributable to the sex differences in individual- and family-level factors [17,24-27].

It is important to uncover the population heterogeneity in the longitudinal trends of depression and adiposity over time and to further explore whether the sex differences exist. Findings from such research could equip us to develop personalized, sex-specific interventions that consider the individual differences in the risk profile over time: depression alone, adiposity alone, or depression and adiposity simultaneously. For these reasons, we aimed to first identify the population heterogeneity in the joint trajectories of depressive symptoms and BMI from adolescence to early adulthood and then explore the sex differences in the joint trajectories.

Methods

Data Source and Study Population

The data source of this study was the China Family Panel Studies (CFPS), a nationally representative survey conducted by Peking University [28]. CFPS was first launched in 2010 with 5 subsequent rounds of surveys conducted in 2012, 2014, 2016, 2018, and 2020. The target sample of CFPS represents 95% of the population in China. Specifically, CFPS used a multistage probability-proportional-to-size sampling method and randomly sampled 640 communities nested within 144 counties from 24 provinces and 32 townships in Shanghai. Survey participants included all economically connected household members. CFPS has collected rich data at the individual, family, and community levels [28]. In this study, we included adolescents aged 10 - 19 years without overweight 25 or depressive symptoms 26 at baseline, while some of them would enter the period of early adulthood during the 10-year follow-up surveys. To be eligible, participants should also have at least 2 measurements of BMI, BMI (kg/m^2)=weight (kg)/(height [m])^2 and at least 2 measurements of depressive symptoms available between 2010 and 2020.

Sex

The exposure variable of this study was the sex of the adolescents, referring to the differences in biological aspects between males and females.

Outcome Variables

Depressive Symptoms

Depressive symptoms were measured using the 20- or 8-item Center for Epidemiologic Studies Depression Scale (CES-D) during the 4 rounds (2012, 2016, 2018, and 2020) of surveys from 2012 to 2020. The CES-D has been validated and widely used to screen for depressive symptoms globally and in China [29-32]. To ensure comparability of outcomes measured by the 20- or 8-item CES-D, we converted the outcomes derived from the 8-item CES-D to the corresponding values measured by the 20-item CES-D based on the equipercentile equating method. We also calculated the *z* score of depressive symptoms: (score–mean score)/the SD of the scores.

BMI

Participants self-reported their height and weight in the CFPS questionnaires during the 6 rounds of surveys: 2010, 2012, 2014, 2016, 2018, and 2020. Studies have indicated that self-reporting data of height and weight are often highly correlated with the corresponding measurement data [33,34]. CFPS had very strict and standard criteria to control the quality of self-reporting data (Multimedia Appendix 1). Moreover, considering that the height and weight data of adolescents aged 10 to 15 were obtained

XSL•FO
RenderX

from both the adolescents and their parents, we have comprehensively considered these data as follows: (1) when adolescents' self-reported data and parents' proxy-reported data were both available, we prioritized the adolescents' self-reported responses as the primary data source. Meanwhile, we compared the data from those 2 sources and found that there was almost no difference. (2) For participants with only one available data source (either adolescents' self-report or parents' proxy report), the existing responses were retained for analysis. We then calculated the BMI *z* score to classify adolescents' weight status relative to their age and sex based on the World Health Organization standard [35]. That is, a BMI *z* score higher than zero means that adolescents' weight status was above the average weight status among those of the same age and sex. According to the World Health Organization standard [35], we defined adolescents with a BMI *z* score range of –2 to 1 as normal weight.

Covariates

We identified covariates based on our literature review and domain knowledge for the present topic [18,36-38]. We grouped the covariates into 2 classifications: the individual- and family-level covariates. The individual-level covariates included age (old or young), area (urban or rural), region (western or central or eastern), high birth weight (yes or no), preterm birth (yes or no), and the only child (yes or no) at baseline. The family-level covariates include parents' education level (college or above, or high school or below), whether the parents were obese or not, whether the parents were depressive or not, per capita household net income (high or low), left-behind children (yes or no), and primary caregiver (parents or other) at baseline.

Statistical Analyses

First, we adopted the latent class trajectory modeling to identify the combined trajectories of depressive symptoms and BMI and classified the participants into heterogeneous groups [39,40]. To decide the suitable number of trajectories, we comprehensively considered multiple parameters such as the average of maximum probabilities, odds of correct classification, and so on (Tables S1 and S2 in Multimedia Appendix 2). We also validated the identified trajectories by analyzing their associations with subjective well-being and physical activity (Tables S3 and S4 in Multimedia Appendix 2).

Second, we used the multinomial logistic regression models to examine the association of sex with the participants' classifications. We used 3 models to ensure the robustness of the study findings. In Model 1, we analyzed the crude association without covariates; in Model 2, we analyzed the association with the individual-level covariates only, including age, area, region, high birth weight, prematurity, and being the only child; in Model 3, we analyzed the association with both the individual- and family-level covariates, including age, area, region, high birth weight, prematurity, being the only child, father's and mother's education, obese status of father and mother, depression status of father and mother, per capita household net income, left-behind children, and primary caregiver. We also conducted sensitivity analyses by (1) using multiple imputations by chained equations [41] to account for the missing values of covariates; (2) using the Chinese criteria to define wasting [42], overweight, or obesity [43] in adolescents; (3) using the data from the 5 rounds of surveys: 2010, 2012, 2014, 2016, and 2018, excluding the data from 2020 (during the COVID-19 pandemic); (4) identifying the combined trajectories of depressive symptoms and BMI among males and females, respectively. All statistical analyses were performed with R (version 4.4.2; R Core Team). "LCTMtools" [39] and "mice" packages were used for trajectory analyses and multiple imputations, respectively. Statistical significance was determined by a 2-sided $P<.05$.

Ethical Considerations

This cohort study was conducted based on the guidelines for reporting observational studies: the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement [44]. This study was ethically approved by the Peking University Institutional Review Board (IRB00001052-22091, IRB00001052-14010). The data used for this study were deidentified. For each completed individual questionnaire, respondents were compensated—either in cash or as phone credit—at an average value of approximately US $6, with the exact amount varying by region and survey mode.

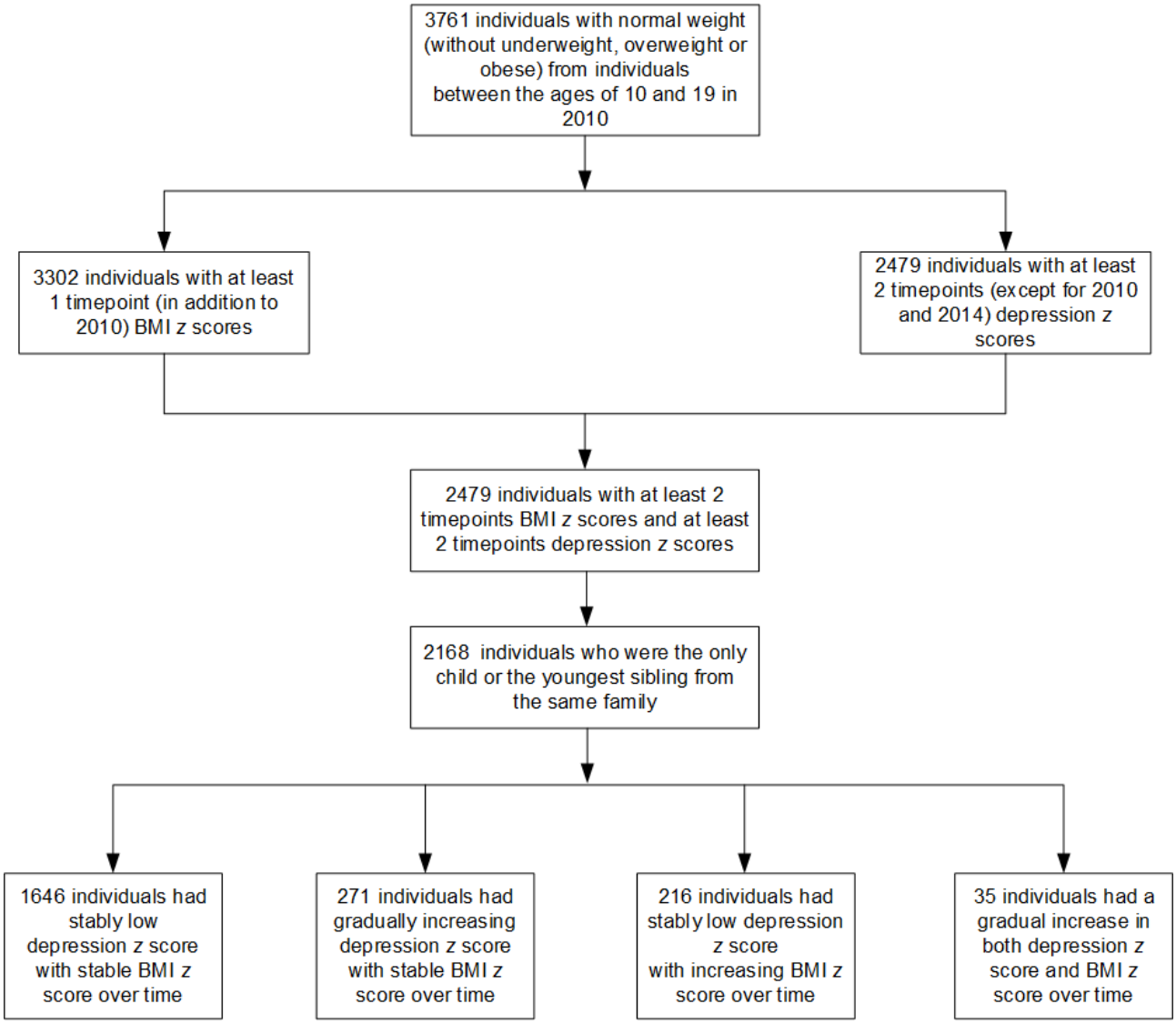
Results

Study population

Figure 1 shows the flowchart of the selection process of the study population. Among 3761 adolescents (aged 10 - 19 years) with normal weight in 2010, 2479 individuals had at least 2 time points of measurement of depression as well as 2 time points of measurement of BMI from 2010 to 2020. Finally, we included 2168 individuals who were the only child or the youngest sibling from the same family to meet the requirement of statistical modeling for independence between individuals. The characteristics between the included 2168 individuals and the excluded 1593 individuals were broadly comparable (Table S5 in Multimedia Appendix 2).

XSL•FO
RenderX

Figure 1. Selection of study population based on World Health Organization standards of BMI *z* score.



Description of the Joint Trajectories of Depressive Symptoms and BMI

Figures 2 and 3 show the trajectories of depressive symptoms and BMI *z* score over time, respectively. The study participants were classified into 4 types of joint trajectories of depressive symptoms and BMI: (1) “health-sustaining group” represented by stably low depression *z* score with stable BMI *z* score over time (1646/2168 individuals, 75.92%); (2) “depression-dominant group” characterized by gradually increasing depression *z* score with stable BMI *z* score over time (271/2168 individuals, 12.50%); (3) “adiposity-dominant group” marked with stably low depression *z* score with increasing BMI *z* score over time (216/2168 individuals, 9.96%); (4) “multimorbidity group” with gradual increase in both depression *z* score and BMI *z* score over time (35/2168 individuals, 1.61%).

XSL•FO
RenderX

Figure 2. Classification of depression z score trajectory among individuals selected based on the World Health Organization standards Class 1: 1862 individuals; Class 2: 306 individuals.

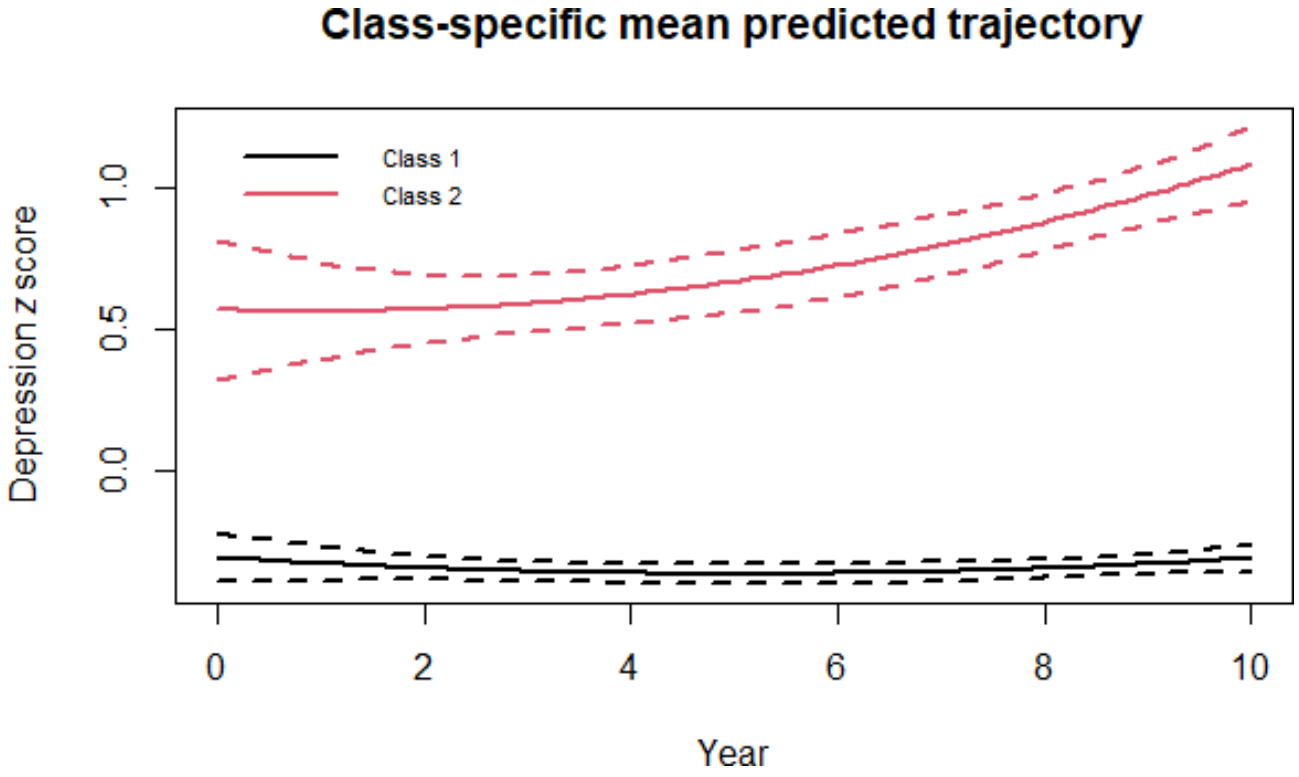
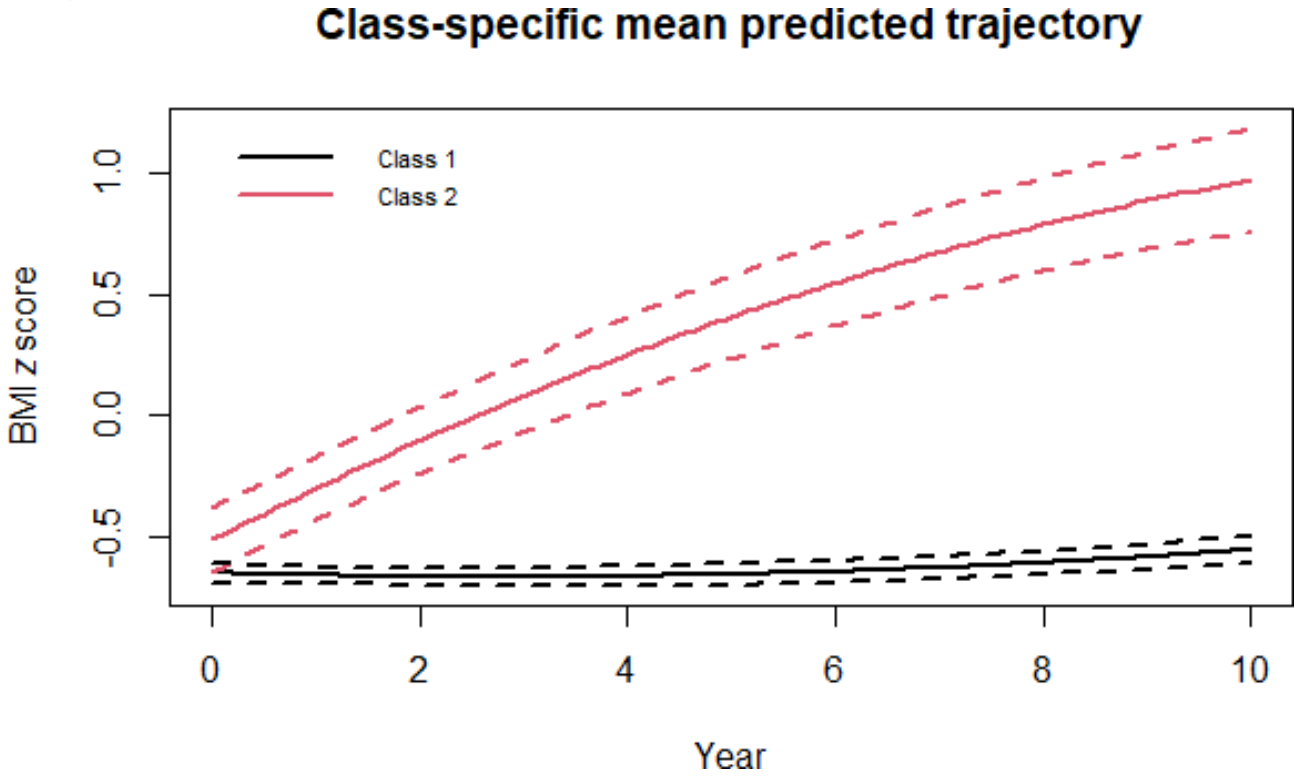


Figure 3. Classification of BMI z score trajectory among individuals selected based on the World Health Organization standards. Class 1: 1917 individuals; Class 2: 251 individuals.



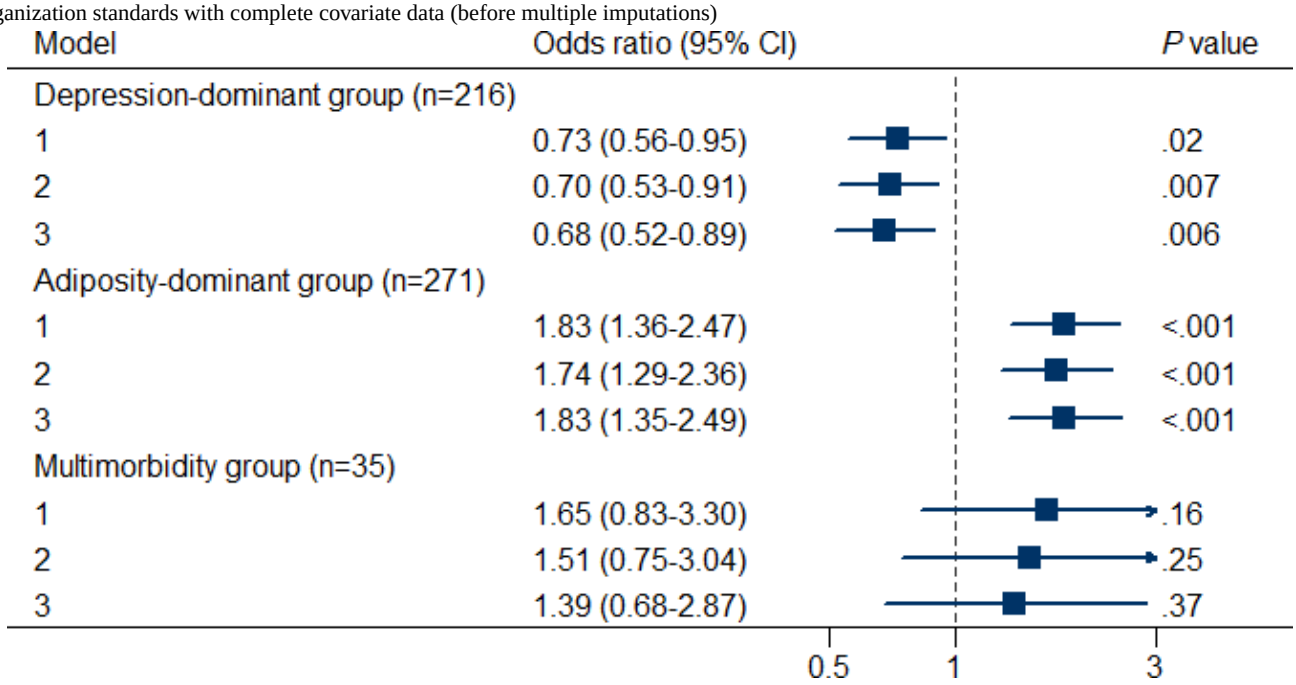
We further validated the classifications of joint trajectories of depressive symptoms and BMI by analyzing their associations with subjective well-being scores and physical activity levels. Concerning the subjective well-being scores, individuals with stable depressive symptoms had higher scores than their counterparts. Concerning physical activity levels, individuals with stable depressive symptoms or stable BMI *z* score over time tended to exercise more often than the remaining individuals (Tables S3 and S4 in Multimedia Appendix 2).

XSL•FO
RenderX

Association of Sex with the Joint Trajectories of Depressive Symptoms and BMI

From adolescence to early adulthood, the females occupied the majority (n=168/306, 54.9%) in the trajectory of gradually increasing depressive symptoms (N=306) over time; in comparison, the males occupied the majority (n=163/251, 64.9%) in the trajectory of gradually increasing BMI (N=251) over time. There were significant sex differences in the 4 types of joint trajectories of depressive symptoms and BMI. Specifically, the proportion of males in the depression-dominant group (116/271, 42.80%) was lower (*P*=.02) than that in the health group (833/1646, 50.61%). The proportion of males in the adiposity-dominant group (141/216, 64.98%) was higher (*P*<.001) than that in the health group. No difference was found in the proportion of males in the multimorbidity group (22/35, 62.86%) compared with the health group (*P*=.21). As shown in Figure 4, the results from Model 1 to Model 3 consistently showed that the females were more likely to be classified into the depression-dominant group (OR 0.68, 95% CI 0.52-0.89); in comparison, the males were more likely to be classified into the adiposity-dominant group (OR 1.83, 95% CI 1.35-2.49).

Figure 4. Sex differences in the joint trajectories of depression *z* score and BMI *z* score among individuals selected based on the World Health Organization standards with complete covariate data (before multiple imputations)



Sensitivity Analyses

The results from our sensitivity analyses were similar to those from the main analyses. Figure S1 in Multimedia Appendix 3 shows the results of using multiple imputations by chained equations. Figures S2-S5 in Multimedia Appendix 3 show the results of using the Chinese criteria to define wasting [42], overweight, or obesity [43] in adolescents. Figures S6-S8 in Multimedia Appendix 3 show the results of using the data of the 5 rounds of surveys: 2010, 2012, 2014, 2016, and 2018, excluding the data from 2020 (during the COVID-19 pandemic). Figures S9 and S10 in Multimedia Appendix 3 show the trajectories of depressive symptoms and BMI among males and female participants, respectively.

Discussion

Summary of Study Findings

This study used the population-based, nationally representative cohort study in China and showed that the joint trajectories of depressive symptoms and BMI from adolescence to early adulthood varied greatly and were classified into 4 groups with distinct characteristics: health-sustaining, depression-dominant, adiposity-dominant, and multimorbidity groups. Moreover, the joint trajectories showed a clear sex-specific pattern: females were at a higher risk of developing depressive symptoms but maintained a relatively stable weight status over time, while males were at a lower risk of developing depressive symptoms but showed an increasing risk of developing adiposity over time.

Interpretation of Study Findings

Around a quarter of the participants were prone to depression or adiposity from before to during the COVID-19 pandemic, mirroring the health vulnerabilities during adolescence and early adulthood also shown in other studies [45,46]. Among these high-risk individuals, special attention should be given to those affected by both depression and adiposity, which could be interpreted by the shared genetic predisposition and brain circuitries that regulate both mood responses and homeostatic functions [47-49].

Interestingly, not all trajectories were parallel in the longitudinal changes in depressive symptoms and BMI. A possible interpretation is that the interaction between depression and BMI is a cumulative effect with some delays [50] rather than an instantaneous effect. This reminds us to continuously monitor and track the health status during adolescence and early adulthood with single depression or adiposity for a longer time and provide timely intervention to prevent the occurrence of multimorbidity.

XSL•FO
RenderX

Our findings, the female and male individuals showing a distinct pattern of the joint trajectories of depressive symptoms and BMI from adolescence to early adulthood, could be interpreted by the sex differences in genetic backgrounds and inflammation process [24,47,51]. Our proposed interpretations of the genetic backgrounds and inflammation process are one of the common causes of depression and adiposity. Studies [47] have suggested that some genetic loci, such as NEGR1 (neuronal growth regulator 1 gene, enables protein binding) or neural growth regulators, were associated with depression on the one hand and BMI and severe early-onset obesity on the other hand. It remained to further explore sex-specific genes or genetic pathways that determine both depression and adiposity. Concerning the inflammation process, another pathway potentially connecting depression with adiposity [24], females were shown to produce more inflammatory cytokines than males within a similar immune response [51].

Other potential interpretations of our findings were related to body dissatisfaction [25], stress coping [52,53], and personality traits [27,54]. Body dissatisfaction, being more prevalent in females than males [55], might result in poorer trajectories of depressive symptoms and eating disorders [25]. Regarding stress coping, studies suggested that females tend to be more sensitive to social stress than males [53], thus posing females at a higher risk of depression than males [52]. In addition, the social stress on body image is more specific to females, making them more likely to maintain a normal weight than males. Regarding personality traits, studies have indicated that low agreeableness, more prevalent in males [27], was associated with a greater increase in BMI [54]. However, it remains to explore the specific mechanisms of personality traits underlying our findings.

The biological mechanisms underlying our findings are likely multifaceted. Beyond previously discussed factors such as stress coping, which may concurrently contribute to both depression and adiposity, the bidirectional vicious cycle between depression and adiposity [56] could also play a significant role. For instance, depression might promote adiposity (and subsequent multimorbidity development), and adiposity might also promote depression, resulting in a self-reinforcing loop. The strength of these bidirectional relationships may differ between males and females, potentially explaining the observed sex differences in the joint trajectories from normal state to comorbid depression and adiposity. More specific mechanisms should be further elucidated through targeted investigations in the future.

Comparison With Other Similar Studies

To the best of our knowledge, we have not found other studies that have explored the joint trajectories of depressive symptoms and BMI from adolescence to early adulthood. The existing studies have only focused on the trajectories of depressive symptoms or adiposity separately.

Concerning studies examining the trajectories of depressive symptoms, Kwong et al [20] found similar findings to ours that females were associated with the childhood-persistent trajectory of depressive symptoms compared with the stable-low trajectory. Zhang et al [57] also found a poorer trajectory of depressive symptoms in Chinese females than in males. Concerning studies examining the trajectories of adiposity, Koning et al [58] found that the proportion of males in the group with increasing BMI *z* score tended to be higher than that in the group with a gradually decreasing BMI *z* score, which was also consistent with our findings.

Strengths and Limitations

Our study findings should be interpreted with caution. First, the height and weight data used for trajectory analyses were based on a self-report questionnaire. However, previous studies had found that self-reported height and weight data were often closely related to actual measured data [33,34], and the CFPS had strict criteria for controlling the quality of self-reported data (Multimedia Appendix 1), which could strengthen the reliability of our results. Second, a small proportion of study participants were classified into the multimorbidity group, limiting us to identifying potential sex differences compared to the reference group. Third, other potential confounding factors that could simultaneously influence depressive symptoms and BMI were not adjusted for due to unavailable data, such as individual dietary behaviors. Fourth, individuals' health problems that could be the source of depression and adiposity were not clear. However, we have analyzed whether there were differences in the distribution of malignant tumors or endocrine diseases among different sexes based on available data and found no statistically significant results (P>.05). Moreover, the probability of developing other chronic diseases is low in adolescents or early adults aged 10 to 24. Therefore, individuals' health problems will not have a significant impact on the results of our study.

Nevertheless, our study population was from a representative sample in China, which indicates great generalizability in the Chinese population. In addition, results from several sensitivity analyses were rather consistent, increasing the robustness of our study findings.

Research Implications

Adolescence and early adulthood are a critical "watershed" period when multiple risk behaviors might emerge, and in the meanwhile, these risk behaviors can be prevented and healthy behavior habits can also be established. Thus, this transitional period is also a critical "window" period when prevention-oriented interventions might come in. Multimorbidity of depression and adiposity has been widely recognized, and relevant pilot interventions are currently in the design or early implementation stage [59]. Our study is unique in taking a sex-specific view of the combined longitudinal trends of depressive symptoms and BMI from adolescence to early adulthood. Our findings indicated that multimorbidity intervention for both depression and adiposity may benefit more from designing sex-specific intervention measures compared with the "one-size-fits-all" approach, as females tend to be depression-prone but adiposity-resistant while males show the opposite pattern.

Conclusions

The findings of our study could pave the way for future multimorbidity interventions that aim to simultaneously prevent the 2 common health issues during adolescence and early adulthood: depression and adiposity. Data from the large,

XSL•FO
RenderX

representative sample in China showed that the depressive symptoms and BMI might not increase or decrease simultaneously from adolescence to early adulthood over 10 years; instead, there emerged 4 distinct groups of trajectories in the changes of depressive symptoms and BMI: health-sustaining, depression-dominant, adiposity-dominant, or multimorbidity group. We also identified sex differences in the joint trajectories of depressive symptoms and BMI from adolescence to early adulthood. This will guide the development of future sex-specific interventions tailored to the distinct profiles of males and females from adolescence to early adulthood, respectively, thereby optimizing intervention effectiveness for preventing both depression and adiposity in early life.

Acknowledgments

This study was funded by Beijing Education Sciences Planning Program during the 14th Five-Year Plan (BECA23111).

Authors' Contributions

ZL conceptualized the study, acquired funding, curated the data, provided resources, supervised the project, administered the project, validated the findings, and contributed to writing the original draft and reviewing and editing the manuscript. JC and RS conducted the formal analysis and visualization, and contributed to the investigation, methodology development, original draft writing, and manuscript review and editing. WY, QW, YY, Y-HY, J-YL, W-CX, SZ, L-MW, X-RZ, and YS contributed to the investigation, methodology development, and manuscript writing and review.
YS contributed to this work as the senior author.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Data quality control criteria for self-reported height and weight, data cleaning procedures, and definitions of well-being and physical activity measures.
[DOCX File, 16 KB - pediatrics_v8i1e72722_app1.docx]

Multimedia Appendix 2
Participant characteristics, model adequacy assessments for depression and BMI z score trajectories, and distributions of well-being and physical activity across trajectory groups, based on World Health Organization standards.
[DOCX File, 25 KB - pediatrics_v8i1e72722_app2.docx]

Multimedia Appendix 3
Results of sensitivity analyses.
[DOCX File, 104 KB - pediatrics_v8i1e72722_app3.docx]

References

1. Zhong BL, Ding J, Chen HH, et al. Depressive disorders among children in the transforming China: an epidemiological survey of prevalence, correlates, and service use. Depress Anxiety 2013 Sep;30(9):881-892. [doi: 10.1002/da.22109] [Medline: 23554081]
2. Sawyer SM, Afifi RA, Bearinger LH, et al. Adolescence: a foundation for future health. Lancet 2012 Apr 28;379(9826):1630-1640. [doi: 10.1016/S0140-6736(12)60072-5] [Medline: 22538178]
3. McGrath JJ, Al-Hamzawi A, Alonso J, et al. Age of onset and cumulative risk of mental disorders: a cross-national analysis of population surveys from 29 countries. Lancet Psychiatry 2023 Sep;10(9):668-681. [doi: 10.1016/S2215-0366(23)00193-1] [Medline: 37531964]
4. Hargreaves D, Mates E, Menon P, et al. Strategies and interventions for healthy adolescent growth, nutrition, and development. Lancet 2022 Jan 8;399(10320):198-210. [doi: 10.1016/S0140-6736(21)01593-2] [Medline: 34856192]
5. Luo W, Zhong BL, Chiu HFK. Prevalence of depressive symptoms among Chinese university students amid the COVID-19 pandemic: a systematic review and meta-analysis. Epidemiol Psychiatr Sci 2021 Mar 26;30:e31. [doi: 10.1017/S2045796021000202] [Medline: 33766163]
6. Xu YM, Pu SS, Li Y, Zhong BL. Possible avoidant personality disorder magnifies the association between bullying victimization and depressive symptoms among Chinese university freshmen. Front Psychiatry 2022;13:822185. [doi: 10.3389/fpsyt.2022.822185] [Medline: 35250671]

XSL•FO
RenderX

7. Shorey S, Ng ED, Wong CHJ. Global prevalence of depression and elevated depressive symptoms among adolescents: a systematic review and meta-analysis. Br J Clin Psychol 2022 Jun;61(2):287-305. [doi: 10.1111/bjc.12333] [Medline: 34569066]
8. NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in body-mass index, underweight, overweight, and obesity from 1975 to 2016: a pooled analysis of 2416 population-based measurement studies in 128·9 million children, adolescents, and adults. Lancet 2017 Dec 16;390(10113):2627-2642. [doi: 10.1016/S0140-6736(17)32129-3] [Medline: 29029897]
9. Whitfield-Gabrieli S, Nieto-Castanon A. Conn: a functional connectivity toolbox for correlated and anticorrelated brain networks. Brain Connect 2012;2(3):125-141. [doi: 10.1089/brain.2012.0073] [Medline: 22642651]
10. Zhou M, Zhu NB, Yu CQ, et al. Analysis on adulthood weight change in adults in China. Zhonghua Liu Xing Bing Xue Za Zhi 2019 May 10;40(5):510-514. [doi: 10.3760/cma.j.issn.0254-6450.2019.05.004] [Medline: 31177729]
11. Smith JD, Fu E, Kobayashi MA. Prevention and management of childhood obesity and its psychological and health comorbidities. Annu Rev Clin Psychol 2020 May 7;16:351-378. [doi: 10.1146/annurev-clinpsy-100219-060201] [Medline: 32097572]
12. Jelalian E, Jandasek B, Wolff JC, Seaboyer LM, Jones RN, Spirito A. Cognitive-behavioral therapy plus healthy lifestyle enhancement for depressed, overweight/obese adolescents: results of a pilot trial. J Clin Child Adolesc Psychol 2019;48(sup1):S24-S33. [doi: 10.1080/15374416.2016.1163705] [Medline: 27310418]
13. Bjerregaard LG, Jensen BW, Ängquist L, Osler M, Sørensen TIA, Baker JL. Change in overweight from childhood to early adulthood and risk of type 2 diabetes. N Engl J Med 2018 Apr 5;378(14):1302-1312. [doi: 10.1056/NEJMoa1713231] [Medline: 29617589]
14. Mirza SS, Wolters FJ, Swanson SA, et al. 10-year trajectories of depressive symptoms and risk of dementia: a population-based study. Lancet Psychiatry 2016 Jul;3(7):628-635. [doi: 10.1016/S2215-0366(16)00097-3] [Medline: 27138970]
15. Abate KH. Gender disparity in prevalence of depression among patient population: a systematic review. Ethiop J Health Sci 2013 Nov;23(3):283-288. [doi: 10.4314/ejhs.v23i3.11] [Medline: 24307828]
16. Chang E, Varghese M, Singer K. Gender and sex differences in adipose tissue. Curr Diab Rep 2018 Jul 30;18(9):69. [doi: 10.1007/s11892-018-1031-3] [Medline: 30058013]
17. Mauvais-Jarvis F, Bairey Merz N, Barnes PJ, et al. Sex and gender: modifiers of health, disease, and medicine. Lancet 2020 Aug 22;396(10250):565-582. [doi: 10.1016/S0140-6736(20)31561-0] [Medline: 32828189]
18. Thapar A, Eyre O, Patel V, Brent D. Depression in young people. Lancet 2022 Aug 20;400(10352):617-631. [doi: 10.1016/S0140-6736(22)01012-1] [Medline: 35940184]
19. Dattani S, Rodés-Guirao L, Ritchie H, Roser M. Mental health. Our World in Data. 2023. URL: https://ourworldindata.org/mental-health [accessed 2025-07-17]
20. Kwong ASF, López-López JA, Hammerton G, et al. Genetic and environmental risk factors associated with trajectories of depression symptoms from adolescence to young adulthood. JAMA Netw Open 2019 Jun 5;2(6):e196587. [doi: 10.1001/jamanetworkopen.2019.6587] [Medline: 31251383]
21. Musliner KL, Munk-Olsen T, Eaton WW, Zandi PP. Heterogeneity in long-term trajectories of depressive symptoms: patterns, predictors and outcomes. J Affect Disord 2016 Mar 1;192:199-211. [doi: 10.1016/j.jad.2015.12.030] [Medline: 26745437]
22. Dong YH, Chen L, Liu JY, et al. Epidemiology and prediction of overweight and obesity among children and adolescents aged 7-18 years in China from 1985 to 2019. Zhonghua Yu Fang Yi Xue Za Zhi 2023 Feb 28;57(4):11-19. [doi: 10.3760/cma.j.cn112150-20220906-00881] [Medline: 36854438]
23. World obesity atlas 2023. World Obesity Federation (WOF). 2023. URL: https://www.worldobesity.org/resources/resource-library/world-obesity-atlas-2023 [accessed 2025-07-17]
24. Byrne ML, O'Brien-Simpson NM, Mitchell SA, Allen NB. Adolescent-onset depression: are obesity and inflammation developmental mechanisms or outcomes? Child Psychiatry Hum Dev 2015 Dec;46(6):839-850. [doi: 10.1007/s10578-014-0524-9] [Medline: 25666100]
25. Ferreiro F, Seoane G, Senra C. Toward understanding the role of body dissatisfaction in the gender differences in depressive symptoms and disordered eating: a longitudinal study during adolescence. J Adolesc 2014 Jan;37(1):73-84. [doi: 10.1016/j.adolescence.2013.10.013] [Medline: 24331307]
26. Dallman MF. Stress-induced obesity and the emotional nervous system. Trends Endocrinol Metab 2010 Mar;21(3):159-165. [doi: 10.1016/j.tem.2009.10.004] [Medline: 19926299]
27. Costa PT, Terracciano A, McCrae RR. Gender differences in personality traits across cultures: robust and surprising findings. J Pers Soc Psychol 2001 Aug;81(2):322-331. [doi: 10.1037/0022-3514.81.2.322] [Medline: 11519935]
28. Xie Y, Hu J. An introduction to the China family panel studies (CFPS). Chin Sociol Rev 2014;47(1):3-29. [doi: 10.2753/CSA2162-0555470101.2014.11082908]
29. Carleton RN, Thibodeau MA, Teale MJN, et al. The Center for Epidemiologic Studies Depression Scale: a review with a theoretical and empirical examination of item content and factor structure. PLoS ONE 2013;8(3):e58067. [doi: 10.1371/journal.pone.0058067] [Medline: 23469262]

XSL•FO
RenderX

30. Garber J, Clarke GN, Weersing VR, et al. Prevention of depression in at-risk adolescents: a randomized controlled trial. JAMA 2009 Jun 3;301(21):2215-2224. [doi: 10.1001/jama.2009.788] [Medline: 19491183]
31. Chin WY, Choi EPH, Chan KTY, Wong CKH. The psychometric properties of the Center for Epidemiologic Studies Depression Scale in Chinese primary care patients: factor structure, construct validity, reliability, sensitivity and responsiveness. PLoS ONE 2015;10(8):e0135131. [doi: 10.1371/journal.pone.0135131] [Medline: 26252739]
32. Yang L, Jia CX, Qin P. Reliability and validity of the Center for Epidemiologic Studies Depression Scale (CES-D) among suicide attempters and comparison residents in rural China. BMC Psychiatry 2015 Apr 9;15:76. [doi: 10.1186/s12888-015-0458-1] [Medline: 25886490]
33. Rios-Leyvraz M, Ortega N, Chiolero A. Reliability of self-reported height and weight in children: a school-based cross-sectional study and a review. Nutrients 2022 Dec 23;15(1):75. [doi: 10.3390/nu15010075] [Medline: 36615731]
34. Field AE, Aneja P, Rosner B. The validity of self-reported weight change among adolescents and young adults. Obesity (Silver Spring) 2007 Sep;15(9):2357-2364. [doi: 10.1038/oby.2007.279] [Medline: 17890505]
35. Growth reference data for 5-19 years. World Health Organization (WHO). 2007. URL: https://www.who.int/tools/growth-reference-data-for-5to19-years [accessed 2025-07-17]
36. Williams EP, Mesidor M, Winters K, Dubbert PM, Wyatt SB. Overweight and obesity: prevalence, consequences, and causes of a growing public health problem. Curr Obes Rep 2015 Sep;4(3):363-370. [doi: 10.1007/s13679-015-0169-4] [Medline: 26627494]
37. Neves SC, Rodrigues LM, Bento PADSS, Minayo MCDS. Risk factors involved in adolescent obesity: an integrative review. Cien Saude Colet 2021;26(suppl 3):4871-4884. [doi: 10.1590/1413-812320212611.3.30852019] [Medline: 34787182]
38. Liu Z, Gao P, Gao AY, et al. Effectiveness of a multifaceted intervention for prevention of obesity in primary school children in China: a cluster randomized clinical trial. JAMA Pediatr 2022 Jan 1;176(1):e214375. [doi: 10.1001/jamapediatrics.2021.4375] [Medline: 34747972]
39. Lennon H, Kelly S, Sperrin M, et al. Framework to construct and interpret latent class trajectory modelling. BMJ Open 2018 Jul 7;8(7):e020683. [doi: 10.1136/bmjopen-2017-020683] [Medline: 29982203]
40. Herle M, Micali N, Abdulkadir M, et al. Identifying typical trajectories in longitudinal data: modelling strategies and interpretations. Eur J Epidemiol 2020 Mar;35(3):205-222. [doi: 10.1007/s10654-020-00615-6] [Medline: 32140937]
41. Azur MJ, Stuart EA, Frangakis C, Leaf PJ. Multiple imputation by chained equations: what is it and how does it work? Int J Methods Psychiatr Res 2011 Mar;20(1):40-49. [doi: 10.1002/mpr.329] [Medline: 21499542]
42. Screening standard for malnutrition of school-age children and adolescents [Article in Chinese]. National Health and Family Planning Commission of the People's Republic of China. 2014. URL: www.nhc.gov.cn/wjw/pqt/201407/38b15c0a1ed444e8908e12752decaffa/files/1739781146755_22583.pdf [accessed 2025-07-17]
43. Screening for overweight and obesity among school-age children and adolescents [Article in Chinese]. National Health and Family Planning Commission of the People's Republic of China. 2018. URL: www.nhc.gov.cn/wjw/pqt/201803/a7962d1ac01647b9837110bfd2d69b26/files/1739781209962_63132.pdf [accessed 2025-07-17]
44. Elm EV, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. BMJ 2007 Oct 20;335(7624):806-808. [doi: 10.1136/bmj.39335.541782.AD]
45. Sideli L, Lo Coco G, Bonfanti RC, et al. Effects of COVID-19 lockdown on eating disorders and obesity: a systematic review and meta-analysis. Eur Eat Disord Rev 2021 Nov;29(6):826-841. [doi: 10.1002/erv.2861] [Medline: 34460991]
46. Melamed OC, Selby P, Taylor VH. Mental health and obesity during the COVID-19 pandemic. Curr Obes Rep 2022 Mar;11(1):23-31. [doi: 10.1007/s13679-021-00466-6] [Medline: 35254633]
47. Milaneschi Y, Simmons WK, van Rossum EFC, Penninx BW. Depression and obesity: evidence of shared biological mechanisms. Mol Psychiatry 2019 Jan;24(1):18-33. [doi: 10.1038/s41380-018-0017-5] [Medline: 29453413]
48. Milano W, Ambrosio P, Carizzone F, et al. Depression and obesity: analysis of common biomarkers. Diseases 2020 Jun 14;8(2):32545890. [doi: 10.3390/diseases8020023] [Medline: 32545890]
49. Minkwitz J, Scheipl F, Cartwright L, et al. Why some obese people become depressed whilst others do not: exploring links between cognitive reactivity, depression and obesity. Psychol Health Med 2019 Mar;24(3):362-373. [doi: 10.1080/13548506.2018.1524153] [Medline: 30252503]
50. Gallagher C, Waidyatillake N, Pirkis J, et al. The effects of weight change from childhood to adulthood on depression and anxiety risk in adulthood: a systematic review. Obes Rev 2023 Jul;24(7):e13566. [doi: 10.1111/obr.13566] [Medline: 37062534]
51. Marques-Vidal P, Bochud M, Bastardot F, et al. Levels and determinants of inflammatory biomarkers in a Swiss population-based sample (CoLaus study). PLoS One 2011;6(6):e21002. [doi: 10.1371/journal.pone.0021002] [Medline: 21695270]
52. Hankin BL, Young JF, Abela JRZ, et al. Depression from childhood into late adolescence: influence of gender, development, genetic susceptibility, and peer stress. J Abnorm Psychol 2015 Nov;124(4):803-816. [doi: 10.1037/abn0000089] [Medline: 26595469]
53. Bangasser DA, Cuarenta A. Sex differences in anxiety and depression: circuits and mechanisms. Nat Rev Neurosci 2021 Nov;22(11):674-684. [doi: 10.1038/s41583-021-00513-0] [Medline: 34545241]

XSL•FO
RenderX

54. Sutin AR, Ferrucci L, Zonderman AB, Terracciano A. Personality and obesity across the adult life span. J Pers Soc Psychol 2011 Sep;101(3):579-592. [doi: 10.1037/a0024286] [Medline: 21744974]
55. Vijayalakshmi P, Thimmaiah R, Nikhil Reddy SS, B V K, Gandhi S, BadaMath S. Gender differences in body mass index, body weight perception, weight satisfaction, disordered eating and Weight control strategies among Indian medical and nursing undergraduates. Invest Educ Enferm 2017 Oct;35(3):276-268. [doi: 10.17533/udea.iee.v35n3a04] [Medline: 29767908]
56. Plackett B. The vicious cycle of depression and obesity. Nature New Biol 2022 Aug;608(7924):S42-S43. [doi: 10.1038/d41586-022-02207-8] [Medline: 36002500]
57. Zhang Y, Zhao M. Gender disparities and depressive symptoms over the life course and across cohorts in China. J Affect Disord 2021 Dec;295:620-627. [doi: 10.1016/j.jad.2021.08.134]
58. Koning M, Hoekstra T, de Jong E, Visscher TLS, Seidell JC, Renders CM. Identifying developmental trajectories of body mass index in childhood using latent class growth (mixture) modelling: associations with dietary, sedentary and physical activity behaviors: a longitudinal study. BMC Public Health 2016 Oct 28;16(1):1128. [doi: 10.1186/s12889-016-3757-7] [Medline: 27793201]
59. Schladitz K, Luppa M, Riedel-Heller SG, Loebner M. Effectiveness of internet-based and mobile-based interventions for adults with overweight or obesity experiencing symptoms of depression: a systematic review protocol. BMJ Open 2023 Jun 20;13(6):e067930. [doi: 10.1136/bmjopen-2022-067930] [Medline: 37339836]

Abbreviations

CES-D: Center for Epidemiologic Studies Depression Scale
CFPS: China Family Panel Studies
OR: odds ratio
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

Edited by J Hagström; submitted 17.02.25; peer-reviewed by F Tseliou, O Abasilim; revised version received 27.06.25; accepted 27.06.25; published 10.09.25.

Please cite as:
Chen J, Shan R, Yuan W, Wu Q, Yang Y, Yang YH, Liu JY, Xiao WC, Zhang S, Wen LM, Zhang XR, Liu Z, Song Y
Sex Differences in the Joint Trajectories of Depressive Symptoms and Body Mass Index From Adolescence to Early Adulthood: Longitudinal Observational Study
JMIR Pediatr Parent 2025;8:e72722
URL: https://pediatrics.jmir.org/2025/1/e72722
doi:10.2196/72722

© Jing Chen, Rui Shan, Wen Yuan, Qiong Wu, Yang Yang, Yi-Hang Yang, Jing-Yao Liu, Wu-Cai Xiao, Shanghang Zhang, Li-Ming Wen, Xiao-Rui Zhang, Zheng Liu, Yi Song. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 10.9.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Adapting Cognitive Behavioral Therapy for Adolescents in Iraq via Mobile Apps: Qualitative Study of Usability and Outcomes

Radhwan Hussein Ibrahim[1], PhD, Prof Dr; Marghoob Hussein Yaas[2], PhD; Mariwan Qadir Hamarash[2], MCS; Salwa Hazim Al-Mukhtar[3], PhD, Prof Dr; Mohammed Faris Abdulghani[1], PhD; Osama Al Mushhadany[4], Prof Dr

[1]Department of Clinical Nursing Sciences, College of Nursing, Ninevah University, Kirkuk St, Mosul, Iraq

[2]College of Nursing, Al Kitab University, Kirkuk, Iraq

[3]Department of Clinical Nursing Sciences, College of Nursing, University of Mosul, Mosul, Iraq

[4]College of Medicine, Ninevah University, Mosul, Iraq

Corresponding Author:
Radhwan Hussein Ibrahim, PhD, Prof Dr
Department of Clinical Nursing Sciences, College of Nursing, Ninevah University, Kirkuk St, Mosul, Iraq

Abstract

Background: Mental health challenges, including anxiety and depression, are increasingly common among adolescents. Mobile health (mHealth) apps offer a promising way to deliver accessible cognitive behavioral therapy (CBT) interventions. However, research on the usability and effectiveness of apps explicitly tailored for adolescents is limited.

Objective: This study aimed to explore the usability, engagement, and perceived effectiveness of a mobile CBT app designed for adolescents, focusing on user experiences and mental health outcomes.

Methods: A qualitative study was conducted with 40 adolescents aged 13 - 19 years (mean age 15.8, SD 1.9 years; 18/40, 45% male; 22/40, 55% female) who engaged with a CBT app for 4 weeks. Mental health diagnoses included anxiety (20/40, 50%), depression (15/40, 38%), and both (5/40, 13%). Of these, 10 (25%) of the 40 participants had previous CBT experience. Feedback was gathered through focus groups and individual interviews, and thematic analysis identified key themes related to usability, engagement, and perceived effectiveness. Quantitative data on mood and anxiety scores were analyzed with paired *t* tests.

Results: The mean usability score was 3.8 (SD 0.6), and the mean effectiveness score was 3.9 (SD 0.7). Older participants (aged 16 - 19 years) reported significantly higher usability (mean 4.1, SD 0.4) and effectiveness scores (mean 4.3, SD 0.5) compared to younger participants (aged 13 - 15 years) (*P*=.03). Females had higher usability (mean 4, SD 0.6) and effectiveness scores (mean 4.2, SD 0.7) than males (mean 3.6, SD 0.7, and mean 3.5, SD 0.8, respectively; *P*=.03). Participants with prior CBT experience had 2.8 times higher odds of reporting high usability scores (95% CI 1.6 - 5; *P*=.002) and 3.1 times higher odds of reporting high effectiveness scores (95% CI 1.7 - 5.6; *P*=.001). Usability challenges included complex navigation (20/40, 50%), interface design issues (12/40, 30%), and content overload (8/40, 20%). Factors positively influencing engagement were motivation driven by personal relevance (20/40, 50%) and gamification features (10/40, 25%), while lack of personalization (14/40, 35%) and external distractions (18/40, 45%) were significant barriers. Mood improvement (15/40, 38%) and learning new coping skills (12/40, 30%) were the most reported outcomes.

Conclusions: The mobile CBT app shows potential for improving adolescent mental health, with initial improvements in mood and anxiety. Future app iterations should prioritize simplifying navigation, adding personalization features, and enhancing technical stability to support long-term engagement.

(JMIR Pediatr Parent 2025;8:e67137) doi:10.2196/67137

KEYWORDS

cognitive behavioral therapy; CBT; psychotherapy; mHealth; app; adolescents; teenager; mental health; usability; engagement; anxiety; depression; user experience; UX; focus group; interview; digital health

Introduction

Mental health challenges among adolescents have become increasingly prevalent, with issues like anxiety, depression, and stress-related disorders affecting a significant portion of this population [1-4]. Adolescence is a critical developmental period marked by emotional, cognitive, and social changes, which can increase vulnerability to mental health disorders [5-7]. The World Health Organization estimates that up to 20% of adolescents experience mental health conditions, highlighting the urgent need for effective and accessible interventions [8-10].

In response to this growing demand, mobile health (mHealth) apps have emerged as a promising solution for delivering mental health care [11-14]. These apps offer a flexible, cost-effective,

XSL•FO
RenderX

and private means for adolescents to access psychological interventions, which may otherwise be limited due to stigma, lack of resources, or geographical barriers [15-19]. Among the various therapeutic approaches, cognitive behavioral therapy (CBT) has proven to be particularly effective in addressing common adolescent mental health issues like anxiety and depression [20-24]. CBT focuses on helping individuals identify and modify negative thought patterns and behaviors, making it well suited for delivery via mobile platforms that offer interactive and self-guided modules [25-28].

Despite the promise of mobile CBT apps, there remains a significant research gap regarding their usability and effectiveness for adolescents [29,30]. Most existing studies focus on adult populations or general app evaluations without considering younger users' unique needs and preferences [31,32]. Adolescents may have different expectations for user experience, engagement, and motivation when interacting with digital health tools [33,34]. Additionally, this age group's developmental and emotional characteristics necessitate a design that fosters engagement and provides adequate support [35-39].

In Iraq, mental health services face significant barriers due to stigma, lack of resources, and geographical constraints, which limit adolescents' access to traditional therapy. Postconflict instability, socioeconomic challenges, and strained health care systems have compounded mental health issues among Iraqi youth, creating a need for innovative solutions tailored to this population. Adolescents in Iraq, particularly those in low-resource settings, may be unable to access face-to-face therapy due to the limited availability of mental health professionals and the high costs associated with treatment.

While the potential of mobile CBT apps is evident, there is a lack of research on their usability and effectiveness among adolescents, particularly in regions like Iraq. This study aims to address this gap by exploring the usability, engagement, and outcomes of a mobile CBT app tailored specifically for adolescents in Iraq. The findings will provide valuable insights into how digital mental health tools can be optimized to better serve this vulnerable population in low-resource settings.

This study aimed to evaluate the usability, engagement, and perceived effectiveness of a mobile CBT app for adolescents, with a focus on user experiences and its impact on mental health outcomes.

Methods

Participants

The study recruited adolescents aged 13 - 19 years who were experiencing mental health challenges, including anxiety and depression. A convenience sampling method was used to select participants from various sources, including local schools, mental health clinics, and online mental health communities. Participants were referred by counselors or health care providers and expressed interest in participating. Inclusion criteria required that participants had a self-reported diagnosis of anxiety or depression, regular access to a smartphone, and, for those aged <18 years, parental consent. A sample size of 40 adolescents was chosen for an in-depth qualitative analysis of diverse perspectives while maintaining manageability for detailed thematic analysis. The study was conducted in Mosul, Iraq, ensuring a regional context for the findings. Data confidentiality and participant anonymity were prioritized throughout the study. Each participant was assigned a unique identifier code used in place of personal information during data collection, transcription, and analysis. This ensured that no identifying details were linked to the responses. Informed consent was obtained from all participants, outlining their rights to privacy and the confidential handling of their data. Interview and focus group recordings were securely stored in encrypted files, accessible only to authorized research team members. All transcripts were deidentified prior to analysis to protect participant identities further, and findings were reported in aggregate to prevent any individual from being identified.

Intervention

Participants were introduced to a CBT mobile app designed specifically for adolescents. The app was commercially available and selected based on its adherence to established CBT principles, as well as its focus on common adolescent mental health issues such as anxiety, depressive thoughts, and stress management. The app featured interactive modules, journaling functions, mood tracking, and self-assessment tools, all aimed at guiding users through CBT-based interventions. The selection of the app was influenced by its popularity, user ratings, and evidence-based framework, ensuring that it met the study's requirements for delivering structured CBT exercises. Participants were asked to engage with the app for 4 weeks, with a recommendation to complete at least 3 CBT exercises per week, though they were free to use it at their discretion.

Study Design

The study adopted a qualitative approach to gather rich, in-depth insights into the participants' experiences with the mobile CBT app. Data were collected through focus groups and one-on-one semistructured interviews after the 4-week intervention period. This design allowed for exploring the app's usability, engagement, and perceived outcomes from the adolescent perspective. The qualitative approach was well suited in understanding users' subjective experiences and identifying themes related to app interaction and mental health improvement.

Data Collection

Data collection focused on both app interaction and user feedback. The following methods were used.

App Usage Metrics

In-app data were collected to track the frequency of app usage, time spent on activities, completion of CBT modules, and interaction with various app features (eg, journaling and mood tracking).

User Feedback

Participants provided feedback through focus groups and interviews, where they discussed their experiences with the app. Topics of discussion included usability (ease of navigation and design preferences), engagement (motivation to use the app and consistency of use), and perceived outcomes (changes in mood,

XSL•FO
RenderX

anxiety, or stress levels). Interviews were recorded and transcribed for analysis.

Outcome Measures

The study evaluated the following outcomes.

Usability

This included ease of navigation, design intuitiveness, and app aesthetics. Participants shared feedback on the app's user-friendliness and any barriers they encountered.

Effectiveness

Participants self-reported any changes in their mental health symptoms, particularly about anxiety and depression. Symptom reduction was assessed using qualitative descriptions of mood changes and mental health improvements throughout the study.

Overall Satisfaction

Participants reflected on their satisfaction with the app, including its features, content relevance, and overall impact on their mental health. Satisfaction was gauged through subjective feedback on whether they would recommend the app to peers or continue using it poststudy.

Ethical Considerations

This study was conducted in accordance with the ethical guidelines set in the Declaration of Helsinki and was approved by the institutional review board of the University of Ninevah (approval reference number: NURIRB/041/2023). All the processes involving human subjects were reviewed and deemed ethically acceptable by the institutional review board. As most participants were minors aged <18 years, extra ethical precautions were exercised. For participants aged <18 years, written informed consent was obtained from parents or their legal guardians and assent from the adolescents. The assent forms were read in age-specific terms so the minors would clearly understand the purpose of the study, procedures to be followed, risks and benefits, if any, and their rights, such as withdrawal from the study at any time without any penalty. Parents and guardians received full written and verbal explanations of the study, including confidentiality protocols and data privacy protections, so that participation would be based on fully informed decision-making. All data were anonymized and stored securely to protect participant privacy and confidentiality. Identifying information was stored separately from the main dataset and was accessible only to authorized research team members. No financial incentives or rewards were promised to the participants or their families for participating in this study, so as to avoid coercion or undue influence.

Results

Age, Usability, and Effectiveness

The study found that age was slightly correlated with app usability and effectiveness. Older adolescents (aged 17 - 19 years) generally reported higher usability scores and perceived greater effectiveness than younger participants (Table 1). This could be due to increased digital literacy and maturity in using therapeutic tools among older users, who may navigate the app more intuitively and apply CBT techniques more consistently.

XSL•FO
RenderX

Table . Demographic characteristics (N=40) and correlation with usability and effectiveness outcomes for the CBT[a] app.

Characteristic	Participants, n (%)	Usability score, mean (SD)	Effectiveness score, mean (SD)	Preferred features	Notable observations
Age (years)					
13 - 15	15 (38)	3.2 (0.5)	3.4 (0.6)	Gamification and mood tracking	Less consistent engagement but reported mood improvements
16 - 19	25 (62)	4.1 (0.4)	4.3 (0.5)	Journaling and thought reframing	Higher digital literacy correlated with better usability
Gender					
Male	18 (45)	3.6 (0.7)	3.5 (0.8)	Gamification and relaxation techniques	Gamification boosted engagement; preferred reward-based elements
Female	22 (55)	4.0 (0.6)	4.2 (0.7)	Journaling and mood tracking	Consistent journaling and tracking helped manage emotions
Mental health diagnosis					
Anxiety	20 (50)	4.0 (0.5)	4.1 (0.6)	Mood tracking and relaxation techniques	Frequent mood tracking to manage anxiety triggers
Depression	15 (38)	3.7 (0.6)	3.8 (0.5)	Journaling	Journaling as a primary emotional outlet
Both	5 (12)	3.5 (0.7)	3.6 (0.8)	Combination of all features	Mixed feature use, desire for more personalization
Previous CBT experience					
Yes	10 (25)	4.2 (0.4)	4.3 (0.6)	Thought reframing and relaxation	Higher familiarity led to easier app navigation
No	30 (75)	3.5 (0.6)	3.6 (0.7)	Mood tracking and gamification	Accessibility for beginners; tutorial recommended

[a]CBT: cognitive behavioral therapy.

Gender Differences

Gender differences were evident in feature engagement and overall satisfaction with the app. Female participants reported using journaling and mood tracking more frequently and found these features particularly beneficial for managing their emotions. Males, however, demonstrated a stronger preference for gamification elements, suggesting they might respond better to reward-based interactions within the app. This result indicates that gender-sensitive adaptations, like balancing gamified elements with reflective exercises, could optimize engagement.

Mental Health Diagnosis

Diagnosis type influenced how participants interacted with different app features. Adolescents diagnosed with anxiety frequently engaged with mood tracking to monitor their anxiety triggers and reported that it helped them feel more in control. In contrast, participants with depression found journaling more beneficial, as it provided an outlet for emotional expression. Those with both anxiety and depression reported mixed results, finding both features helpful but expressing a need for more personalized guidance. These findings suggest that tailoring app features based on specific mental health diagnoses may enhance effectiveness.

Previous CBT Experience

Prior CBT experience was associated with higher usability scores. Participants familiar with CBT concepts found the app easier to navigate and were able to engage more readily with tools like thought reframing and relaxation exercises. Those without prior CBT experience still reported short-term improvements, indicating that the app is accessible for beginners, though they noted that a brief tutorial on CBT basics could improve initial engagement.

Interaction Between Characteristics

When analyzing the interaction between age and diagnosis, older adolescents with anxiety showed a unique pattern of consistent engagement with mood tracking and relaxation exercises, possibly due to increased awareness of their symptoms and the therapeutic benefits of tracking. This contrasts with younger adolescents with depression, who were less consistent with engagement but reported substantial short-term mood

XSL•FO
RenderX

improvements when they did engage, highlighting age and symptom-specific usage patterns.

Usability Challenges

Overview

Several usability challenges were identified through participant feedback (Table 2). While the majority of adolescents found the app's interface visually appealing, many encountered issues related to its design and navigation. For example, one participant stated, "It was hard to find the tools I needed; sometimes I got lost in the app" [Participant 3, female, 16 years old].

Table . Themes identified in usability challenges (N=40).

Usability challenge	Description	Values, n (%)
Complex navigation	Difficulty in finding features or completing multistep tasks	20 (50)
Interface design	Issues with text size, button placement, or layout on mobile devices	12 (30)
Content overload	Feeling overwhelmed by the amount of content in some sections	8 (20)

Complex Navigation

Of the 40 participants, 20 (50%) reported difficulty navigating through the app, particularly when attempting to access multistep CBT modules. They expressed a desire for clearer instructions and a more simplified user interface.

Interface Design

Of the 40 participants, 12 (30%) mentioned that the app's text size and button placement were not user-friendly, especially when using smaller mobile devices. This affected their overall experience and led to frustration in some cases.

Content Overload

Of the 40 participants, 8 (20%) felt overwhelmed by the amount of information presented in certain sections of the app. They indicated that the extensive content occasionally discouraged further use.

Engagement

Participant engagement with the app varied and was influenced by several factors, including personal relevance and gamification features (Table 3).

Table . Factors influencing engagement with the CBT[a] app (N=40).

Factor	Description	Values, n (%)
Motivation (personal relevance)	Continued use linked to personal mental health needs and recognition of the app's benefits	20 (50)
Gamification and rewards	Positive response to interactive features and rewards	10 (25)
Personalization	Engagement hindered by lack of tailored content and goals	10 (25)

[a]CBT: cognitive behavioral therapy.

Motivation and Personal Relevance

Of the 40 participants, 20 (50%) who found the app's content personally relevant and aligned with their mental health needs reported higher levels of engagement. These participants were more likely to use the app consistently throughout the 4-week period. For example, one participant noted, "The rewards made it fun and kept me coming back" [Participant 5, male, 17 years old].

Gamification and Rewards

Of the 40 participants, 10 (25%) responded positively to the app's gamified elements, such as rewards for completing exercises and interactive features like mood tracking. They reported that these features enhanced their motivation to continue using the app.

Lack of Personalization

Of the 40 participants, 10 (25%) noted that the absence of personalization options, such as customized goals or tailored content, negatively impacted their long-term engagement with the app.

Perceived Effectiveness

The majority of participants reported experiencing positive mental health outcomes, although the duration of the benefits varied (Table 4). For example, one participant stated, "The app gave me exercises that helped calm me down before an exam" [Participant 2, male, 14 years old].

XSL•FO
RenderX

Table . Perceived effectiveness of the app (N=40).

Effectiveness outcome	Description	Values, n (%)
Mood improvement	Participants reported a reduction in anxiety or improved mood after using the app	15 (38)
Learning coping skills	Users noted acquiring new coping mechanisms for managing stress and negative thoughts	12 (30)
Short-term benefits	Short-term improvements, but benefits were not sustained without continuous app use	13 (32)

Mood Improvement

Of the 40 participants, 15 (38%) reported a noticeable reduction in anxiety levels and an improvement in their mood after completing CBT exercises, particularly those focused on breathing techniques and cognitive restructuring.

Learning Coping Skills

Of the 40 participants, 12 (30%) highlighted that they learned new coping mechanisms, such as identifying and challenging negative thought patterns, which helped them manage day-to-day stress.

Short-Term Benefits

Despite these positive outcomes, 13 (32%) out of 40 participants mentioned that the improvements were short-term and did not last without regular app usage. This suggests that sustained engagement is necessary for long-term benefits.

Barriers to App Usage

Several barriers were identified that limited participants' consistent use of the app or reduced its perceived effectiveness (Table 5).

Table . Barriers to app usage (N=40).

Barrier	Description	Values, n (%)
App functionality issues	Technical problems like slow loading times or app crashes	8 (20)
Lack of personalization	Limited customization options for individual needs	14 (35)
External distractions	Schoolwork, social media, or lack of time impacting regular usage	18 (45)

App Functionality Issues

Of the 40 participants, 8 (20%) experienced technical problems, such as slow load times or occasional crashes, which discouraged them from using the app regularly.

Lack of Personalization

As previously mentioned, 14 (35%) out of the 40 participants felt that the lack of individualized content limited their overall engagement and the app's relevance to their specific mental health needs. One participant shared, "I felt like the app understood what I was going through, and that kept me using it" [Participant 7, male, 15 years old].

External Distractions

Of the 40 participants, 18 (45%) cited external distractions, such as schoolwork, social media, and general time constraints, as reasons for inconsistent app usage. They suggested that push notifications or reminders could help them stay on track with their CBT exercises. A participant commented, "Knowing others were going through the same thing made me feel less alone" [Participant 4, female, 16 years old].

Data Analysis Process

A thematic analysis was used to systematically explore the data gathered from focus groups and individual interviews. This qualitative approach is particularly suited to understanding the nuanced experiences of participants, as it allows for the identification of patterns and themes within textual data [40]. The analysis followed an inductive approach, where themes were derived directly from the data without imposing pre-existing frameworks, ensuring that the findings reflect participants' perspectives authentically [41].

Steps of Thematic Analysis

The steps of thematic analysis were as follows:

1. Data Familiarization: all interview transcripts were thoroughly reviewed to immerse the research team in the data and gain an initial understanding of the content.
2. Coding: initial codes were generated to highlight recurring patterns, unique responses, and significant statements related to usability, engagement, and perceived effectiveness.
3. Theme Development: codes were then grouped into broader themes that encapsulated the key insights, such as barriers to engagement, facilitators of usability, and outcomes of perceived effectiveness.
4. Review and Refinement: themes were refined iteratively to ensure they were distinct, relevant, and reflective of the dataset as a whole.

This method is appropriate for the study as thematic analysis provides flexibility in analyzing diverse qualitative data and is well suited for understanding user experiences with interventions

XSL•FO
RenderX

such as mobile CBT apps [42]. It enables researchers to capture both explicit content and latent meanings in the data.

Adequacy of Sample Size

The sample size for this study is adequate based on qualitative research standards. Data saturation—a point where no new themes or insights emerge—can often be achieved with 6 - 12 interviews, depending on the study's scope and participant homogeneity [43]. In this study, combining focus groups and individual interviews ensured a rich dataset that captured a range of perspectives while adhering to the principle of saturation.

Discussion

Principal Findings and Interpretation

This study explored the usability, engagement, and perceived effectiveness of a mobile CBT app designed for adolescents facing mental health challenges, such as anxiety and depression. The findings provide valuable insights into the potential of mobile CBT apps while highlighting areas for improvement, especially for adolescents in low-resource settings like Iraq.

Usability and Personalization

One key finding was the usability challenges reported by participants, including complex navigation and nonintuitive design. Participants frequently mentioned difficulties in locating tools or navigating through the app's interface. This underscores the need for developers to prioritize user-centered design that is simple, clear, and adaptable to different devices and screen sizes.

Features such as guided tutorials and step-by-step walkthroughs can facilitate easier navigation for adolescents with varying levels of digital literacy. Additionally, the app should be rigorously tested across multiple devices to ensure smooth performance and minimize technical barriers that deter consistent use.

A significant recommendation based on the feedback is the incorporation of personalization features, which could enhance the app's effectiveness and user engagement. Developers could implement adaptive algorithms that adjust content based on user input and progress, allowing the app to deliver more targeted interventions. For example, users could set personal mental health goals, such as reducing anxiety before exams, and the app could tailor CBT exercises accordingly to align with these objectives. Additionally, personalized content delivery based on self-assessment responses could ensure that users receive modules or exercises most relevant to their emotional state or specific stressors. Regular mood check-ins could further refine these recommendations, offering targeted suggestions that align with the user's evolving needs and experiences.

Consistent with earlier studies, such as Zhang et al [44], the app demonstrated potential in improving adolescents' mental health outcomes by providing accessible and flexible therapeutic tools. Previous work has highlighted the importance of user-friendly interfaces in promoting app adherence [45], and this study reinforces those conclusions. Participants' feedback about challenges in navigating the app echoes findings from Cheng et al [46], where adolescents reported that complex interfaces reduced their motivation to engage consistently.

Furthermore, the study aligns with the conclusions of Miller et al [47], which emphasized the critical role of personalization in enhancing the efficacy of digital interventions. Like Milleret al [47], our results suggest that tailoring app content to users' unique needs and progress is key to maintaining engagement and achieving desired outcomes.

The study revealed that engagement was strongly influenced by participants' perceptions of the app's relevance to their specific mental health needs. Participants who felt that the app effectively addressed their challenges were more likely to use it consistently, a finding supported by Banneyer et al [48], who demonstrated that content alignment with user needs significantly improves adherence to digital mental health interventions. Gamification features, such as badges, levels, and progress tracking, were identified as key motivators that sustained interest and encouraged continued use. These findings align with Ng and Wong [49], who reported that gamification elements enhance user engagement by creating a sense of achievement and progress.

Additionally, social features like anonymous peer support or community forums emerged as promising strategies for fostering connection and reducing feelings of isolation. This observation resonates with Silberg et al's [50] findings, who highlighted the role of social support mechanisms in increasing the acceptability and usage of mental health apps. In collectivist cultures like Iraq, where community and social bonds are deeply valued, enabling adolescents to share their progress or experiences anonymously could enhance engagement by leveraging these cultural strengths. This aligns with Patel et al [51], who noted the importance of culturally sensitive features in ensuring the success of digital health interventions. Future research should investigate the impact of such social features in different cultural contexts to determine their broader applicability and effectiveness.

Perceived Effectiveness

The perceived effectiveness of the app was influenced by its ability to address specific mental health challenges faced by participants. Such feedback highlights the importance of targeted interventions that address adolescents' real-world stressors. Participants also emphasized the need for evidence-based tools that provide tangible benefits. Incorporating features that explain the rationale behind each exercise and how it aligns with CBT principles could enhance perceived effectiveness and build user trust.

The findings align with prior research on adolescent mHealth engagement, such as those of Ghosh et al [52] features like personalization, gamification, and caregiver endorsement are critical for adolescent engagement in mHealth apps. Similarly, Oakley-Girvan et al [53] emphasized the importance of adaptive content and user-centered design in sustaining engagement. These studies underscore the importance of tailoring mHealth interventions to meet the unique needs of adolescent users while addressing cultural and contextual factors.

XSL•FO
RenderX

Long-Term Benefits and Sustainability

While most participants reported short-term improvements in mood and anxiety, the benefits were not sustained without regular app usage. This finding highlights the need for future mobile CBT apps to incorporate features that foster long-term engagement and sustained mental health improvements. Features such as regular reminders, progress tracking, and reinforcement of positive behaviors over time could play a crucial role in maintaining user involvement. For instance, push notifications reminding users to complete CBT exercises, celebrate milestones, or provide motivational messages have been shown to improve engagement and adherence in similar interventions [51].

Additionally, there is significant potential to integrate digital and human support in future app iterations. Adolescents could benefit from a hybrid model that combines the self-guided app with access to mental health professionals or peer mentors when needed. This approach aligns with findings from Gentry et al [54], which demonstrated that blending digital tools with human interaction significantly enhances mental health outcomes. Similarly, Patel et al [51] emphasized that hybrid models are particularly effective in resource-limited settings, where direct access to therapists is scarce. In regions like Iraq, where mental health resources are constrained, a blended approach could address both accessibility and sustainability challenges. By combining the strengths of digital and human support, mobile CBT apps could ensure broader and more enduring benefits, providing an effective solution for sustaining mental health improvements over time.

Implications for Future Development

The findings of this study highlight several key recommendations for the future development of mobile CBT apps for adolescents, particularly in low-resource settings like Iraq:

- Simplify navigation to enhance usability, ensuring the app is easy to use across different devices and levels of digital literacy.
- Incorporate adaptive personalization that tailors content based on individual user needs, goals, and progress.
- Gamify engagement to sustain motivation and encourage regular use, with a focus on rewards that resonate with the adolescent user base.
- Address external barriers such as distractions and time constraints by providing flexible features like push notifications and offline accessibility.
- Consider cultural and regional factors when designing apps, ensuring that features such as peer support align with the social values of the target audience.

Recommendations

Enhance Personalization

Adaptive Content Delivery

Integrate artificial intelligence–based algorithms to tailor content to the user's progress, mood, and engagement level. For example, adaptive modules can adjust the difficulty of activities based on the user's performance or offer reminders tailored to individual schedules.

User-Centered Goal Setting

Allow users to set personal goals within the app, such as managing daily stress or improving sleep. Personalized progress tracking and feedback can enhance motivation and sustain engagement over time.

Localized and Culturally Relevant Content

Incorporate content that resonates with the cultural background and life experiences of adolescents in Iraq, such as language options and culturally sensitive scenarios that foster user connection and comfort.

Incorporate Gamification Elements

Reward Systems and Badges

Introduce badges, points, or achievements for completing exercises, engaging regularly, or reaching personal milestones. A reward system can make engagement feel more rewarding and less clinical.

Interactive Challenges and Quests

Design challenges that encourage users to engage with the app routinely, such as completing daily mindfulness exercises or participating in weekly reflections. This can add a playful dimension to the app while reinforcing positive habits.

Social Sharing Features

Users can share their achievements with peers or within safe, moderated groups. Social elements can increase accountability, foster community, and provide an additional layer of engagement.

Streamline Navigation and Interface Design

Simplified User Flows

Minimize the steps required to reach core functionalities like exercises or mood tracking. Intuitive navigation should allow users to quickly locate and engage with tools, even if they only have a few minutes available.

Onboarding Tutorials

A brief, interactive onboarding process can familiarize new users with app functions, making it easier to navigate from the start. Offering short tutorials on new features introduced in updates can also enhance usability.

Improve Technical Stability

Offline Functionality

Given connectivity challenges, especially in rural areas, consider building offline capabilities for essential features, allowing users to complete exercises or track their mood without internet access.

Regular Testing and Updates

Frequent testing for bugs, usability issues, and prompt updates will improve overall stability and user satisfaction.

XSL•FO
RenderX

Conclusions

Overall, this study demonstrates that mobile CBT apps hold great promise for improving adolescent mental health, particularly in low-resource settings like Iraq. By addressing usability challenges, enhancing engagement through personalization and gamification, and overcoming barriers to usage, mobile CBT interventions can become more effective and accessible tools for young people. As digital health solutions continue to evolve, developers should prioritize user-centered, flexible designs that cater to the unique needs of adolescents in diverse cultural contexts. Future research should explore how to extend the long-term impact of these interventions, potentially through hybrid models that combine self-guided app use with professional support.

Acknowledgments

The authors thank the district health office and health facility staff for supporting and facilitating the data collection.

Authors' Contributions

RHI, MHY, MQH, SHAM, MFA and OAM conceived the study. RHI analyzed the data and wrote the first draft. All the authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

References

1. Nesi J. The impact of social media on youth mental health: challenges and opportunities. N C Med J 2020;81(2):116-121. [doi: 10.18043/ncm.81.2.116] [Medline: 32132255]
2. Bitsko RH, Claussen AH, Lichstein J, et al. Mental health surveillance among children—United States, 2013-2019. MMWR Suppl 2022 Feb 25;71(2):1-42. [doi: 10.15585/mmwr.su7102a1] [Medline: 35202359]
3. Aguirre Velasco A, Cruz ISS, Billings J, Jimenez M, Rowe S. What are the barriers, facilitators and interventions targeting help-seeking behaviours for common mental health problems in adolescents? A systematic review. BMC Psychiatry 2020 Jun 11;20(1):293. [doi: 10.1186/s12888-020-02659-0] [Medline: 32527236]
4. Horita H, Seki Y, Yamaguchi T, Shiko Y, Kawasaki Y, Shimizu E. Videoconference-delivered cognitive behavioral therapy for parents of adolescents with internet addiction: pilot randomized controlled trial. JMIR Pediatr Parent 2024 Oct 3;7:e60604. [doi: 10.2196/60604] [Medline: 39361415]
5. Aoki C, Romeo RD, Smith SS. Adolescence as a critical period for developmental plasticity. Brain Res 2017 Jan 1;1654(Pt B):85-86. [doi: 10.1016/j.brainres.2016.11.026] [Medline: 27955766]
6. Tohi M, Bay JL, Tu'akoi S, Vickers MH. The developmental origins of health and disease: adolescence as a critical lifecourse period to break the transgenerational cycle of NCDs—a narrative review. Int J Environ Res Public Health 2022 May 16;19(10):6024. [doi: 10.3390/ijerph19106024] [Medline: 35627561]
7. Carona C, Pereira M, Araújo-Pedrosa A, Canavarro MC, Fonseca A. The efficacy of be a mom, a web-based intervention to prevent postpartum depression: examining mechanisms of change in a randomized controlled trial. JMIR Ment Health 2023 Mar 17;10:e39253. [doi: 10.2196/39253] [Medline: 36930182]
8. Becker M, Correll CU. Suicidality in childhood and adolescence. Dtsch Arztebl Int 2020 Apr 10;117(15):261-267. [doi: 10.3238/arztebl.2020.0261] [Medline: 32449889]
9. Magson NR, Freeman JYA, Rapee RM, Richardson CE, Oar EL, Fardouly J. Risk and protective factors for prospective changes in adolescent mental health during the COVID-19 pandemic. J Youth Adolesc 2021 Jan;50(1):44-57. [doi: 10.1007/s10964-020-01332-9] [Medline: 33108542]
10. Nakao S, Nakagawa A, Oguchi Y, et al. Web-based cognitive behavioral therapy blended with face-to-face sessions for major depression: randomized controlled trial. J Med Internet Res 2018 Sep 21;20(9):e10743. [doi: 10.2196/10743] [Medline: 30249583]
11. VanHeerwaarden N, Ferguson G, Abi-Jaoude A, et al. The optimization of an eHealth solution (Thought Spot) with transition-aged youth in postsecondary settings: participatory design research. J Med Internet Res 2018 Mar 6;20(3):e79. [doi: 10.2196/jmir.8102] [Medline: 29510970]
12. Wiljer D, Abi-Jaoude A, Johnson A, et al. Enhancing self-efficacy for help-seeking among transition-aged youth in postsecondary settings with mental health and/or substance use concerns, using crowd-sourced online and mobile technologies: the Thought Spot protocol. JMIR Res Protoc 2016 Nov 4;5(4):e201. [doi: 10.2196/resprot.6446] [Medline: 27815232]
13. Kanoosh HM, Abbas AF, Kamal NN, Khadim ZM, Majeed DA, Algburi S. Image-based CAPTCHA recognition using deep learning models. Presented at: AICCONF '24: Proceedings of the Cognitive Models and Artificial Intelligence Conference; May 25-26, 2024; Istanbul, Turkey. [doi: 10.1145/3660853.3660927]
14. Mohsin SK, Abdul Kadeem SR, Sheel S, et al. Artificial intelligence-assisted pattern discovery for narrow domains of human activity using a heuristic-optimised approach. Presented at: 2024 International Conference on Smart Systems for

XSL•FO
RenderX

Electrical, Electronics, Communication and Computer Engineering (ICSSEECC); Jun 28-29, 2024; Coimbatore, India. [doi: 10.1109/ICSSEECC61126.2024.10649462]
15. Wiljer D, Shi J, Lo B, et al. Effects of a mobile and web app (Thought Spot) on mental health help-seeking among college and university students: randomized controlled trial. J Med Internet Res 2020 Oct 30;22(10):e20790. [doi: 10.2196/20790] [Medline: 33124984]
16. Almansour M, AlQurmalah SI, Abdul Razack HI. Motivational interviewing—an evidence-based, collaborative, goal-oriented communication approach in lifestyle medicine: a comprehensive review of the literature. J Taibah Univ Med Sci 2023 Oct;18(5):1170-1178. [doi: 10.1016/j.jtumed.2023.03.011] [Medline: 37206188]
17. Sato D, Sutoh C, Seki Y, Nagai E, Shimizu E. Treatment preferences for internet-based cognitive behavioral therapy for insomnia in Japan: online survey. JMIR Form Res 2019 May 15;3(2):e12635. [doi: 10.2196/12635] [Medline: 31094319]
18. Hammad AA, Ahmed SR, Abdul-Hussein MK, Ahmed MR, Majeed DA, Algburi S. Deep reinforcement learning for adaptive cyber defense in network security. Presented at: AICCONF '24: Proceedings of the Cognitive Models and Artificial Intelligence Conference; May 25-26, 2024; Istanbul, Turkey. [doi: 10.1145/3660853.3660930]
19. Abdulkareem SA, Ftaiet AA, Hameed W, et al. Application of machine learning classifiers for human health care monitoring system. Presented at: 2024 International Conference on Smart Systems for Electrical, Electronics, Communication and Computer Engineering (ICSSEECC); Jun 28-29, 2024; Coimbatore, India. [doi: 10.1109/ICSSEECC61126.2024.10649464]
20. Teeter BS, Kavookjian J. Telephone-based motivational interviewing for medication adherence: a systematic review. Transl Behav Med 2014 Dec;4(4):372-381. [doi: 10.1007/s13142-014-0270-3] [Medline: 25584086]
21. Reinauer C, Platzbecker AL, Viermann R, et al. Efficacy of motivational interviewing to improve utilization of mental health services among youths with chronic medical conditions: a cluster randomized clinical trial. JAMA Netw Open 2021 Oct 1;4(10):e2127622. [doi: 10.1001/jamanetworkopen.2021.27622] [Medline: 34596672]
22. Meyer B, Utter GL, Hillman C. A personalized, interactive, cognitive behavioral therapy-based digital therapeutic (MODIA) for adjunctive treatment of opioid use disorder: development study. JMIR Ment Health 2021 Oct 8;8(10):e31173. [doi: 10.2196/31173] [Medline: 34623309]
23. Stawarz K, Preist C, Tallon D, Wiles N, Coyle D. User experience of cognitive behavioral therapy apps for depression: an analysis of app functionality and user reviews. J Med Internet Res 2018 Jun 6;20(6):e10120. [doi: 10.2196/10120] [Medline: 29875087]
24. Naser ZL, Adile M, Hussain AK, et al. An enhanced digital technology to analyze the combined effect of artificial intelligence and big data analytics for multimedia information processing. Presented at: 2024 International Conference on Smart Systems for Electrical, Electronics, Communication and Computer Engineering (ICSSEECC); Jun 28-29, 2024; Coimbatore, India. [doi: 10.1109/ICSSEECC61126.2024.10649479]
25. Kip H, Keizer J, da Silva MC, Beerlage-de Jong N, Köhle N, Kelders SM. Methods for human-centered eHealth development: narrative scoping review. J Med Internet Res 2022 Jan 27;24(1):e31858. [doi: 10.2196/31858] [Medline: 35084359]
26. Wootton BM, Hunn A, Moody A, Lusk BR, Ranson VA, Felmingham KL. Accelerated outpatient individual cognitive behavioural therapy for social anxiety disorder: a preliminary pilot study. Behav Cogn Psychother 2018 Nov;46(6):690-705. [doi: 10.1017/S1352465818000267] [Medline: 29692291]
27. Peters L, Romano M, Byrow Y, et al. Motivational interviewing prior to cognitive behavioural treatment for social anxiety disorder: a randomised controlled trial. J Affect Disord 2019 Sep 1;256(70-8):70-78. [doi: 10.1016/j.jad.2019.05.042] [Medline: 31158718]
28. Cooper K, Chatters R, Kaltenthaler E, Wong R. Psychological and psychosocial interventions for cannabis cessation in adults: a systematic review short report. Health Technol Assess 2015 Jul;19(56):1-130. [doi: 10.3310/hta19560] [Medline: 26202542]
29. Wright JH, Mishkind M. Computer-assisted CBT and mobile apps for depression: assessment and integration into clinical care. Focus (Am Psychiatr Publ) 2020 Apr;18(2):162-168. [doi: 10.1176/appi.focus.20190044] [Medline: 33162853]
30. Hansen B, Eide TO, Reiråskag MA, Tjelle KA, Solem S, Hagen K. The Bergen 4-day treatment for social anxiety disorder: a pilot study. BMC Psychiatry 2024 Feb 21;24(1):145. [doi: 10.1186/s12888-024-05607-4] [Medline: 38383324]
31. Wright JH, Mishkind M, Eells TD, Chan SR. Computer-assisted cognitive-behavior therapy and mobile apps for depression and anxiety. Curr Psychiatry Rep 2019 Jun 27;21(7):31250242. [doi: 10.1007/s11920-019-1031-2] [Medline: 31250242]
32. Wims E, Titov N, Andrews G, Choi I. Clinician-assisted Internet-based treatment is effective for panic: a randomized controlled trial. Aust N Z J Psychiatry 2010 Jul;44(7):599-607. [doi: 10.3109/00048671003614171] [Medline: 20560847]
33. Ebert DD, Zarski AC, Christensen H, et al. Internet and computer-based cognitive behavioral therapy for anxiety and depression in youth: a meta-analysis of randomized controlled outcome trials. PLoS One 2015;10(3):e0119895. [doi: 10.1371/journal.pone.0119895] [Medline: 25786025]
34. Titov N, Dear BF, Schwencke G, et al. Transdiagnostic internet treatment for anxiety and depression: a randomised controlled trial. Behav Res Ther 2011 Aug;49(8):441-452. [doi: 10.1016/j.brat.2011.03.007] [Medline: 21679925]
35. Johnston L, Dear BF, Gandy M, et al. Exploring the efficacy and acceptability of Internet-delivered cognitive behavioural therapy for young adults with anxiety and depression: an open trial. Aust N Z J Psychiatry 2014 Sep;48(9):819-827. [doi: 10.1177/0004867414527524] [Medline: 24622977]

XSL•FO
RenderX

36. Eide TO, Hjelle KM, Sætre IU, et al. The Bergen 4-day treatment for panic disorder: implementation in a rural clinical setting. BMC Psychiatry 2023 May 1;23(1):305. [doi: 10.1186/s12888-023-04812-x] [Medline: 37127598]
37. Furukawa TA, Horikoshi M, Fujita H, et al. Cognitive and behavioral skills exercises completed by patients with major depression during smartphone cognitive behavioral therapy: secondary analysis of a randomized controlled trial. JMIR Ment Health 2018 Jan 11;5(1):e4. [doi: 10.2196/mental.9092] [Medline: 29326098]
38. Nakagami Y, Uwatoko T, Shimamoto T, et al. Long-term effects of internet-based cognitive behavioral therapy on depression prevention among university students: randomized controlled factorial trial. JMIR Ment Health 2024 Sep 24;11:e56691. [doi: 10.2196/56691] [Medline: 39319584]
39. Jones C, Miguel-Cruz A, Smith-MacDonald L, et al. Virtual trauma-focused therapy for military members, veterans, and public safety personnel with posttraumatic stress injury: systematic scoping review. JMIR Mhealth Uhealth 2020 Sep 21;8(9):e22079. [doi: 10.2196/22079] [Medline: 32955456]
40. Gautam K, Aguilar C, Paudel K, et al. Preferences for mHealth intervention to address mental health challenges among men who have sex with men in Nepal: qualitative study. JMIR Hum Factors 2024 Mar 29;11:e56002. [doi: 10.2196/56002] [Medline: 38551632]
41. Dumassais S, Grewal KS, Aubin G, O'Connell M, Phillips NA, Wittich W. Exploring the qualitative experiences of administering and participating in remote research via telephone using the Montreal Cognitive Assessment-Blind: cross-sectional study of older adults. JMIR Form Res 2024 Nov 15;8:e58537. [doi: 10.2196/58537] [Medline: 39546346]
42. Gao S, He L, Chen Y, Li D, Lai K. Public perception of artificial intelligence in medical care: content analysis of social media. J Med Internet Res 2020 Jul 13;22(7):e16649. [doi: 10.2196/16649] [Medline: 32673231]
43. Hamarash MQ, Ibrahim R, Yaas MH, Abdulghani MF, Al Mushhadany O. Comparative effectiveness of health communication strategies in nursing: a mixed methods study of internet, mHealth, and social media versus traditional methods. JMIR Nurs 2024 Nov 19;7:e55744. [doi: 10.2196/55744] [Medline: 39622705]
44. Zhang C, Liu Y, Guo X, Liu Y, Shen Y, Ma J. Digital cognitive behavioral therapy for insomnia using a smartphone application in China: a pilot randomized clinical trial. JAMA Netw Open 2023 Mar 1;6(3):e234866. [doi: 10.1001/jamanetworkopen.2023.4866] [Medline: 36972049]
45. Jakob R, Harperink S, Rudolf AM, et al. Factors Influencing Adherence to mHealth Apps for Prevention or Management of Noncommunicable Diseases: Systematic Review. J Med Internet Res 2022 May 25;24(5):e35371. [doi: 10.2196/35371] [Medline: 35612886]
46. Cheng P, Casement MD, Kalmbach DA, Castelan AC, Drake CL. Digital cognitive behavioral therapy for insomnia promotes later health resilience during the coronavirus disease 19 (COVID-19) pandemic. Sleep 2021 Apr 9;44(4):zsaa258. [doi: 10.1093/sleep/zsaa258] [Medline: 33249492]
47. Miller CB, Gu J, Henry AL, et al. Feasibility and efficacy of a digital CBT intervention for symptoms of generalized anxiety disorder: a randomized multiple-baseline study. J Behav Ther Exp Psychiatry 2021 Mar;70(101609):101609. [doi: 10.1016/j.jbtep.2020.101609] [Medline: 32950939]
48. Banneyer KN, Bonin L, Price K, Goodman WK, Storch EA. Cognitive behavioral therapy for childhood anxiety disorders: a review of recent advances. Curr Psychiatry Rep 2018 Jul 28;20(8):30056623. [doi: 10.1007/s11920-018-0924-9] [Medline: 30056623]
49. Ng TK, Wong DFK. The efficacy of cognitive behavioral therapy for Chinese people: a meta-analysis. Aust N Z J Psychiatry 2018 Jul;52(7):620-637. [doi: 10.1177/0004867417741555] [Medline: 29143541]
50. Silberg T, Kapil N, Caven I, Levac D, Fehlings D. Cognitive behavioral therapies for individuals with cerebral palsy: a scoping review. Dev Med Child Neurol 2023 Aug;65(8):1012-1028. [doi: 10.1111/dmcn.15507] [Medline: 36725690]
51. Patel SA, Vashist K, Jarhyan P, et al. A model for national assessment of barriers for implementing digital technology interventions to improve hypertension management in the public health care system in India. BMC Health Serv Res 2021 Oct 15;21(1):1101. [doi: 10.1186/s12913-021-06999-9] [Medline: 34654431]
52. Ghosh P, Proffitt R, Bosworth KT, et al. mHealth app features that facilitate adolescent use for lifestyle management, and are endorsed by caregivers and health care providers. Mhealth 2024;10(21):21. [doi: 10.21037/mhealth-24-3] [Medline: 39114461]
53. Oakley-Girvan I, Yunis R, Longmire M, Ouillon JS. What works best to engage participants in mobile app interventions and e-Health: a scoping review. Telemed J E Health 2022 Jun;28(6):768-780. [doi: 10.1089/tmj.2021.0176] [Medline: 34637651]
54. Gentry E, Nichele E, Azim T, et al. "I don't trust it, but I have to trust it": the paradox of trust vs use of online technology across the mental health spectrum. Open Science Framework. Preprint posted online on Oct 31, 2024. [doi: 10.31219/osf.io/n6rvx]

Abbreviations

CBT: cognitive behavioral therapy
mHealth: mobile health

XSL•FO
RenderX

Edited by S Badawy; submitted 03.10.24; peer-reviewed by H Mahmood, P Ghosh; revised version received 27.12.24; accepted 28.12.24; published 11.04.25.

Please cite as:
Ibrahim RH, Yaas MH, Hamarash MQ, Al-Mukhtar SH, Abdulghani MF, Al Mushhadany O
Adapting Cognitive Behavioral Therapy for Adolescents in Iraq via Mobile Apps: Qualitative Study of Usability and Outcomes
JMIR Pediatr Parent 2025;8:e67137
URL: https://pediatrics.jmir.org/2025/1/e67137
doi:10.2196/67137

© Radhwan Hussein Ibrahim, Marghoob Hussein Yaas, Mariwan Qadir Hamarash, Salwa Hazim Al-Mukhtar, Mohammed Faris Abdulghani, Osama Al Mushhadany. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 11.4.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

The Impact of Parental Support on Adherence to Therapist-Assisted Internet-Delivered Acceptance and Commitment Therapy in Primary Care for Adolescents With Anxiety: Naturalistic 12-Month Follow-Up Study

Anna Larsson[1,2], MS; Sandra Weineland[1,2,3], PhD; Linnea Nissling[1,2,3], PhD; Josefine L Lilja[1,2,3,4], PhD

[1]General Practice/Family Medicine, School of Public Health and Community Medicine, Institute of Medicine, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

[2]Research, Education, Development & Innovation, Primary Health Care, Region Västra Götaland, Borås, Sweden

[3]Department of Psychology, University of Gothenburg, Gothenburg, Sweden

[4]Department of Psychology, Faculty of Health and Life Sciences, Linnaeus University, Växjö, Sweden

Corresponding Author:
Anna Larsson, MS
Research, Education
Development & Innovation, Primary Health Care
Region Västra Götaland
FoU primär och nära vård Södra Älvsborg
Sven Eriksonsplatsen 4
Borås, 503 38
Sweden
Phone: 46 104359410
Email: psy.ac.larsson@gmail.com

Related Article:

This is a corrected version. See correction statement: https://www.jmir.org/2025/1/e82840

Abstract

Background: Mental health problems among adolescents are increasing, and internet-delivered acceptance and commitment therapy (iACT) constitutes a possible way to improve access to care while reducing costs. Nevertheless, few studies have investigated iACT for adolescents in regular primary care nor the role of parental support.

Objective: This is an exploratory evaluation investigating iACT, with or without parental support, for adolescents. The aims were to examine treatment adherence, symptoms of anxiety and depression, psychological flexibility, and overall functioning.

Methods: Adolescents with anxiety were recruited within the regular primary care patient flow during the implementation phase of therapist-assisted iACT for adolescents. Assessment and inclusion were executed face-to-face. Due to organizational reasons, the assignment of treatment methods could not be randomized. Adherence was investigated by measuring the number of completed modules. Outcome measures were collected by self-assessment questionnaires including the Revised Children's Anxiety and Depression Scale and Avoidance and Fusion Questionnaire for Youth, as well as interviews using the Children's Global Assessment Scale. The analysis was performed as an exploratory evaluation using descriptive data for treatment adherence and nonparametric within-group analysis with the Wilcoxon signed rank test for related samples and treatment outcomes. This evaluation is naturalistic, and the results are preliminary and of a hypothesis-generating character and should be handled with caution.

Results: The iACT group without parental support (n=9) exhibited a gradual dropout throughout the treatment period (n=5), whereas the iACT group with parental support (n=15) exhibited the lowest number of dropouts from treatment before completion (n=2), of which all occurred during the second half of treatment. The within-group, per-protocol analyses for the Revised Children's Anxiety and Depression Scale indicated reduced symptoms of anxiety and depression at the 12-month follow-up (z score: –2.94; P=.003; r=–0.6). The within-group, per-protocol analyses for the Avoidance and Fusion Questionnaire for Youth indicated

XSL•FO
RenderX

increased psychological flexibility at the 12-month follow-up (*z* score: –2.54; *P*=.01; *r*=0.55). Nevertheless, no differences in overall functioning measured by the Children's Global Assessment Scale were found.

Conclusions: The results indicate that parental support might play a role in treatment adherence in iACT for adolescents with anxiety. Moreover, the outcome measures suggest that iACT for adolescents in primary care could constitute an effective treatment for both anxiety and depression, as indicated by the symptom reduction and increased psychological flexibility, maintained at the 12-month follow-up. Nevertheless, due to a small and gender-biased sample size with a large proportion of dropouts and missing data, a nonrandomized assignment of intervention, and an analysis limited to within group, this study should be considered an explorative evaluation rather than an outcome study.

(JMIR Pediatr Parent 2025;8:e59489) doi:10.2196/59489

KEYWORDS

adolescents; parental support; anxiety; depression; primary care; mental health; ACT; acceptance and commitment therapy; iACT; internet-delivered acceptance and commitment therapy

Introduction

According to the National Board of Health and Welfare in Sweden, mental health among children and young people has deteriorated, both based on self-reported psychological symptoms and on diagnosed mental disorders [1]. Anxiety and depression have been identified as significant factors, of which anxiety is the most common [2]. Furthermore, both anxiety and depression are associated with social withdrawal, adverse effects on academic performance, functional impairment, and ultimately, risk factors for suicide [3,4]. For adolescents with generalized anxiety disorder (GAD), separation anxiety disorder, and social phobia, the selective serotonin reuptake inhibitor Sertraline, as well as cognitive behavioral therapy (CBT), are the recommended treatment methods [1]. According to the Swedish National Board of Health and Welfare, CBT is well documented, recommended as a first intervention [5], and considered an effective treatment for anxiety disorders in children and adolescents [6].

In Sweden, primary care services include performing an initial assessment on children and adolescents regarding symptoms, symptom severity, and eventual need for treatment. If an anxiety disorder is assessed to be mild, an intervention shall be offered, and if moderate to severe, the patient shall be triaged to psychiatric care [5]. Furthermore, early intervention is crucial in preventing chronic mental illness [7], but many adolescents do not seek help from mental health care. O'Dea et al [8] have identified a lack of awareness among the population of signs of mental ill health, limited access to health care, and costs as possible obstacles. The authors suggest internet-based CBT (iCBT) as a way of increasing accessibility to treatment while reducing costs and that iCBT exhibits similar effect sizes as face-to-face treatment.

In a systematic review and meta-analysis, Vigerland et al [9] evaluated 25 studies on iCBT, including only studies in which the mean participant age was younger than 18 years. Of the studies, 7 studies were based on a Swedish population and 6 studies were on anxiety. The authors concluded that iCBT has positive outcomes, may be feasible, and exhibited moderate effect sizes compared to the waitlist. In a Danish randomized controlled trial (RCT), 70 adolescents with anxiety disorders were randomized into either iCBT or waitlist, and the iCBT group exhibited significant improvement based on both adolescent and parent ratings and that iCBT exhibited moderate to large effect sizes between groups [10]. Moreover, in an Australian RCT, 115 adolescents with anxiety from a community sample were randomized to either iCBT, face-to-face CBT, or waitlist conditions. At the 12-month follow-up, the authors found no significant differences regarding treatment outcomes between the groups and concluded that iCBT offers reduced therapist time and hence increased accessibility [11]. In a Swedish study, 120 adolescents were randomized to either standard iCBT, iCBT with learning support, iCBT with chat, or iCBT with learning support and chat. The group with learning support initially exhibited better outcomes but the difference was not sustained at the 6-month follow-up, and the authors determined iCBT to be an effective treatment method for adolescents with anxiety and depression. The authors found small effect sized on secondary outcomes related to anxiety and that the effect sized indicated the benefits of memory support during iCBT [12]. Nevertheless, in all the abovementioned studies, the participants were recruited either via advertisements or referral to secondary care. Thus, none of the studies were conducted in regular primary care.

Acceptance and commitment therapy (ACT) is a third-wave behavioral therapy oriented at acceptance and mindfulness and aimed at increasing psychological flexibility, defined as the ability to be present and act accordingly in line with one's values [13]. Face-to-face ACT is considered an effective treatment for children and adolescents with anxiety disorders [14,15] and exhibits small to medium effect sizes regarding anxiety and depression [16]. In a Swedish study, Nissling et al [17] investigated the effectiveness of internet-delivered ACT (iACT) on adolescents with anxiety by randomizing 52 participants aged 15-19 years from all over Sweden into either iACT or waitlist. Both groups improved but the participants in the intervention group exhibited significantly higher improvements regarding anxiety and exhibited moderate effect sizes between groups. The authors concluded that iACT is effective in improving quality of life and psychological flexibility, which in turn was associated with reduced anxiety symptoms. Another study randomized 348 adolescents to either (1) iACT student coach and a digital coach group, (2) only iACT digital coach group, or (3) no intervention. The authors found significant improvements in the iACT groups compared to the control

XSL•FO
RenderX

group regarding reduced anxiety and increased valued action and self-compassion [18].

Few studies have examined iACT for adolescents in a routine primary care setting. To broaden the understanding of iACT in primary care for adolescents with anxiety, the Internet Mediated Psychological Treatment-Acceptance and Commitment Therapy (IMPACT) project was conducted as an ongoing evaluation during the implementation of iACT for adolescents in the region Västra Götaland in southwestern Sweden. The intervention in focus is the same as that in the study by Nissling et al [17] and contains ACT features [19].

In the first IMPACT paper, the authors highlighted the importance of parental involvement in iACT for adolescents, suggesting it might compensate for low treatment motivation [20]. In the second IMPACT paper, the authors concluded that the role of the parents needs clarification [21]. Attention to parental engagement in mental health treatments of adolescents has increased in recent years, and in 2015, a review of 23 papers was conducted by Haine-Schlagel and Walsh [22]. The results indicated potential links between parental participation and positive outcomes. The authors concluded that further research is needed to determine treatment factors, as well as organizational factors, regarding parental engagement in mental health treatment for both children and families. Moreover, Lundkvist-Houndoumadi et al [23] performed a phenomenological analysis of 24 semistructured interviews with Danish families in which the youth received CBT for anxiety with parental involvement. The authors concluded that the therapists' expectations of the parents to be cotherapists were difficult to implement in some cases due to the family dynamics and the expectations and resources among the parents. Overall, there seems to be a need for further information regarding the parental role in iCBT and iACT for adolescents and how the parents can support the adolescent's treatment. Haine-Schagel and Walsh [22] have concluded that research regarding parental engagement would benefit from more studies on specific parent-supportive behaviors in clinical interactions [22].

In summary, few studies have investigated iACT for adolescents in a routine primary care setting nor the role of the parents. Therefore, the IMPACT project aimed to conduct an ongoing evaluation of introducing iACT for adolescents with anxiety in primary care. This is the third part of the IMPACT project and is aimed at conducting a follow-up 12 months after receiving iACT with or without parental support. The primary outcomes consist of treatment adherence and symptoms of anxiety and depression, and the secondary outcomes consist of psychological flexibility and overall functioning in adolescents. Thus, the aims of this evaluation can be concretized as follows:

1. Is there a connection between parental support and adherence to iACT for adolescents with anxiety?
2. Does iACT for adolescents with anxiety result in decreased symptoms of anxiety and depression between pretreatment and 12 months after terminating treatment?
3. Does iACT for adolescents with anxiety result in increased psychological flexibility between pretreatment and 12 months after terminating treatment?
4. Does iACT for adolescents with anxiety result in improved overall functioning between pretreatment and 12 months after terminating treatment?

Methods

In this section, the study design, participants, procedure, intervention, measures, data analysis, and ethical considerations are presented.

Study Design

Initially, the intention was to perform a follow-up of iACT during the implementation phase in primary care and to conduct between-group analyses. However, due to organizational limitations, the authors instead opted for a pragmatic approach to the data. Consequently, the analysis was converted into an exploratory evaluation of iACT for adolescents with anxiety in primary care.

The IMPACT project was conducted within the regular patient flow during the implementation phase and due to organizational reasons, randomization of the participants could not be made. Using a non-RCT, the therapists assigned the participants to either iACT with or without parental support or treatment as usual (TAU), consisting of face-to-face treatment for anxiety individually or in a group format. Therefore, the authors had limited insight into the assignment process. Therefore, this study is naturalistic and the results are preliminary and of a hypothesis-generating character.

Quantitative data were collected before, during, and after treatment, and follow-ups were performed 6 and 12 months after terminating treatment. In this evaluation, pretreatment and the 12-month follow-up are being compared. Due to difficulties in recruiting therapists, the sample size is relatively small, which further decreases the quality of the data, furthermore, the amount of missing data is relatively large.

No a priori power analysis was conducted, so between-group analyses could not be made. Therefore, the TAU group is not included in this evaluation, adherence measures are analyzed using descriptive data, and outcome measures are analyzed using within-group analyses. Therefore, the results are treated as an explorative evaluation of iACT in practice rather than a scientific study.

Participants

The participants were recruited from adolescents seeking help in primary care for anxiety symptoms at 3 different health care centers located in southwestern Sweden and specialized in treating adolescents with mental health issues. Previously, there was no iACT program for young people in Sweden, and the treatment program was developed and adapted for the 13-18 years age group, hence the age group that was studied. The inclusion criteria consisted of being aged 13-18 years; having access to a computer, iPad, or smartphone with internet access; being able to read and write in Swedish; and having been diagnosed with mild to moderate anxiety such as GAD, social phobia, panic disorder, or unspecified anxiety disorder. The exclusion criteria consisted of having a neuropsychiatric diagnosis, intellectual disability, bipolar disease, suicidality, or

XSL•FO
RenderX

ongoing psychotherapeutic treatment or daily consumption of benzodiazepines.

This evaluation originally included 35 participants aged 13-18 years. Of these participants, 9 participants received iACT without parental support; 15 participants received iACT with parental support; and 11 participants received TAU, of which, 8 participants received group therapy and 3 participants received individual therapy. Besides providing iACT, 2 of the health care centers involved in the study only provided group therapy, whereas the third only provided individual therapy. Since no power analysis was performed before the data collection, comparisons between groups could not be made, hence the TAU group was excluded from this evaluation. Table 1 demonstrates the distribution of age and gender among the participants.

Table 1. The distribution of age and gender among the participants.

Variable	Frequencies		
	iACT[a] without parental support (n=9)	iACT with parental support (n=15)	TAU[b] (n=11)
Age group (years), n (%)			
13-15	8 (89)	10 (67)	9 (82)
16-18	1 (11)	5 (33)	2 (18)
Sex, n (%)			
Female	8 (89)	15 (100)	10 (91)
Male	1 (11)	0 (0)	1 (9)
Other	0 (0)	0 (0)	0 (0)

[a]iACT: internet-delivered acceptance and commitment therapy.

[b]TAU: treatment as usual.

Procedure

Patients aged 13-18 years, accompanied by a parent, seeking help in primary care for anxiety problems were informed about the study and were offered participation by the therapist. All the adolescents included provided verbal consent and the parents provided written consent prior to participation. The patient and the parent participated in an assessment and inclusion meeting conducted by a participating therapist. The parent was subsequently led to another room to fill in a questionnaire whereas the adolescent was interviewed further.

After the assessment, all the participants who met the inclusion criteria were assigned by the therapist to either iACT, with or without parental support, or TAU. The assignment of groups was not randomized, and the authors have no information on how many patients were excluded from the study by the therapists nor how the therapists assigned the patients into groups.

Furthermore, the participating adolescents completed questionnaires before, during, and after treatment, as well as 6 and 12 months after treatment termination, and participated in diagnostic clinical interviews before and after treatment, as well as 12 months after treatment. To ensure the integrity of the adolescents and data security, the forms were distributed via the survey platform Esmaker [24], if possible, and otherwise in paper format. The paper forms and interview protocols were also added to a research journal to collect additional data such as other ongoing treatments.

The recruitment process took place from 2018 to 2020, hence parts of the data collection coincided with the COVID-19 pandemic, during which some upper secondary schools in Sweden introduced distance learning for periods of time while other schools did not [25]. It is possible that the pandemic affected the number of participants in the study. Furthermore, due to the difficulty of recruiting therapists, the number of participants in the study is relatively low. Despite the low number of participants, the recruitment was terminated due to financial reasons.

Intervention

In this study, the participants were recruited from 3 health care centers that were specialized in adolescent mental health and located in southwestern Sweden: Gothenburg, Borås, and Uddevalla. These centers form a part of primary care and are specialized in helping patients aged 6-18 years. The therapists in this study were either licensed psychologists or intern psychologists, and as a part of implementing iACT at these centers, they participated in a 2-day course and received specific training in iACT for adolescents.

iACT Without Parental Support

These participants received a guided, internet-based, self-help program called Anxiety Help for Adolescents (in Swedish: Ångesthjälpen Ung) developed by Psykologpartners W&W AB. The program is adapted for patients aged 13-19 years with mild to moderate anxiety, for example, social phobia, GAD, panic disorder, obsessive-compulsive disorder, or unspecified anxiety disorder [19].

The iACT intervention consists of 8 modules and the recommended treatment duration is 10 weeks with weekly feedback from the therapist. The program is adapted to the target group of adolescents regarding formulations, concretizations of theoretical concepts, and clinical examples, as well as the overall structure, and presents different strategies through text, videos, exercises, and forms. There is a messaging function in which the therapist and the patient can communicate asynchronously, and the therapist can initiate conversations

XSL•FO
RenderX

through telephone, video calls, or physical meetings at the clinic. The therapist supports the patient through motivation, giving feedback, answering questions, and prompting upcoming parts of the program [19]. For a detailed list of contents of the iACT intervention, see Multimedia Appendix 1.

iACT With Parental Support

These participants were assigned to the iACT program described above, with the addition of receiving parental support on how to support their adolescent's anxiety regulation. Both the participants and parents were initially given information about the content and structure of the iACT program [19]. Subsequently, the parents took part in 3 physical meetings during their adolescent's treatment period, either individually or in groups, and were conducted with the help of a manual (Multimedia Appendix 2). The content included psychoeducation about anxiety and different reactions, examples of different anxiety disorders, and behavioral strategies to handle anxiety such as exposure, relaxation, breathing, balance activity, and rest. All the information was condensed into a pamphlet called More Than Afraid (in Swedish: Mer än rädd) [26].

TAU Group

The participants in the TAU group received the treatment they would normally be offered at the clinics, consisting of face-to-face treatment for anxiety individually or in a group format, both 8 weeks long, as conventional in clinical settings. The TAU group is not included in this evaluation since the groups could not be compared.

Measures

The adolescent filled in the following forms before, during, and after treatment, as well as 6 and 12 months after treatment:

- Revised Children's Anxiety and Depression Scale (RCADS-Children, 47 items), consisting of the 2 main scales, anxiety and depression, and the 6 subscales, social phobia, panic disorder, GAD, compulsive disorder, separation anxiety, and depression, on which higher scores indicate a higher number of symptoms. The subscales exhibit a high internal consistency (α=.78-.88) in a sample of 513 children in the United States [27,28].
- Avoidance and Fusion Questionnaire Youth (AFQ-Y8), designed to measure the level of psychological flexibility in youth aged 12-20 years: higher scores indicate higher levels of psychological inflexibility. In a Swedish sample of 62 children undergoing cancer treatment, AFQ-Y8 exhibited acceptable internal consistency (α=.76), good test-retest reliability (ICC=0.64), and convergent validity (r=0.42) [29].

Furthermore, the adolescent was interviewed before and after treatment and 12 months after completion. The assessments were performed by a psychologist or intern psychologist using the following measures:

- The Mini International Neuropsychiatric Interview for Children and Adolescents was used for diagnostics [30] and exhibits validity and test-retest reliability comparable to other standardized screening tools [31,32].
- The Children's Global Assessment Scale (CGAS) was used to assess overall functioning. The interviewer performs an assessment of the adolescent's level of functioning on a scale from 1 to 100, of which a higher score indicates a higher level of functioning [33]. CGAS exhibits high interrater and test-retest reliability, as well as high discriminant and concurrent validity [34-36].

Data Analysis

This study aimed to investigate whether there is a connection between parental support and adherence to iACT for adolescents with anxiety and whether the treatment results in differences in symptoms of anxiety and depression, psychological flexibility, and overall functioning at 12 months after terminating treatment.

Due to a nonrandomized design, a small sample, a large dropout, and the fact that no a priori power analysis was made, the data are nonparametric, which makes between-group comparisons less meaningful. Therefore, the TAU group (n=11) is not included in this evaluation. Adherence was analyzed using descriptive data and Meier-Kaplan survival analysis, a statistical method used for measuring the distribution of time of occurrences in cohort groups [37]. In this study, dropout is defined as terminating the iACT program before the last module. Participants with missing time-to-event data were excluded from the Kaplan-Meier analysis. Meanwhile, the outcome measures were analyzed using within-group comparisons.

Adherence was analyzed for all participants receiving iACT without parental support (n=9) and with parental support (n=15), presented in separate groups. In contrast, for the outcome measures, all participants receiving iACT are presented as 1 group, including both with and without parental support due to small groups. In the outcome measures, the pretreatment measurement and the 12-month follow-up were compared and only included participants completing both the premeasurement and the 12-month follow-up.

For the outcome measures, patient-rated scores using RCADS and AFQ-Y8, as well as therapist-rated scores using CGAS and within-group analyses were performed using the nonparametric statistical method Wilcoxon signed rank test for related samples. Effect sizes were calculated based on the formula described by Field [38] and were interpreted as 0.10-<0.3 (small effect), 0.30-<0.5 (moderate effect), and ≥0.5 (large effect). The within-group analyses were performed in SPSS Statistics (version 29; IBM Corp).

Ethical Considerations

This evaluation constitutes a part of the research project IMPACT in 2017-2021 (Swedish National Research Register; ID: 240221), approved by the Regional Ethics Committee in Gothenburg (Dnr: 703-17). The IMPACT project was designed to conduct an ongoing evaluation of introducing iACT for adolescents with anxiety in primary care during the implementation phase, and this evaluation is a 12-month follow-up. The participants have been informed that their participation is voluntary and that they have the right to cancel without further explanation. Moreover, the participants have been informed that participation in the study will not in any way affect their future opportunities for care and treatment at

XSL•FO
RenderX

the health center and that participation in the study will not be mentioned in medical records. Both accessing care and participating in the study were free. Furthermore, the participants have been informed about how the data will be managed, including confidentiality aspects, as well as analysis and presentation. The confidentiality of all participants is thus guaranteed, and consent from all participants has been obtained including both adolescents and parents. Digital forms were collected using the survey platform Esmaker [24], and data were analyzed using SPSS Statistics.

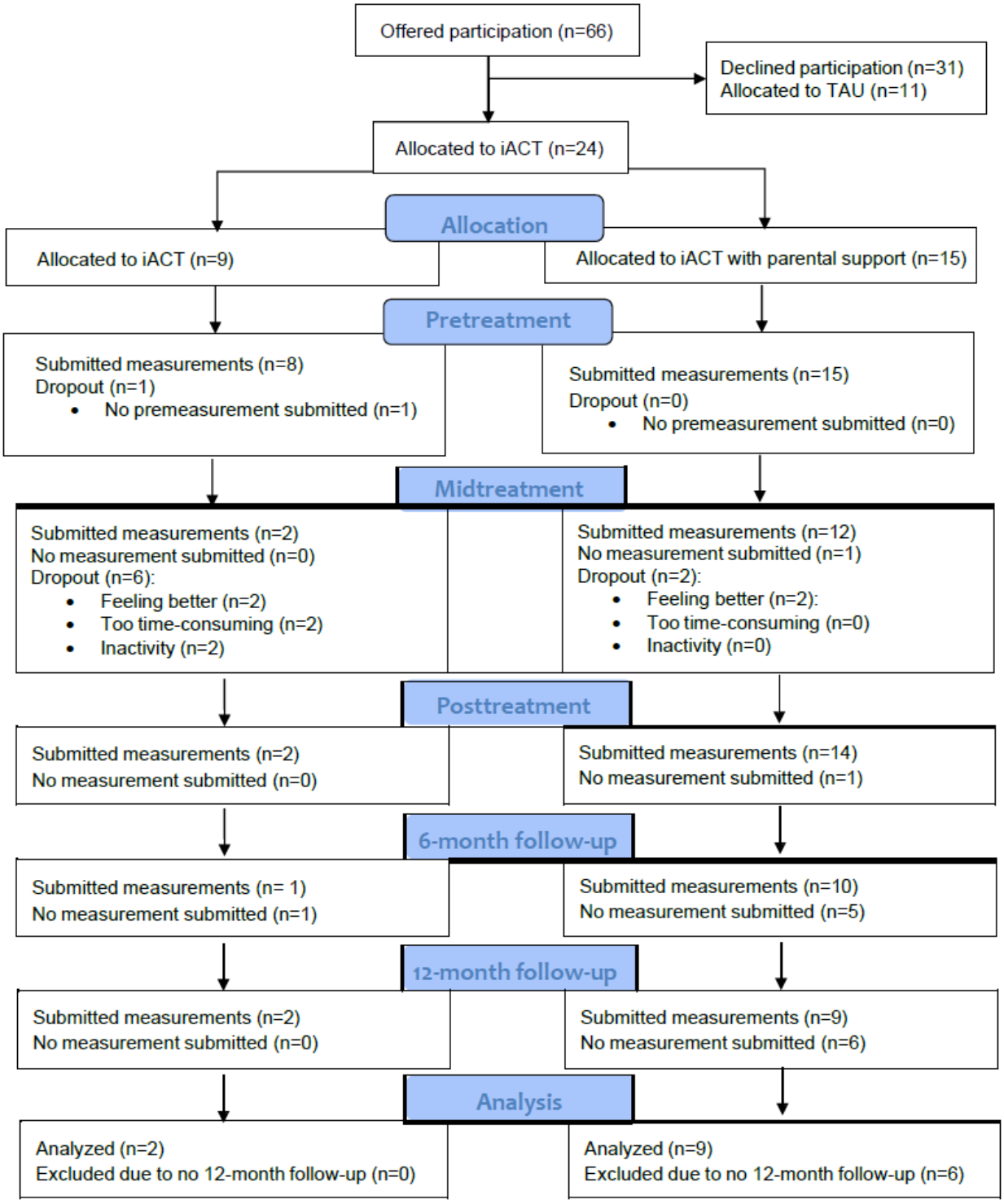
Results

Overview

In this section, the results are presented regarding treatment adherence and outcome measures based on the questions of the aims. Adherence is presented for all participants (n=35), and the participants receiving iACT are presented in 2 separate groups: iACT without parental support and iACT with parental support. The outcome measures are presented for the participants who completed the assessments for both the pretreatment and the 12-month follow-up (n=11). Moreover, the iACT participants are presented as 1 group, regardless of whether they have received parental support or not. Below, the primary outcomes are presented. Figure 1 demonstrates a CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the study.

XSL•FO
RenderX

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) Flow diagram of internet-delivered Acceptance and Commitment Therapy (iACT) and treatment as usual (TAU).



Is There a Connection Between Parental Support and Adherence to iACT for Adolescents With Anxiety?

For the analyses regarding adherence to treatment, the participants were presented in 2 groups: iACT without parental support (n=9) and iACT with parental support (n=15). Table 2 demonstrates descriptive statistics for the number of completed modules or sessions at the time of terminating the program.

XSL•FO
RenderX

Table 2. Descriptive statistics for the number of completed modules.

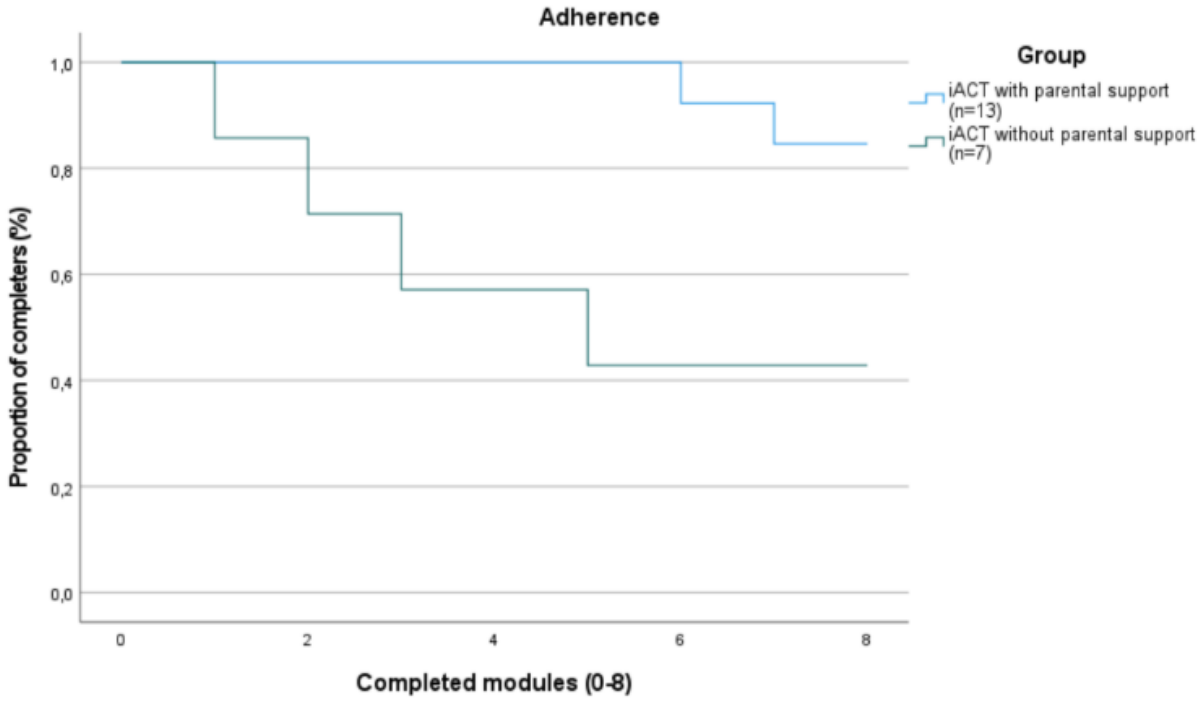
Completed modules or sessions(%)	iACT[a] without parental support (n=9), n (%)	iACT with parental support (n=15), n (%)
<25	1 (11)	0 (0)
25-50	2 (22)	0 (0)
50-75	1 (11)	1 (7)
75-100	3 (33)	12 (80)
Missing	2 (22)	2 (13)

[a]iACT: internet-delivered acceptance and commitment therapy.

The participants receiving iACT without parental support (n=9) exhibited a gradual dropout rate throughout treatment, of which 5 participants dropped out before treatment completion. In contrast, the participants receiving iACT with parental support (n=15) exhibited the least number of dropouts (n=2), of which all occurred during the second half of the treatment.

Figure 2 demonstrates a Meier-Kaplan graph illustrating the dropouts. The x-axis represents at which module the dropout occurred, with 0 indicating dropout before initiating treatment and 8 representing complete treatment. The y-axis represents the percentage of participants remaining in treatment.

Figure 2. Proportion of dropouts between groups of internet-delivered Acceptance and Commitment Therapy (iACT) with or without parental support.



Does iACT for Adolescents With Anxiety Result in Decreased Symptoms of Anxiety and Depression Between Pretreatment and 12 Months After Terminating Treatment?

In this section, the results of the patient-rated RCADS scores are analyzed for all participants completing both the premeasurement and the 12-month follow-up (n=11). In this section, the participants receiving iACT are in the same group, regardless of whether they have received parental support or not. Table 3 demonstrates descriptive statistics for the therapist-rated measurement points on RCADS.

XSL•FO
RenderX

Table 3. Descriptive statistics for the measurement points on RCADS[a].

iACT[b] (n=11)	Score, mean (SD)	Score, median (IQR)	Score, range
RCADS			
Pretreatment	71.7 (17.5)	70 (65-86)	41-104
Posttreatment	52.9 (22.3)	52 (38-71)	25-98
6-month follow-up	47.1 (26.9)	40 (27-63)	13-104
12-month follow-up	49.3 (25.4)	44 (32-63)	18-111
RCADS—Anxiety			
Pretreatment	58.6 (14.1)	58 (52-71)	33-84
Posttreatment	42.9 (17.9)	42 (32-53)	21-83
6-month follow-up	38.5 (22.4)	30 (22-46)	12-87
12-month follow-up	39.4 (19.8)	39 (24-49)	15-88
RCADS—Depression			
Pretreatment	13.1 (4.4)	14 (8-17)	6-20
Posttreatment	10.0 (5.4)	10 (5-16)	3-18
6-month follow-up	8.5 (5.3)	9 (4-12)	1-17
12-month follow-up	9.8 (6.2)	8 (5-14)	3-23

[a]RCADS: Revised Children's Anxiety and Depression Scale.

[b]iACT: internet-delivered acceptance and commitment therapy.

The results from the Wilcoxon signed rank test for related samples for the RCADS total scores demonstrated a decrease in symptoms of anxiety and depression and a large effect size for the RCADS total scores from preassessment to the 12-month follow-up (*z* score: –2.81; *P*=.005; *r*=0.60). When analyzing anxiety and depression scores separately by subscales, reductions between the pretreatment assessment to the 12-month follow-up assessment for both anxiety (*z* score: –2.81; *P*=.005; *r*=0.60) and depression (*z* score: –2.67; *P*=.008; *r*=0.57) and large effect sizes were obtained. Below, the secondary outcomes are presented.

Does iACT for Adolescents With Anxiety Result in Increased Psychological Flexibility Between Pretreatment and 12 Months After Terminating Treatment?

In this section, the results of the patient-rated AFQ-Y8 scores are analyzed, indicating the adolescent's self-rated levels of psychological flexibility. In this section, the participants receiving iACT are presented in the same group, regardless of whether they have received parental support or not. Table 4 demonstrates descriptive statistics for the therapist-rated measurement points on AFQ-Y8 and CGAS.

Table 4. Descriptive statistics for the measurement points on AFQ-Y8[a] and CGAS[b].

iACT[c] (n=11)	Score, mean (SD)	Score, median (IQR)	Score, range
AFQ-Y8			
Pretreatment	18.8 (5.8)	21 (12-22)	11-30
Posttreatment	14.9 (7.7)	13 (10-20)	3-30
6-month follow-up	12.3 (7.6)	11 (7-17)	3-27
12-month follow-up	12.7 (6.7)	11 (8-17)	5-29
CGAS			
Pretreatment	64.1 (5.8)	65 (60-65)	55-75
Posttreatment	72.7 (13.3)	75 (55-85)	55-90
12-month follow-up	70.0 (14.3)	70 (55-85)	45-85

[a]AFQ-Y8: Avoidance and Fusion Questionnaire for Youth.

[b]CGAS: Children's Global Assessment Scale.

[c]iACT: internet-delivered acceptance and commitment therapy.

XSL•FO
RenderX

The results from the Wilcoxon signed rank test for related samples for the AFQ-Y8 demonstrated increased psychological flexibility from preassessment to the 12-month follow-up (*z* score: –2.54; *P*=.01; *r*=0.55).

Does iACT for Adolescents With Anxiety Result in Improved Overall Functioning Between Pretreatment and 12 Months After Terminating Treatment?

In this section, the results of the therapist-rated CGAS scores are presented. The results from the Wilcoxon signed rank test on the CGAS total scores indicated no difference between measurement points from pretreatment to the 12-month follow-up for the iACT group (*z* score: –0.51; *P*=.96; *r*=0.146).

Discussion

Overview

This evaluation aimed to investigate whether there is a connection between parental support and adherence to iACT for adolescents with anxiety and whether iACT for adolescents with anxiety results in a difference in symptoms of anxiety and depression, psychological flexibility, and overall functioning, between the pretreatment measurement and 12 months after terminating treatment. In this section, the principal findings, limitations, and implications will be discussed in contrast to other studies. Overall, the results must be handled with caution due to the nonrandomized design, small sample size, and large amount of missing data.

Principal Findings

Overview

The IMPACT project was conducted as an ongoing evaluation to broaden the understanding of iACT for adolescents with anxiety in a routine primary care setting during the implementation phase. In the first IMPACT paper, Weineland et al [20] concluded that the interviewed therapists were positive to iACT for adolescents but also identified challenges such as motivating patients. In the second paper, Lilja et al [21] found that the interviewed parents expressed uncertainty about their role in the treatment and clearer parental treatment support was suggested. This is the third part of the IMPACT project, consisting of a follow-up on adolescents with anxiety 12 months after receiving iACT, with or without parental support regarding treatment adherence, symptoms of anxiety and depression, and psychological flexibility, as well as overall functioning. The primary outcomes are discussed below.

Is There a Connection Between Parental Support and Adherence to iACT for Adolescents With Anxiety?

Regarding treatment adherence, the participants receiving iACT with parental support exhibited later and fewer dropouts than the participants receiving iACT without parental support. These findings might be due to the idea suggested by Weineland et al [20] that parental support could compensate for low treatment motivation among adolescents. However, due to the nonrandomized design and small sample size in this, further research is needed to test this hypothesis in RCTs and with larger samples. Other potential mediating effects could be giving the parents a deeper understanding of anxiety in both themselves and the adolescent, as well as how to support their adolescent and function as a cotherapist alongside the therapist. In addition, in each group, 2 participants discontinued treatment due to feeling better, indicating that dropouts from treatment are not necessarily negative.

In previous research, the authors have pointed to potential connections between parental support and positive treatment outcomes in children and families [22], including that some parents need support in their role as cotherapists in treatment [23]. The current research on the role of motivation in iACT for adolescents with anxiety is currently limited. Nevertheless, in a Norwegian study, Fjermestad et al [39] concluded that motivation predicts early alliance in CBT for youth with anxiety. Furthermore, in a Danish study by Stjerneklar et al [10], both the parents and the therapists were encouraged to help motivate the adolescent in their iCBT, in which iCBT exhibited moderate to large effect sizes between groups on anxiety compared to the waitlist.

Furthermore, iACT with parental support can be considered a complex intervention, which can be defined as an intervention consisting of multiple components. Complex interventions cause challenges in the development and identification [40] and Hasson and von Thiele Schwartz [41] claim that complex interventions tend to be at a disadvantage in research due to the difficulty in isolating them from the context. The authors argue that this applies to a large amount of psychological treatment methods, compared to medical treatments.

Does iACT for Adolescents With Anxiety Result in Decreased Symptoms of Anxiety and Depression Between Pretreatment and 12 Months After Terminating Treatment?

Outcome measures were investigated using a within-group analysis, in which the iACT-group demonstrated reduced symptoms of anxiety and depression between the preassessment and 12-month follow-up. Multiple previous studies have indicated positive treatment outcomes for iACT for adolescents with anxiety [9-12], but few have performed follow-ups at 12 months after treatment or longer. In the meta-analysis by Vigerland et al [9], of the papers on iACT for children and adolescents with anxiety, 2 papers had a 1-year follow-up: Spence et al [11] concluded that the improvements in both CBT and iACT were maintained at the 12-month follow-up and Tillfors et al [42] discovered significant improvements in iACT for high school students with anxiety disorder, maintained at the 12-month follow-up. Nevertheless, none of the studies included follow-ups more than 1 year after treatment, hence the long-term effects of iACT for adolescents with anxiety should be investigated further.

In this evaluation, in 2 of the cases, the results of Mini International Neuropsychiatric Interview for Children and Adolescents and CGAS exhibited an increase in symptoms and a decrease in functioning between the post and 12-month follow-up. Therefore, the interviewer had the impression that the COVID-19 pandemic influenced the results. In both cases, of which 1 participant from the iACT group and 1 from the

XSL•FO
RenderX

TAU group, the participant was diagnosed with social phobia at the 12-month follow-up and described that at least some of the symptoms were due to returning from distance to classroom learning. In addition, the authors suspect that the pandemic itself could have affected the anxiety levels and functioning of the participants, for example, fear of the disease itself or uncertainty about the future.

In a Swedish study, the authors surveyed 1818 adolescents, of which approximately 80% transferred to distance learning during the pandemic. The authors concluded that most of the participants experienced decreased mental health, especially female participants and those in distance learning. The authors also discovered that distance learning could result in less victimization and poorer mental health overall [43]. In another Swedish study, 3068 participants aged 16-17 years filled in a questionnaire about the impact of the COVID-19 pandemic from December 2020 to March 2021. The author concluded that female participants reported more worry than male participants and that participants with a lower socioeconomic background reported higher levels of worry in general, except for climate anxiety [44].

In an international systematic review and meta-analysis of 74 papers on anxiety among children and adolescents during the pandemic, the authors concluded that anxiety levels were more prevalent among female participants than male participants in North America and Europe than South America and Asia, during the second wave of COVID-19 and school closures [45]. A Finnish study surveyed 450,000 participants aged 13-20 years about the pandemic. The authors discovered that social anxiety increased from 2013 to 2021, especially among the female participants, and that unmet needs for schoolwork support, and fear of getting infected by COVID-19 or transmitting it to others were associated with high levels of social anxiety. Nevertheless, the authors observed no clear connection between time spent in distance learning and levels of social anxiety [46].

Furthermore, in an American study, 280 high schoolers were surveyed on social anxiety and the use of technology. The author discovered a positive relationship between social anxiety and a preference for using technological communication instead of face-to-face communication [47]. In an international study, 2665 participants aged 18-25 years from 121 countries, of which the majority from Australia, the United States, and the United Kingdom, were surveyed on social restrictions related to COVID-19 and its effect on loneliness, social anxiety, and depression. The authors concluded that reductions in social restrictions resulted in an increase in social anxiety due to having to readjust to the social environment [48]. In other words, the relationship between the COVID-19 pandemic and anxiety among youth is a complex matter with a diversity of outcomes, of which multiple possible scenarios might have affected the results of this study.

In this study, COVID-19 can be considered a confounding factor, which Jager et al [49] defined as a risk factor, unequally distributed among the participants, and not included in the causal pathway. Pourhoseingholi et al [50] define confounding factors as a variable affecting the variables studied but not their relationship. To prevent or reduce the confounding factors, Jager et al [49] suggest using exclusion criteria, for example, participant age, randomizing the assignment to groups, matching participants for example in pairs with or without exposure, or stratifying the participants into subgroups. Pourhoseingholi et al [50] mention that stratification is suitable with a low number of strata, whereas multivariate models, such as analysis of covariance, as well as logistic and linear regression, can be used with a larger number of covariates and confounders. The secondary outcomes are discussed below.

Does iACT for Adolescents With Anxiety Result in Increased Psychological Flexibility Between Pretreatment and 12 Months After Terminating Treatment?

In this evaluation, the analyses of AFQ-Y8 demonstrated an increase in psychological flexibility between the pretreatment measurement and the 12-month follow-up. These results are in line with previous research, concluding iACT to be effective in reducing symptoms of anxiety and increasing psychological flexibility, as well as suggesting a possible link between anxiety levels and psychological flexibility [17].

Does iACT for Adolescents With Anxiety Result in Improved Overall Functioning Between Pretreatment and 12 Months After Terminating Treatment?

In this evaluation, the analyses of overall functioning using CGAS did not indicate differences between the pretreatment measurement and the 12-month follow-up. However, in a meta-analysis of 9 RCTs on iACT for pediatric anxiety disorders, of which 7 included CGAS as a measure of functioning, the authors concluded that their confidence in the effect of iACT on functioning is low [51].

In summary, the results of this evaluation support a possible connection between parental support and adherence to iACT for adolescents with anxiety. Further research is needed to investigate the nature of the connection. Furthermore, the analyses of the outcome measures indicate reduced symptoms of anxiety and depression and increased psychological flexibility between the pretreatment measurement and the 12-month follow-up but no difference regarding overall functioning. However, due to a nonrandomized design, a small sample size, and a large amount of missing data, the results are uncertain, and the generalizability is severely limited.

Limitations

In this evaluation, the participants were recruited within the regular patient flow in primary care, which on one hand increases the ecological validity of the study but on the other hand decreases the control of several third variables influencing the groups. Performing pragmatic evaluations on how the treatment method works under regular conditions is a concrete way to achieve local evidence. Evaluating iACT the way it is provided in clinical practice, without adding resources or excluding patients for the sake of the evaluation, can provide a closer input on the actual effect, which in turn can increase the external validity.

Due to organizational problems in conducting the study, the participants could not be randomized and were instead assigned

XSL•FO
RenderX

to iACT or TAU following a nonrandomized design. Since the authors could not control the assignment of treatment method, no conclusions on eventual differences in treatment outcomes between groups could be made. Therefore, the TAU group was omitted from this evaluation and the internal validity is reduced.

This evaluation took place during the implementation phase of iACT in primary care, which poses its own unique challenges. Hasson and von Thiele Schwarz [41] suggest that performing follow-ups and giving feedback are ways to increase the motivation to implement a new method. In other words, the evaluation itself can influence the object of evaluation. During the IMPACT project, one of the staff members at one of the clinics involved mentioned that the project helped them initiate the implementation.

For the therapists involved in this study, the implementation phase included a learning phase in assessing and assigning iACT to patients. In the first IMPACT paper, the interviewed therapists discussed which patients iACT can be helpful for. The therapists concluded that iACT is more suitable for patients with self-discipline, acceptance of personal responsibility, capability of introspection, and appreciation of working independently with the program. Furthermore, the therapists concluded that iACT is better suited for patients with anxiety rather than depression and that the symptoms should not be too severe, wide-ranging, or long-standing, and that the patient preferably should be in the upper teens. Furthermore, several therapists expressed that iACT is less suitable for patients with learning disabilities, neuropsychiatric illness, or dyslexia [20].

The participant recruitment took place between 2018 and 2020, hence parts of the data collection took place during the COVID-19 pandemic. The authors suspect that the pandemic influenced the anxiety and functioning of the participants both directly, such as fear of infection, and indirectly such as transferring between distance and classroom learning in some cases. Ideally, the authors could have addressed this during the study, for example, by specifically asking about the effect of the pandemic. Thus, the results should be handled with caution.

The sample size in this study is relatively small, especially in the subgroup analyses, which severely limits the generalizability of the results. Furthermore, this evaluation contained a relatively large amount of missing data in proportion to the sample size. In a review paper, Kang [52] reviews techniques for managing missing data and argues that the best method is prevention, for example, by minimizing the number of follow-ups. The data collection for the IMPACT project consisted of surveys before, during, and after treatment and at 6- and 12-month follow-ups, as well as interviews before, during, after, and 12 months after treatment. It is possible that the number of measurements might have had an impact on the participation, for example, by reducing the motivation to participate. On the other hand, a larger number of measurement points, as well as both written and spoken, results in more opportunities to collect data.

In this evaluation, missing data were handled by complete case analysis, which Kang [52] does not recommend with small sample sizes. Applying the last-observation-carried-forward method would have increased the amount of data included in the analyses. However, since the previous measurements occur closer to the treatment phase, this could also create a bias in the data. Furthermore, due to a large number of missing data, the authors determined that the last-observation-carried-forward method would risk being too misleading; therefore, only participants with complete data were included in the analysis.

Regarding dropouts, Kang [52] recommends documenting the reason and thus enabling further analysis. In this evaluation, treatment adherence was investigated by analyzing the timing and reason behind the dropouts. Nevertheless, more actions could have been taken in preventing and investigating the dropouts. In a Swedish RCT, 162 adults were investigated regarding their participation in iACT to explore variables predicting dropout, adherence, and outcomes. The authors concluded that the level of treatment credibility predicted dropouts whereas attrition was associated with higher levels of impulsivity and low levels of intrinsic treatment motivation [53].

The generalizability of the results in this evaluation is limited due to the small and gender-based sample of young people that were included. To achieve a better understanding of mental health in male adolescents and to enhance primary care services, it is important to address gender bias in future research and clinical work. Furthermore, the amount of missing data was relatively high, which further reduced the possibility of drawing conclusions based on the data.

Due to limitations in the study design regarding a small and gender-biased sample size with a large proportion of dropouts and missing data, a nonrandomized assignment of intervention, and analysis limited to within-group, this investigation should be considered an explorative evaluation of a new method rather than a scientific outcome study. Further research on iACT in the regular patient flow in primary care is needed.

Conclusions

This evaluation consists of a follow-up on adolescents, 12 months after receiving iACT, with or without parental support. Due to a large amount of missing data, the results should be viewed as an evaluation rather than a scientific study. Adherence to treatment was investigated, indicating that parental support could increase adherence to iACT, which in turn might improve the conditions for young patients undertaking iACT treatment. The results also underscore the importance of parental involvement in the treatment of adolescents with mental illness. More research is needed to explore the relationship between parental support and treatment outcomes and how clinicians can facilitate the process.

Future research should investigate internet-based treatments for adolescents in primary care with additional, possibly digital, parental support programs in RCTs. After the IMPACT project was conducted, an internet-delivered parental support program was developed, in which information about how to support the adolescent during treatment was added [19]. Further research is needed on parental support in this format as well. Moreover, further research is needed on involving next of kin in health care in general.

Furthermore, the analyses of the outcome measures suggest that iACT might be an effective treatment for both anxiety and

XSL•FO
RenderX

depression and has the potential to be an effective treatment of comorbidity and a broader spectrum of anxiety problems.

Acknowledgments

First and foremost, the authors would like to acknowledge Närhälsan and Omtanken, as well as Research and Development Primary Health Care, Region Västra Götaland, Gothenburg, Sweden, for making the Internet Mediated Psychological Treatment-Acceptance and Commitment Therapy (IMPACT) project possible. Furthermore, we would like to thank all health care staff and participants for their time and contributions. Finally, we would like to thank the project managers in Region Västra Götaland. Regional R&D, DNR: 834181 and DNR: 758551 funded the study, received by the second author as the main applicant.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The contents of the internet-delivered acceptance and commitment therapy (iACT) intervention translated into English.
[PDF File (Adobe PDF File), 147 KB - pediatrics_v8i1e59489_app1.pdf]

Multimedia Appendix 2
User manual for the Anxiety School (Användarmanual till Ångestskolan in Swedish).
[PDF File (Adobe PDF File), 468 KB - pediatrics_v8i1e59489_app2.pdf]

References

1. Inrapporterade depressioner och ångestsyndrom bland barn och unga vuxna -utvecklingen till och med 2018. Socialstyrelsen (Swedish National Board of Health and Welfare). URL: https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/ovrigt/2020-6-6768.pdf
2. Thapar A, Pine DS, Leckman JF, Scott S, Snowling MJ, Taylor EA. Rutter's Child and Adolescent Psychiatry. Hoboken, NJ: John Wiley & Sons; 2017.
3. Sareen J, Cox BJ, Afifi TO, de Graaf R, Asmundson GJG, ten Have M, et al. Anxiety disorders and risk for suicidal ideation and suicide attempts: a population-based longitudinal study of adults. Arch Gen Psychiatry 2005;62(11):1249-1257. [doi: 10.1001/archpsyc.62.11.1249] [Medline: 16275812]
4. Thapar A, Collishaw S, Pine DS, Thapar AK. Depression in adolescence. Lancet 2012;379(9820):1056-1067. [doi: 10.1016/S0140-6736(11)60871-4] [Medline: 22305766]
5. Nationella Riktlinjer för Vård Vid Depression Och Angestsyndrom. Socialstyrelsen (Swedish National Board of Health and Welfare). 2024. URL: https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/nationella-riktlinjer/2021-4-7339.pdf [accessed 2024-07-09]
6. James AC, James G, Cowdrey FA, Soler A, Choke A. Cognitive behavioural therapy for anxiety disorders in children and adolescents. Cochrane Database Syst Rev 2013(6):CD004690. [doi: 10.1002/14651858.CD004690.pub3] [Medline: 23733328]
7. Sawyer SM, Afifi RA, Bearinger LH, Blakemore S, Dick B, Ezeh AC, et al. Adolescence: a foundation for future health. Lancet 2012;379(9826):1630-1640. [doi: 10.1016/S0140-6736(12)60072-5] [Medline: 22538178]
8. O'Dea B, Calear AL, Perry Y. Is e-health the answer to gaps in adolescent mental health service provision? Curr Opin Psychiatry 2015;28(4):336-342. [doi: 10.1097/YCO.0000000000000170] [Medline: 26001926]
9. Vigerland S, Lenhard F, Bonnert M, Lalouni M, Hedman E, Ahlen J, et al. Internet-delivered cognitive behavior therapy for children and adolescents: a systematic review and meta-analysis. Clin Psychol Rev 2016;50:1-10 [FREE Full text] [doi: 10.1016/j.cpr.2016.09.005] [Medline: 27668988]
10. Stjerneklar S, Hougaard E, McLellan LF, Thastum M. A randomized controlled trial examining the efficacy of an internet-based cognitive behavioral therapy program for adolescents with anxiety disorders. PLoS One 2019;14(9):e0222485 [FREE Full text] [doi: 10.1371/journal.pone.0222485] [Medline: 31532802]
11. Spence SH, Donovan CL, March S, Gamble A, Anderson RE, Prosser S, et al. A randomized controlled trial of online versus clinic-based CBT for adolescent anxiety. J Consult Clin Psychol 2011;79(5):629-642. [doi: 10.1037/a0024512] [Medline: 21744945]
12. Berg M, Rozental A, de Brun Mangs J, Näsman M, Strömberg K, Viberg L, et al. The role of learning support and chat-sessions in guided internet-based cognitive behavioral therapy for adolescents with anxiety: a factorial design study. Front Psychiatry 2020;11:503 [FREE Full text] [doi: 10.3389/fpsyt.2020.00503] [Medline: 32587533]
13. Hayes SC, Pistorello J, Levin ME. Acceptance and commitment therapy as a unified model of behavior change. Couns Psychol 2012;40(7):976-1002. [doi: 10.1177/0011000012460836]

XSL•FO
RenderX

14. Fang K, Ding D. A meta-analysis of the efficacy of acceptance and commitment therapy for children. J Contextual Behav Sci 2013;15(1):225-234. [doi: 10.1016/j.medengphy.2012.06.015]
15. Petersen JM, Zurita Ona P, Twohig MP. A review of acceptance and commitment therapy for adolescents: developmental and contextual considerations. Cognit Behav Pract 2022;31(1):72-89. [doi: 10.1016/j.cbpra.2022.08.002]
16. Gloster AT, Walder N, Levin ME, Twohig MP, Karekla M. The empirical status of acceptance and commitment therapy: a review of meta-analyses. J Contextual Behav Sci 2020;18:181-192. [doi: 10.1016/j.medengphy.2012.06.015] [Medline: 22818403]
17. Nissling L, Weineland S, Vernmark K, Radvogin E, Engström AK, Schmidt S, et al. Effectiveness of and processes related to internet-delivered acceptance and commitment therapy for adolescents with anxiety disorders: a randomized controlled trial. Res Psychother 2023;26(2):681 [FREE Full text] [doi: 10.4081/ripppo.2023.681] [Medline: 37401474]
18. Lappalainen P, Lappalainen R, Keinonen K, Kaipainen K, Puolakanaho A, Muotka J, et al. In the shadow of COVID-19: a randomized controlled online ACT trial promoting adolescent psychological flexibility and self-compassion. J Contextual Behav Sci 2023;27:34-44. [doi: 10.1016/j.jcbs.2022.12.001]
19. Ångesthjälpen Ung. Psykologpartners. URL: https://sob.kbtonline.se/?page_id=2229 [accessed 2024-07-09]
20. Weineland S, Ribbegårdh R, Kivi M, Bygdell A, Larsson A, Vernmark K, et al. Transitioning from face-to-face treatment to iCBT for youths in primary care—therapists' attitudes and experiences. Internet Interventions 2020;22:100356 [FREE Full text] [doi: 10.1016/j.invent.2020.100356] [Medline: 33318951]
21. Lilja JL, Ljustina MR, Nissling L, Larsson AC, Weineland S. Correction: youths' and parents' experiences and perceived effects of internet-based cognitive behavioral therapy for anxiety disorders in primary care: mixed methods study. JMIR Pediatr Parent 2021;4(4):e35350 [FREE Full text] [doi: 10.2196/35350] [Medline: 34860680]
22. Haine-Schlagel R, Walsh NE. A review of parent participation engagement in child and family mental health treatment. Clin Child Fam Psychol Rev 2015;18(2):133-150 [FREE Full text] [doi: 10.1007/s10567-015-0182-x] [Medline: 25726421]
23. Lundkvist-Houndoumadi I, Thastum M, Nielsen K. Parents' difficulties as co-therapists in CBT among non-responding youths with anxiety disorders: parent and therapist experiences. Clin Child Psychol Psychiatry 2016;21(3):477-490. [doi: 10.1177/1359104515615641] [Medline: 26614573]
24. Entergate. URL: https://www.entergate.se/en [accessed 2024-09-27]
25. Sweden's advice-making process on schools during the COVID-19 pandemic: good practices and lessons learnt. European Centre for Disease Prevention and Control. URL: https://www.ecdc.europa.eu/en/news-events/swedens-advice-making-process-schools-during-covid-19-pandemic-good-practices-and [accessed 2024-07-09]
26. Mer An Rädd. Region Västra Götaland. URL: https://www.vgregion.se/halsa-och-vard/vardgivarwebben/amnesomraden/psykisk-halsa/kph/Informationsmaterial/ [accessed 2024-07-09]
27. Chorpita BF, Yim L, Moffitt C, Umemoto LA, Francis SE. Assessment of symptoms of DSM-IV anxiety and depression in children: a revised child anxiety and depression scale. Behav Res Ther 2000;38(8):835-855. [doi: 10.1016/s0005-7967(99)00130-8]
28. Chorpita BF, Moffitt CE, Gray J. Psychometric properties of the revised child anxiety and depression scale in a clinical sample. Behav Res Ther 2005;43(3):309-322. [doi: 10.1016/j.brat.2004.02.004] [Medline: 15680928]
29. Cederberg TT, Weineland S, Dahl J, Ljungman G. A preliminary validation of the Swedish short version of the avoidance and fusion questionnaire for youth (AFQ-Y8) for children and adolescents with cancer. J Contextual Behav Sci 2018;10:103-107. [doi: 10.1016/j.jcbs.2018.09.004]
30. Lecrubier Y, Sheehan D, Weiller E, Amorim P, Bonora I, Sheehan K, et al. The Mini International Neuropsychiatric Interview (MINI). A short diagnostic structured interview: reliability and validity according to the CIDI. Eur. psychiatr 2020 Apr 16;12(5):224-231. [doi: 10.1016/s0924-9338(97)83296-8]
31. Högberg C, Billstedt E, Björck C, Björck PO, Ehlers S, Gustle LH, et al. Diagnostic validity of the MINI-KID disorder classifications in specialized child and adolescent psychiatric outpatient clinics in sweden. BMC Psychiatry 2019;19(1):142 [FREE Full text] [doi: 10.1186/s12888-019-2121-8] [Medline: 31072319]
32. Sheehan DV, Sheehan KH, Shytle RD, Janavs J, Bannon Y, Rogers JE, et al. Reliability and validity of the Mini International Neuropsychiatric Interview for Children and Adolescents (MINI-KID). J Clin Psychiatry 2010;71(3):313-326. [doi: 10.4088/JCP.09m05305whi] [Medline: 20331933]
33. Shaffer D, Gould MS, Brasic J, Ambrosini P, Fisher P, Bird H, et al. A Children's Global Assessment Scale (CGAS). Arch Gen Psychiatry 1983;40(11):1228-1231. [doi: 10.1001/archpsyc.1983.01790100074010] [Medline: 6639293]
34. Children's Global Assessment Scale (CGAS) for children 4-16 years of age. Adaptation of the Adult Global Assesssment Scale. American Academy of Child and Adolescent Psychiatry. URL: https://www.aacap.org/App_Themes/AACAP/docs/member_resources/toolbox_for_clinical_practice_and_outcomes/symptoms/CGAS.pdf [accessed 2024-07-09]
35. Steinhausen HC. Global assessment of child psychopathology. J Am Acad Child Adolesc Psychiatry 1987;26(2):203-206. [doi: 10.1097/00004583-198703000-00014] [Medline: 3584018]
36. Canino GJ, Bird HR, Rubio-Stipec M, Woodbury MA, Ribera JC, Huertas SE, et al. Reliability of child diagnosis in a hispanic sample. J Am Acad Child Adolesc Psychiatry 1987;26(4):560-555. [doi: 10.1097/00004583-198707000-00018] [Medline: 3654512]

XSL•FO
RenderX

37. D'Arrigo G, Leonardis D, ElHafeez SA, Fusaro M, Tripepi G, Roumeliotis S. Methods to analyse time-to-event data: the Kaplan-Meier survival curve. Oxid Med Cell Longevity 2021;2021:2290120 [FREE Full text] [doi: 10.1155/2021/2290120] [Medline: 34594473]
38. Field A. Discovering Statistics Using IBM SPSS Statistics. 5th Edition. London, United Kingdom: Sage Publications; 2017.
39. Fjermestad KW, Lerner MD, McLeod BD, Wergeland GJH, Haugland BSM, Havik OE, et al. Motivation and treatment credibility predict alliance in cognitive behavioral treatment for youth with anxiety disorders in community clinics. J Clin Psychol 2018;74(6):793-805. [doi: 10.1002/jclp.22551] [Medline: 29143977]
40. Campbell M, Fitzpatrick R, Haines A, Kinmonth A, Sandercock P, Spiegelhalter D. Framework for designevaluation of complex interventions to improve health. BMJ 2000;321(7262):694-696. [doi: 10.1136/bmj.321.7262.694]
41. Hasson H, von Thiele Schwarz U. Användbar Evidens Om Följsamhet Och Anpassningar. Stockholm, Sweden: Natur & Kultur; 2017.
42. Tillfors M, Andersson G, Ekselius L, Furmark T, Lewenhaupt S, Karlsson A, et al. A randomized trial of Internet-delivered treatment for social anxiety disorder in high school students. Cogn Behav Ther 2011;40(2):147-157. [doi: 10.1080/16506073.2011.555486] [Medline: 25155815]
43. Kapetanovic S, Gurdal S, Ander B, Sorbring E. Reported changes in adolescent psychosocial functioning during the COVID-19 outbreak. Adolescents 2021 Jan 15;1(1):10-20. [doi: 10.3390/adolescents1010002]
44. Hagquist C. Worry and psychosomatic problems among adolescents in Sweden in the wake of the COVID-19 pandemic: unequal patterns among sociodemographic groups? J Adolesc Health 2023 May;72(5):688-695 [FREE Full text] [doi: 10.1016/j.jadohealth.2022.12.013] [Medline: 36781326]
45. Panchal U, Vaquerizo-Serrano JD, Conde-Ghigliazza I, Aslan Genç H, Marchini S, Pociute K, et al. Anxiety symptoms and disorders during the COVID-19 pandemic in children and adolescents: systematic review and meta-analysis. Eur J Psychiatry 2023 Oct;37(4):100218. [doi: 10.1016/j.ejpsy.2023.06.003]
46. Ranta K, Aalto-Setälä T, Heikkinen T, Kiviruusu O. Social anxiety in Finnish adolescents from 2013 to 2021: change from pre-COVID-19 to COVID-19 era, and mid-pandemic correlates. Soc Psychiatry Psychiatr Epidemiol 2024 Jan;59(1):121-136 [FREE Full text] [doi: 10.1007/s00127-023-02466-4] [Medline: 37095373]
47. Pierce T. Social anxiety and technology: Face-to-face communication versus technological communication among teens. Comput Hum Behav 2009 Nov;25(6):1367-1372. [doi: 10.1016/j.chb.2009.06.003]
48. Lim MH, Qualter P, Thurston L, Eres R, Hennessey A, Holt-Lunstad J, et al. A global longitudinal study examining social restrictions severity on loneliness, social anxiety, and depression. Front Psychiatry 2022;13:818030 [FREE Full text] [doi: 10.3389/fpsyt.2022.818030] [Medline: 35418888]
49. Jager KJ, Zoccali C, Macleod A, Dekker FW. Confounding: what it is and how to deal with it. Kidney Int 2008 Feb;73(3):256-260 [FREE Full text] [doi: 10.1038/sj.ki.5002650] [Medline: 17978811]
50. Pourhoseingholi MA, Baghestani AR, Vahedi M. How to control confounding effects by statistical analysis. Gastroenterol Hepatol Bed Bench 2012;5(2):79-83 [FREE Full text] [Medline: 24834204]
51. Cervin M, Lundgren T. Technology-delivered cognitive-behavioral therapy for pediatric anxiety disorders: a meta-analysis of remission, posttreatment anxiety, and functioning. J Child Psychol Psychiatry 2022 Jan;63(1):7-18. [doi: 10.1111/jcpp.13485] [Medline: 34235730]
52. Kang H. The prevention and handling of the missing data. Korean J Anesthesiol 2013 May;64(5):402-406 [FREE Full text] [doi: 10.4097/kjae.2013.64.5.402] [Medline: 23741561]
53. Alfonsson S, Olsson E, Hursti T. Motivation and treatment credibility predicts dropout, treatment adherence, and clinical outcomes in an internet-based cognitive behavioral relaxation program: a randomized controlled trial. J Med Internet Res 2016 Mar 08;18(3):e52 [FREE Full text] [doi: 10.2196/jmir.5352] [Medline: 26957354]

Abbreviations

ACT: acceptance and commitment therapy
AFQ-Y8: Avoidance and Fusion Questionnaire for Youth
CBT: cognitive behavioral therapy
CGAS: Children's Global Assessment Scale
CONSORT: Consolidated Standards of Reporting Trials
GAD: generalized anxiety disorder
iACT: internet-delivered acceptance and commitment therapy
iCBT: internet-based cognitive behavioral therapy
IMPACT: Internet Mediated Psychological Treatment-Acceptance and Commitment Therapy
RCADS: Revised Children's Anxiety and Depression Scale
RCT: randomized controlled trial
TAU: treatment as usual

XSL•FO
RenderX

Edited by A Serlachius; submitted 01.05.24; peer-reviewed by S Cross, S Sheth - MD; comments to author 05.08.24; revised version received 30.09.24; accepted 01.10.24; published 03.01.25.

Please cite as:
Larsson A, Weineland S, Nissling L, Lilja JL
The Impact of Parental Support on Adherence to Therapist-Assisted Internet-Delivered Acceptance and Commitment Therapy in Primary Care for Adolescents With Anxiety: Naturalistic 12-Month Follow-Up Study
JMIR Pediatr Parent 2025;8:e59489
URL: https://pediatrics.jmir.org/2025/1/e59489
doi:10.2196/59489
PMID:39752209

©Anna Larsson, Sandra Weineland, Linnea Nissling, Josefine L Lilja. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 03.01.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Changes in Internet Activities and Influencing Factors for Problematic Internet Use During the COVID-19 Pandemic in Korean Adolescents: Repeated Cross-Sectional Study

Sol I Kim[1], MD; Jae-Chan Jin[2], PhD; Seo-Koo Yoo[2], PhD; Doug Hyun Han[3], PhD

[1]Department of Psychiatry, Woori Children's Hospital, Seoul, Republic of Korea

[2]School of Social Welfare, Soongsil University, Seoul, Republic of Korea

[3]Department of Psychiatry, Chung Ang University Hospital, Seoul, Republic of Korea

Corresponding Author:
Doug Hyun Han, PhD
Department of Psychiatry, Chung Ang University Hospital
102 Heusok ro
Seoul, 06973
Republic of Korea
Phone: 82 62993132
Fax: 82 62987265
Email: hduk70@gmail.com

Abstract

Background: As adolescents increasingly engage with digital experiences, the internet serves as a platform for social interaction, entertainment, and learning. The COVID-19 pandemic accelerated this trend, with remote learning and restricted physical interactions driving changes in internet behavior. Adolescents spent more time on gaming and social media, reflecting a notable shift in use patterns.

Objective: We hypothesized that the COVID-19 pandemic changed internet use patterns among Korean adolescents, including content types, time spent on web-based activities, and pathological use prevalence. Additionally, we anticipated that these changes would correlate with shifts in adolescents' psychological status during the pandemic.

Methods: Data from 827 adolescents aged 12 to 15 years (n=144 in 2018, n=142 in 2019, n=126 in 2020, n=130 in 2021, n=143 in 2022, and n=142 in 2023) were gathered over 6 years from 43 middle schools across 16 regions and 1 hospital in South Korea. The demographic data collected included age, sex, and school year. Participants also provided information on their internet use patterns and levels of internet addiction. Additionally, psychological status, including mood, anxiety, attention, and self-esteem, was assessed.

Results: There were significant differences in the depression scale (Patient Health Questionnaire 9). The Patient Health Questionnaire 9 scores for 2018, 2019, and 2023 decreased compared to those in 2020, 2021, and 2022 (F_5=3.07; P=.007). Regarding changes in internet use behavior, game playing among adolescents decreased after the pandemic compared to before, while watching videos increased. Additionally, the rate of problematic internet use was highest for games before COVID-19, but after COVID-19, it was highest for videos, and this trend continued until 2023 (χ^2_3=8.16, P=.04). Furthermore, this study showed that the Young's Internet Addiction Scale (YIAS) score was highest in the game group in 2018 compared to other groups before COVID-19 (F_5=14.63; P<.001). In 2019, both the game and video groups had higher YIAS scores than other groups (F_5=9.37; P<.001), and by 2022, the YIAS scores among the game, video, and Social Network Service groups did not differ significantly. The degree of influence on the severity of internet addiction was also greatest for games before COVID-19, but after COVID-19, the effect was greater for videos than for games.

Conclusions: During the COVID-19 pandemic, internet use for academic and commercial purposes, including remote classes and videoconferences, increased rapidly worldwide, leading to a significant rise in overall internet use time. The demand for and dependence on digital platforms is expected to grow even further in the coming era. Until now, concerns have primarily focused on the use of games, but it is now necessary to consider what types of internet behaviors cause problems and how to address them.

XSL•FO
RenderX

(JMIR Pediatr Parent 2025;8:e66448) doi:10.2196/66448

KEYWORDS

coronavirus pandemic; internet use pattern; internet games; short-form videos; social network system; depressed mood; internet use; pandemic; internet; COVID-19; video; internet behavior; social media; internet addiction; depression; anxiety; digital platforms; mobile phone

Introduction

Background

Since its first appearance in a psychiatric context in 1998 [1], the maladaptive and addictive use of the internet, often referred to as internet addiction or internet use disorder, has been increasingly addressed over the past two decades. The internet use rate of Korean adolescents was around 50% in 1999, rising to 99.5% in 2023 [2,3].

Among adolescents, internet applications have shifted from being a supportive function to dominating their daily lives, sometimes leading to addictive use. Both the American Psychiatric Association and the World Health Organization have acknowledged this behavioral phenomenon in their classification manuals, the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5; since 2013 as a condition for further study) and the forthcoming *International Classification of Diseases, 11th Revision* (in the chapter on "Disorders due to behavioral addictions"). However, several authors have criticized this decision, citing a lack of conceptual and empirical foundations [4-9]. Moreover, Griffiths [10] insisted that the context (activities) of internet use is far more important than the amount of time spent on web-based activities.

In almost all studies, adolescents and young adults are consistently identified as the group with the highest prevalence of internet use. As adolescents increasingly engage in digital experiences, the internet serves as a versatile platform for social interaction, entertainment, and information acquisition [11]. Empirical studies have explored the intricate relationships between different types of internet activities and their associated risks. For instance, the problematic use of video games, social media, and the internet has been linked to various mental health issues, such as emotional distress, self-esteem problems, and attention problems, among adolescents [12]. A systematic review of the literature by Coutelle et al [13] suggested that psychological status including inattention, anxiety, and depression significantly impact internet addiction. Additionally, the heterogeneity in internet behavior patterns during the pandemic underscores the importance of considering individual differences when addressing problematic internet use [14].

The COVID-19 pandemic's impact on internet use highlights the need to understand the complexities of adolescent web-based activities and their mental health. In a review of longitudinal or repeated cross-sectional, follow-up studies, Wolf and Schmitz [15] declared that the COVID-19 pandemic and related stressors could impact the mental health of children and adolescents. Moreover, latent profile analyses reveal distinct patterns of internet and gaming use, suggesting that adolescents' engagement with digital platforms can be categorized into different profiles based on the intensity and type of use [16-18].

The COVID-19 pandemic further accentuated the use of digital platforms, as social restrictions necessitated remote learning and limited physical interactions. This shift resulted in altered internet behavior patterns among adolescents, with a notable increase in the time spent on internet gaming and social media [11,16].

Hypothesis

We hypothesized that the COVID-19 pandemic changed psychological status, as well as internet use patterns regarding internet content, use time, and pathological use, in Korean adolescents. Additionally, the severity of pathological internet use was influenced by psychological factors, including mood and attention, during the COVID-19 pandemic.

Methods

This study is a repeated cross-sectional study that tracked data from 827 students over 6 years.

Participants

Over 6 years, data from 827 adolescents (n=144 in 2018, n=142 in 2019, n=126 in 2020, n=130 in 2021, n=143 in 2022, and n=142 in 2023) aged 12 to 15 years were gathered from 43 middle schools across 16 regions and 1 hospital in South Korea.

Through a web-based advertisement on the Korean Game Culture Foundation website from January 1, 2018, to December 30, 2023, a total of 69 middle schools from 32 regions and 2 hospitals from 2 regions in South Korea applied to the Visiting Game Class program for game literacy education. Of these, 43 middle schools from 16 regions and 1 hospital were selected through the multistage sampling method. First, the selection was divided by region and hospital; 16 (50%) out of 32 regions were randomly selected, and 1 (50%) of the 2 hospitals in each selected region was chosen at random. Then, among the 52 schools within these 32 regions, 44 (85%) schools were selected. However, 1 school deferred its participation to 2024 due to its academic schedule, so it did not contribute to the research data. Trained agents from the Korean Game Culture Foundation visited schools and hospitals to conduct an investigation.

Ethical Considerations

All data collected by the agents were anonymized, and participants were rewarded with school supplies worth approximately US $10. Approval for the current study was granted by the Institutional Review Board at Chung-Ang University (1041078-202201-HR-052). We obtained informed consent for research participation from both the students and their parents.

XSL•FO
RenderX

Demographics and Internet Use Patterns

The demographic data collected included age, sex, and school year. Participants also provided information on their internet use patterns and levels of internet addiction. We defined "problematic internet use" as answering "yes" to the following questions: "Did you hear that people important or close to you consider your internet use to be a problem or suggest you meet a doctor or specialist for it?" [19].

The Young's Internet Addiction Scale (YIAS), a commonly used instrument for assessing internet addiction and web-based activities such as gaming, was used. This scale comprises 20 items, each rated on a 5-point Likert scale. The internal consistency of the Korean version of the scale has been reported to range from 0.90 to 0.93.

Psychological Assessment Scales

The Patient Health Questionnaire 9 (PHQ-9) was used to assess depression, with each item rated on a Likert scale from 0 to 3. A cutoff score of 10 (out of 27) was used to indicate depression. Park et al [20] validated the Korean version of the PHQ-9, which demonstrated an internal consistency of α=.81.

The DuPaul Attention-Deficit/Hyperactivity Disorder (ADHD) scale, particularly the ADHD symptom severity scale (ADHD Rating Scale [ARS]), includes 18 items, with 9 items dedicated to inattention and 9 to hyperactivity [21]. So et al [22] validated the Korean version of the ARS (K-ARS) and reported an internal consistency ranging from 0.77 to 0.89.

The Social Phobia Inventory (SPIN) is a self-report questionnaire consisting of 17 items designed to measure three dimensions of social anxiety. Cho et al [23] developed a Korean version of the SPIN (K-SPIN) and reported a high internal consistency with a Cronbach α of 0.91.

The Two-Factor Self-Esteem Scale (SE) is based on a modified version of the Rosenberg Self-Esteem Scale. It conceptualizes self-esteem as an individual's perception of their worth, incorporating elements of self-respect and self-confidence [24]. This scale contains 10 statements that assess overall feelings toward oneself. Participants indicate their level of agreement on a 4-point Likert scale, ranging from 1 (disagree completely) to 4 (agree completely). The internal consistency of the Korean version of the scale, referred to as the Self-Esteem Scale-Korean, has been reported with a Cronbach α of 0.79 [25].

Data Analysis

Demographic characteristics, including age, school year, and internet use time across years, were analyzed using ANOVA tests. Sex and internet activity across years were analyzed using chi-square tests. The YIAS scores and psychological scale scores, including PHQ-9, K-ARS, K-SPIN, and SE were also analyzed using ANOVA tests. The correlations between age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, and YIAS were assessed using Pearson correlation analyses. The correlations between sex (IT activity) and age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, and YIAS were assessed using Spearman correlation analyses. The correlation between sex and IT activity was assessed using Kendall tau-b correlation analysis.

We conducted hierarchical linear regression analyses using YIAS scores as the dependent variable to identify factors influencing the severity of problematic internet use. In Model 1, we tested the associations of demographic factors with the severity of problematic internet use. In Model 2, psychological factors were added to test their associations beyond the effects of demographic factors. In Model 3, internet use time was added to test its association beyond the effects of demographic and psychological factors. Finally, in Model 4, internet activities were added to test their associations beyond the effects of demographic factors, psychological factors, and internet use time. Statistical significance was set a priori at α=.05 (two-sided) to limit type-I error. All analyses were conducted using the *Complex Samples* module of the *PASW* statistics software package (version 19; IBM Corp).

Results

Demographic and Clinical Characteristics

There were no differences in sex ratio and age across the 6 years. Similarly, there were no differences in the scores of the self-esteem, social anxiety, and attention scales over the same period. However, significant differences were observed in the PHQ-9 scores (F_5=3.07; P=.007). The PHQ-9 scores for 2018, 2019, and 2023 were lower compared to those in 2020, 2021, and 2022. Additionally, there was a significant difference in internet use time (F_5=6.30; P<.001). Internet use time was highest in 2020 and 2021, followed by 2022 and 2023, and lowest in 2018 and 2019 (Table 1).

XSL•FO
RenderX

Table 1. Demographic characteristics.

	2018 (n=144)	2019 (n=142)	2020 (n=126)	2021 (n=130)	2022 (n=143)	2023 (n=142)
Demographic characteristics						
Sex, n (%)						
Male	83 (57.6)	80 (56.3)	74 (58.7)	77 (59.2)	80 (55.9)	86 (60.6)
Female	61 (42.4)	62 (43.7)	52 (41.3)	53 (40.8)	63 (44.1)	56 (39.4)
Age (years), mean (SD)	13.56 (1.10)	13.59 (0.59)	13.55 (1.11)	13.34 (1.33)	13.35 (0.73)	13.64 (0.92)
IT use pattern						
Internet use time[a], mean (SD)	2.82 (1.23)	3.09 (1.67)	3.55 (1.14)	3.69 (1.78)	3.21 (1.01)	3.20 (1.71)
YIAS[b], mean (SD)	45.08 (15.67)	43.87 (12.83)	43.87 (13.17)	45.08 (13.81)	44.41 (13.05)	44.32 (14.61)
Psychological scales						
SE[c], mean (SD)	27.09 (5.09)	27.20 (3.13)	27.33 (7.16)	28.15 (5.33)	27.89 (5.02)	27.04 (3.21)
PHQ-9[d,e], mean (SD)	9.69 (7.76)	9.88 (5.24)	11.90 (4.66)	11.13 (6.84)	11.13 (5.93)	9.58 (7.14)
K-SPIN[f], mean (SD)	18.58 (11.05)	18.65 (11.92)	19.61 (11.51)	20.11 (12.75)	19.39 (13.51)	18.37 (12.89)
K-ARS[g], mean (SD)	10.37 (7.98)	9.19 (8.82)	9.17 (8.09)	10.01 (9.37)	10.10 (9.96)	9.28 (9.30)

[a]F_5=6.30; P<.001; 2018=2019<2022=2023<2020=2021.

[b]YIAS: Young's Internet Addiction Scale.

[c]SE: Two-Factor Self-Esteem Scale.

[d]PHQ-9: Patient Health Questionnaire 9.

[e]F_5=3.07; P=.007; 2018=2019=2023<2020=2021=2022.

[f]K-SPIN: Korean version of the Social Phobia Inventory.

[g]K-ARS: Korean version of the Attention Deficit/Hyperactivity Disorder Rating Scale.

The Correlations Between All Variables

In the comparison of variable correlations, PHQ-9 scores were positively correlated with K-ARS scores (r=0.45; P<.001). YIAS scores were positively correlated with PHQ-9 scores (r=0.43; P<.001) and K-ARS scores (r=0.43; P<.001; Table 2).

XSL•FO
RenderX

Table 2. Correlation matrix of all variables[a].

Variables	Age	Sex	SE[b]	PHQ-9[c]	K-SPIN[d]	K-ARS[e]	IT use time	IT activity	YIAS[f]
Age									
r	1	–0.05	–0.04	0.04	0.07	0.10	0.09	0.09	0.05
P value	—[g]	.11	.25	.31	.06	.004	.007	.03	.09
Sex									
r	–0.05	1	–0.06	–0.01	0.05	–0.32	0.02	0.15	–0.07
P value	.11	—	.12	.55	.19	.75	.53	<.001	.03
SE									
r	–0.04	–0.06	1	–0.03	–0.21	–0.13	–0.02	–0.04	–0.02
P value	.25	.12	—	.38	<.001	<.001	.49	.21	.25
PHQ-9									
r	0.04	–0.03	–0.03	1	0.14	0.45	0.07	0.08	0.43
P value	.31	.55	.38	—	<.001	<.001	.05	.02	<.001
K-SPIN									
r	0.07	0.05	–0.21	0.14	1	0.28	0.05	0.06	0.18
P value	.06	.19	<.001	<.001	—	<.001	.16	.08	<.001
K-ARS									
r	0.10	–0.32	–0.13	0.45	0.28	1	0.08	0.04	0.43
P value	.004	.75	<.001	<.001	<.001	—	.03	.29	<.001
IT use time									
r	0.09	0.02	–0.02	0.07	0.05	0.08	1	0.52	0.08
P value	.007	.53	.49	.05	.16	.03	—	.14	.04
IT activity									
r	0.09	0.15	–0.04	0.08	0.06	0.04	0.52	1	0.03
P value	.03	<.001	.21	.02	.08	.29	.14	—	.34
YIAS									
r	0.05	–0.07	–0.02	0.43	0.18	0.43	0.08	0.03	1
P value	.09	.03	.25	<.001	<.001	<.001	.04	.34	—

[a]Pearson correlation: age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, YIAS; Spearman correlation: sex, IT activity versus age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, YIAS; Kendall tau-b: sex, IT activity.

[b]SE: Two-Factor Self-Esteem Scale.

[c]PHQ-9: Patient Health Questionnaire 9.

[d]K-SPIN: Korean version of the Social Phobia Inventory.

[e]K-ARS: Korean version of the Attention Deficit Hyperactivity Disorder Scale.

[f]YIAS: Young's Internet Addiction Scale score.

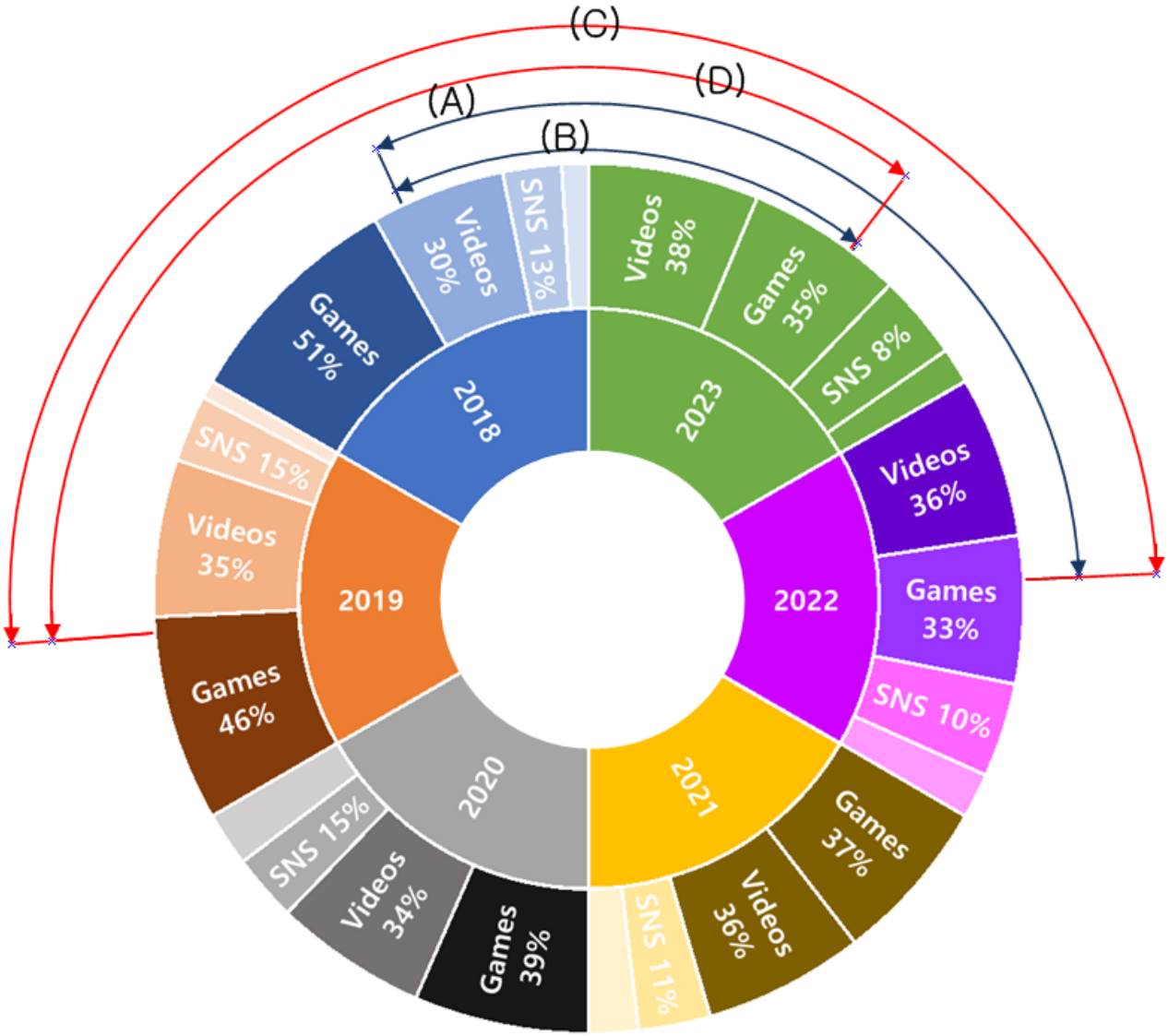
[g]Not applicable.

Changes in Internet Activities of Korean Adolescents Over 6 Years

Over the past 6 years, the population engaged in gameplay had decreased, while the population watching videos had increased. In 2018, a total of 51.4% (74/144) of the population engaged in gameplay, and 29.9% (43/144) watched videos. By 2022, these figures had shifted to 32.9% (47/143) for gameplay and 35.7% (51/143) for video watching, and in 2023, to 35% (50/142) for gameplay and 37.8% (54/142) for video watching (2022: χ^2_3=11.20, *P*=.01; 2023: χ^2_3=12.32, *P*=.006). Similarly, in 2019, a total of 46.2% (66/142) engaged in gameplay and 35% (50/142) watched videos. By 2022, these figures had changed to 32.9% (47/143) for gameplay and 35.7% (51/143) for video watching, and in 2023, to 35% (50/142) for gameplay and 37.8% (54/142) for video watching (2022: χ^2_3=8.68, *P*=.03; 2023: χ^2_3=8.16, *P*=.04; Figure 1).

XSL•FO
RenderX

Figure 1. Changes in internet activities of Korean adolescents over 6 years (chi-square test). (A) Comparison of internet activities between 2018 and 2022 (χ^2_3=11.20, *P*=.01); (B) comparison of internet activities between 2018 and 2023 (χ^2_3=12.32, *P*=.006); (C) comparison of internet activities between 2019 and 2022 (χ^2_3=8.68, *P*=.03); and (D) comparison of internet activities between 2019 and 2023 (χ^2_3=8.16, *P*=.04). SNS: Social Network Service.

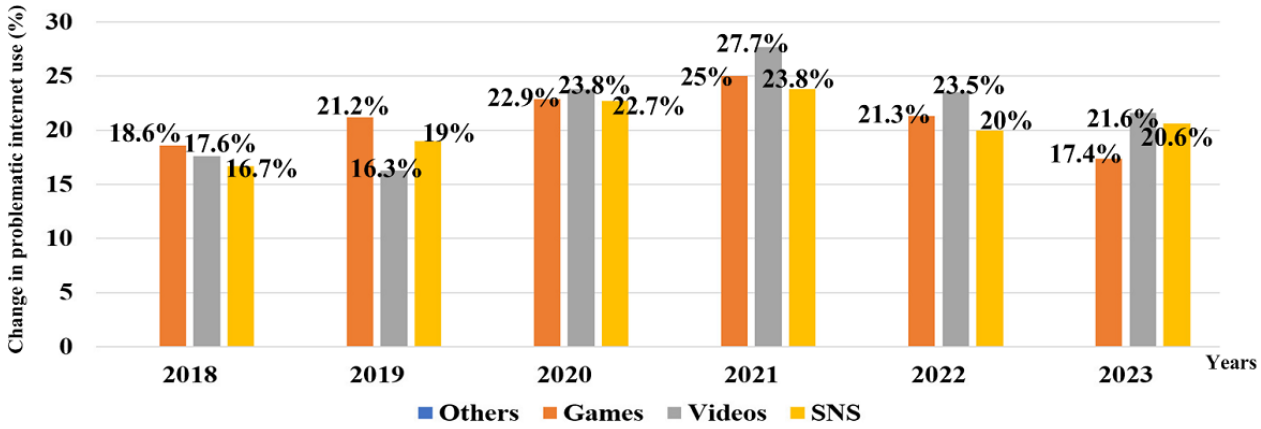


Differences in Problematic Internet Use for 4 Activities in Korean Adolescents Over 6 Years

Until 2019, the proportion of problematic internet use was highest in the gaming group among the 4 types of internet use. However, the proportion of problematic internet use in watching videos abruptly increased in 2020 and has maintained its top position until 2023. The proportion of problematic internet use in Social Network Service (SNS) use continuously increased until 2021 but decreased in 2022 and 2023 (Figure 2).

XSL•FO
RenderX

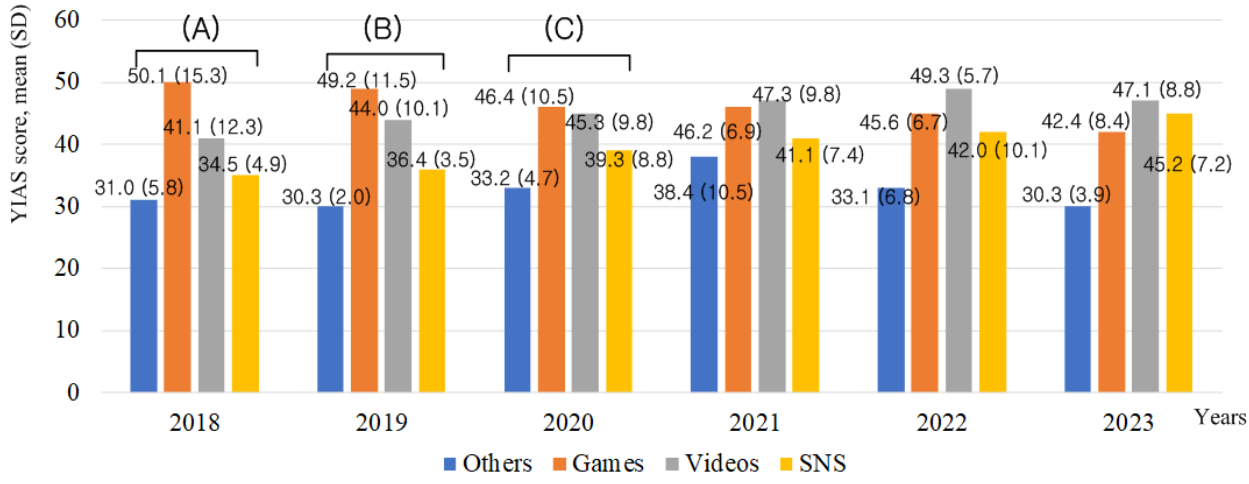
Figure 2. Changes in problematic internet use for 4 activities in Korean adolescents over 6 years. SNS: Social Network Service.



Differences in YIAS Scores for 4 Activities in Korean Adolescents Over 6 Years

In 2018, the YIAS scores for gameplay (mean 50.1, SD 15.3) were the highest compared to other activities. The YIAS scores for watching videos (mean 41.1, SD 12.3) were higher than those for SNS use (mean 34.5, SD 4.9) and other activities (mean 31.0, SD 5.8; F_3=14.63; P<.001). In 2019, the YIAS scores for gameplay (mean 49.2, SD 11.5) and watching videos (mean 44.0, SD 10.1) were higher than those for SNS use (mean 36.4, SD 3.5) and other activities (mean 30.3, SD 2.0; F_3=9.37; P<.001). In 2020, the YIAS scores for gameplay (mean 46.4, SD 10.5) and watching videos (mean 45.3, SD 9.8) were higher than those for SNS use (mean 39.3, SD 8.8) and other activities (mean 33.2, SD 4.7; F_3=4.98; P=.003). In 2021, there was no significant difference between the scores of the four activities (F_3=2.33; P=.08). In 2022, the YIAS scores for other activities (mean 33.1, SD 6.8) were significantly lower than those for gameplay (mean 45.6, SD 6.7), watching videos (mean 49.3, SD 5.7), and SNS use (mean 42.0, SD 10.1; F_3=6.83; P<.001). However, there was no significant difference between the scores for gameplay, watching videos, and SNS use. In 2023, the YIAS scores for other activities (mean 30.3, SD 3.9) were significantly lower, than those for gameplay (mean 42.4, SD 8.4), watching videos (mean 47.1, SD 8.8), and SNS use (mean 45.2, SD 7.2; F_3=4.73; P=.004). However, there was no significant difference between the scores for gameplay, watching videos, and SNS use (Figure 3).

Figure 3. The changes in YIAS scores for 4 activities in Korean adolescents over 6 years. (A) Game>Videos>SNS=Others (F_3=14.63; P<.001). (B) Game=Videos>SNS=Others (F_3=9.37; P<.001). (C): Game=Videos>SNS=Others (F_3=4.98; P=.003). SNS: Social Network Service; YIAS: Young's Internet Addiction Scale.



Differences in Influencing Factors for YIAS Scores

Considering the beta values of Model 4, the order of statistically significant influences on the severity of internet addiction in 2018 was as follows: game playing, PHQ-9 scores, watching videos, K-ARS scores, and IT use time (Table 3 and Table S1 in Multimedia Appendix 1). In 2019, the order was game playing, watching videos, PHQ-9 scores, K-ARS scores, and IT use time (Table 3 and Table S2 in Multimedia Appendix 1). In 2020, the order was K-ARS scores, game playing, and watching videos (Table 3 and Table S3 in Multimedia Appendix 1). In 2021, the order was PHQ-9 scores and watching videos (Table 3 and Table S4 in Multimedia Appendix 1). In 2022, the order was watching videos, game playing, PHQ-9 scores, K-ARS scores, and SNS use (Table 3 and Table S5 in Multimedia Appendix 1). In 2023, the order was PHQ-9 scores, K-ARS scores, watching videos, SNS use, and game playing (Table 3 and Table S6 in Multimedia Appendix 1).

XSL•FO
RenderX

Table 3. Differences in influencing factors for YIAS[a] scores over 6 years.

Variables	2018	2019	2020	2021	2022	2023
Demographic factors						
Age	—[b]	—	—	—	—	—
Sex	—	—	—	—	—	—
Psychological test						
SE[c]	—	—	—	—	—	—
PHQ-9[d]	X2[e] (0.40)	X3 (0.30)	—	X1 (0.51)	X3 (0.31)	X1 (0.57)
K-SPIN[f]	—	—	—	—	—	—
K-ARS[g]	X4 (0.23)	X4 (0.30)	X1 (0.60)	—	X4 (0.25)	X2 (0.33)
IT use time	X5 (0.17)	X5 (0.13)	—	—	—	—
IT activity						
Game	X1 (0.52)	X1 (0.39)	X2 (0.24)	—	X2 (0.37)	X5 (0.24)
Videos	X3 (0.26)	X2 (0.36)	X3 (0.24)	X2 (0.25)	X1 (0.43)	X3 (0.28)
SNS[h]	—	—	—	—	X5 (0.25)	X4 (0.26)

[a]YIAS: Young's Internet Addiction Scale.

[b]Not applicable.

[c]SE: Two-Factor Self-Esteem Scale.

[d]PHQ-9: Patient Health Questionnaire 9.

[e]Xn (beta value): X: statistically significant; n: ranking; 1: most effective factor.

[f]K-SPIN: Korean version of the Social Phobia Inventory.

[g]K-ARS: Korean version of the Attention Deficit/Hyperactivity Disorder Rating Scale.

[h]SNS: Social Network Service.

Discussion

Principal Findings

The goal of this study was to examine changes in internet use patterns among adolescents, from before to after the outbreak of the COVID-19 pandemic. Our findings revealed several changes in internet use time and patterns, as well as shifts in problematic use behavior before, during, and after COVID-19.

The results showed that PHQ-9 scores were low before and after the COVID-19 pandemic, but high from 2020 to 2022, when the pandemic was at its peak. This aligns with previous studies indicating a high proportion of adolescents experiencing depression and anxiety during the pandemic [26,27]. The COVID-19 pandemic brought significant changes to adolescents' lives, potentially acting as environmental stressors [28]. To avoid exposure to the virus, young people actively avoided social activities, and many children and adolescents were confined to their homes for extended periods due to lockdowns. This social isolation has been associated with an increased risk of depression and anxiety in children and adolescents [29]. Additionally, the fear of infection itself was linked to anxiety and depression [30]. With the lifting of lockdowns, most people have resumed their lives, and depression and anxiety likely diminished since the peak of the pandemic due to the development of coping mechanisms and hopeful news about vaccines during the "honeymoon phase" of the disaster [31-33].

Similar results regarding the relationship between mental health and internet addiction during the COVID-19 pandemic were reported in several studies [34,35]. Ye et al [34] reported that depression is positively correlated with internet addiction during the COVID-19 pandemic. Moreover, adolescents with depressive disorders could have a higher risk of internet addiction. In a meta-analysis, Tang et al [35] reported that the association between problematic smartphone use and depressive symptoms became stronger after the COVID-19 outbreak.

To our knowledge, there is evidence of changes in internet use patterns during the pandemic, including increased dependence on the internet [36]. In a large, national youth sample, cross-sectional study conducted in the United States during the early period of the COVID-19 pandemic, the absolute time of internet use among teenagers more than doubled compared to prepandemic times [37]. Additionally, a systematic review and meta-analysis of screen time among children and youth aged 0 to 21 years before and after the pandemic showed a 1.6-fold increase in screen time during the pandemic [38]. Similarly, in this study, from 2020 to 2021, during the COVID-19 outbreak, adolescents used the internet more than before, and their internet use time decreased as the COVID-19 peak passed. Previous studies have shown that internet use time increased as physical activity decreased due to the lockdowns caused by COVID-19 [39,40]. These results may reflect decreased screen time as physical and offline activity increased when daily life recovered after COVID-19 [41].

XSL•FO
RenderX

During the pandemic, teenagers increased their internet use for various purposes, such as interacting with friends, doing homework, enjoying games, and attending remote classes [42]. Generally, internet addiction is suspected when an individual devotes excessive time to internet use [43]. Excessive internet use is known to likely lead to internet addiction, especially in children and adolescents [44]. Similarly, as adolescents spend more time on web-based activities during the pandemic, many studies have shown an increased risk of internet addiction. For instance, a study examining internet addiction in Taiwanese high school students during COVID-19 found a 24.4% rate of addiction, indicating an increase compared to prepandemic levels [45]. In a longitudinal study on the developmental qualities of children and adolescents during the COVID-19 pandemic, Wang et al [46] suggested that the pandemic may lead to a decline in positive youth development, making them more vulnerable to internet addiction. Additionally, a study conducted in India investigated the effect of the COVID-19 lockdown on internet addiction in late teenagers, showing a 14.84% increase in internet gaming disorder (IGD) frequency compared to previous studies in the same region [47]. However, most studies focused only on excessive internet use and did not differentiate specific internet activities. Therefore, to address problematic internet use among adolescents, it is necessary to examine in more detail which specific internet activities are problematic.

Looking at the changes in internet use behavior that this study focused on, game playing decreased in adolescents after the pandemic compared to before the pandemic, and watching videos increased further. In addition, in this paper, the problematic internet use rate of games was the highest before COVID-19. Still, after COVID-19, the problematic internet use rate was the highest in the video group, and this trend continued until 2023. In addition, as our study showed, the YIAS score was the highest in the game group in 2018 compared to other groups before COVID-19. Still, in 2019, the YIAS scores in the game and video groups were higher than other groups, and the YIAS scores between the game, video, and SNS groups did not differ significantly as we went into 2022. The degree of influence on the severity of internet addiction was also the largest in the game group before COVID-19, but the effect on the video group was greater than in the game group after COVID-19.

Similar to these findings, several studies have reported significant changes in how individuals allocate time across different activities during the COVID-19 pandemic, noting increased SNS use, watching videos, and more, not just gaming [36,48,49]. According to a probability-based tracking survey of tweens and teens in the United States, there was no significant difference in teen gaming time between 2019 and 2021. Still, the time spent watching videos increased significantly, up to 23 minutes daily [50]. As several reports suggest, overall, the global gaming market has shrunk since the COVID-19 pandemic [51], and gaming users' gaming hours have declined since the peak [52]. On the other hand, the video-related industry has grown significantly as lockdowns have made it one of the major recreational activities [53]. According to Morse et al [54], TV or streams or movies have emerged as a new leisure activity, with activities experiencing the greatest increase during COVID-19. Another study suggests that Netflix, Hulu, and Amazon Prime Video are now recognized as some of the most important TV networks and video sources for the younger adult generation, further highlighting the popularity of streaming services [55]. Similarly, other studies point to the problematic use of SNS platforms, including video consumption by adolescents [36,56,57].

In the paper by Nawaz et al [36] on technology utilization in the new post–COVID-19 era, social networking platform engagement has increased markedly as study participants have been given more time for web-based social interaction. Meanwhile, in one study conducted in Italy, video consumption through certain platforms, like TikTok, during the COVID-19 pandemic strongly predicted social media addiction [56]. In addition, similar to previous studies that revealed that adolescents' social anxiety can lead to problematic social media use [57]; the increasing web-based social interaction trend, rather than internet gaming, reflects the growing dependence on digital connections as a coping mechanism during physical distancing and quarantines, with web-based streaming services, including videos, also experiencing notable use increases [36]. Taken together, even before COVID-19, video-sharing platforms such as YouTube [58] and social media platforms such as Instagram or Snapchat were already gaining popularity [59]. However, short video consumption worldwide saw the fastest and largest increase in the early stages of the pandemic, especially among those aged 15-29 years [60], where teenagers would have sought self-expression and social rewards by recording and communicating their daily lives [61]. Furthermore, the rise in the use of SNS and video apps during COVID-19 suggests a shift in overall trends during physical distancing, searching for information, and using platforms to help maintain social relationships [62].

As mentioned in the previous results, the COVID-19 pandemic has significantly changed people's lives worldwide, with internet use at the center of this change. Although internet use has alleviated mental health symptoms for many and helped them cope with new trends [63,64], adolescents have been able to devote more time to web-based activities, especially during emotionally demanding times, which can lead to problematic use [65]. It is essential to provide guidance to reduce the risk of such addiction. Adults should observe how much time adolescents spend on web-based activities (eg, playing games and watching videos) and help them manage these activities [48].

However, problematic internet use has not yet been sufficiently discussed. The American Psychiatric Association included IGD in *DSM-5* [66], and the World Health Organization included gaming disorder in the *International Classification of Diseases, 11th Revision* [67], but current societies present only diagnostic criteria for games. This study shows that games no longer account for a high percentage of adolescents' problematic internet use time. In addition, the *DSM-5* acknowledges the limitations of the absence of well-studied subtypes for IGD and acknowledges that there are limitations to the diagnosis, such as the fact that it is not clear which game type is specifically included in IGD diagnosis [66]. Furthermore, a survey of

XSL•FO
RenderX

adolescents in China on IGD, problematic smartphone use, and problematic SNS use found that each has a different core symptom, with problematic SNS use requiring a different therapeutic approach as it shows a different core symptom [68]. Similarly, as Griffiths [10] argued in his study on the concept of internet addiction and IGD, it should be understood that people addicted to web-based activities, such as web-based games, web-based gambling, web-based sex, and web-based shopping, should not be defined as people with internet addictions, but rather as people with game addictions, sex addictions, or shopping addictions, who are engaged in addictive behavior using the internet as a tool. Chen et al [69] reported that problematic smartphone use was associated with the COVID-19 pandemic outbreak, whereas problematic internet gaming was not. Previous studies suggest that the focus should be on how the internet is used, rather than seeing the excessive internet use itself as the problem. It is not just gameplay time that is a problem—as individual internet behavior patterns have changed during the COVID-19 pandemic, these points should be considered when solving problematic internet use.

Limitations

There are some limitations to this study. First, there may be sampling errors in representing the overall internet use patterns of teenagers, as the survey only included teenagers aged 13 to 15 years. Second, because this study did not track the same population over 6 years, it was unable to fully capture the trends in internet addiction and patterns of internet use among adolescents. Third, this study could not fully capture changes in internet addiction and mental health because it was not a longitudinal study within a single group.

Although literature on the pandemic has surged with the global spread of COVID-19, little has been studied about the changes in media and content use caused by the pandemic [70]. To the best of our knowledge, this is the first study to focus on changes in internet use patterns due to the pandemic. The strength of our study lies in surveying the same teenage group over 6 years before, during, and after COVID-19 and further investigating which types of internet use were identified as problematic. Based on these changes in internet use patterns and problems among teenagers, this study contributes to the literature on understanding the trends in internet use behavior caused by COVID-19 and helps predict future changes in internet use.

Conclusions

During the COVID-19 pandemic, academic and commercial internet use through remote classes and videoconferences increased rapidly worldwide, leading to a rise in overall internet use time. The demand for digital platforms will continue to grow in the coming era. Until now, discussions have primarily focused on the use of games, but it is now necessary to consider what types of internet behavior cause problems and how to address them.

Acknowledgments

The authors would like to thank the Korean Game Culture Foundation for helping with data collection and game literacy education. This research was supported by a grant from the Korea Health Industry Development Institute (grant HI22C0775), Ministry of Health & Welfare, Republic of Korea.

Data Availability

The datasets generated and analyzed during this study are not publicly available as they contain information that could compromise the privacy and consent of the research participants but are available from the corresponding author upon reasonable request.

Authors' Contributions

SIK and DHH contributed to the study design, data collection, and initial drafting of the manuscript. JCJ and SY participated in data analysis and interpretation and revised the manuscript critically for important intellectual content. JCJ and SIK assisted in developing the research methodology and contributed to data validation and visualization. DHH supervised the study, provided resources and funding, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Hierarchical linear regression analyses.
[DOCX File , 28 KB - pediatrics_v8i1e66448_app1.docx]

References

1. Young K. Caught in the Net: Understanding Internet Addiction. New York, NY: Wiley; 1998.
2. Korean internet statistics yearbook. Korea Network Information Center. 2002. URL: https://www.uaipit.com/en/link-record?/50/korea-network-information-center-krnic [accessed 2025-01-15]
3. Internet usage rate in South Korea from 2015 to 2023, by age group. Statista. 2024. URL: https://www.statista.com/statistics/226740/age-composition-of-internet-users-in-south-korea/ [accessed 2025-01-15]

XSL•FO
RenderX

4. Griffiths MD, van Rooij AJ, Kardefelt-Winther D, Starcevic V, Király O, Pallesen S, et al. Working towards an international consensus on criteria for assessing internet gaming disorder: a critical commentary on Petry et al. (2014). Addiction 2016;111(1):167-175 [FREE Full text] [doi: 10.1111/add.13057] [Medline: 26669530]
5. King DL, Delfabbro PH. Internet gaming disorder treatment: a review of definitions of diagnosis and treatment outcome. J Clin Psychol 2014;70(10):942-955. [doi: 10.1002/jclp.22097] [Medline: 24752874]
6. Kuss DJ, Griffiths MD. Internet gaming addiction: a systematic review of empirical research. Int J Ment Health Addiction 2011;10(2):278-296. [doi: 10.1007/s11469-011-9318-5]
7. Petry N, O'Brien CP. Internet gaming disorder and the DSM-5. Addiction 2013;108(7):1186-1187. [doi: 10.1111/add.12162] [Medline: 23668389]
8. Pies R. Should DSM-V designate "Internet Addiction" a mental disorder? Psychiatry (Edgmont) 2009;6(2):31-37 [FREE Full text] [Medline: 19724746]
9. van Rooij A, Prause N. A critical review of "Internet addiction" criteria with suggestions for the future. J Behav Addict 2014;3(4):203-213 [FREE Full text] [doi: 10.1556/JBA.3.2014.4.1] [Medline: 25592305]
10. Griffiths MD. Conceptual issues concerning internet addiction and internet gaming disorder: further critique on Ryding and Kaye (2017). Int J Ment Health Addict 2018;16(1):233-239 [FREE Full text] [doi: 10.1007/s11469-017-9818-z] [Medline: 29491772]
11. Kim D, Lee J. Addictive internet gaming usage among Korean adolescents before and after the outbreak of the COVID-19 pandemic: a comparison of the latent profiles in 2018 and 2020. Int J Environ Res Public Health 2021;18(14):7275 [FREE Full text] [doi: 10.3390/ijerph18147275] [Medline: 34299725]
12. Wong HY, Mo HY, Potenza MN, Chan MNM, Lau WM, Chui TK, et al. Relationships between severity of internet gaming disorder, severity of problematic social media use, sleep quality and psychological distress. Int J Environ Res Public Health 2020;17(6):1879 [FREE Full text] [doi: 10.3390/ijerph17061879] [Medline: 32183188]
13. Coutelle R, Balzer J, Rolling J, Lalanne L. Problematic gaming, psychiatric comorbidities, and adolescence: a systematic review of the literature. Addict Behav 2024;157:108091. [doi: 10.1016/j.addbeh.2024.108091] [Medline: 38901145]
14. Jo YS, Bhang SY, Choi JS, Lee HK, Lee SY, Kweon YS. Internet, gaming, and smartphone usage patterns of children and adolescents in Korea: a c-CURE clinical cohort study. J Behav Addict 2020;9(2):420-432 [FREE Full text] [doi: 10.1556/2006.2020.00022] [Medline: 32644934]
15. Wolf K, Schmitz J. Scoping review: longitudinal effects of the COVID-19 pandemic on child and adolescent mental health. Eur Child Adolesc Psychiatry 2024;33(5):1257-1312 [FREE Full text] [doi: 10.1007/s00787-023-02206-8] [Medline: 37081139]
16. Wartberg L, Kammerl R. Empirical relationships between problematic alcohol use and a problematic use of video games, social media and the internet and their associations to mental health in adolescence. Int J Environ Res Public Health 2020;17(17):6098 [FREE Full text] [doi: 10.3390/ijerph17176098] [Medline: 32825700]
17. Nilsson A, Rosendahl I, Jayaram-Lindström N. Gaming and social media use among adolescents in the midst of the COVID-19 pandemic. Nordisk Alkohol Nark 2022;39(4):347-361 [FREE Full text] [doi: 10.1177/14550725221074997] [Medline: 35999947]
18. Wu Q, Ren Q, Zhong N, Bao J, Zhao Y, Du J, et al. Internet behavior patterns of adolescents before, during, and after COVID-19 pandemic. Front Psychiatry 2022;13:947360 [FREE Full text] [doi: 10.3389/fpsyt.2022.947360] [Medline: 36440398]
19. Starcevic V, Choi TY, Kim TH, Yoo SK, Bae S, Choi BS, et al. Internet gaming disorder and gaming disorder in the context of seeking and not seeking treatment for video-gaming. J Psychiatr Res 2020;129:31-39. [doi: 10.1016/j.jpsychires.2020.06.007] [Medline: 32559506]
20. Park SJ, Choi HR, Choi JH, Kim KW, Hong JP. Reliability and validity of the Korean version of the patient health questionnaire-9. Anxiety Mood 2010;6(2):119-124 [FREE Full text]
21. DuPaul GJ, Rapport MD, Perriello LM. Teacher ratings of academic skills: the development of the academic performance rating scale. School Psychol Rev 2019;20(2):284-300. [doi: 10.1080/02796015.1991.12085552]
22. So Y, Noh J, Kim Y, Ko S, Koh Y. The reliability and validity of Korean parent and teacher ADHD rating scale. J Korean Neuropsychiatr Assoc 2002:283-289 [FREE Full text]
23. Cho Y, Choi Y, Kim S, Hong S. Factor structure and other psychometric properties of the social phobia inventory in Korean samples. Meas Eval Couns Dev 2018;51(4):263-280. [doi: 10.1080/07481756.2018.1435188]
24. Rosenberg M. Society and the Adolescent Self-Image: 2015. Princeton, NJ: Princeton University Press; 2015.
25. Han Y, Chung J. Two-factor self-esteem scale: individualistic and collectivistic factors. Korean J Soc Pers Psychol 2007;21(4):117-131. [doi: 10.21193/kjspp.2007.21.4.007]
26. Barendse ME, Flannery J, Cavanagh C, Aristizabal M, Becker SP, Berger E, et al. Longitudinal change in adolescent depression and anxiety symptoms from before to during the COVID-19 pandemic. J Res Adolesc 2023;33(1):74-91 [FREE Full text] [doi: 10.1111/jora.12781] [Medline: 35799311]
27. Madigan S, Racine N, Vaillancourt T, Korczak DJ, Hewitt JMA, Pador P, et al. Changes in depression and anxiety among children and adolescents from before to during the COVID-19 pandemic: a systematic review and meta-analysis. JAMA Pediatr 2023;177(6):567-581 [FREE Full text] [doi: 10.1001/jamapediatrics.2023.0846] [Medline: 37126337]

XSL•FO
RenderX

28. Wang S, Chen L, Ran H, Che Y, Fang D, Sun H, et al. Depression and anxiety among children and adolescents pre and post COVID-19: a comparative meta-analysis. Front Psychiatry 2022;13:917552 [FREE Full text] [doi: 10.3389/fpsyt.2022.917552] [Medline: 35990058]
29. Loades ME, Chatburn E, Higson-Sweeney N, Reynolds S, Shafran R, Brigden A, et al. Rapid systematic review: the impact of social isolation and loneliness on the mental health of children and adolescents in the context of COVID-19. J Am Acad Child Adolesc Psychiatry 2020;59(11):1218-1239.e3 [FREE Full text] [doi: 10.1016/j.jaac.2020.05.009] [Medline: 32504808]
30. Deolmi M, Pisani F. Psychological and psychiatric impact of COVID-19 pandemic among children and adolescents. Acta Biomed 2020;91(4):e2020149 [FREE Full text] [doi: 10.23750/abm.v91i4.10870] [Medline: 33525229]
31. Fard HA, Borazjani R, Shams A, Rezaee V, Aminnia S, Salimi M, et al. Anxiety and stress seem temporary during the pneumonia COVID-19 pandemic: a survey on the mental health status of healthcare workers. Bull Emerg Trauma 2022;10(3):128-134 [FREE Full text] [doi: 10.30476/BEAT.2022.94720.1344] [Medline: 35991375]
32. Myruski S, Pérez-Edgar K, Buss KA. Adolescent coping and social media use moderated anxiety change during the COVID-19 pandemic. J Adolesc 2024;96(1):177-195. [doi: 10.1002/jad.12267] [Medline: 37919867]
33. Rong R, Xu Q, Jordan KP, Chen Y. Perceived epidemic impacts and mental symptom trajectories in adolescents back to school after COVID-19 restriction: a longitudinal latent class analysis. J Adolesc Health 2024;74(3):487-495. [doi: 10.1016/j.jadohealth.2023.09.011] [Medline: 37966411]
34. Ye XL, Zhang W, Zhao FF. Depression and internet addiction among adolescents:a meta-analysis. Psychiatry Res 2023;326:115311. [doi: 10.1016/j.psychres.2023.115311] [Medline: 37348449]
35. Tang S, Chen R, Ma Z, Li X, Chen J, Zhao J. Associations of problematic smartphone use with depressive symptoms and suicidal ideation in university students before and after the COVID-19 outbreak: a meta-analysis. Addict Behav 2024;152:107969. [doi: 10.1016/j.addbeh.2024.107969] [Medline: 38290322]
36. Nawaz S, Bhowmik J, Linden T, Mitchell M. Adapting to the new normal: understanding the impact of COVID-19 on technology usage and human behaviour. Entertain Comput 2024;51:100726. [doi: 10.1016/j.entcom.2024.100726]
37. Nagata JM, Cortez CA, Cattle CJ, Ganson KT, Iyer P, Bibbins-Domingo K, et al. Screen time use among US adolescents during the COVID-19 pandemic: findings from the adolescent brain cognitive development (ABCD) study. JAMA Pediatr 2022;176(1):94-96 [FREE Full text] [doi: 10.1001/jamapediatrics.2021.4334] [Medline: 34724543]
38. Choi EJ, King G, Duerden EG. Screen time in children and youth during the pandemic: a systematic review and meta-analysis. Global Pediatr 2023;6:100080. [doi: 10.1016/j.gpeds.2023.100080]
39. Claesdotter-Knutsson E, André F, Håkansson A. Gaming activity and possible changes in gaming behavior among young people during the COVID-19 pandemic: cross-sectional online survey study. JMIR Serious Games 2022;10(1):e33059 [FREE Full text] [doi: 10.2196/33059] [Medline: 34817386]
40. Saunders T, Colley RC. Regional trends in the moderate-to-vigorous intensity physical activity and screen time of Canadians before and during the COVID-19 pandemic. PeerJ 2024;12:e16913 [FREE Full text] [doi: 10.7717/peerj.16913] [Medline: 38436001]
41. Katewongsa P, Widyastari DA, Haemathulin N, Khanawapee A, Penmai S. Recovery shape of physical activity after COVID-19 pandemic. J Sport Health Sci 2023;12(4):501-512 [FREE Full text] [doi: 10.1016/j.jshs.2023.02.007] [Medline: 36868376]
42. Dong H, Yang F, Lu X, Hao W. Internet addiction and related psychological factors among children and adolescents in China during the coronavirus disease 2019 (COVID-19) epidemic. Front Psychiatry 2020;11:00751 [FREE Full text] [doi: 10.3389/fpsyt.2020.00751] [Medline: 32982806]
43. Kaya A, Dalgiç AI. How does internet addiction affect adolescent lifestyles? Results from a school-based study in the mediterranean region of Turkey. J Pediatr Nurs 2021;59:e38-e43. [doi: 10.1016/j.pedn.2021.01.021] [Medline: 33589290]
44. Kurniasanti KS, Assandi P, Ismail RI, Nasrun MWS, Wiguna T. Internet addiction: a new addiction? Med J Indones 2019;28(1):82-91. [doi: 10.13181/mji.v28i1.2752]
45. Lin MP. Prevalence of internet addiction during the COVID-19 outbreak and its risk factors among junior high school students in Taiwan. Int J Environ Res Public Health 2020;17(22):8547 [FREE Full text] [doi: 10.3390/ijerph17228547] [Medline: 33218018]
46. Wang Z, Hong B, Zhang Y, Su Y, Li M, Zhao L, et al. Children and adolescents' positive youth development qualities and internet addiction during the COVID-19 pandemic: a longitudinal study in China. Front Psychiatry 2022;13:1068737 [FREE Full text] [doi: 10.3389/fpsyt.2022.1068737] [Medline: 36713917]
47. Balhara YPS, Kattula D, Singh S, Chukkali S, Bhargava R. Impact of lockdown following COVID-19 on the gaming behavior of college students. Indian J Public Health 2020;64(Supplement):S172-S176 [FREE Full text] [doi: 10.4103/ijph.IJPH_465_20] [Medline: 32496250]
48. Akdağ B, Önder A, Gül ME, Yorulmaz Ş, Kopuz HY, Çoban Ö, et al. Online behavioral addictions among adolescents before and after the COVID-19 pandemic. Cureus 2023;15(8):e43231 [FREE Full text] [doi: 10.7759/cureus.43231] [Medline: 37692657]
49. Rouleau RD, Beauregard C, Beaudry V. A rise in social media use in adolescents during the COVID-19 pandemic: the French validation of the bergen social media addiction scale in a Canadian cohort. BMC Psychol 2023;11(1):92 [FREE Full text] [doi: 10.1186/s40359-023-01141-2] [Medline: 37004081]

XSL•FO
RenderX

50. Rideout V, Peebles A, Mann S, Robb MB. Common Sense Census: Media Use by Tweens and Teens, 2021. San Francisco, CA: Common Sense; 2022.
51. Ying W. The long-term impact of COVID-19 on the game industry: evidence from daily new confirmed cases. BCP Bus Manage 2022;35:179-187 [FREE Full text]
52. The PC and Console Gaming Report 2024. Newzoo. URL: https://newzoo.com/resources/trend-reports/pc-console-gaming-report-2024 [accessed 2024-04-02]
53. Piñeiro-Chousa J, López-Cabarcos M, Pérez-Pico AM, Caby J. The influence of twitch and sustainability on the stock returns of video game companies: before and after COVID-19. J Bus Res 2023;157:113620 [FREE Full text] [doi: 10.1016/j.jbusres.2022.113620] [Medline: 36618961]
54. Morse KF, Fine PA, Friedlander KJ. Creativity and leisure during COVID-19: examining the relationship between leisure activities, motivations, and psychological well-being. Front Psychol 2021;12:609967 [FREE Full text] [doi: 10.3389/fpsyg.2021.609967] [Medline: 34290635]
55. Ball BL. Marketing Video Games to Aging Demographics: A Generational Profile Analysis. Saint Charles, MO: Lindenwood University; 2024.
56. Marengo D, Angelo Fabris M, Longobardi C, Settanni M. Smartphone and social media use contributed to individual tendencies towards social media addiction in Italian adolescents during the COVID-19 pandemic. Addict Behav 2022;126:107204. [doi: 10.1016/j.addbeh.2021.107204] [Medline: 34875508]
57. Durak HY. Modeling of variables related to problematic internet usage and problematic social media usage in adolescents. Curr Psychol 2018;39(4):1375-1387. [doi: 10.1007/s12144-018-9840-8]
58. Koeze E, Popper N. The virus changed the way we internet. The New York Times 2020;7(04).
59. Dixon S. Number of monthly active Facebook users worldwide as of 2nd quarter 2022. Statista. URL: https://www.statista.com/statistics/264810/number-of-monthly-active-facebook-users-worldwide/ [accessed 2024-08-15]
60. Klug D, Evans M, Kaufman G. How TikTok served as a platform for young people to share and cope with lived COVID-19 experiences. MedieKultur 2023;38(73):152-170. [doi: 10.7146/mk.v38i73.128463]
61. Lee E, Lee JA, Moon JH, Sung Y. Pictures speak louder than words: motivations for using instagram. Cyberpsychol Behav Soc Netw 2015;18(9):552-556. [doi: 10.1089/cyber.2015.0157] [Medline: 26348817]
62. Bowden-Green T, Hinds J, Joinson A. Personality and motives for social media use when physically distanced: a uses and gratifications approach. Front Psychol 2021;12:607948 [FREE Full text] [doi: 10.3389/fpsyg.2021.607948] [Medline: 34194354]
63. Mäntymäki M, Najmul Islam AKM, Turel O, Dhir A. Coping with pandemics using social network sites: a psychological detachment perspective to COVID-19 stressors. Technol Forecast Soc Change 2022;179:121660 [FREE Full text] [doi: 10.1016/j.techfore.2022.121660] [Medline: 35400767]
64. Marciano L, Ostroumova M, Schulz PJ, Camerini A. Digital media use and adolescents' mental health during the COVID-19 pandemic: a systematic review and meta-analysis. Front Public Health 2021;9:793868 [FREE Full text] [doi: 10.3389/fpubh.2021.793868] [Medline: 35186872]
65. Putra PY, Fithriyah I, Zahra Z. Internet addiction and online gaming disorder in children and adolescents during COVID-19 pandemic: a systematic review. Psychiatry Investig 2023;20(3):196-204 [FREE Full text] [doi: 10.30773/pi.2021.0311] [Medline: 36990662]
66. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-5-TR). Washington, DC: American Psychiatric Association; 2013.
67. The ICD-10 Classification of Mental and Behavioural Disorders: Diagnostic Criteria for Research. Geneva, Switzerland: World Health Organization; 1993.
68. Li Y, Mu W, Xie X, Kwok SY. Network analysis of internet gaming disorder, problematic social media use, problematic smartphone use, psychological distress, and meaning in life among adolescents. Digital Health 2023;9:205520762311580. [doi: 10.1177/20552076231158036]
69. Chen CY, Chen IH, Hou WL, Potenza MN, O'Brien KS, Lin CY, et al. The relationship between children's problematic internet-related behaviors and psychological distress during the onset of the COVID-19 pandemic: a longitudinal study. J Addict Med 2022;16(2):e73-e80 [FREE Full text] [doi: 10.1097/ADM.0000000000000845] [Medline: 33770003]
70. Sung N, Kim M. COVID-19 and changes in content usage behavior: the case of South Korea. Telecomm Policy 2023;47(1):102461 [FREE Full text] [doi: 10.1016/j.telpol.2022.102461] [Medline: 36246454]

Abbreviations

ADHD: attention-deficit/hyperactivity disorder
ARS: Attention-Deficit/Hyperactivity Disorder Rating Scale
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
IGD: internet gaming disorder
K-ARS: Korean version of the Attention-Deficit/Hyperactivity Disorder Rating Scale
K-SPIN: Korean version of the Social Phobia Inventory

XSL•FO
RenderX

PHQ-9: Patient Health Questionnaire 9
SE: Two-Factor Self-Esteem Scale
SNS: Social Network Service
SPIN: Social Phobia Inventory
YIAS: Young's Internet Addiction Scale

Edited by S Badawy; submitted 13.09.24; peer-reviewed by K Lee; comments to author 24.10.24; revised version received 18.11.24; accepted 20.12.24; published 11.02.25.

Please cite as:
Kim SI, Jin JC, Yoo SK, Han DH
Changes in Internet Activities and Influencing Factors for Problematic Internet Use During the COVID-19 Pandemic in Korean Adolescents: Repeated Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e66448
URL: https://pediatrics.jmir.org/2025/1/e66448
doi:10.2196/66448
PMID:

©Sol I Kim, Jae-Chan Jin, Seo-Koo Yoo, Doug Hyun Han. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 11.02.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Effects of Web-Based Single-Session Growth Mindset Interventions for Reducing Adolescent Anxiety: Four-Armed Randomized Controlled Trial

Shimin Zhu[1], PhD; Yuxi Hu[1], MAP; Di Qi[1], PhD; Samson Tse[2], PhD; Ko Ling Chan[1], PhD; Jessica Sun[3], MD; Paul Lee[4], PhD

[1]Department of Applied Social Sciences, The Hong Kong Polytechnic University, Hong Kong, China (Hong Kong)

[2]Department of Social Work and Social Administration, The University of Hong Kong, Hong Kong, China (Hong Kong)

[3]Kowloon Hospital Child & Adolescent Mental Health Centre, Hong Kong, China (Hong Kong)

[4]Southampton Clinical Trials Unit, University of Southampton, Southampton, United Kingdom

Corresponding Author:
Shimin Zhu, PhD
Department of Applied Social Sciences
The Hong Kong Polytechnic University
GH348, 11 Yuk Choi Rd, Hung Hom
Hong Kong
China (Hong Kong)
Phone: 852 2766 5787
Email: jasmine.zhu@polyu.edu.hk

Abstract

Background: Anxiety disorders are the most common mental health conditions worldwide, yet 65% of those affected do not access services. The high prevalence of anxiety and the low rate of intervention uptake highlight the urgent need to develop timely, scalable, and effective interventions suitable for adolescents. This study adapted existing single-session interventions (SSIs) to further develop an SSI focused on a growth mindset regarding negative emotions for adolescent mental health.

Objective: The study aims to compare the effectiveness of 4 SSIs, SSI of a growth mindset for anxiety (SIGMA), SIGMA with boosters (SIGMA-Booster), SSI of a growth mindset of personality (SSIGP), and an active control group (support therapy [ST]), in reducing adolescent anxiety.

Methods: Classes from each secondary school were randomized to 1 of 4 intervention conditions: SIGMA, SIGMA-Booster, SSIGP, or ST. Each intervention took approximately 45 minutes online. Participants reported on anxiety symptoms (primary outcome), depressive symptoms, suicidal/self-harming thoughts, perceived control, hopelessness, attitude toward help-seeking, and psychological well-being (secondary outcomes) at preintervention, 2-week follow-up, and 8-week follow-up. Participants also completed a feedback scale postintervention. Generalized estimating equations were used to examine the effectiveness of the SSIs.

Results: A total of 731 adolescents from 7 secondary schools were randomized. The intent-to-treat analysis found a significant decrease in anxiety symptoms. The mean and 95% CI at baseline were 6.8 (6.0-7.6) for SIGMA-Booster, 6.5 (5.8-7.3) for SIGMA, 7.0 (6.2-7.7) for SSIGP, and 6.9 (6.1-7.7) for ST. At the 2-week follow-up, the mean and 95% CI were 5.9 (5.1-6.7) for SIGMA-Booster, 5.7 (4.9-6.5) for SIGMA, 5.4 (4.6-6.2) for SSIGP, and 5.7 (4.9-6.4) for ST. At the 8-week follow-up, the mean and 95% CI were 5.9 (5.1-6.7) for SIGMA-Booster, 5.3 (4.5-6.0) for SIGMA, 5.6 (4.8-6.4) for SSIGP, and 5.8 (5.1-6.6) for ST. These reductions were observed across all 4 groups. Moderation analysis found that participants with higher motivation for change, higher baseline anxiety scores, and fixed mindsets showed greater improvements in anxiety symptoms. Most participants (459/731, 62.8%) viewed the feasibility and acceptability of the SSIs positively.

Conclusions: The SSI for all 4 groups was effective in reducing anxiety and depression among adolescents over 8 weeks. Our data suggest the potential benefits of brief web-based interventions for adolescents, which could serve as scalable, destigmatized, and cost-effective alternatives to school-based programs. The intervention effects may have been underestimated, as this study did not exclude adolescents with minimal or no anxiety symptoms. Future studies should focus on the specific effects of interventions for adolescents with varying levels of anxiety symptoms.

XSL•FO
RenderX

Trial Registration: ClinicalTrials.gov NCT05027880; https://clinicaltrials.gov/ct2/show/NCT05027880

(JMIR Pediatr Parent 2025;8:e63500) doi:10.2196/63500

KEYWORDS

belief-in-change; growth mindset; mental health; secondary school students; brief intervention; randomized controlled trial

Introduction

Background

Anxiety is one of the leading causes of illness and disability among adolescents aged 10-19 years [1]. Approximately 6.5% of adolescents worldwide and 6.9% in Hong Kong have been diagnosed with anxiety disorders [2,3]. In Hong Kong, for example, 1 in 4 secondary school students experienced high subclinical anxiety symptoms over a 3-month period, requiring clinical intervention [4]. Based on prevalence rates and local youth population data [5], it is estimated that approximately 85,000 secondary school students in Hong Kong require help and intervention for anxiety symptoms.

However, an estimated 65% of individuals with generalized anxiety disorder in Hong Kong did not access mental health services [6]. Among those who sought help, the median waiting time from symptom onset to receiving public child and adolescent psychiatric services was 58 weeks. Meanwhile, the cost of private treatment was reported to be HK $3000 (US $386) per monthly consultation, making it unaffordable for many families, who were left with no choice but to wait for public services [7]. Existing approaches, such as clinic-based treatments provided by highly trained mental health professionals, face significant limitations, including lengthy waitlists, high costs, and challenges in large-scale dissemination. This traditional setting further restricts access to services in special circumstances, such as during the COVID-19 pandemic [8]. Moreover, adolescents with mental health symptoms are particularly vulnerable to stigma and discrimination and may be reluctant to seek school-based interventions [9]. Even among youth who access care, most drop out prematurely, completing only 3-4 therapy sessions on average [10]. While natural remission without treatment may occur, it is uncommon [11]. Given these challenges, there is a clear need to develop briefer, scalable, nonstigmatizing, and youth-friendly interventions for adolescents with general anxiety symptoms. A brief intervention that fosters insight or reduces anxiety about mental health symptoms may help alleviate mental health problems and support remission.

Single-session interventions (SSIs) are structured programs designed to involve only 1 visit or encounter with a clinic, provider, or program [12]. These interventions can function as stand-alone treatments or as adjuncts to clinical services. Notably, research has shown that the number of sessions is not related to the magnitude of the treatment effect [13]. As a very brief intervention consisting of just 1 session, SSIs have demonstrated a relatively substantial effect on youth psychiatric problems. A previous meta-analysis [14] reported a mean postintervention effect size of 0.32 (Hedges *g*), with the largest effect size observed for anxiety (0.56). Although the effects of SSIs were moderated by follow-up length, with smaller effect sizes observed in follow-ups exceeding 13 weeks [14], Schleider and Weisz [15] still found significant improvements in youth depression and perceived behavioral control following growth mindset SSIs, with effects lasting up to 9 months compared with an active control. They also found that enhancing belief in personality change improved treatment access for adolescent depression [16], although no significant changes were recorded for general anxiety, social anxiety, or conduct problems [17]. Walton and Wilson [18,19] emphasized the importance of precise interventions that target the underlying psychological processes contributing to social or psychological problems, as well as the need for an adaptive context to maximize the potency of brief interventions. Thus, the effectiveness of SSIs is closely tied to their content (what to intervene) and implementation strategies (how to intervene).

Given the substantial evidence linking fixed mindsets to youth mental health problems [20] and the positive effects of growth mindset SSIs on anxiety-related outcomes [21], this study developed and examined the efficacy of growth mindset SSIs for adolescent anxiety in the Chinese context. Although some cultural adaptations of growth mindset SSIs have been made for non-Western populations, such as Indian adolescents [22], few studies have examined growth mindset SSIs in the Chinese context, particularly for anxiety-related outcomes [23]. We aimed to advance the existing literature by implementing and comparing different domains of growth mindset and developing implementation strategies for SSIs among Chinese adolescents. First, this study developed the SSI of a growth mindset for anxiety (SIGMA). As fixed mindsets about negative emotions (beliefs that one's negative emotions cannot change) have been closely associated with adolescent depression and anxiety [24,25], interventions that promote growth mindsets about negative emotions (beliefs in the changeability of one's negative emotions) may help alleviate worry and anxiety in adolescents. Second, to examine the effectiveness of SIGMA, we adapted the existing SSIs into Chinese and compared them with SSI of a growth mindset of personality (SSIGP) and support therapy (ST) [15,26]. Third, we collected feedback from social workers and counselors based on the principle of patient and public involvement, and they suggested that boosters could help strengthen the effectiveness of brief interventions. Thus, we designed booster reminders for SIGMA and examined whether reinforcing the core messages of the intervention with boosters would strengthen its effectiveness. A deviation from the 3-arm intervention protocol is that we increased the sample size of participants receiving SIGMA with booster (SIGMA-Booster) messages, establishing it as an independent group. As a result, the SIGMA-Booster group and the SIGMA group now have sample sizes equivalent to the other 2 groups (SSIGP and ST), rather than selecting only half of the original SIGMA group to receive booster messages. We proposed this 4-arm randomized controlled trial to provide evidence on the effectiveness of

XSL•FO
RenderX

SIGMA (including SIGMA and SIGMA-Booster) and compare it against the existing growth mindset intervention (SSIGP) and support theory as an active control. Beyond its research significance, the study's findings could have broad implications for mental health care practice and policy. If the SSIs in this study are found to be effective, they could be scaled up in schools and community settings, offering a cost-effective and accessible solution to address youth mental health needs. This could reduce the burden on overstretched traditional mental health services and inform public health policies, such as integrating SSIs into school mental health programs or national strategies.

Objectives

The primary objective of the study was to evaluate the effectiveness of a single-session growth mindset intervention for negative emotions (abbreviated as SIGMA) in reducing general anxiety symptoms among secondary school students.

The secondary objective was to compare the effectiveness of the aforementioned programs on secondary outcomes, including reductions in depressive symptoms, suicidal/self-harming thoughts, and hopelessness, as well as increases in perceived control over emotions, attitudes toward help-seeking, and psychological well-being.

Study Hypothesis

- Hypothesis 1: SIGMA (including SIGMA and SIGMA-Booster) and SSIGP are more effective than the active control, ST, in the primary outcome of (1) reducing general anxiety symptoms, and in the secondary outcomes of (2) reducing depressive symptoms, (3) reducing suicidal/self-harming thoughts, (4) reducing hopelessness, (5) enhancing perceived control, (6) increasing positive attitudes toward help-seeking, and (7) enhancing psychological well-being.
- Hypothesis 2: SIGMA (including SIGMA and SIGMA-Booster) is more effective than SSIGP in the outcomes listed from (1) to (7).
- Hypothesis 3: The effectiveness of SIGMA-Booster is greater than that of SIGMA in the outcomes listed from (1) to (7).
- Hypothesis 4: The effectiveness of SIGMA is greater in participants with higher motivation for change than in those with low or no motivation.
- Hypothesis 5: The effectiveness of SIGMA is greater in participants with higher baseline anxiety levels than in those with lower baseline anxiety levels.
- Hypothesis 6: The effectiveness of SIGMA is greater in participants with a more fixed mindset at baseline than in those with a more growth-oriented mindset at baseline.

Methods

Ethical Considerations

This study received ethical approval from the Hong Kong Polytechnic University Institutional Review Board (reference number HSEARS20201004001-01) and complied with institutional guidelines and the Declaration of Helsinki. Parental consent and student assent were obtained for all participants. Participants were informed of their right to withdraw at any time without penalty. Data were anonymized (eg, school names removed, unique codes assigned) and stored securely. Participants who completed the entire study received HK $100 (US $13) worth of supermarket coupons as compensation, while participating schools were provided with aggregate mental health reports for institutional support purposes.

Study Design

The study design was described in the published protocol [27]. The trial was prospectively registered at ClinicalTrials.gov (NCT05027880) under the trial ID NCT05027880.

Unlike the published protocol, we made SIGMA-Booster a separate arm to examine whether booster reminders would help promote the long-term effects of the SSI. Based on the principle of patient and public involvement, we consulted the targeted participant population as well as their teachers and counselors. They suggested that boosters, as reminders, should be helpful for long-term changes. Thus, we designed 5 boosters and printed them into folders to be used as weekly reminders between the 2- and 8-week follow-ups (from week 3 to week 7). Only the SIGMA-Booster group received these boosters.

Thus, 4 classes from the same grade of the participating school were randomized (using computer-generated random numbers) into the (1) SIGMA group, (2) SIGMA-Booster group, (3) SSIGP group, and (4) ST group (active control condition group), all of which received the ST intervention at the same time (Figures 1 and 2). Participants in the SIGMA-Booster arm received the SIGMA intervention along with weekly reminders of key intervention messages as boosters from weeks 3 to 7. Two schools did not have enough classes in 1 grade, so classes from other grades at those schools were invited to join the study. All participants received regular interventions at school. Three repeated assessments were conducted for the 4 groups simultaneously at (1) baseline, (2) 2 weeks postintervention, and (3) 8 weeks postintervention. The cluster randomization at the classroom level helped balance the risk of contamination between the experimental and active control groups, as well as account for school heterogeneity due to factors such as school culture, schedule, and management.

XSL•FO
RenderX

Figure 1. Design of the 4-arm waitlist randomized controlled trial. SIGMA: single-session intervention of a growth mindset for anxiety; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.

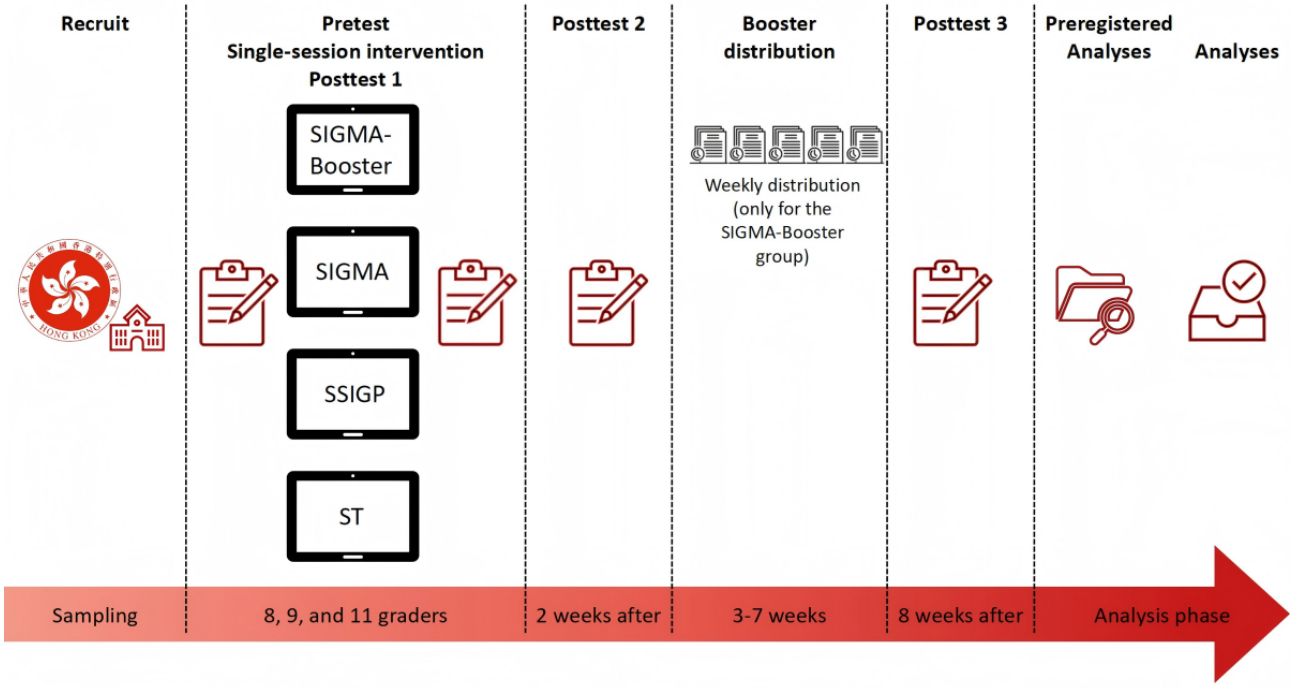
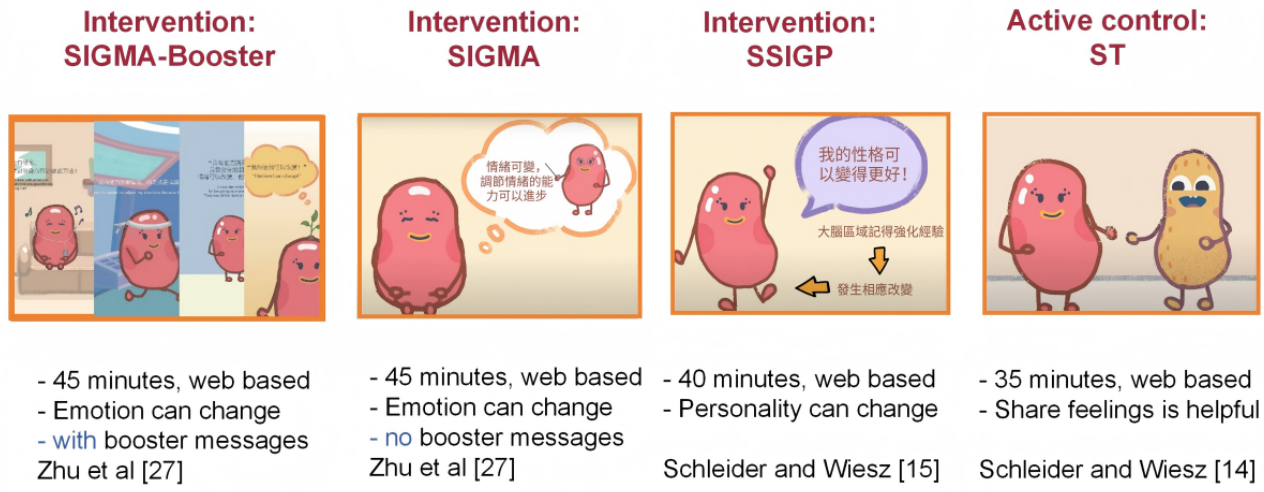


Figure 2. Intervention designs. SIGMA: single-session intervention of a growth mindset for anxiety; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



Participants

Seven schools from Hong Kong Island, Kowloon, and the New Territories participated in the study. These included schools that used English, Chinese, and mixed English and Chinese as the teaching medium. We targeted participants from form 2 to form 3 (grades 8-9). If a school did not have 4 classes in 1 grade, or if the number of eligible participants in a class was too few, we invited additional classes from other grades to participate.

Inclusion Criteria

Eligible participants were recruited from the 7 secondary schools through cluster randomized sampling. We included participants who (1) were Chinese youth able to read and write Chinese, (2) had sufficient visual and auditory abilities to complete the intervention and assessment, and (3) were able to give assent to participate in the study. As 2 schools did not have enough classes in 1 grade and invited classes from other grades to participate, a few participants above the age of 16 years were included, which did not follow the inclusion criteria outlined in the protocol (12-16 years old).

Exclusion Criteria

Exclusion criteria included (1) lack of parental consent; (2) inability to stay focused for the duration of the intervention, which is approximately 45 minutes; and (3) intellectual disability or severe illness or pain that could introduce significant bias in the students' health and mental health conditions. Eligible participants were not screened for anxiety symptoms, so this study comprehensively examined the efficacy of the interventions among students with absent, mild, moderate, and severe levels of anxiety.

XSL•FO
RenderX

Procedure

The school and student recruitment process included the following steps: First, we sent research invitations to schools randomly selected from the school list. Invitations ceased when 7 schools agreed to participate. To ensure sufficient participant recruitment, we recruited 1 additional school beyond the protocol's plan. Four classes from the same selected grade(s) at each school were randomly chosen to join the study. The 4 selected classes were then randomized to the SIGMA condition, SIGMA-Booster condition, SSIGP condition, and the active control condition using random numbers. All students in those classes were invited to participate, with final participation contingent upon parental consent and students' assent.

After providing consent, students scanned a QR code to access the baseline questionnaire and the intervention program via the Qualtrics survey system (SAP SE). Students within the same class were assigned to the same intervention conditions. The interventions were conducted separately for each group in the school activity rooms, which were equipped with sufficient computers or tablets and headphones (Figure 3). All intervention activities were self-administered and delivered in a web-based format. The principal investigator (SZ) and well-trained research assistants remained in the intervention rooms to provide guidance and assistance if needed. All groups in the same school received interventions concurrently to minimize the influence of the time factor.

Figure 3. Intervention in a classroom.



Trial Power and Sample Size

To ensure the sample size was sufficient to test the hypotheses, a small to medium effect size (Cohen *d*=0.33) was used based on prior research [15]. Power was set at 0.80, and α was set at .05. A final sample size of 584 (146 per arm) was required. Considering the attrition rate from our previous studies in school settings (<20%), the baseline recruitment target was set at 732 participants (183 per arm). We ultimately recruited 731 participants. As the number of participants in each class varied, the final number of participants in each of the 4 arms differed.

Measures

Primary Outcome

Anxiety symptoms, measured using the 7-item Generalized Anxiety Disorder (GAD-7) scale [28,29], were the primary outcome. The 7 items assessed whether anxiety symptoms had bothered the individual during the previous 2 weeks, with frequency ranging from 0 (not at all) to 3 (nearly every day). Example items included: "Feeling nervous, anxious, or on edge" and "Not being able to stop or control worrying." The GAD-7 is a self-rating scale that effectively reflects symptom severity in adolescents and is highly correlated with clinician-administered ratings of anxiety symptoms. It is brief and suitable for self-report studies [30]. The Cronbach α for the scale was 0.93 [31]. By summing the scores of the 7 items, the following classifications were used: 0-4 indicated the absence of anxiety symptoms, 5-9 indicated mild anxiety, 10-14 indicated moderate anxiety, and 15-21 indicated severe anxiety. Based on the severity of anxiety, participants were categorized into 2 groups: the high anxiety group (scores of 10-21) and the nonhigh anxiety group (scores of 0-9) in this study.

Secondary Outcomes

The 9-Item Patient Health Questionnaire

The 9-item Patient Health Questionnaire (PHQ-9) [32,33] was used to assess participants' depression levels and suicidal/self-hurting thoughts over the previous 2 weeks, with frequency ranging from 0 (not at all) to 3 (nearly every day). The first 8 items (PHQ-8) were used to measure depression severity (sum of the 8 items), while the last item assessed suicidal/self-hurting thoughts. Responses of 1-3 on the last item were coded as "yes," and a response of 0 was coded as "no." Example items from the PHQ-9 included "Little interest or pleasure in doing things" and "Feeling down, depressed, or hopeless." The item assessing suicidal/self-hurting thoughts was "Thoughts that you would be better off dead or of hurting yourself in some way."

Perceived Control

The Anxiety Control Questionnaire [34] is a 15-item tool that measures participants' perceived control over their anxiety. The Emotion Control subscale, 1 of the 3 validated subscales, consists of 5 items (eg, "I am able to control my level of anxiety"), including 1 reverse-scored item (When I am anxious, I find it hard to focus on anything other than my anxiety). Responses are rated from 0 (strongly disagree) to 5 (strongly agree). The sum of the 5 items indicates the level of perceived control. The Cronbach α was 0.73.

Hopelessness

The 4-item Helplessness subscale of the Demoralization Scale [35] was used to measure participants' outlook on the future. Each item was rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). The sum of the 4 items

XSL•FO
RenderX

was used to assess hopelessness, with a higher score indicating a correspondingly higher level of hopelessness. An example item was "I feel hopeless." The Cronbach α for the Chinese version of this Helplessness subscale was 0.72 [36].

Attitude Toward Seeking Help

We used 3 items from the Attitude Toward Seeking Counselling Help Assessment [37] to measure participants' understanding of counseling and attitudes toward seeking counseling help. Example items included "If I believed I was having a mental breakdown, my first inclination would be to get professional attention" and "Professional counseling and treatments can help people improve mental health." The Cronbach α was 0.72 [37]. Additionally, 2 items were used to assess participants' intention to seek help. The 2 items were "When I encounter difficulties, I will not ask for help from teachers" and "When I encounter difficulties, I will not ask for help from social workers/counselors." These 5 items were rated on a 7-point Likert scale, ranging from 1 (strongly disagree) to 7 (strongly agree). After reverse-scoring the 2 help-seeking intention items, the sum score of the 5 items represented participants' attitudes toward seeking help, with a higher score indicating more positive attitudes toward seeking help.

Psychological Well-Being

The short version of the 14-item Warwick-Edinburgh Mental Well-Being Scale (WEMWBS-14) [38,39] was used to measure the extent to which participants generally experienced well-being states. The WEMWBS-14 consists of 14 items, each rated on a 5-point Likert scale ranging from 1 (none of the time) to 5 (all of the time). The sum score of the 14 items indicated the participants' overall well-being level. An example item was "I have been feeling optimistic about the future." The scale's Cronbach α was 0.93.

Fidelity Checking and Intervention Feedback

Mindsets of Negative Emotions

The validated Chinese version of the 12-item Mindset of Depression, Anxiety, and Stress Scale (MDASS) was used to assess participants' beliefs regarding the changeability of negative emotional states, such as depression, anxiety, and stress [24]. Sample items included: "When you have a certain level of depression, you really cannot do much to change it," "To be honest, people cannot really change how anxious they are," and "No matter how hard people try, they cannot really change the level of stress that they have." Each item was scored on a 6-point Likert scale ranging from 1 (strongly disagree) to 6 (strongly agree); a higher score indicated a more fixed mindset toward negative emotions (Cronbach α=0.94). It included 3 subscales: depression mindset, anxiety mindset, and stress mindset, with 4 items in each subscale. The Cronbach α values for the 3 subscales were 0.91, 0.89, and 0.90, respectively [24]. By summing the total score, we defined fixed and growth mindsets using a cutoff score of 42, which was calculated by adding the midpoint (ie, 3.5) of the 6-point scale for the 12 items. Individuals scoring equal to or greater than 42 were considered to have more fixed mindsets, while those scoring below this cutoff were considered more inclined to have growth mindsets.

Mindset of Personality

Three items from implicit theories of personality [40,41] were used to measure the belief in the changeability of personality on a 6-point Likert scale, ranging from 1 (strongly disagree) to 6 (strongly agree). A higher score indicated a more fixed mindset of personality. A sample item was "People can do things differently, but the important parts of who they are can't really be changed." The Cronbach α was 0.85.

Motivation to Apply What Was Learned From the Program

In addition to the baseline assessment, immediately after the intervention, participants were asked to rate the extent to which they would like to apply the intervention content and improve their emotion regulation on a 6-point Likert scale (1-6), with a higher score indicating higher motivation. We defined high and low motivation groups based on the median cutoff after summing the 2 motivation items.

The Intervention Feedback Scale

This scale was developed based on the Theoretical Framework of Acceptability, which includes 7 component constructs: affective attitude, burden, intervention coherence, perceived effectiveness, opportunity costs, self-efficacy, and ethicality [42]. A general acceptability item, 6 items corresponding to the 6 components of the Theoretical Framework of Acceptability (excluding ethicality), and 4 items—including an open-ended written feedback item—were integrated to comprehensively assess the acceptability of the intervention. These items were drawn from the well-validated Program Feedback Scale [43]. For the Feedback Scale, except for the open-ended item, the other 10 items were assessed on a 5-point scale (eg, "How acceptable was the intervention to you?" with responses ranging from "1=completely unacceptable" to "5=completely acceptable"). The Feedback Scale was administered immediately after the intervention.

Attention-Checking Items

To ensure data quality and assess participant attention, 2 attention-checking items were included at all assessment points (baseline and follow-up surveys). These items directly instructed participants to select a specific option based on the given instructions. A sample question was "Please select 'strongly agree' for this item."

Sociodemographic Information

Sociodemographic information of participants was collected at baseline to examine group variability in factors such as gender, age, grade, ethnicity, and socioeconomic status (SES).

Data Analysis

We used an intention-to-treat approach in our primary analysis, where all participants who consented to participate were included. Participants who completed all assessments and passed both attention-checking items at each assessment point were classified in the per-protocol population. A per-protocol analysis was conducted as a sensitivity analysis. Multilevel modeling was used to account for the cluster randomization of classes within the same school [44]. All percentages and scores were presented with 1 decimal place. To examine the effects of the interventions, generalized estimating equations were used to

XSL•FO
RenderX

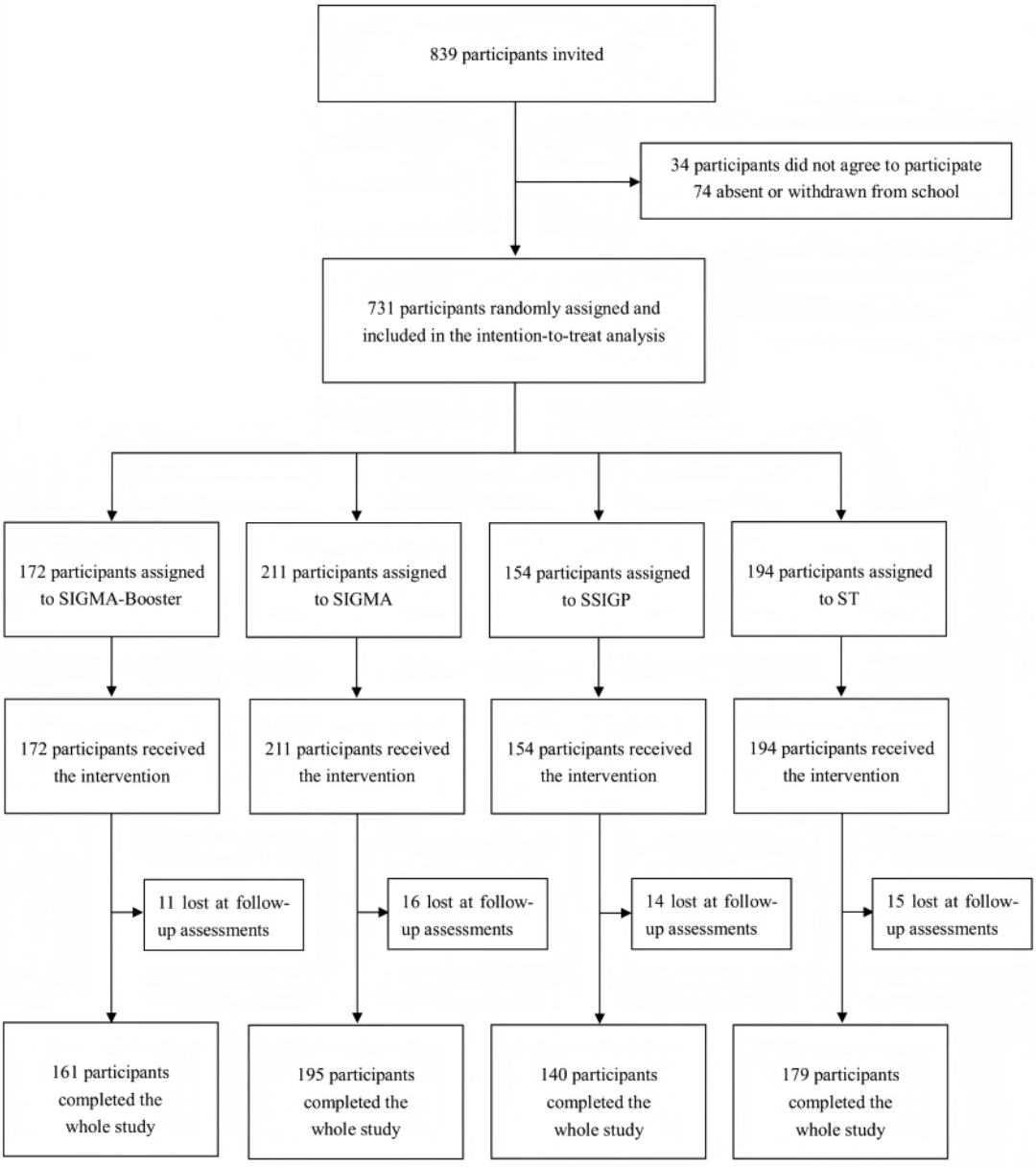
test the group effect, time effect, and their interaction effect on outcome measures. A statistically significant interaction effect indicated the effectiveness of the treatments. Additionally, we calculated effect sizes using estimated marginal means. These effect sizes, expressed as Cohen *d*, compared mean gain scores reflecting changes in each outcome from baseline to the 2 follow-ups for youth receiving the mindset versus active control interventions. The effect sizes were also compared between participants in the intervention group who received booster messages and those who did not. Additionally, we tested the following moderators on the effectiveness of the treatment for the primary and secondary outcomes: baseline anxiety level (dichotomized by the severity of GAD-7), motivation for change (dichotomized by the median of the sum motivation score on the 2 motivation items), and mindset group (fixed vs growth). The corrected quasi-likelihood under the independence model criterion (QICC) for the models with and without the moderator was examined, with evidence of a moderation effect indicated by a smaller QICC for the models including the moderator. Multiple comparisons were not conducted, and a *P* value of <.05 was considered statistically significant. Data analysis was performed using SPSS version 26 (IBM Corp.).

Results

Recruitment

Figure 4 depicts the CONSORT (Consolidated Standards of Reporting Trials) diagram of the recruitment and participation flow (also see Multimedia Appendix 1). A total of 731 participants were recruited and randomized into 4 groups: SIGMA-Booster (n=172, 23.5%), SIGMA (n=211, 28.9%), SSIGP (n=154, 21.1%), and ST (n=194, 26.5%). All participants received the interventions and were contacted for follow-ups. All participants were included in the intention-to-treat analysis. No participants explicitly requested to be removed from the trial.

Figure 4. CONSORT (Consolidated Standards of Reporting Trials) flowchart. SIGMA: single-session intervention of a growth mindset for anxiety; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



XSL•FO
RenderX

Baseline Characteristics of Participants

Table 1 summarizes the baseline characteristics of the recruited participants. Of the 731 participants, 421 (57.6%) were girls. Statistical differences in grade and age were observed among the 4 groups, as some schools selected classes from 2 different grades. However, there were no statistical differences in ethnicity or SES.

There were no significant differences between the intervention groups on the primary and secondary outcome measures at baseline: anxiety symptoms, $F_{3,727}$=0.25, P=.86; depressive symptoms, $F_{3,727}$=0.13, P=.94; suicidal/self-hurting thoughts, χ^2_3 (N=731)=3.66, P=.30; perceived control, $F_{3,727}$=0.31, P=.82; hopelessness, $F_{3,727}$=0.74, P=.53; attitude toward seeking help, $F_{3,727}$=0.61, P=.61; and psychological well-being, $F_{3,727}$=0.63, P=.60.

XSL•FO
RenderX

Table 1. Sample characteristics.

Variables	SIGMA-Booster[a] (n=172)	SIGMA[b] (n=211)	SSIGP[c] (n=154)	ST[d] (n=194)	Overall (N=731)	*P* value
Age						<.001
Mean (SD)	14.0 (0.9)	14.0 (1.0)	14.5 (1.5)	13.8 (0.8)	14.1 (1.1)	
Range	12-16	12-18	12-20	12-18	12-20	
Missing, n (%)	0 (0)	1 (0.5)	0 (0)	0 (0)	1 (0.1)	
Gender, n (%)						.005
Male	55 (32.0)	94 (44.5)	64 (41.6)	97 (50.0)	310 (42.4)	
Female	117 (68.0)	117 (55.5)	90 (58.4)	97 (50.0)	421 (57.6)	
Ethnicity, n (%)						.67
Chinese	168 (97.7)	204 (96.7)	152 (98.7)	189 (97.4)	713 (97.5)	
Other	4 (2.3)	7 (3.3)	2 (1.3)	5 (2.6)	18 (2.5)	
Grade, n (%)						<.001
Secondary 2	80 (46.5)	99 (46.9)	59 (38.3)	135 (69.6)	373 (51.0)	
Secondary 3	92 (53.5)	112 (53.1)	69 (44.8)	59 (30.4)	332 (45.4)	
Secondary 5	0 (0)	0 (0)	26 (16.9)	0 (0)	26 (3.6)	
Socioeconomic status, n (%)						.75
Low	0 (0.0)	1 (0.5)	1 (0.6)	0 (0)	2 (0.3)	
Medium	139 (80.8)	172 (81.5)	120 (77.9)	151 (77.8)	582 (79.6)	
High	33 (19.2)	38 (18.0)	33 (21.4)	43 (22.2)	147 (20.1)	
Willingness to participate in emotional control course (1-6), mean (SD)	3.5 (1.3)	3.5 (1.3)	3.3 (1.3)	3.4 (1.4)	3.4 (1.3)	.69
Willingness to improve emotional control (1-6), mean (SD)	4.2 (1.3)	4.0 (1.2)	4.0 (1.3)	4.0 (1.4)	4.0 (1.3)	.46
Mindset of anxiety (4-24), mean (SD)	14.6 (4.2)	13.8 (4.6)	14.5 (4.6)	13.7 (4.7)	14.1 (4.5)	.17
Mindset of depression (4-24), mean (SD)	13.6 (4.9)	12.8 (5.2)	13.4 (5.0)	12.8 (5.2)	13.1 (5.1)	.32
Mindset of stress (4-24), mean (SD)	15.5 (4.8)	14.3 (5.0)	14.6 (5.2)	14.9 (5.4)	14.8 (5.1)	.14
Mindset of personality (3-18), mean (SD)	13.5 (3.2)	13.0 (3.5)	13.0 (3.2)	13.1 (3.5)	13.1 (3.4)	.51
7-item Generalized Anxiety Disorder (0-21), mean (SD)	6.9 (5.1)	6.6 (5.4)	7.0 (5.1)	6.9 (5.8)	6.8 (5.4)	.86
8-item Patient Health Questionnaire-8 (0-24), mean (SD)	7.3 (5.6)	7.1 (5.7)	7.2 (5.4)	7.4 (5.6)	7.2 (5.6)	.94
Anxiety Control Questionnaire—Emotion Control (0-25), mean (SD)	13.6 (5.0)	13.5 (4.9)	13.7 (4.8)	13.2 (5.4)	13.5 (5.0)	.82
Demoralization Scale—Helplessness (4-20), mean (SD)	9.8 (3.6)	10.2 (4.0)	9.6 (3.8)	9.9 (4.0)	9.9 (3.9)	.53
Attitude Toward Seeking Help (5-35), mean (SD)	19.3 (4.6)	19.3 (5.6)	18.7 (5.2)	19.4 (5.6)	19.2 (5.3)	.61
Warwick-Edinburgh Mental Well-Being Scale (14-70), mean (SD)	41.7 (9.9)	42.3 (11.0)	43.1 (10.8)	43.0 (11.0)	42.5 (10.7)	.60
Suicidal/self-hurting thoughts, n (%)						.30
Yes	53 (30.8)	78 (37.0)	50 (32.5)	55 (28.4)	236 (32.3)	
No	119 (69.2)	133 (63.0)	104 (67.5)	139 (71.6)	495 (67.7)	

[a]SIGMA-Booster: SIGMA with boosters.

[b]SIGMA: single-session intervention of a growth mindset for anxiety.

[c]SSIGP: single-session intervention of a growth mindset of personality.

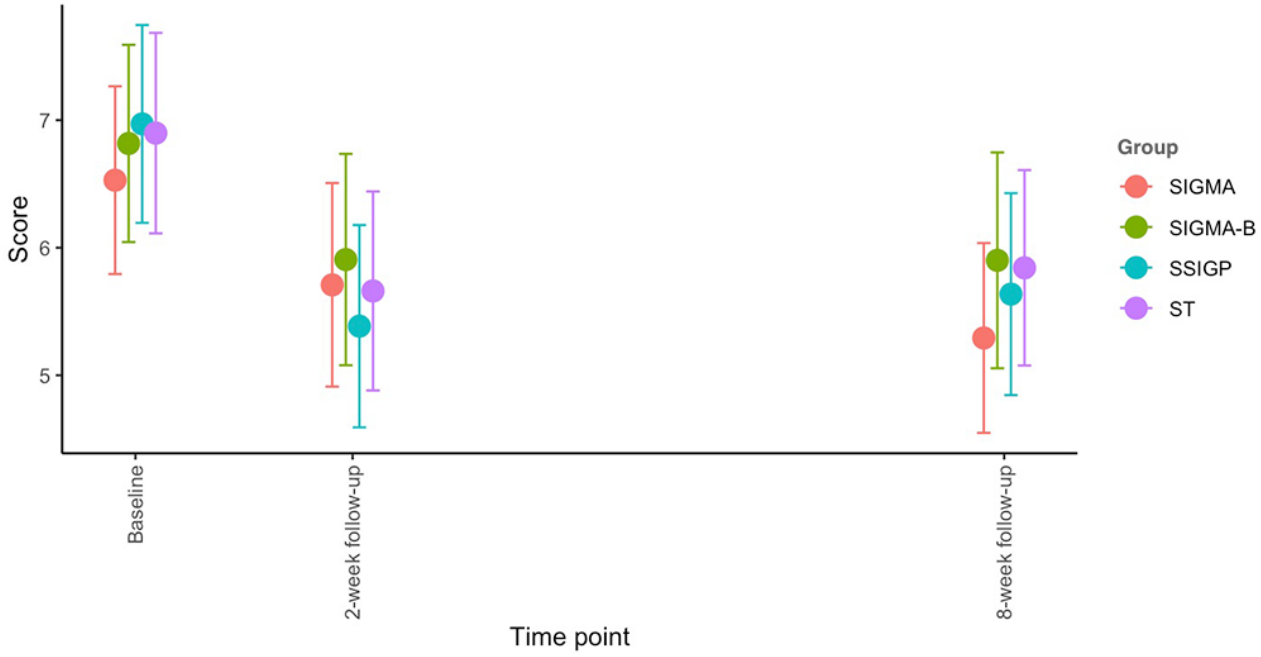
XSL•FO
RenderX

[d]ST: support therapy.

Changes in Primary and Secondary Outcomes

For the primary outcome, we found a significant main effect of time (P<.001), but no significant main effect of group (P=.88) or group-by-time interaction (P=.54). Participants in all 4 intervention groups showed significant improvement in anxiety symptoms at both the 2- and 8-week follow-ups: $P_{2\ weeks}$=.02 and $P_{8\ weeks}$=.02 for SIGMA-Booster; $P_{2\ weeks}$=.006, $P_{8\ weeks}$<.001 for SIGMA; $P_{2\ weeks}$<.001, $P_{8\ weeks}$<.001 for SSIGP, and $P_{2\ weeks}$<.001, $P_{8\ weeks}$=.003 for ST. This improvement was sustained at the 8-week follow-up, and no significant differences were observed between the 2- and 8-week follow-ups: P=.99 for SIGMA-Booster, P=.17 for SIGMA, P=.46 for SSIGP, and P=.59 for ST (Multimedia Appendix 2 and Figure 5). When comparing the changes from baseline to follow-up between each pair of groups, the SSIGP intervention appeared to be more effective than SIGMA (including SIGMA and SIGMA-Booster) in reducing general anxiety symptoms. However, the effect sizes ranged from very small to small (Table 2).

Figure 5. The 7-item Generalized Anxiety Disorder scale (total score) changes over time. Each dot represents the mean score of each group at each time point. Each line around the dot represents the 95% Wald CI of the mean. SIGMA: single-session intervention of a growth mindset for anxiety; SIGMA-B: SIGMA-Booster; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



XSL•FO
RenderX

Table 2. Effect sizes[a] of the treatment and intention-to-treat population.

Outcome variables	2-week follow-up, Cohen *d* (SE)	8-week follow-up, Cohen *d* (SE)
7-item Generalized Anxiety Disorder		
SIGMA-Booster[b] versus SIGMA[c]	–0.02 (0.12)	0.06 (0.12)
SIGMA-Booster versus SSIGP[d]	0.13 (0.13)	0.08 (0.13)
SIGMA-Booster versus ST[e]	0.06 (0.13)	0.03 (0.13)
SIGMA versus SSIGP	0.14 (0.15)	0.02 (0.15)
SIGMA versus ST	0.08 (0.15)	–0.03 (0.15)
SSIGP versus ST	–0.06 (0.15)	–0.05 (0.15)
8-item Patient Health Questionnaire		
SIGMA-Booster versus SIGMA	0.06 (0.13)	0.01 (0.13)
SIGMA-Booster versus SSIGP	0.10 (0.13)	–0.03 (0.13)
SIGMA-Booster versus ST	0.06 (0.13)	–0.04 (0.13)
SIGMA versus SSIGP	0.04 (0.15)	–0.04 (0.15)
SIGMA versus ST	–0.002 (0.15)	–0.05 (0.15)
SSIGP versus ST	–0.05 (0.16)	–0.01 (0.16)
Suicidal/self-hurting thoughts		
SIGMA-Booster versus SIGMA	0.20 (0.13)	0.18 (0.13)
SIGMA-Booster versus SSIGP	0.18 (0.13)	0.27 (0.13)
SIGMA-Booster versus ST	0.03 (0.13)	0.04 (0.13)
SIGMA versus SSIGP	–0.02 (0.15)	0.09 (0.15)
SIGMA versus ST	–0.17 (0.15)	–0.14 (0.15)
SSIGP versus ST	–0.15 (0.15)	–0.23 (0.15)
Anxiety Control Questionnaire—Emotion Control		
SIGMA-Booster versus SIGMA	–0.004 (0.13)	–0.01 (0.13)
SIGMA-Booster versus SSIGP	–0.03 (0.13)	0.05 (0.14)
SIGMA-Booster versus ST	–0.14 (0.13)	–0.26 (0.13)
SIGMA versus SSIGP	–0.03 (0.15)	0.06 (0.15)
SIGMA versus ST	–0.13 (0.15)	–0.25 (0.15)
SSIGP versus ST	–0.10 (0.15)	–0.31 (0.16)
Demoralization Scale—Helplessness		
SIGMA-Booster versus SIGMA	0.24 (0.13)	0.16 (0.12)
SIGMA-Booster versus SSIGP	0.07 (0.13)	0.05 (0.12)
SIGMA-Booster versus ST	0.20 (0.13)	0.08 (0.13)
SIGMA versus SSIGP	–0.18 (0.15)	–0.11 (0.15)
SIGMA versus ST	–0.04 (0.15)	–0.08 (0.15)
SSIGP versus ST	0.14 (0.15)	0.03 (0.15)
Attitude Toward Seeking Help		
SIGMA-Booster versus SIGMA	–0.03 (0.11)	0.05 (0.11)
SIGMA-Booster versus SSIGP	–0.15 (0.11)	–0.05 (0.12)
SIGMA-Booster versus ST	–0.12 (0.12)	0.08 (0.12)
SIGMA versus SSIGP	–0.12 (0.14)	–0.09 (0.14)
SIGMA versus ST	–0.09 (0.14)	0.03 (0.14)

XSL•FO
RenderX

Outcome variables	2-week follow-up, Cohen *d* (SE)	8-week follow-up, Cohen *d* (SE)
SSIGP versus ST	0.04 (0.14)	0.12 (0.15)
Warwick-Edinburgh Mental Well-Being Scale		
SIGMA-Booster versus SIGMA	0.02 (0.12)	0.02 (0.13)
SIGMA-Booster versus SSIGP	0.02 (0.13)	0.10 (0.13)
SIGMA-Booster versus ST	–0.08 (0.12)	–0.11 (0.13)
SIGMA versus SSIGP	–0.003 (0.16)	0.08 (0.16)
SIGMA versus ST	–0.10 (0.15)	–0.13 (0.16)
SSIGP versus ST	–0.10 (0.16)	–0.21 (0.15)

[a]Effect size values were calculated by subtracting the latter group's mean gain score from the former group's mean gain score for each outcome from baseline to the 2- and 8-week follow-ups, then dividing by the pooled SD of all participants at baseline.

[b]SIGMA-Booster: SIGMA with boosters.

[c]SIGMA: single-session intervention of a growth mindset for anxiety.

[d]SSIGP: single-session intervention of a growth mindset of personality.

[e]ST: support therapy.

For the secondary outcomes, all the main effects of time were significant, while the main effects of group and the interaction effects of group and time were insignificant (main effects of group: *P*=.87 for depressive symptoms; *P*=.41 for suicidal/self-hurting thoughts; *P*=.97 for perceived control; *P*=.73 for hopelessness; *P*=.87 for help-seeking attitude; *P*=.39 for psychological well-being and interaction effects; *P*=.85 for depressive symptoms; *P*=.10 for suicidal/self-hurting thoughts; *P*=.20 for perceived control; *P*=.23 for hopelessness; *P*=.33 for help-seeking attitude; and *P*=.68 for psychological well-being), similar to the primary outcome. Specifically, the results for depressive symptoms mirrored those for anxiety (main effect of time, *P*<.001 and main effect of group, *P*=.87). All 4 groups showed a reduction in depressive symptoms at follow-ups, and the effects observed at the 8-week follow-up were comparable to those at the 2-week follow-up (see Multimedia Appendix 2 and Figure 6). Moreover, the effect sizes for the comparison between groups on the changes from baseline to follow-ups were all very small (Table 2). Second, a significant main effect of time was found for suicidal/self-hurting thoughts (*P*=.005), but the main effect of group was not significant (*P*=.41). Specifically, the SIGMA group showed a reduction in suicidal/self-hurting thoughts at both the 2- and 8-week follow-ups, with the effect sustained at the 8-week follow-up compared with the 2-week follow-up. The SSIGP group showed a significant reduction in suicidal/self-hurting thoughts at the 8-week follow-up (*P*<.001), but not at the 2-week follow-up (*P*=.14). The other 2 groups did not report significant changes in suicidal/self-hurting thoughts at either follow-up with $P_{2\ weeks}$=.50, $P_{8\ weeks}$=.96 for SIGMA-Booster and $P_{2\ weeks}$=.75, $P_{8\ weeks}$=.61 for ST (see Multimedia Appendix 2 and Figure 7). Both the SIGMA and SSIGP interventions appeared to be more effective in reducing suicidal/self-hurting thoughts than the SIGMA-Booster and ST, although the effect sizes were small (Table 2). For the other secondary outcomes, the main effects of time were significant for all variables (for perceived control, *P*=.03; for hopelessness, *P*<.001; for help-seeking attitude, *P*<.001; and for psychological well-being, *P*<.001). However, the main effects of the group were not significant (*P* values ranged from .39 to .97). For perceived control, only the ST group reported significant improvement at both the 2- and 8-week follow-ups ($P_{2\ weeks}$=.02, $P_{8\ weeks}$=.007). The ST intervention appeared to be more effective than the other 3 groups in improving perceived control, though the effect sizes were small (Table 2). For hopelessness, both the SIGMA and ST groups showed significant improvement at both the 2-week (*P*<.001 for SIGMA and *P*<.001 for ST) and 8-week follow-ups (*P*=.001 for SIGMA and *P*=.005 for ST), while the SSIGP group only reported significant improvement at the 8-week follow-up (*P*=.02). The SIGMA group seemed to outperform the SIGMA-Booster group in reducing hopelessness, although the effect sizes were small (Table 2). For help-seeking attitude, both the SIGMA-Booster and SSIGP groups reported significant improvement at both the 2-week (*P*=.01 for SIGMA-Booster and *P*<.001 for SSIGP) and 8-week follow-ups (*P*=.01 for SIGMA-Booster and *P*=.003 for SSIGP), while the SIGMA and ST groups showed significant improvement only at the 2-week follow-up (*P*=.006 for SIGMA and *P*<.001 for ST). For psychological well-being, the ST group showed significant improvement at both the 2- and 8-week follow-ups with *P*=.01 and *P*<.001, respectively, while the SIGMA-Booster and SIGMA groups demonstrated significant improvement only at the 8-week follow-up with *P*=.02 (Multimedia Appendix 2). The effect sizes for changes in attitude toward seeking help and psychological well-being were all very small between groups. The only effect size that reached a small magnitude (>0.2) was for the improvement in psychological well-being at the 8-week follow-up, where the ST group showed greater improvement compared with the SSIGP group (Table 2).

The sensitivity analysis conducted for the per-protocol population showed results similar to those of the intention-to-treat population. The specific results of the sensitivity analysis can be found in Multimedia Appendix 3.

XSL•FO
RenderX

Figure 6. The 8-item Patient Health Questionnaire scale (total score) changes over time. Each dot represents the mean score of each group at each time point. Each line around the dot represents the 95% Wald CI of the mean. SIGMA: single-session intervention of a growth mindset for anxiety; SIGMA-B: SIGMA-Booster; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.

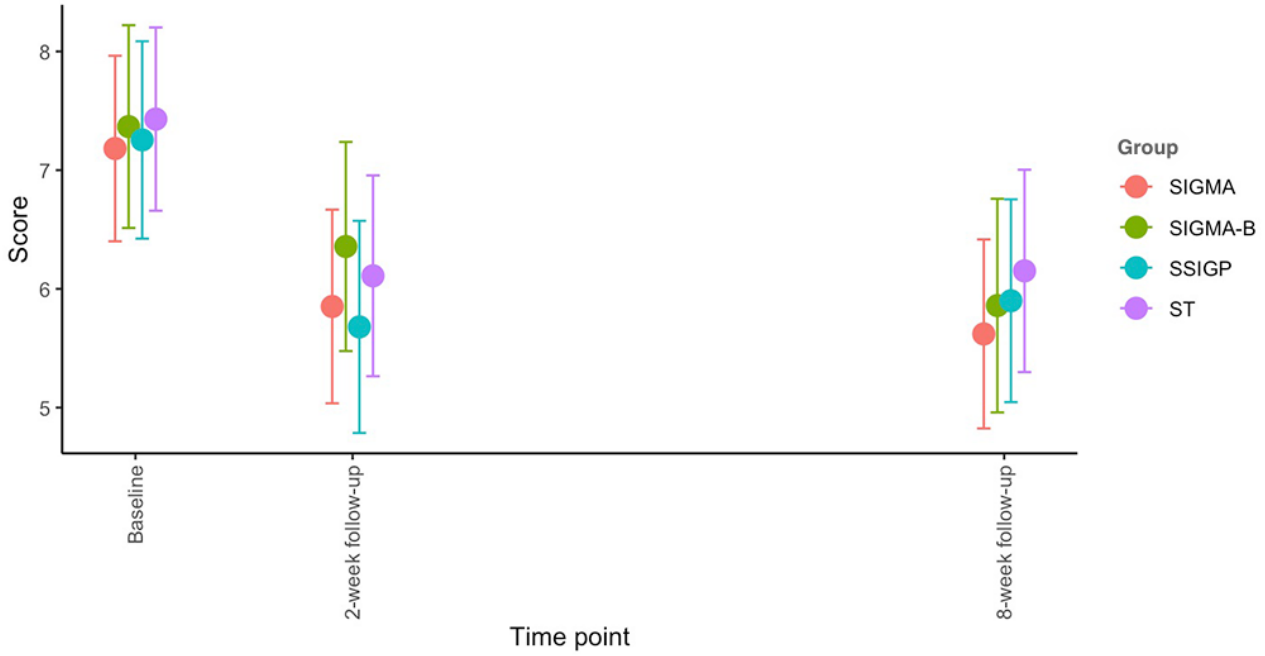
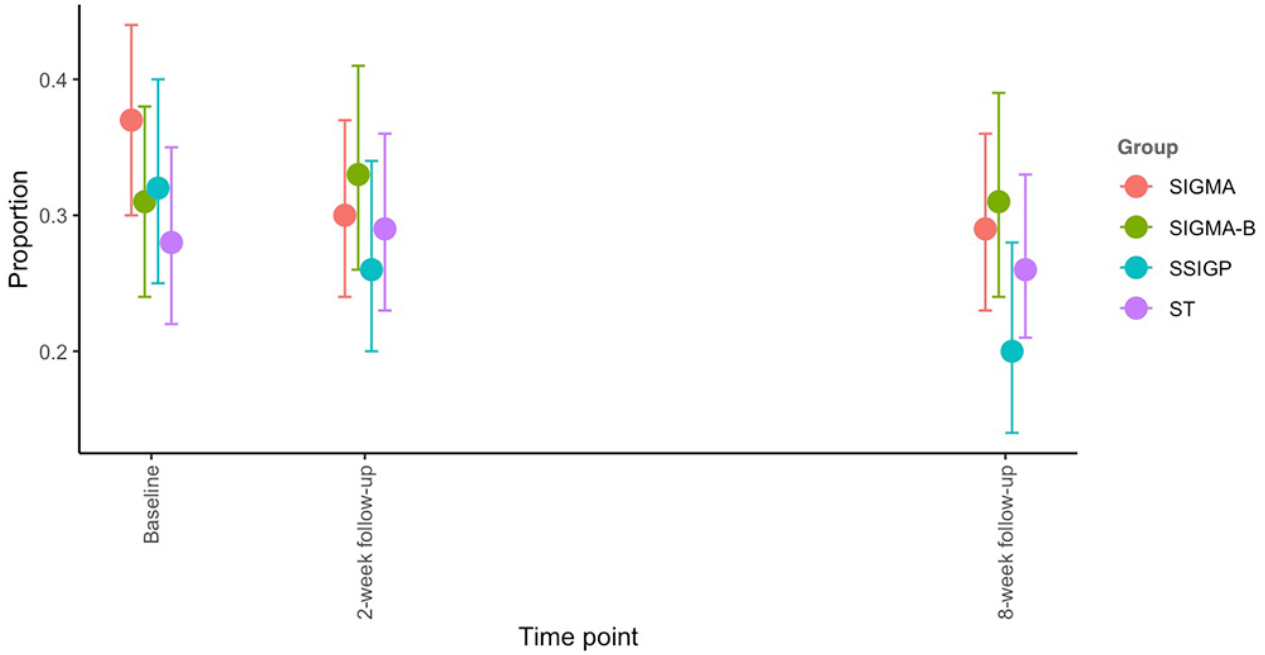


Figure 7. The proportion of participants with suicidal/self-hurting thoughts changes over time. Each dot represents the mean score of each group at each time point. Each line around the dot represents the 95% Wald CI of the mean. SIGMA: single-session intervention of a growth mindset for anxiety; SIGMA-B: SIGMA-Booster; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



Moderation Analysis

We conducted moderation analyses based on baseline anxiety (high/low), motivation to change (high/low), and mindset (growth mindset vs fixed mindset). Including these moderation factors improved model fit, as indicated by the decreases in QICC, ranging from 210 to 31,519.23. This was true for all outcomes, except for suicidal/self-hurting thoughts when motivation level was used as the moderator. These results indicate that baseline anxiety level and mindset had moderating effects on all outcome measures, while motivation level moderated all outcomes except for suicidal/self-hurting thoughts. Participants with higher baseline anxiety, greater motivation to change their situation, and a more fixed baseline mindset showed greater improvements in the outcome measures (see Multimedia Appendices 4-6 for details).

Intervention Feedback

Participants' feedback on the SSIs is detailed in Table 3. Most participants reported understanding (536/731, 73.3%) and

XSL•FO
RenderX

agreeing (504/731, 68.9%) with the intervention content. More than half found the intervention helpful (465/731, 63.6%) and interesting (417/731, 57.0%). Some indicated that they liked the course (404/731, 55.2%) and expressed a willingness to recommend it to others (402/731, 55.9%). Additionally, 437 out of 731 (59.8%) reported increased confidence in their ability to cope with emotions following the intervention. Meanwhile, very few found this course burdensome (28/731, 3.8%) or interfering (70/731, 9.58%). The findings showed that 459 out of 731 (62.8%) participants indicated that they accept or highly accept the intervention. However, about 237 (32.4%) participants were neutral, indicating that there is still significant room for improvement.

Table 3. Feedback on the intervention.

Variables	SIGMA-Booster[a] (n=172), n (%)	SIGMA[b] (n=211), n (%)	SSIGP[c] (n=154), n (%)	ST[d] (n=194), n (%)	Overall (N=731), n (%)
Like this course	93 (54.1)	113 (53.6)	87 (56.5)	111 (57.2)	404 (55.3)
Understand this course	124 (72.1)	149 (70.6)	116 (75.3)	147 (75.8)	536 (73.3)
This course is useful	104 (60.5)	128 (60.7)	102 (66.2)	131 (67.5)	465 (63.6)
Recommend this course to others	92 (53.5)	117 (55.5)	81 (52.6)	112 (57.7)	402 (55.0)
This course is interesting	91 (52.9)	113 (53.6)	88 (57.1)	125 (64.4)	417 (57.0)
Agree with this course	115 (66.9)	143 (67.8)	106 (68.8)	140 (72.2)	504 (68.9)
Emotional control improved after this course	100 (58.1)	128 (60.7)	85 (55.2)	124 (63.9)	437 (59.8)
Burden in joining this course	9 (5.2)	6 (2.8)	5 (3.2)	8 (4.1)	28 (3.8)
Affect other arrangement due to joining this course	20 (11.6)	15 (7.1)	16 (10.4)	19 (9.8)	70 (9.6)
Acceptance to this course	103 (59.9)	127 (60.2)	110 (71.4)	119 (61.3)	459 (62.8)

[a]SIGMA-Booster: SIGMA with boosters.

[b]SIGMA: single-session intervention of a growth mindset for anxiety.

[c]SSIGP: single-session intervention of a growth mindset of personality.

[d]ST: support therapy.

Discussion

Overview

Contrary to our hypotheses, we found that all 4 SSIs, including ST, significantly reduced general anxiety symptoms and improved some secondary outcomes. Although the core messages delivered in approximately 40 minutes differed among these interventions, nearly all improvements in the 4 groups were sustained from the 2-week to the 8-week follow-ups. These findings provide evidence for the effectiveness of low-dosage nonpharmacological interventions in improving youth mental health outcomes. SIGMA, which enhances the belief in change regarding negative emotions, showed an intervention effect on all outcome measures except perceived control. The SSIGP, targeting personality mindset, was more effective in reducing self-harm and suicidal thoughts. ST had a greater effect on perceived control. Surprisingly, the SIGMA-Booster group, which received booster messages, did not achieve better results than the SIGMA group. By contrast, the SIGMA group outperformed the SIGMA-Booster group in outcomes such as reducing suicidal and self-harming thoughts as well as hopelessness. The SIGMA interventions were not more effective than SSIGP, particularly in the primary outcome of reducing anxiety symptoms. Moreover, the ST intervention was especially effective in improving perceived control, outperforming the other 3 interventions. Moderation tests revealed that some adolescents benefited more from the interventions. Consistent with our hypotheses on moderation effects, participants showed greater improvement if they had more severe anxiety symptoms, stronger baseline fixed mindsets, and a greater motivation to change. Although the effect sizes for group comparisons on outcome changes were small, it is encouraging that SSIs produced sustained outcomes over 8 weeks.

Our findings align closely with existing research on SSIs for youth psychiatric problems. A previous meta-analysis by Schleider and Weisz [14] found that a young person receiving an SSI had a 58% likelihood of performing better than a youth in the control group. The effect sizes varied depending on the control conditions, with larger effect sizes observed in studies with no-treatment or waitlist controls (0.41) compared with those with active controls (0.14). In our study, the effect sizes for SIGMA versus SSIGP at the 2-week follow-up were approximately 0.14 (SIGMA vs SSIGP: 0.14 and SIGMA-Booster vs SSIGP: 0.13), while the effect sizes for SIGMA versus ST were smaller. The finding that SSIs were effective for multiple outcomes, including anxiety and depression symptoms, aligns with a recent umbrella review on SSIs, which showed that over 80% of reviews reported significant positive effects on at least one outcome [21]. In summary, our study provides additional evidence supporting the modest yet significant clinical utility of certain SSIs for youth, including those targeting anxiety symptoms [21].

The design of the interventions and the implementation of the RCT for SSIs provided valuable insights and implications for local practice. Generally, these SSIs were designed following recommended guidelines to ensure the efficacy of brief

XSL•FO
RenderX

interventions [45-47]. First, we formed a youth advisory group to ensure the content was relevant to the target users. Second, we incorporated cartoons and animated videos into the intervention. The cartoon heroine, "Hong Dou" (the Red Bean), and her friends were created by artists and digital designers to make the animations and videos more engaging. As a result, the intervention videos effectively captured participants' attention. Third, because SSIs should be highly focused on delivering 1 or a few core messages, each SSI in our study conveyed a single core message to participants. We reinforced learning through multiple methods, including examples, testimonials, authoritative research findings, and saying-is-believing exercises. Fourth, to ensure active participation in the online web-based intervention, we embedded it in the Qualtrics survey tool and included interactive exercises after each session. Participants received timely feedback on these exercises. Feedback from participants indicated that the SSIs in our study were well-suited to adolescents' needs and expectations for mental health care. This study provides a clear protocol for implementation, including content and strategies, which will be valuable for the future use and development of SSIs.

This study is a pioneering investigation into web-based SSIs among Chinese adolescents. The efficacy of SSIs, particularly self-administered web-based interventions, has been understudied. This study examined the effects of SSIs on mental health among Chinese adolescents using a cluster RCT design. The 4 conditions in this study showed improvements in mental health over 2 weeks, with the effects sustained after 8 weeks. There were no significant group differences among the 4 conditions. As the interventions were implemented at different times across the academic year in different schools, any potential school schedule effects were minimized. On the one hand, these results suggest that providing low-dosage self-help interventions may help adolescents gain insights and strategies for managing their emotions and coping. On the other hand, an RCT with an added waitlist control group would be valuable for further testing the effectiveness of the intervention.

The SIGMA-Booster group did not show a better effect at the 8-week follow-up. There may be several reasons for this. First, there may be no difference between the booster and nonbooster groups. If an SSI has instilled changes in the emotional mindset, those changes could be long-lasting. Second, the booster group might have a greater effect in the longer term, so a more extended follow-up would be necessary to capture any differences between the booster and nonbooster groups. Third, the booster design in this study may not have been effective. Future studies should carefully examine the format and content of booster interventions.

This study makes several significant contributions. First, the SSIs developed and tested with an RCT could serve as an alternative mental health service for adolescents. Although the effect size of the SSI was small, it can benefit a proportion of youth who would otherwise go without services. It can also support youth on the waitlist for psychiatric services by fostering intrinsic motivation and reducing hesitation to seek treatment. It can also complement multisession psychosocial treatments [21]. Second, these SSIs expanded existing mindset interventions to include emotional mindset and adapted them to the Chinese context. This project may provide a generalizable model for the development and implementation of SSIs for youth in the Chinese context. Third, this study initiated the development and evaluation of boosters for SSIs. Although we did not find significant differences among the groups, the findings of this study could serve as a foundation for further research. In summary, the easy-access self-help program enables adolescents with anxiety symptoms to receive timely help and may help reduce the risk of worsening anxiety symptoms and the development of comorbid mental health issues before they can access therapy from a trained therapist or psychiatrist.

Limitations

There are limitations to consider. First, because this study did not exclude individuals based on the severity of their anxiety symptoms, the efficacy of the interventions in reducing anxiety symptoms among students without anxiety or with very low levels of anxiety may not have been significant, potentially affecting the overall statistical significance. However, future RCT studies could examine the differentiated impacts on youth across a broader range of anxiety problems through subgroup analyses. In this study, we simply divided participants into 2 groups (high baseline anxiety and low baseline anxiety) and examined the moderation effects. Second, there was no waitlist control group, as all groups received specific interventions, with even the control group receiving ST (active control). Adding a waitlist control group would help provide a better understanding of the overall effect of SSIs. Third, although we used cluster randomization at the classroom level to balance the risk of contamination between groups and school heterogeneity, and employed multilevel modeling to account for the clustering of classes within the same school, it was still challenging to completely eliminate the risk of contamination. Students in different classes may interact and share information about their interventions, which could potentially influence the outcomes. Fourth, the study only included a follow-up period of 8 weeks, which may not have allowed us to capture the long-term effects. Future studies with a longer follow-up period will be necessary to better understand the sustained impact of the interventions.

Conclusions

This study presents evidence-based implementation of web-based single-session growth mindset interventions for adolescent anxiety and compares the efficacy of SSIs using growth mindsets on negative emotions and personality, along with an active control group. The findings support that the easy-access self-help program led to improvements in adolescent anxiety, depression, and suicidal and self-harm thoughts at the 8-week follow-up. These interventions may enable adolescents with anxiety symptoms to access timely help, reducing the risk of worsening anxiety symptoms and the development of comorbid mental health issues before they can access therapy from a trained therapist or psychiatrist. This study also provides an example of implementing SSIs among Chinese adolescents and will contribute to the development of easy-access, low-cost, and scalable interventions for mental health promotion among young people.

XSL•FO
RenderX

Acknowledgments

This study was supported by a grant funded by the Hong Kong Research Grants Council (grant 15601621) that was awarded to SZ. The funding body played no role in the study design, data collection, or manuscript writing. We acknowledge the contributions of the principals, school counselors, and social workers who share their insights into students' mental health care needs. We are grateful for school principals' invaluable suggestions on digital intervention implementation in school, including Principals Cheung Fung, Wan Ho-yin, Tu Sze Ching, Annissa Wong, Cheng Hong Yung, Sen Chun Wing, and Lui Sze Yan. We thank our design team, including Angel Lee, Hui Lok Chan, Jie Deng, Emma Kong, and Zijie Zhao. We are thankful for the suggestions from Mr Yau Tak Yu and Ms Wong Ka Ka, local experts in single-session intervention.

Data Availability

Data are not publicly available but can be obtained for proper purposes by contacting the corresponding author.

Authors' Contributions

SZ designed the intervention and the evaluation study initially. YH assisted in the intervention design and implementation. SZ and DQ drafted the first draft of the report. PL contributed to the data analysis plan. ST, KLC, QC, and JS provided comments and revised the first draft. SZ developed all aspects of the proposal and manuscript related to the implementation of intervention and data collection. All authors edited and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 2556 KB - pediatrics_v8i1e63500_app1.pdf]

Multimedia Appendix 2
Generalized estimating equation results for the intention-to-treat population.
[DOCX File , 23 KB - pediatrics_v8i1e63500_app2.docx]

Multimedia Appendix 3
Generalized estimating equation results for the per-protocol population—presented as estimated marginal means (SE).
[DOCX File , 33 KB - pediatrics_v8i1e63500_app3.docx]

Multimedia Appendix 4
Moderating effect of baseline anxiety levels on treatment outcomes.
[DOCX File , 53 KB - pediatrics_v8i1e63500_app4.docx]

Multimedia Appendix 5
Moderating effect of baseline motivation levels on treatment outcomes.
[DOCX File , 52 KB - pediatrics_v8i1e63500_app5.docx]

Multimedia Appendix 6
Moderating effect of baseline growth mindset levels on treatment outcomes.
[DOCX File , 50 KB - pediatrics_v8i1e63500_app6.docx]

References

1. World Health Organization (WHO). Adolescent mental health. WHO. 2020 Sep 20. URL: https://www.who.int/news-room/fact-sheets/detail/adolescent-mental-health [accessed 2024-11-11]
2. Leung PWL, Hung S, Ho T, Lee C, Liu W, Tang C, et al. Prevalence of DSM-IV disorders in Chinese adolescents and the effects of an impairment criterion: a pilot community study in Hong Kong. Eur Child Adolesc Psychiatry 2008 Oct;17(7):452-461. [doi: 10.1007/s00787-008-0687-7] [Medline: 18427862]
3. Polanczyk GV, Salum GA, Sugaya LS, Caye A, Rohde LA. Annual research review: a meta-analysis of the worldwide prevalence of mental disorders in children and adolescents. J Child Psychol Psychiatry 2015 Mar;56(3):345-365. [doi: 10.1111/jcpp.12381] [Medline: 25649325]

XSL•FO
RenderX

4. Survey of depression and anxiety among secondary school students. Baptist Oi Kwan Social Service. 2017. URL: https://www.bokss.org.hk/content/press/27/MHI_PressRelease2017_final2.pdf [accessed 2025-04-08]
5. Student enrolment statistics, 2019/20 (kindergartens, primary and secondary schools). Hong Kong Education Bureau. 2020. URL: https://www.edb.gov.hk/attachment/en/about-edb/publications-stat/figures/Enrol_2019.pdf [accessed 2023-10-02]
6. Lam LC, Wong CS, Wang M, Chan W, Chen EY, Ng RM, et al. Prevalence, psychosocial correlates and service utilization of depressive and anxiety disorders in Hong Kong: the Hong Kong Mental Morbidity Survey (HKMMS). Soc Psychiatry Psychiatr Epidemiol 2015 Sep;50(9):1379-1388. [doi: 10.1007/s00127-015-1014-5] [Medline: 25660760]
7. Bauhinia Foundation Research Centre. Mental health care services for Hong Kong youth. The Legislative Council of the Hong Kong Special Administrative Region of the People's Republic of China. 2017. URL: https://www.legco.gov.hk/research-publications/english/essentials-2021ise31-mental-health-services-for-young-people.htm [accessed 2024-01-06]
8. World Health Organization (WHO). COVID-19 disrupting mental health services in most countries. WHO. 2020 Oct 5. URL: https://www.who.int/news/item/05-10-2020-covid-19-disrupting-mental-health-services-in-most-countries-who-survey [accessed 2023-10-19]
9. Food and Health Bureau. Mental health review report. Food and Health Bureau Hong Kong Special Administrative Region Government. 2017. URL: https://www.healthbureau.gov.hk/download/press_and_publications/otherinfo/180500_mhr/e_mhr_full_report.pdf [accessed 2024-01-15]
10. Harpaz-Rotem I, Leslie D, Rosenheck RA. Treatment retention among children entering a new episode of mental health care. Psychiatr Serv 2004 Sep;55(9):1022-1028. [doi: 10.1176/appi.ps.55.9.1022] [Medline: 15345762]
11. Mekonen T, Ford S, Chan GCK, Hides L, Connor JP, Leung J. What is the short-term remission rate for people with untreated depression? A systematic review and meta-analysis. J Affect Disord 2022 Jan 01;296:17-25. [doi: 10.1016/j.jad.2021.09.046] [Medline: 34583099]
12. Schleider JL, Dobias ML, Sung JY, Mullarkey MC. Future directions in single-session youth mental health interventions. J Clin Child Adolesc Psychol 2020;49(2):264-278 [FREE Full text] [doi: 10.1080/15374416.2019.1683852] [Medline: 31799863]
13. Weisz JR, Kuppens S, Ng MY, Eckshtain D, Ugueto AM, Vaughn-Coaxum R, et al. What five decades of research tells us about the effects of youth psychological therapy: a multilevel meta-analysis and implications for science and practice. Am Psychol 2017;72(2):79-117. [doi: 10.1037/a0040360] [Medline: 28221063]
14. Schleider JL, Weisz JR. Little treatments, promising effects? meta-analysis of single-session interventions for youth psychiatric problems. J Am Acad Child Adolesc Psychiatry 2017 Feb;56(2):107-115. [doi: 10.1016/j.jaac.2016.11.007] [Medline: 28117056]
15. Schleider J, Weisz J. A single-session growth mindset intervention for adolescent anxiety and depression: 9-month outcomes of a randomized trial. J Child Psychol Psychiatry 2018 Feb;59(2):160-170. [doi: 10.1111/jcpp.12811] [Medline: 28921523]
16. Schleider JL, Dobias M, Fassler J, Shroff A, Pati S. Promoting treatment access following pediatric primary care depression screening: randomized trial of web-based, single-session interventions for parents and youths. J Am Acad Child Adolesc Psychiatry 2020 Jun;59(6):770-773. [doi: 10.1016/j.jaac.2020.01.025] [Medline: 32666919]
17. Schleider JL, Burnette JL, Widman L, Hoyt C, Prinstein MJ. Randomized trial of a single-session growth mind-set intervention for rural adolescents' internalizing and externalizing problems. J Clin Child Adolesc Psychol 2020;49(5):660-672 [FREE Full text] [doi: 10.1080/15374416.2019.1622123] [Medline: 31219698]
18. Walton GM. The new science of wise psychological interventions. Curr Dir Psychol Sci 2014 Feb 03;23(1):73-82. [doi: 10.1177/0963721413512856]
19. Walton GM, Wilson TD. Wise interventions: psychological remedies for social and personal problems. Psychol Rev 2018 Oct;125(5):617-655. [doi: 10.1037/rev0000115] [Medline: 30299141]
20. Schleider JL, Abel MR, Weisz JR. Implicit theories and youth mental health problems: a random-effects meta-analysis. Clin Psychol Rev 2015 Feb;35:1-9. [doi: 10.1016/j.cpr.2014.11.001] [Medline: 25462109]
21. Schleider JL, Zapata JP, Rapoport A, Wescott A, Ghosh A, Kaveladze B, et al. Single-session interventions for mental health problems and service engagement: umbrella review of systematic reviews and meta-analyses. Annu Rev Clin Psychol 2025 Jan 28;21:1-42 (forthcoming)(forthcoming). [doi: 10.1146/annurev-clinpsy-081423-025033] [Medline: 39874601]
22. Wasil AR, Park SJ, Gillespie S, Shingleton R, Shinde S, Natu S, et al. Harnessing single-session interventions to improve adolescent mental health and well-being in India: development, adaptation, and pilot testing of online single-session interventions in Indian secondary schools. Asian J Psychiatr 2020 Apr;50:101980. [doi: 10.1016/j.ajp.2020.101980] [Medline: 32146337]
23. Yu C, Zhao S, Jin L, Wang Y, Lin D. A single-session growth mindset intervention among Chinese junior secondary school students. Appl Psychol Health Well Being 2024 Nov;16(4):2397-2420. [doi: 10.1111/aphw.12596] [Medline: 39301781]
24. Zhu S, Zhuang Y, Lee P. Psychometric properties of the Mindsets of Depression, Anxiety, and Stress Scale (MDASS) in Chinese young adults and adolescents. Early Interv Psychiatry 2022 Apr;16(4):380-392. [doi: 10.1111/eip.13177] [Medline: 34056868]
25. Zhu S, Wong PWC. What matters for adolescent suicidality: Depressive symptoms or fixed mindsets? Examination of cross-sectional and longitudinal associations between fixed mindsets and suicidal ideation. Suicide Life Threat Behav 2022 Oct;52(5):932-942 [FREE Full text] [doi: 10.1111/sltb.12891] [Medline: 35686883]

XSL•FO
RenderX

26. Schleider JL, Weisz JR. Reducing risk for anxiety and depression in adolescents: effects of a single-session intervention teaching that personality can change. Behav Res Ther 2016 Dec;87:170-181 [FREE Full text] [doi: 10.1016/j.brat.2016.09.011] [Medline: 27697671]
27. Zhu S, Tse S, Chan KL, Lee P, Cheng Q, Sun J. Examination of web-based single-session growth mindset interventions for reducing adolescent anxiety: study protocol of a 3-arm cluster randomized controlled trial. JMIR Res Protoc 2023 Mar 17;12:e41758 [FREE Full text] [doi: 10.2196/41758] [Medline: 36930199]
28. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006 May 22;166(10):1092-1097. [doi: 10.1001/archinte.166.10.1092] [Medline: 16717171]
29. He XY, Li C, Qian J, Cui HS. Reliability and validity of a Generalized Anxiety Disorder scale in general hospital outpatients [in Chinese]. Shanghai Archives of Psychiatry 2010;22(4):200-203 [FREE Full text] [doi: 10.3969/j.issn.1002-0829.2010.04.002]
30. Mossman SA, Luft MJ, Schroeder HK, Varney ST, Fleck DE, Barzman DH, et al. The Generalized Anxiety Disorder 7-item scale in adolescents with generalized anxiety disorder: signal detection and validation. Ann Clin Psychiatry 2017 Nov;29(4):227-234A [FREE Full text] [Medline: 29069107]
31. Zhu S, Zhuang Y, Lee P, Wong PWC. The changes of suicidal ideation status among young people in Hong Kong during COVID-19: a longitudinal survey. J Affect Disord 2021 Nov 01;294:151-158 [FREE Full text] [doi: 10.1016/j.jad.2021.07.042] [Medline: 34298219]
32. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001 Sep;16(9):606-613 [FREE Full text] [doi: 10.1046/j.1525-1497.2001.016009606.x] [Medline: 11556941]
33. Leung DYP, Mak YW, Leung SF, Chiang VCL, Loke AY. Measurement invariances of the PHQ-9 across gender and age groups in Chinese adolescents. Asia Pac Psychiatry 2020 Sep;12(3):e12381 [FREE Full text] [doi: 10.1111/appy.12381] [Medline: 32011101]
34. Brown TA, White KS, Forsyth JP, Barlow DH. The structure of perceived emotional control: psychometric properties of a revised anxiety control questionnaire. Behavior Therapy 2004;35(1):75-99. [doi: 10.1016/s0005-7894(04)80005-4]
35. Kissane DW, Wein S, Love A, Lee XQ, Kee PL, Clarke DM. The Demoralization Scale: a report of its development and preliminary validation. J Palliat Care 2004;20(4):269-276. [Medline: 15690829]
36. Hung HC, Chen HW, Chang YF, Yang YC, Liu CL, Hsieh RK, et al. Evaluation of the reliability and validity of the Mandarin Version of Demoralization Scale for cancer patients [in Chinese]. Journal of Internal Medicine of Taiwan 2010;21(6):427-435. [doi: 10.6314/JIMT.2010.21(6).06]
37. Fischer E, Farina A. Attitudes toward seeking professional psychologial help: a shortened form and considerations for research. Journal of College Student Development 1995;36(4):368-373. [doi: 10.1037/t05375-000]
38. Stewart-Brown S, Janmohamed K. Warwick-Edinburgh Mental Well-being Scale (WEMWBS) user guide version 1. European Network for Mental Health Promotion. 2008. URL: http://www.mentalhealthpromotion.net/resources/user-guide.pdf [accessed 2024-12-02]
39. Ng SSW, Lo AWY, Leung TKS, Chan FSM, Wong ATY, Lam RWT, et al. Translation and validation of the Chinese version of the short Warwick-Edinburgh Mental Well-being Scale for patients with mental illness in Hong Kong. East Asian Arch Psychiatry 2014 Mar;24(1):3-9 [FREE Full text] [Medline: 24676481]
40. Chiu CY, Hong YY, Dweck CS. Lay dispositionism and implicit theories of personality. Journal of Personality and Social Psychology 1997 Jul;73(1):19-30. [doi: 10.1037//0022-3514.73.1.19] [Medline: 9216077]
41. Zhu S, Zhuang Y, Cheung S. Domain specificity or generality: assessing the Chinese Implicit Theories Scale of six fundamental psychological attributes. Front Psychol 2020;11:142 [FREE Full text] [doi: 10.3389/fpsyg.2020.00142] [Medline: 32116943]
42. Sekhon M, Cartwright M, Francis JJ. Development of a theory-informed questionnaire to assess the acceptability of healthcare interventions. BMC Health Serv Res 2022 Mar 01;22(1):279 [FREE Full text] [doi: 10.1186/s12913-022-07577-3] [Medline: 35232455]
43. Schleider JL, Dobias M, Sung J, Mumper E, Mullarkey MC. Acceptability and utility of an open-access, online single-session intervention platform for adolescent mental health. JMIR Ment Health 2020 Jun 30;7(6):e20513 [FREE Full text] [doi: 10.2196/20513] [Medline: 32602846]
44. Jo B, Asparouhov T, Muthén BO. Intention-to-treat analysis in cluster randomized trials with noncompliance. Stat Med 2008 Nov 29;27(27):5565-5577 [FREE Full text] [doi: 10.1002/sim.3370] [Medline: 18623608]
45. Schleider JL, Mullarkey MC, Chacko A. Harnessing wise interventions to advance the potency and reach of youth mental health services. Clin Child Fam Psychol Rev 2020 Mar;23(1):70-101. [doi: 10.1007/s10567-019-00301-4] [Medline: 31440858]
46. Yeager DS, Dahl RE, Dweck CS. Why interventions to influence adolescent behavior often fail but could succeed. Perspect Psychol Sci 2018 Jan;13(1):101-122 [FREE Full text] [doi: 10.1177/1745691617722620] [Medline: 29232535]
47. Walton GM, Yeager DS. Seed and soil: psychological affordances in contexts help to explain where wise interventions succeed or fail. Curr Dir Psychol Sci 2020 Jun;29(3):219-226 [FREE Full text] [doi: 10.1177/0963721420904453] [Medline: 32719574]

XSL•FO
RenderX

Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
GAD-7: 7-item Generalized Anxiety Disorder
MDASS: Mindset of Depression, Anxiety, and Stress Scale
PHQ-9: 9-item Patient Health Questionnaire
QICC: Corrected Quasi-Likelihood under the Independence Model Criterion
SES: socioeconomic status
SIGMA: single-session intervention of a growth mindset for anxiety
SSI: single-session intervention
SSIGP: single-session intervention of a growth mindset of personality
WEMWBS-14: 14-item Warwick-Edinburgh Mental Well-Being Scale

Edited by A Serlachius; submitted 21.06.24; peer-reviewed by M Subotic-Kerry, R Nooripour; comments to author 19.11.24; revised version received 13.03.25; accepted 19.03.25; published 18.04.25.

Please cite as:
Zhu S, Hu Y, Qi D, Tse S, Chan KL, Sun J, Lee P
Effects of Web-Based Single-Session Growth Mindset Interventions for Reducing Adolescent Anxiety: Four-Armed Randomized Controlled Trial
JMIR Pediatr Parent 2025;8:e63500
URL: https://pediatrics.jmir.org/2025/1/e63500
doi:10.2196/63500
PMID:40249649

©Shimin Zhu, Yuxi Hu, Di Qi, Samson Tse, Ko Ling Chan, Jessica Sun, Paul Lee. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 18.04.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Developing Digital Mental Health Tools With Culturally Diverse Parents and Young People: Qualitative User-Centered Design Study

Isobel Butorac[1], MSc; Roisin McNaney[2], PhD; Joshua Paolo Seguin[3], MSIS; Patrick Olivier[3], PhD; Jaimie C Northam[4,5], PhD; Lucy A Tully[4,5], PhD; Talia Carl[4,5], PhD; Adrian Carter[1], PhD

[1]School of Psychological Sciences, Monash University, Clayton, Australia

[2]School of Computing and Information Systems, The University of Melbourne, Melbourne, Australia

[3]Action Lab, Faculty of Information Technology, Melbourne, Australia

[4]The School of Psychology, Faculty of Science, The University of Sydney, Camperdown, Australia

[5]Growing Minds Australia, Australia's Clinical Trials Network in Child and Youth Mental Health, Sydney, Australia

Corresponding Author:
Isobel Butorac, MSc
School of Psychological Sciences
Monash University
770 Blackburn Road
Clayton, 3800
Australia
Phone: 61 9905 0100
Fax: 61 9905 0100
Email: isobel.butorac@monash.edu

Abstract

Background: Approximately 39% of young people (aged 16-24 y) experience mental ill health, but only 23% seek professional help. Early intervention is essential for reducing the impacts of mental illness, but young people, particularly those from culturally diverse communities, report experiencing shame and stigma, which can deter them from engaging with face-to-face services. Digital mental health (DMH) tools promise to increase access, but there is a lack of literature exploring the suitability of DMH tools for culturally diverse populations.

Objective: The project was conducted in partnership with a large-scale national DMH organization that promotes evidence-based early intervention, treatment, and support of mental health in young people and their families. The organization wanted to develop a self-directed web-based platform for parents and young people that integrates psychological assessments and intervention pathways via a web-based “check-in” tool. Our project explored the views of culturally diverse parents and young people on the opportunities and barriers to engagement with a web-based DMH screening tool.

Methods: We conducted a 2-phase qualitative study aiming to identify potential issues faced by culturally diverse communities when engaging with DMH tools designed for the Australian public. We worked with 18 culturally diverse participants (parents: n=8, 44%; young people: n=10, 56%) in a series of design-led workshops drawing on methods from speculative design and user experience to understand the opportunities and barriers that organizations might face when implementing population-level DMH tools with culturally diverse communities. NVivo was used to conduct thematic analyses of the audio-recorded and transcribed workshop data.

Results: Five themes were constructed from the workshops: (1) trust in the use and application of a DMH tool, (2) data management and sharing, (3) sociocultural influences on mental health, (4) generational differences in mental health and digital literacy, and (5) stigma and culturally based discrimination in mental health support.

Conclusions: The emergent themes have important considerations for researchers wishing to develop more inclusive DMH tools. The study found that healthy parent-child relationships will increase engagement in mental health support for young persons from culturally diverse backgrounds. Barriers to engagement with DMH tools included culturally based discrimination, the influence of culture on mental health support, and the potential impact of a diagnostic label on help seeking. The study’s findings

XSL•FO
RenderX

suggest a need for culturally safe psychoeducation for culturally diverse end users that fosters self-determination with tailored resources. They also highlight important key challenges when working with culturally diverse populations.

(JMIR Pediatr Parent 2025;8:e65163) doi:10.2196/65163

KEYWORDS

digital mental health; young people; cultural diversity; web-based and mobile health interventions; qualitative methods; user-centered design; human-computer interaction

Introduction

Background

Approximately 13% of the global population living with mental health problems are young people (aged 16-24 y) [1]. Young people with mental health disorders also experience higher rates of morbidity and mortality risk than the general population, leading to a 10- to 20-year reduction in life expectancy [2,3]. These rates were compounded during the COVID-19 pandemic, during which globally 1 in 4 young people experienced clinically elevated levels of depression, and 1 in 5 experienced clinically elevated levels of anxiety [4]. Nevertheless, during this period, there was no concurrent increase in the uptake of mental health support [5]. For young people, untreated mental health problems can have long-lasting impacts due to the important social, emotional, and cognitive developmental changes that are being experienced simultaneously [6].

Cultural Diversity in the Context of Australia

Australia is a culturally diverse society, with 27.6% of its population born overseas [1]. This diversity spans across differences in cultural identity, language, country of birth, religion, heritage, and national origin [7]. Shaped by a legacy of colonialism, racial inequality has influenced Australia and its relationship with racial and ethnic minority immigrants [8] and First Nations peoples [9].

Studies have identified higher rates of mental ill-health among culturally diverse groups compared to the broader Australian population [10,11]. This is, in part, due to mental health risk factors, such as language barriers, cultural adjustment, the loss of family connection, and an inability to apply knowledge and occupational skills to attain meaningful employment, all of which hinder active participation in society for people from culturally diverse backgrounds [12]. Young people from culturally diverse backgrounds tend to be the most reluctant to seek help, and if they do, they typically turn to informal sources such as family, friends, and elders [13,14]. Among those who have sought professional support, many report that the types of support they were offered were inaccessible, culturally inappropriate, or lacking cultural relevance [15-17].

Common barriers to mental health care for culturally diverse communities include a lack of information and knowledge about available services, language differences, culturally specific conceptions of mental health, and lengthy waitlists [18-22]. Discrimination can be experienced throughout a person's mental health journey, with studies showing that culturally diverse people are far less likely to engage in mental health visits or seek specialist care than White ethnic groups [23]. Research has also found that clinicians are less likely to involve culturally diverse patients in friendly discussions or include them in the treatment decision-making process [24]. Instead, people from culturally diverse backgrounds tend to access mental health services through clinical emergency services during an acute crisis rather than accessing early interventions before the problem is severe, hindering their prospect of recovery [25,26]. People from culturally diverse backgrounds in Australia also experience more involuntary hospital admissions for mental health treatment [16].

Current Landscape of Digital Mental Health Tools and Opportunities

Digital mental health (DMH) tools (eg, apps and web-based services) delivered through smartphones [27-31], computers [32,33], and wearable devices [34,35] hold promise for overcoming many of the aforementioned barriers [36]. DMH tools can include self-directed online interventions [37,38], mental health screenings or "check-ins" to assess mental health status [39], digital health apps that allow the real-time monitoring of mental health [40,41], chatbots to support help seeking [42], and even interventions on specialist technologies such as virtual reality headsets [43,44]. Studies have shown that young people and parents prefer digital treatment over face-to-face care [45,46]. DMH tools offer easily accessible, low-cost services to address common mental health problems [47,48]. Self-directed DMH tools may offer alternative or complementary options to face-to-face clinical care, with the potential to provide support to people on waitlists for clinical care in remote locations or those who may not have the financial means to seek face-to-face treatment [43]. There is increasing interest in developing culturally sensitive DMH tools [17,49], with some DMH apps and online platforms being designed especially for ethnically diverse groups [50]. However, such examples remain limited; moreover, considerations of diversity, equity, and inclusion are rarely integrated into their design or evaluation [51].

Online self-screening tools provide useful information about self-reported mental health symptoms, offering clinical cutoffs to indicate when further assessment or support is needed, along with relevant resources for support. They also allow anonymous pathways for disclosing mental health symptoms and offer digital interventions [4,52,53] that have been shown to be fundamental for the mental health journey of culturally diverse users because digital interventions and resources are more likely to reach culturally diverse populations who may not have access to or are not yet engaging in mental health support [54]. Large-scale DMH platforms that incorporate screening, access to online clinicians, self-directed resources, and curated suites of trusted apps are increasingly being adopted by public health organizations across Western contexts (eg, the UK National

XSL•FO
RenderX

Health Service's Talking Therapies program) [48]. However, while these public-facing DMH tools are intended for use by all of society, they tend to be designed by and for the dominant Western culture [55].

In addition, DMH tools hold the potential for supporting mental health beyond traditional 1-to-1 contexts. Online health-oriented communities offer benefits such as peer support networks (eg, Headspace and Orygen both offer online youth mental health support in Australia). Similarly, social media groups focused on mental health have been shown to play a substantial role for end users in rural areas, where geographic location limits access to mental health service providers [56]. These groups provide support for guided online therapy [57], skills building [58], symptom monitoring [59], and social connection [60,61]. However, among culturally diverse communities, where English may be a second language, willingness to engage in these types of peer support offerings tends to be lower [50].

Designing With Diverse Populations

There is increasing recognition of the importance of designing digital services tailored for culturally diverse populations using responsive and inclusive design processes. Many researchers and designers in this space have adopted participatory research and user-centered approaches wherein members of the community are involved in the design process to identify their unique needs, goals, and concerns and to ensure that these are considered and integrated into the final service design [62-67]. Technologies developed for an underserved community are most impactful when designed with members of that community [68]. The use of user-centered approaches has been shown to improve the acceptability, effectiveness, and contextual relevance of novel technologies for communities [55]. Engaging members of the community in a design process often requires creative methods and tools to ensure that it is safe, beneficial, and easy for them to participate. Some studies have used creative tool kits, personas, and vignettes to scaffold design thinking [69,70].

User-centered design approaches that recommend the inclusion of meaningful engagement with consumers and carers in the service design are also increasingly recognized among mental health researchers and practitioners, including government agencies [71]. Research interest in culturally sensitive design through participatory research and user-centered design methods is mounting [72-74]. However, despite the political and cultural shift, there is still only a small, though growing, body of work in the field of human-computer interaction that explores the needs of culturally diverse populations in the area of DMH services [17,49,75,76]. While these studies provide useful insights, they tend to focus on a single community or culture and offer specific rather than generalized interventions. While there are steps being taken to engage culturally diverse communities in technology design across various fields of research, there are still various mental health factors that could impact the uptake of novel DMH tools (eg, cultural concepts of mental health and stigma around mental health). As such, it is vital that we aim to better understand how to design tools that account for these factors and enhance service engagement for culturally diverse communities. For the successful implementation of clinical innovations at a public scale, novel digital solutions need to be designed *with* diverse populations to ensure that these solutions meet their needs [17,77]. Engaging with the perspectives of groups considered marginalized and those outside Western traditional norms will help ensure that DMH tools are designed more inclusively [78,79].

Building on these insights, we worked with culturally diverse young people and parents to design a national digital self-directed mental health check-in tool, called Growing Minds Check-In (GMCI), for the Australian public. The GMCI aims to provide an assessment of mental health and well-being symptoms as well as recommendations to tailored online mental health services and information. This study engaged with user-centered design due to the restrictions on the level of involvement the participants would have on the final production of the GMCI. Due to the narrow development timelines, the participants in this study were able to contribute to the design process but did not have decision-making powers; instead, they were involved in appropriate ways throughout the development of the GMCI [80]. We conducted a 2-phase study aiming to identify potential issues faced by culturally diverse communities when engaging with DMH tools such as the GMCI. The purpose of this study is to describe the attitudes, barriers, and benefits associated with DMH tool engagement among culturally diverse parents and young people. This information is likely to be relevant to DMH interventions for parenting and child well-being; it may also be relevant to other online programs, especially those delivered as universal public health interventions. We propose a set of design strategies for developing public-facing DMH tools and provide reflections on our own design process and the challenges we faced while engaging with culturally diverse communities in research.

Methods

Study Context

This project was conducted in partnership with the Growing Minds Australia Clinical Trials Network, Australia's first clinical trials network for child and youth mental health research [81]. It is part of the first phase of design for the Growing Minds Australia Clinical Trials Network flagship trial, the GMCI: a national online platform for parents and young people that integrates a mental health and well-being "check-in" with personalized feedback and suggestions for online mental health services and resources. We came into the project with the aim of focusing inquiry on how the future-facing platform could be designed more inclusively to ensure that it is relevant and accessible for diverse communities. We used a speculative DMH app containing features similar to those proposed by digital phenotyping software that could collect both passive and active data.

The study comprised 2 phases to engage groups of parents and young people from culturally diverse backgrounds with lived experience of mental health challenges. The first was a scoping phase that applied user-centered design methods, which included using speculative DMH tools to tease out potential benefits, concerns, and trade-offs. The second was a prototype exploration phase, whereby a proposed nationwide mental health screening

XSL•FO
RenderX

tool was used as an artifact for participants to determine possible challenges and ethical issues that culturally diverse populations may face when engaging with DMH tools. This included a facilitated emotional walk-through of the screening tool using a workbook, followed by a data consolidation workshop where participants reflected on their experiences of using the tool. We aimed to identify the potential benefits and possible challenges of using a large-scale web-based check-in service and incorporate these insights into a more inclusive design for future DMH technologies. The design justice framework was applied to the design of the research questions (RQs), the activity schedule, and the analysis of the findings. This approach promotes the exploration of how benefits and burdens are distributed across groups, challenging design-driven inequalities by using an intersectional lens that considers race, gender, sexual orientation, and culture [82,83]. This framework incorporates participatory and user-centered design methods that prioritize community needs and encourage researchers to consider how power can shape participation in the design processes [82] (Figure 1).

Figure 1. Visualization of the study design. DMH: digital mental health.



Ethical Considerations

Our study received ethics approval from Monash University (31138). All participants were provided with an explanatory statement detailing the project and were asked to read and sign a consent form before participating. These documents were provided to participants in advance of the workshops. Consent and demographic information (eg, country of origin and culture they identify with, years lived in Australia, and languages spoken at home) were collected before the workshops began. Participants across all study phases were compensated Aus $40 (US $24) per hour for their time. Data was anonymized with all names removed from the data. Names were changed during transcription before any analysis commenced.

Recruitment

We partnered with a multicultural community mental health organization to recruit participants and facilitate the workshops. We used the organization's advertising channels to recruit participants who were involved as volunteers with the organization and were likely to be mental health literate. Workshop participants were required to have a high school level of spoken English due to time limitations and budget restrictions, which precluded the use of translators. Calls for participation in the workshops were advertised through flyers distributed via the community organization. For inclusion in the study, participants needed to identify as either having lived experience with mental health problems or having children who had experienced mental health challenges. These workshops were conducted in person and therefore limited to communities living in Victoria, Australia. A majority of the participants (12/18, 67%) were from South or East Asia, reflecting the demographic composition of the Australian population [1]. In phase 2, we included an Anglo-Australian participant (P8) who was recommended as a research participant by the mental health organization. Although not from a culturally diverse background, this participant was an experienced peer support worker with multicultural populations, had lived experience of complex mental health challenges, and was a parent. Phase 1 and phase 2 participant demographics are presented in Table 1.

XSL•FO
RenderX

Table 1. Phase 1 and phase 2 participant demographics.

Phases and participant IDs	Age (y)	Parent or young person	Duration of residence in Australia (y)	Self-identified cultural background	Languages spoken at home
Phase 1					
P1	65	Parent	35	Indian	English, Tamil, and Hindi
P2	57	Parent	35	Indian	English and Tamil
P3	53	Parent	23	Indian	Tamil
P4	67	Parent	50	German	German and English
P5	48	Parent	48	Italian	Italian and English
P6	58	Parent	41	Indian	Hindi, Punjabi, and English
P7	67	Parent	67	Australian and German	English and German
YP1	22	Young person	3.5	Turkish	Turkish
YP2	16	Young person	7	German and Indian	German and English
YP3	22	Young person	11	Malaysian	Cantonese and English
YP4	21	Young person	4	Indian	Hindi
YP5	23	Young person	21	Han Chinese	Mandarin Chinese
YP6	22	Young person	12	Australian Chinese	Mandarin Chinese
YP7	18	Young person	17	Malaysian	English
YP8	24	Young person	5	South African	Zulu
YP9	24	Young person	11	Malaysian Chinese	Cantonese, Mandarin, and Bahasa Melayu
YP10	21	Young person	20	Indian or Hindu	English and Tamil
Phase 2					
P1	65	Parent	35	Indian	English, Tamil, and Hindi
P2	57	Parent	35	Indian	English and Tamil
P3	53	Parent	23	India	Tamil
YP3	22	Young person	11	Malaysian	Cantonese and English
YP4	21	Young person	4	India	Hindi
YP10	21	Young person	20	India or Hindu	English and Tamil
P7	67	Parent	67	Australian and German	English and German
P8	47	Parent	47	Australian	English

Phase 1: Contextual Inquiry Through User-Centered Design

Overview

We conducted 2 user-centered design workshops: one with 10 young people (female: n=7, 70%; male: n=3, 30%; aged 16-25 y) and another with 8 parents of young people (female: n=4, 50%; male: n=4, 50%; aged 21-67 y). Each workshop included a researcher facilitator and a cofacilitator provided by the mental health organization who assisted with recruitment. Power imbalances were mitigated by conducting the workshops at an office space provided by the multicultural organization, where participants were affiliated and felt comfortable. The workshops ran for 3 hours with a 20-minute refreshment break. We examined 3 broad RQs:

1. How do culturally diverse end users perceive the value of mental health data? With whom would they share their mental health data? How might their mental health data differ in the future?
2. How is screening information communicated and understood? What impact would this have on therapeutic relationships?
3. What are the social factors that influence the likely use and application of DMH technologies? Are culturally diverse users concerned about third-party use of their data?

We aimed to not only explore the inclusion of culturally diverse communities in the design of a digital platform but also consider the impact of future data use, particularly how an end user's sensitive data may later be used. Given the propensity for alternative data use by third parties, we wanted to better understand the degree to which culturally diverse end users

XSL•FO
RenderX

worried about how their data may be used and whether they felt it would have future implications.

The workshop sessions followed a semistructured activity guide that was developed by the authors and reviewed by colleagues independent of the study (refer to Multimedia Appendix 1 for details). We began each session with an icebreaker activity and initiated a group discussion to set the context for the following activities. Using a whiteboard and markers, we asked participants about their understanding of mental health and what makes for good and poor mental health. This activity was intended to provide insight into the participants' mental health literacy. We then provided participants with a speculative design probe, the "mental health vault" (Figure 2), to unpack abstract conceptions of sensitive digital health data. The vault included 3 layers to indicate varying levels of personal information that may be uncovered by DMH tools: (1) a locked safe represented by a metal box (most personal), (2) an inner layer bound by a thick metal chain, and (3) an outer layer framed by a thin rope (least personal). The activity schedule included four activities: (1) digital vault, (2) blank keys, (3) data sharing, and (4) future forecasting. These activities were centered on an imagined DMH tool that could actively and passively collect end user data, which differs from the GMCI's intended use and functionality as a web-based tool that provides personalized feedback and suggestions for online mental health services and information matched to need.

Figure 2. The "digital vault" activity in phase 1.



Activity 1: Digital Vault

The aim of this activity was to address RQ 1 by gauging participants' level of understanding of mental health data, how sensitive they perceived the data to be, and with whom they would want to share the data. To scaffold their thinking, we provided stimuli picture cards of potential mental health data points (eg, a diary, a mobile phone, GPS data, survey test results, and social media data) and asked participants to place each card, depending on how secure they felt each data point was, within the different layers of the vault (ie, inside the metal box, within the chain, or in the outer rope layer). The most private data points were placed inside the metal box, while the least private were positioned in the outer rope layer. After participants arranged the cards according to their preferences, we asked them to describe what each layer represented to them and why they placed each data point where they did (eg, why they would be okay with sharing social media data publicly but not their survey test results).

Activity 2: Blank Keys

The aim of this activity was to understand whom the participants were willing to share their data with and their reasons, addressing RQ 1. Using an inductive approach, we used this component of the activity to leverage and broaden the discussion to generate ideas on new "trusted" or "nontrusted" people that the participants could think of on their own, without the researcher's prompts or suggestions. We gave participants 6 blank paper "keys" and asked them to write down the individuals (eg, their imam, family member, or teacher) to whom they would be willing to grant access to the vault. They then placed each key in the vault layer they felt most comfortable allowing that individual to access. Next, we asked participants to use these blank keys to write down who they thought might "rob" the vault and to place the newly labeled keys in the layer of the vault they felt the "data robber" might access. The activity schedule script included the following prompt: "Now let's imagine digital bank robbers broke into your vault. What is the worst thing that can happen? Who might the robbers be? Why would they want your data? Which specific area of the vault would they be most interested in?"

XSL•FO
RenderX

Activity 3: Data Sharing

Building on the digital vault scenario, we introduced a "digital vault manager" who has access to the data contained in the digital vault and could use the data to identify mental health issues. This activity addressed RQ 2 and RQ 3. We then asked the participants whether they would want anyone to know about mental health challenge identified, and if so, whom they would share it with. This activity was designed to get participants thinking about their individual perspectives as well as how others may feel about having their personal data shared with the intention of helping individuals or their community (eg, whether a school or current employer should be notified).

Activity 4: Future Forecasting

This activity examined how screening information is likely to be communicated, understood, and applied in face-to-face sessions with a clinician. This activity addressed RQ2 and RQ3. We asked participants to imagine that the digital vault had been passively collecting data and had generated a prediction about their mental health over the next 20 years. First, we gathered emotional reactions to the prediction using printed emoji faces and by asking participants to indicate how they felt about having predictions made about them. Next, through a discussion-based activity, we explored how the prediction their trust, and sense of empowerment, and agency, as well as how and by whom the prediction would best be communicated. The activity schedule script included the following prompt: "Do you feel empowered knowing this prediction in advance so you can seek help? Do you trust its accuracy? Would you prefer your GP [general practitioner] or mental health clinician had told you? Would you trust it more if your GP told you? Are you concerned about who else is accessing this digital vault from some years ago?"

The findings from the future-facing DMH tool discussion in phase 1 were used to frame the emotional walk-through activity and focus groups with parents and young people in phase 2. We considered the benefits, burdens, and trade-offs that the culturally diverse participants discussed in these workshops and wove them into the emotional walk-through activity in an attempt to highlight challenges with an existing system that could then feed into a future design. This activity series was designed to address RQs 1 to 3.

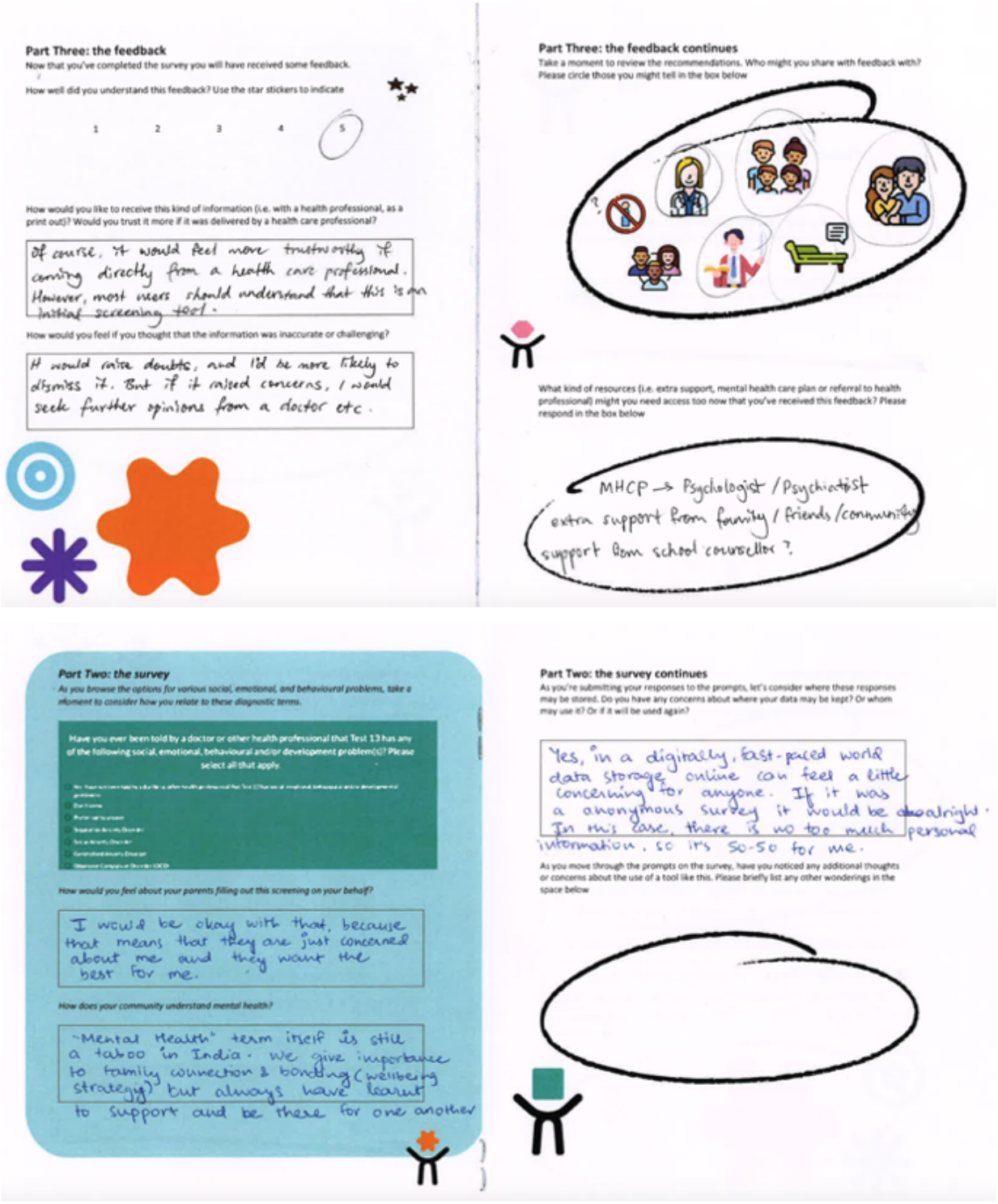
Phase 2: Emotional Walk-Through

Using a user experience technique traditionally referred to as a cognitive walk-through, we aimed to explore participants' emotional responses as they engaged with the interface [84,85]. We adapted a walk-through user testing methodology [86] and created a 6-page emotional walk-through booklet (Figure 3) that was distributed to participants along with a link to a prototype of the web-based mental health screening platform intended for national deployment in the near future. This was a written task that was designed to help facilitate discussion and ideas about the issues we intended to explore in the prototype testing workshop. Participants (parents and young people) were then invited to take part in a joint consolidation workshop to discuss their thoughts in further detail. We supplied participants with a booklet that was designed by the team, 2 weeks before the workshop to allow them time in their daily schedule to complete the booklet and explore GMCI prototype. Participants used their completed booklets during the session as mnemonic aids to recall their thoughts and experiences. A total of 6 participants (parents: n=3, 50%; young people: n=3, 50%; female: n=3, 50%; male: n=3, 50%) agreed to participate in the joint consolidation workshop. The aim was to elicit their thoughts and feelings about DMH data as they completed the web-based mental health check-in journey. The booklet included a range of questions designed to gauge emotional reactions as well as rating scale assessments as participants used the web-based screening platform. Within each section of the booklet, we included ethical considerations to encourage participants to consider the social impact of the DMH tools, including their understanding of mental health, how their community understands mental health, views on data privacy and management, how they would like to receive feedback about their mental health, and whether they felt they could challenge a mental health assessment. Participants then took part in the consolidation workshop to discuss their experience of using the prototype and to consolidate their ideas and expectations of engaging with an online mental health screening service. The session was broken down into four parts:

1. What are the motivations, benefits, and challenges of accessing such a tool?
2. Where does the data entered on the web go?
3. How well did the participants understand the feedback supplied? Did it resonate with their cultural background?
4. What suggestions did the participants have to make this tool more accepted within specific communities (dos and don'ts).

XSL•FO
RenderX

Figure 3. A completed emotional walk-through booklet in phase 2.1.



Positionality Statement

Our authorship team represents a variety of cultural backgrounds and perspectives on the topic, shaped by our own experiences. We took part in this research because we believe strongly in fostering equal access to mental health services for culturally diverse end users. Our team comprises 8 authors: 5 (62%) female individuals with European, Anglo-Celtic, and Irish heritage; and 3 (38%) male individuals with Anglo-Celtic, Anglo-Australian, and Filipino heritage. Of the 8 authors, 3 (38%) are first-generation migrants to Australia; 4 (50%) identify as parents; and 3 (38%) work with young people, parents, caregivers, and families. Our team consists of clinical and registered psychologists, a neuroscientist and bioethicist, a human-computer interaction and design practitioner, and researchers working in DMH and responsible innovation. We are committed to extending our knowledge and understanding of culturally diverse research practice to empathize and engage with research involving culturally diverse parents and young

XSL•FO
RenderX

people in this work. This commitment has informed our approach to the study design and data analysis.

Data Analysis

Audio recordings from all 3 face-to-face workshops (phase 1: n=2, 67%; phase 2: n=1, 33%) were transcribed and thematically analyzed using NVivo software (Lumivero). An inductive thematic analysis was conducted on all transcripts, without a preexisting coding framework, to identify themes and subthemes [87]. Initial codes were generated by IB to organize the data from phase 1 into potential items of interest. Three additional researchers (AC, RM, and JPS) familiarized themselves with the data from phase 1 and reviewed the initial codes. Iterative coding was then completed by IB, and 21 subthemes were generated that informed the design of the emotional walk-through. Three additional research members (AC, RM, and JPS) cross-coded themes from the emotional walk-through booklets and transcripts from the consolidation workshop. The codes were reviewed to ensure that the themes were clear and descriptive. The coded data from both phases were combined for analysis with 5 themes. In each workshop, an activity schedule was used to scaffold free-flowing discussion among participants. Variations in participant opinions were coded and contrasted to develop the subthemes. Participants were collaborative and brought culturally diverse and unique experiences, offering rich anecdotes in each session.

Results

Five major themes were developed from the analysis of the data collected from both phases: (1) trust in the use and application of a DMH tool, (2) data management and sharing, (3) sociocultural influences on mental health, (4) generational differences in mental health and digital literacy, and (5) stigma and culturally based discrimination in mental health support.

The Potential Impact of DMH Tools on Interpersonal and Therapeutic Relationships

The discussions on how DMH tools may impact the therapeutic relationship with a current or future clinician varied; however, both groups (parents and young people) expressed greater trust in a clinician in a face-to-face setting than in a digital tool. Participants in both groups also agreed that they would be more likely to trust a mental health recommendation or diagnosis generated by a DMH tool if a clinician was involved at some point:

> *I feel like I would still and then like accept whatever the app tells me, but it will be very helpful if the psychiatrist or psychologist are linked with this app. Like they sort of like, acknowledge that this app is useful or something like that.* [YP5]

Participants acknowledged that they would seek advice from a DMH platform if a clinician was hard to access or as a first step in help seeking. However, some participants (YP10, YP7, YP5, and P2) felt that it was hard to know where to search and stated that they would use DMH tools as a screening tool but would seek help from a trusted health professional, such as a GP, psychiatrist, or psychologist, regarding the information provided by a DMH tools. Conversely, other participants found face-to-face interactions to be "embarrassing" (YP10), "confronting" (P8), or rushed:

> *I feel like because GPs usually see patients 15 minutes per block, it feels that it's quite rushed and sometimes GPs wouldn't take the time to go over time...it will make us feel that we're not as like important.* [YP9]

Once a recommendation or treatment suggestion has been provided by DMH tools, participants in both groups (P6, YP5, and P3) expressed a desire to process it on their own first:

> *I would want to see the information first and then several steps down the road, consulting with a specialist might be an option.* [P3]

Once they had reached a point of acceptance regarding the recommendation or treatment suggestion, there was variability in whom they would share the data with, with disclosures to family, friends, and practitioners varying within both groups. Some parents (P1, P2, and P3) preferred to be given the recommendation before sharing it with their children. Two younger participants (YP2 and YP5) were happy to share the information with their parents and siblings, while many of the other young participants (YP1, YP3, YP8, YP9, and YP10) indicated that they would prefer to share it with a trusted contact or friend—rather than with their parents and siblings—who they believed would help put them in touch with a professional or assist in accessing additional resources.

One young person (YP3) suggested having the option to choose to download feedback from a DMH tool depending on the severity of the user's mental health problems. Another young person made the following suggestion:

> *If you delete it, they ask you, "Are you sure?" or like, "Are like are you too busy?" "Is it distracting?" Like it ask you the reasons why you are downloading it. Have you met your match? [similar to a dating app] I think the same should be with the app. Like if you don't like the app, but you still, you downloaded this, but you still feel like you need someone to talk to, call these numbers. And it shouldn't be triple zero, because why would I call triple zero in my, like I don't...maybe triple zero can be like the last thing, but like call this person or locate the nearest center or psychologist, or locate your nearest person or something else.* [YP8]

Suggestions were made in regard to having a trusted contact who would receive a notification if a user was determined to be at high risk for poor mental health, with the understanding that the trusted person would not be obligated to assume responsibility. Two parents (P7 and P8) emphasized the importance of a DMH tool's recommendation or resource that offered access to peer support networks. Another suggestion was for the user to predetermine a lower threshold for a risk notification if they were at risk of increased suicidality, allowing earlier intervention:

> *There's blurred lines to it, but at least like...having an accountability system...accepting, declining, being able to be there, or if I'm not, if I can be an emergency contact, but I'll accept, just going through*

XSL•FO
RenderX

> *this with you. Like, being there with you but I will not be your emergency contact. Like, I can share experience. In the case where it is an emergency, I don't want to be an emergency contact, but I can maybe assist you in contacting your emergency contact or something.* [YP8]

Participants agreed that DMH tools should offer additional resources and alternative options once a screening or check-in is initiated, such as "resources to learn more about what I might be going through" (YP4). Both parents and young people emphasized that healthy parent-to-parent and child-to-parent relationships were important in cases where parents chose to complete a screening on behalf of their child. A parent elaborated as follows:

> *Obviously we agree to disagree on a lot of topics, but you know, after a certain years, you know your child very well. And...it depends on the relationship between the father and the mother as well.* [P2]

The closeness between parent and child would be a significant factor in the quality of input into a DMH tool's screening process, which would then impact the meaningfulness of any subsequent recommendation or prediction:

> *It'd be a case of if you could offer it as a dual package. So if the child was up to do it with their parents as one option, then you'd have, so you'd have three options, you'd have an adult, you'd have the youth separate, and then you'd have a child and a youth and a parent combo...there's something to suit everyone depending on their communication space with their family members and how open they are to their mental health.* [P10]

DMH tools were suggested as a complementary support alongside a clinician in both phase 1 workshops. Additional benefits of using DMH tools included setting reminders or nudges to promote healthy activities such as going for a walk or engaging in mindfulness meditation. A participant in the workshop for young persons also suggested that DMH tools could be useful for users with acute mental health challenges:

> *I think it would be good for bipolar disorder. For example, if you were able to get a new notification about your hyper episode, then you would able, you wouldn't be able to change your episodes like change your, arrange your calendar according to that.* [YP1]

In relation to the technology, a young person described enjoying how music apps and YouTube catered to her mood:

> *So I relate how I'm feeling, even if it's like a chronic like mental illness, like how I'm feeling is through my algorithm of my music. So like I'd be on YouTube and I'd probably right now I'm, like...I just figured out I had ADHD so like I'm like constantly watching things that have to do with that. So like I feel like different platforms can algorithmize my personal experience.* [YP8]

Another young person echoed this and made the following suggestion:

> *I think technology in essence should be supporting humans and human work, rather than trying to replace it. Um, if my GP or my psychologist fails to diagnose or intervene with me early, I recognize that everything they know about me is what I've told them, and those people are human. It's people they might miss things. So I'll be more than happy for this sort of data to assist in diagnosing me. Um, and together it will be more valid that just one source or the other.* [YP7]

In summary, when considering how results are communicated and what impact DMH tools may have on clinical practice, culturally diverse end users wanted to first process a recommendation or prediction on their own, viewed DMH tools as complementary to face-to-face clinical intervention, and were open to having a trusted contact with whom a recommendation or prediction could be shared.

Data Management and Sharing

Conversations in both phases established that participants had a moderate level of understanding about their personal data and how to manage the data. They acknowledged being aware of daily data collection via internet searches and app use and that the data can be outsourced to different countries and third parties through data harvesting (P3, YP10, P2, P7, YP7, YP8, and YP5). A participant in the workshop for young persons suggested that some data have to be shared to build more accurate and personalized apps:

> *I feel like data collection should be a two-way street. If you, I mean, like it should be mutual benefit, right?* [YP7]

Unauthorized data access by governments, concerns after experiences with surveillance measures during the COVID-19 pandemic, recent government health data breaches, and identity theft were key concerns of participants (P8, P7, P2, YP9, P6, and P5). A participant shared another concern:

> *It could be mental health related or something else related. And then that information goes to your doctor, you consult a specialist or a GP or someone. And then it goes back to your insurance provider. And the insurance provider knows about it and straight away your premium goes up because they classify you as a high risk.* [P3]

By contrast, young people were more open to having their data tracked or shared, having grown up with much of their information already available on the web and accessible by others. However, a young person acknowledged the difficult dilemma of accepting data collection in exchange for a more personalized online experience but described it as a "gray area" when it comes to broader data collection, stating as follows:

> *When they click "Accept All," that gives a warrant basically, and that's nothing that you can do because the website can just say, "You said, 'Accept All'" and continue. That's the warrant for me to say...to collect all your data and personalize it for you. And I feel like it's, it's quite a grey area basically.* [YP7]

XSL•FO
RenderX

Another young person expressed uncertainty regarding their preference for certain data points to be collected or tracked by specific services:

> *I would want my location to be tracked by medical services. Say, for example, I get hurt and then, um, my phone...like my watch has this thing where it says, "Accident Detected." But I think about who gets access to what data and what they do with it and I think that's also really hard to track so it depends.* [YP2]

In summary, culturally diverse mental health service users valued data about mental health, with variation in openness to data sharing and how the data may be shared in future.

Sociocultural Influences on Mental Health

Participants' experiences with mental health were grounded in sociocultural complexities, with variations in cultural understandings of mental health, help seeking, parental influence, community and spiritual support, and migration status, all playing a role in diverse communities' engagement with DMH support.

Many of the participants (YP7, YP1, YP8, and P8) self-identified as having lived experience with mental ill-health and discussed the importance of self-understanding when it came to mental well-being. Parents, in particular, recognized the importance of acceptance and education around mental health:

> *Probably because nobody wants to tell anyone, I'm going through not a very nice day or I'm going through mental health issues, so basically we have to come out of that state so we have to educate ourselves there's no point in just keeping everything to yourself.* [P2]

Participants agreed that, outside of the family unit, their ethnic communities placed more importance on family connection and bonding than mental health specifically. This was highlighted in the comment written by a young person in the emotional walk-through booklet:

> *The "Mental health" term itself was still a taboo in India. We give importance to family connection and bonding (as a well-being strategy) but always have learnt to support and be there for one another.* [YP4]

In addition, some participants (P1, P7, and YP4) discussed how their communities relied on religious leaders for mental health support rather than accessing formal care. However, the dominant cultural lens within a household impacted whether mental health was openly discussed. A parent explained as follows:

> *I would say it's very culturally influenced. From my perspective, the culture which we're connected to, you know. For everything there is a step-up process for you to understand, you know, why this is done, why it is not done. The reasons behind it. So where we grew up in our culture, we explain to them why we are doing this, to keep them on track. To keep you calm. It will protect you. The faith base.* [P1]

Migratory experiences and differences in the availability of support depending on visa status were also significant:

> *When I came from Turkey to here, one of the biggest surprises I have come across was the, how common suicide was among younger generations of Turkish people here. I was shocked, I lived in Turkey for 19 years, and I'd never even heard of someone who has heard of someone else's suicide. Like, never even came across it from the third degree or fourth degree. Many here, I spoke to a family member of someone who was a victim to suicide. The mother told me about her son's suicide, and I was so shocked. And then I heard the same story from multiple other people as well, and it just made me realize how widespread it was here, in younger generations of Turkish people.* [YP1]

In summary, sociocultural factors influenced the use and application of DMH tools, with culturally diverse end users describing how their culture informed their understanding of mental health and help seeking.

Generational Differences in Mental Health and Digital Literacy

There were notable differences between the 2 generations across both study phases, particularly in terms of accessing mental health professionals, digital literacy, and whether participants were first- or second-generation migrants. Language barriers were identified, with a parent stating as follows:

> *That support is lacking. So you can imagine for some of these cultural communities, English might be a barrier, language might be a very big barrier.* [P6]

Parents (P6, P2, P8, and P3) preferred confiding in a close friend and face-to-face interactions over digital therapies. By contrast, young people (YP8, YP10, YP3, and P8) seemed more willing to share their mental health experiences. A young person stated as follows:

> *I know that like when I was a young teenager, going through my rebellious phase in an ethnic household where I didn't feel like it was safe to open up to my parents, the online anonymous aspect was what made online like, Tumblr, a safe place for me to, I guess, voice my mental health concerns about myself.* [YP5]

Some parents also believed that young people were more mentally healthy and digitally literate:

> *I think teenagers today are really, because they do things like that in school now, they understand about self-care, they do mindfulness, they do all that sort of thing as teenagers now in high schools and things. I think that the word self-care is so synonymous now, everyone knows what that means. There's depths of it, of course, but to a teenager even knowing, and they know how much time they spend, too much time on social media, they know they need to get more sleep, but you know, when they do all those things and they know they shouldn't eat McDonald's every day, they're not silly, these kids are smart.* [P8]

XSL•FO
RenderX

As a first-generation migrant, a parent felt that it was important not to impose her own cultural rules on her Australian-born children:

> *Because they're going to be Indian Australians, or Indian whatever it is. Deep down, they're Indian, they grew up as Australian children. They're more Australian than Indian sometimes. So we don't, um, there's no hard and fast rules. We can't tell them, you have to get up at 5 o'clock and pray.* [P2]

The discrepancy between how young people perceived mental health challenges compared to their parents was regularly raised, with a young person elaborating as follows:

> *I think another aspect of like, immigrant parents on things about mental health, gender identity, sexuality that's a big thing that, I know people, who are even single parents, who come from the immigrant background, they don't understand what their young child is going through with gender identity and all that stuff, because it's...it wasn't really a thing when they were growing up, and, suddenly it's become something now, and they don't know how to deal with it.* [YP10]

In summary, generational differences were a central social factor that influenced the use and application of DMH tools.

Stigma and Culturally Based Discrimination

Challenges with mental health stigma were discussed in both phases, with participants explaining that different cultural beliefs informed alternative explanations for poor mental health. Moreover, concerns were expressed that assigning a mental health diagnosis to a young person could lead to further marginalization because it might trigger defensive barriers in community members and contribute to increased ostracization. These experiences were centered on both internalized and externalized mental health stigma from family, friends, and extended cultural communities (P6, P3, P2, YP7, and YP3).

When discussing a potential mental health diagnosis for a child or young person, a parent stated as follows:

> *It's denial first, thinking that nothing is wrong with your child...automatically you think, my child is fine, there's nothing wrong...So the acceptance [of poor mental health] is going to be very difficult.* [P2]

For a young person with culturally diverse parents, the experience of mental ill-health was particularly challenging:

> *When my parents found out that I had some mental health issues...I noticed changes in their behaviors and in terms of my parents and carers being from an ethnic environment, they're very judgmental. I just feel like my parents have zero understanding on mental health and mental illness so they wouldn't take any of that as a form of "I need help." They'll take it as I'm being ungrateful.* [YP7]

A parent described how "mental illness ignites defensive barriers within people" (P6), suggestive of an internalized resistance that may impact help seeking in a community. A young person stated as follows:

> *It might also depend on the person and if they have internalized stigma. I think if an app has some sort of measure that can account for that [internalized stigma]. And that can frame the message depending on that, it would be really nice. So, even in ethnic communities, even if somebody is seeking help, for example. Learning that you're depressed can be quite burdensome on your own mental health. The diagnosis might actually worsen your situation. Because the view of depressed people within your culture might always be these helpless people who cannot do anything basically.* [YP1]

Regarding the diagnostic potential of DMH tools, parents were cautious about making their children "feel like they're different" (P8). A parent described how the diagnosis could be enduring and punitive:

> *You're assuming the parent can put a diagnosis on a condition and that's going to stick somehow. Because you're sort of leading them down a particular path. I'm a great believer in diagnoses, but a diagnosis can be a sentence. Rather than a word, you know.* [P7]

There were concerns that a diagnosis can result in "lifelong stigma for a child or young person" (P7). A parent put it as follows:

> *You know what, suddenly my kid gets this thing as a mental health patients, that's the end of their life. For the rest of their life they'll be on medication or for the rest of their life they'll be on this. They're branded like that.* [P2]

There was a perception among some parents that they would "lose face" and be stigmatized in the eyes of their community if they or their child received a mental health diagnosis:

> *When we talk about the ethnic communities, for them, their saving face becomes a very big issue. And you know, none of them want to lose face in the community in public and what have you. If somebody else doesn't even use their name then, for them, that stigma sort of stays, it's always going to take me years to rebuild that trust again.* [P6]

Participants in both phases raised concerns about culturally based discrimination when seeking mental health support, including an inequity in the availability of psychological assessments, screenings, and support. Psychological assessments and mental health screenings were identified as a form of systemic discrimination by the young participants, who noted how most tools are only available in English, with questions reflecting Western understandings of mental health. This often results in people performing poorly due to an inability to understand the questions and being misdiagnosed. A young person described her lived experience of working in a Turkish-speaking psychologist's office in Australia and raised her concern about the limited number of bilingual psychologists:

> *They were one of the few Turkish-speaking psychologists we had, four or five months of waitlists. So, it was cheaper than private practitioners. Only 20% of the fee would be paid out of pocket. And it*

XSL•FO
RenderX

> *was impossible to get through. Even if you have, um, some sort of government supplement like Medicare or some sort of private insurance, it was just impossible to make an appointment with her. And the same thing was the case for our Bosnian psychologist and our other psychologist as well.* [YP1]

Difficulties accessing mental health support were raised across both groups, with participants discussing the challenges, such as visa status, that migrants face when accessing mental health services, which can prevent them from receiving the same standard of support as other residents. This was particularly important for young international students waiting for permanent residency visas:

> *But because they're still waiting for that process to get their PR [permanent residency visa]. They're [asylum seekers] still in our schools. They go to private schools. They're living a good life. But because they're asylum seekers. We're international students. We don't have access to Medicare.* [YP2]

Discrimination from family members, friends, ethnic communities, and third-party systems upon receiving a mental health diagnosis was a concern raised by both groups (YP5, YP6, P6, and YP1). Both groups identified concerns about future discrimination from third parties who may use their mental health diagnoses to deny visa applications, steal their identities, or charge them higher insurance premiums (P1, P3, P5, P6, YP5, and YP6). In summary, stigma and diagnostic barriers, culturally based discrimination, and third-party access that may impact visa status and migration were central concerns.

Discussion

Principal Findings

The aim of the project was to explore the views of culturally diverse parents and young people on the opportunities and barriers to engagement with a web-based DMH screening tool. Through this work, we have explored the benefits, burdens, and trade-offs of using DMH tools from the perspectives of culturally diverse end users. On the basis of these findings, we provide our provisional set of reflections on the future of culturally sensitive DMH tools. Consideration of parental influence based on their country of origin, culture, and level of mental health literacy and how that is paired with raising a child in Australia is complex. Young people were perceived to have a higher level of general mental health and digital literacy, with greater awareness of their mood and self-care routines, as well as an understanding of healthy diet and lifestyle routines. They were also more willing to share information about their mental health with others. These generational differences highlight the importance of accounting for perceived barriers such as the influence of culture on mental health support, culturally based discrimination in seeking mental health support, and how a diagnostic label may impact the likelihood of engaging in help seeking.

Leveraging Family Connectedness

We found that our participants' understanding of their mental health was centered on their connection to family and parent-child relationships. Our findings suggest that family ties and family connectedness may influence the uptake of mental health treatments or interventions or whether and with whom DMH tool recommendations are shared. For culturally diverse youth, families provide an immediate social context (eg, as YP4 wrote in the emotional walk-through booklet: "The 'Mental health' term itself was still a taboo in India. We give importance to family connection and bonding [as a well-being strategy] but always have learnt to support and be there for one another"). Previous research found that the pace of cultural adaptation differs between parents and young people who resettle in Australia, with young people adapting faster but finding it hard to become independent from their families [16,88].

Family connectedness has been linked with lower odds of significant stress and despair for youth during acculturation and may protect them from other risk factors. In fact, the quality of family relationships can have a positive effect on well-being [89-91]. More research identifying positive family processes (eg, closeness with both mother and father) that build emotional well-being in culturally diverse young people is needed [92]. We found that familial influence informed young people's understanding of mental health, which, according to some parents, could be explained and managed through religious practices or alternative methods. This is an important finding because it suggests that future iterations of DMH tools should emphasize the inclusion of culturally sensitive parental support and psychoeducation on mental health problems. It also highlights the importance of engaging community leaders, elders, religious leaders, or mental health advocates from different cultures and communities to gather their insights on and explanations of well-being and mental health to ensure that the technologies are culturally safe. We suggest that culturally appropriate and culturally informed psychoeducation for families is needed to encourage community buy-in, ultimately leading to more effective DMH tools for culturally diverse populations. This education would have to be offered thoughtfully, paired with data governance education to promote digital literacy and awareness of the insufficiently regulated data industry and unregulated practices that exist currently.

Culturally Based Discrimination: Stigma, Loss of Face, and Collectivist Approaches to Mental Health

Barriers such as stigma, shame, and perceived judgment from community members were regularly raised. Many parents voiced concern about losing face in their community. Collectivist cultures that share a collective identity, emotional dependence, and shared duties and obligations operate under a "we" consciousness. These cultures are common outside Western societies that prioritize individualism [93]. The difference between individualism and collectivism ought to be considered when creating DMH tools, building an awareness that psychological support may be shared within a broad family network and that the "burden of results" may not be carried by the individual alone in collectivist communities. People from many collectivist cultures may struggle to understand the typical individualistic approach to treatment because they expect to receive care within the context of their family [94].

XSL•FO
RenderX

Some people may also have deeply held negative beliefs or attitudes toward those experiencing mental health challenges, making it important to design mental health services that incorporate informal support avenues (eg, friends and family) on which individuals may rely for help [95,96]. Loss of face is an important cultural factor in the Asian context and has been found to be a significant predictor of self-stigma and public stigma that impacts attitudes toward help seeking [97-99], especially given that community belonging plays a large role in migrant mental health [12].

Culturally diverse communities may minimize the reporting of psychological symptoms or may be resistant to sharing personal health information because of mistrust, perceived racism, or a sense that public mental health services do not accommodate or respect their cultural beliefs [100,101]. Culturally sensitive psychoeducation within communities is needed to combat stigma. To achieve this, we suggest engaging with community and religious leaders as well as mental health advocates with lived experience of mental health challenges, given their influential reach among diverse end users, to promote community-informed education, self-determination, and self-advocacy. DMH tool designs should offer transparent data collection policies, with tiered consent, to ensure that end users feel comfortable sharing their data, and this should be paired with the inclusion of digital navigators, who are members of health care teams dedicated to help end users [102].

Young people in our study voiced concern about the lack of culturally and linguistically diverse clinicians and assessment tools, noting that information was mostly communicated in English using a Western framework for assessing mental health. Research has found that diagnostic assessments tend to not be sensitive to racial and ethnic minority populations due to their exclusion from mental health research [103,104]. Furthermore, culturally diverse community members are less likely to have satisfactory access to mental health support and are less likely to receive a diagnosis for a mental health condition [105,106]. If DMH tools are to be relevant, accessible, and effective for culturally diverse populations, future designs and implementations must be available in languages other than English and incorporate cultural approaches to mental health. The very term *mental health* is a Western concept, and Western cultural traditions and understandings have informed much of the theory, practice, and understandings of mental health, including within psychology and psychiatry, with a central focus on individual pathology instead of sociocultural contexts and determinants [107,108]. Furthermore, how patients from culturally diverse backgrounds express their symptoms may vary, making it challenging to accurately diagnose or treat their conditions [104]. Individualized models of care may not be appropriate for those who are accustomed to community- or family-focused models of care [108]. The British Psychology Society proposed the power threat meaning framework as a nonmedicalized and nondiagnostic approach that instead describes how coping and survival mechanisms are adapted based on lived experience, previous threats, and social context, accounting for cultural differences in the experience and expression of distress, with less emphasis placed on Western views [109].

We ought to consider how to design culturally sensitive DMH tools that are informed by attitudes from diverse communities and encourage self-determination and cultural context within a well-being framework. One suggestion is for DMH tool developers to offer enhanced psychoeducation that is culturally safe and fosters self-determination, with tailored psychological assessments and resources that account for language variations and barriers for users coming from collectivist cultures whose conceptions of mental health vary from the Western medicalized understanding.

Medicalization by Design

Concerns were raised about making a child or young person feel different. Participants worried that “a diagnosis may worsen your situation,” suggesting that a diagnostic label or the detection of a mental health problem, as well as the diagnostic process itself, may further marginalize diverse communities through the medicalization of culturally appropriate cognitions or behaviors. Medicalization pathologizes behaviors according to a Western psychiatric framework, putting the responsibility back on the individual to stay healthy without considering other important social factors [110,111]. Online screening tools and mobile apps are being designed to promote well-being and provide psychological support, but they can also work to endorse ongoing surveillance [112] of mood and activity and set expectations about healthy behaviors and cognitions. A shift is needed in how mental health is conceptualized and designed for in a way that accounts for cultural barriers that may limit engagement and usability for diverse end users of DMH tools [109]. Importantly, we need to invest in community-led practices that promote community leadership in the design and innovation of DMH tools [82] to avoid built-in discrimination that reproduces inequities due to normative or Western-oriented assumptions about mental health [113]. We suggest that when designing DMH tool outputs, such as the communication of health information, recommendations for services and interventions, and referral pathways, the reported symptoms entered by the end user are phrased in a way that avoids pathologization and diagnosis. Currently, DMH platforms tend to recommend resources on anxiety, depression and suicidal ideation, and eating disorders [39,114]; however, we believe that it is imperative that symptoms are spoken about in clusters, rather than specifying specific diagnostic criteria that may then pigeonhole or “label” an end user without appropriate access to clinical care.

Attitudes Toward Data Collection Are a Two-Way Street

When using DMH tools, participants felt that there was less concern about privacy and data sharing when the data collected were more generalized. This is consistent with a recent study on diverse communities using mindLAMP, a DMH platform, where participants wanted their DMH apps to pull data from their current health care records to enhance app personalization [115]. Participants acknowledged that innovations and interventions require consent for collecting substantial amounts of data to tailor services or for platforms to “algorithmize my personal experiences”; however, research has found that DMH tools are often not culturally tailored or responsive due to

XSL•FO
RenderX

culturally diverse or racial and ethnic minority populations often not being considered in their development and evaluation [116,117]. Young people from culturally diverse communities recognized that they would need to provide access to personal digital health data to realize the benefits promoted by DMH tools. Critics have argued that young people may not comprehend the longevity and potential harms of a digital footprint and that thoughtful education and support around this is important for their future privacy [118]. While research has demonstrated an unwillingness from end users to share their sensitive health data with commercial organizations [23,119-121], there was a sense in our findings that participants expected an "algorithmized experience," which would require health data to be treated as open data [122]. Due to the sensitive nature of mental health data, further education on data governance and the potential reuse of big data is recommended for young people, given the nature of cross-sectoral data sharing. One approach may be incorporating speculative design approaches, such as the one suggested in the study by McNaney et al [23], to engage young people in discussions around their digital futures, the potential harms of data sharing, and the misuse of their data.

In both phases, the participants identified concerns about data breaches, including potential identity theft and the impact it could have on visa and migration status. These concerns are reflected in the literature, with 1 study finding that nearly half of the DMH apps surveyed did not have a privacy policy, although it is known that health care apps often share data points (eg, age, contact information, and other user data) with multiple third parties for commercial purposes [123,124]. Efforts have been made to establish ethical standards for digital data gathered from DMH tools, including accounting for data breaches, which advise developers to account for hidden assumptions and unintended consequences [125]. Regulations such as the General Data Protection Regulation in Europe and similar privacy acts being developed in Brazil, Chile, and Canada aim to protect data privacy. However, even the General Data Protection Regulation has limitations, particularly in the context of emerging generative artificial intelligence innovations.

Reflections and Limitations

This study sought to engage with culturally diverse representatives in relation to cultural background and lived experience of mental health challenges. To achieve this, we approached an organization focused on multicultural mental health that advertised the study, recruited participants, and supplied bicultural workers for our study. While we were able to have meaningful discussions in our workshops, the participants were all affiliated with the organization, meaning that the sample was not necessarily representative of a truly culturally diverse population, given that each participant was already mental health literate, able to communicate in English, and held a preconceived understanding of mental health, rather than being a layperson. The addition of an Anglo-Australian participant was also a limitation. Future research needs to engage with a broader range of culturally diverse participants, including those with less digital and mental health literacy and those who may be in a more contemplative stage of their mental health journey and possibly unaware of support services. Future research might consider recruiting through youth organizations or well-being counselors who may have access to a more culturally diverse range of participants who reflect a more culturally diverse picture of mental health literacy and help seeking. Future research should also engage in participatory action research methods (eg, co-design and coproduction) that allow end users to develop RQs and study designs. However, this approach can present additional challenges to building social capital and gaining trust to engage with culturally diverse end users in a meaningful way, and this needs to be factored into study timelines. Our study was bound to an innovation timeline, making the recruitment of a truly diverse sample impossible. We were conscious that we did not invite the participants to review the data analysis or final manuscript, which could have reduced the power imbalances further by allowing the participants to join as coresearchers in the project from start to finish. Future iterations would benefit from inviting culturally diverse participants on board as coresearchers, not just as participants. We believe that it is important to embed the voices of diverse community members within a research project throughout its lifespan.

Most of our participants were from South-East Asia. While this is an accurate reflection of the majority of culturally diverse Australians [1], it may not capture the views of ethnic and racial minority cultures within Australia. We hoped to avoid essentializing all experiences as one by including quotes from individuals because we believe that culturally diverse communities do not share a single common experience due to varying sociopolitical differences such as age, culture, and citizenship. The median age of the young participants was relatively high, with one aged 16 years and one aged 18 years, while the remaining participants were aged 20 to 22 years. As such, our findings may not reflect the views of younger adolescents. Future endeavors should aim to apply the insights gained from this research in the development and pilot testing of DMH interventions and applications by evaluating their effectiveness and refining them based on the outcomes.

Conclusions

Inclusive design considerations for the future development of DMH tools that account for culturally based discrimination, are culturally safe, consider family and cultural influence on mental health support, and are thoughtful in how mental health problems are detected and communicated to end users would improve engagement in DMH tools and help seeking. We recommend encouraging culturally sensitive psychoeducation, thoughtful nonpathologizing language that avoids providing a specific diagnosis, and the inclusive involvement of community leaders and mental health advocates in the future design of DMH tools to ensure that they are designed to meet the needs of culturally diverse end users.

XSL•FO
RenderX

Acknowledgments

This research was supported by Growing Minds Australia: A National Trials Strategy to Transform Child and Youth Mental Health Services, and the Growing Minds Australia Clinical Trials Network in Child and Youth Mental Health" (Medical Research Future Fund: MRF2006438).

Authors' Contributions

The study was designed by IB, AC, RM, and JCN. IB prepared the first draft of the manuscript. All authors contributed to and approved the final manuscript.

Conflicts of Interest

This study was funded by the Growing Minds Australia Clinical Trials Network. JCN, LAT, and PO are listed as principal investigators on this grant, and the positions of JCN, LAT, and TC are supported by this funding.

Multimedia Appendix 1
Digital mental health co-design workshop schedule.
[DOCX File , 23 KB - pediatrics_v8i1e65163_app1.docx]

References

1. Cultural diversity of Australia. Australian Bureau of Statistics. 20022 Sep 20. URL: https://www.abs.gov.au/articles/cultural-diversity-australia [accessed 2024-04-29]
2. Chesney E, Goodwin GM, Fazel S. Risks of all-cause and suicide mortality in mental disorders: a meta-review. World Psychiatry 2014 Jun 02;13(2):153-160 [FREE Full text] [doi: 10.1002/wps.20128] [Medline: 24890068]
3. Fusar-Poli P, Correll CU, Arango C, Berk M, Patel V, Ioannidis JP. Preventive psychiatry: a blueprint for improving the mental health of young people. World Psychiatry 2021 Jun 18;20(2):200-221 [FREE Full text] [doi: 10.1002/wps.20869] [Medline: 34002494]
4. Racine N, McArthur BA, Cooke JE, Eirich R, Zhu J, Madigan S. Global prevalence of depressive and anxiety symptoms in children and adolescents during COVID-19: a meta-analysis. JAMA Pediatr 2021 Nov 01;175(11):1142-1150 [FREE Full text] [doi: 10.1001/jamapediatrics.2021.2482] [Medline: 34369987]
5. Upton E, Clare PJ, Aiken A, Boland VC, Torres CD, Bruno R, et al. Changes in mental health and help-seeking among young Australian adults during the COVID-19 pandemic: a prospective cohort study. Psychol Med 2023 Feb 10;53(3):687-695 [FREE Full text] [doi: 10.1017/S0033291721001963] [Medline: 33966686]
6. Brown A, Rice SM, Rickwood DJ, Parker AG. Systematic review of barriers and facilitators to accessing and engaging with mental health care among at-risk young people. Asia Pac Psychiatry 2016 Mar 03;8(1):3-22. [doi: 10.1111/appy.12199] [Medline: 26238088]
7. Cultural diversity definition 2020. Diversity Council Australia. URL: https://www.dca.org.au/resources/cultural-diversity-religion/culture-and-religion-overview [accessed 2024-04-29]
8. Elias A, Ben J, Mansouri F, Paradies Y. Racism and nationalism during and beyond the COVID-19 pandemic. In: Solomos J, editor. Race and Ethnicity in Pandemic Times. New York, NY: Routledge; 2022:65-75.
9. Paradies Y. Colonisation, racism and indigenous health. J Pop Research 2016 Feb 18;33(1):83-96 [FREE Full text] [doi: 10.1007/S12546-016-9159-Y]
10. Straiton M, Grant JF, Winefield HR, Taylor A. Mental health in immigrant men and women in Australia: the North West Adelaide Health Study. BMC Public Health 2014 Oct 28;14(1):1111 [FREE Full text] [doi: 10.1186/1471-2458-14-1111] [Medline: 25349060]
11. Jatrana S, Richardson K, Pasupuleti SS. Investigating the dynamics of migration and health in Australia: a longitudinal study. Eur J Popul 2018 Oct 21;34(4):519-565 [FREE Full text] [doi: 10.1007/s10680-017-9439-z] [Medline: 30976253]
12. Minas H, Kakuma R, Too LS, Vayani H, Orapeleng S, Prasad-Ildes R, et al. Mental health research and evaluation in multicultural Australia: developing a culture of inclusion. Int J Ment Health Syst 2013 Oct 07;7(1):23 [FREE Full text] [doi: 10.1186/1752-4458-7-23] [Medline: 24093216]
13. Rickwood DJ, Deane FP, Wilson CJ. When and how do young people seek professional help for mental health problems? Med J Aust 2007 Oct 01;187(S7):S35-S39. [doi: 10.5694/j.1326-5377.2007.tb01334.x] [Medline: 17908023]
14. Westerman T. Engaging Australian aboriginal youth in mental health services. Aust Psychol 2010 Sep 02;45(3):212-222. [doi: 10.1080/00050060903451790]
15. Wohler Y, Dantas JA. Barriers accessing mental health services among culturally and linguistically diverse (CALD) immigrant women in Australia: policy implications. J Immigr Minor Health 2017 Jun;19(3):697-701. [doi: 10.1007/s10903-016-0402-6] [Medline: 27002625]

XSL•FO
RenderX

16. Radhamony R, Cross WM, Townsin L, Banik B. Perspectives of culturally and linguistically diverse (CALD) community members regarding mental health services: a qualitative analysis. J Psychiatr Ment Health Nurs 2023 Aug 22;30(4):850-864. [doi: 10.1111/jpm.12919] [Medline: 36947100]
17. Soubutts E, Shrestha P, Davidson B, Qu C, Mindel C, Sefi A. Challenges and opportunities for the design of inclusive digital mental health tools: understanding culturally diverse young people's experiences. In: Proceedings of the 2024 CHI Conference on Human Factors in Computing Systems. 2024 Presented at: CHI '24; May 11-16, 2024; Honolulu, HI p. 1-16 URL: https://dl.acm.org/doi/10.1145/3613904.3642641 [doi: 10.1145/3613904.3642641]
18. Small R, Lumley J, Yelland J. Cross-cultural experiences of maternal depression: associations and contributing factors for Vietnamese, Turkish and Filipino immigrant women in Victoria, Australia. Ethn Health 2003 Aug;8(3):189-206. [doi: 10.1080/1355785032000136416] [Medline: 14577995]
19. Silva AL, Dawson MT. The impact of international migration on the health of brazilian women living in Australia. Texto Contexto Enferm 2004 Sep;13(3):339-350. [doi: 10.1590/S0104-07072004000300002]
20. May S, Rapee RM, Coello M, Momartin S, Aroche J. Mental health literacy among refugee communities: differences between the Australian lay public and the Iraqi and Sudanese refugee communities. Soc Psychiatry Psychiatr Epidemiol 2014 May 19;49(5):757-769. [doi: 10.1007/s00127-013-0793-9] [Medline: 24248469]
21. de Anstiss H, Ziaian T. Mental health help-seeking and refugee adolescents: qualitative findings from a mixed-methods investigation. Aust Psychol 2009 Nov 05;45(1):29-37. [doi: 10.1080/00050060903262387]
22. Chan JK, Farrer LM, Gulliver A, Bennett K, Griffiths KM. University students' views on the perceived benefits and drawbacks of seeking help for mental health problems on the internet: a qualitative study. JMIR Hum Factors 2016 Jan 19;3(1):e3 [FREE Full text] [doi: 10.2196/humanfactors.4765] [Medline: 27026140]
23. McNaney R, Morgan C, Kulkarni P, Vega J, Heidarivincheh F, McConville R, et al. Exploring perceptions of cross-sectoral data sharing with people with Parkinson's. In: Proceedings of the 2022 CHI Conference on Human Factors in Computing Systems. 2022 Presented at: CHI '22; April 29-May 5, 2022; New Orleans, LA p. 1-14 URL: https://dl.acm.org/doi/10.1145/3491102.3501984 [doi: 10.1145/3491102.3501984]
24. Cooper LA, Roter DL, Carson KA, Beach MC, Sabin JA, Greenwald AG, et al. The associations of clinicians' implicit attitudes about race with medical visit communication and patient ratings of interpersonal care. Am J Public Health 2012 May;102(5):979-987. [doi: 10.2105/AJPH.2011.300558] [Medline: 22420787]
25. Mental health and Australia's culturally and linguistically diverse communities a submission to the senate standing committee on community affairs. Federation of Ethnic Communities' Councils of Australia (FECCA). 2011. URL: https://www.pc.gov.au/__data/assets/pdf_file/0015/242430/sub524-mental-health.pdf [accessed 2024-04-29]
26. Moss K, Wyder M, Braddock V, Arroyo D, Kisely S. Compulsory community treatment and ethnicity: findings from a culturally and linguistically diverse area of Queensland. Int J Law Psychiatry 2019 Jan;62:154-159. [doi: 10.1016/j.ijlp.2018.09.007] [Medline: 30274852]
27. Insel TR. Digital phenotyping: a global tool for psychiatry. World Psychiatry 2018 Oct 07;17(3):276-277 [FREE Full text] [doi: 10.1002/wps.20550] [Medline: 30192103]
28. Linardon J, Fuller-Tyszkiewicz M. Attrition and adherence in smartphone-delivered interventions for mental health problems: a systematic and meta-analytic review. J Consult Clin Psychol 2020 Jan;88(1):1-13. [doi: 10.1037/ccp0000459] [Medline: 31697093]
29. Lewis S, Ainsworth J, Sanders C, Stockton-Powdrell C, Machin M, Whelan P, et al. Smartphone-enhanced symptom management in psychosis: open, randomized controlled trial. J Med Internet Res 2020 Aug 13;22(8):e17019 [FREE Full text] [doi: 10.2196/17019] [Medline: 32788150]
30. Hemmings NR, Kawadler JM, Whatmough R, Ponzo S, Rossi A, Morelli D, et al. Development and feasibility of a digital acceptance and commitment therapy-based intervention for generalized anxiety disorder: pilot acceptability study. JMIR Form Res 2021 Feb 09;5(2):e21737 [FREE Full text] [doi: 10.2196/21737] [Medline: 33560232]
31. Wilhelm S, Bernstein EE, Bentley KH, Snorrason I, Hoeppner SS, Klare D, et al. Feasibility, acceptability, and preliminary efficacy of a smartphone app-led cognitive behavioral therapy for depression under therapist supervision: open trial. JMIR Ment Health 2024 Apr 09;11:e53998 [FREE Full text] [doi: 10.2196/53998] [Medline: 38592771]
32. van der Meulen H, McCashin D, O'Reilly G, Coyle D. Using computer games to support mental health interventions: naturalistic deployment study. JMIR Ment Health 2019 May 09;6(5):e12430 [FREE Full text] [doi: 10.2196/12430] [Medline: 31094346]
33. Honary M, Fisher NR, McNaney R, Lobban F. A web-based intervention for relatives of people experiencing psychosis or bipolar disorder: design study using a user-centered approach. JMIR Ment Health 2018 Dec 07;5(4):e11473 [FREE Full text] [doi: 10.2196/11473] [Medline: 30530457]
34. Robinson T, Condell J, Ramsey E, Leavey G. Self-management of subclinical common mental health disorders (anxiety, depression and sleep disorders) using wearable devices. Int J Environ Res Public Health 2023 Feb 01;20(3):2636 [FREE Full text] [doi: 10.3390/ijerph20032636] [Medline: 36768002]
35. Guillodo E, Lemey C, Simonnet M, Walter M, Baca-García E, Masetti V, HUGOPSY Network, et al. Clinical applications of mobile health wearable-based sleep monitoring: systematic review. JMIR Mhealth Uhealth 2020 Apr 01;8(4):e10733 [FREE Full text] [doi: 10.2196/10733] [Medline: 32234707]

XSL•FO
RenderX

36. Fu Z, Burger H, Arjadi R, Bockting CLH. Effectiveness of digital psychological interventions for mental health problems in low-income and middle-income countries: a systematic review and meta-analysis. Lancet Psychiatry 2020 Oct;7(10):851-864. [doi: 10.1016/s2215-0366(20)30256-x]
37. Jagayat JK, Kumar A, Shao Y, Pannu A, Patel C, Shirazi A, et al. Incorporating a stepped care approach into internet-based cognitive behavioral therapy for depression: randomized controlled trial. JMIR Ment Health 2024 Feb 09;11:e51704 [FREE Full text] [doi: 10.2196/51704] [Medline: 38173167]
38. Kahl BL, Miller HM, Cairns K, Giniunas H, Nicholas M. Evaluation of ReachOut.com, an unstructured digital youth mental health intervention: prospective cohort study. JMIR Ment Health 2020 Oct 15;7(10):e21280 [FREE Full text] [doi: 10.2196/21280] [Medline: 33055066]
39. Jacobson NC, Yom-Tov E, Lekkas D, Heinz M, Liu L, Barr PJ. Impact of online mental health screening tools on help-seeking, care receipt, and suicidal ideation and suicidal intent: evidence from internet search behavior in a large U.S. cohort. J Psychiatr Res 2022 Jan;145:276-283 [FREE Full text] [doi: 10.1016/j.jpsychires.2020.11.010] [Medline: 33199054]
40. Seegan PL, Miller MJ, Heliste JL, Fathi L, McGuire JF. Efficacy of stand-alone digital mental health applications for anxiety and depression: a meta-analysis of randomized controlled trials. J Psychiatr Res 2023 Aug;164:171-183. [doi: 10.1016/j.jpsychires.2023.06.019] [Medline: 37352813]
41. Alvarez-Jimenez M, Rice S, D'Alfonso S, Leicester S, Bendall S, Pryor I, et al. A novel multimodal digital service (moderated online social therapy+) for help-seeking young people experiencing mental ill-health: pilot evaluation within a national youth e-mental health service. J Med Internet Res 2020 Aug 13;22(8):e17155 [FREE Full text] [doi: 10.2196/17155] [Medline: 32788151]
42. Liu H, Peng H, Song X, Xu C, Zhang M. Using AI chatbots to provide self-help depression interventions for university students: a randomized trial of effectiveness. Internet Interv 2022 Mar;27:100495 [FREE Full text] [doi: 10.1016/j.invent.2022.100495] [Medline: 35059305]
43. Bond RR, Mulvenna MD, Potts C, O'Neill S, Ennis E, Torous J. Digital transformation of mental health services. Npj Ment Health Res 2023 Aug 22;2(1):13 [FREE Full text] [doi: 10.1038/s44184-023-00033-y] [Medline: 38609479]
44. Bell IH, Nicholas J, Alvarez-Jimenez M, Thompson A, Valmaggia L. Virtual reality as a clinical tool in mental health research and practice . Dialogues Clin Neurosci 2020 Jun;22(2):169-177 [FREE Full text] [doi: 10.31887/DCNS.2020.22.2/lvalmaggia] [Medline: 32699517]
45. Horgan A, Sweeney J. Young students' use of the Internet for mental health information and support. J Psychiatr Ment Health Nurs 2010 Mar;17(2):117-123. [doi: 10.1111/j.1365-2850.2009.01497.x] [Medline: 20465756]
46. Tully LA, Piotrowska PJ, Collins DA, Mairet KS, Black N, Kimonis ER, et al. Optimising child outcomes from parenting interventions: fathers' experiences, preferences and barriers to participation. BMC Public Health 2017 Jun 07;17(1):550 [FREE Full text] [doi: 10.1186/s12889-017-4426-1] [Medline: 28592244]
47. Torous J, Haim A. Dichotomies in the development and implementation of digital mental health tools. Psychiatr Serv 2018 Dec 01;69(12):1204-1206 [FREE Full text] [doi: 10.1176/appi.ps.201800193] [Medline: 30256182]
48. Mulvenna MD, Bond R, Delaney J, Dawoodbhoy FM, Boger J, Potts C, et al. Ethical issues in democratizing digital phenotypes and machine learning in the next generation of digital health technologies. Philos Technol 2021 Mar 21;34(4):1945-1960 [FREE Full text] [doi: 10.1007/s13347-021-00445-8] [Medline: 33777664]
49. Shrestha P, Haghighi PD, Sharp G, Xie J, McNaney R. One size (doesn't) fit all: exploring design considerations for digital body dissatisfaction interventions with underrepresented populations. In: Proceedings of the 2024 ACM Designing Interactive Systems Conference. 2024 Presented at: DIS '24; July 1-5, 2024; Copenhagen, Denmark p. 3534-3550 URL: https://doi.org/10.1145/3643834.3661539 [doi: 10.1145/3643834.3661539]
50. Ramos G, Ponting C, Labao JP, Sobowale K. Considerations of diversity, equity, and inclusion in mental health apps: a scoping review of evaluation frameworks. Behav Res Ther 2021 Dec;147:103990 [FREE Full text] [doi: 10.1016/j.brat.2021.103990] [Medline: 34715396]
51. Ramos G, Chavira DA. Use of technology to provide mental health care for racial and ethnic minorities: evidence, promise, and challenges. Cogn Behav Pract 2022 Feb;29(1):15-40. [doi: 10.1016/j.cbpra.2019.10.004]
52. Martínez-Miranda J, López-Flores F, Palacios-Isaac A, Jiménez L, Medina L, Moreno-Robles R, et al. Implementation of a health information system to support the screening and surveillance of suicidal behaviours. In: Proceedings of the 4th International Conference on Medical and Health Informatics. 2020 Presented at: ICMHI '20; August 14-16, 2020; Kamakura City, Japan p. 136-144 URL: https://dl.acm.org/doi/abs/10.1145/3418094.3418108 [doi: 10.1145/3418094.3418108]
53. Webb M, Sanci L, Kauer S, Wadley G. Designing a health screening tool to help young people communicate with their general practitioner. In: Proceedings of the Annual Meeting of the Australian Special Interest Group for Computer Human Interaction. 2015 Presented at: OzCHI '15; December 7-10, 2015; Parkville, Australia p. 124-133 URL: https://dl.acm.org/doi/10.1145/2838739.2838756 [doi: 10.1145/2838739.2838756]
54. Kruzan K, Meyerhoff J, Nguyen T, Mohr DC, Reddy M, Kornfield R. "I Wanted to see how bad it was": online self-screening as a critical transition point among young adults with common mental health conditions. Proc SIGCHI Conf Hum Factor Comput Syst 2022 Apr;2022:328 [FREE Full text] [doi: 10.1145/3491102.3501976] [Medline: 35531062]

XSL•FO
RenderX

55. Ellis DM, Draheim AA, Anderson PL. Culturally adapted digital mental health interventions for ethnic/racial minorities: a systematic review and meta-analysis. J Consult Clin Psychol 2022 Oct;90(10):717-733 [FREE Full text] [doi: 10.1037/ccp0000759] [Medline: 36227330]
56. Cassidy L. Online communities of practice to support collaborative mental health practice in rural areas. Issues Ment Health Nurs 2011 Jan 19;32(2):98-107. [doi: 10.3109/01612840.2010.535648] [Medline: 21247275]
57. Jardine J, Earley C, Richards D, Timulak L, Palacios J, Duffy D. The experience of guided online therapy: a longitudinal, qualitative analysis of client feedback in a naturalistic RCT. In: Proceedings of the 2020 CHI Conference on Human Factors in Computing Systems. 2020 Presented at: CHI '20; April 25-30, 2020; Honolulu, HI p. 1-15 URL: https://dl.acm.org/doi/abs/10.1145/3313831.3376254 [doi: 10.1145/3313831.3376254]
58. Mohr DC, Tomasino KN, Lattie EG, Palac HL, Kwasny MJ, Weingardt K, et al. IntelliCare: an eclectic, skills-based app suite for the treatment of depression and anxiety. J Med Internet Res 2017 Jan 05;19(1):e10 [FREE Full text] [doi: 10.2196/jmir.6645] [Medline: 28057609]
59. Kornfield R, Zhang R, Nicholas J, Schueller SM, Cambo SA, Mohr D, et al. "Energy is a finite resource": designing technology to support individuals across fluctuating symptoms of depression. In: Proceedings of the 2020 CHI Conference on Human Factors in Computing Systems. 2020 Presented at: CHI '20; April 25-30, 2020; Honolulu, HI p. 1-17 URL: https://dl.acm.org/doi/10.1145/3313831.3376309 [doi: 10.1145/3313831.3376309]
60. Selkie E, Adkins V, Masters E, Bajpai A, Shumer D. Transgender adolescents' uses of social media for social support. J Adolesc Health 2020 Mar;66(3):275-280. [doi: 10.1016/j.jadohealth.2019.08.011] [Medline: 31690534]
61. Sharma E, De Choudhury M. Mental health support and its relationship to linguistic accommodation in online communities. In: Proceedings of the 2018 CHI Conference on Human Factors in Computing Systems. 2018 Presented at: CHI '18; April 21-26, 2018; Montreal, QC p. 1-13 URL: https://dl.acm.org/doi/10.1145/3173574.3174215 [doi: 10.1145/3173574.3174215]
62. Ospina-Pinillos L, Davenport TA, Ricci CS, Milton AC, Scott EM, Hickie IB. Developing a mental health eClinic to improve access to and quality of mental health care for young people: using participatory design as research methodologies. J Med Internet Res 2018 May 28;20(5):e188 [FREE Full text] [doi: 10.2196/jmir.9716] [Medline: 29807878]
63. LaMonica HM, Davenport TA, Roberts AE, Hickie IB. Understanding technology preferences and requirements for health information technologies designed to improve and maintain the mental health and well-being of older adults: participatory design study. JMIR Aging 2021 Jan 06;4(1):e21461 [FREE Full text] [doi: 10.2196/21461] [Medline: 33404509]
64. Povey J, Sweet M, Nagel T, Lowell A, Shand F, Vigona J, et al. Determining priorities in the aboriginal and islander mental health initiative for youth app second phase participatory design project: qualitative study and narrative literature review. JMIR Form Res 2022 Feb 18;6(2):e28342 [FREE Full text] [doi: 10.2196/28342] [Medline: 35179498]
65. Milton AC, Hambleton A, Dowling M, Roberts AE, Davenport T, Hickie I. Technology-enabled reform in a nontraditional mental health service for eating disorders: participatory design study. J Med Internet Res 2021 Feb 16;23(2):e19532 [FREE Full text] [doi: 10.2196/19532] [Medline: 33591283]
66. What is the framework for innovation? Design Council. 2015. URL: https://tinyurl.com/2zjcfjbv [accessed 2024-04-29]
67. Norman DA, Draper SW. User Centered System Design: New Perspectives on Human-Computer Interaction. Boca Raton, FL: CRC Press; 1986.
68. Oliver K, Kothari A, Mays N. The dark side of coproduction: do the costs outweigh the benefits for health research? Health Res Policy Syst 2019 Mar 28;17(1):33 [FREE Full text] [doi: 10.1186/s12961-019-0432-3] [Medline: 30922339]
69. Neate T, Bourazeri A, Roper A, Stumpf S, Wilson S. Co-created personas: engaging and empowering users with diverse needs within the design process. In: Proceedings of the 2019 CHI Conference on Human Factors in Computing Systems. 2019 Presented at: CHI '19; May 4-9, 2019; Glasgow, UK p. 1-12 URL: https://dl.acm.org/doi/abs/10.1145/3290605.3300880 [doi: 10.1145/3290605.3300880]
70. Sanders EB, Stappers PJ. Probes, toolkits and prototypes: three approaches to making in codesigning. CoDesign 2014 Mar 06;10(1):5-14. [doi: 10.1080/15710882.2014.888183]
71. Co-design of the new national mental health lived experience consumer peak body. Department of Health and Aged Care, Australian Government. URL: https://consultations.health.gov.au/mental-health-access-branch/nationalmentalhealthlivedexperienceconsumerpeak/ [accessed 2024-04-29]
72. Smith W, Wadley G, Daly O, Webb M, Hughson J, Hajek J. Designing an app for pregnancy care for a culturally and linguistically diverse community. In: Proceedings of the 29th Australian Conference on Computer-Human Interaction. 2017 Presented at: OzCHI '17; November 28-December 1, 2017; Brisbane, Australia p. 337-346 URL: https://dl.acm.org/doi/10.1145/3152771.3152807 [doi: 10.1145/3152771.3152807]
73. Lachner F, Nguyen MA, Butz A. Culturally sensitive user interface design: a case study with German and Vietnamese users. In: Proceedings of the Second African Conference for Human Computer Interaction: Thriving Communities. 2018 Presented at: AfriCHI '18; December 3-7, 2018; Windhoek, Namibia p. 1-12 URL: https://dl.acm.org/doi/10.1145/3283458.3283459 [doi: 10.1145/3283458.3283459]
74. Alshehri T, Kirkham R, Dombrowski L, Olivier P. Designing for culturally sensitive cultural change: a case study of designing for the visibility of Saudi women in the digital media. In: Proceedings of the 2022 ACM Designing Interactive Systems Conference. 2022 Presented at: DIS '22; June 13-17, 2022; Virtual Event p. 599-611 URL: https://dl.acm.org/doi/10.1145/3532106.3533512 [doi: 10.1145/3532106.3533512]

XSL•FO
RenderX

75. Stowell E, Lyson MC, Saksono H, Wurth RC, Jimison H, Pavel M, et al. Designing and evaluating mHealth interventions for vulnerable populations: a systematic review. In: Proceedings of the 2018 CHI Conference on Human Factors in Computing Systems. 2018 Presented at: CHI '18; April 21-26, 2018; Montreal, QC p. 1-17 URL: https://dl.acm.org/doi/10.1145/3173574.3173589 [doi: 10.1145/3173574.3173589]
76. O'Brien J, Fossey E, Palmer VJ. A scoping review of the use of co-design methods with culturally and linguistically diverse communities to improve or adapt mental health services. Health Soc Care Community 2021 Jan 20;29(1):1-17. [doi: 10.1111/hsc.13105] [Medline: 32686881]
77. Smith KA, Blease C, Faurholt-Jepsen M, Firth J, Van Daele T, Moreno C, et al. Digital mental health: challenges and next steps. BMJ Ment Health 2023 Feb 17;26(1):e300670 [FREE Full text] [doi: 10.1136/bmjment-2023-300670] [Medline: 37197797]
78. Ahmed S. On Being Included: Racism and Diversity in Institutional Life. Durham, NC: Duke University Press; 2020.
79. Shen FX. Racial injustice and neuroethics: time for action. AJOB Neurosci 2020 Jul 27;11(3):212-216. [doi: 10.1080/21507740.2020.1778133] [Medline: 32716756]
80. Duque E, Fonseca G, Vieira H, Gontijo G, Ishitani L. A systematic literature review on user centered design and participatory design with older people. In: Proceedings of the 18th Brazilian Symposium on Human Factors in Computing Systems. 2019 Presented at: IHC '19; October 22-25, 2019; Vitória Espírito Santo, Brazil p. 1-11 URL: https://dl.acm.org/doi/10.1145/3357155.3358471 [doi: 10.1145/3357155.3358471]
81. Hawes DJ, Dadds MR, Tully LA, Northam JC, Growing Minds Australia Clinical Trials Network. Building a national clinical trials network in child and youth mental health: growing minds Australia. Aust N Z J Psychiatry 2023 Feb;57(2):164-168. [doi: 10.1177/00048674221082525] [Medline: 35253467]
82. Costanza-Chock S. Design Justice: Community-Led Practices to Build the Worlds We Need. Cambridge, MA: MIT Press; 2020.
83. Crenshaw K. Demarginalizing the intersection of race and sex: a black feminist critique of antidiscrimination doctrine, feminist theory, and antiracist politics. In: Bartlett K, editor. Feminist Legal Theory: Readings In Law And Gender. New York, NY: Routledge; 1989.
84. Huda B, Hartomo KD, Nataliani Y, Sembiring I. HCI approach to increasing e-learning using a combination of cognitive walkthrough and user-centered design. In: Proceedings of the 2nd International Conference on Technology Innovation and Its Applications. 2024 Presented at: ICTIIA '24; September 12-13, 2024; Medan, Indonesia p. 1-6 URL: https://ieeexplore.ieee.org/document/10761368 [doi: 10.1109/ictiia61827.2024.10761368]
85. Lyon AR, Coifman J, Cook H, McRee E, Liu FF, Ludwig K, et al. The Cognitive Walkthrough for Implementation Strategies (CWIS): a pragmatic method for assessing implementation strategy usability. Implement Sci Commun 2021 Jul 17;2(1):78 [FREE Full text] [doi: 10.1186/s43058-021-00183-0] [Medline: 34274027]
86. Lewis C, Polson PG, Wharton C, Rieman J. Testing a walkthrough methodology for theory-based design of walk-up-and-use interfaces. In: Proceedings of the 1990 SIGCHI Conference on Human Factors in Computing Systems. 1990 Presented at: CHI '90; April 1-5, 1990; Washington, DC p. 235-242 URL: https://doi.org/10.1145/97243.97279 [doi: 10.1145/97243.97279]
87. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
88. McMichael C, Gifford SM, Correa-Velez I. Negotiating family, navigating resettlement: family connectedness amongst resettled youth with refugee backgrounds living in Melbourne, Australia. J Youth Stud 2010 Aug 25;14(2):179-195. [doi: 10.1080/13676261.2010.506529]
89. Hilario CT, Vo DX, Johnson JL, Saewyc EM. Acculturation, gender, and mental health of Southeast Asian immigrant youth in Canada. J Immigr Minor Health 2014 Dec 28;16(6):1121-1129. [doi: 10.1007/s10903-014-9978-x] [Medline: 24469590]
90. Stuart J, Jose PE. The protective influence of family connectedness, ethnic identity, and ethnic engagement for New Zealand Ma ori adolescents. Dev Psychol 2014 Jun;50(6):1817-1826 [FREE Full text] [doi: 10.1037/a0036386] [Medline: 24708455]
91. Foster CE, Horwitz A, Thomas A, Opperman K, Gipson P, Burnside A, et al. Connectedness to family, school, peers, and community in socially vulnerable adolescents. Child Youth Serv Rev 2017 Oct;81:321-331 [FREE Full text] [doi: 10.1016/j.childyouth.2017.08.011] [Medline: 30202142]
92. Obradović J, Tirado-Strayer N, Leu J. The importance of family and friend relationships for the mental health of Asian immigrant young adults and their nonimmigrant peers. Res Hum Dev 2013 Apr;10(2):163-183. [doi: 10.1080/15427609.2013.786559]
93. Kim U. Individualism and Collectivism: A Psychological, Cultural and Ecological Analysis. New York, NY: NIAS Press; 1995.
94. Lwembe S, Green SA, Chigwende J, Ojwang T, Dennis R. Co-production as an approach to developing stakeholder partnerships to reduce mental health inequalities: an evaluation of a pilot service. Prim Health Care Res Dev 2016 May 2;18(01):14-23. [doi: 10.1017/s1463423616000141]
95. Yaser A, Slewa-Younan S, Smith CA, Olson RE, Guajardo MG, Mond J. Beliefs and knowledge about post-traumatic stress disorder amongst resettled Afghan refugees in Australia. Int J Ment Health Syst 2016 Apr 12;10(1):31 [FREE Full text] [doi: 10.1186/s13033-016-0065-7] [Medline: 27073412]

XSL•FO
RenderX

96. Nickerson A, Byrow Y, Pajak R, McMahon T, Bryant RA, Christensen H, et al. 'Tell Your Story': a randomized controlled trial of an online intervention to reduce mental health stigma and increase help-seeking in refugee men with posttraumatic stress. Psychol Med 2019 Apr 11;50(5):781-792. [doi: 10.1017/s0033291719000606]
97. Goffman E. The presentation of self in everyday life. In: Longhofer W, Winchester D, editors. Social Theory Re-Wired New Connections to Classical and Contemporary Perspectives. New York, NY: Routledge; 2023:450-459.
98. Kim PY, Yon KJ. Stigma, loss of face, and help-seeking attitudes among South Korean college students. Couns Psychol 2019 Aug 31;47(3):331-357. [doi: 10.1177/0011000019872790]
99. Martinez AB, Co M, Lau J, Brown JSL. Filipino help-seeking for mental health problems and associated barriers and facilitators: a systematic review. Soc Psychiatry Psychiatr Epidemiol 2020 Nov 20;55(11):1397-1413 [FREE Full text] [doi: 10.1007/s00127-020-01937-2] [Medline: 32816062]
100. Henderson S, Kendall E. Culturally and linguistically diverse peoples' knowledge of accessibility and utilisation of health services: exploring the need for improvement in health service delivery. Aust J Prim Health 2011;17(2):195-201. [doi: 10.1071/py10065]
101. Colucci E, Minas H, Szwarc J, Guerra C, Paxton G. In or out? Barriers and facilitators to refugee-background young people accessing mental health services. Transcult Psychiatry 2015 Dec 02;52(6):766-790. [doi: 10.1177/1363461515571624] [Medline: 25731986]
102. Wisniewski H, Gorrindo T, Rauseo-Ricupero N, Hilty D, Torous J. The role of digital navigators in promoting clinical care and technology integration into practice. Digit Biomark 2020 Nov 26;4(Suppl 1):119-135 [FREE Full text] [doi: 10.1159/000510144] [Medline: 33442585]
103. Burgess DJ, Ding Y, Hargreaves M, van Ryn M, Phelan S. The association between perceived discrimination and underutilization of needed medical and mental health care in a multi-ethnic community sample. J Health Care Poor Underserved 2008 Aug;19(3):894-911. [doi: 10.1353/hpu.0.0063] [Medline: 18677077]
104. Johnson JL, Cameron MC. Barriers to providing effective mental health services to American Indians. Ment Health Serv Res 2001 Dec;3(4):215-223. [doi: 10.1023/a:1013129131627] [Medline: 11859967]
105. Bhui K, Warfa N, Edonya P, McKenzie K, Bhugra D. Cultural competence in mental health care: a review of model evaluations. BMC Health Serv Res 2007 Jan 31;7(1):15 [FREE Full text] [doi: 10.1186/1472-6963-7-15] [Medline: 17266765]
106. Stewart SM, Simmons A, Habibpour E. Treatment of culturally diverse children and adolescents with depression. J Child Adolesc Psychopharmacol 2012 Feb;22(1):72-79. [doi: 10.1089/cap.2011.0051] [Medline: 22251021]
107. Ahmedani BK. Mental health stigma: society, individuals, and the profession. J Soc Work Values Ethics 2011;8(2):41-416 [FREE Full text] [Medline: 22211117]
108. Tribe R. The mental health needs of refugees and asylum seekers. Ment Health Rev J 2005;10(4):8. [doi: 10.1108/13619322200500033]
109. Johnstone L, Boyle M. The power threat meaning framework: an alternative nondiagnostic conceptual system. J Humanist Psychol 2018 Aug 05. [doi: 10.1177/0022167818793289]
110. Gosselin A. "Clinician knows best"? Injustices in the medicalization of mental illness. Fem Philos Q 2019 Jul 25;5(2):1-5. [doi: 10.5206/fpq/2019.2.7285]
111. Ciolfi Felice M, Søndergaard ML, Balaam M. Resisting the medicalisation of menopause: reclaiming the body through design. In: Proceedings of the 2021 CHI Conference on Human Factors in Computing Systems. 2021 Presented at: CHI '21; May 8-13, 2021; Yokohama, Japan p. 1-16 URL: https://dl.acm.org/doi/10.1145/3411764.3445153 [doi: 10.1145/3411764.3445153]
112. Davies B. 'Personal health surveillance': the use of mHealth in healthcare responsibilisation. Public Health Ethics 2021 Nov;14(3):268-280 [FREE Full text] [doi: 10.1093/phe/phab013] [Medline: 34899983]
113. Benjamin R. Race After Technology: Abolitionist Tools for the New Jim Code. Hoboken, NJ: John Wiley & Sons; 2019.
114. Fitzsimmons-Craft EE, Balantekin KN, Graham AK, Smolar L, Park D, Mysko C, et al. Results of disseminating an online screen for eating disorders across the U.S.: reach, respondent characteristics, and unmet treatment need. Int J Eat Disord 2019 Jun;52(6):721-729 [FREE Full text] [doi: 10.1002/eat.23043] [Medline: 30761560]
115. Rodriguez-Villa E, Naslund J, Keshavan M, Patel V, Torous J. Making mental health more accessible in light of COVID-19: scalable digital health with digital navigators in low and middle-income countries. Asian J Psychiatr 2020 Dec;54:102433. [doi: 10.1016/j.ajp.2020.102433] [Medline: 33271713]
116. Schueller SM, Hunter JF, Figueroa C, Aguilera A. Use of digital mental health for marginalized and underserved populations. Curr Treat Options Psych 2019 Jul 5;6(3):243-255. [doi: 10.1007/s40501-019-00181-z]
117. Narayan S, Mok H, Ho K, Kealy D. "I don't think they're as culturally sensitive": a mixed-method study exploring e-mental health use among culturally diverse populations. J Ment Health 2023 Feb 30;32(1):241-247. [doi: 10.1080/09638237.2022.2091762] [Medline: 35770901]
118. Sussman N, DeJong SM. Ethical considerations for mental health clinicians working with adolescents in the digital age. Curr Psychiatry Rep 2018 Oct 13;20(12):113. [doi: 10.1007/s11920-018-0974-z] [Medline: 30317406]

XSL•FO
RenderX

119. Hill EM, Turner EL, Martin RM, Donovan JL. "Let's get the best quality research we can": public awareness and acceptance of consent to use existing data in health research: a systematic review and qualitative study. BMC Med Res Methodol 2013 Jun 04;13:72 [FREE Full text] [doi: 10.1186/1471-2288-13-72] [Medline: 23734773]
120. Stevenson F, Lloyd N, Harrington L, Wallace P. Use of electronic patient records for research: views of patients and staff in general practice. Fam Pract 2013 Apr 06;30(2):227-232. [doi: 10.1093/fampra/cms069] [Medline: 23132893]
121. Tully MP, Hassan L, Oswald M, Ainsworth J. Commercial use of health data-a public "trial" by citizens' jury. Learn Health Syst 2019 Oct 18;3(4):e10200 [FREE Full text] [doi: 10.1002/lrh2.10200] [Medline: 31641688]
122. Bacon S, Goldacre B. Barriers to working with national health service England's open data. J Med Internet Res 2020 Jan 13;22(1):e15603 [FREE Full text] [doi: 10.2196/15603] [Medline: 31929101]
123. Martinez-Martin N, Insel TR, Dagum P, Greely HT, Cho MK. Data mining for health: staking out the ethical territory of digital phenotyping. NPJ Digit Med 2018 Dec 19;1(1):68 [FREE Full text] [doi: 10.1038/s41746-018-0075-8] [Medline: 31211249]
124. Parker L, Bero L, Gillies D, Raven M, Mintzes B, Jureidini J, et al. Mental health messages in prominent mental health apps. Ann Fam Med 2018 Jul 09;16(4):338-342 [FREE Full text] [doi: 10.1370/afm.2260] [Medline: 29987082]
125. Wykes T, Lipshitz J, Schueller SM. Towards the design of ethical standards related to digital mental health and all its applications. Curr Treat Options Psych 2019 Jul 5;6(3):232-242. [doi: 10.1007/S40501-019-00180-0]

Abbreviations

DMH: digital mental health
GMCI: Growing Minds Check-In
GP: general practitioner
RQ: research question

Edited by A Serlachius; submitted 07.08.24; peer-reviewed by MRUZ Sajib; comments to author 12.02.25; revised version received 04.03.25; accepted 05.03.25; published 22.04.25.

Please cite as:
Butorac I, McNaney R, Seguin JP, Olivier P, Northam JC, Tully LA, Carl T, Carter A
Developing Digital Mental Health Tools With Culturally Diverse Parents and Young People: Qualitative User-Centered Design Study
JMIR Pediatr Parent 2025;8:e65163
URL: https://pediatrics.jmir.org/2025/1/e65163
doi:10.2196/65163
PMID:

©Isobel Butorac, Roisin McNaney, Joshua Paolo Seguin, Patrick Olivier, Jaimie C Northam, Lucy A Tully, Talia Carl, Adrian Carter. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 22.04.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Real-World Symptom Trajectories in Adolescents With and Without Suicide Risk Receiving Care from Rula Health: Retrospective Study

Lara Baez[1], PhD; Kelsey L McAlister[1], PhD; Douglas Newton[2], MD, MPH; Sam Seiniger[2], BA; Allie Woodhouse[2], BS; Jennifer Huberty[1], PhD

[1]Fit Minded Inc, Phoenix, AZ, United States

[2]Rula Health, Santa Clara, CA, United States

Corresponding Author:
Lara Baez, PhD
Fit Minded Inc
2901 E Greenway Road
PO Box 30271
Phoenix, AZ, 85046
United States
Phone: 1 (602) 935 6986
Email: lara@fit-minded.com

Abstract

Background: More than 5 million US adolescents experience mental or behavioral health conditions, yet two-thirds remain untreated, and suicide is the second leading cause of death. These gaps highlight the urgent need for accessible care. Digital mental health interventions that integrate measurement-based care (MBC) and personalized mental health care provider matching offer a promising solution, but few studies have examined their real-world impact among adolescents at elevated suicide risk.

Objective: This study aims to evaluate symptom improvements among adolescents with and without elevated suicide risk receiving care from Rula Health, an MBC-based digital mental health intervention with personalized intake through mental health care provider matching. We aimed to (1) compare baseline demographic and clinical characteristics between adolescents with and without elevated suicide risk at intake and (2) examine depression and anxiety symptom trajectories over the first 12 visits between adolescents with and without elevated suicide risk at intake.

Methods: We conducted a retrospective analysis of real-world clinical data from adolescents who received mental health services through Rula Health. Adolescents were classified as no suicide risk or elevated suicide risk based on the Columbia-Suicide Severity Rating Scale. Depression and anxiety symptoms were assessed using the Patient Health Questionnaire-9 (PHQ-9) and the Generalized Anxiety Disorder-7 (GAD-7) at baseline and before each session. Minimal clinically important differences were defined as a reduction of 5 more points for PHQ-9 and 4 or more points for GAD-7. Symptom changes were examined up to 12 visits. We used *t* tests and chi-square tests to compare baseline characteristics between suicide risk groups and linear mixed-effects models (adjusted for demographics and clinical factors) to assess symptom change and trajectory differences over time.

Results: The sample included 3533 adolescents in the no suicide risk group and 2712 in the elevated suicide risk group. The elevated suicide risk group had a greater proportion of female adolescents, younger adolescents (P<.001), non-Hispanic individuals (P=.002), and those with a primary depressive diagnosis, comorbid conditions, psychiatric involvement, and higher baseline PHQ-9 and GAD-7 scores (P<.001). The no suicide risk group attended more sessions and stayed in care longer (P<.001). Depression and anxiety scores decreased over visits (PHQ-9: B=–0.39; P<.001; GAD-7: B=–0.35; P<.001), with average improvements exceeding minimal clinically important difference thresholds. The elevated suicide risk group's depression and anxiety symptoms decreased at a higher rate than those of the no suicide risk group (PHQ-9: B=–0.32; P<.001; GAD-7: B=–0.18; P<.001).

Conclusions: Adolescents with elevated suicide risk showed greater and faster improvement in depression and anxiety symptoms, reaching similar levels as those without elevated suicide risk by 12 visits. Rula Health's model can support high-risk youth in real-world settings. Future research should assess the impact of MBC and mental health care provider matching, including study designs that isolate their specific effects on outcomes.

XSL•FO
RenderX

(JMIR Pediatr Parent 2025;8:e81444) doi:10.2196/81444

KEYWORDS

digital therapy; telehealth; measurement-based care; suicidality; teenagers; youth

Introduction

Background

Adolescence is a critical developmental period marked by heightened vulnerability to mental health disorders, with more than 5 million adolescents in the United States diagnosed with a mental or behavioral condition, most commonly depression and anxiety [1]. Depression and anxiety symptoms can deeply impact how adolescents function in their daily lives, affecting their relationships, academic performance, and overall well-being [2,3]. Even more concerning is the fact that these symptoms are strongly linked to suicide, the second leading cause of death among adolescents, with rates rising to 62% from 2007 to 2021, even as they plateau or decline in other populations in the United States [4-6]. One in 5 high school students has seriously considered suicide, with more than 1 in 10 reporting that they attempted suicide [7]. Rates of hospitalization for suicide-related behaviors in adolescents have sharply increased, placing added strain on families, school systems, and the broader health care system [8,9]. Despite the urgency of these trends, 61% of adolescents with mental health needs report difficulty accessing treatment due to barriers, such as mental health care provider shortages, long waitlists, stigma, and cost [1]. These realities underscore the urgent need for timely, accessible, and effective mental health interventions.

Digital mental health interventions (DMHIs), including virtual therapy and psychiatric services, have emerged as a scalable and flexible solution to address the growing demand for adolescent mental health care [10]. By offering therapy and psychiatric services through virtual platforms, DMHIs can help overcome many of the barriers that limit access to traditional in-person care, such as geographic limitations, mental health care provider shortages, long wait times, and stigma [11], though access may remain uneven due to disparities in broadband connectivity, device availability, and digital literacy [12,13]. These platforms are particularly well-suited to adolescents, who are often comfortable with technology and may prefer the privacy and convenience of engaging in care from home [14,15]. In addition to expanding access, DMHIs offer the potential to deliver more personalized care by adapting treatment to individual needs, goals, and preferences in a flexible, user-centered format. While emerging evidence suggests that DMHIs can reduce depression and anxiety symptoms among youth experiencing suicidal thoughts [16,17], their effectiveness depends on how care is tailored and monitored over time. Consequently, there is a growing need for digital platforms to deliver care that is both personalized and informed by structured symptom monitoring.

Measurement-based care (MBC) is an evidence-based approach that uses standardized assessments to monitor symptoms and guide clinical decision-making throughout treatment [18]. It has been linked to improved outcomes and stronger therapeutic alliance across diverse mental health settings [18,19]. Although some studies in routine outpatient care have found modest or variable effects [20], and meta-analytic evidence suggests MBC does not consistently improve symptom outcomes [21], this variability highlights the importance of examining MBC in populations where its impact may be most critical. For adolescents at elevated suicide risk, MBC may offer a mechanism to detect rapid symptom changes, support timely adjustments in treatment, and complement clinical decision-making in high-stakes contexts. In parallel, personalization strategies, such as offering a curated list of mental health care provider options tailored to clinical needs and individual preferences, may help ensure that care is well-aligned from the outset [22,23]. DMHIs are well-positioned to implement both approaches efficiently, using technology to support structured symptom tracking and individualized mental health care provider selection at scale.

Despite the promise of DMHIs, including virtually delivered therapy and psychiatry, important gaps remain, particularly for adolescents at elevated risk for suicide. DMHIs have demonstrated effectiveness in reducing depression and anxiety symptoms among adolescents in both clinical trials and real-world settings [24-26]. However, relatively few studies have assessed whether adolescents with elevated suicide risk experience similar patterns of symptom improvement compared to those without such risk [27]. While emerging research on DMHIs has begun to include adolescents with elevated risk for suicide [16,28], most studies do not stratify outcomes by suicide risk status, limiting our understanding of whether this subgroup benefits equally from care. Moreover, a recent systematic review and multiple studies show that adolescents with suicidal thoughts or behaviors are often excluded from DMHI studies for safety reasons, which limits generalizability and contributes to the lack of real-world evidence for this high-risk group [16,29-31]. In addition, little is known about how digital care models that incorporate both MBC and intake personalization perform for adolescents at elevated suicide risk. Addressing these gaps is essential for designing digital mental health services that are not only scalable but also safe, effective, and equitable for the youth who face the greatest clinical challenges.

Objectives

The purpose of this study was to evaluate symptom improvements among adolescents with and without elevated suicide risk receiving care from Rula Health, an MBC-based DMHI with personalized intake through mental health care provider matching. We aimed to (1) compare baseline demographic and clinical characteristics between adolescents with and without elevated suicide risk at intake and (2) examine depression and anxiety symptom trajectories over the first 12 visits between adolescents with and without elevated suicide risk at intake.

XSL•FO
RenderX

Methods

Study Design and Participants

This retrospective study examined secondary data from Rula Health, a DMHI that connects individuals across the United States with licensed therapists and psychiatry providers. Rula Health's care model is grounded in MBC and personalized treatment approaches aimed at improving clinical outcomes. Adolescents (aged 12-17 years) were included in this study if they received therapy and psychiatry services from Rula Health between August 24, 2022, and June 30, 2025, and completed the Columbia-Suicide Severity Rating Scale (C-SSRS) during their initial visit as part of standard clinical procedures. Patients were sent the C-SSRS when their baseline total Patient Health Questionnaire-9 (PHQ-9; refer to the description mentioned subsequently in the Study Measures section) score was above 15 or if PHQ-9 item 9 indicated risk. In this study, participants were classified as no suicide risk (total C-SSRS score=0) or elevated suicide risk (total C-SSRS score ≥1) [32]. This threshold aligned with clinical practice, where any endorsement of suicidal ideation or behavior on the C-SSRS was considered a positive screen requiring further evaluation [32,33].

Ethical Considerations

Before beginning care, all individuals receiving services through Rula Health were required to provide informed consent. The consent process included an explanation of the nature and scope of the services, confidentiality protections, and how personal data may be used. In addition to the informed consent process, patients reviewed and accepted Rula Health's privacy policy, which detailed how personal information was collected, used, and protected in accordance with applicable regulatory standards. In accordance with US regulations governing research on human participants, this study was determined to be exempt from further informed consent requirements. Therefore, no additional consent procedures were conducted. The protocol was reviewed and approved by the institutional review board of the Biomedical Research Alliance of New York (25-035-2061). No compensation was provided to individuals whose data were included in this study.

Treatment

Rula Health's therapy and psychiatry care models have been detailed elsewhere [34]. Patients accessed Rula Health through a range of referral sources, including primary care providers, insurance partners, employer-sponsored mental health benefits, health care organizations, and direct online searches. The platform is designed to simplify access to mental health services while supporting patient autonomy in mental health care provider selection. After completing a brief intake questionnaire, individuals were matched with a curated list of licensed therapists or psychiatric providers based on their clinical needs, insurance coverage, and personal preferences (eg, provider specialty, background, and availability), from which they selected the mental health care provider who best fits their needs.

Treatment was delivered virtually via secure video sessions. For therapy, initial visits focused on collaboratively developing a personalized treatment plan that includes therapy goals, intervention strategies, and a schedule of care. Therapists drew from a range of evidence-based modalities, such as cognitive behavioral therapy, dialectical behavior therapy, and acceptance and commitment therapy, tailoring care to each patient's needs. Data related to fidelity or adherence to specific evidence-based treatment protocols were not collected. For psychiatric care, initial visits included a comprehensive review of medical and psychiatric history, discussion of presenting concerns, and the development of an individualized treatment plan that may include medication management. Provider quality was monitored through clinical tools and quality assurance protocols. For example, mental health care provider quality was monitored by clinical quality specialists, who were licensed clinicians who provided consultation and feedback to providers. Providers were also flagged for issues related to documentation quality and were given targeted feedback and ongoing monitoring until issues were resolved.

As part of MBC, patients completed standardized symptom assessments at regular intervals, and mental health care providers were encouraged to use these data to inform treatment decisions. For therapy, these scores supported progress tracking and treatment adjustment, while in psychiatry, they informed decisions related to medication, referrals, or other interventions. Rula Health implemented rigorous safety protocols for managing elevated suicide risk, including proactive risk identification (eg, using the C-SSRS), crisis response, and care coordination. The patient safety and clinical risk (PSCR) team guided providers to ensure best practices in clinical risk management and patient safety. When elevated risk was detected, mental health care providers developed and documented a safety plan and reached out to the PSCR team for consultation and help with referrals. Patients also had access to a 24×7 crisis support line. When a patient accessed the crisis line, the PSCR team followed up with the mental health care provider and helped initiate referrals when appropriate.

Study Measures

Overview

At the start of care, patients provided demographic information, such as age, sex assigned at birth, race, and ethnicity. Primary diagnoses were documented by the treating provider. Beginning August 20, 2020, measures of mental health symptoms were administered before each scheduled visit or up to once weekly. As of December 8, 2024, the frequency of assessment shifted to biweekly. This analysis focused on symptom data related to depression and anxiety.

Depression

Depression symptoms over the past 2 weeks were assessed using the first 9 items of the PHQ-9 modified for adolescents [35,36]. Patients rated each item on a 4-point Likert scale ranging from 0 (*not at all*) to 3 (*nearly every day*), yielding a total score from 0 to 27. Higher scores indicated greater levels of depression. The PHQ-9 has demonstrated strong internal consistency (Cronbach α=0.89) and excellent test-retest reliability (Pearson r=0.84) [37,38]. Results were contextualized using minimal clinically important difference (MCID) in the PHQ-9, the change

XSL•FO
RenderX

in symptom severity that is perceived as meaningful by patients (defined as a reduction of ≥5 points [39]).

Anxiety

Anxiety symptoms were assessed using the Generalized Anxiety Disorder-7 (GAD-7), a 7-item tool that assesses symptom severity over the past 2 weeks [40]. Each item is rated on a 4-point Likert scale from 0 (*not at all*) to 3 (*nearly every day*), yielding a total score from 0 to 21. Higher scores indicate greater levels of anxiety. The GAD-7 demonstrates high internal consistency (Cronbach α=0.89-0.92) and strong test-retest reliability (intraclass correlation=0.83) [40-42]. Results were also contextualized using MCID in the GAD-7, defined as a reduction of 4 or more points [43].

Statistical Analyses

Data were limited to the first 12 visits because this is a common length of treatment for adolescent mood and anxiety disorders [44] and represents a relative episode of care at Rula Health. Demographic and baseline descriptive statistics were calculated for those in the no suicide risk (ie, total C-SSRS score=0) and those in the elevated suicide risk group (ie, total C-SSRS score ≥1), and differences between the groups were tested using independent sample 2-tailed *t* tests for continuous variables and chi-square tests for categorical variables. Effect sizes were calculated using Cohen d for the *t* tests and Cramér V for the chi-square test.

To examine changes in depression and anxiety symptoms over time and determine whether trajectories differed by suicide risk group, linear mixed-effects models were fit. Separate models were fitted for depression and anxiety outcomes. The following elements were added subsequently and tested using the likelihood ratio test to determine the best-fitting model: main effect of visit number, main effect of baseline suicide risk group, and the visit number×suicide risk group interaction (this tested whether the rate of change in symptoms differed between groups). All models were adjusted for covariates, including patient age, sex, race, ethnicity, primary diagnosis, and comorbid diagnosis (ie, whether patients had at least 2 diagnoses or not). A random intercept was included in all models to account for repeated measures nested within patients. Random slopes for visit number were also included and retained if they improved model fit based on the likelihood ratio test. If random slopes models did not converge, models were refitted assuming an independent covariance structure (ie, uncorrelated random effects). Significance of fixed effects was assessed using the Satterthwaite approximation of degrees of freedom [45]. To visualize model-predicted symptom trajectories, model-predicted depression and anxiety scores over visits were calculated using the fixed effects from each best-fitting model. Predicted values were calculated for each suicide risk group at each visit, and 95% CIs were derived from the model-based SEs of the predicted means. Assumptions, including multicollinearity and normality of residuals, were checked (Multimedia Appendix 1 [46]). All analyses were conducted in R (version 4.3.1; R Foundation for Statistical Computing; [47]).

Results

Descriptive Statistics and Group Comparisons

Both the no suicide risk and elevated suicide risk groups consisted of individuals, on average, aged 15 years (SD 1.46), and they were mostly female, White, and non-Hispanic. The no suicide risk and elevated suicide risk groups differed on several demographic and clinical characteristics. The elevated suicide risk group had a greater proportion of female adolescents, younger adolescents (aged 12-14 years), non-Hispanic adolescents, and adolescents with a primary diagnosis of a depressive disorder. These differences were largest in age (Cramér V=0.17) and primary diagnosis (Cramér V=0.17). The elevated suicide risk group also had a greater proportion of adolescents with a comorbid diagnosis and adolescents receiving psychiatry services and also greater baseline PHQ-9 and GAD-7 scores. These differences were largest for baseline PHQ-9 score (Cohen *d*=–0.90) and baseline GAD-7 score (Cohen *d*=–0.61). The no suicide risk group had a greater number of visits up to 12 and were in treatment for a longer time on average (Table 1).

XSL•FO
RenderX

Table 1. Descriptive statistics of demographic, baseline, and treatment characteristics in the no suicide risk and elevated suicide risk groups[a].

Demographic characteristic	No suicide risk (n=3533)	Elevated suicide risk (n=2712)	Chi-square (*df*)	*t* test (*df*)	Effect size	*P* value
Sex, n/N (%)			45.1 (1)	—[b]	0.086[c]	<.001
Female	2247/3507 (64.07)	1918/2657 (72.19)				
Male	1260/3507 (35.93)	739/2657 (27.81)				
Race, n/N (%)			2.2 (5)	—	0.026[c]	.82
African American or Black	173/1739 (9.95)	141/1432 (9.85)				
American Indian or Alaska Native	17/1739 (0.98)	17/1432 (1.19)				
Asian	134/1739 (7.71)	129/1432 (9.01)				
Mixed race	415/1739 (23.88)	341/1432 (23.81)				
Native Hawaiian or Pacific Islander	39/1,739 (2.24)	33 (2.30)				
White	960/1739 (55.24)	771/1432 (53.84)				
Ethnicity—Hispanic, n/N (%)	850/2014 (42.20)	591/1591 (37.15)	9.3 (1)	—	0.051[c]	.002
Age (y; categorical), n/N (%)			170.7 (5)	—	0.17[c]	<.001
12	191/3533 (5.41)	275/2712 (10.1)				
13	245/3533 (6.93)	326/2712 (12.02)				
14	281/3533 (7.95)	341/2712 (12.57)				
15	597/3533 (16.90)	425/2712 (15.67)				
16	1045/3533 (29.58)	633/2712 (23.34)				
17	1174/3533 (33.23)	712/2712 (26.25)				
Age (y, continuous), mean (SD)	15.58 (1.46)	15.09/2712 (1.67)	—	12.17 (5395.3)	0.32[d]	<.001
Primary diagnosis, n/N (%)			186.6 (3)	—	0.17[c]	<.001
Depressive disorders	665/3456 (19.24)	916/2660 (34.44)				
Anxiety disorder	1121/3456 (32.44)	643/2660 (24.17)				
Trauma- and stress-related disorders	928/3456 (26.85)	592/2660 (22.26)				
Other	742/3456 (21.47)	509/2660 (19.14)				
Comorbid diagnosis, n/N (%)	1094/3534 (30.97)	1071/2713 (39.49)	48.9 (1)	—	0.089[c]	<.001
Psychiatry patient, n/N (%)	113/3531 (3.20)	179/2712 (6.60)	39.1 (1)	—	0.080[c]	<.001
Baseline Patient Health Questionnaire-9 score, mean (SD)	9.35 (6.95)	15.11 (5.64)	—	–16.15 (6223.4)	–0.90[d]	<.001
Baseline Generalized Anxiety Disorder-7 score, mean (SD)	8.60 (5.71)	11.83 (4.79)	—	–24.26 (6191)	–0.61[d]	<.001
Total visits up to 12, mean (SD)	7.32 (4.32)	6.54 (4.21)	—	7.23 (5900.6)	0.18[d]	<.001
Length of treatment (wk), mean (SD)	12.03 (11.79)	9.70 (9.92)	—	8.50 (6190)	0.21[d]	<.001

[a]Mean (SD) was reported for continuous variables, and percentages were reported for categorical variables. *t* tests were used to compare continuous variables, and chi-square tests were used for categorical variables.

XSL•FO
RenderX

[b]Not applicable.

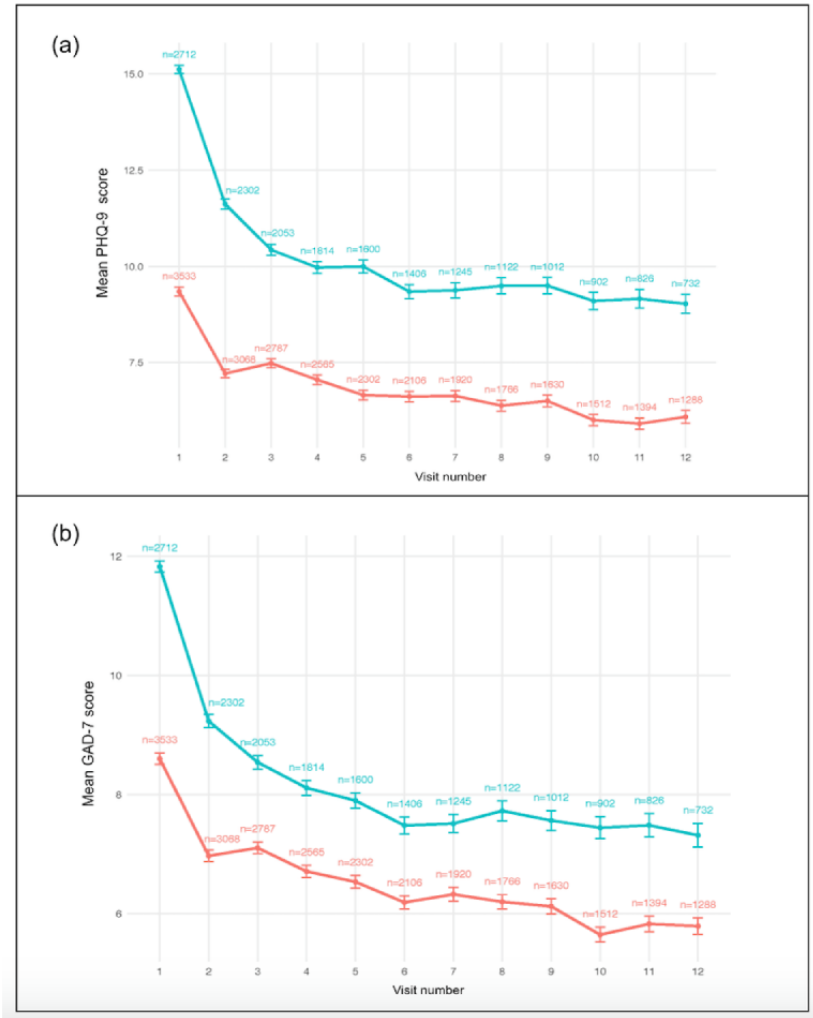
[c]Refers to Cramér V values.

[d]Refers to Cohen *d* values.

Trajectories of Depression and Anxiety Symptoms

Raw trajectories of PHQ-9 and GAD-7 for both suicide risk groups are presented in Figure 1. In Figure 1, the blue line represents adolescents with elevated suicide risk and the red line represents those with no suicide risk; "n" indicates the number of patient observations at each visit. Successively including a main effect of visit number, a main effect of suicide risk group, and an interaction between visit number and suicide risk group improved model fit at each step (Table S1 in Multimedia Appendix 1). At all steps, a random intercept-only model was compared to a model that included a random slope. At all steps, models with random slopes fit best, as indicated by the likelihood ratio test. Thus, the best-fitting models for both PHQ-9 and GAD-7 trajectories were the final models that included random slopes for visit number and an interaction of suicide risk group and visit number.

Figure 1. Raw trajectories of depression (A) and anxiety (B) symptoms by baseline suicide risk group.



Results of the best-fitting models adjusted for covariates showed that, on average, adolescents' depression and anxiety scores decreased over visits (PHQ-9: B=–0.39; *P*<.001; GAD-7: B=–0.35; *P*<.001) and that, on average, the elevated suicide risk group had greater depression and anxiety scores over time than the no suicide risk group (PHQ-9: B=4.95; *P*<.001; GAD-7: B=2.83; *P*<.001). The significant visit number×suicide risk group interaction terms showed that the elevated suicide risk group's depression and anxiety symptoms decreased at a higher rate than the no suicide risk group (PHQ-9: B=–0.32; *P*<.001; GAD-7: B=–0.18; *P*<.001; Table 2; Figure 2). As shown in Figure 2, model-estimated trajectories were adjusted for age, gender, race, ethnicity, primary diagnosis, and comorbidity; the blue line represents the elevated suicide risk group and the red line represents the no suicide risk group, with shaded areas denoting 95% CIs. The covariate effects of these models are presented in Table S2 in Multimedia Appendix 1. Briefly, older age and comorbidities were associated with higher symptom scores, while male sex and African American or Black race (vs White race) were associated with lower scores. Depressive disorders predicted higher depression scores, and anxiety disorders predicted higher anxiety scores.

To contextualize our findings, the no suicide risk group's slope of –0.39 on the PHQ-9 corresponded to an average reduction

XSL•FO
RenderX

in PHQ-9 of 4.68 points over 12 visits, and the elevated suicide risk group's slope of –0.39 to –0.36 (=–0.75) corresponded to an average reduction in PHQ-9 of 9 points over 12 visits. The no suicide risk group's slope of –0.35 on the GAD-7 corresponded to an average reduction in GAD-7 score of 4.2 points over 12 visits, and the elevated suicide risk group's slope of –0.35 to –0.19 (=–0.54) corresponded to an average reduction in GAD-7 of 6.48 points over 12 visits. Average reductions in the no suicide risk group approached the MCID threshold for PHQ-9 (at least a 5-point reduction) and exceeded the threshold for GAD-7 (at least a 4-point reduction). Average reductions in the elevated suicide risk group were well over these established MCID thresholds.

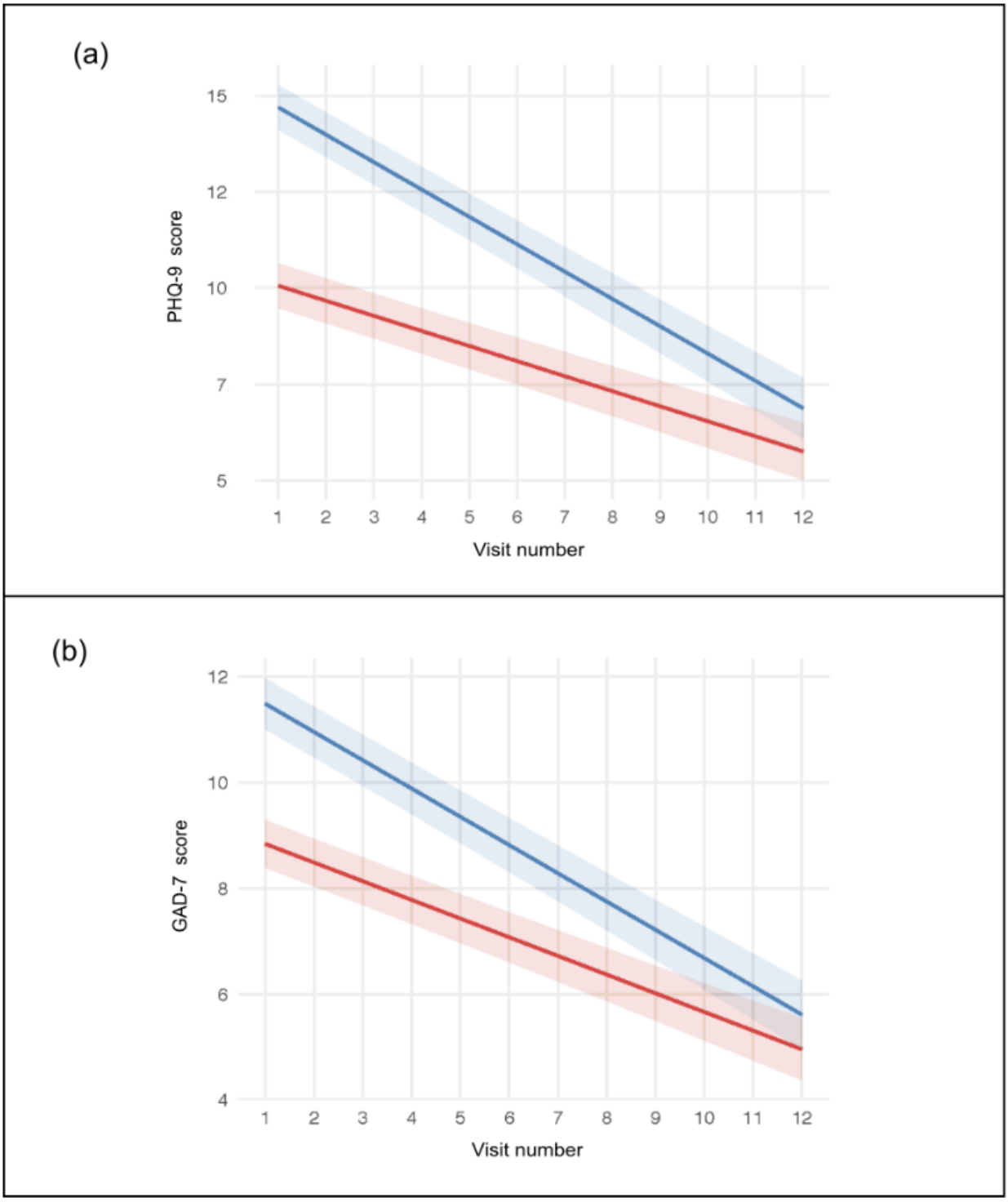
Table 2. Results (fixed effects) for best-fitting models for depression and anxiety symptom trajectories.

Outcome	Unadjusted model			Adjusted model[a]		
	B (SE)	*t* test (*df*)	*P* value	B (SE)	*t* test (*df*)	*P* value
Patient Health Questionnaire-9 score						
Intercept	9.11 (0.10)	87.81 (7882.74)	<.001	10.36 (0.30)	34.75 (4039.90)	<.001
Visit number	–0.39 (0.018)	–21.64 (2162.71)	<.001	–0.39 (0.024)	–16.37 (1171.80)	<.001
Suicide risk group (at risk)	5.55 (0.15)	35.21 (7954.48)	<.001	4.95 (0.22)	22.88 (4015.3)	<.001
Visit number×suicide risk group (at risk)	–0.36 (0.027)	–13.18 (2278.87)	<.001	–0.32 (0.036)	–8.76 (1221.36)	<.001
Generalized Anxiety Disorder-7 score						
Intercept	8.45 (0.085)	99.45 (8093.66)	<.001	9.12 (0.23)	39.48 (3721.34)	<.001
Visit number	–0.35 (0.015)	–23.61 (2316.27)	<.001	–0.35 (0.020)	–17.87 (1270.67)	<.001
Suicide risk group (at risk)	3.05 (0.13)	23.59 (8165.40)	<.001	2.83 (0.18)	15.74 (4175.83)	<.001
Visit number×suicide risk group (at risk)	–0.19 (0.022)	–8.55 (2443.60)	<.001	–0.18 (0.030)	–6.03 (1325. 80)	<.001

[a]Adjusted for age, sex, race, ethnicity, primary diagnosis, and comorbidity.

XSL•FO
RenderX

Figure 2. Depression (A) and anxiety (B) model-estimated symptom trajectories by suicide risk group.



Discussion

Principal Findings

The purpose of this study was to evaluate symptom improvements among adolescents with and without elevated suicide risk receiving care from Rula Health, an MBC-based DMHI with personalized intake through mental health care provider matching. We aimed to (1) compare baseline demographic and clinical characteristics between adolescents with and without elevated suicide risk at intake and (2) examine depression and anxiety symptom trajectories over the first 12 visits between adolescents with and without elevated suicide risk at intake. The elevated suicide risk group had more female adolescents, younger adolescents, non-Hispanic adolescents, and adolescents with depressive disorder diagnoses. The elevated suicide risk group had more adolescents with comorbid diagnoses, more adolescents receiving psychiatry services, and greater baseline depression and anxiety scores. The no suicide risk group attended more visits (up to 12) and was in treatment for a longer time than the elevated suicide risk group. Across all adolescents, depression and anxiety scores decreased over

XSL•FO
RenderX

12 visits. The elevated suicide risk group's depression and anxiety symptoms decreased at a higher rate than the no suicide risk group, and the elevated suicide risk group achieved similar depression and anxiety scores as the no risk group by 12 visits.

Among adolescents who received care through Rula Health, those with elevated suicide risk at intake differed from their no-risk peers. This group included higher proportions of female adolescents, non-Hispanic adolescents, and younger adolescents. These differences largely mirror national epidemiological patterns. For example, data from US adolescents, including national-level surveys, consistently show that adolescent girls report higher rates of suicidal ideation and attempts than boys [48-51]. National survey data also show that non-Hispanic White adolescents are more likely to report suicidal ideation than Hispanic youth [51,52], which aligns with our finding that elevated risk was more common among non-Hispanic participants. The overrepresentation of non-Hispanic adolescents aligns with research indicating that Hispanic and Latino identity may be protective against suicidality, possibly due to cultural values, such as familism and religiosity [53,54], and that Hispanic and Latino youth face barriers to accessing mental health care [55,56]. Interestingly, greater proportions of younger adolescents were in the elevated suicide risk group. This is different from national surveillance data and previous longitudinal studies showing that risk for suicidal ideation, suicide attempts, and death by suicide increases from early to midadolescence [57,58]. Emerging evidence points to a sharp rise in suicidality among preteenagers, which may help explain increased help seeking in this group [59,60]. The presence of high-risk youth across multiple demographic groups in Rula Health's patient population is encouraging, suggesting that this type of DMHI may help expand access to care for adolescents at greatest risk. Building on this, future research should examine how Rula Health's personalized intake and mental health care provider matching systems influence access and outcomes across sex, ethnicity, and age groups.

Adolescents with elevated suicide risk at intake presented with greater rates of depressive disorder as well as greater clinical complexity as indicated by higher rates of comorbid diagnoses, greater use of psychiatric services, and more severe baseline depression and anxiety symptoms. Major depressive disorder and co-occurring conditions are strongly linked to heightened suicide risk [61,62]. Clinically complex adolescents at risk of suicide need more intensive, frequent, and specialized care [63,64]. However, more than two-thirds of adolescents who die by suicide had no treatment contact within the month before death, highlighting the critical gaps in traditional service access and engagement [65]. Our findings point to the critical importance of DMHIs, such as Rula Health, in reaching and serving clinically complex adolescents who may otherwise face significant barriers to accessing timely evidence-based care [66,67]. Future research should examine whether there is an optimal type of treatment or therapy modality for adolescents with elevated suicide risk, high symptom severity, and multiple comorbidities.

The individuals in the elevated suicide risk group attended fewer sessions and were in treatment for less time than the individuals in the no suicide risk group. Adolescents at risk of suicide face attitudinal barriers to care, such as shame and stigma, which can impact how they engage with mental health services, including contributing to premature dropout [68-70]. Alternatively, some adolescents in the elevated suicide risk group may have had fewer sessions because they were transitioned appropriately to higher levels of care or experienced a more rapid reduction in symptoms, warranting discharge from care. Rula Health is known for both retention and appropriate transitions with data-driven monitoring via MBC and established referral pathways. However, distinguishing between premature dropout versus clinically appropriate transition is critical, as each has different implications for continuity and safety. Future research should use methods, such as survival analyses and qualitative follow-up, to clarify reasons for disengagement and should further investigate the mechanisms underlying engagement (eg, perceptions of safety, trust, and therapeutic alliance) to better understand how adolescents interact with digital care and inform strategies to support continuity of care.

Rula Health's model, which included personalized intake and MBC integration, decreased depression and anxiety symptoms over the course of 12 visits across the entire adolescent sample. Both groups showed clinically meaningful improvements, with average reductions meeting or exceeding established MCID thresholds. This study is one of the few real-world evaluations of the effects of a commercial MBC-based DMHI on depression and anxiety symptom trajectories in adolescents with and without suicide risk. Recent research shows that virtual therapy is as effective as face-to-face treatment for adolescents with anxiety and depression [24,71]. However, few studies have disaggregated outcomes by suicide risk status or included high-risk populations due to safety and liability concerns [29,72]. Our findings address these gaps by demonstrating that a virtual therapy DMHI, Rula Health, decreases depression and anxiety symptoms among adolescents with varying levels of suicide risk in the real world. Future research should identify which specific components of Rula Health's digital platform (eg, personalized matching, MBC, or their combination) most strongly contribute to treatment effectiveness in this real-world setting.

MBC-based DMHIs (such as Rula Health) have the potential to deliver rapid, meaningful clinical improvement for high-risk youth. Adolescents with elevated suicide risk experienced a decrease in both anxiety and depression symptoms at a greater rate than adolescents with no suicide risk. The elevated suicide risk group also achieved similar depression and anxiety scores as the no-risk group by 12 visits, after accounting for demographic and clinical characteristics. These findings align with previous research showing that adolescents with severe symptoms and suicidality can improve rapidly in outpatient treatment, often at rates comparable to those with lower symptom severity or no suicide risk [16,73]. MBC delivered digitally, as in Rula Health's model, may accelerate symptom relief in adolescents with elevated suicide risk by flagging patients who are in crisis and prompting timely adjustments to treatment. Rula Health patients can select mental health care providers based on characteristics such as demographics and clinical specialty, which may enhance therapeutic alliance, an especially important factor for individuals experiencing

XSL•FO
RenderX

suicidality [74]. Alternatively, the differences between risk groups might partly reflect regression to the mean, where those starting with more severe symptoms tend to show greater improvement over time regardless of treatment [75]. Although our mixed-effects models account for individual baseline severity, regression to the mean remains a plausible alternative explanation. Future research should use designs that can disentangle regression to the mean from treatment effects and more directly test the unique contribution of MBC to adolescent outcomes.

Strengths and Limitations

This study had several strengths. First, the large, naturalistic sample of more than 6000 adolescents from Rula Health, a widely available commercial DMHI, enhanced the generalizability of our findings. Second, this study examined treatment delivered under naturalistic conditions with real-world constraints, increasing the external validity of our findings compared to research in controlled settings. Third, the inclusion of adolescents with elevated suicide risk offers rare outcomes data on this important group that is usually underrepresented in DMHI research due to safety or liability concerns [29,72]. Finally, collecting MBC measures at regular intervals and using validated clinical outcomes measures (PHQ-9 and GAD-7) enabled us to model symptom trajectories instead of less nuanced pre-post analyses.

This study also had limitations; it lacked a more thorough assessment of suicidality, including the range of suicidal ideation and behaviors, as well as nonsuicidal self-injury. This study also lacked additional outcomes that could be important for adolescents, such as functioning at school and home, stress, and substance use. This study's naturalistic design involved collecting neither data on specific treatment content, therapy modality, or fidelity to evidence-based practices nor other potentially important variables, such as treatment completion, dropout, or referrals. This means we could not assess either the variability in how care was delivered across mental health care providers or true attrition. Future studies should collect data on fidelity to clarify how treatment delivery influences outcomes while balancing real-world applicability with methodological rigor. In addition, because our sample was predominantly White and non-Hispanic, future research is warranted among more diverse populations to increase the generalizability of our findings. Finally, follow-up was restricted to 12 visits without any postdischarge data. Thus, the long-term effectiveness of treatment on adolescent outcomes remains unknown. Future research should include both self-report and clinician assessments of suicide risk and collect outcomes over longer follow-up periods to establish the long-term effectiveness of DMHIs for adolescents across the suicide risk spectrum.

Conclusions

Results from this retrospective analysis highlight the potential of commercial DMHIs, such as Rula Health, to effectively reduce depression and anxiety symptoms in adolescents across varying levels of suicide risk. Baseline demographic and clinical characteristics revealed important differences between risk groups and extended current research on growing high-risk populations. All adolescents experienced substantial symptom improvements, with those at elevated suicide risk showing steeper rates of symptom reduction and ultimately achieving similar symptom levels as their no-risk peers by 12 visits. These findings highlight the capacity of structured, virtual care platforms, such as Rula Health, to deliver timely and effective support to high-risk youth. Future research and implementation efforts should explore concrete strategies for optimizing digital personalization and MBC (eg, using machine learning to enhance mental health care provider matching and comparing different schedules for symptom monitoring), particularly by including more racially and ethnically diverse adolescent populations to ensure equity and generalizability. At the policy level, integrating DMHIs into school-based mental health programs and expanding insurance reimbursement models for virtual care could help translate these findings into scalable solutions within public health systems.

Acknowledgments

This work was supported by Rula Health.

Data Availability

The datasets generated or analyzed during this study are not publicly available, given Rula Health's privacy policy for patient data, but aggregated and anonymized data are available from the corresponding author on reasonable request.

Authors' Contributions

LB contributed to conceptualization, methodology, formal analysis, visualization, writing the original draft, reviewing and editing the manuscript, and final approval. KLM contributed to conceptualization, methodology, writing the original draft, reviewing and editing the manuscript, and final approval. DN contributed to conceptualization, resources, data curation, writing the original draft, reviewing and editing the manuscript, final approval, and supervision. SS contributed to conceptualization, resources, data curation, writing the original draft, reviewing and editing the manuscript, and final approval. AW contributed to conceptualization, resources, data curation, writing the original draft, reviewing and editing the manuscript, and final approval. JH contributed to conceptualization, writing the original draft, reviewing and editing the manuscript, final approval, and supervision.

XSL•FO
RenderX

Conflicts of Interest

DN, SS, and AW are employed by Rula Health, and Rula Health was the behavioral health treatment used in this study. JH is a paid consultant of Rula Health. LB and KLM are employed by JH. To mitigate potential conflicts of interest, data analysis and interpretation were led by authors not employed by Rula Health. The analysis plan was prespecified, and results were interpreted collaboratively to ensure objectivity. Authors' employment status and salary are not dependent upon the results of their research.

Multimedia Appendix 1
Model selection results, full results including covariate effects, and model assumption checks (Tables S1-S3 and Figure S1).
[DOCX File , 401 KB - pediatrics_v8i1e81444_app1.docx]

References

1. Sappenfield O, Alberto C, Minnaert J, Donney J, Lebrun-Harris L, Ghandour R. National survey of children's health data briefs: adolescent mental and behavioral health. National Library of Medicine. 2018. URL: https://www.ncbi.nlm.nih.gov/books/NBK608531/ [accessed 2025-07-24]
2. Wang Y, Han L. The bidirectional cyclical relationship between early adolescents' subjective well-being and depression, math anxiety, and academic engagement in academic development. Child Ind Res 2025 May 15:1. [doi: 10.1007/S12187-025-10253-7]
3. Chiu K, Clark DM, Leigh E. Prospective associations between peer functioning and social anxiety in adolescents: a systematic review and meta-analysis. J Affect Disord 2021 Jan 15;279:650-661 [FREE Full text] [doi: 10.1016/j.jad.2020.10.055] [Medline: 33190116]
4. Suicide data and statistics: suicide prevention. Centers for Disease Control and Prevention (CDC). URL: https://www.cdc.gov/suicide/facts/data.html [accessed 2025-07-24]
5. Garnett MF, Curtin SC. Products: data briefs: suicide mortality in the United States, 2002-2022. NCHS Data Brief 2024 Sep(509):160504 [FREE Full text] [doi: 10.15620/cdc/160504] [Medline: 39392858]
6. Suicide and homicide rates increase among young Americans. Centers for Disease Control and Prevention (CDC). URL: https://blogs.cdc.gov/nchs/2023/06/15/7396/ [accessed 2025-05-29]
7. Verlenden JV, Fodeman A, Wilkins N, Jones SE, Moore S, Cornett K, et al. Mental health and suicide risk among high school students and protective factors - youth risk behavior survey, United States, 2023. MMWR Suppl 2024 Oct 10;73(4):79-86. [doi: 10.15585/mmwr.su7304a9] [Medline: 39378246]
8. Twenge JM. Increases in depression, self-harm, and suicide among U.S. adolescents after 2012 and links to technology use: possible mechanisms. Psychiatr Res Clin Pract 2020;2(1):19-25. [doi: 10.1176/appi.prcp.20190015] [Medline: 36101887]
9. Plemmons G, Hall M, Doupnik S, Gay J, Brown C, Browning W, et al. Hospitalization for suicide ideation or attempt: 2008-2015. Pediatrics 2018 Jun;141(6):e20172426. [doi: 10.1542/peds.2017-2426] [Medline: 29769243]
10. Ebert DD, Van Daele T, Nordgreen T, Karekla M, Compare A, Zarbo C, et al. Internet- and mobile-based psychological interventions: applications, efficacy, and potential for improving mental health. Eur Psychol 2018 Apr;23(2):167-187. [doi: 10.1027/1016-9040/a000318]
11. Cantor J, Schuler MS, Matthews S, Kofner A, Breslau J, McBain RK. Availability of mental telehealth services in the US. JAMA Health Forum 2024 Feb 02;5(2):e235142 [FREE Full text] [doi: 10.1001/jamahealthforum.2023.5142] [Medline: 38306092]
12. Kohli K, Jain B, Patel TA, Eken HN, Dee EC, Torous J. The digital divide in access to broadband internet and mental healthcare. Nat Mental Health 2024 Jan 04;2(1):88-95. [doi: 10.1038/S44220-023-00176-Z]
13. Ramesh T, McBain RK, Cantor JH, Stein BD, Yu H. Mental health outcomes among patients living in US counties lacking broadband access and psychiatrists. JAMA Netw Open 2023 Sep 05;6(9):e2333781 [FREE Full text] [doi: 10.1001/jamanetworkopen.2023.33781] [Medline: 37707819]
14. North S. Expanding telehealth in adolescent care: moving beyond the COVID-19 pandemic. Pediatrics 2023 Apr 01;151(Suppl 1):e2022057267J. [doi: 10.1542/peds.2022-057267J] [Medline: 37010401]
15. Aschbrenner KA, Naslund JA, Tomlinson EF, Kinney A, Pratt SI, Brunette MF. Adolescents' use of digital technologies and preferences for mobile health coaching in public mental health settings. Front Public Health 2019;7:178 [FREE Full text] [doi: 10.3389/fpubh.2019.00178] [Medline: 31312629]
16. Lawrence-Sidebottom D, Huffman LG, Beam AB, McAlister K, Guerra R, Parikh A, et al. Using a digital mental health intervention for crisis support and mental health care among children and adolescents with self-injurious thoughts and behaviors: retrospective study. JMIR Form Res 2024 Aug 16;8:e54816. [doi: 10.2196/54816] [Medline: 39151166]
17. Toscos T, Coupe A, Flanagan M, Drouin M, Carpenter M, Reining L, et al. Teens using screens for help: impact of suicidal ideation, anxiety, and depression levels on youth preferences for telemental health resources. JMIR Ment Health 2019 Jun 21;6(6):e13230 [FREE Full text] [doi: 10.2196/13230] [Medline: 31228179]
18. Scott K, Lewis CC. Using measurement-based care to enhance any treatment. Cogn Behav Pract 2015 Feb;22(1):49-59. [doi: 10.1016/j.cbpra.2014.01.010] [Medline: 27330267]

XSL•FO
RenderX

19. Fortney JC, Unützer J, Wrenn G, Pyne JM, Smith GR, Schoenbaum M, et al. A tipping point for measurement-based care. Psychiatr Serv 2017 Feb 01;68(2):179-188. [doi: 10.1176/appi.ps.201500439] [Medline: 27582237]
20. Bickman L, Douglas SR, De Andrade AR, Tomlinson M, Gleacher A, Olin S, et al. Implementing a measurement feedback system: a tale of two sites. Adm Policy Ment Health 2016 May 16;43(3):410-425 [FREE Full text] [doi: 10.1007/s10488-015-0647-8] [Medline: 25876736]
21. Kendrick T, El-Gohary M, Stuart B. Routine use of patient reported outcome measures (PROMs) for improving treatment of common mental health disorders in adults. Cochrane Database Syst Rev 2016;7(7):CD011119. [doi: 10.1002/14651858.CD011119]
22. Yeh M, Diaz D, Zerr A, Macias A, McCabe K. Youth-therapist and parent-therapist match and mismatch on internalizing and externalizing treatment goals as predictors of treatment engagement. Adolescents 2023 Dec 13;3(4):678-692. [doi: 10.3390/adolescents3040048] [Medline: 38389932]
23. Constantino MJ, Boswell JF, Kraus DR, Swales T. Matching patients with therapists to improve mental health care. Patient-Centered Outcomes Research Institute. URL: https://pubmed.ncbi.nlm.nih.gov/39208171/ [accessed 2025-05-29]
24. Orsolini L, Pompili S, Salvi V, Volpe U. A systematic review on TeleMental health in youth mental health: focus on anxiety, depression and obsessive-compulsive disorder. Medicina (Kaunas) 2021 Jul 31;57(8):793. [doi: 10.3390/medicina57080793] [Medline: 34440999]
25. Zhu S, Wang Y, Hu Y. Facilitators and barriers to digital mental health interventions for depression, anxiety, and stress in adolescents and young adults: scoping review. J Med Internet Res 2025 Mar 24;27:e62870. [doi: 10.2196/62870] [Medline: 40127430]
26. Lehtimaki S, Martic J, Wahl B, Foster KT, Schwalbe N. Evidence on digital mental health interventions for adolescents and young people: systematic overview. JMIR Ment Health 2021 Apr 29;8(4):e25847. [doi: 10.2196/25847] [Medline: 33913817]
27. Kruzan KP, Biernesser C, Hoffmann JA, Meyerhoff J. Digital interventions for adolescents and young adults experiencing self-injurious thoughts and behaviors. Curr Treat Options Psychiatry 2024 Jun 24;11(2):76-89. [doi: 10.1007/s40501-024-00318-9] [Medline: 39525358]
28. Pardes A, Lynch W, Miclette M, McGeoch E, Daly BP. Use of a mobile health (mHealth) platform for remote assessment of suicidal ideation, depression, and anxiety: a longitudinal retrospective study. Innov Digit Health Diagn Biomark 2021;5:8-15. [doi: 10.36401/IDDB-21-03]
29. McCall HC, Hadjistavropoulos HD, Loutzenhiser L. Reconsidering the ethics of exclusion criteria in research on digital mental health interventions. Ethics Behav 2019 Oct 31;31(3):171-180. [doi: 10.1080/10508422.2019.1684295]
30. Nielssen O, Dear BF, Staples LG, Dear R, Ryan K, Purtell C, et al. Procedures for risk management and a review of crisis referrals from the MindSpot Clinic, a national service for the remote assessment and treatment of anxiety and depression. BMC Psychiatry 2015 Dec 01;15:304. [doi: 10.1186/s12888-015-0676-6] [Medline: 26626712]
31. Taher R, Hsu CW, Hampshire C, Fialho C, Heaysman C, Stahl D, et al. The safety of digital mental health interventions: systematic review and recommendations. JMIR Ment Health 2023 Oct 09;10:e47433. [doi: 10.2196/47433] [Medline: 37812471]
32. Crandal BR, Aguinaldo LD, Carter C, Billman GF, Sanderson K, Kuelbs C. Opportunities for early identification: implementing universal depression screening with a pathway to suicide risk screening in a pediatric health care system. J Pediatr 2022 Feb;241:29-35.e1 [FREE Full text] [doi: 10.1016/j.jpeds.2021.10.031] [Medline: 34695448]
33. Posner K, Brent D, Lucas C, Gould M, Stanley B, Brown G, et al. Columbia-suicide severity rating scale (C-SSRS). The Research Foundation for Mental Hygiene. URL: https://cssrs.columbia.edu/wp-content/uploads/C-SSRS_Pediatric-SLC_11.14.16.pdf [accessed 2025-05-29]
34. McAlister KL, Baez L, Newton D, Seiniger S, Pearlman A, Woodhouse A, et al. Predictors and correlates of depression and anxiety symptom trajectories in a large digital mental health provider: retrospective analysis of data from Rula Health. J Med Internet Res 2025 Jul 25;27:e75750. [doi: 10.2196/75750] [Medline: 40712128]
35. Johnson JG, Harris ES, Spitzer RL, Williams JB. The patient health questionnaire for adolescents: validation of an instrument for the assessment of mental disorders among adolescent primary care patients. J Adolesc Health 2002 Mar;30(3):196-204. [doi: 10.1016/S1054-139x(01)00333-0]
36. PHQ-9 modified for adolescents (PHQ-A). National Institute of Mental Health (NIMH). URL: https://www.nimh.nih.gov/research/research-conducted-at-nimh/asq-toolkit-materials/asq-tool/phq-9-modified-for-adolescents-phq-a [accessed 2025-05-29]
37. Sun Y, Kong Z, Song Y, Liu J, Wang X. The validity and reliability of the PHQ-9 on screening of depression in neurology: a cross sectional study. BMC Psychiatry 2022 Feb 09;22(1):98 [FREE Full text] [doi: 10.1186/s12888-021-03661-w] [Medline: 35139810]
38. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001 Sep;16(9):606-613 [FREE Full text] [doi: 10.1046/j.1525-1497.2001.016009606.x] [Medline: 11556941]
39. Löwe B, Unützer J, Callahan CM, Perkins AJ, Kroenke K. Monitoring depression treatment outcomes with the patient health questionnaire-9. Med Care 2004 Dec;42(12):1194-1201. [doi: 10.1097/00005650-200412000-00006] [Medline: 15550799]

XSL•FO
RenderX

40. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006 May 22;166(10):1092-1097. [doi: 10.1001/archinte.166.10.1092] [Medline: 16717171]
41. Löwe B, Decker O, Müller S, Brähler E, Schellberg D, Herzog W, et al. Validation and standardization of the Generalized Anxiety Disorder Screener (GAD-7) in the general population. Med Care 2008 Mar;46(3):266-274. [doi: 10.1097/MLR.0b013e318160d093] [Medline: 18388841]
42. Sapra A, Bhandari P, Sharma S, Chanpura T, Lopp L. Using generalized anxiety disorder-2 (GAD-2) and GAD-7 in a primary care setting. Cureus 2020 May 21;12(5):e8224 [FREE Full text] [doi: 10.7759/cureus.8224] [Medline: 32582485]
43. Toussaint A, Hüsing P, Gumz A, Wingenfeld K, Härter M, Schramm E, et al. Sensitivity to change and minimal clinically important difference of the 7-item Generalized Anxiety Disorder Questionnaire (GAD-7). J Affect Disord 2020 Mar 15;265:395-401. [doi: 10.1016/j.jad.2020.01.032] [Medline: 32090765]
44. Oud M, de Winter L, Vermeulen-Smit E, Bodden D, Nauta M, Stone L, et al. Effectiveness of CBT for children and adolescents with depression: a systematic review and meta-regression analysis. Eur Psychiatry 2019 Apr 16;57:33-45. [doi: 10.1016/j.eurpsy.2018.12.008] [Medline: 30658278]
45. Satterthwaite FE. An approximate distribution of estimates of variance components. Biom Bull 1946 Dec;2(6):110. [doi: 10.2307/3002019]
46. Schielzeth H, Dingemanse NJ, Nakagawa S, Westneat DF, Allegue H, Teplitsky C, et al. Robustness of linear mixed ‐ effects models to violations of distributional assumptions. Methods Ecol Evol 2020 Jul 16;11(9):1141-1152. [doi: 10.1111/2041-210x.13434]
47. The R project for statistical computing. R Foundation for Statistical Computing. URL: https://www.r-project.org/ [accessed 2025-03-26]
48. Adolescent mental health service use and reasons for using services in specialty, educational, and general medical settings. Substance Abuse and Mental Health Services Administration. URL: https://www.samhsa.gov/data/sites/default/files/report_1973/ShortReport-1973.html [accessed 2024-07-24]
49. Gaylor EM, Krause KH, Welder LE, Cooper AC, Ashley C, Mack KA, et al. Suicidal thoughts and behaviors among high school students - youth risk behavior survey, United States, 2021. MMWR Suppl 2023 Apr 28;72(1):45-54 [FREE Full text] [doi: 10.15585/mmwr.su7201a6] [Medline: 37104546]
50. Miranda-Mendizabal A, Castellví P, Parés-Badell O, Alayo I, Almenara J, Alonso I, et al. Gender differences in suicidal behavior in adolescents and young adults: systematic review and meta-analysis of longitudinal studies. Int J Public Health 2019 Mar;64(2):265-283. [doi: 10.1007/s00038-018-1196-1] [Medline: 30635683]
51. Ostanin J, Miranda H, Shugar S, Abdo D, Mejia MC, Hennekens CH, et al. Suicidal behaviors among United States adolescents: increasing clinical and public health challenges. Children (Basel) 2025 Jan 03;12(1):57. [doi: 10.3390/children12010057] [Medline: 39857887]
52. Cruz N, Duberstein P, Samples H. Racial/ethnic differences in risk of suicidal ideation and suicide attempts in a nationally representative sample of U.S. adolescents. J Affect Disord 2024 Nov 15;365:32-35 [FREE Full text] [doi: 10.1016/j.jad.2024.08.034] [Medline: 39142591]
53. Peña JB, Kuhlberg JA, Zayas LH, Baumann AA, Gulbas L, Hausmann-Stabile C, et al. Familism, family environment, and suicide attempts among Latina youth. Suicide Life Threat Behav 2011 Jun;41(3):330-341 [FREE Full text] [doi: 10.1111/j.1943-278X.2011.00032.x] [Medline: 21463357]
54. Boyas JF, Kim YJ, Villarreal-Otálora T, Sink JK. Suicide ideation among Latinx adolescents: examining the role of parental monitoring and intrinsic religiosity. Child Youth Serv Rev 2019 Jul;102:177-185. [doi: 10.1016/j.childyouth.2019.04.026]
55. Marrast L, Himmelstein DU, Woolhandler S. Racial and ethnic disparities in mental health care for children and young adults: a national study. Int J Health Serv 2016 Oct;46(4):810-824 [FREE Full text] [doi: 10.1177/0020731416662736] [Medline: 27520100]
56. Isasi CR, Rastogi D, Molina K. Health issues in Hispanic/Latino youth. J Lat Psychol 2016 May;4(2):67-82. [doi: 10.1037/lat0000054] [Medline: 27347457]
57. Yu B, Chen X. Age and birth cohort-adjusted rates of suicide mortality among US male and female youths aged 10 to 19 years from 1999 to 2017. JAMA Netw Open 2019 Sep 04;2(9):e1911383 [FREE Full text] [doi: 10.1001/jamanetworkopen.2019.11383] [Medline: 31517968]
58. Curtin SC, Garnett MF. Suicide and homicide death rates among youth and young adults aged 10–24: United States, 2001–2021. Centers for Disease Control and Prevention (CDC). 2023. URL: https://stacks.cdc.gov/view/cdc/128423 [accessed 2025-05-29]
59. Ivey-Stephenson AZ, Demissie Z, Crosby AE, Stone DM, Gaylor E, Wilkins N, et al. Suicidal ideation and behaviors among high school students - youth risk behavior survey, United States, 2019. MMWR Suppl 2020 Aug 21;69(1):47-55. [doi: 10.15585/mmwr.su6901a6] [Medline: 32817610]
60. Thiagarajan TC, Newson JJ, Swaminathan S. Protecting the developing mind in a digital age: a global policy imperative. J Human Dev Capabil 2025 Jul 20;26(3):493-504. [doi: 10.1080/19452829.2025.2518313]
61. Cai H, Xie XM, Zhang Q, Cui X, Lin J, Sim K, et al. Prevalence of suicidality in major depressive disorder: a systematic review and meta-analysis of comparative studies. Front Psychiatry 2021 Sep 16;12:690130 [FREE Full text] [doi: 10.3389/fpsyt.2021.690130] [Medline: 34603096]

XSL•FO
RenderX

62. Bilsen J. Suicide and youth: risk factors. Front Psychiatry 2018 Oct 30;9:540 [FREE Full text] [doi: 10.3389/fpsyt.2018.00540] [Medline: 30425663]
63. Grover S, Avasthi A. Clinical practice guidelines for the management of depression in children and adolescents. Indian J Psychiatry 2019;61(8):226. [doi: 10.4103/psychiatry.indianjpsychiatry_563_18]
64. Shain BN, American Academy of Pediatrics Committee on Adolescence. Suicide and suicide attempts in adolescents. Pediatrics 2007 Sep;120(3):669-676. [doi: 10.1542/peds.2007-1908] [Medline: 17766542]
65. Renaud J, Berlim MT, Séguin M, McGirr A, Tousignant M, Turecki G. Recent and lifetime utilization of health care services by children and adolescent suicide victims: a case-control study. J Affect Disord 2009 Oct;117(3):168-173. [doi: 10.1016/j.jad.2009.01.004] [Medline: 19187970]
66. Rushton J, Bruckman D, Kelleher K. Primary care referral of children with psychosocial problems. Arch Pediatr Adolesc Med 2002 Jun;156(6):592-598. [doi: 10.1001/archpedi.156.6.592] [Medline: 12038893]
67. Mora Ringle VA, Sung JY, Roulston CA, Schleider JL. Mixed-methods examination of adolescent-reported barriers to accessing mental health services. J Adolesc Health 2024 Feb;74(2):268-276. [doi: 10.1016/j.jadohealth.2023.08.034] [Medline: 37804301]
68. DeLuca JS. Conceptualizing adolescent mental illness stigma: youth stigma development and stigma reduction programs. Adolescent Res Rev 2019 Jan 2;5(2):153-171. [doi: 10.1007/S40894-018-0106-3]
69. McGillivray L, Rheinberger D, Wang J, Burnett A, Torok M. Non-disclosing youth: a cross sectional study to understand why young people do not disclose suicidal thoughts to their mental health professional. BMC Psychiatry 2022 Jan 04;22(1):3 [FREE Full text] [doi: 10.1186/s12888-021-03636-x] [Medline: 34983460]
70. Pellmar TC, Kleinman AM, Bunney WE. Barriers to effective treatment and intervention suicide I of M (US) C on PP of A and A. Goldsmith SK 2002;23:33. [doi: 10.17226/10398] [Medline: 25057611]
71. Rabner J, Norris LA, Olino TM, Kendall PC. A comparison of telehealth and in-person therapy for youth anxiety disorders. J Clin Child Adolesc Psychol 2025;54(5):555-566 [FREE Full text] [doi: 10.1080/15374416.2024.2372770] [Medline: 38995683]
72. Melia R, Francis K, Hickey E, Bogue J, Duggan J, O'Sullivan M, et al. Mobile health technology interventions for suicide prevention: systematic review. JMIR Mhealth Uhealth 2020 Jan 15;8(1):e12516 [FREE Full text] [doi: 10.2196/12516] [Medline: 31939744]
73. Scott K, Lewis CC, Marti CN. Trajectories of symptom change in the treatment for adolescents with depression study. J Am Acad Child Adolesc Psychiatry 2019 Mar;58(3):319-328 [FREE Full text] [doi: 10.1016/j.jaac.2018.07.908] [Medline: 30768414]
74. Huggett C, Gooding P, Haddock G, Quigley J, Pratt D. The relationship between the therapeutic alliance in psychotherapy and suicidal experiences: a systematic review. Clin Psychol Psychother 2022 Jul 25;29(4):1203-1235 [FREE Full text] [doi: 10.1002/cpp.2726] [Medline: 35168297]
75. Barnett AG, van der Pols JC, Dobson AJ. Regression to the mean: what it is and how to deal with it. Int J Epidemiol 2005 Feb 27;34(1):215-220. [doi: 10.1093/ije/dyh299] [Medline: 15333621]

Abbreviations

C-SSRS: Columbia-Suicide Severity Rating Scale
DMHI: digital mental health intervention
GAD-7: Generalized Anxiety Disorder-7
MBC: measurement-based care
MCID: minimal clinically important difference
PHQ-9: Patient Health Questionnaire-9
PSCR: patient safety and clinical risk

Edited by S Badawy; submitted 28.07.25; peer-reviewed by R Nooripour; comments to author 08.09.25; revised version received 12.09.25; accepted 20.09.25; published 15.10.25.

Please cite as:
Baez L, McAlister KL, Newton D, Seiniger S, Woodhouse A, Huberty J
Real-World Symptom Trajectories in Adolescents With and Without Suicide Risk Receiving Care from Rula Health: Retrospective Study
JMIR Pediatr Parent 2025;8:e81444
URL: https://pediatrics.jmir.org/2025/1/e81444
doi:10.2196/81444
PMID:41100172

XSL•FO
RenderX

©Lara Baez, Kelsey L McAlister, Douglas Newton, Sam Seiniger, Allie Woodhouse, Jennifer Huberty. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 15.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Empowering Caregiver Well-Being With the Adhera Caring Digital Program for Family Caregivers of Children Living With Type 1 Diabetes: Mixed Methods Feasibility Study

Antonio de Arriba Muñoz[1], MD; Elisa Civitani Monzon[1], RN; Maria Pilar Ferrer[1], RN; Marta Ferrer-Lozano[1], MD; Silvia Quer-Palomas[2], MSc, PhD; Joia Nuñez[2], MD, MSc; Alba Xifra-Porxas[2], PhD; Francesca Aimée Mees Mlatiati[2], BEng, MSc; Ioannis Bilionis[2], BEng, MSc; Ricardo C Berrios[2], BSc; Luis Fernández-Luque[2], PhD

[1]Pediatric Endocrinology Unit, Miguel Servet Children's University Hospital, Zaragoza, Spain

[2]Adhera Health Inc, 101 Cooper St., Santa Cruz, CA, United States

Corresponding Author:
Luis Fernández-Luque, PhD
Adhera Health Inc, 101 Cooper St., Santa Cruz, CA, United States

Abstract

Background: Caregivers of children living with type 1 diabetes (T1D) face multiple challenges that significantly impact their mental health and quality of life. The well-being of caregivers directly affects the management of the child's condition. The Adhera Caring Digital Program (ACDP) is a comprehensive, digitally delivered program, designed to support family caregivers in enhancing self-management and well-being. This study aims to assess how the ACDP influences caregivers' mood, emotional well-being, and health-related quality of life within the context of T1D.

Objective: This study aimed to evaluate the impact of ACDP on caregivers' psychological well-being and caregiving outcomes.

Methods: This was a two-step, prospective, mixed methods study targeting caregivers of children living with T1D who were under the care of a pediatric endocrinologist at Miguel Servet Children's University Hospital in Zaragoza, Spain. In substudy 1 (SS1), qualitative and quantitative data were collected to optimize the ACDP. In substudy 2 (SS2), caregivers used the optimized ACDP for three months. Psychometric assessments were conducted at baseline and follow-up to evaluate positive mood states, general well-being, self-efficacy, and lifestyle behaviors. This paper focuses on SS2.

Results: Ninety caregivers participated in SS2. Positive affect significantly increased (P<.001), and negative affect decreased (P<.001) on the Positive and Negative Affect Schedule (PANAS). Depression, anxiety, and stress scores were reduced (P<.001) on the Depression, Anxiety and Stress Scale-21 Items (DASS-21). General well-being, measured by the Mental Health Continuum-Short Form (MHC-SF) and self-efficacy, assessed using General Self-Efficacy Scale (GSE), improved significantly (P<.001). Health-related quality of life (HrQoL) scores and Mediterranean Diet Quality Index scores increased modestly (P=.03, and P=.04, respectively).

Conclusions: The ACDP intervention improved caregivers' psychological well-being and self-efficacy. These findings highlight the potential of digital solutions to support caregiver mental health and positively influence diabetes management. Future research should explore long-term outcomes and scalability.

Trial Registration: ClinicalTrials.gov NCT05483803; https://clinicaltrials.gov/ct2/show/NCT05483803

(JMIR Pediatr Parent 2025;8:e66914) doi:10.2196/66914

KEYWORDS

type 1 diabetes; caregiver wellbeing; digital health; digital program; coaching; diabetic; diabetes; T1D; pediatrics; children; chronic; endocrinology; CGM; glucose; caregiving; caregiver; carer; informal care; family care; parents; parental; guardian; continuous glucose monitoring

Introduction

Children living with type 1 diabetes (T1D) face unique challenges, including deficient insulin production, psychosocial stress, stigmatization, social isolation, and bullying, which can negatively impact their quality of life [1,2]. Caregivers' are often the primary source of support for these children, and experience significant emotional burdens that are closely linked to the children's health–related quality of life (HrQoL) [3-7]. Therefore, addressing caregiver well-being is critical for holistic diabetes management [6].

Comprehensive strategies and programs that prioritize caregiver emotional health have shown promise in improving outcomes for both caregivers and children [8,9]. For instance, programs

XSL•FO
RenderX

such as PRISM-P (Promoting Resilience in Stress Management for Parents) have demonstrated the efficacy of resilience-building interventions for parents of children living with serious illnesses [9]. Positive mood states in caregivers are critical predictors of HrQoL in adolescents with T1D [10]. The diagnosis of a chronic condition such as T1D in a child is often stressful and potentially traumatic [11]. Furthermore, scalable digital interventions such as the Remedy to Diabetes Distress (R2D2) program underscore the growing need for innovative, technology-enabled solutions to address caregiver distress [12].

Achieving optimal HrQoL for children living with T1D may also require providing caregivers with personalized emotional and behavioral support [13]. This issue should be examined from the perspectives of mental health and technology acceptance theoretical frameworks [14]. The psychological well-being of caregivers is closely tied to the HRQoL and treatment adherence of children living with T1D [15]. For example, the PsyVoice study highlights the importance of understanding expectations surrounding voice-based digital health solutions to manage diabetes distress among children and their caregivers [16]. Furthermore, a recent narrative synthesis of systematic reviews underscores ongoing developments in the design and delivery of self-management support for children and young people with diabetes, emphasizing the necessity of tailored interventions to meet diverse needs [17].

The Adhera Caring Digital Program ACDP is a comprehensive, digitally delivered program designed to support the physical and mental well-being of caregivers of children living with chronic conditions. By providing personalized emotional and behavioral support, the ACDP seeks to improve self-management, mental health. and overall well-being for both patients and their families. This study evaluates the impact of the ACDP on caregivers' positive mood states, emotional health, and perceived HrQoL in the context of T1D.

Methods

Design and Setting

This study used a two-step, prospective, mixed methods (qualitative-quantitative) feasibility trial, composed of two substudies. Substudy (SS1) gathered qualitative and quantitative data to inform the optimization of the ACDP. Substudy 2 (SS2) evaluated the optimized intervention over a three-month period. Caregivers of children living with T1D under the care of a pediatric endocrinologist at the Miguel Servet Children's University Hospital (Zaragoza, Spain), following general clinical Spanish practices, participated in this study.

Sample Size and Eligibility Criteria

One hundred caregivers were recruited for SS2. Inclusion criteria were (1) caregivers who are legal guardians of children living with T1D under 18 years of age; (2) child's T1D diagnosis for at least three months; (3) use of continuous glucose monitor; (4) caregivers' willingness to use the mobile solution and share data.

Exclusion criteria included only one legal guardian per child could participate, prior participation in SS1, and incomplete or refusal to provide consent.

Digital Solution

The ACDP supports the physical and mental well-being of family caregivers of individuals with chronic conditions, enhancing self-management and health outcomes. This noninvasive, digitally delivered program offers condition-specific educational content, personalized motivational messages, and self-management tools, using data from wearables and patient-reported outcomes. It includes Adhera Collaboration, a health coaching service, and leverages the Adhera Health AI-driven Health Recommender System for personalized interventions. ACDP is part of the Adhera Health Precision Digital Companion Platform, developed according to best practices in data protection and quality management, following ISO 27001 and ISO 13465 guidelines. The family caregivers accessed the digital program via a mobile application which is compatible with both Android and Apple operative systems. Screenshots of the ACDP can be found in the Multimedia Appendix 1.

The ACDP was applied to families managing T1D due to the significant caregiving demands associated with this condition. The program was tailored to address the psychological and emotional challenges faced by caregivers in supporting children with T1D, including continuous glucose monitoring, insulin management, and responding to hypoglycemic and hyperglycemic events. These challenges made T1D an optimal use case for evaluating the intervention's impact on caregiver well-being.

Study Procedures

SS1 aimed to identify caregivers' psychological burdens and perceived barriers and facilitators associated with adopting the ACDP. Participants used the digital intervention for one month, and their feedback was used to generate an optimized version of the platform. Full details of SS1 can be found in Multimedia Appendix 1.

SS2 assessed the impact of the optimized ACDP on caregivers' psychological well-being, mood and HrQoL. Demographic data collected included caregiver gender, age, marital status, and education level, as well as the children's gender, age, and time since T1D diagnosis. These characteristics were analyzed to understand the context and diversity of the caregiving population. Furthermore, psychometric assessments used in this study included the following validated surveys:

- Positive and Negative Affect Schedule (PANAS**)** measures positive and negative affect. Higher scores on the positive affect subscale indicate greater positive emotions, while higher scores on the negative affect subscale indicate greater negative emotions.
- Depression, Anxiety, and Stress Scale (DASS-21) evaluates emotional distress across three domains, including depression, anxiety, and stress. Higher scores indicate greater levels of distress in each domain.
- Mental Health Continuum-Short Form (MHC-SF) assesses general well-being across emotional, psychological, and

XSL•FO
RenderX

social domains. Higher scores reflect better overall mental well-being.
- General Self-Efficacy Scale (GSE**)** measures confidence in managing challenging situations. Higher scores indicate greater self-efficacy.
- Clarke Questionnaire typically applied to patients with diabetes to assess hypoglycemia awareness; in this study. it was adapted to capture caregivers' awareness and understanding of hypoglycemic episodes in their children. Higher scores suggest better awareness and understanding of hypoglycemia.
- KIDSCREEN-10 measures HRQoL in children. Higher scores indicate better HRQoL.
- Mediterranean Diet Quality Index (KIDMED**)** assesses adherence to a Mediterranean diet. Higher scores reflect greater adherence to a Mediterranean dietary pattern.

While KIDSCREEN-10 and KIDMED are primarily validated for ages 8 - 18, caregivers completed them to provide insight into their perception of the child's quality of life and dietary habits, respectively. Their inclusion aimed to explore indirect caregiver influences on child health behaviors.

Intervention and Measures

The recruitment for SS2 took two months, and participants joined ACDP for three months. Caregivers were onboarded to the Adhera platform through an initial in-person training session at the study site. This session included a demonstration of platform functionality, account setup, and navigation support. Data were collected through the Adhera platform's integrated survey tools, which allowed participants to complete assessments digitally. Additionally, demographic and baseline data were gathered via paper forms during the initial study visit. At baseline and at follow-up, the data collected included (1) demographic data; (2) multiple daily injections and continuous subcutaneous insulin infusion questionnaire (insulin delivery methods); (3) positive mood by PANAS, (4) distress by DASS-21, general wellbeing by MHC-SF, self-efficacy by GSE; (5) lifestyle questionnaires by KIDMED; (6) hypoglycemia awareness by Clarke questionnaire; (7) Quality of life (HrQoL) by KIDSCREEN-10; (8) system usability scale (SUS; only at 3 months), and (9) continuous glucose monitoring.

Data Management and Quality Control

All the data gathered in the study was recorded in MicroSoft Forms at Adhera Health servers. Data were processed, evaluated, and stored in an anonymous form following the General Data Protection Regulation (GDPR) regulations. Adhera Health was responsible for data processing in accordance with its data management and quality procedures. Data quality and integrity were ensured through ISO 27001, which is related to the quality management system for ensuring information security.

Statistical Analysis

Baseline demographic and clinical characteristics of the study cohort were summarized using means (SD) for continuous variables, and frequencies with percentages for categorical variables. Mean values (SD) were presented for each psychometric outcome (eg, stress, quality of life, depressive symptoms) were calculated at baseline (preintervention) and after the 3-month intervention (postintervention). Differences in pre- and postintervention questionnaire scores were assessed using a parametric paired *t* test or a nonparametric Wilcoxon signed-rank test, as appropriate, depending on whether the normality and homogeneity assumptions of the *t* test were met. Effect sizes (η^2) were calculated to gauge the magnitude of any significant differences. All hypothesis tests were two-sided, and statistical significance was defined as $P<.05$. The statistical analysis was conducted using the Python packages *scipy* (version 1.14.1) and *pingouin* (version 0.5.5).

Ethical Considerations

All procedures performed in this study were in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study posed minimal risk to the participants. The anonymized information collected was handled following the right of privacy and anonymity according to the rules of GDPR (EU Regulation 2016/679). Prior to the commencement of the study at Miguel Servet University Hospital, the protocol and its associated documents (information sheet for the patient and informed consent form) were submitted to the CEICA (Aragonese Ethical Committee for Clinical Research). A written favorable opinion or approval was obtained from CEICA. Written informed consent to participate in the study was obtained from all patients before any study-related activities were carried out. Moreover, to comply with local regulations, for children 12 years and older, additional consent was obtained. Data were anonymized as per GDPR standards. The study participants were not compensated monetarily. However, they were provided with free access to the digital health platform for the duration of the study, which included tailored support and resources.

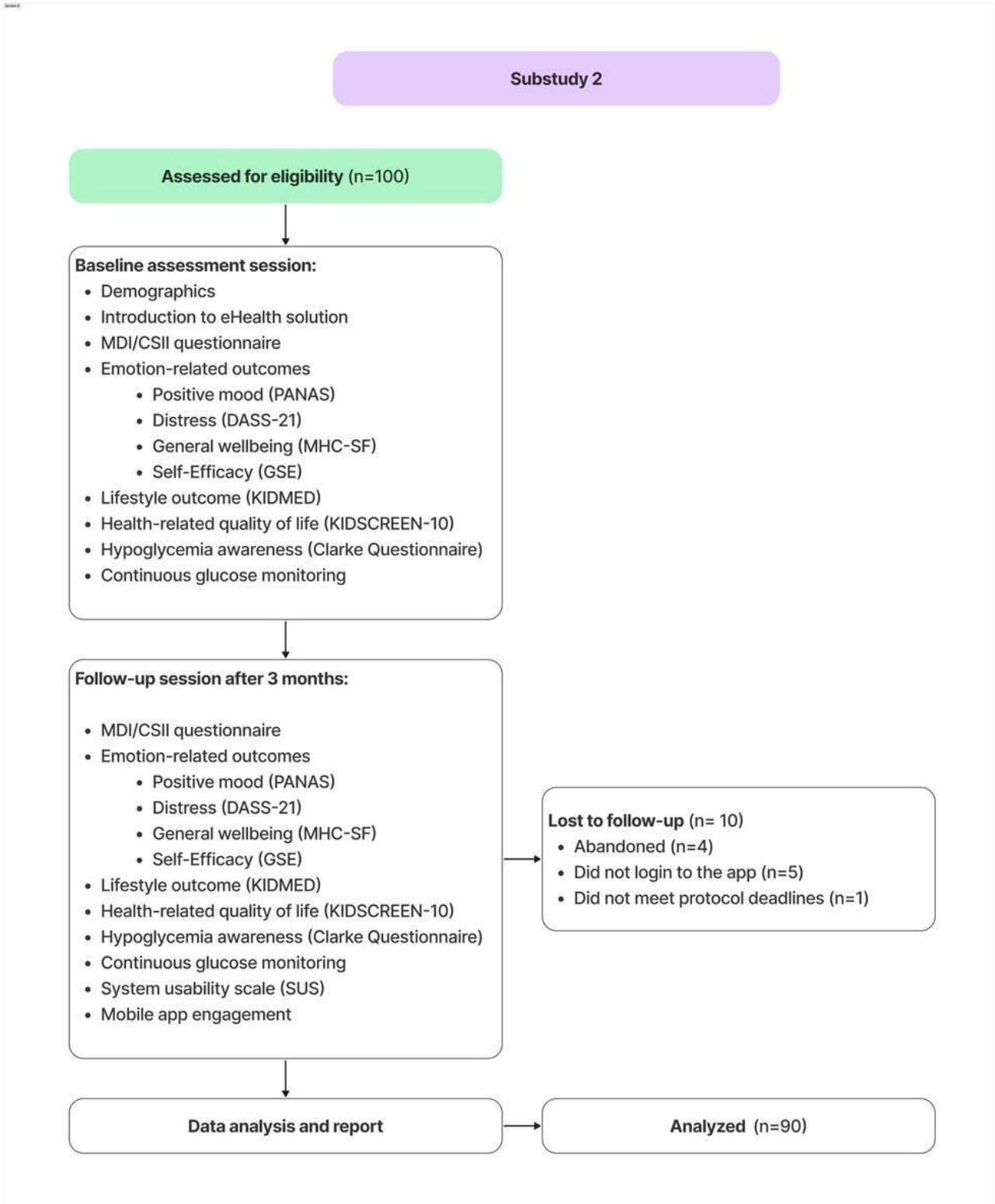
Results

Demographics

Of the 100 caregivers recruited, 90 completed the study (Figure 1). Reasons for drop out were as follows: 4 caregivers abandoned the study, 5 did not log in to the application, and 1 did not meet the protocol deadlines. Participants' mean age was 45.15 (SD 6.03) years, and they were predominantly female (71/90, 78.9%). The mean age of the children was 10.78 (SD 3.34) years, with a mean time since diagnosis of 4.42 (SD 3.38) years. Full demographic details are provided in Table 1. The differences in pre- and postintervention questionnaire are presented in Table 2.

XSL•FO
RenderX

Figure 1. Substudy 2 diagram. DASS-21:depression, anxiety and stress scale-21 items; GSE: general self-efficacy scale; MDI/CSII: multiple daily injections and continuous subcutaneous insulin infusion; MHC-SF: mental health continuum-short form; PANAS: positive and negative affect schedule; SUS: system usability scale.



XSL•FO
RenderX

Table . Demographics of participants of substudy 2.

Characteristics	Participants (N=90), n (%)
Caregiver's gender, n (%)	
Men	19 (21.1)
Women	71 (78.9)
Caregiver's age (years), mean (SD)	45.27 (5.04)
Caregiver's marital status, n (%)	
Single	3 (3.4)
Married	79 (87.8)
Divorced	8 (8.9)
Education, n (%)	
Primary education	2 (2.2)
Secondary education/high school	13 (14.4)
Professional training	35 (38.9)
University degree	40 (44.4)
Child's gender, n (%)	
Male	51 (56.7)
Female	39 (43.3)
Child's age (years), mean (SD)	10.78 (3.33)
Time since diagnosis (years), mean (SD)	4.42 (3.38)
Therapy, n (%)	
CSII[a]	46 (51.1)
MDI[b]	44 (48.9)

[a]CSII: subcutaneous insulin infusion.

[b]MDI: multiple daily injections.

XSL•FO
RenderX

Table . Comparison of family caregiver characteristics at baseline and three months after the start of the intervention in Substudy 2.

Variables	At baseline (mean, SD)	At 3 months (mean, SD)	*t* test (*df*)/nonparametric test	*P* value	Effect size (η^2)[a]
PANAS[b]					
Positive affect	34.26 (7.69)	37.40 (6.95)	-4.7[c]	<.001	.044
Negative affect	24.34 (8.83)	21.23 (8.36)	941.0[d]	<.001	.032
DASS-21[e]					
Depression scale	4.21 (4.65)	2.96 (3.90)	550.5[d]	<.001	.021
Anxiety scale	3.54 (4.24)	2.50 (3.65)	362.5[d]	<.001	.017
Stress scale	8.98 (5.30)	5.75 (4.7)	536.5[d]	<.001	.048
MHC-SF[f]					
General well-being	0.61 (0.19)	0.67 (0.17)	-3.4[c]	.001	.021
Emotional well-being	0.62 (0.21)	0.70 (0.22)	661.0[d]	<.001	.028
Psychological well-being	0.68 (0.21)	0.72 (0.17)	957.5[d]	.02	.011
Social well-being	0.52 (0.22)	0.58 (0.22)	741.5[d]	<.001	.017
GSE[g]	30.44 (5.18)	32.28 (4.81)	785.5[d]	<.001	.033
KIDSCREEN-10 index					
Total Score (T-value)	57.76 (15.22)	60.39 (15.58)	1164.5[d]	.03	.007
KIDMED questionnaire	8.60 (1.80)	9.00 (1.90)	716.0[d]	.04	.011
Knowledge of T1D[h]	7.47 (2.18)	7.59 (1.66)	1092.5[d]	.62	<.001
Clarke hypoglycemia score	2.60 (1.06)	2.48 (1.01)	496.5[d]	.22	.003

[a]η^2>0.01 indicates a significant effect.

[b]PANAS: positive and negative affect schedule.

[c]*t* test (89).

[d]Nonparametric test.

[e]DASS-21: depression, anxiety and stress scale-21 item.

[f]MHC-SF: mental health continuum-short form..

[g]GSE: general self-efficacy scale..

[h]T1D: type 1 diabetes.

Pre-Post Intervention Results

Significant improvements were observed across multiple outcomes (see Table 2). Positive affect increased from 34.26 (SD 7.69) to 37.40 (SD 6.95; *P*<.001) on the PANAS. Negative affect decreased from 24.34 (SD 8.83) to 21.23 (SD 8.36; *P*<.001) on the PANAS. Depression, anxiety, and stress scores on the DASS-21 significantly reduced across all domains, including significant decreases in depression (mean difference =1.25, *P*<.001), anxiety (mean difference=1.04; *P*<.001), and stress (mean difference=3.23; *P*<.001).

General well-being, as assessed by the MHC-SF, showed significant improvements across domains such as general well-being (mean change=0.06; *P*=.001), emotional (mean change=0.08; *P*<.001), psychological (mean change = 0.04; *P*=.02), and social well-being (mean change=0.06, *P*<.001). The GSE scores increased from 30.44 (SD 5.18) to 32.28 (SD 4.81; *P*<.001) and the HRQoL scores improved significantly (*P*=.03). The Mediterranean Diet Quality Index scores were also improved (*P*=.04).

Discussion

Principal Findings

This feasibility study shows that a 3-month digital intervention can significantly improve the psychological wellbeing and emotional health of caregivers of children living with T1D. The intervention effectively increased positive affect, decreased negative affect, and reduced depression, anxiety, and stress levels among caregivers. These findings align with existing

XSL•FO
RenderX

research emphasizing the importance of caregiver support in pediatric chronic condition management [18,19].

The observed improvements in survey scores suggest clinically meaningful benefits. For example, reductions in DASS-21 scores correspond to a shift from moderate to mild emotional distress categories for many participants, reflecting improved mental health. Similarly, increases in PANAS positive affect scores and MHC-SF well-being scores indicate enhanced emotional and psychological resilience. These clinically significant changes underscore the impact of the ACDP on caregiver well-being and its potential to support families managing T1D. Higher self-efficacy is associated with better coping strategies and more effective problem-solving [15,20]. Although improvements in T1D knowledge and hypoglycemia awareness were not statistically significant, the observed trends suggest potential benefits [21]. It is possible that with a larger sample size or a longer intervention period, these trends could reach statistical significance, providing a more comprehensive understanding of the intervention's impact.

Caregiver burden has been strongly linked to adverse psychological effects, including depression, family dysfunction, and difficulties in glycemic control [7,22]. Addressing these challenges is essential for both caregiver well-being and effective diabetes management in children. The combination of digital coaching, motivational messaging, and tailored interventions in ACDP offers a structured approach to alleviating caregiver distress. Additionally, resilience plays a crucial role in mitigating the negative impact of caregiver burden on quality of life [11]. The improvements in self-efficacy and emotional well-being observed in this study highlight how digital interventions can empower caregivers with better coping mechanisms and stress management strategies.

Moreover, the observed improvements in caregiver psychological well-being and self-efficacy align with prior studies, such as PRISM-P and R2D2, which have demonstrated the efficacy of resilience-building and digital health interventions in supporting families managing chronic conditions [9,12]. For instance, the PANAS and DASS-21 score changes in this study are comparable to those reported in similar interventions, indicating a meaningful reduction in caregiver distress and an increase in positive affect. Furthermore, the MHC-SF improvements reflect better emotional and social functioning, consistent with findings from resilience-focused digital interventions. These results underscore the potential of personalized, tech-enabled support to fill critical gaps in caregiver support, as highlighted by Yu et al [21]. However, this study uniquely integrates personalized modules and psychometric assessments tailored to caregivers of children living with T1D, addressing a distinct population need. The significant improvements observed in this study demonstrate the scalability and real-world applicability of the ACDP for enhancing caregiver and family well-being.

This study has several strengths. First, it leverages a personalized digital intervention tailored specifically for caregivers of children with T1D, addressing an important but often overlooked population. The integration of psychometric assessments and AI-driven personalization ensures that the intervention adapts to individual caregiver needs, enhancing its real-world applicability. Additionally, the study employs a mixed methods approach, combining validated psychometric tools with engagement metrics to provide a comprehensive understanding of both subjective and objective outcomes.

Despite these positive outcomes, the study has limitations. The sample size, although adequate for a feasibility study, limits the generalizability of the findings. Additionally, the intervention's three-month duration may not capture long-term sustainability of the observed benefits. Potential biases in self-reported data and a lack of a control group further constrain the robustness of conclusions. Future research should focus on exploring the long-term effects of digital interventions and their potential to include other domains of caregiver and child well-being. Additionally, examining the cost-effectiveness of such interventions could provide valuable insights for health care providers and policymakers considering the implementation of digital support programs for caregivers.

However, the study's findings are promising, indicating that digital interventions can effectively support caregivers' psychological and emotional well-being. The significant improvements in affect, mental health, self-efficacy, and quality of life highlight the potential of such interventions to enhance the caregiving experience and ultimately benefit the well-being of children living with T1D [21]. While improvements in emotional well-being and self-efficacy may indirectly influence caregiving behaviors, these were not directly targeted or assessed in this study. Future research could explore the potential behavioral impacts of digital interventions such as the ACDP.

Conclusions

The ACDP has demonstrated significant potential in supporting caregivers of children living with T1D. By improving psychosocial well-being and self-efficacy, the intervention offers a scalable solution for enhancing caregiving experiences and, ultimately, child health outcomes. Further studies are warranted to explore long-term impacts and broader applications.

Acknowledgments

This investigator-sponsored study has been funded by Novo Nordisk and Anne-Marie Kappelgaard Scholarship for Research in Pediatric Endocrinology. We would like to thank the contributors to this study, particularly the participating families, the clinical team at Hospital Miguel Servet, and the team at Adhera Health.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request

XSL•FO
RenderX

Authors' Contributions

Conceptualization: AdAM, LFL, RCB
Data curation: ECM, MPF, MFL,
Formal analysis: AXP, FAMM, IB
Methodology: AdAM, LFL, IB, SQP
Project administration: AdAM, ECM, MPF, MFL, LFL, SQP
Supervision: LFL, AdAM,
Writing – original draft – SQP, JN
Writing – review & editing: AdAM, AXP, ECM, FAMM, IB, JN, MPF, MFL, LFL, RCB, SQP

Conflicts of Interest

AXP, IB, RCB, SQP, and LFL are current employees at Adhera Health; JN and FAMM are former employees.

Multimedia Appendix 1
Substudy 1 and Adhera Caring Digital Program information and captions.
[DOCX File, 935 KB - pediatrics_v8i1e66914_app1.docx]

References

1. Andrade CDN, Alves CDA. Relationship between bullying and type 1 diabetes mellitus in children and adolescents: a systematic review. J Pediatr (Rio J) 2019;95(5):509-518. [doi: 10.1016/j.jped.2018.10.003] [Medline: 30391140]
2. Nieuwesteeg A, Pouwer F, van der Kamp R, van Bakel H, Aanstoot HJ, Hartman E. Quality of life of children with type 1 diabetes: a systematic review. Curr Diabetes Rev 2012 Nov;8(6):434-443. [doi: 10.2174/157339912803529850] [Medline: 22934548]
3. Alsaigh R, Coyne I. Mothers' experiences of caring for children receiving growth hormone treatment. J Pediatr Nurs 2019;49:e63-e73. [doi: 10.1016/j.pedn.2019.09.005] [Medline: 31575443]
4. Eckshtain D, Ellis DA, Kolmodin K, Naar-King S. The effects of parental depression and parenting practices on depressive symptoms and metabolic control in urban youth with insulin dependent diabetes. J Pediatr Psychol 2010 May;35(4):426-435. [doi: 10.1093/jpepsy/jsp068] [Medline: 19710249]
5. Carona C, Silva N, Crespo C, Canavarro MC. Caregiving burden and parent-child quality of life outcomes in neurodevelopmental conditions: the mediating role of behavioral disengagement. J Clin Psychol Med Settings 2014 Dec;21(4):320-328. [doi: 10.1007/s10880-014-9412-5] [Medline: 25228103]
6. Celano M, Bakeman R, Gaytan O, Smith CO, Koci A, Henderson S. Caregiver depressive symptoms and observed family interaction in low-income children with persistent asthma. Fam Process 2008 Mar;47(1):7-20. [doi: 10.1111/j.1545-5300.2008.00236.x] [Medline: 18411827]
7. Azimi T, Johnson J, Campbell SM, Montesanti S. Caregiver burden among parents of children with type 1 diabetes: A qualitative scoping review. Heliyon 2024 Mar 30;10(6):e27539. [doi: 10.1016/j.heliyon.2024.e27539] [Medline: 38524615]
8. Raina P, O'Donnell M, Schwellnus H, et al. Caregiving process and caregiver burden: conceptual models to guide research and practice. BMC Pediatr 2004 Jan 14;4:1. [doi: 10.1186/1471-2431-4-1] [Medline: 14723791]
9. Yi-Frazier JP, Fladeboe K, Klein V, et al. Promoting Resilience in Stress Management for Parents (PRISM-P): an intervention for caregivers of youth with serious illness. Fam Syst Health 2017 Sep;35(3):341-351. [doi: 10.1037/fsh0000281] [Medline: 28541057]
10. Lord JH, Rumburg TM, Jaser SS. Staying positive: positive affect as a predictor of resilience in adolescents with type 1 diabetes. J Pediatr Psychol 2015 Oct;40(9):968-977. [doi: 10.1093/jpepsy/jsv042] [Medline: 25979081]
11. Luo D, Gu W, Bao Y, et al. Resilience outstrips the negative effect of caregiver burden on quality of life among parents of children with type 1 diabetes: an application of Johnson-Neyman Analysis. J Clin Nurs 2021 Jul;30(13-14):1884-1892. [doi: 10.1111/jocn.15739] [Medline: 33656212]
12. Patton SR, Pierce JS, Fox L, Benson M, Mc Donough R, Clements MA. Remedy to Diabetes Distress (R2D2): development protocol for a scalable screen-to-treat program for families of school-age children. Contemp Clin Trials 2022 Aug;119:106829. [doi: 10.1016/j.cct.2022.106829] [Medline: 35716992]
13. López-Bastida J, López-Siguero JP, Oliva-Moreno J, et al. Health-related quality of life in type 1 diabetes mellitus pediatric patients and their caregivers in Spain: an observational cross-sectional study. Curr Med Res Opin 2019 Sep 2;35(9):1589-1595. [doi: 10.1080/03007995.2019.1605158]
14. Mohr DC, Schueller SM, Montague E, Burns MN, Rashidi P. The behavioral intervention technology model: an integrated conceptual and technological framework for eHealth and mHealth interventions. J Med Internet Res 2014 Jun 5;16(6):e146. [doi: 10.2196/jmir.3077] [Medline: 24905070]
15. Thorsteinsson EB, Loi NM, Rayner K. Self-efficacy, relationship satisfaction, and social support: the quality of life of maternal caregivers of children with type 1 diabetes. PeerJ 2017;5:e3961. [doi: 10.7717/peerj.3961] [Medline: 29085757]

XSL•FO
RenderX

16. Aguirre Vergara F, Fischer A, Seuring T, de Beaufort C, Fagherazzi G, Aguayo GA. Mixed-methods study protocol to identify expectations of people with type 1 diabetes and their caregivers about voice-based digital health solutions to support the management of diabetes distress: the PsyVoice study. BMJ Open 2023 Sep 13;13(9):e068264. [doi: 10.1136/bmjopen-2022-068264] [Medline: 37709324]
17. Litchfield I, Barrett T, Hamilton-Shield JP, et al. Developments in the design and delivery of self-management support for children and young people with diabetes: a narrative synthesis of systematic reviews. Diabet Med 2023 Apr;40(4):e15035. [doi: 10.1111/dme.15035] [Medline: 36576331]
18. Whittemore R, Jaser S, Chao A, Jang M, Grey M. Psychological experience of parents of children with type 1 diabetes: a systematic mixed-studies review. Diabetes Educ 2012;38(4):562-579. [doi: 10.1177/0145721712445216] [Medline: 22581804]
19. Bassi G, Mancinelli E, Di Riso D, Salcuni S. Parental stress, anxiety and depression symptoms associated with self-efficacy in paediatric type 1 diabetes: a literature review. Int J Environ Res Public Health 2020 Dec 28;18(1):152. [doi: 10.3390/ijerph18010152] [Medline: 33379307]
20. Grover S, Bhadada S, Kate N, et al. Coping and caregiving experience of parents of children and adolescents with type-1 diabetes: An exploratory study. Perspect Clin Res 2016;7(1):32-39. [doi: 10.4103/2229-3485.173776] [Medline: 26955574]
21. Yu J, Wang Y, Wang H, et al. Association between eHealth literacy, diabetic behavior rating, and burden among caregivers of children with type 1 diabetes: cross-sectional survey study. J Pediatr Nurs 2023;73:1-6. [doi: 10.1016/j.pedn.2023.08.012] [Medline: 37597400]
22. Balcázar-Hernández L, Huerta-Martínez H, Garrido Magaña E, Nishimura-Meguro E, Jiménez Márquez A, Rivera-Hernández A. Burden in primary informal caregivers of children and adolescents with type 1 diabetes: Is it associated with depression, family dysfunction, and glycemic control? Front Endocrinol (Lausanne) 2022;13:1089160. [doi: 10.3389/fendo.2022.1089160] [Medline: 36743923]

Abbreviations

ACDP: Adhera Caring Digital Program
DASS-21: depression, anxiety and stress scale-21 items
GDPR: General Data Protection Regulation
GSE: general self-efficacy scale
HrQoL: health-related quality of life
MHC-SF: mental health continuum-short form
PANAS: positive and negative affect schedule
SS1: Substudy 1
SS2: Substudy 2
T1D: type 1 diabetes

Edited by S Badawy; submitted 01.10.24; peer-reviewed by SN Mehta, S Amed; revised version received 19.02.25; accepted 18.03.25; published 09.07.25.

Please cite as:
de Arriba Muñoz A, Civitani Monzon E, Ferrer MP, Ferrer-Lozano M, Quer-Palomas S, Nuñez J, Xifra-Porxas A, Aimée Mees Mlatiati F, Bilionis I, Berrios RC, Fernández-Luque L
Empowering Caregiver Well-Being With the Adhera Caring Digital Program for Family Caregivers of Children Living With Type 1 Diabetes: Mixed Methods Feasibility Study
JMIR Pediatr Parent 2025;8:e66914
URL: https://pediatrics.jmir.org/2025/1/e66914
doi:10.2196/66914

© Antonio de Arriba Muñoz, Elisa Civitani Monzon, Maria Pilar Ferrer, Marta Ferrer-Lozano, Silvia Quer-Palomas, Joia Nuñez, Alba Xifra-Porxas, Francesca Aimée Mees Mlatiati, Ioannis Bilionis, Ricardo C Berrios, Luis Fernández-Luque. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 9.7.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Effects of the Jump Step Kids Program on Functional Movement and Self-Report Outcomes in Children Aged 7 to 12 Years With Chronic Ankle Instability: Randomized Controlled Trial

Kitiyawadee Srisim[1], PhD; Supannikar Yingyongsaksri[2], PhD; Janya Chuadthong[1,3], PhD

[1]Department of Physical Therapy, School of Integrative Medicine, Mae Fah Luang University, 333 Moo 1, Thasud Subdistrict, Muang District, Chiang Rai, Thailand

[2]Faculty of Physical Therapy, Mahidol University, Nakhon Pathom, Thailand

[3]Research Group on Smart Integrative Medicine and Technology Sustainability, Mae Fah Luang University, Chiang Rai, Thailand

Corresponding Author:
Janya Chuadthong, PhD
Department of Physical Therapy, School of Integrative Medicine, Mae Fah Luang University, 333 Moo 1, Thasud Subdistrict, Muang District, Chiang Rai, Thailand

Abstract

Background: Chronic ankle instability (CAI) is a common musculoskeletal problem in children, characterized by mechanical instability, perceived instability, and recurrent sprains. Inadequate rehabilitation can cause symptoms to persist, increase the risk of reinjury, and negatively affect long-term quality of life. Research on the rehabilitation of children with CAI concerning ankle stability, running speed, and agility has been limited. Therefore, the Jump Step Kids (JSKs) program was developed as a rhythmic, multidirectional jumping program to improve functional movement and agility in children with CAI.

Objective: This study aimed to investigate the effects of the JSKs program on functional movement and self-reported outcomes in children aged 7 to 12 years with CAI.

Methods: A stratified, randomized controlled trial was conducted involving 34 school-aged children with CAI. Participants were randomly allocated to either the intervention group (n=17), which underwent the JSKs program supervised by a physiotherapist, or the control group (n=17), which performed a home-based stretching program for ankle instability. Both groups participated in 30-minute sessions, 3 times per week, for 4 weeks. Outcome measurements were the heel raise test (HRT), standing long jump test, 6-meter crossover hop test, the Bruininks-Oseretsky Test of Motor Proficiency-second edition (BOT-2), and the Foot and Ankle Ability Measure questionnaire. Assessments were performed at baseline and after 4 weeks of training.

Results: After 4 weeks, both groups improved in the 6-meter crossover hop test (JSKs: mean 6.60, SD 2.47 s; P=.02; and control: mean 6.82, SD 3.45 s; P=.04). The JSKs group performed better than the control group in the HRT (mean 37.88, SD 11.85 repetitions vs mean 27.65, SD 7.65 repetitions; P=.005), whereas the standing long jump test improved in the control group (mean 104.56, SD 21.88 cm to mean 112.05, SD 19.95 cm; P=.04). For BOT-2 outcomes, the 1-legged stationary hop decreased in controls (mean 35.35, SD 5.45 repetitions to mean 30.24, SD 9.21 repetitions; P=.01), with significant between-group differences (mean 38.18, SD 9.53 repetitions vs mean 30.24, SD 9.21 repetitions; P=.02). The 2-legged side hop improved in both groups (JSKs: mean 12.24, SD 4.54 repetitions to mean 25.24, SD 7.40 repetitions; control: mean 11.47, SD 3.81 repetitions to mean 26.53, SD 6.88 repetitions; P<.001). Self-reported outcomes, including Foot and Ankle Ability Measure-Activities of Daily Living and sports scores, did not differ significantly between groups (P>.05).

Conclusions: The 4-week JSKs program improved functional performance in children with CAI compared with the control group in HRT and BOT-2 outcomes, although self-reported function remained unchanged. These findings provide preliminary evidence supporting the potential efficacy of the JSKs program for children with CAI. The program may serve as an addition to conventional therapy to improve physical performance in the pediatric population.

Trial Registration: Thai Clinical Trials Registry TCTR20220727002; https://www.thaiclinicaltrials.org/show/TCTR20240515002

(JMIR Pediatr Parent 2025;8:e81860) doi:10.2196/81860

KEYWORDS

chronic ankle instability; children; pediatric rehabilitation; functional movement; ankle strength; dynamic balance; agility; motor proficiency; Jump Step Kids program; randomized controlled trial

XSL•FO
RenderX

Introduction

Chronic ankle instability (CAI) is a common musculoskeletal condition, especially among active populations, notably children [1]. CAI consists of mechanical instability (MI), recurrent sprains, and perceived instability, which can occur separately or together [2]. In children, the prevalence is notably high in those with a history of lateral ankle sprain, 23% to 71% develop instability symptoms, and 18% to 47% develop MI [1]. A recent study on school-aged children found that 36.6% of those aged 7 to 12 met CAI criteria, with MI, perceived instability, and recurrent sprains reported at 11.6%, 35.3%, and 27.3%, respectively [3].

An updated CAI model suggests that primary injury to the lateral ankle ligaments may cause sensory-perceptual and motor-behavioral impairments, which in turn impact clinical outcomes [4]. These include joint laxity, pain, reduced range of motion, decreased joint position sense, altered reflexes, and perceived instability, all of which negatively affect quality of life. In children, ankle instability has been linked to reduced functional movement, such as standing long jump performance, balance, and physical activity, compared with those without instability [5]. While perceived ankle instability influences function, self-reported outcomes, such as the Foot and Ankle Ability Measure (FAAM), have not shown noticeable differences between groups [6]. Additionally, other functional aspects—such as ankle function, stability, running speed, and agility—have not been systematically evaluated or trained in children with CAI.

Inadequate rehabilitation can extend symptoms, raise reinjury risk, and compromise long-term quality of life [4]. Therefore, effective programs are crucial. Plyometric training, which utilizes rapid stretch-shortening cycles to enhance neuromuscular control, has been demonstrated to improve balance, power, agility, and functional performance in individuals with functional ankle instability [7]. However, traditional programs may lack engagement and reduce adherence, especially in children. Recent studies using exergaming and active video games have demonstrated benefits in balance, foot and ankle function, and motivation in children with CAI, but their progression and challenge levels remain limited [6,8].

To address this gap, the Jump Step Kids (JSKs) program was created as a structured, plyometric-based intervention designed for children with CAI. Incorporating rhythm, music, and agility-based jump patterns, the program aims to improve functional outcomes while maintaining an enjoyable experience. This study examines the effects of the JSKs program on functional movement and self-reported outcomes in children aged 7 to 12 years with CAI. We hypothesized that participation would improve functional movement and foot and ankle ability, offering practical guidance for pediatric rehabilitation programs.

Methods

Study Design and Participants

This study was a single-blind (assessor-blind), stratified randomized controlled trial. The sample size was calculated using G*Power (v3.1.9.4; Heinrich Heine University Düsseldorf) for comparing 2 independent means, with α=.05 and a power of 0.80 [9], accounting for a 20% dropout rate, resulting in 34 participants (17 per group).

Thirty-four children aged 7 to 12 years with CAI from rural primary schools were recruited to participate in this study. The inclusion criteria are as follows: (1) a history of unilateral ankle sprain at least 1 year before the study [10], (2) had experienced ankle instability or *giving way* at least twice within the 6 months before the study [10], (3) Cumberland Ankle Instability Tool-Youth Thai version score ≤25 [9], (4) BMI within the normal range (5th to 85th percentile) according to the United States Centers for Disease Control and Prevention (CDC) growth chart [11], (5) no pain in the lower extremities at the time of participation, (6) ability to understand and follow instructions given by the researchers, and (7) ability to recognize and read numbers 1 to 9. The exclusion criteria were as follows: (1) acute ankle injury within 3 months before the study, (2) presence of comorbidities such as heart disease, attention deficit hyperactivity disorder, autism spectrum disorder, or asthma, (3) foot deformities, (4) history of surgery on the lower extremities, (5) history of bone fractures in the lower limbs, (6) uncontrolled health conditions including seizure disorders or uncorrected vision problems, and (7) receiving other ongoing treatments related to lower limb injuries.

Ethical Considerations

This study was approved by the Human Research Ethics Committee of Mae Fah Luang University (EC 23146 - 25, COA No. 250/2023) and conducted in accordance with the Declaration of Helsinki. Before participation, written informed consent was obtained from the legal guardians, and an assent form for the children included in the study guaranteed the protection of participants' rights and safety. All research activities were conducted in accordance with ethical standards, including strict adherence to privacy and confidentiality principles, to protect the data and identities of participants. Participants received compensation of 100 Thai Baht per visit to cover time and travel expenses, with no coercive intent.

Outcome Measurements

Overview

The 34 eligible participants were randomly stratified by age and gender and assigned to 2 groups: 17 participants received the JSKs program, and 17 participants received a home-based stretching program. Functional movement and self-reported outcomes were assessed before and after the 4-week training period. All assessments were conducted by a single trained assessor who was blinded to the group assignment. The assessments included the following tests.

XSL•FO
RenderX

Heel Raise Test

The heel raise test (HRT) was used to assess calf muscle strength and endurance [12]. Before testing, participants performed their highest possible heel raise to establish a reference height. They were then instructed to perform as many single-leg heel raises as possible within 30 seconds. The number of valid repetitions—completed without allowing the non-testing foot to touch the ground or losing balance—was recorded for analysis [13].

Standing Long Jump Test

The standing long jump test (SLJT), a strength subtest of the Bruininks-Oseretsky Test of Motor Proficiency, Second Edition (BOT-2), was used to assess lower extremity muscle strength [14]. Participants stood behind a starting line with their feet shoulder-width apart and performed a forward jump as far as possible. The distance from the starting line to the nearest heel upon landing was measured in centimeters. Each participant completed 1 trial, with a second trial permitted only if they stumbled or fell during the first attempt.

Six-Meter Crossover Hop Test

The 6-meter crossover hop test (6mCHT) is a dynamic test that assesses ankle function and stability. Participants stood on their injured leg, arms free, and jumped as fast as they could in a diagonal pattern across 2 parallel lines spaced 15 cm apart for 6 meters. The test was repeated if the untested foot did not contact the ground, lost balance, or crossed the tape line incorrectly. The assessor recorded the time taken in seconds. The test was performed 3 times, and the average time was analyzed [15].

Shuttle Run

The shuttle run, a subtest of the BOT-2, was used to assess speed and agility in children [14]. Participants stood behind the starting line and sprinted as fast as possible to retrieve blocks placed 15.24 meters away, then returned to the starting line. One trial was performed, with a second trial administered only if the participant tripped or failed to retrieve the blocks. The time in seconds was used for analysis [14].

Stepping Sideways Over a Balance Beam

This is a running speed and agility subtest of the BOT-2. Participants stood beside the beam with feet together and hands on hips, then stepped laterally across it, alternating feet continuously for 15 seconds. A second trial was allowed only if they tripped or fell. The number of correct steps was recorded for analysis [14].

One-Legged Stationary Hop

This is another running speed and agility subtest of the BOT-2. The participants stood on the injured leg, hands on the hips, then hopped up and down on the injured leg for 15 seconds. A second attempt was performed only if the subject tripped or fell during the first attempt. The number of correct attempts for statistical analysis [14].

One-Legged Side Hop

This is also a running speed and agility subtest of the BOT-2. Participants stood on the injured leg behind a line, hands on hips, and hopped vertically on the injured leg across the line to the left and right continuously for 15 seconds. A second test was performed if the participant tripped or fell during the test. The number of successful jumps was used for analysis [14].

Two-Legged Side Hop

This is a running speed and agility subtest of the BOT-2. Participants stood feet together parallel to a line with hands on hips, hopped both feet sideways across the line simultaneously for 15 seconds. A second trial is performed if they trip or fall. The number of correct hops was recorded [14].

FAAM-Thai Version

The FAAM is a 5-point scale self-reported questionnaire used for foot and ankle conditions [16]. It comprises 2 subscales including the 21 Activities of Daily Living (ADL) and 8 Sports scale, with a total score of 84 (ADL) and 32 (Sports), then converted into percentages (100%=full function; 0%=complete disability). Items not completed for reasons unrelated to foot or ankle conditions were marked as “not applicable or N/A” and excluded from the final score [17]. Participants reported their function over the past week. To ensure reliability, the FAAM questionnaire was conducted by a single trained researcher who interviewed each participant throughout the study period.

Intervention Programs

Participants were randomly assigned to either the intervention or control group, with sessions lasting 30 minutes, 3 times a week, over 4 weeks.

The JSKs Program

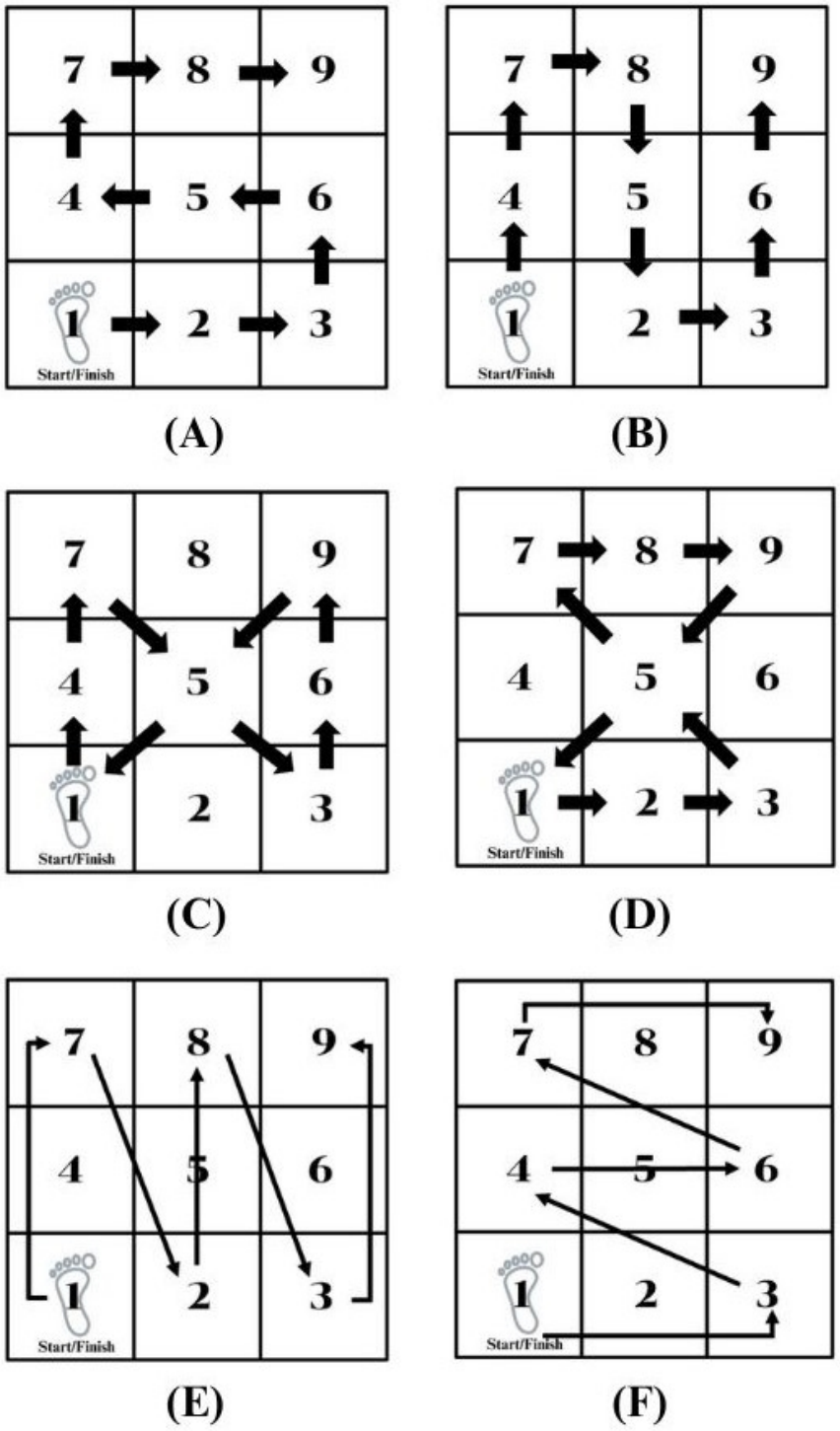
The JSKs program is supervised by a licensed physical therapist with over 15 years of experience working with children. All participants were instructed to perform the intervention under the guidance of a physical therapist. Each session includes 3 parts: a 5-minute warm-up, a 20-minute core exercise period, and a 5-minute cool-down. All sessions are carried out using a 3×3 agility training grid.

Warm-Up and Cool-Down

Participants stood on the center mat (square 5 of a 3×3 agility grid) and performed dynamic stretching by stepping 1 leg as far as possible in 8 directions adapted from the Star Excursion Balance Test [18]. The order for stepping the left leg started from numbers 9 to 6, and the right leg started from numbers 7 to 4 (Figure 1). Then, they were instructed to practice a single-leg stand with eyes closed for 30 seconds each side.

XSL•FO
RenderX

Figure 1. Jump Step Kids program exercises: (A) 1-leg lateral side hopping; (B) 1-leg forward-backward hopping; (C) 1-leg figure-of-eight hopping (vertical pattern); (D) 1-leg figure-of-eight hopping (horizontal pattern); (E) 1-leg long jump (N-Shape pattern); and (F) 1-leg long jump (Z-shape pattern).



Main Exercise

Overview

Participants completed a 20-minute JSKs program, consisting of 4 progressive tasks, each lasting 5 minutes (Figure 1). Exercises were presented in sequence, from easy to difficult, moving from Exercise 1 to Exercise 4. Surface conditions changed from a hard surface during weeks 1 to 2 to a foam surface in weeks 3 to 4. All movements were demonstrated via video and practiced on both sides of the body.

Exercise 1: 1-Leg Lateral Side Hopping

Participants stood on 1 leg in square 1 with their hands on their hips and performed single-leg lateral hops across the grid in this sequence: 1 → 9 (Figure 1A). When they reached square

XSL•FO
RenderX

9, they balanced statically for 5 seconds, then reversed the path back to square 1, followed by another 5-second pause. The exact sequence was then repeated on the other leg. Each leg completed 3 sets.

Exercise 2: 1-Leg Forward-Backward Hopping

Participants stood on the supporting leg in square 7 with their hands on their hips and performed single-leg forward and backward hops along the sequence: 1 → 9 (Figure 1B). Upon reaching square 9, they maintained balance for 5 seconds, then returned along the same path to square 1, followed by another 5-second pause. The sequence was repeated on the opposite leg. Each leg completed 3 sets.

Exercise 3: 1-Leg Figure-of-Eight Hopping

Participants stood on the supporting leg in square 1 with their hands on their hips and performed single-leg hops following a vertical figure-of-eight pattern: 1 → 1 (Figure 1C, vertical pattern). After completing the sequence, they paused for 5 seconds before repeating the task on the opposite leg. Each leg completed 3 sets. Then, participants stood on the supporting leg in square 1 with their hands on their hips and performed single-leg hops following a horizontal figure-of-eight pattern: 1 → 1 (Figure 1D, horizontal pattern). After finishing the sequence, they paused for 5 seconds and repeated the task on the opposite leg. Each leg completed 3 sets.

Exercise 4: 1-Leg Long Jump

Participants stood on the supporting leg in square 1 with their hands on their hips and performed single-leg long jumps laterally, following an N-shaped sequence: 1 → 9. Upon reaching square 9, they paused for 5 seconds before returning along the same path in reverse order (Figure 1E, N-Shape Pattern). A second 5-second pause was observed upon return. The task was then repeated on the opposite leg. Each leg completed one full N-pattern in both directions. After that, participants stood on the supporting leg in square 1 with their hands on their hips and executed single-leg long jumps along a Z-shaped sequence: 1 → 9. After reaching square 9, they paused for 5 seconds before retracing the path in reverse order (Figure 1F, Z-Shape Pattern). A final 5-second pause was observed at square 1. The sequence was repeated on the opposite leg. Each leg completed one full Z-pattern in both directions.

Control Group Program

Participants were asked to follow a home-based stretching program outlined in the brochure. This program is adapted from a general exercise used in their school. It included 6 exercises designed to actively stretch the hip, knee, and ankle muscles in sitting and standing positions. Each exercise was held for 15 seconds and repeated 10 times, with 3 sets per leg. Each session lasted approximately 30 minutes, 3 times a week, for a period of 4 weeks. A researcher contacted the participants to remind them and their parents to follow the stretching protocol. Additionally, all participants recorded their stretching sessions in a child logbook throughout the 4 weeks.

Statistical Analysis

The data were analyzed using SPSS (version 20.0; IBM Corp). Descriptive statistics are shown as mean (SD) for continuous variables and frequency (percentage) for categorical variables. The normality of continuous data was checked with the Shapiro-Wilk test. Between-group differences were tested using univariate analysis of covariance (ANCOVA) with Bonferroni post hoc corrections. Within-group differences were examined using two-tailed paired sample *t* tests. A $P<.05$ was considered statistically significant.

Results

A total of 34 children with CAI were analyzed. Participant enrollment, allocation, follow-up, and analysis are presented in the CONSORT (Consolidated Standards of Reporting Trials) flow diagram (Figure 2). In the JSKs program group, all participants completed all 12 training sessions as scheduled over a 4-week period. Similarly, in the control group, all participants attended every scheduled session. Descriptive statistics were used to describe the baseline characteristics of participants, including sex, age, height, weight, side of CAI, and Cumberland Ankle Instability Tool-Youth Thai version scores. No significant differences were found between the JSKs program and control groups at baseline ($P>.05$; Table 1).

XSL•FO
RenderX

Figure 2. The CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the study participant recruitment, allocation, follow-up, and analysis.

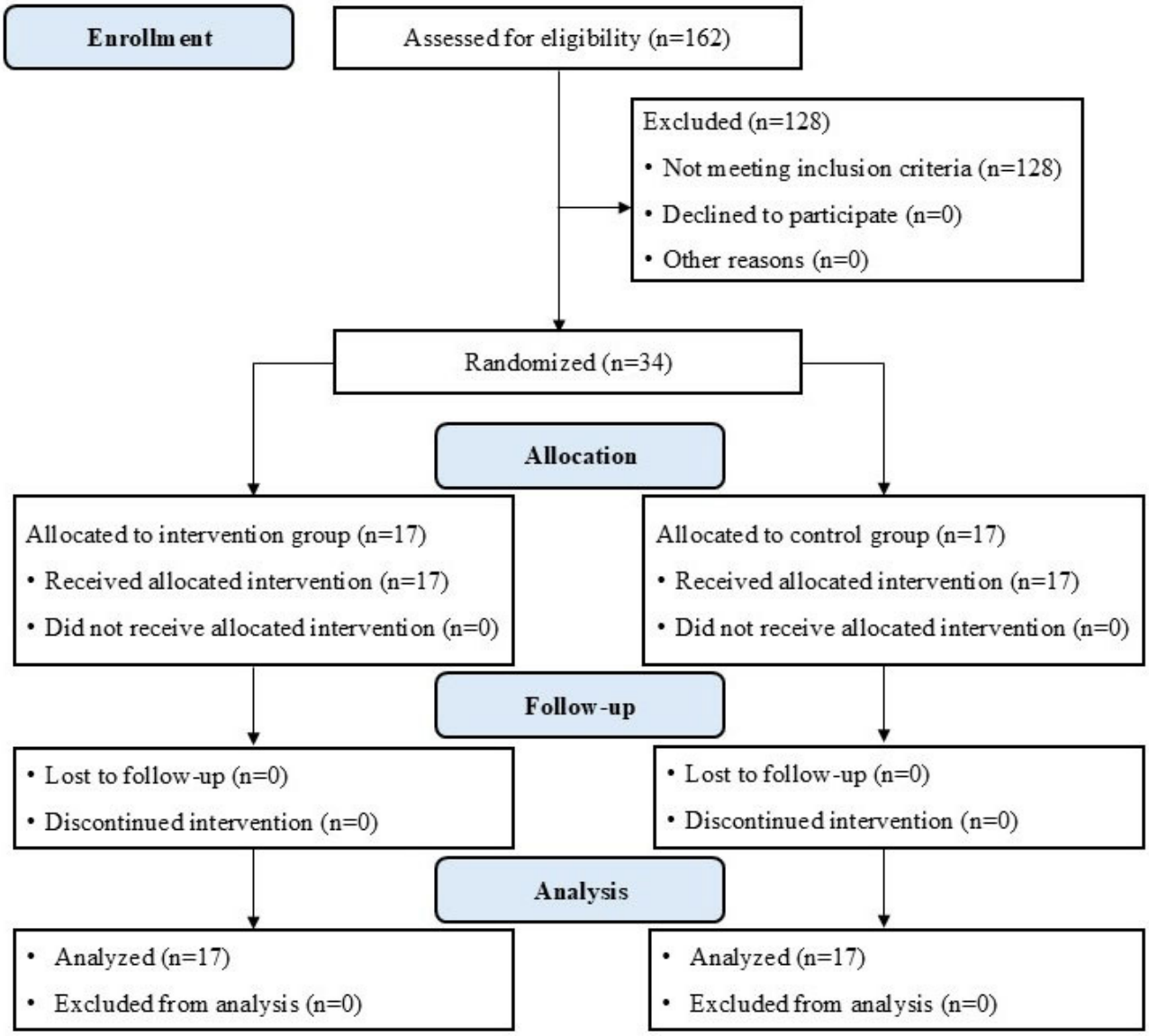


Table . Baseline characteristics of the participants (N=34).

Variable	JSKs[a] program group (n=17)	Control group (n=17)	*P* value
Age (years), mean (SD)	9.39 (2.05)	9.09 (1.72)	.64
Weight (kg), mean (SD)	31.06 (10.85)	32.06 (8.93)	.77
Height (cm), mean (SD)	134.62 (14.35)	131.68 (9.02)	.48
CAITY-T[b] score, mean (SD)	18.65 (4.37)	16.41 (4.72)	.16
Sex, n (%)			.49
Female	9 (53)	7 (41)	
Male	8 (47)	10 (59)	
Side of chronic ankle instability, n (%)			>.99
Right	10 (59)	10 (59)	
Left	7 (41)	7 (41)	

[a]JSK: Jump Step Kids.

[b]CAITY-T: Cumberland Ankle Instability Tool-Youth Thai version.

XSL•FO
RenderX

Foot and ankle function outcomes were assessed within and between groups at baseline and after 4 weeks of training. Within the JSKs program group, significant improvements were observed in the 6mCHT after week 4 (P=.02). Similarly, the 2-legged side hop test of BOT-2 showed a significantly increased score (P<.001). No significant within-group changes were observed in the HRT, SLJT, shuttle run, sideways stepping over a balance beam, or FAAM scores in the JSKs group (P>.05).

In the control group, there was a significant decrease in the 6mCHT at week 4 (P=.04), and the 1-legged stationary hop test also decreased significantly (P=.01). Additionally, there was a significant improvement in the SLJT (P=.04), and the 2-legged side hop test of BOT2 increased substantially in the control group (P<.001). Other outcomes did not show significant changes over the 4 weeks (Table 2).

Between-group comparisons using ANCOVA adjusted for baseline values revealed significant differences for the HRT ($F_{1,32}$=4.39; P=.005; ηp^2=0.12) and the 1-legged stationary hop test of BOT-2 ($F_{1,32}$=6.17; P=.02; ηp^2=0.20), with the JSKs program group showing greater improvements than the control group at week 4. Other outcomes did not change over the 4-week training period (Table 2).

Table . Comparison within and between-group analysis of functional movement and self-reported outcomes between Jump Step Kids (JSKs) program and control groups.

Variables	JSKs[a] program group (n=17)			Control group (n=17)			Effect size (Cohen *d*)	Between groups *P* value	95% CI
	Baseline, mean (SD)	Week 4, mean (SD)	*P* value	Baseline, mean (SD)	Week 4, mean (SD)	*P* value			
Heel raise test (repetition)	36.47 (9.01)	37.88 (11.85)	.60	30.35 (6.95)	27.65 (7.65)	.23	−1.026	.04[b]	3.26 to 17.20
Standing long jump test (cm)	107.85 (21.95)	113.23 (26.44)	.33	104.56 (21.88)	112.05 (19.95)	.04[c]	0.073	.26	−6.24 to 25.73
Six-meter crossover hop test (second)	8.43 (4.07)	6.60 (2.47)	.02[c]	9.54 (6.39)	6.82 (3.45)	.04[c]	0.073	.28	−2.41 to 1.98
Shuttle run (second)	9.27 (1.25)	8.96 (1.10)	.11	9.13 (2.42)	9.06 (1.16)	.88	0.09	.64	−0.89 to 0.69
Stepping sideways over a balance beam (repetition)	29.65 (6.59)	30.47 (5.20)	.58	28.00 (7.37)	30.65 (5.45)	.12	0.034	.17	−3.90 to 3.55
One-legged stationary hop (repetition)	35.88 (7.31)	38.18 (9.53)	.14	35.35 (5.45)	30.24 (9.21)	.01[c]	−0.847	.02[b]	1.39 to 14.49
One-legged side hop (repetition)	21.94 (6.30)	23.88 (8.72)	.28	16.29 (5.03)	20.56 (9.00)	.12	−0.375	.81	−2.97 to 9.61
Two-legged side hop (repetition)	12.24 (4.54)	25.24 (7.40)	<.001[c]	11.47 (3.81)	26.53 (6.88)	<.001[c]	0.181	.62	−6.28 to 3.69
FAAM-ADL[d] (%)	85.97 (10.06)	86.62 (13.02)	.81	87.69 (5.93)	86.43 (6.09)	.36	−0.019	.59	−6.91 to 7.29
FAAM-Sport[e] (%)	85.59 (14.38)	84.30 (15.91)	.53	86.00 (10.69)	89.35 (6.24)	.52	0.418	.43	−13.49 to 3.39

[a]JSKs: Jump Step Kids.

[b]Between-group comparisons were analyzed using univariate ANCOVA with Bonferroni post hoc adjustments.

[c]Within-group comparisons were analyzed using paired *t* tests.

[d]FAAM-ADL: Foot and Ankle Ability Measure-Activities of Daily Living.

[e]FAAM-Sport: Foot and Ankle Ability Measure-Sport.

XSL•FO
RenderX

Discussion

Principal Findings

This study is the first to evaluate a program designed to improve functional movement and agility in children with CAI. The purpose of this study was to investigate the effect of the JSKs program on functional movement and self-reported outcomes in children with CAI. After 4 weeks, the JSKs program significantly enhanced the 6mCHT (P=.02) and 2-legged side hop (P<.001), with improvements in the HRT (P=.04) and 1-legged stationary hop (P=.02) observed between groups. The control group improved in SLJT (P=.04) and 2-legged side hop (P<.001) but declined in HRT and 1-legged stationary hop (P=.01). No significant differences were found for FAAM-ADL or Sport (P>.05).

The effects of the intervention on functional muscle strength were evaluated using the HRT and the SLJT. The HRT was used to assess both the strength and endurance of the ankle plantarflexor and dorsiflexor muscle groups [13,19]. After 4 weeks of training, the HRT performance remained stable in the JSKs group, while the control group showed a decline in this performance. The absence of improvement in ankle strength within the JSKs group may be attributed to the nature of the training program, which primarily consists of multidirectional jumping tasks. These exercises emphasize the development of explosive power, neuromuscular responsiveness, and dynamic muscle strengthening, rather than isolated static muscle strengthening or slow, fully controlled concentric contractions—precisely the type of muscular demand assessed by the HRT [20,21]. In addition, although jumping exercises use body weight as resistance, they focus on building momentum rather than maintaining a constant muscle load. In contrast, the HRT involves continuous, controlled resistance, thereby offering a more accurate measure of calf muscle endurance and strength [21,22]. Consequently, it is likely that the JSKs program did not provide sufficient training stimulus to induce measurable gains in ankle muscle strength. Nevertheless, this study demonstrates that the JSKs program was effective in maintaining ankle muscle strength in children with CAI when compared to the control group.

In contrast, the SLJT is widely used to assess overall lower extremity muscle strength and explosive power and requires coordinated force generation from both legs [14,23]. In this study, only the control group revealed a statistically significant improvement in jump distance (from 104.56 cm to 112.05 cm). This improvement may be attributed to increased muscle flexibility and joint range of motion resulting from regular stretching, which can increase muscle compliance and optimize force production during jumping [24]. In contrast, the JSKs group demonstrated a nonsignificant increase in jump distance (from 107.85 cm to 113.23 cm). The JSKs program emphasizes multidirectional jumping activities, focusing on balance, speed, and agility rather than maximal jump distance. Consistent with Legnani et al [25], who demonstrated that side hop tests could be more accurate than vertical jump tests for detecting functional impairment in patients suffering from CAI, our findings may explain the lack of significant improvement in SLJT performance in this group. Moreover, the bilateral nature of the SLJT may conceal unilateral impairments, supporting prior recommendations for single-leg assessments using force plates [26,27].

The 6mCHT assessed dynamic balance capability and ankle stability [15]. The findings of this study indicated a significant improvement in both groups after 4 weeks. The JSKs group demonstrated improvements through program components that promoted multidirectional jumping, dynamic balance, and lower extremity coordination. This training has likely enhanced ankle stability, body position awareness, and motor control, which are essential for effective performance in crossover hopping tasks. The findings align with a prior study by Myer et al [28], who indicated that youth athletes exhibited enhanced dynamic stability and hop performance after engaging in plyometric and neuromuscular training. Moreover, the control group also showed significant improvements over 4 weeks of training. These changes may result from natural developmental progress, increased awareness of physical activity during the study period, or learning effects linked to repeated test exposure. Gribble et al [29] observed that performance increased on repeated hop tests without specific training. This improved performance may be due to task familiarity and motor learning. However, the magnitude of improvement was greater in the JSKs group, reinforcing the efficacy of a structured, progressive training program. The JSKs protocol, which included exercises progressing from stable to unstable surfaces, is consistent with the approach used in the previous study [30]. Eils and Rosenbaum [30] found improved hop performance after a balance-focused intervention in individuals with CAI. Therefore, this study suggested that multidirectional jumping activity in the JSKs program could be beneficial for ankle movement to maintain dynamic balance control for children with CAI.

For the agility test, it was assessed using the BOT-2 subtests of running speed and agility. Agility is an important characteristic of motor development, which is crucial for maintaining and controlling body posture when changing direction. The results of this study indicated that both the JSKs program and a self-stretching program increased the number of jumps in 2-legged side hop test after 4 weeks of training. These findings support the role of agility as an important aspect of motor development, which is closely related to physical coordination, speed, and balance skills [31]. In the experimental group receiving the JSKs program, the children practiced alternating forward-backward and side-to-side hops, stimulating the central nervous system and the proprioceptive system through postural control and rapid direction changes in movement. These findings align with previous studies showing that hop-based training enhances ankle stability, functional performance, and postural control in individuals with CAI [32,33]. In addition, Hale et al [34] aimed to examine the effects of a 4-week rehabilitation program for CAI on postural control and lower extremity function. This comprehensive rehabilitation program consisted of range of motion exercises, strength exercises, neuromuscular control, and functional tasks. Their findings showed that rehabilitation effectively improves postural control and functional limitations in individuals with CAI. In addition, the results showed a significant decrease in the 1-legged stationary

XSL•FO
RenderX

hop test in control groups when compared with the JSKs group. This finding suggests that the JSKs program is more effective in enhancing single-limb control, unilateral coordination, and maintaining strength over time. These findings are supported by previous studies which demonstrated that hopping, balance, and proprioceptive training can improve motor control and stability in children with CAI [26,28]. Thus, this finding suggests that the JSKs program has an impact on the improvement or maintenance of performance in children with CAI. Although the 2-legged hop test does not fully replicate real-world situations, it provides a safe and specific test of agility for children, supporting the development of coordination, balance, and spatial awareness. These skills are essential for activities requiring speed, such as running, avoiding obstacles, playing sports, and participating in physical education, thereby enhancing safety in daily life.

The FAAM was used to assess physical functioning in individuals with foot and ankle disorders [18]. Self-reported questionnaires may be influenced by children's mood, confidence, or understanding, as they reflect perceived rather than actual physical changes. This study revealed no statistically significant differences between the intervention and control groups after 4 weeks of training. This finding was similar to Kim et al [35], who also reported no difference between a jumping training and control group even though the training period was 6 weeks in adults with CAI. In contrast, Kim et al [36] and Ardakani et al [37] reported both FAAM-ADL and FAAM-Sport improved in hop-stabilization and balance training between pre- and posttraining for 6 to 8 weeks. The 4-week training period in this study may be too short to produce significant changes in self-perceived ability, especially in children with CAI [23]. The authors of the present study further suggest that longer interventions may be necessary.

Limitations

This study only investigated the short-term effects of the JSKs program on functional movement and self-reported outcomes related to the foot and ankle in children with CAI. Therefore, future research should include ongoing follow-up to assess the sustainability of the training effects over time. Additionally, this study did not evaluate factors associated with ankle function and movement control that could help elucidate the underlying mechanisms behind the observed outcomes. Future studies should incorporate additional assessments, such as measurements of muscle strength, to gain a more comprehensive understanding of the training effects. Furthermore, the FAAM used in this study has not been validated for pediatric populations, which may limit the interpretability of the self-reported functional outcomes. Therefore, future studies should consider using or developing validated outcome measures for children to ensure more accurate assessment of ankle function.

Conclusions

After 4 weeks of training, the JSKs program showed greater improvement in functional movement than the home-based stretching program in children aged 7 to 12 years with CAI, as measured by HRT and the 1-legged stationary hop test. Additionally, both training programs enhance performance in the 6mCHT and 2-legged side hop. However, the self-reported outcomes (FAAM-ADL and FAAM-Sport subscales) did not change between groups. For clinical applications, the JSKs program offers a practical, accessible, and time-efficient plyometric training protocol that can be easily integrated into the rehabilitation of children with CAI. Clinicians should consider incorporating this program alongside conventional treatment to promote ankle stability and potentially reduce the risk of recurrent ankle sprains.

Acknowledgments

The authors sincerely thank all the participants and their families for their time and dedication to this study.

Funding

This research was supported by the Fundamental Fund, Basic Research Fund 2025, Mae Fah Luang University.

Authors' Contributions

JC contributed to the conceptualization and design of the study, performed the investigation and data curation, conducted formal analysis, validated the results, and wrote the original draft of the manuscript. KS and SY contributed to the conceptualization and design of the study, performed formal analysis, interpreted the results, and participated in writing – review & editing. All authors have read and approved the final version of the manuscript and agree with the order of authorship.

Conflicts of Interest

None declared.

Checklist 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File, 2987 KB - pediatrics_v8i1e81860_app1.pdf]

References

XSL•FO
RenderX

1. Mandarakas M, Pourkazemi F, Sman A, Burns J, Hiller CE. Systematic review of chronic ankle instability in children. J Foot Ankle Res 2014 Mar 19;7(1):21. [doi: 10.1186/1757-1146-7-21] [Medline: 24641786]
2. Hiller CE, Kilbreath SL, Refshauge KM. Chronic ankle instability: evolution of the model. J Athl Train 2011;46(2):133-141. [doi: 10.4085/1062-6050-46.2.133] [Medline: 21391798]
3. Lekskulchai R, Kadli S. Prevalence and factors associated with chronic ankle instability among children aged 7 to 12 years. J Assoc Med Sci 2020;53(1):42-48. [doi: 10.14456/jams.2020.6]
4. Hertel J, Corbett RO. An updated model of chronic ankle instability. J Athl Train 2019 Jun;54(6):572-588. [doi: 10.4085/1062-6050-344-18] [Medline: 31162943]
5. Suphasubtrakul T, Lekskulchai R, Jalayondeja C. Balance, strength and physical activity after ankle sprain: comparison between children with chronic ankle instability and copers. Phys Ther Sport 2024 Jan;65:49-53. [doi: 10.1016/j.ptsp.2023.11.004] [Medline: 38011816]
6. Chuadthong J, Lekskulchai R, Hiller C, Ajjimaporn A. A home-based exercise program with active video games for balance, motor proficiency, foot and ankle ability, and intrinsic motivation in children with chronic ankle instability: feasibility randomized controlled trial. JMIR Serious Games 2023 Dec 20;11:e51073. [doi: 10.2196/51073] [Medline: 38235982]
7. Surakhamhaeng A, Bovonsunthonchai S, Vachalathiti R. Effects of balance and plyometric training on balance control among individuals with functional ankle instability. Physiother Quart 2020;28(2):38-45. [doi: 10.5114/pq.2020.92474]
8. Fitzgerald D, Trakarnratanakul N, Smyth B, Caulfield B. Effects of a wobble board-based therapeutic exergaming system for balance training on dynamic postural stability and intrinsic motivation levels. J Orthop Sports Phys Ther 2010 Jan;40(1):11-19. [doi: 10.2519/jospt.2010.3121] [Medline: 20044704]
9. Yingyongsaksri S, Hiller CE, Tharawadeepimuk K, Nanbancha A. Reliability and validation of the Thai version of the Cumberland Ankle Instability Tool (CAIT-THA). Disabil Rehabil 2023 Nov;45(22):3762-3767. [doi: 10.1080/09638288.2022.2135778] [Medline: 36263888]
10. Gribble PA, Delahunt E, Bleakley C, et al. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. J Orthop Sports Phys Ther 2013 Aug;43(8):585-591. [doi: 10.2519/jospt.2013.0303] [Medline: 23902805]
11. Hales CM, Freedman DS, Akinbami L, Wei R, Ogden CL. Evaluation of alternative body mass index (BMI) metrics to monitor weight status in children and adolescents with extremely high BMI using CDC BMI-for-age growth charts. Vital Health Stat 1 2022 Dec(197):1-42. [doi: 10.15620/cdc:121711] [Medline: 36598420]
12. Sman AD, Hiller CE, Imer A, Ocsing A, Burns J, Refshauge KM. Design and reliability of a novel heel rise test measuring device for plantarflexion endurance. Biomed Res Int 2014;2014:391646. [doi: 10.1155/2014/391646] [Medline: 24877089]
13. Yocum A, McCoy SW, Bjornson KF, Mullens P, Burton GN. Reliability and validity of the standing heel-rise test. Phys Occup Ther Pediatr 2010 Aug;30(3):190-204. [doi: 10.3109/01942631003761380] [Medline: 20608857]
14. Bruininks RH, Bruininks BD. Bruininks-Oseretsky Test of Motor Proficiency, 2nd edition: Pearson Publishing; 2005.
15. Yalfani A, Gandomi F, Kohboomi M. The effect of G-max and G-med muscle fatigue on functional performance and balance in athletes with and without chronic ankle instability. Asian J Sports Med 2017;8(3):e55444. [doi: 10.5812/asjsm.55444]
16. Arunakul M, Arunakul P, Suesiritumrong C, Angthong C, Chernchujit B. Validity and reliability of Thai version of the foot and ankle ability measure (FAAM) subjective form. J Med Assoc Thai 2015 Jun;98(6):561-567. [Medline: 26219160]
17. Martin RL, Irrgang JJ, Burdett RG, Conti SF, Van Swearingen JM. Evidence of validity for the foot and ankle ability measure (FAAM). Foot Ankle Int 2005 Nov;26(11):968-983. [doi: 10.1177/107110070502601113] [Medline: 16309613]
18. Gribble PA, Hertel J, Plisky P. Using the Star Excursion Balance Test to assess dynamic postural-control deficits and outcomes in lower extremity injury: a literature and systematic review. J Athl Train 2012;47(3):339-357. [doi: 10.4085/1062-6050-47.3.08] [Medline: 22892416]
19. Bohannon RW. The heel-raise test for ankle plantarflexor strength: a scoping review and meta-analysis of studies providing norms. J Phys Ther Sci 2022 Jul;34(7):528-531. [doi: 10.1589/jpts.34.528] [Medline: 35784604]
20. Kadlubowski B, Keiner M, Wirth K, Csapo R. Effects of traditional strength vs. combined strength and plyometric training on sprint, jump, and maximum strength performance in elite youth soccer players-a 6-month controlled trial. J Strength Cond Res 2025 May 16;39(7):e878-e889. [doi: 10.1519/JSC.0000000000005113] [Medline: 40440548]
21. Ramírez-delaCruz M, Bravo-Sánchez A, Esteban-García P, Jiménez F, Abián-Vicén J. Effects of plyometric training on lower body muscle architecture, tendon structure, stiffness and physical performance: a systematic review and meta-analysis. Sports Med Open 2022 Mar 21;8(1):40. [doi: 10.1186/s40798-022-00431-0] [Medline: 35312884]
22. Markovic G, Mikulic P. Neuro-musculoskeletal and performance adaptations to lower-extremity plyometric training. Sports Med 2010 Oct 1;40(10):859-895. [doi: 10.2165/11318370-000000000-00000] [Medline: 20836583]
23. Luan L, Zhu M, Adams R, Witchalls J, Pranata A, Han J. Effects of acupuncture or similar needling therapy on pain, proprioception, balance, and self-reported function in individuals with chronic ankle instability: a systematic review and meta-analysis. Complement Ther Med 2023 Oct;77:102983. [doi: 10.1016/j.ctim.2023.102983] [Medline: 37666474]
24. Behm DG, Chaouachi A. A review of the acute effects of static and dynamic stretching on performance. Eur J Appl Physiol 2011 Nov;111(11):2633-2651. [doi: 10.1007/s00421-011-1879-2] [Medline: 21373870]

XSL•FO
RenderX

25. Legnani C, Saladini M, Faraldi M, Peretti GM, Ventura A. A battery of jump tests helps discriminating between subjects with and without chronic ankle instability. Sports (Basel) 2025 May 30;13(6):171. [doi: 10.3390/sports13060171] [Medline: 40559683]
26. Hu X, Feng T, Li P, Liao J, Wang L. Bilateral sensorimotor impairments in individuals with unilateral chronic ankle instability: a systematic review and meta-analysis. Sports Med Open 2024 Apr 8;10(1):33. [doi: 10.1186/s40798-024-00702-y] [Medline: 38589676]
27. Ross SE, Guskiewicz KM, Gross MT, Yu B. Balance measures for discriminating between functionally unstable and stable ankles. Med Sci Sports Exerc 2009 Feb;41(2):399-407. [doi: 10.1249/MSS.0b013e3181872d89] [Medline: 19127184]
28. Myer GD, Ford KR, Brent JL, Hewett TE. The effects of plyometric vs. dynamic stabilization and balance training on power, balance, and landing force in female athletes. J Strength Cond Res 2006 May;20(2):345-353. [doi: 10.1519/R-17955.1] [Medline: 16686562]
29. Gribble PA, Hertel J, Denegar CR, Buckley WE. The effects of fatigue and chronic ankle instability on dynamic postural control. J Athl Train 2004 Dec;39(4):321-329. [Medline: 15592604]
30. Eils E, Rosenbaum D. A multi-station proprioceptive exercise program in patients with ankle instability. Med Sci Sports Exerc 2001 Dec;33(12):1991-1998. [doi: 10.1097/00005768-200112000-00003] [Medline: 11740289]
31. João PV, Simões I, Alves L, Santos L, Pereira A, Mota MP. Physical activity with agility motor development for children ages 6–10. Sci Sports 2014 Oct;29(Suppl 1):S48. [doi: 10.1016/j.scispo.2014.08.095]
32. Anguish B, Sandrey MA. Two 4-week balance-training programs for chronic ankle instability. J Athl Train 2018 Jul;53(7):662-671. [doi: 10.4085/1062-6050-555-16] [Medline: 30192681]
33. Park HS, Oh JK, Hong YI, Kim JY, Yoon JH. Effect of hop-stabilization training on ankle instability and function of adolescent female basketball players with chronic ankle instability: a double-blind, prospective, cluster-randomized controlled trial. J Clin Med 2025 May 16;14(10):3502. [doi: 10.3390/jcm14103502] [Medline: 40429497]
34. Hale SA, Hertel J, Olmsted-Kramer LC. The effect of a 4-week comprehensive rehabilitation program on postural control and lower extremity function in individuals with chronic ankle instability. J Orthop Sports Phys Ther 2007 Jun;37(6):303-311. [doi: 10.2519/jospt.2007.2322] [Medline: 17612356]
35. Kim KM, Estudillo-Martínez MD, Castellote-Caballero Y, Estepa-Gallego A, Cruz-Díaz D. Short-term effects of balance training with stroboscopic vision for patients with chronic ankle instability: a single-blinded randomized controlled trial. Int J Environ Res Public Health 2021 May 18;18(10):5364. [doi: 10.3390/ijerph18105364] [Medline: 34069907]
36. Kim KM, Estepa-Gallego A, Estudillo-Martínez MD, Castellote-Caballero Y, Cruz-Díaz D. Comparative effects of neuromuscular- and strength-training protocols on pathomechanical, sensory-perceptual, and motor-behavioral impairments in patients with chronic ankle instability: randomized controlled trial. Healthcare (Basel) 2022 Jul 22;10(8):1364. [doi: 10.3390/healthcare10081364] [Medline: 35893186]
37. Ardakani MK, Wikstrom EA, Minoonejad H, Rajabi R, Sharifnezhad A. Hop-stabilization training and landing biomechanics in athletes with chronic ankle instability: a randomized controlled trial. J Athl Train 2019 Dec;54(12):1296-1303. [doi: 10.4085/1062-6050-550-17] [Medline: 31618073]

Abbreviations

6mCHT: 6-meter crossover hop test
ADL: activity of daily living
BOT-2: Bruininks-Oseretsky Test of Motor Proficiency, Second Edition
CAI: chronic ankle instability
CDC: Centers for Disease Control and Prevention
FAAM: Foot and Ankle Ability Measure
HRT: heel raise test
JSKs: Jump Step Kids
MI: mechanical instability
SLJT: standing long jump test

Edited by S Badawy; submitted 05.08.25; peer-reviewed by G Dar, J Kunritt, S Bagherian; revised version received 08.11.25; accepted 27.11.25; published 19.12.25.

Please cite as:
Srisim K, Yingyongsaksri S, Chuadthong J
Effects of the Jump Step Kids Program on Functional Movement and Self-Report Outcomes in Children Aged 7 to 12 Years With Chronic Ankle Instability: Randomized Controlled Trial
JMIR Pediatr Parent 2025;8:e81860
URL: https://pediatrics.jmir.org/2025/1/e81860
doi:10.2196/81860

XSL•FO
RenderX

© Kitiyawadee Srisim, Supannikar Yingyongsaksri, Janya Chuadthong. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 19.12.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Feasibility, Barriers, and Facilitators of Long-Term Physical Activity Tracking During Treatment: Interview Study Among Childhood Cancer Patients

Emma den Hartog[1], MSc; Wim J E Tissing[1,2], PhD; Sebastian B B Bon[1], MSc; Patrick van der Torre[1], MSc; Emma J Verwaaijen[1], PhD

[1]Department of Suportive Care, Princess Máxima Center for Pediatric Oncology, Heidelberglaan 25, Utrecht, The Netherlands

[2]Department of Pediatric Oncology and Hematology, Beatrix Children's Hospital, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands

Corresponding Author:
Wim J E Tissing, PhD
Department of Suportive Care, Princess Máxima Center for Pediatric Oncology, Heidelberglaan 25, Utrecht, The Netherlands

Abstract

Background: Children with cancer are at risk of reduced physical activity. Gaining insight into physical activity using smartwatches could improve understanding of individual potential during treatment, support early recognition of aberrant physical activity, and enable tailored support.

Objective: This study aimed to explore the feasibility, barriers, facilitators, and considerations of long-term physical activity tracking using a smartwatch during childhood cancer treatment.

Methods: In this prospective study, 30 children (age 8 - 18 years) under active cancer treatment were included in 2 phases. During phase 1, 15 children wore a smartwatch daily for 12 consecutive weeks, and in-depth interviews were conducted to identify principal considerations used to optimize wearability and the methods for phase 2. In phase 2, another 15 children wore the smartwatch, and semistructured interviews were conducted at weeks 1, 3, 6, and 12. These interviews were thematically analyzed to identify barriers and facilitators. An iterative process of alternating data collection and analysis allowed for ongoing method refinement and deepening thematic analysis during the study period.

Results: Key considerations for improvement identified in phase 1 led to refinements in phase 2, including enhanced engagement, regular prompts, customized plans, personalized setup, and improved aesthetics and comfort. The interviews conducted during phase 2 identified barriers and facilitators. The 4 most prominent themes were burden and resilience, motivational drivers and perception, insight and evaluation, and user experience and functionality. Feasibility was influenced by the child's physical state and perceived burden. Motivation, perceived value, and expectations played crucial roles in sustaining adherence, while also the balance between positive reinforcement and potential confrontation affected long-term use. User experience, including attractiveness, comfort, and usability, impacted acceptance.

Conclusions: Real-time and long-term physical activity tracking using a smartwatch in children during cancer treatment was not feasible in our cohort. A personalized approach, incorporating individual preferences and physical condition, is essential to support adherence.

(JMIR Pediatr Parent 2025;8:e75322) doi:10.2196/75322

KEYWORDS

physical activity; tracking; smartwatch; pediatric oncology; feasibility

Introduction

The overall 5-year survival of childhood cancer has improved tremendously over the past decades, reaching around 80% [1-3]. Despite this improvement, pediatric cancer and its treatment are often accompanied by adverse health effects, such as muscle deficits, pain, and fatigue, that negatively influence physical functioning [1,4,5]. Physical activity may help mitigate these adverse health effects by improving body composition, muscle strength, flexibility, and cardiorespiratory fitness and subsequently enhancing physical functioning and quality of life [6-8].

However, children with cancer may experience physical weakness, limited opportunities to engage in physical activity, and a shift in focus due to emotional strain because of their disease, its treatment, and other medical needs [9-12]. Although it is well established that children with cancer are at risk of reduced physical activity [5,10,11,13], there is limited

XSL•FO
RenderX

knowledge about variation in physical activity levels both between and within children during treatment. These variations depend on the child's diagnosis, treatment type and intensity, and medical complications, as well as personal and environmental factors [11,12,14,15]. Gaining insight into physical activity levels could improve understanding of children's physical potential during different treatment phases, support early recognition of aberrant physical activity levels, and enable tailored advice and guidance to promote physical activity that aligns with the child's needs, their family, and the treatment phase they are in. Understanding variations in physical activity levels requires accurate and continuous measurement of physical activity.

Currently, the most commonly used methods to monitor physical activity levels in children with cancer include questionnaires and accelerometry devices [10-13,16]. Questionnaires are prone to subjective inaccuracies, as children and parents have to recall and may under- or overestimate their physical activity [17]. Accelerometry addresses these limitations but has notable drawbacks that restrain usability, including the need for installation to collect data, the lack of real-time accessible data for children, parents, and health care professionals, and a nonmodern design that does not offer visual feedback to the user. Furthermore, objective devices have primarily been used for short-term monitoring (1 - 2 weeks) [10,11,13,15,18], which limits their ability to capture variations in physical activity levels across different treatment phases of childhood cancer.

Consumer-level smartwatches are increasingly being used in health care and research to track physical activity [19-25]. A major advantage of smartwatches is that they provide insight into real-time data and visual feedback for the patient. Their use during treatment for childhood cancer would enlarge knowledge about physical activity levels during different treatment phases and therefore support both patients and their health care professionals in managing expectations of physical activity. Moreover, using smartwatches to track physical activity would facilitate early recognition of children with aberrant physical activity levels and enable timely initiation of interventions to prevent aggravation. In children with a brain tumor who received an intervention, including the use of a smartwatch combined with coaching by a physiotherapist for 12 weeks during treatment, no adverse effects of using the smartwatch were reported [26]. In addition, children with acute lymphoblastic leukemia were able to use a fitness tracker clipped on clothing for around 3 weeks during their treatment, consistently with low effort [27]. During the maintenance phase of childhood acute lymphoblastic leukemia and after treatment for childhood cancer, the daily use of a smartwatch for 6 months was feasible as measured by retention, receptivity, and belief of utility [28]. However, in healthy children and adolescents, several issues concerning the use of smartwatches, including technical difficulties, a novelty effect, and lack of comfort, were identified, which limit long-term use [29,30]. There is limited knowledge about the feasibility and wearing experiences of long-term physical activity tracking using smartwatches during different phases of childhood cancer treatment [31].

Therefore, the aim of this study was to determine the feasibility and to identify barriers, facilitators, and key considerations of real-time and long-term physical activity tracking using a consumer-level smartwatch in children during cancer treatment. We hypothesized that physical activity tracking using a smartwatch in children undergoing cancer treatment would be feasible and imagined that factors, including treatment phase, medical needs, and personal desires, could hamper long-term use.

Methods

Study Design

This prospective study consisted of 2 phases in which quantitative data and qualitative data were collected to determine feasibility and to identify barriers, facilitators, and key considerations for long-term physical activity tracking in children with cancer during treatment, respectively.

Participants and Inclusion

Children aged 8 - 18 years, diagnosed with a malignancy, and undergoing active treatment in the Princess Máxima Center for Pediatric Oncology were eligible for participation. Inclusion criteria were the ability to walk at least 50 meters without aid, adequate understanding of the Dutch language, and access to a digital device capable of downloading an app (eg, a smartphone). Exclusion criteria included not being able to attend evaluation moments, undergoing stem cell transplantation during the study period, and pre-existing intellectual disabilities that prevented participation in interviews or long-term smartwatch use.

Potential participants were recruited by the researcher (EdH) in collaboration with their pediatric physiotherapist or oncologist.

Ethical Considerations

Written informed consent was obtained from participants aged ≥12 years and parents or caregivers of participants aged 8 - 16 years. The Medical Research Ethics Committee (MREC) confirmed this study was not subject to the Medical Research Involving Human Subjects Act (23-003). Data were pseudonymized. Participants were not compensated.

Study Procedure

In phase 1, conducted between May and September 2023, 15 children undergoing active cancer treatment were asked to wear a smartwatch daily for 12 consecutive weeks. A time frame of 12 weeks was chosen, as this was the first effort to explore the potential of a smartwatch to track long-term physical activity in children with cancer during different phases of treatment. Moreover, we expected that if wearing the smartwatch was feasible for 12 weeks, it would remain so for a longer period. In addition, within 12 weeks, they usually undergo several treatment courses that vary in type and intensity, allowing them to experience the smartwatch during different phases of treatment. After 12 weeks, in-depth interviews were conducted to identify key considerations for long-term physical activity tracking during childhood cancer treatment. These findings were then used to optimize the methods for phase 2.

In phase 2, conducted between February and June 2024, another 15 children wore the smartwatch for 12 consecutive weeks.

XSL•FO
RenderX

After having optimized the methods for phase 2 during phase 1, total wear time was calculated, and semistructured interviews were conducted at weeks 1, 3, 6, and 12 during phase 2. The total wear time and interviews were used to evaluate feasibility and identify barriers, facilitators, and key considerations. The iterative approach of alternating data collection and analysis enabled ongoing method refinement based on children's experiences, while incorporating emerging topics and deepening thematic analysis during the study period.

Upon inclusion, children were instructed to wear the smartwatch daily during the upcoming 12 weeks. An app (Health Mate, Withings) was installed on a smartwatch or tablet of children or their parents. The smartwatch was linked to an account created in the app, which enabled the researcher to gain insight into physical activity data, which was transferred to a dashboard developed by the Information Technology, Data Provision, and Technology department of the Princess Máxima Center. In the app, physical activity, including steps and heart rate, was displayed for children themselves. Children received a notification on the smartwatch and in the app when they reached their self-chosen, adjustable daily step goal. Moreover, during phase 2, children or their parents received prompts with feedback on wearing behavior and tips for smartwatch use. These prompts were sent as text messages to their phones or via emails every other week.

Smartwatch

In this study, children wore a Withings (Withings, Issy-les-Moulineaux, France) Steel Heart rate (HR) (Model: HWA03b-36black/white-Inter) or Pulse HR (Model: WAM03-Black Mirror-All-Inter) smartwatch. The model for each child was determined by the researcher in agreement with the child to optimize wearability. Generally, larger children were assigned a Steel HR, while those with a slim wrist received a Pulse HR. The device measured step count and HR and was able to track a variety of sport activities. Withings smartwatches have been used in a number of previous clinical studies as a method to evaluate physical activity [20,21,23,25]. Also, in healthy children (8 - 11 years old), a Withings smartwatch has previously been used to evaluate an intervention aiming to increase physical activity [22]. In healthy adults, Withings smartwatches have been validated against a reference device (ActiGraph) for counting steps [32]. Among a set of smartwatches, these were found to be the most user-friendly, satisfactory, accurate, and repeatable for tracking steps [33] and showed excellent test-retest reliability (intraclass correlation: 0.92, 95% CI 0.83 - 0.96, p<0.01) [34].

Data Collection

Feasibility

Feasibility was evaluated by acceptance (ie, the percentage of eligible participants who agree to take part after being invited), attrition (ie, the percentage of participants who remain in the study until the end), and adherence (ie, the total wear time) [35]. Adherence was examined only in the 15 children included in phase 2 after 12 weeks of wearing the smartwatch, as the goal of phase 1 was to optimize the methods for phase 2. We defined that the adherence feasibility target for long-term physical activity tracking in children with cancer during treatment was reached when at least 60% (9/15) of the children in phase 2 adhered to wearing the smartwatch for a minimum of 75% of the study period. This target was based on previous studies using activity trackers in childhood cancer survivors [28,36,37].

Key Considerations, Barriers, and Facilitators

Key considerations for improvement, along with barriers, facilitators, and future key considerations of long-term physical activity tracking during childhood cancer treatment, were identified through in-depth interviews at the end of phase 1 and semistructured interviews during phase 2, respectively.

During the interviews, an interview guide was used that covered topics, including reasons for wearing or not wearing the smartwatch, barriers and facilitators, and children's thoughts on wearing it for the entire treatment and sharing their physical activity data with their physiotherapist. The interview guide for the in-depth interviews was developed based on previous studies and experiences raised during phase 1, while the interview guide for the semistructured interviews was constructed and adjusted according to findings of phase 1 and experiences during phase 2. The interview guides used in both study phases are shown in Sections A and B in Multimedia Appendix 1, respectively. All interviews were conducted by EdH and planned on the same day as participants' medical appointments at the Princess Máxima Center, or they were held via a phone or video call to avoid extra study visits to the hospital. For children aged <12 years, children themselves and their parents were interviewed. Children aged ≥12 years were interviewed themselves or with the help of their parents, depending on the family's preferences. In case of questions or issues between the evaluation moments, participants contacted the researcher via email or phone.

Data Analysis

Descriptive statistics were used to describe patient characteristics, acceptance, and attrition. Categorical variables were presented as numbers with percentages. Continuous variables were presented as mean with SD for normally distributed data or as median with IQR for non-normally distributed data. Analyses were performed in IBM SPSS Statistics version 30.0.0.

To determine adherence, the total wear time was calculated as a percentage by dividing the total number of valid days children wore the smartwatch by the total number of days a child was included in the study. A day was considered valid when HR was measured at least once per hour for a minimum of 8 hours between 6 AM and 12 PM.

The interviews were recorded on a mobile phone and transcribed verbatim. The in-depth interviews from phase 1 were analyzed using Braun and Clarke's [38] thematic approach. Transcripts were initially coded by EdH, and the final codes and themes were formulated in discussion with EJV and SBBB. Themes were subsequently discussed within the entire research team to identify key considerations that were used to guide the development of phase 2.

The interviews from phase 2 were analyzed using Braun and Clarke's [38] inductive thematic approach, which included an

XSL•FO
RenderX

iterative process of data collection and analysis [39,40]. The first step involved reading interview transcripts to familiarize yourself with the data. In the second step, EJV and EdH independently coded 12 transcripts. These codes were discussed with SBBB, resulting in a preliminary thematic map, which EdH used in the remaining transcripts. In the third step, subthemes and themes were collaboratively established by SBBB, EJV, and EdH and further discussed within the entire research team. The last step involved finalizing the codes, subthemes, and main themes while identifying connections within and across themes. The thematic analysis was conducted using ATLAS.ti (Scientific Software Development GmbH, v8.3.0).

Results

Cohort

Most of the 15 children included in phase 1 were male (11/15, 73%) and diagnosed with a hematological malignancy (13/15, 86%) (Table 1). They had a mean age of 12.2 (SD 2.9) years at the time of inclusion, and the median time since diagnosis was 262.0 (IQR 108.5 - 325.5) days. The acceptance and attrition rates were 45% (15/33) and 93% (14/15), respectively. Reasons for refusing participation included already owning a smartwatch, unwillingness to wear a smartwatch, disliking the smartwatch's feeling or appearance, not perceiving the need for a smartwatch to measure physical activity, and considering the smartwatch as an additional burden alongside medical needs.

Of the 15 children included in phase 2, 7 (47%) were male, and 12 (80%) were diagnosed with a hematological malignancy (Table 1). Children had a mean age of 12.5 (SD 2.9) years at time of inclusion, and the median time since diagnosis was 96.0 (IQR 80.5 - 151.0) days. The acceptance and attrition rates for phase 2 were 83% (15/18) and 93% (14/15), respectively. Reasons for refusing participation included unwillingness to wear a smartwatch that measures physical activity during treatment and parental concerns related to their child's autism.

An overview of the number of dropouts and patients included in quantitative and qualitative data analyses is shown in Table 1. During both study phases, 1 child dropped out because wearing the smartwatch was considered too much of a burden in combination with medical needs. All available data of these children were used for data analysis, and no new children were recruited. In 71% (10/14) of the in-depth interviews at the end of phase 1, parents were present during the interview. During phase 2, parents were involved in 79% (11/14), 73% (11/14), 50% (6/12), and 71% (10/14) of the semistructured interviews at weeks 1, 3, 6, and 12, respectively.

XSL•FO
RenderX

Table . Patient characteristics at time of inclusion and an overview of the number of dropouts and children included in quantitative and qualitative data analyses during study phase 1 and 2.

Study phase	Phase 1 (n=15)	Phase 2 (n=15)
Patient characteristics at time of inclusion		
Sex, n (%)		
Female	4 (27)	8 (53)
Male	11 (73)	7 (47)
Age (year), mean (SD)	12.2 (2.9)	12.5 (2.9)
Time since diagnosis (days), median (IQR)	262.0 (108.5-325.5)	96.0 (80.5-151.0)
Diagnosis, n (%)		
Acute lymphoblastic leukemia	8 (53)	7 (47)
Lymphoblastic lymphoma	5 (33)	3 (20)
Hodgkin lymphoma	0	1 (7)
Langerhans cell histiocytosis	0	1 (7)
Medulloblastoma	0	3 (20)
Osteosarcoma	1 (7)	0
Ewing sarcoma	1 (7)	0
Weight-to-height *z*-score, mean (SD)	0.3 (1.2)	0.1 (1.5)
Cohort overview		
Acceptance, n included/n eligible approached (%)	15/33 (45)	15/18 (83)
Dropouts, n (%)	1 (7)	1 (7)
Children included in quantitative data analysis, n (%)	—[a]	13 (87)
Adherence, median proportion (IQR)	—	68 (39-92)
Children included in qualitative data analysis, n (%)	14 (93)	15 (100)
In-depth interview	14 (100)	—
Semistructured interview after 1 week	—	15 (100)
Semistructured interview after 3 week	—	14 (93)
Semistructured interview after 6 week	—	12 (80)
Semistructured interview after 12 week	—	14 (93)
Model smartwatch, n (%)		
Steel HR[b]	10 (67)	10 (67)
Pulse HR	5 (33)	5 (33)

[a]Not applicable.

[b]HR: heart rate.

Phase 1

The in-depth interviews highlighted that children were generally willing to wear the smartwatch during cancer treatment, as it motivated them to remain physically active and achieve their daily activity goal. Parents mentioned that the smartwatch provided valuable insights into their child's symptoms linked to physical activity. However, some children found the smartwatch occasionally annoying or burdensome. The primary reasons for not wearing the smartwatch were having a lack of knowledge about potential benefits or a sense of relevance for its use, having a lack of stimulating environment, and not perceiving it as beneficial, especially when not engaging in physical activity. Moreover, children did not feel attached to the smartwatch, forgot to wear it due to not being used to wearing a watch, had a lack of external assistance, and had no desire to wear it or had issues with their preferences or comfort. Quotes from the in-depth interviews emphasizing the barriers for not wearing the smartwatch mentioned by children and their parents are reported below.

XSL•FO
RenderX

> *It would help wearing the smartwatch more often when showing us the usefulness. For example, we only really realized how useful the smartwatch was once he started wearing it.* [Father of an 11-year-old boy]

> *Sometimes during the day when I did not do anything, I either forgot the smartwatch or I thought "Well, yes, I am not really doing anything right now thus it is not so much use."* [17-year-old boy]

> *If you have worn the smartwatch continuously, you get…*
>
> *Father: …maybe something like a small reward. Something that shows appreciation — it does not have to be expensive or big, but something that says 'thank you for your help'. A card, a little thing, just something — yeah, I think that would be motivating.* [9-year-old boy and his father]

> *I only took the smartwatch off because it irritated my skin. Maybe a fabric strap would be more comfortable.* [13-year-old girl]

Based on the barriers to wearing identified in phase 1, several key considerations were identified and implemented to optimize phase 2 (Table 2). The considerations were structured into the following points:

(1) Enhanced engagement: When children received the smartwatch, they were extensively informed about the importance of wearing it, personal benefits, and its features. The information provided by the researcher was tailored to individual children. If a child, for example, was eager to move a lot, the benefits of seeing its own physical activity were emphasized. Parents were actively engaged in the process to ensure support and understanding.

(2) Regular prompts: Children or their parents, depending on the family's preferences, received prompts with feedback on wearing behavior and tips for smartwatch use as a text message on their phone or via email. Such prompts looked like:

> *When you start moving, your muscles and bones become stronger, making it easier to stay physically active. Tip: You can track your heart rate over the day, week, or month in the application by clicking on 'Heart Rate.' Did you know your heart rate goes up when being physically active?*

These prompts were sent after the first week of wearing and subsequently every other week. Prior research has demonstrated that such prompts were effective in maintaining engagement in children with acute lymphoblastic leukemia [41] and sustaining health-enhancing behaviors in adolescents [42,43].

(3) Customized plans: To address practical challenges, a personalized plan was created with input from children to ensure the smartwatch was not forgotten. Examples of issues addressed in such a personalized plan included placing the smartwatch on the child's bedside table or next to the child's smartphone during the night and putting it on directly after waking up. Parents were encouraged to assist their child in wearing the smartwatch daily if needed by giving them an active role in incorporating the smartwatch into the daily routine.

(4) Personalized setup: The smartwatch was tailored to each child's preferences. If desired, features, such as phone call and message notifications were activated, and a daily step goal was set.

(5) Improved aesthetics and comfort: To meet individual preferences and address potential irritation, children were provided with a variety of wristbands in different colors and made of different materials.

XSL•FO
RenderX

Table . Principal considerations for long-term physical activity tracking during childhood cancer treatment gathered during phase 1 and used to optimize phase 2.

Key considerations and barriers for wearing	Specific considerations
Enhanced engagement	
Lack of knowledge about potential benefits and relevance	Provide extensive information on the benefits and relevance of wearing the smartwatch, also when not being physically active
No perceived benefit	Provide information regarding potential benefits of wearing and using the smartwatch, with a focus on benefits for children themselves
Lack of stimulating environment	Increase social support and engage parents
Regular prompts	
No attachment	Send 2 weekly prompts, including feedback on wearing behavior and tips for smartwatch use
Customized plans	
Forgotten to wear	Create a plan to not forget the smartwatch using input from children themselves to optimize wearability
Lack of external assistance	Encourage parents to assist children in wearing the smartwatch
Personalized setup	
No desire to wear	Activate incoming phone calls and messages and set a daily step goal
Improved aesthetics and comfort	
Issues with preferences or comfort	Offer a variety of wristbands in different colors, which are made of different materials

Phase 2

Technical difficulties while synchronizing the smartwatch with the app occurred in 2 children, resulting in incomplete data retrieval. Therefore, these children were not included in the calculations of adherence. One child dropped out after 36 days because wearing the smartwatch was considered too much of a burden in combination with medical needs but was still included in the analysis. Thirteen children had a median adherence of 68 % (IQR 39% - 92%) of total days included in the study (Table 1). Overall, 6/13 children (46%) adhered to wearing the smartwatch for a minimum of 75% of the 12-week study period and reached the adherence target.

All interviews performed during phase 2 were analyzed according to an iterative approach to define themes during as well as after the study period. These interviews identified key barriers and facilitators of real-time and long-term physical activity tracking using a smartwatch in children during cancer treatment. The most prominent themes were (1) burden and resilience, (2) motivational drivers and perception, (3) insight and evaluation, and (4) user experience and functionality (Table 3). These themes are elaborated in the following paragraphs and supported with quotes from children and parents.

XSL•FO
RenderX

Table . Barriers and facilitators of real-time and long-term physical activity tracking using a smartwatch in children during cancer treatment.

Main themes, subthemes, and codes	Barrier	Facilitator
Burden and resilience		
Physical state		
Being fatigued	Feeling too exhausted during admission or intensive treatment courses.	—[a]
Feeling ill	Children find the smartwatch too burdensome when feeling sick, nauseous, and unwell.	—
Low resilience	It is too much and burdensome to wear the smartwatch on top of medical needs, such as taking medication, being hospitalized, having a drip line, receiving radiation, or tube feeding.	—
Perception of burden		
Overload	Children expect that the smartwatch is not something they could focus on shortly after diagnosis or have no interest in the smartwatch during intensive treatment courses and do therefore not expect to be willing to wear it during the entire treatment. For some parents, the smartwatch would feel like an overload during early treatment phases, as it would have been too much to deal with.	—
(No) pressure to wear	Some children feel pressured to wear the smartwatch continuously, which can become overwhelming.	Other children feel no such pressure to wear the smartwatch, enabling flexible use.
Not burdensome to wear		Wearing the smartwatch is considered not burdensome.
Enforcing the obligation may lead to resistance	The feeling of wearing the smartwatch being an obligation is unpleasant and would make wearing it during the entire treatment unbearable.	—
Motivational drivers and perception		
Motivation and stimulus		
(No) stimulus for physical activity	The smartwatch is no additional stimulus for physical activity for some children. Parents question the smartwatch's ability to motivate or provide value if the child does not experience it as a stimulus.	For other children, the smartwatch is an additional stimulus for physical activity.
Stimulus despite pain	—	Despite experiencing treatment-related nerve pain, the smartwatch is a stimulus for physical activity.
Reward for sufficient physical activity	—	Willingness to wear the smartwatch for the visual reward after reaching the step goal.
Value and meaningfulness		
Attachment to the smartwatch	—	Feeling proud to wear the smartwatch.
Lack of obligation	The absence of expectation or mandate allows children to deprioritize the smartwatch. Therefore, children consider it as one of the first things they can let go.	—
Decreasing novelty	The initial enthusiasm for the smartwatch diminishes over time.	—

XSL•FO
RenderX

Main themes, subthemes, and codes	Barrier	Facilitator
Not useful during inactivity	Depending on the intensity of treatment and its effect on how physically active children can be, wearing the smartwatch may not be doable for some children. Especially when children are physically inactive, such as when they feel unwell or tired, are resting, or shortly after diagnosis, they are unsure about the meaningfulness of the smartwatch.	For other children, it might be doable to wear the smartwatch during treatment with varying intensity and effect on physical activity.
Lack of intrinsic motivation	—	Some children wear the smartwatch out of habit or external expectation rather than personal interest.
Concerns around smartwatches		
Inaccurate tracking of physical activity	Children are disappointed when steps or other activities are not tracked accurately, as they want all their physical activity to be captured.	—
Parental concerns about overemphasis on physical activity	Some parents feel their child places too much focus on the smartwatch, potentially leading to excessive physical activity or obsession with activity tracking.	—
Insight and evaluation		
Self-monitoring and positive evaluation		
Tracking physical activity for self-monitoring and evaluation	—	Having insight into steps, heart rate, sleep, distance covered, calories burned, and time is convenient and used as an evaluation of the number of steps taken on different days and during and after physiotherapy consultations.
Confirmation of sufficient physical activity	—	Insight provides confirmation of being sufficiently physically active.
Insight and health evaluation by parents	—	Parents appreciate having insight, linking their child's physical activity to its feelings or complaints, and using the smartwatch as an additional medical tool. Also for parents, the smartwatch motivates them to be physically active or helps with seeking opportunities.
Sharing insight with the environment		
Providing insight into physical activity for oneself and others	—	Children feel positive about having insight into their own physical activity and being able to share this with others. It helps them show others that being ill does not prevent them from staying physically active.
Support from a pediatric physiotherapist	—	Children find it beneficial when their pediatric physiotherapist has access to their physical activity data and supports them through encouraging messages to stay active.
Challenges with tracking and insight		
Negative feelings about tracking and external feedback	Failing to meet daily step goals can feel confronting for some children. Parents worry that such confrontation could have a discouraging effect. Furthermore, children might find it unpleasant if their pediatric physiotherapist had insight into their low physical activity levels and pointed out their physical inactivity.	Other children do not perceive it as problematic when failing to meet daily step goals.
User experience and functionality		
Comfort and fit		
Appearance	Some children find the smartwatch unattractive.	Other children consider the smartwatch attractive, appreciating features like a preferred strap color or matching it with their clothes.

XSL•FO
RenderX

Main themes, subthemes, and codes	Barrier	Facilitator
Wearing comfort	Particularly shortly after diagnosis or during early treatment, wearing the smartwatch is sometimes considered unpleasant. The smartwatch sometimes leaves an imprint, presses on the skin or bone, or causes skin irritation, which makes children not willing to wear the smartwatch for the entire treatment.	For most children, the smartwatch feels comfortable and unobtrusive, and they think it is doable to wear the smartwatch throughout the entire treatment.
Skin irritation	The smartwatch can cause skin irritation, such as itching, bumps, or small lesions, particularly shortly after diagnosis, when combined with certain medications, such as treatment with glucocorticoids, or sweating.	—
Fit	The smartwatch can sometimes be too tight or too loose, shifting on the wrist.	Even the smallest smartwatch may feel oversized for young children due to their small wrists, but they may still prefer to keep it on.
Strap material	Some children think that a fabric strap is not better than a rubber strap.	Other children think that a strap made of a different material than rubber, such as metal or fabric, might be more comfortable or attractive.
Needs and preferences		
Ease of use	—	The smartwatch is considered easy to use.
Features and functionalities	—	The long battery life and waterproof design are appreciated. Preferences vary: one child prefers a smartwatch without a digital screen while another favors a fully digital display.
Preference for phone-based physical activity tracking	One child prefers to wear an attractive, nontracking watch and use a phone to track physical activity rather than wearing a less attractive smartwatch that tracks physical activity.	—
Technical functionality		
Phone notifications	Inconsistent visibility of notifications on the smartwatch can be frustrating.	Receiving phone notifications on the smartwatch is considered convenient and enjoyable.
Difficulty synchronizing with the app	When the smartwatch is not properly connected to a phone or tablet, some activity data may not be recorded in the app, limiting its usefulness.	—
Incorrect setup limits functionality	If the smartwatch screen is not set up correctly, physical activity data may not be displayed.	—
Reliability and sustainability		
Strap quality	The strap and its loops are of low quality, which is seen as inconvenient.	—
Inconsistent activity measurement	Steps or heart rate do not always seem to be measured continuously or consistently.	—

[a]Not available.

Burden and Resilience

The experience of wearing the smartwatch varied widely among children, with some who found it overly burdensome, particularly during periods of fatigue, nausea, or general illness. For children with low resilience or high medical needs, the additional effort of wearing the smartwatch could be perceived as overwhelming.

> *But everything that came with it, was too much for her. She no longer wanted to take medication. In the meantime, she has been given a feeding tube. She was very ill, so she had absolutely no interest in the smartwatch anymore, you know.* [Mother of an 11-year-old girl]

The timing of introducing the smartwatch played an important role. Shortly after diagnosis or during intensive treatment phases, children may not be emotionally ready to engage with the smartwatch. Parents noted that during the initial month of treatment, the smartwatch could feel like an overload on top of an already overwhelming situation. While some children found the associated expectations and pressure of wearing the smartwatch overwhelming, making it unsustainable, others experienced no such difficulty and wore it with ease. When children had the feeling that wearing the smartwatch was mandatory and that they were not supposed to take it off,

XSL•FO
RenderX

wearing it became unpleasant and unsustainable for the entire treatment.

> *I could have worn the smartwatch at the beginning of the treatment, closer to the diagnosis, but I do not know if it would have been very useful, because at that time I could not really do anything. So I am not sure if it would have helped much. I think probably yes, but I do not know for sure, because I was not thinking about that back then. It was more like, "Oh shit, I cannot walk," you know?* [16-year-old girl]

> *The thought that you are not supposed to take it off is exactly what makes you want to take it off.* [12-year-old boy]

Motivational Drivers and Perception

The smartwatch served as a motivator for physical activity for some children, even in the presence of pain. For others, however, it did not provide an additional motivation. Parents questioned its value when their child did not perceive it as a stimulus for physical activity.

> *I wore the smartwatch to track how much I moved during the day and things like that. At the end of the day, I would check what I did — like how many steps, how many meters. And it was really very little. That made me realize that I could probably do a little bit more.* [17-year-old boy]

> *At the moment when it does not provide any benefit to yourself, so if it does not provide that stimulation, I am not sure how fun or motivating it is. … Then, yeah, it does not really offer you anything directly.* [Father of a 13-year-old girl]

Without clear expectations or a sense of obligation, some children may deprioritize the use of the smartwatch, and the initial excitement may fade. While some children found it challenging to use the smartwatch during intensive treatment phases, others continued to wear it. Uncertainty about its usefulness emerged when children were physically inactive.

> *Yeah, only when I received Dexa (dexamethasone) — I found it a bit irritating then, so I did not wear it for a few days. Especially during those 2 or 3 days when I was really at my peak, I took it off for a bit. But after that, I pretty much always wore it again. Yeah, but that was really just because of Dexa — and that kind of speaks for itself, you know. That was the only reason.* [16-year-old girl]

> *Well, it is more like, I wear it mainly because it is practical, and if you are just lying in bed all day, yeah, then it is basically useless.* [12-year-old boy]

Accurate tracking of physical activity was crucial for maintaining engagement. Children sometimes expressed disappointment when the smartwatch failed to capture their physical activity correctly. In addition, some parents worried that their child might become overly focused on the smartwatch, potentially leading to excessive physical activity or an unhealthy preoccupation with tracking.

> *The only downside is that when you are on the treadmill, I think it does not count all the steps — it seems to miss some of them.* [17-year-old boy]

Insight and Evaluation

Self-monitoring through the smartwatch provided the opportunity to evaluate physical activity levels and confirmed that the child had been sufficiently physically active. Parents particularly appreciated having insight into their child's physical activity, with some who used it as an extra tool to assess their child's health status.

> *But it is also helpful for me personally, especially now, because I can start feeling unwell quite quickly — so it is good to be able to see how things are going.* [16-year-old boy]

> *Actually, it was really practical because we saw that suddenly her resting heart rate was much higher and this helped also with, well let's say, she needed a blood transfusion and probably this was related to her too low hemoglobin level. So it did help us as we thought: 'Well, her heart rate is really very high'. Yes, so that is really practical. In that way, we can also make use of it to know in time what is going on. … So, it is also, we now have an extra tool. Convenient, right?* [Mother of a 9-year-old girl]

For children, tracking and sharing physical activity data may be empowering and provide proof that they can remain active despite their illness. Positive reinforcement from their pediatric physiotherapist, enabled by access to their physical activity data, would be valued.

> *To prove to myself and others that, even though you are sick, you can still do a lot and you can definitely stay fit.* [12-year-old boy]

However, the experience of activity tracking was not uniformly positive. While some children found it encouraging, others perceived it as confronting, particularly if their activity levels were low. This perception may discourage using the smartwatch. Children expressed discomfort at the thought of their pediatric physiotherapist having insight into their low physical activity levels and pointing this out.

> *I think that if you get a smartwatch at a time like that, and you just cannot reach your goal of the minimum number of steps because you feel too unwell, I think it works counterproductively.* [Mother of a 9-year-old girl]

User Experience and Functionality

The design and comfort of the smartwatch influenced its usability during treatment. Most children found the smartwatch attractive and comfortable to wear throughout the entire treatment, while others found the design unattractive or experienced irritation or pressure on their skin. These issues were more likely during early or intensive treatment phases. Factors, such as loose or oversized straps as well as material preferences, impacted wearability.

XSL•FO
RenderX

> *Well, it is just — I mean, it is not like it really bothers me. I wear bracelets too, so why would I not be able to wear a watch?* [16-year-old girl]
>
> *Uh, when I move, it keeps sliding forward and backward, and that was just really annoying.* [11-year-old boy]

The smartwatch was considered easy to use, though children's preferences varied. Some children favored a nondigital or visually appealing watch, which may present a barrier to using a smartwatch designed to track physical activity.

Technical limitations also affected the smartwatch's functionality and reliability. Issues, such as inconsistent visibility of phone notifications, difficulty connecting to digital devices, incorrect setup, improper material, and inaccuracies in physical activity measurements diminished its overall functionality.

Key Considerations for Long-Term Physical Activity Tracking During Childhood Cancer Treatment

Based on the barriers and facilitators suggested by children and their parents and interpreted by the researchers, the following key considerations are proposed for the future (Table 4):

(1) Personalized approach: A consideration should be made whether the smartwatch is a stimulus or a burden. Daily life feasibility should be discussed, tailoring usage to the individual child and its treatment phases. Providing information on its benefits and relevance may help to reduce perceived burden.

(2) Enhanced persistence: Children who do not perceive a motivational stimulus from the smartwatch should be timely identified, and strategies to wear should be adapted to their needs. Having the ability to set an adjustable, achievable step goal could be motivating for those who fail to reach the lowest daily step goal. Sending motivational and empowering prompts when not being sufficiently physically active might help to reduce negative feelings about sharing physical activity data.

(3) Aligned design and comfort: The smartwatch should align with preferences of children, including color, size, display, strap material, and comfort.

(4) Expanded functionalities: Children suggest additional functions, such as tracking various sports and calling parents, while parents value functions like monitoring temperature.

Table . Future key considerations for long-term physical activity tracking during childhood cancer treatment gathered during phase 2.

Key considerations and barriers for wearing	Specific considerations
Personalized approach	
Too burdensome for children with low resilience or low physical activity	Consider whether the smartwatch acts as a stimulus or a burden, discuss its feasibility in daily life and tailor its use to each individual child and their treatment phases
High perceived burden by child or parent	Provide information regarding the benefits and relevance of the smartwatch
Enhanced persistence	
No stimulus for physical activity	Identify and guide children who do not perceive motivational stimulus and adapt strategies to needs
Negative feelings about insight into low physical activity	Allow adjustable, achievable daily goal
Negative feelings about sharing insight	Send motivational and empowering prompts by enabling access to children's physical activity data
Aligned design and comfort	
Unattractive smartwatch	Align the smartwatch with preferences of children, such as features, color, size, and display
Uncomfortable smartwatch	Align the smartwatch with preferences of children, such as size, strap material, and comfort, and consider the effect of treatment on wearing comfort
Expanded functionalities	
Limited features and functionalities for children	Add functions, such as selecting more types of sports or calling
Limited features and functionalities for parents	Add functions, such as measuring additional health outcomes, for example, temperature

Discussion

Principal Findings and Comparison With Previous Work

In this study, we showed that long-term physical activity tracking using a smartwatch during childhood cancer treatment was not feasible in our cohort according to the feasibility target we set. Furthermore, we defined barriers, facilitators, and key considerations of real-time and long-term physical activity tracking using a smartwatch in children during cancer treatment.

The result from our study that physical activity tracking using a smartwatch in children with cancer was not feasible is not in line with a previous study in children with acute lymphoblastic leukemia who used a fitness tracker for around 3 weeks during their treatment [27]. This previous study showed that these children were able to consistently use the fitness tracker with

XSL•FO
RenderX

low effort. However, 40% (11/28) of eligible patients refused participation, which might induce a potential selection bias. Moreover, the fitness tracker used in the previous study was clipped to clothing rather than a watch worn on the wrist, and the study period was substantially shorter as compared to our study. The authors of the previous study suggested that the use of the smartwatch might only be feasible in a subset of children. Contrary to the results of our study, another previous study in children with a brain tumor reported no adverse effects of using a smartwatch combined with coaching by a physiotherapist for 12 weeks during treatment [26]. However, in the previous study, only children with a brain tumor were included, while in our study, children with a variety of cancer diagnoses were included, which entails a more heterogeneous population. Moreover, the children in the previous study received coaching by a physiotherapist, which was not the case for the children included in our study. Also, inconsistent with the results of our study, during the maintenance phase of childhood acute lymphoblastic leukemia and after treatment for childhood cancer, the daily use of a smartwatch for 6 months was reported to be feasible [28]. Nonetheless, in the previous study, children at the end of their treatment were included while we included a more diverse group of children during different phases of treatment. According to our results, we emphasize the need to consider whether the smartwatch is a stimulus or a burden, discuss daily life feasibility, and tailor usage to the needs and preferences of a child. Furthermore, in our study, tracking physical activity was feasible in some of the children. For the future, it would be of added value to study the characteristics of those who adhered to wearing the smartwatch to find out for which children wearing the smartwatch is feasible.

Besides feasibility and in contrast to the aforementioned studies, our study aimed to identify barriers, facilitators, and key considerations of real-time and long-term physical activity tracking using a consumer-level smartwatch in children during cancer treatment. We found that some children perceived wearing the smartwatch as confronting and felt a pressure to wear it, which may become overwhelming. Although knowledge about wearing experiences of using smartwatches in children with cancer during different phases of treatment is limited, a previous study, exploring the influence of smartwatches on motivation for physical activity in healthy children, reported a potential negative internal pressure to reach a certain step goal, which might have a negative effect on self-image [44]. The authors emphasized the importance of personalizing goals, which is in accordance with our key considerations to apply a personalized approach and tailor the smartwatch to each child individually. Furthermore, empowering children using motivational prompts might help to reduce negative feelings about having and sharing insight. Finally, providing information on its benefits and relevance may aid in reducing perceived burden.

We found that children might perceive the smartwatch in diverse ways, where motivation, value, and expectations play key roles in the success of wearing the smartwatch. These factors not only influence how the smartwatch is perceived but also affect how engaged children and parents feel with the smartwatch. During phase 1, we highlighted the importance of enhancing engagement. Both reducing perceived burden and enhancing engagement are essential for ensuring the smartwatch's long-term use. Previous literature also mentioned the importance of feeling engaged as a key determinant of the success of physical activity interventions in adolescent and young adult survivors of childhood cancer [36], a smartwatch intervention in children with a chronic health condition [45], or the use of wearable devices to measure physical activity in healthy children [46,47]. For the future, we suggest increasing interest and creating value and meaningfulness by, for example, explaining the possibility of early recognition of aberrant physical activity levels and providing tailored advice and guidance when wearing the smartwatch.

In our study, children reported that the initial excitement of the smartwatch may fade over time. A decrease in the use of a smartwatch during physical activity interventions has earlier been reported in adolescent, young adult childhood cancer survivors [28] and healthy children [29]. Such a novelty effect might be the result of a reduced perceived usefulness. This might consequently have a negative effect on the smartwatch's wearability in the long term. Based on children's experiences and previous literature [48,49], we suggest identifying children who do not perceive a motivational stimulus from the smartwatch in a timely manner and adapting strategies to wear it according to their needs. Persistence might be enhanced by, for instance, allowing adjustable, achievable goals for those who fail to reach the lowest daily step goal, sending motivational and empowering prompts when not being sufficiently physically active, and keeping on aligning the smartwatch with the preferences and needs of the child. Moreover, it might be helpful to consider the first period of use as an opportune moment to incorporate the smartwatch into children's daily living. During this period, children should be informed about the use of the smartwatch, and ideally, this should be continued to encourage them to keep on using it [48-50]. Furthermore, developing and implementing an app that fits with a child's preferences might be helpful to increase wearability of the smartwatch, especially for those who experienced wearing the smartwatch as overwhelming or confronting.

Children had mixed experiences with wearing the smartwatch during treatment, where attractiveness, comfort, and usability played key roles in its acceptance. These findings are in line with the literature on healthy children [29,50]. We advocate aligning the smartwatch with preferences of children, including color, size, display, strap material, and comfort. Moreover, we suggest incorporating additional functions, as this might increase usefulness. For the future, the importance of personal preferences, comfort, and practical and technical performance should not be underestimated, and appropriate functionality, reliability, and sustainability should be ensured to promote sustained use.

Although a strength of this study is that the feasibility, barriers, facilitators, and considerations of real-time and long-term physical activity tracking using a consumer-level smartwatch in children during cancer treatment were examined using both quantitative and qualitative methods, it does have limitations. First, biases should not be overlooked. Selection bias should be considered, as especially children who are interested in a

XSL•FO
RenderX

smartwatch to track their physical activity might have been enrolled. However, in particular, the recruitment rate of 83% for phase 2 undermines selection bias. Confirmation bias should be recognized, as only 1 researcher conducted all interviews. Nonetheless, by using an interview guide and refining the methods and incorporating emerging topics based on children's experiences, we tried to prevent confirmation bias. Second, the differences in sex and time since diagnosis between children included in phase 1 and 2 might have influenced acceptance as well as the proposed key considerations. Finally, as a qualitative approach has been used, issues of credibility, transferability, and dependability should be acknowledged. We tried to consider these issues by prolonged engagement and persistent observation, thick description, and methodological transparency, respectively [51].

The barriers and facilitators we identified in this study might be helpful for improving the feasibility of physical activity tracking using a smartwatch in children during cancer treatment by acknowledging the key considerations we propose. In addition to these, identifying which children can feasibly wear a smartwatch would provide additional value for them. Furthermore, for future implementation, it would be helpful to explore the fine line between creating a certain commitment without overwhelming children. In addition, understanding how pediatric physiotherapists' access to children's physical activity data might be supportive during physiotherapeutic treatment would be valuable. Finally, developing a smartwatch in line with these and other needs of children with cancer and expanding functionalities according to their preferences would be of added value.

Conclusion

Real-time and long-term physical activity tracking using a smartwatch in children during cancer treatment was not feasible in our cohort. The success of wearing the smartwatch depends on the child's physical state and the perceived burden by both children and parents. Motivation, perceived value, and expectations play key roles in enhancing persistence, while the balance between positive reinforcement and potential stress from data interpretation affects long-term use. User experiences, including attractiveness, comfort, and usability impact acceptance, emphasizing the essence of a personalized approach, incorporating individual preferences and physical condition, to support adherence.

Data Availability

The datasets generated or analyzed during the study are available from the corresponding author on reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary material feasibility, barriers, and facilitators of long-term physical activity tracking during childhood cancer treatment.
[DOCX File, 20 KB - pediatrics_v8i1e75322_app1.docx]

References

1. Dimitri P, Joshi K, Jones N, Moving Medicine for Children Working Group. Moving more: physical activity and its positive effects on long term conditions in children and young people. Arch Dis Child 2020 Nov;105(11):1035-1040. [doi: 10.1136/archdischild-2019-318017] [Medline: 32198161]
2. Gatta G, Botta L, Rossi S, et al. Childhood cancer survival in Europe 1999-2007: results of EUROCARE-5--a population-based study. Lancet Oncol 2014 Jan;15(1):35-47. [doi: 10.1016/S1470-2045(13)70548-5] [Medline: 24314616]
3. Schulpen M, Visser O, Reedijk AMJ, et al. Significant improvement in survival of advanced stage childhood and young adolescent cancer in the Netherlands since the 1990s. Eur J Cancer 2021 Nov;157:81-93. [doi: 10.1016/j.ejca.2021.08.001] [Medline: 34492587]
4. Ospina PA, McComb A, Pritchard-Wiart LE, Eisenstat DD, McNeely ML. Physical therapy interventions, other than general physical exercise interventions, in children and adolescents before, during and following treatment for cancer. Cochrane Database Syst Rev 2021 Aug 3;8(8):CD012924. [doi: 10.1002/14651858.CD012924.pub2] [Medline: 34343340]
5. Gaser D, Peters C, Götte M, et al. Analysis of self-reported activities of daily living, motor performance and physical activity among children and adolescents with cancer: baseline data from a randomised controlled trial assessed shortly after diagnosis of leukaemia or non-Hodgkin lymphoma. Eur J Cancer Care (Engl) 2022 Mar;31(2):e13559. [doi: 10.1111/ecc.13559] [Medline: 35150025]
6. Braam KI, van der Torre P, Takken T, Veening MA, van Dulmen-den Broeder E, Kaspers GJ. Physical exercise training interventions for children and young adults during and after treatment for childhood cancer. Cochrane Database Syst Rev 2016 Mar 31;2017(3):27030386. [doi: 10.1002/14651858.CD008796.pub3]
7. Chang CW, Mu PF, Jou ST, Wong TT, Chen YC. Systematic review and meta-analysis of nonpharmacological interventions for fatigue in children and adolescents with cancer. Worldviews Ev Based Nurs 2013 Nov;10(4):208-217 [FREE Full text] [doi: 10.1111/wvn.12007]

XSL•FO
RenderX

8. Huang TT, Ness KK. Exercise interventions in children with cancer: a review. Int J Pediatr 2011;2011:461512. [doi: 10.1155/2011/461512] [Medline: 22121378]
9. Götte M, Taraks S, Boos J. Sports in pediatric oncology: the role(s) of physical activity for children with cancer. J Pediatr Hematol Oncol 2014 Mar;36(2):85-90. [doi: 10.1097/MPH.0000000000000101] [Medline: 24390449]
10. Tan SY, Poh BK, Chong HX, et al. Physical activity of pediatric patients with acute leukemia undergoing induction or consolidation chemotherapy. Leuk Res 2013 Jan;37(1):14-20. [doi: 10.1016/j.leukres.2012.09.005]
11. Winter C, Müller C, Brandes M, et al. Level of activity in children undergoing cancer treatment. Pediatr Blood Cancer 2009 Sep;53(3):438-443. [doi: 10.1002/pbc.22055] [Medline: 19415742]
12. Winter C, Müller C, Hoffmann C, Boos J, Rosenbaum D. Physical activity and childhood cancer. Pediatr Blood Cancer 2010 Apr;54(4):501-510. [doi: 10.1002/pbc.22271]
13. Rehorst-Kleinlugtenbelt LB, Bekkering WP, van der Torre P, van der Net J, Takken T. Physical activity level objectively measured by accelerometery in children undergoing cancer treatment at home and in a hospital setting: a pilot study. Pediatr Hematol Oncol J 2019 Dec;4(4):82-88. [doi: 10.1016/j.phoj.2019.12.004]
14. Grimshaw SL, Taylor NF, Shields N. The feasibility of physical activity interventions during the intense treatment phase for children and adolescents with cancer: a systematic review. Pediatr Blood Cancer 2016 Sep;63(9):1586-1593. [doi: 10.1002/pbc.26010] [Medline: 27186955]
15. Grimshaw SL, Taylor NF, Conyers R, Shields N. Evaluating the measurement properties and feasibility of physical activity and physical function assessments for children undergoing acute cancer treatment. JSAMS Plus 2024 Dec;4:100065. [doi: 10.1016/j.jsampl.2024.100065]
16. Brunet J, Wurz A, Shallwani SM. A scoping review of studies exploring physical activity among adolescents and young adults diagnosed with cancer. Psychooncology 2018 Aug;27(8):1875-1888. [doi: 10.1002/pon.4743] [Medline: 29719077]
17. Götte M, Seidel CC, Kesting SV, Rosenbaum D, Boos J. Objectively measured versus self-reported physical activity in children and adolescents with cancer. PLoS One 2017;12(2):e0172216. [doi: 10.1371/journal.pone.0172216] [Medline: 28207820]
18. Aznar S, Webster AL, San Juan AF, et al. Physical activity during treatment in children with leukemia: a pilot study. Appl Physiol Nutr Metab 2006 Aug;31(4):407-413. [doi: 10.1139/h06-014] [Medline: 16900230]
19. Ha L, Mizrahi D, Wakefield CE, Cohn RJ, Simar D, Signorelli C. The use of activity trackers in interventions for childhood cancer patients and survivors: a systematic review. J Adolesc Young Adult Oncol 2021 Feb;10(1):1-14. [doi: 10.1089/jayao.2020.0099] [Medline: 32897805]
20. Delrieu L, Pialoux V, Pérol O, et al. Feasibility and health benefits of an individualized physical activity intervention in women with metastatic breast cancer: intervention study. JMIR Mhealth Uhealth 2020 Jan 28;8(1):e12306. [doi: 10.2196/12306] [Medline: 32012082]
21. Hale TM, Guardigni V, Roitmann E, et al. Middle-aged men with HIV have diminished accelerometry-based activity profiles despite similar lab-measured gait speed: pilot study. JMIR Mhealth Uhealth 2019 Feb 1;7(2):e11190. [doi: 10.2196/11190] [Medline: 30707104]
22. Lanckriet S, Brissieux E, Borys JM, et al. Assessment of the impact of a sports kit on physical activity in children 8 to 11 years of age. J Phys Act Res 2017 Jan 26;2(1):50-60. [doi: 10.12691/jpar-2-1-9]
23. Le Hello C, Trombert B, Morel A, Chieh A, Brouard B, Boissier C. Performance analysis of walking of 10,000 regular users of a connected activity tracker. J Med Vasc 2018 Jul;43(4):231-237. [doi: 10.1016/j.jdmv.2018.04.001] [Medline: 29981731]
24. Purswani JM, Ohri N, Champ C. Tracking steps in oncology: the time is now. Cancer Manag Res 2018;10:2439-2447. [doi: 10.2147/CMAR.S148710] [Medline: 30122993]
25. Treskes RW, van Winden LAM, van Keulen N, et al. Effect of smartphone-enabled health monitoring devices vs regular follow-up on blood pressure control among patients after myocardial infarction: a randomised clinical trial. JAMA Netw Open 2020 Apr 1;3(4):e202165. [doi: 10.1001/jamanetworkopen.2020.2165] [Medline: 32297946]
26. Ovans JA, Hooke MC, Bendel AE, Tanner LR. Physical therapist coaching to improve physical activity in children with brain tumors: a pilot study. Pediatr Phys Ther 2018 Oct;30(4):310-317. [doi: 10.1097/PEP.0000000000000531] [Medline: 30199514]
27. Hooke MC, Gilchrist L, Tanner L, Hart N, Withycombe JS. Use of a fitness tracker to promote physical activity in children with acute lymphoblastic leukemia. Pediatr Blood Cancer 2016 Apr;63(4):684-689. [doi: 10.1002/pbc.25860] [Medline: 26756736]
28. Le A, Mitchell HR, Zheng DJ, et al. A home-based physical activity intervention using activity trackers in survivors of childhood cancer: a pilot study. Pediatr Blood Cancer 2017 Feb;64(2):387-394. [doi: 10.1002/pbc.26235] [Medline: 27615711]
29. Creaser AV, Clemes SA, Costa S, et al. The acceptability, feasibility, and effectiveness of wearable activity trackers for increasing physical activity in children and adolescents: a systematic review. Int J Environ Res Public Health 2021 Jun 8;18(12):6211. [doi: 10.3390/ijerph18126211] [Medline: 34201248]
30. Ridgers ND, McNarry MA, Mackintosh KA. Feasibility and effectiveness of using wearable activity trackers in youth: a systematic review. JMIR Mhealth Uhealth 2016 Nov 23;4(4):e129. [doi: 10.2196/mhealth.6540] [Medline: 27881359]

XSL•FO
RenderX

31. Collier L, Grimshaw SL, Stolper J, et al. Scoping review of the utilization of wearable devices in pediatric and young adult oncology. NPJ Digit Med 2025 Jul 31;8(1):488. [doi: 10.1038/s41746-025-01842-5] [Medline: 40745222]
32. Ferguson T, Rowlands AV, Olds T, Maher C. The validity of consumer-level, activity monitors in healthy adults worn in free-living conditions: a cross-sectional study. Int J Behav Nutr Phys Act 2015 Mar 27;12:42. [doi: 10.1186/s12966-015-0201-9] [Medline: 25890168]
33. Kaewkannate K, Kim S. A comparison of wearable fitness devices. BMC Public Health 2016 May 24;16:433. [doi: 10.1186/s12889-016-3059-0] [Medline: 27220855]
34. Kooiman TJM, Dontje ML, Sprenger SR, Krijnen WP, van der Schans CP, de Groot M. Reliability and validity of ten consumer activity trackers. BMC Sports Sci Med Rehabil 2015 Dec;7(1):26464801. [doi: 10.1186/s13102-015-0018-5]
35. Schmidt-Andersen P, Møller T, Mogensen PR, Schmiegelow K, Larsen HB, Nielsen MKF. Feasibility and validity of the actiheart activity monitor in children who were hospitalized with cancer coadmitted with classmates: a RESPECT study. Pediatr Phys Ther 2020 Jul;32(3):226-233. [doi: 10.1097/PEP.0000000000000712] [Medline: 32604366]
36. Mendoza JA, Baker KS, Moreno MA, et al. A Fitbit and Facebook mHealth intervention for promoting physical activity among adolescent and young adult childhood cancer survivors: a pilot study. Pediatr Blood Cancer 2017 Dec;64(12):e26660. [doi: 10.1002/pbc.26660] [Medline: 28618158]
37. King-Dowling S, Harris S, Daniel LC, et al. A pilot study of device-assessed physical activity and ecological momentary assessment among adolescent and young adult survivors of childhood cancer. Ann Behav Med 2025 Jan 4;59(1):kaaf002. [doi: 10.1093/abm/kaaf002] [Medline: 39898877]
38. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
39. Boeije H. Analysis in qualitative research: thinking and doing. 2005 Jan 1 URL: https://api.pageplace.de/preview/DT0400.9781446205402_A24010263/preview-9781446205402_A24010263.pdf [accessed 2025-08-22]
40. Evers J. Qualitative Interviewing: Art and Expertise.
41. Yeh CH, Man Wai JP, Lin US, Chiang YC. A pilot study to examine the feasibility and effects of a home-based aerobic program on reducing fatigue in children with acute lymphoblastic leukemia. Cancer Nurs 2011;34(1):3-12. [doi: 10.1097/NCC.0b013e3181e4553c] [Medline: 20706112]
42. Thompson D, Cantu D, Ramirez B, et al. Texting to increase adolescent physical activity: feasibility assessment. Am J Health Behav 2016 Jul;40(4):472-483. [doi: 10.5993/AJHB.40.4.9] [Medline: 27338994]
43. Militello LK, Kelly SA, Melnyk BM. Systematic review of text-messaging interventions to promote healthy behaviors in pediatric and adolescent populations: implications for clinical practice and research. Worldviews Evid Based Nurs 2012 Apr;9(2):66-77. [doi: 10.1111/j.1741-6787.2011.00239.x] [Medline: 22268959]
44. Kerner C, Goodyear VA. The motivational impact of wearable healthy lifestyle technologies: a self-determination perspective on Fitbits with adolescents. Am J Health Educ 2017 Sep 3;48(5):287-297. [doi: 10.1080/19325037.2017.1343161]
45. Butler S, Sculley D, Santos D, Gironès X, Singh-Grewal D, Coda A. Paediatric preparedness: document analysis of the challenges experienced using smartwatch technologies to support children living with a chronic health condition. Int J Environ Res Public Health 2025 Jan 21;22(2):133. [doi: 10.3390/ijerph22020133] [Medline: 40003359]
46. Schaefer SE, Van Loan M, German JB. A feasibility study of wearable activity monitors for pre-adolescent school-age children. Prev Chronic Dis 2014 May 22;11:E85. [doi: 10.5888/pcd11.130262] [Medline: 24854236]
47. Schaefer SE, Ching CC, Breen H, German JB. Wearing, thinking, and moving: testing the feasibility of fitness tracking with urban youth. Am J Health Educ 2016 Jan 2;47(1):8-16. [doi: 10.1080/19325037.2015.1111174]
48. Clawson J, Pater J, Miller A, Mynatt E, Mamykina L. No longer wearing: investigating the abandonment of personal health-tracking technologies on craigslist. Presented at: UbiComp '15: Proceedings of the 2015 ACM International Joint Conference on Pervasive and Ubiquitous Computing; Sep 7-11, 2015; Osaka, Japan p. 647-658. [doi: 10.1145/2750858.2807554]
49. Goodyear VA, Kerner C, Quennerstedt M. Young people's uses of wearable healthy lifestyle technologies; surveillance, self-surveillance and resistance. Sport Educ Soc 2019 Mar 24;24(3):212-225. [doi: 10.1080/13573322.2017.1375907]
50. Ridgers ND, Timperio A, Brown H, et al. Wearable activity tracker use among Australian adolescents: usability and acceptability study. JMIR Mhealth Uhealth 2018 Apr 11;6(4):e86. [doi: 10.2196/mhealth.9199] [Medline: 29643054]
51. Lincoln YS, Guba EG. But is it rigorous? Trustworthiness and authenticity in naturalistic evaluation. New Directions for Program Evaluation 1986 Jun;1986(30):73-84. [doi: 10.1002/ev.1427]

Abbreviations

HR: heart rate
MREC: Medical Research Ethics Committee

XSL•FO
RenderX

Edited by S Badawy; submitted 01.04.25; peer-reviewed by A Pouplier, C Karlson, G Engvall; revised version received 03.06.25; accepted 01.07.25; published 27.08.25.

Please cite as:
den Hartog E, Tissing WJE, Bon SBB, van der Torre P, Verwaaijen EJ
Feasibility, Barriers, and Facilitators of Long-Term Physical Activity Tracking During Treatment: Interview Study Among Childhood Cancer Patients
JMIR Pediatr Parent 2025;8:e75322
URL: https://pediatrics.jmir.org/2025/1/e75322
doi:10.2196/75322

©Emma den Hartog, Wim J E Tissing, Sebastian B B Bon, Patrick van der Torre, Emma J Verwaaijen. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 27.8.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Digital Interventions for Patients With Juvenile Idiopathic Arthritis: Systematic Review and Meta-Analysis

Zihan Ren[1], BEng; Yawen Chen[1], BEng; Yufeng Li[1], BEng; Panyu Fan[2], BSN; Zhao Liu[1], BEng, MEng, PhD; Biyu Shen[2], BSN, MSN, PhD

[1]School of Design, Shanghai Jiao Tong University, 800 Dongchuan Road, Minhang District, Shanghai, China

[2]Shanghai Children's Medical Center, School of Medicine, Shanghai Jiao Tong University, Shanghai, China

Corresponding Author:
Zhao Liu, BEng, MEng, PhD
School of Design, Shanghai Jiao Tong University, 800 Dongchuan Road, Minhang District, Shanghai, China

Abstract

Background: Juvenile idiopathic arthritis (JIA) is a chronic rheumatic condition requiring long-term, multidisciplinary treatment, which consumes significant health care resources and family energy. This study aims to analyze the effectiveness of digital interventions on patient outcomes in individuals with JIA.

Objective: This meta-analysis aimed to evaluate the impact of digital interventions on alleviating symptoms and improving overall well-being in children and adolescents with JIA.

Methods: A systematic search of 5 databases identified randomized controlled trials assessing the impact of digital interventions on physiological and psychological outcomes in adolescents and children (average age ≤19 y). Outcomes included pain, physical activity, health-related quality of life, self-efficacy, and disease-related issues. A total of 2 reviewers independently screened papers and extracted data on intervention functionalities and outcomes, assessing the risk of bias. A meta-analysis using a random-effects model synthesized the results.

Results: The review included 11 studies involving 885 patients with JIA. Digital interventions included educational (eg, self-management training), therapeutic (eg, pain management), and behavioral (eg, promoting physical activity) approaches. These were delivered through websites, telephone consultations, video conferences, apps, and interactive games, with durations ranging from 8 to 24 weeks and no clear link observed between intervention length and outcomes. Compared with conventional control groups, digital interventions were significantly effective in alleviating pain (standardized mean difference [SMD] −0.19, 95% CI −0.35 to −0.04) and enhancing physical activity levels (SMD 0.37, 95% CI 0.06-0.69). Marginal improvements in health-related quality of life, self-efficacy, and disease-related issues were observed, but these did not reach statistical significance (SMD −0.04, 95% CI −0.19 to 0.11; SMD 0.05, 95% CI −0.11 to 0.20; and SMD 0.09, 95% CI −0.11 to 0.29, respectively). The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach rated the quality of evidence for pain, health-related quality of life, self-efficacy, and disease-related issues as moderate, while the evidence quality for physical activity was assessed as low.

Conclusions: Digital interventions can alleviate pain and enhance physical activity in patients with JIA. However, given the limited sample size and high risk of bias in some studies, further high-quality research is needed to improve the treatment and management of JIA.

Trial Registration: PROSPERO CRD42023471223; https://www.crd.york.ac.uk/PROSPERO/view/CRD42023471223

(JMIR Pediatr Parent 2025;8:e65826) doi:10.2196/65826

KEYWORDS

juvenile idiopathic arthritis; digital intervention; application; children health care; pediatrics

Introduction

Juvenile idiopathic arthritis (JIA) is a prevalent chronic rheumatic ailment affecting children, causing joint pain and inflammation that can disrupt their daily lives [1]. During flare-ups, it can hinder academic performance, social interactions, and normal activities [2], while the complexity of treatment and associated complications further strain health care systems and drive up costs [3-6]. Since JIA requires ongoing monitoring and treatment [7,8], patients face a lifelong responsibility for managing the disease as they grow older [9]. Consequently, patients are encouraged to actively engage in lifestyle modifications and health-related decision-making [10]. Physical activity, including aerobic fitness and strength training, is recognized as a helpful nondrug intervention, offering

XSL•FO
RenderX

potential benefits in improving overall well-being and lessening the impact of JIA symptoms [11-13].

Internet-based digital tools, including mobile applications, websites, and other platforms, have become essential components of nonpharmaceutical interventions. These tools enable remote interaction and offer timely responses, making health care resources more accessible [14]. They can provide tailored rehabilitation interventions for pediatric chronic diseases and transitional care [15], such as fostering healthy behavioral habits through social media–based peer coaching [16]. Several mobile medical applications have been developed for adolescents and young individuals with JIA [17-22]. However, the research on their effectiveness has yielded varied results. While some studies have shown promising outcomes in terms of pain alleviation and physical function improvement, others have not replicated these results [22-24]. This variability in research findings highlights the need for further investigation and systematic evaluation to better understand the most effective components and digital health solutions in this domain, ensuring an accurate assessment of the evidence.

To date, previous reviews have assessed the effectiveness of mobile and e-medical interventions in aiding children and adolescents with JIA [25,26]. However, existing reviews have not focused on analyzing randomized controlled trials (RCTs), which could yield more precise results and reduce heterogeneity. The inclusion of only a minimal number of relevant outcomes (n≤3) in some meta-analyses, such as physical activity, limits the interpretation of findings cautiously and results in the absence of an effective theory of digital interventions for patients with JIA. Consequently, it remains unclear whether such interventions enhance clinical outcomes. Furthermore, as research on mobile medical interventions for JIA patients continues to evolve, it is essential to promptly integrate new research findings. This underscores the necessity for a fresh comprehensive evaluation of clinical interventions in this domain.

Therefore, our study aims to address these gaps by conducting a thorough analysis of digital interventions and their impact on clinical outcomes for patients with JIA.

Methods

Overview

This study follows the guidelines published in Preferred Reporting Items for Systematic reviews and Meta-Analyses [27] and the Cochrane Handbook of Systematic Reviews [28]. The priori protocol for the review is published in the International Prospective Register of Systematic Reviews (PROSPERO CRD42023471223).

Search Strategy

The research was conducted with the guidance and support of institutional librarians. A subject-specific librarian, along with researchers ZR and YC, developed a search strategy without language restrictions, which was used to conduct a comprehensive search in PubMed, Embase, Cochrane Library, Ovid, and Medline [29], covering records from the earliest available to the latest date. The search used Boolean operators in combination with Medical Subject Headings terms and free-text keywords to identify studies on the impact of digital interventions on JIA. The following search string was used as an example: (“Juvenile Idiopathic Arthritis” OR “Pediatric Rheumatic Diseases” OR “Juvenile Chronic Arthritis”) AND (“mHealth” OR “Digital Health” OR “Mobile Health”) AND (“Randomized Controlled Trial” OR “RCT” OR “Clinical Trial”). The full search strategy is provided in Multimedia Appendix 1, the specific keywords used for the search are provided in Multimedia Appendix 2.

The studies identified through this strategy were managed through the literature management software, Zotero (Corporation for Digital Scholarship). The 2 authors, ZR and YC, screened the identified studies, in line with predefined inclusion and exclusion criteria. Any discrepancies during this process were resolved through discussion between the researchers. Multimedia Appendix 1 shows the detailed search formulas. RCTs of any design, including crossover, multicenter, and cross-over trials, that were published in English are included in this review.

Participants

Episodes of JIA typically manifest in individuals before the age of 16 years [30]. However, considering the chronic nature of the condition and the need for ongoing treatment, the minimum age for inclusion in international pediatric treatment reference populations has risen to an average of 18.7 (SD 2.6) years.

Hence, for the purpose of this review, the term “children and adolescents” refers to individuals between the ages of 1 and 19 years [31]. The study population comprises children and adolescents diagnosed with JIA by a rheumatologist, ranging from 1 to 19 years old. Infants and neonates under the age of 1 year were excluded from the study population.

Intervention

In assessing the effectiveness of interventions for JIA recovery, the study focused on digital platforms such as somatic gaming, smart applications, teleconferencing, televideo, and health websites.

Control Condition

All types of control groups were considered in this study, including waitlists, physical therapy or minimal intervention groups, alternative treatments, and standard care delivered through web-based health care websites and apps. For example, the control group may use platforms like jong-en-reuma.nl, which provides information on medical issues and emotional support [32].

Outcome

Primary Outcome

There were 2 primary outcomes: pain (47-item Recalled Pain Inventory and 11-point Numeric Rating Scale) and physical activity (7-day activity diary [subjective], accelerometer [objective measurement], and Duruoz Hand Index Questionnaire.

XSL•FO
RenderX

Secondary Outcome

There were 2 secondar outcomes: health-related quality of life (Juvenile Arthritis Quality of Life Questionnaire, Pediatric Quality of Life Arthritis Module, Dutch Consensus Health Assessment Questionnaire Disability Index, and Pediatric Quality of Life Inventory [version 4.0]), self-efficacy (Children's Arthritis Self-Efficacy scale and Dutch Arthritis Self-Efficacy Scale), and illness-related issues (Medical Issues, Exercise, Pain, and Social Support questionnaire).

Risk of Bias

Risk of bias was assessed using the risk of bias tool of the Cochrane Handbook for Systematic Reviews [28]. Quality of evidence for outcomes was assessed according to the 5 Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) domains, including study limitation (risk of bias), inconsistency, indirectness, imprecision, and publication bias [33]. The bias was assessed by the 2 independent authors, ZR and YL. Any discrepancies were resolved through discussion and reexamination within the research group.

Data Extraction and Analysis

In order to identify and present common statistical descriptions of methodological heterogeneity, a descriptive integrated methodology was used. All findings were interpreted within the context of each study, considering the total number of studies and the assessed risk of bias. Using Review Manager (RevMan) software (version 5.4; Cochrane), this study conducted a random-effect meta-analysis to compare the standardized mean difference (SMD) for parameters across at least 3 studies between patients receiving general care and those using internet-based interventions. SMD and 95% CI were calculated using baseline and study end scores inputted into RevMan 5.4. Forest plots were generated using random-effect models for continuous data, presenting a summary of the effect distribution. Cohen's general rule of experience was applied, where an SMD of 0.2 signifies a "small" effect, 0.5 denotes a "moderate" effect, and 0.8 indicates a "large" effect. Furthermore, subgroup analysis was conducted to assess the impact of professional caregivers and intervention tools on the efficacy of e-medical intervention outcomes. Heterogeneity within the compiled studies was evaluated using I^2 statistics, and the carat test was used to assess significance. Heterogeneity levels were classified as low (I^2<25%; P>.1), moderate (I^2=25% - 49%), or high (I^2>50%).

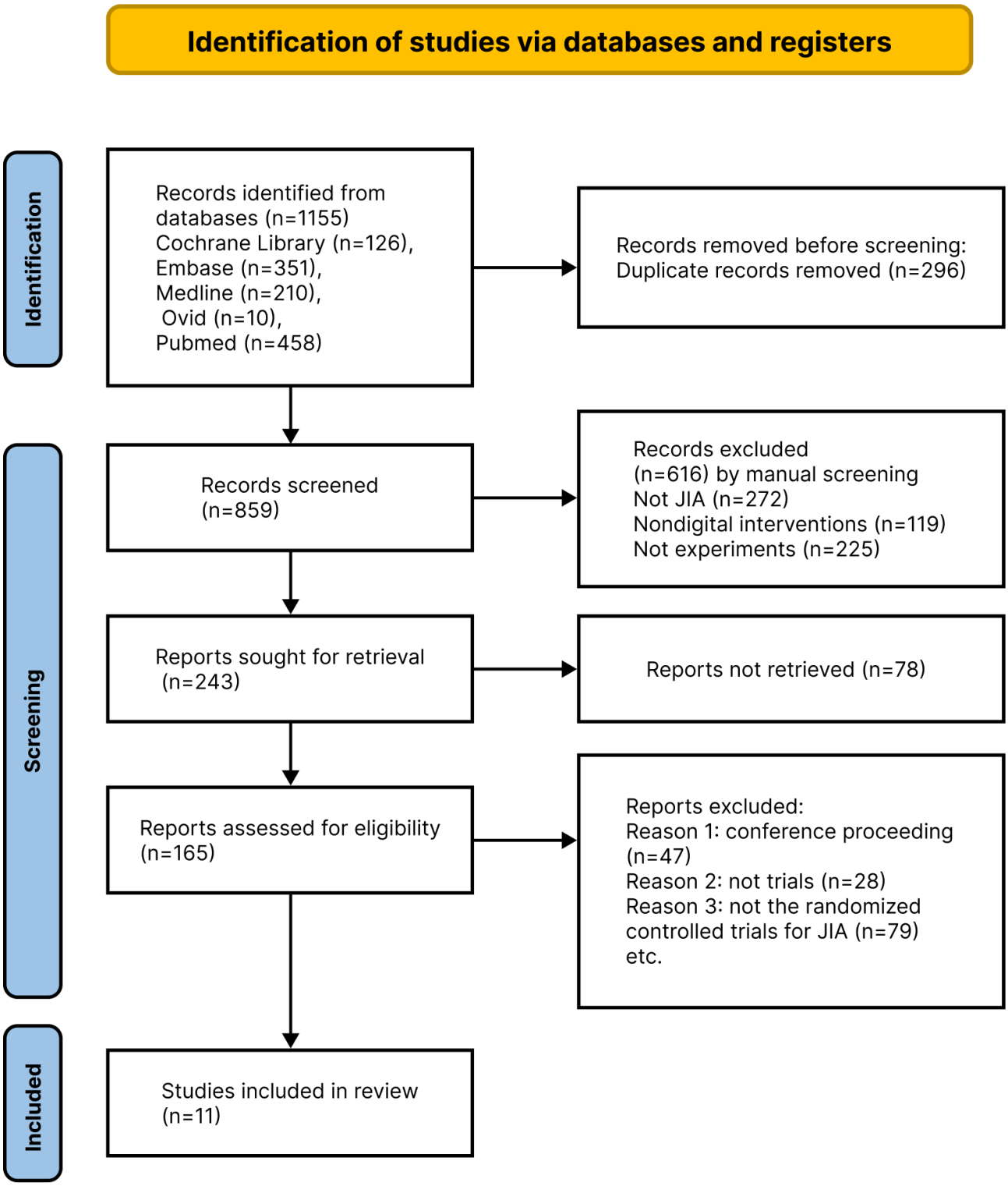
Results

Literature Selection

We initially identified 1155 studies. After excluding duplicate studies (n=296) and irrelevant studies (n=694), 165 studies remained for abstract evaluation. A total of 154 studies were excluded for the following reasons: conference proceedings (n=47), not trials (n=28), and not RCTs for JIA (n=79). Ultimately, 11 RCTs were included in the meta-analysis. The screening process is illustrated in Figure 1.

XSL•FO
RenderX

Figure 1. Summary of the study selection process using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses). JIA: juvenile idiopathic arthritis.



Participant Statistics

Table 1 shows the population characteristics, interventions, outcomes and study types of the 11 studies. Of these studies, 3 were from the Netherlands [32,34,35], 5 from Canada [36-40], and 1 each in the United States, Switzerland, and Turkey [38,40,41]. These studies included 289 individuals, predominantly female children and adolescents (663/885, 74.9%). A variety of juvenile arthritis subtypes were observed, with oligoarthritis being the most prevalent subtype (259/885, 29.3%). Almost all studies, with the exception of one [42], accounted for disease activity. The duration of the disease since diagnosis was documented in the majority of studies (7/11) [32,35-37,39,40,42].

XSL•FO
RenderX

Table . Population characteristics, interventions, outcomes, and study types of the 11 studies.

Author, country	Particular year	Average age (years)		Percentage of women, n/N (%)		Subtypes of JIA[c]	Participants		Outcomes	Type of study
		IG[a]	CG[b]	IG	CG		IG	CG		
Lelieveld et al [34], the Netherlands	2010	10.6 (1.5)[d]	10.8 (1.4)[d]	15/16 (88)	14/16 (88)	55% Persistent oligoarticular, 6% extended oligoarticular, 27% polyarticular, and 12% systemic	Internet-based meeting	—[e]	Physical activity level, number of days with ≥1 hour of moderate to intense activity per day, aerobic capacity, maximum heart rate, and resting heart rate.	Pilot randomized controlled trial
Stinson et al [36], Canada	2010	14.4 (1.3)[d]	14.8 (1.7)[d]	15/22 (68)	16/24 (67)	22% oligoarticular, 9% oligoarticular-extended, 24% polyarticular (RF–)[f], 7% polyarticular (RF+), 7% systemic, 7% psoriatic, 20% enthesitis-related, and 7% Unknown or other	Internet intervention	Attention control	Healthy life-related quality (primary outcome), pain intensity, stress, knowledge, adherence, and self-efficacy (secondary outcomes)	Experimental randomized controlled trial

XSL•FO
RenderX

Author, country	Particular year	Average age (years)		Percentage of women, n/N (%)		Subtypes of JIA[c]	Participants		Outcomes	Type of study
		IG[a]	CG[b]	IG	CG		IG	CG		
Stinson et al [37], Canada	2016	14.11 (1.53)[d]	14.42 (2.04)[d]	17/18 (94)	14/14 (100)	19% Polyarthritis (RF positive), 19% polyarthritis (RF negative), 3% polyarthritis (RF status unknown), 31% oligoarthritis, 25% psoriatic arthritis, and 3% enthesitis-related arthritis	Skype group	Standard care only	Feasibility (primary outcome) Self-management, self-efficacy, pain, social support, and health-related quality of life (secondary outcome)	Experimental randomized controlled trial
Ammerlaan et al [32], the Netherlands	2017	19.1 (2.7)[d]	19.1 (2.9)[d]	29/35 (83)	30/32 (94)	21% Oligoarticular JIA, 36% polyarticular JIA, 12% systemic JIA, and 31% other	Specific internet project intervention and designated website	Standard care and designated website	Self-efficacy (primary outcome), self-management, disease activity, health-related quality of life absence from courses , medication use, and adherence (secondary outcomes)	Randomized controlled trial

XSL•FO
RenderX

Author, country	Particular year	Average age (years)		Percentage of women, n/N (%)		Subtypes of JIA[c]	Participants		Outcomes	Type of study
		IG[a]	CG[b]	IG	CG		IG	CG		
Armbrust et al [35], the Netherlands	2017	9.7 (8.7 - 11.3)[g]	10.2 (9.0 - 10.8)[g]	21/28 (75)	12/21 (57)	24% Persistent oligoarticular JIA, 14% extended oligoarticular JIA, 37% polyarticular JIA, 4% rheumatoid factor positive, 4% enthesitis-related JIA, 4% psoriasis-related JIA, and 12% systemic JIA	Internet intervention, school and physical education	Access to standard care, school and physical education	Physical activity (primary outcome), exercise capacity, healthy life–related quality, disease activity, functional capacity, pain and well-being, and school engagement (secondary outcomes)	Multicenter randomized controlled trial
Ramelet et al [43], Switzerland	2017	—[h]	—	8/14 (57)	6/10 (60)	29% enthesitis-related JIA, 5% undifferenciated JIA, 27% oligoarticular JIA, 7% polyarticular JIA, 2% systemic JIA, and 30% other	Medical and telephone care consultations	Medical consultations only	Satisfaction (primary outcome), morning stiffness, and pain (secondary outcome)	Cross-over randomized clinical trial
Arman et al [42], Turkey	2019	12.36 (2.98)[d]	13.16 (3.35)[d]	21/25 (84)	21/25 (84)	44% oligoarticular JIA and 56% polyarticular JIA	Practice everyday activities with video-based games (Xbox 360 Kinect)	Practice daily activities with real-life materials	Upper extremity function (primary outcome), pain, upper extremity muscle strength, grip and pinch strength, and time-based activity performance (secondary outcome)	Randomized clinical trial

XSL•FO
RenderX

Author, country	Particular year	Average age (years)		Percentage of women, n/N (%)		Subtypes of JIA[c]	Participants		Outcomes	Type of study
		IG[a]	CG[b]	IG	CG		IG	CG		
Chadi et al [38], Canada	2019	15.4 (13-18)[i]	15.2 (13-17)[i]	7/9 (78)	7/9 (78)	—	Take video conferencing courses at home	Take offline courses in hospital	Acquisition of positive thinking skills (primary outcome), mood and anxiety, self-esteem, illness perception, salivary cortisol changes (secondary outcome)	Pilot randomized controlled trial
Connelly et al [41], United States	2019	14.6 (1.8)[d]	14.5 (1.7)[d]	98/144 (68)	111/145 (77)	21% Oligoarticular (extended or persistent), 45% polyarticular (RF-, RF+ ,or RF unknown), 34% other (enthesitis-related JIA, psoriatic, systemic, and undifferentiated)	Teens taking charge	An educational website	Pain interference and intensity, health-related quality of life (primary outcome), self-efficacy, pain coping, emotional regulation, and condition knowledge (secondary outcome)	Multicenter randomized clinical trial
Stinson et al [39], Canada	2020	14 (1.5)[d]	14.5 (1.7)[d]	63/88 (72)	91/131 (70)	2% Systemic, 21% oligoarthritis, 11% oligoarthritis—extended, 23% polyarthritis (RF-), 9% polyarthritis (RF+), 11% psoriatic arthritis, 16% enthesitis-related arthritis, 4% undifferentiated, and 3% other	Specific website and phone consultations	Public website and telephone consultation	Pain intensity, pain interference and HRQL[j] (primary outcomes), emotional symptoms, compliance, coping, knowledge, and self-efficacy (secondary outcomes)	Randomized controlled trial

XSL•FO
RenderX

Author, country	Particular year	Average age (years)		Percentage of women, n/N (%)		Subtypes of JIA[c]	Participants		Outcomes	Type of study
		IG[a]	CG[b]	IG	CG		IG	CG		
Lalloo et al [40], Canada	2021	14.9 (1.7)[d]	15.1 (1.6)[d]	23/29 (79)	24/31 (77)	5% Systemic, 16% oligoarthritis, 9% oligoarthritis-extended, 24% polyarthritis (RF–), 5% polyarthritis (RF+), 12% psoriatic arthritis, 21% enthesitis-related arthritis, 5% undifferentiated, and 3% other	iCanCope application version, including symptoms tracking and other functions	A version of icancope that only contains the symptom following feature	Participant accrual and attrition rates, success rate of app deployment, acceptability and compliance (primary outcomes), pain intensity, pain-related activity limitations, and health-related quality of life (secondary outcomes)	Randomized controlled trial

[a]IG: intervention group.

[b]CG: control group.

[c]JIA: juvenile idiopathic arthritis.

[d]Mean (SD).

[e]Not available.

[f]RF: rheumatoid factor.

[g]Median (IQR).

[h]This study only showed the mean age of the overall group (13.1 years).

[i]Median (age range).

[j]HRQL: health-related quality of life.

Intervention Group

Overview

Table 2 demonstrates main digital tools and methods. A total of 6 studies implemented internet-based physical activity intervention programs, health management websites, and telephone support initiatives. Among these, 4 studies included routine telephone consultations and interviews. In addition, 1 study used video conferences for skills training [38], while another used self-management pain applications on mobile phones for experimentation [40]. In addition, an emotional games-based task-oriented activity training study was conducted [42]. All interventions examined lasted at least 8 weeks, with the longest intervention cycle spanning 18 months [35].

XSL•FO
RenderX

Table . Main intervention methods.

Author, country	Digital tools or methods					Duration of intervention
	Specific websites	Telephones	Videoconferencing	Application	Somatosensory game	
Lelieveld et al [34], the Netherlands	✓					17 weeks
Stinson et al [36], Canada		✓				12 weeks
Stinson et al [37], Canada		✓				8 weeks
Ammerlaan et al [32], the Netherlands	✓					24 weeks
Armbrust et al [35], the Netherlands	✓					18 months
Ramelet et al [43], Switzerland		✓				12 months each
Arman et al [42], Turkey					✓	8 weeks
Chadi et al [38], Canada	✓		✓			8 weeks
Connelly et al [41], United States	✓					12 weeks
Stinson et al [39], Canada	✓	✓				12 weeks
Lalloo et al [40], Canada				✓		8 weeks

Functional Classification of Interventions

Digital interventions for patients with JIA are versatile, serving multiple functions. The purposes of these interventions include promoting physical activity (n=4), facilitating self-management for establishing healthy habits and reaching milestones (n=4), providing education on disease and health-related knowledge (n=8), offering stress relief to improve mood (n=4), and enhancing communication skills for better integration into school and society (n=7). Furthermore, half of the studies (n=7) supplemented the digital intervention program with telephone and video communication to augment its positive impact on children.

Statistics of Digital Interventions

A total of 8 studies used internet-based interventions based on previously developed projects or applications (Table 3). In addition, 3 studies used the Teens Taking Charge website as an intervention [36,39,41]. Furthermore, 2 studies used Rheumates@Work as an intervention [34,35]. For the experimental group's digitization project, 1 study used iPeer2Peer [37], Challenge your arthritis [32], and iCanCope [40]. Of all the intervention schemes, only 1 study referenced the theoretical framework as nursing guidance for their intervention schemes [43]. Care assessments conducted by nurses were guided and documented using Cox's interaction model of client health behavior [44] to ensure the continuity of care for children and their families.

XSL•FO
RenderX

Table . Names and functions of digital intervention tools.

Author, country	Intervention project name	Main functions					Additional functions
		Promote physical activity	Set goals	Health education	Manage emotions	Integrate into school or society	Video or phone consultation
Lelieveld et al [34], the Netherlands	Rheumates@Work	✓		✓			
Stinson et al [36], Canada	Teens Taking Charge	✓	✓	✓	✓	✓	✓
Stinson et al [37], Canada	iPeer2Peer			✓	✓	✓	✓
Ammerlaan et al [32], the Netherlands	Challenge your arthritis		✓			✓	
Armbrust et al [35], the Netherlands	Rheumates@Work	✓		✓		✓	
Ramelet et al [43], Switzerland	—[a]			✓		✓	✓
Arman et al [42], Turkey	Xbox 360 Kinect	✓					
Chadi et al [38], Canada	—			✓	✓		✓
Connelly et al [41], United States	Teens Taking Charge			✓	✓		✓
Stinson et al [39], Canada	Teens Taking Charge		✓			✓	✓
Lalloo et al [40], Canada	iCanCope		✓	✓		✓	

[a]Not available.

While enhancing self-management skills is vital for facilitating health care transition [45], only 2 RCTs [32,37] explicitly reported on self-management outcomes. The remaining articles primarily integrated self-management as a core component of digital interventions, with considerations on health education, goal setting, and mood management.

Control Group

One study in this review did not specify the care received by the control group [34]. A total of 5 studies compared the intervention group to a control group that received standard or offline care (without internet and eHealth interventions) [35,37,38,42,43]. One study solely used telephone coaching communication [36]. A total of 4 studies compared a control group using a public website or eHealth with limited functionality to an intervention group receiving a specific digital design program [32,39-41]. The control groups in all trials assessed patients' results at pretest and posttest.

Risk of Bias Assessment

The results of the risk of bias assessment indicate that the criteria most commonly unmet were the blinding of outcome assessment and the adequacy of outcome data (Figure 2). Half of the studies (5/11 and 6/11) were deemed to have a high risk of bias in these 2 categories. In contrast, studies concerning randomized sequence generation were predominantly evaluated as having a low risk (9/11). Furthermore, 7 studies exhibited a medium risk of bias, while 4 studies were categorized as having a high risk of bias.

XSL•FO
RenderX

Figure 2. Risk of bias summary [32,34-43].

XSL•FO
RenderX

Quality of Evidence Rating

Table 4 presents the key comparative results with GRADE ratings. A total of 3 primary outcomes are rated as moderate quality, while 2 primary outcomes are rated as low quality.

XSL•FO
RenderX

Table . Main comparative findings and recommendation grading.

Author (Year of publication)	Outcome	OR[a] (95% CI)	Studies (patients), n	Risk of bias	Inconsistency	Indirectness	Inaccuracy	Publication bias	Quality of evidence
Stinson et al [36] (2010), Stinson et al [37] (2016), Ammerlaan et al [32] (2017), Connelly et al [41] (2019), and Stinson et al [39] (2020).	Pain	−0.19 (−0.35 to −0.04)	5 (653)	Downgrade (High risk of incomplete data)	Nondegradation	Nondegradation	Nondegradation	Nondegradation	Moderate
Lelieveld et al [34] (2010), Ammerlaan et al [32] (2017), Armbrust et al [35] (2017), and Arman et al [42] (2019).	Physical activity	0.37 (0.06-0.69)	4 (160)	Downgrade (High risk of selective reporting)	One level down (low overlap)	Nondegradation	Nondegradation	Nondegradation	Low
Stinson et al [36] (2010), Stinson et al [37] (2016), Ammerlaan et al [32] (2017), Armbrust et al [35] (2017), Connelly et al [41] (2019), and Stinson et al [39] (2020).	Health-related quality of life	−0.02 (−0.17 to 0.13)	6 (702)	Downgrade (High risk of incomplete data)	Nondegradation	Nondegradation	Nondegradation	Nondegradation	Moderate
Stinson et al [36] (2010), Stinson et al [37] (2016), Ammerlaan et al [32] (2017), Connelly et al [41] (2019), and Stinson et al [39] (2020).	Self-efficacy	0.05 (−0.11 to 0.20)	5 (653)	Downgrade (High risk of incomplete data)	Nondegradation	Nondegradation	Nondegradation	Nondegradation	Moderate
Stinson et al [36] (2010), Stinson et al [37] (2016), Chadi et al [38] (2019), Connelly et al [41] (2019), and Stinson et al [39] (2020).	Disease-related issues	0.09 (−0.11 to 0.29)	5 (604)	Downgraded one level (high risk of blinding of outcome assessments)	One level down (low overlap)	Nondegradation	Nondegradation	Nondegradation	Low

[a]OR: odds ratio.

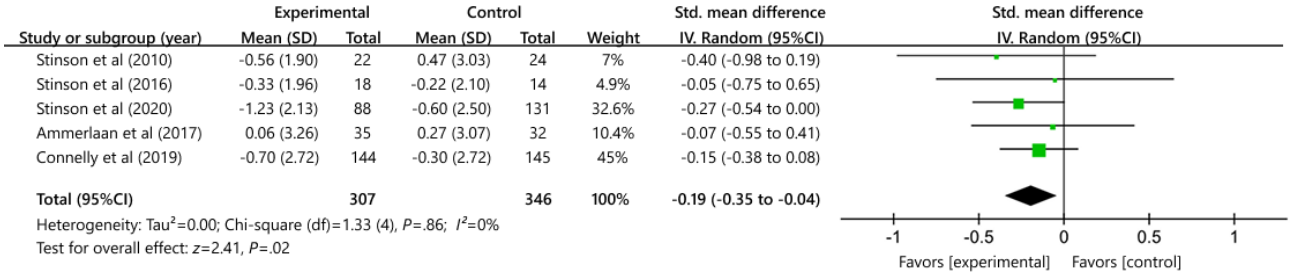
XSL•FO
RenderX

Meta-Analysis Results

Pain

Figure 3 depicts the impact of digital medical intervention on pain outcomes relative to all other control conditions. This analysis is based on findings from 5 studies involving 653 participants. A significant effect in favor of the intervention was observed (SMD −0.19, 95% CI −0.35 to −0.04; *P*=.86; I^2=0%). Several studies posed a high risk of bias, resulting in a moderate GRADE rating for the quality of evidence after the intervention.

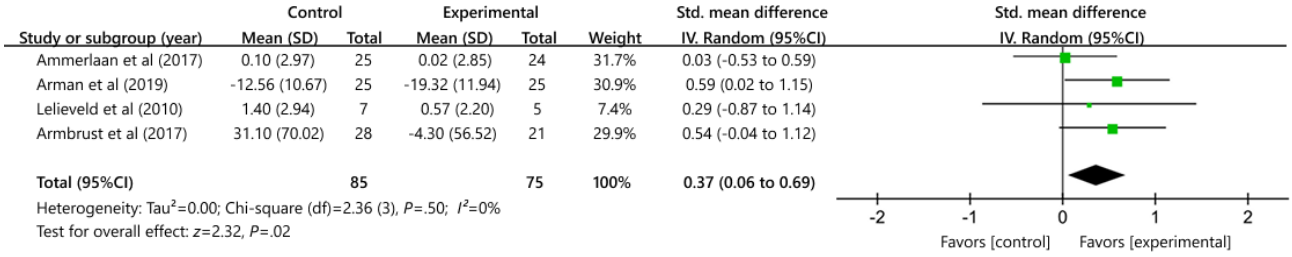
Figure 3. Effectiveness of digital health on pain outcomes [32,36,37,39,41].



Physical Activity

Figure 4 demonstrates the results of the effectiveness of using digital health care on patients' physical activity compared to using usual care and public websites. This analysis is based on findings from 4 studies involving 160 participants. The digital intervention had a statistically significant positive effect (SMD 0.37, 95% CI 0.06-0.69), and the results were not highly heterogeneous (*P*=.50; I^2=0%). Several studies posed a moderate-to-high risk of bias and inconsistency, resulting in a low GRADE rating for the quality of evidence after the intervention.

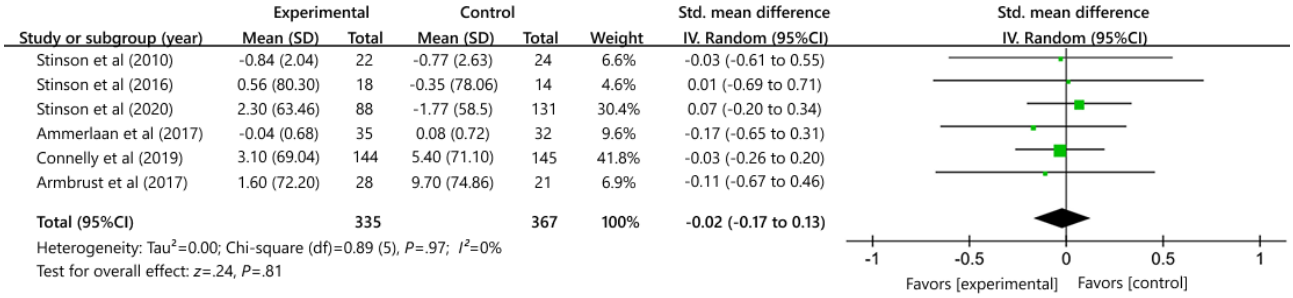
Figure 4. Effectiveness of digital health on physical activity outcomes [32,34,35,42].



Health-Related Quality of Life

A total of 6 studies with 702 participants comparing digital interventions and control conditions did not show a difference in health-related quality of life between the 2 intervention conditions (SMD 0.02, 95% CI −0.17 to 0.13); heterogeneity (*P*=.97; I^2=0%; Figure 5). Using the GRADE approach, the quality of evidence was rated moderate because of the high risk of bias in most studies (ie, incomplete data).

Figure 5. Effectiveness of digital health on health-related quality of life [32,35-37,39,41].

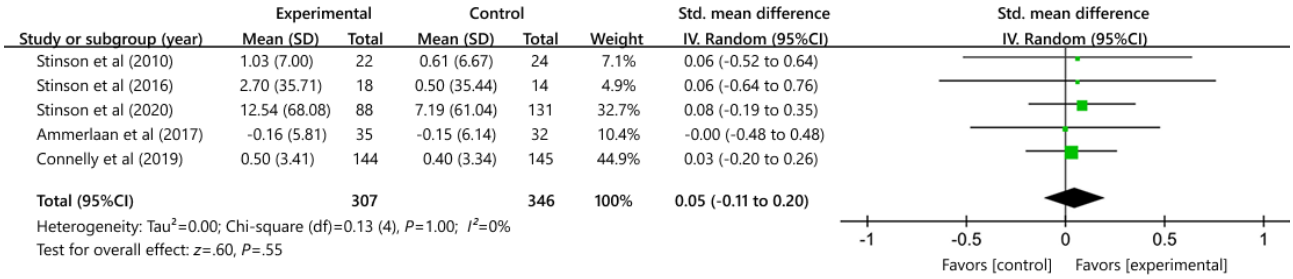


Self-Efficacy

A total of 5 studies with 653 participants comparing digital interventions and control conditions did not show a difference in self-efficacy between the 2 intervention conditions (SMD 0.05, 95% CI −0.11 to 0.20); heterogeneity (*P*=1.00; I^2=0%; Figure 6). Using the GRADE approach, the quality of evidence was rated moderate because of the high risk of bias in most studies (ie, incomplete data).

XSL•FO
RenderX

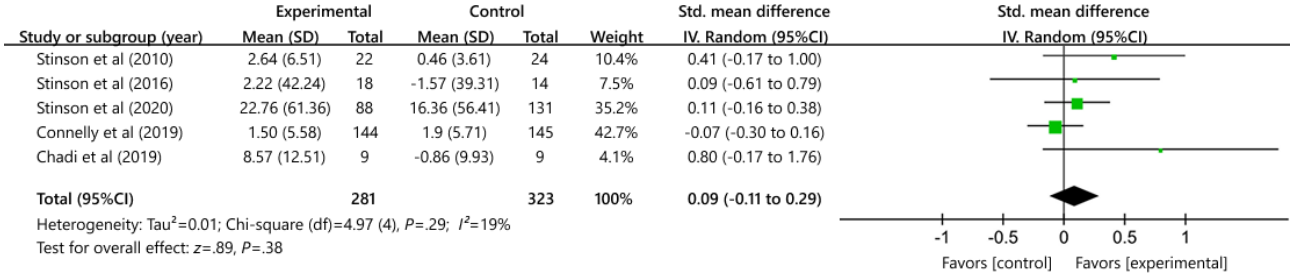
Figure 6. Effectiveness of digital health on self-efficacy outcomes [32,36,37,39,41].



Disease-Related Issues

Figure 7 demonstrates the effectiveness of interventions using digital health technology on patient outcomes for disease-related problems compared with other control conditions. A total of 5 studies included 604 participants (SMD 0.09, 95% CI −0.11 to 0.29) suggests that the effect is ultimately insignificant. The results exhibit minimal heterogeneity (P=.29, I^2=19%). The evidence following the intervention was assessed as moderate in quality using the GRADE methodology, owing to the presence of bias risk and inconsistency across certain studies.

Figure 7. Effectiveness of digital health on disease-related issues [36-39,41].

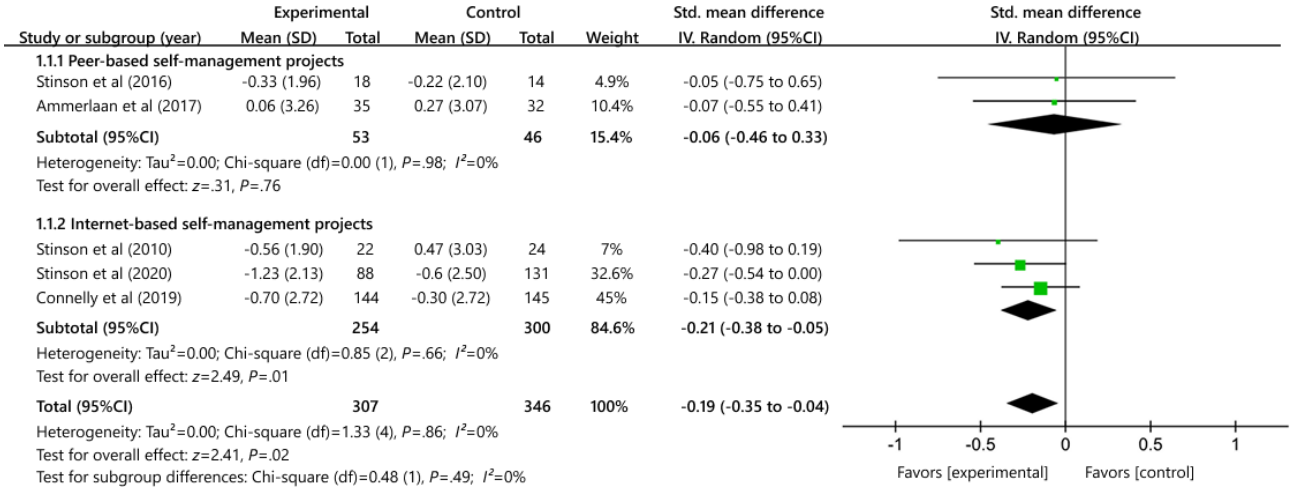


Subgroup Analysis

Effects of Peer Mentoring on Pain Outcome

The subgroup analysis revealed that the internet-based self-management program (n=3) resulted in a moderate effect size in pain reduction (SMD −0.21, 95% CI −0.38 to −0.05; heterogeneity χ^2_2=0.85; P=.66; I^2=0%; Figure 8). However, our findings showed no significant effect of iPeer2Peer and Challenge Your Arthritis (n=2) on pain (SMD −0.06, 95% CI −0.46 to 0.33; heterogeneity χ^2_1=0.00; P=.98; I^2=0%). Subgroup differences in pain outcomes were not significant between peer mentoring programs and other internet programs (P=.49; I^2=0%).

Figure 8. Effects of peer mentoring on pain outcomes [32,36,37,39,41].

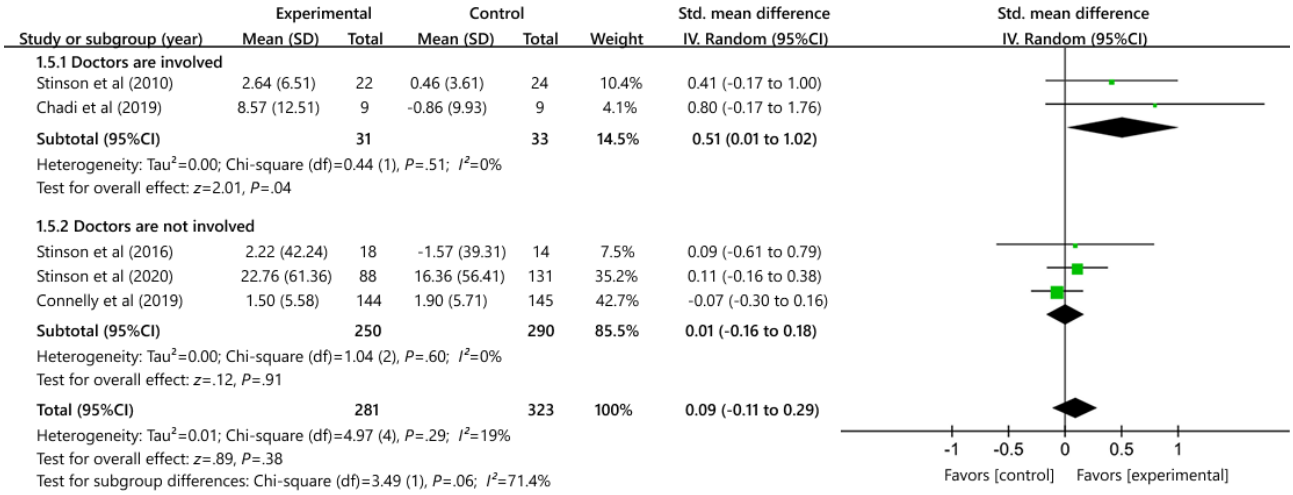


Effects of Physicians on Disease-Related Issues Outcome

The disease-related issues in studies with physicians improve more than those without physicians as the main component of the intervention (SMD 0.51, 95% CI 0.01 to 1.02 and SMD 0.01, 95% CI −0.16 to 0.18, respectively; Figure 9). However, the difference was not statistically significant (SMD 0.09, 95% CI −0.01 to 0.29; heterogeneity χ^2_4=4.97; P=.29; I^2=19%).

XSL•FO
RenderX

Figure 9. Effectiveness of e-health on disease-related issues when physicians are involved [36-39,41].



Discussion

Principal Findings

This systematic review comprehensively assessed studies on the effectiveness of digital interventions in aiding children and adolescents with JIA from physical and psychologically perspectives. According to the findings, patients who received digital medical technology interventions had significantly better physical activity outcomes (SMD 0.37, 95% CI 0.06-0.69) and experienced a reduction in pain outcomes (SMD −0.19, 95% CI −0.35 to −0.04) in comparison with those who received standard care. However, our research did not identify significant enhancements in disease-related issues (SMD 0.09, 95% CI −0.11 to 0.29), health-related quality of life (SMD −0.02, 95% CI −0.17 to 0.13), or self-efficacy (SMD 0.05, 95% CI −0.11 to 0.20).

Primary Findings

Overview

The use of digital interventions delivered through the internet or mobile devices has expanded mental health practices for children and adolescents facing JIA in local contexts [46,47]. These interventions offer flexible training schedules, overcome constraints of space and time [48], ensure anonymity, and allow for behavioral adaptation. Nevertheless, our findings indicate that interventions using digital medical technology have a more pronounced impact on physiological outcomes, aligning with earlier research conducted by Butler et al [26]. This emphasis on physiological outcomes may be attributed to the inclusion of components targeting physical activity and motor skills in the interventions, such as fitness regimens, varied exercises, and intensive training. However, the interpretation of psychological outcomes is more complex, influenced by various factors including personal psychological state, social environment, and cultural background. In addition, achieving and sustaining psychological transformations often requires an extended period. While these potential reasons have not been examined, our findings indeed illuminate the distinct physiological and psychological effects of digital medical interventions, offering a new perspective for understanding and evaluating their merits. Further investigation is needed to compare the impacts of digital medical interventions on physiological and psychological outcomes, and to identify strategies for optimizing intervention effectiveness in diverse contexts.

Pain

Our findings demonstrated a notable reduction in pain-related outcomes following the implementation of digital interventions. Two of these studies focused on young patients with JIA transitioning to adult care facilities, who demonstrated high self-efficacy and positive attitudes. In addition, 3 studies implemented a telephone-based therapeutic communication intervention. Subgroup analysis outcomes revealed that patients using an internet-based self-management program (Teens Taking Charge) [36,39,41] experienced a great reduction in pain symptoms compared with those using a peer-directed self-management program [32,37]. These findings align with a pilot feasibility study on peer coaching for adolescents with chronic pain [18], where the control group showed superior pain reduction status. This discrepancy may be attributed to the absence of explicit pain symptom sections in the self-management programs examined, which focused instead on social relationships and goal-setting. In contrast, the control group's website included comprehensive content addressing pain understanding and management, alongside audio and video features. In addition, Dennis et al [49] demonstrated that trained peer mentors could provide informational, evaluative, and emotional support to individuals with similar conditions, albeit without explicitly addressing pain relief. Hence, there is a need for studies about the usability of digital tools for managing pain symptoms in future research. These tools should go beyond mere documentation of pain symptoms and incorporate functionalities aimed at alleviating functional limitations, providing medication and exercise guidance, and offering strategies for managing low mood. Such enhancements are essential for improving the quality of life for patients coping with pain [50].

Physical Activity

Engaging in physical activity is essential for managing arthritis in patients [51]. Consistent with previous research findings [26], 4 findings emphasized the positive impacts of the internet interventions on physical activity. The majority of these studies

XSL•FO
RenderX

incorporate clinically recommended activity training, which increases physical activity levels and improves endurance among patients. Studies suggest that individuals with arthritis can prevent disability and complications by promoting healthy physical activity throughout their lives [52]. However, as demand for face-to-face health care interventions for supporting physical activity adoption and maintenance increases, resource constraints become more pronounced [53]. In a previous study, serious games were used in joint rehabilitation for patients with JIA [54-56]. The findings indicated that these interventions led to increased levels of physical activity among the patients. Our findings support this observation, as 1 of the 4 studies using video games for task-oriented activity training [42] showed improvements in patient outcomes. However, concerns have arisen regarding potential inaccuracies in the effectiveness of exercise diaries and activity monitoring accelerometers used by children. Therefore, there is a need for more accurate methods of data acquisition. We advocate for the development of additional digital tools that integrate health education and physical activity-focused content.

Secondary Findings

The secondary outcomes such as self-efficacy, health-related quality of life, and perception of disease-related issues did not show statistical significance. The previous research shows similar results. Lancaster et al [57] and Newby et al [58] did not find positive impacts of digital interventions on self-efficacy and quality of life. This discrepancy may be attributed to the measurement of self-efficacy which may not be adequately tailored to the conceptual, linguistic, and objective needs of children [32]. However, it is anticipated that improvements in quality of life may require more time to manifest [59], and changes might not be evident during shorter intervention periods. The Medical Issues, Exercise, Pain, and Social Support questionnaire, encompassing inquiries regarding medical matters, physical activity, psychological well-being, and social support [60], may experience compromised efficacy if a patient is insensitive to one of its components, indicating a limited awareness of disease-related concerns.

Other Findings

It is worth noting that not all psychological interventions are ineffective. The subgroup findings show that when physicians are involved in intervention implementation, children and adolescents show improved understanding of disease-related issues. Previous research shows that online health communities involving both patients and health care providers can improve mental health in chronic conditions by allowing patients to consult and interact with physicians [61,62]. Physicians provide essential health knowledge, emotional support, and guidelines for the use of medical supplies, which is crucial for improving the health status of individuals with chronic conditions [63]. To improve intervention outcomes, digital interventions should incorporate features for real-time interaction with healthcare providers, enabling physicians to offer clinical insights and socioemotional support, thereby strengthening the doctor-patient relationship and improving health outcomes.

Furthermore, video-based mindfulness interventions have shown benefits for populations with chronic illnesses and other conditions [64,65]. A study comparing the efficacy of online mindfulness interventions and in-person interventions in enhancing the mental well-being of patients with JIA observed a notable decrease in anxiety and depression [38]. This reduction may be attributed to adolescents experiencing greater ease and relaxation in the familiar setting of their homes [66]. Furthermore, Voerman et al [67] found that digital interventions incorporating cognitive behavioral therapy led to significant improvements in the psychological and social outcomes of patients. Specifically, relaxation exercises and cognitive behavioral therapy effectively reduced pain frequency in children and adolescents, alleviating depressive symptoms and functional disorders [68]. Future investigations should aim to integrate a theoretical framework that addresses the psychological dimensions of the condition, ensuring a more comprehensive approach to intervention design.

Limitations

Half of the studies (5/11) used digital tools that have been developed for over a decade, they may thus fail to represent the latest advancements in communication technologies and platforms. However, our findings indeed show their continued relevance and effectiveness. Second, the results of this review demonstrate that, from a statistical perspective, digital interventions are effective for certain patient outcomes. However, considering factors such as individual differences and variability in clinical environments, their clinical significance remains to be further validated. Future research should provide stronger evidence from a clinical perspective. Furthermore, the included studies are predominantly conducted in North American and European nations. As such, the findings of this analysis may not be universally applicable and may only offer insights into the integration of digital interventions within this specific population.

Conclusions

This systematic review analyzes self-reported outcomes in patients with JIA, including pain, physical activity, quality of life, self-efficacy, and disease-related issues. The findings from 11 RCTs demonstrate that digital interventions significantly alleviate pain and improve physical activity. These results highlight the potential of digital tools to enhance JIA management and patient outcomes, providing a strong case for their integration into clinical practice. Future studies should consider the inclusion of physicians in digital interventions to better understand their impact on outcomes.

Acknowledgments

The authors acknowledge the support of "Child-friendly Care+X Innovative Talent Practice Training Base" of Shanghai Jiao Tong University. This paper was supported by Construction Project of Shanghai Jiao Tong University School of Medicine (SITUHLXK2022); Innovative Research Team of Shanghai Local High-level Universities (SHSMU-ZDCX20212800); Nursing

XSL•FO
RenderX

Discipline Talent Team Construction Project of Shanghai Jiao Tong University School of Medicine, 2022 (SHJTUHLXK [2022]No.1); Shanghai Jiao Tong University, Shanghai Jiao Tong Nursing System, School of Nursing Shanghai Jiao Tong University (2024)6 and Base for Interdisciplinary Innovative Talent Training.

Data Availability

The meta-analysis conducted in this study is based on data retrieved from the following open-source databases: MEDLINE, PubMed, Embase, Ovid, and Cochrane. The data from these databases are publicly available and can be directly accessed through their respective websites or DOI links. The analyses presented in this paper are based on these public datasets, and the specific data retrieval dates and search strategies have been detailed in the Methods section of the paper.

Authors' Contributions

ZR had full access to all of the data in the study and took responsibility for the integrity of the data and the accuracy of the data analysis. ZR and YC contributed to the study concept and design. All authors contributed to the acquisition, analysis, or interpretation of data. ZR contributed to the drafting of the manuscript. All authors contributed to the critical revision of the manuscript for important intellectual content. YL and ZR performed statistical analysis. YC and ZR contributed to administrative, technical, or material support. YL and YC performed supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File, 42 KB - pediatrics_v8i1e65826_app1.docx]

Multimedia Appendix 2
Medical Subject Headings (MeSH) terms and free-text keywords.
[DOCX File, 18 KB - pediatrics_v8i1e65826_app2.docx]

Checklist 1
PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) 2020 checklist.
[DOCX File, 34 KB - pediatrics_v8i1e65826_app3.docx]

References

1. Giancane G, Consolaro A, Lanni S, Davì S, Schiappapietra B, Ravelli A. Juvenile idiopathic arthritis: diagnosis and treatment. Rheumatol Ther 2016 Dec;3(2):187-207. [doi: 10.1007/s40744-016-0040-4] [Medline: 27747582]
2. Chomistek K, Johnson N, Stevenson R, et al. Patient-reported barriers at school for children with juvenile idiopathic arthritis. ACR Open Rheumatol 2019 May;1(3):182-187. [doi: 10.1002/acr2.1023] [Medline: 31777793]
3. Ravelli A, Consolaro A, Horneff G, et al. Treating juvenile idiopathic arthritis to target: recommendations of an international task force. Ann Rheum Dis 2018 Jun;77(6):819-828. [doi: 10.1136/annrheumdis-2018-213030] [Medline: 29643108]
4. Lipstein EA, Brinkman WB, Sage J, Lannon CM, Morgan Dewitt E. Understanding treatment decision making in juvenile idiopathic arthritis: a qualitative assessment. Pediatr Rheumatol Online J 2013 Sep 30;11(1):34. [doi: 10.1186/1546-0096-11-34] [Medline: 24079577]
5. Grazziotin LR, Currie G, Twilt M, et al. Evaluation of real-world healthcare resource utilization and associated costs in children with juvenile idiopathic arthritis: a Canadian retrospective cohort study. Rheumatol Ther 2021 Sep;8(3):1303-1322. [doi: 10.1007/s40744-021-00331-x] [Medline: 34275124]
6. Conti F, Pontikaki I, D'Andrea M, Ravelli A, De Benedetti F. Patients with juvenile idiopathic arthritis become adults: the role of transitional care. Clin Exp Rheumatol 2018;36(6):1086-1094. [Medline: 29652654]
7. Selvaag AM, Aulie HA, Lilleby V, Flatø B. Disease progression into adulthood and predictors of long-term active disease in juvenile idiopathic arthritis. Ann Rheum Dis 2016 Jan;75(1):190-195. [doi: 10.1136/annrheumdis-2014-206034] [Medline: 25362042]
8. Tollisen A, Selvaag AM, Aulie HA, et al. Physical functioning, pain, and health‐related quality of life in adults with juvenile idiopathic arthritis: a longitudinal 30‐year followup study. Arthritis Care Res (Hoboken) 2018 May;70(5):741-749. [doi: 10.1002/acr.23327]
9. Currie GR, Harris M, McClinton L, et al. Transitions from pediatric to adult rheumatology care for juvenile idiopathic arthritis: a patient led qualitative study. BMC Rheumatol 2022 Nov 14;6(1):85. [doi: 10.1186/s41927-022-00316-5] [Medline: 36376987]

XSL•FO
RenderX

10. Tong A, Jones J, Craig JC, Singh‐Grewal D. Children's experiences of living with juvenile idiopathic arthritis: a thematic synthesis of qualitative studies. Arthritis Care Res (Hoboken) 2012 Sep;64(9):1392-1404. [doi: 10.1002/acr.21695]
11. Currie GR, Kennedy BL, S M B, et al. Managing juvenile idiopathic arthritis within the context of their life: what we learnt from children and youth living with juvenile idiopathic arthritis and their parents. Musculoskeletal Care 2023 Dec;21(4):1248-1260. [doi: 10.1002/msc.1805] [Medline: 37596866]
12. Rochette E, Saidi O, Merlin É, Duché P. Physical activity as a promising alternative for young people with juvenile idiopathic arthritis: towards an evidence-based prescription. Front Immunol 2023;14:1119930. [doi: 10.3389/fimmu.2023.1119930] [Medline: 36860845]
13. Morris PJ. Physical activity recommendations for children and adolescents with chronic disease. Curr Sports Med Rep 2008;7(6):353-358. [doi: 10.1249/JSR.0b013e31818f0795] [Medline: 19005359]
14. Brosseau L, Wells G, Brooks-Lineker S, et al. Internet-based implementation of non-pharmacological interventions of the "people getting a grip on arthritis" educational program: an international online knowledge translation randomized controlled trial design protocol. JMIR Res Protoc 2015 Feb 3;4(1):e19. [doi: 10.2196/resprot.3572] [Medline: 25648515]
15. Stinson J, McGrath P, Hodnett E, et al. Usability testing of an online self-management program for adolescents with juvenile idiopathic arthritis. J Med Internet Res 2010 Jul 29;12(3):e30. [doi: 10.2196/jmir.1349] [Medline: 20675293]
16. Miri S, Ferjani HL, Nessib DB, et al. Growing up with juvenile idiopathic arthritis: social issues. Revista Colombiana de Reumatología 2024 Oct;31(4):452-456. [doi: 10.1016/j.rcreu.2023.08.006]
17. Cai RA, Beste D, Chaplin H, et al. Developing and evaluating JIApp: acceptability and usability of a smartphone app system to improve self-management in young people with juvenile idiopathic arthritis. JMIR Mhealth Uhealth 2017 Aug 15;5(8):e121. [doi: 10.2196/mhealth.7229] [Medline: 28811270]
18. Ahola Kohut S, Stinson JN, Ruskin D, et al. iPeer2Peer program: a pilot feasibility study in adolescents with chronic pain. Pain 2016 May;157(5):1146-1155. [doi: 10.1097/j.pain.0000000000000496] [Medline: 26808145]
19. Korus M, Cruchley E, Stinson JN, Gold A, Anthony SJ. Usability testing of the internet program: "Teens Taking Charge: Managing My Transplant Online". Pediatr Transplant 2015 Feb;19(1):107-117. [doi: 10.1111/petr.12396] [Medline: 25495484]
20. Stinson JN, Lalloo C, Harris L, et al. iCanCope with Pain™: user-centred design of a web-and mobile-based self-management program for youth with chronic pain based on identified health care needs. Pain Res Manag 2014;19(5):257-265. [doi: 10.1155/2014/935278] [Medline: 25000507]
21. Bos J, Armbrust W, Geertzen J, et al. PReS-FINAL-2148: Rheumates@work a cognitive behavioural internet based intervention promoting physical activity in children with juvenile idiopathic arthritis: preliminary results of a randomized clinical trail. Pediatr Rheumatol 2013 Dec;11(S2):1-2. [doi: 10.1186/1546-0096-11-S2-P160]
22. Nelligan RK, Hinman RS, Kasza J, Crofts SJC, Bennell KL. Effects of a self-directed web-based strengthening exercise and physical activity program supported by automated text messages for people with knee osteoarthritis: a randomized clinical trial. JAMA Intern Med 2021 Jun 1;181(6):776-785. [doi: 10.1001/jamainternmed.2021.0991] [Medline: 33843948]
23. Marceau LD, Link C, Jamison RN, Carolan S. Electronic diaries as a tool to improve pain management: is there any evidence? Pain Med 2007 Oct;8 Suppl 3:S101-S109. [doi: 10.1111/j.1526-4637.2007.00374.x] [Medline: 17877520]
24. Xie SH, Wang Q, Wang LQ, Wang L, Song KP, He CQ. Effect of internet-based rehabilitation pograms on improvement of pain and physical function in patients with knee osteoarthritis: systematic review and meta-analysis of randomized controlled trials. J Med Internet Res 2021 Jan 5;23(1):e21542. [doi: 10.2196/21542] [Medline: 33399542]
25. Griffiths AJ, White CM, Thain PK, Bearne LM. The effect of interactive digital interventions on physical activity in people with inflammatory arthritis: a systematic review. Rheumatol Int 2018 Sep;38(9):1623-1634. [doi: 10.1007/s00296-018-4010-8] [Medline: 29556750]
26. Butler S, Sculley D, Santos D, et al. Effectiveness of eHealth and mHealth interventions supporting children and young people living with juvenile idiopathic arthritis: systematic review and meta-analysis. J Med Internet Res 2022 Feb 2;24(2):e30457. [doi: 10.2196/30457] [Medline: 35107431]
27. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. Int J Surg 2021 Apr;88:105906. [doi: 10.1016/j.ijsu.2021.105906] [Medline: 33789826]
28. Higgins JP, Green S. Cochrane Handbook for Systematic Reviews of Interventions: John Wiley & Sons; 2008.
29. Bramer WM, Rethlefsen ML, Kleijnen J, Franco OH. Optimal database combinations for literature searches in systematic reviews: a prospective exploratory study. Syst Rev 2017 Dec 6;6(1):245. [doi: 10.1186/s13643-017-0644-y] [Medline: 29208034]
30. Prakken B, Albani S, Martini A. Juvenile idiopathic arthritis. Lancet 2011 Jun;377(9783):2138-2149. [doi: 10.1016/S0140-6736(11)60244-4]
31. Sawyer SM, McNeil R, Francis KL, et al. The age of paediatrics. Lancet Child Adolesc Health 2019 Nov;3(11):822-830. [doi: 10.1016/S2352-4642(19)30266-4]
32. Ammerlaan J, van Os-Medendorp H, de Boer-Nijhof N, et al. Short term effectiveness and experiences of a peer guided web-based self-management intervention for young adults with juvenile idiopathic arthritis. Pediatr Rheumatol Online J 2017 Oct 13;15(1):75. [doi: 10.1186/s12969-017-0201-1] [Medline: 29029616]

XSL•FO
RenderX

33. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008 Apr 26;336(7650):924-926. [doi: 10.1136/bmj.39489.470347.AD] [Medline: 18436948]
34. Lelieveld OTHM, Armbrust W, Geertzen JHB, et al. Promoting physical activity in children with juvenile idiopathic arthritis through an internet-based program: results of a pilot randomized controlled trial. Arthritis Care Res (Hoboken) 2010 May;62(5):697-703. [doi: 10.1002/acr.20085] [Medline: 20191468]
35. Armbrust W, Bos GJFJ, Wulffraat NM, et al. Internet program for physical activity and exercise capacity in children with juvenile idiopathic arthritis: a multicenter randomized controlled trial. Arthritis Care Res (Hoboken) 2017 Jul;69(7):1040-1049. [doi: 10.1002/acr.23100] [Medline: 27696793]
36. Stinson JN, McGrath PJ, Hodnett ED, et al. An internet-based self-management program with telephone support for adolescents with arthritis: a pilot randomized controlled trial. J Rheumatol 2010 Sep;37(9):1944-1952. [doi: 10.3899/jrheum.091327] [Medline: 20595280]
37. Stinson J, Ahola Kohut S, Forgeron P, et al. The iPeer2Peer Program: a pilot randomized controlled trial in adolescents with juvenile idiopathic arthritis. Pediatr Rheumatol Online J 2016 Sep 2;14(1):48. [doi: 10.1186/s12969-016-0108-2] [Medline: 27590668]
38. Chadi N, Weisbaum E, Malboeuf-Hurtubise C, et al. In-person vs eHealth mindfulness-based intervention for adolescents with chronic illnesses:a pilot randomized trial. Adolesc Psychiatry 2019 May 31;9(1):11-23. [doi: 10.2174/2210676608666181031102235]
39. Stinson JN, Lalloo C, Hundert AS, et al. Teens taking charge: a randomized controlled trial of a web-based self-management program with telephone support for adolescents with juvenile idiopathic arthritis. J Med Internet Res 2020 Jul 29;22(7):e16234. [doi: 10.2196/16234] [Medline: 32723728]
40. Lalloo C, Harris LR, Hundert AS, et al. The iCanCope pain self-management application for adolescents with juvenile idiopathic arthritis: a pilot randomized controlled trial. Rheumatology (Oxford) 2021 Jan 5;60(1):196-206. [doi: 10.1093/rheumatology/keaa178] [Medline: 32613229]
41. Connelly M, Schanberg LE, Ardoin S, et al. Multisite randomized clinical trial evaluating an online self-management program for adolescents with juvenile idiopathic arthritis. J Pediatr Psychol 2019 Apr 1;44(3):363-374. [doi: 10.1093/jpepsy/jsy066] [Medline: 30204919]
42. Arman N, Tarakci E, Tarakci D, Kasapcopur O. Effects of video games–based task-oriented activity training (Xbox 360 Kinect) on activity performance and participation in patients with juvenile idiopathic arthritis. Am J Phys Med Rehabil 2019;98(3):174-181. [doi: 10.1097/PHM.0000000000001001]
43. Ramelet AS, Fonjallaz B, Rio L, et al. Impact of a nurse led telephone intervention on satisfaction and health outcomes of children with inflammatory rheumatic diseases and their families: a crossover randomized clinical trial. BMC Pediatr 2017 Jul 17;17(1):168. [doi: 10.1186/s12887-017-0926-5] [Medline: 28716081]
44. Cox CL. An interaction model of client health behavior: theoretical prescription for nursing. Adv Nurs Sci 1982 Oct;5(1):41-56. [doi: 10.1097/00012272-198210000-00007] [Medline: 6817699]
45. McColl J, Semalulu T, Beattie KA, et al. Transition readiness in adolescents with juvenile idiopathic arthritis and childhood-onset systemic lupus erythematosus. ACR Open Rheumatol 2021 Apr;3(4):260-265. [doi: 10.1002/acr2.11237] [Medline: 33711192]
46. Domhardt M, Schröder A, Geirhos A, Steubl L, Baumeister H. Efficacy of digital health interventions in youth with chronic medical conditions: a meta-analysis. Internet Interv 2021 Apr;24:100373. [doi: 10.1016/j.invent.2021.100373] [Medline: 33732626]
47. Lunkenheimer F, Domhardt M, Geirhos A, et al. Effectiveness and cost-effectiveness of guided Internet- and mobile-based CBT for adolescents and young adults with chronic somatic conditions and comorbid depression and anxiety symptoms (youthCOACHCD): study protocol for a multicentre randomized controlled trial. Trials 2020 Mar 12;21(1):253. [doi: 10.1186/s13063-019-4041-9] [Medline: 32164723]
48. Andersson G, Titov N, Dear BF, Rozental A, Carlbring P. Internet-delivered psychological treatments: from innovation to implementation. World Psychiatry 2019 Feb;18(1):20-28. [doi: 10.1002/wps.20610] [Medline: 30600624]
49. Dennis CL. Peer support within a health care context: a concept analysis. Int J Nurs Stud 2003 Mar;40(3):321-332. [doi: 10.1016/s0020-7489(02)00092-5] [Medline: 12605954]
50. Sawyer MG, Whitham JN, Roberton DM, Taplin JE, Varni JW, Baghurst PA. The relationship between health-related quality of life, pain and coping strategies in juvenile idiopathic arthritis. Rheumatology (Oxford) 2004 Mar;43(3):325-330. [doi: 10.1093/rheumatology/keh030] [Medline: 14566031]
51. Rausch Osthoff AK, Niedermann K, Braun J, et al. 2018 EULAR recommendations for physical activity in people with inflammatory arthritis and osteoarthritis. Ann Rheum Dis 2018 Sep;77(9):1251-1260. [doi: 10.1136/annrheumdis-2018-213585] [Medline: 29997112]
52. Revenäs Å, Opava CH, Ahlén H, Brusewitz M, Pettersson S, Åsenlöf P. Mobile internet service for self-management of physical activity in people with rheumatoid arthritis: evaluation of a test version. RMD Open 2016;2(1):e000214. [doi: 10.1136/rmdopen-2015-000214] [Medline: 27099777]
53. Ndosi M, Ferguson R, Backhouse MR, et al. National variation in the composition of rheumatology multidisciplinary teams: a cross-sectional study. Rheumatol Int 2017 Sep;37(9):1453-1459. [doi: 10.1007/s00296-017-3751-0] [Medline: 28551723]

XSL•FO
RenderX

54. Corona F, Chiuri RM, Filocamo G, et al. Serious games for wrist rehabilitation in juvenile idiopathic arthritis. Presented at: 2018 IEEE Games, Entertainment, Media Conference (GEM); Aug 15-17, 2018; Galway, Ireland. [doi: 10.1109/GEM.2018.8516458]
55. Chitti E, Borghese NA, Anello F, et al. Evaluation of the V-arcade serious games framework to support upper limbs rehabilitation at home for children with juvenile idiopathic arthritis. Presented at: 2022 IEEE 10th International Conference on Serious Games and Applications for Health(SeGAH); Aug 10-12, 2022; Sydney, Australia. [doi: 10.1109/SEGAH54908.2022.9978554]
56. Corona F, Vita A, Filocamo G, et al. Lower limb rehabilitation in juvenile idiopathic arthritis using serious games. Presented at: 2020 IEEE Conference on Games (CoG); Aug 24-27, 2020; Osaka, Japan. [doi: 10.1109/CoG47356.2020.9231930]
57. Lancaster K, Abuzour A, Khaira M, et al. The use and effects of electronic health tools for patient self-monitoring and reporting of outcomes following medication use: systematic review. J Med Internet Res 2018 Dec 18;20(12):e294. [doi: 10.2196/jmir.9284] [Medline: 30563822]
58. Newby K, Teah G, Cooke R, et al. Do automated digital health behaviour change interventions have a positive effect on self-efficacy? A systematic review and meta-analysis. Health Psychol Rev 2021 Mar;15(1):140-158. [doi: 10.1080/17437199.2019.1705873] [Medline: 31847702]
59. Chassany O, Sagnier P, Marquis P, Fullerton S, Aaronson N, For the European Regulatory Issues on Quality of Life Assessment Group. Patient-reported outcomes: the example of health-related quality of life—a European guidance document for the improved integration of health-related quality of life assessment in the drug regulatory process. Drug Information J 2002 Jan;36(1):209-238. [doi: 10.1177/009286150203600127]
60. André M, Hedengren E, Hagelberg S, Stenström CH. Perceived ability to manage juvenile chronic arthritis among adolescents and parents: development of a questionnaire to assess medical issues, exercise, pain, and social support. Arthritis Care Res 1999 Aug;12(4):229-237. [Medline: 10689987]
61. Konstantynowicz J, Marcinowicz L, Abramowicz P, Abramowicz M. What do children with chronic diseases and their parents think about pediatricians? A qualitative interview study. Matern Child Health J 2016 Aug;20(8):1745-1752. [doi: 10.1007/s10995-016-1978-0] [Medline: 27008175]
62. van der Eijk M, Faber MJ, Aarts JWM, Kremer JAM, Munneke M, Bloem BR. Using online health communities to deliver patient-centered care to people with chronic conditions. J Med Internet Res 2013 Jun 25;15(6):e115. [doi: 10.2196/jmir.2476] [Medline: 23803284]
63. Liu QB, Liu X, Guo X. The effects of participating in a physician-driven online health community in managing chronic disease: evidence from two natural experiments. MISQ 2020 Jan 1;44(1):391-419. [doi: 10.25300/MISQ/2020/15102]
64. Abujaradeh H, Safadi R, Sereika SM, Kahle CT, Cohen SM. Mindfulness-based interventions among adolescents with chronic diseases in clinical settings: a systematic review. J Pediatr Health Care 2018;32(5):455-472. [doi: 10.1016/j.pedhc.2018.04.001] [Medline: 29941236]
65. Ahmad F, Wang JJ, El Morr C. Online mindfulness interventions: a systematic review. In: Novel Applications of Virtual Communities in Healthcare Settings 2018:1-27. [doi: 10.4018/978-1-5225-2958-3.ch001]
66. Finkelstein JB, Tremblay ES, Van Cain M, et al. Pediatric clinicians' use of telemedicine: qualitative interview study. JMIR Hum Factors 2021 Dec 2;8(4):e29941. [doi: 10.2196/29941] [Medline: 34860669]
67. Voerman JS, Remerie S, Westendorp T, et al. Effects of a guided internet-delivered self-help intervention for adolescents with chronic pain. J Pain 2015 Nov;16(11):1115-1126. [doi: 10.1016/j.jpain.2015.07.011] [Medline: 26281947]
68. Kashikar-Zuck S, Sil S, Lynch-Jordan AM, et al. Changes in pain coping, catastrophizing, and coping efficacy after cognitive-behavioral therapy in children and adolescents with juvenile fibromyalgia. J Pain 2013 May;14(5):492-501. [doi: 10.1016/j.jpain.2012.12.019] [Medline: 23541069]

Abbreviations

GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
JIA: juvenile idiopathic arthritis
RCT: randomized controlled trial
RevMan: Review Manager

Edited by S Badawy; submitted 29.08.24; peer-reviewed by A Fellas, M Gasmi; revised version received 09.01.25; accepted 13.01.25; published 21.03.25.

Please cite as:
Ren Z, Chen Y, Li Y, Fan P, Liu Z, Shen B
Digital Interventions for Patients With Juvenile Idiopathic Arthritis: Systematic Review and Meta-Analysis
JMIR Pediatr Parent 2025;8:e65826
URL: https://pediatrics.jmir.org/2025/1/e65826
doi:10.2196/65826

XSL•FO
RenderX

© Zihan Ren, Yawen Chen, Yufeng Li, Panyu Fan, Zhao Liu, Biyu Shen. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 21.3.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Children's and Their Parents' Experiences With Home-Based Guided Hypnotherapy: Qualitative Study

Ilse N Ganzevoort[1], MSc; Adriëlla L van der Veen[1], MSc; Manna A Alma[2], PhD; Marjolein Y Berger[1], MD, PhD; Gea A Holtman[1], PhD

[1]Department of Primary- and Long-term Care, University Medical Center Groningen, University of Groningen, 9700 AD, Oostersingel, Groningen, Netherlands

[2]Department of Health Sciences, University Medical Center Groningen, University of Groningen, Groningen, Netherlands

Corresponding Author:
Ilse N Ganzevoort, MSc
Department of Primary- and Long-term Care, University Medical Center Groningen, University of Groningen, 9700 AD, Oostersingel, Groningen, Netherlands

Abstract

Background: Management of children with functional abdominal pain (FAP) or irritable bowel syndrome (IBS) is difficult in primary care. When education and reassurance do not alleviate symptoms, primary care physicians lack treatment options for children with FAP or IBS. Home-based guided hypnotherapy is a promising treatment because of its accessibility. To address feasibility, it is of utmost importance to take experiences from children and their parents into account.

Objective: We aimed to explore children's and their parents' experiences with home-based guided hypnotherapy for children with FAP or IBS.

Methods: This qualitative study used open-ended questions from a questionnaire and in-depth semistructured interviews with children and their parents who had a hypnotherapy intervention prescribed. The interviews were audio-recorded and transcribed verbatim. Data were collected and analyzed iteratively using thematic content analysis.

Results: A total of 76 children were eligible, and we collected questionnaire data from 56 children. A total of 23 interviews were conducted with 10 children and 15 parents. Six themes emerged from questionnaire data and interviews: impression of the exercises, not for everyone, influence of perceived effect, integrating exercises in daily life, content and practicalities of the website, and customization to personal preferences. Children with FAP or IBS experienced home-based guided hypnotherapy and the exercises differently, ranging from boring to fun. From interviews with the parents, it emerged that hypnotherapy is not suitable for everyone; for example, when children are very young or have a low developmental level, cannot sit still, cannot surrender to the exercises, or are too energetic or stressed, it might be difficult to comply. Experiences were shaped by the influence of a perceived effect and to which extent children were able to integrate exercises in daily life. The content and practicalities of the website also influenced experiences, and hypnotherapy that is adaptable to personal preferences, including by appearance and content, would be highly appreciated.

Conclusions: The children and parents experienced home-based guided hypnotherapy differently, ranging from boring to fun. Hypnotherapy might be difficult or boring for some children. The children enjoyed hypnotherapy when they liked the topic or story, felt positive effects, could easily integrate exercises in daily life, or enjoyed the website in general. The children's experiences and adherence can be further improved by adding short exercises and customizing hypnotherapy to their personal preferences on the website's appearance and content. This could increase effectiveness but must be studied further.

Trial Registration: ClinicalTrials.gov NCT05636358; https://clinicaltrials.gov/study/NCT05636358

International Registered Report Identifier (IRRID): RR2-10.1136/bmjopen-2022-069653

(JMIR Pediatr Parent 2025;8:e58301) doi:10.2196/58301

KEYWORDS

qualitative study; primary health care; children; functional abdominal pain; irritable bowel syndrome; hypnotherapy; eHealth; abdominal pain; child; parents; accessibility; questionnaire; interviews; thematic analysis; home guided; primary care; mobile phone

XSL•FO
RenderX

Introduction

Disorders of gut-brain interaction such as functional abdominal pain (FAP) and irritable bowel syndrome (IBS) are chronic pain conditions without organic cause [1]. These disorders are common in primary care, as a general practitioner (GP) sees approximately 10 children with disorders of gut-brain interaction each year [2,3]. Dutch GPs diagnose FAP or IBS when after medical history and physical examination, no underlying tissue damage, somatic causes, or metabolic or anatomic abnormalities can explain the symptoms of the child [4]. FAP and IBS are associated with lower quality of life, school absence, and higher anxiety and depression scores [5,6], and around 50% of children in primary care still report abdominal complaints one year later [7]. Management consists of education and reassurance, but if this fails to alleviate symptoms, there are few evidence-based treatment options in primary care. Children with abdominal pain and their parents report a desire for receiving a specific diagnosis and a need for information about its cause and treatment options [8-10]. Children often adopt coping mechanisms by themselves, such as reassurance and a calm approach, distraction techniques, breathing exercises, and bedtime meditation [11]. Hypnotherapy could be a treatment option, as it has shown to be effective in children referred to secondary pediatric care [12,13]. However, it has not been studied in primary care. Research in primary care is important because a different setting, selection of patients, and organization of care might influence treatment effects.

With hypnotherapy, a patient is induced into a hypnotic state and guided to suggestions by a therapist or by listening to audio-recorded exercises in their home environment (ie, home-based guided hypnotherapy) [13,14]. Home-based guided hypnotherapy is promising in primary care because of its accessibility [15]. Very few mild to moderate side effects of hypnotherapy are reported [16], and the fact that children can do it by themselves without involvement of others makes primary care an interesting setting. Experiences with home-based guided hypnotherapy in children with FAP or IBS have not been studied yet. Insights in experiences of children and their parents are important for successful implementation [17]. In this study, we aimed to explore experiences of children with FAP or IBS and their parents with home-based guided hypnotherapy, and to capture their ideas about potential areas for improvement.

Methods

Design

This qualitative study is part of the ZelfHy study, a randomized controlled trial (RCT) evaluating the effectiveness and cost-effectiveness of home-based guided hypnotherapy in children with FAP or IBS in primary care (ClinicalTrials.gov NCT05636358) [18]. The participants in the intervention group had access to a 3-month, home-based, guided hypnotherapy program. This study used questionnaire data of open questions and log data from the ZelfHy study of participants who received the intervention, and in-depth, semistructured interviews with a purposively selected sample of children and their parents.

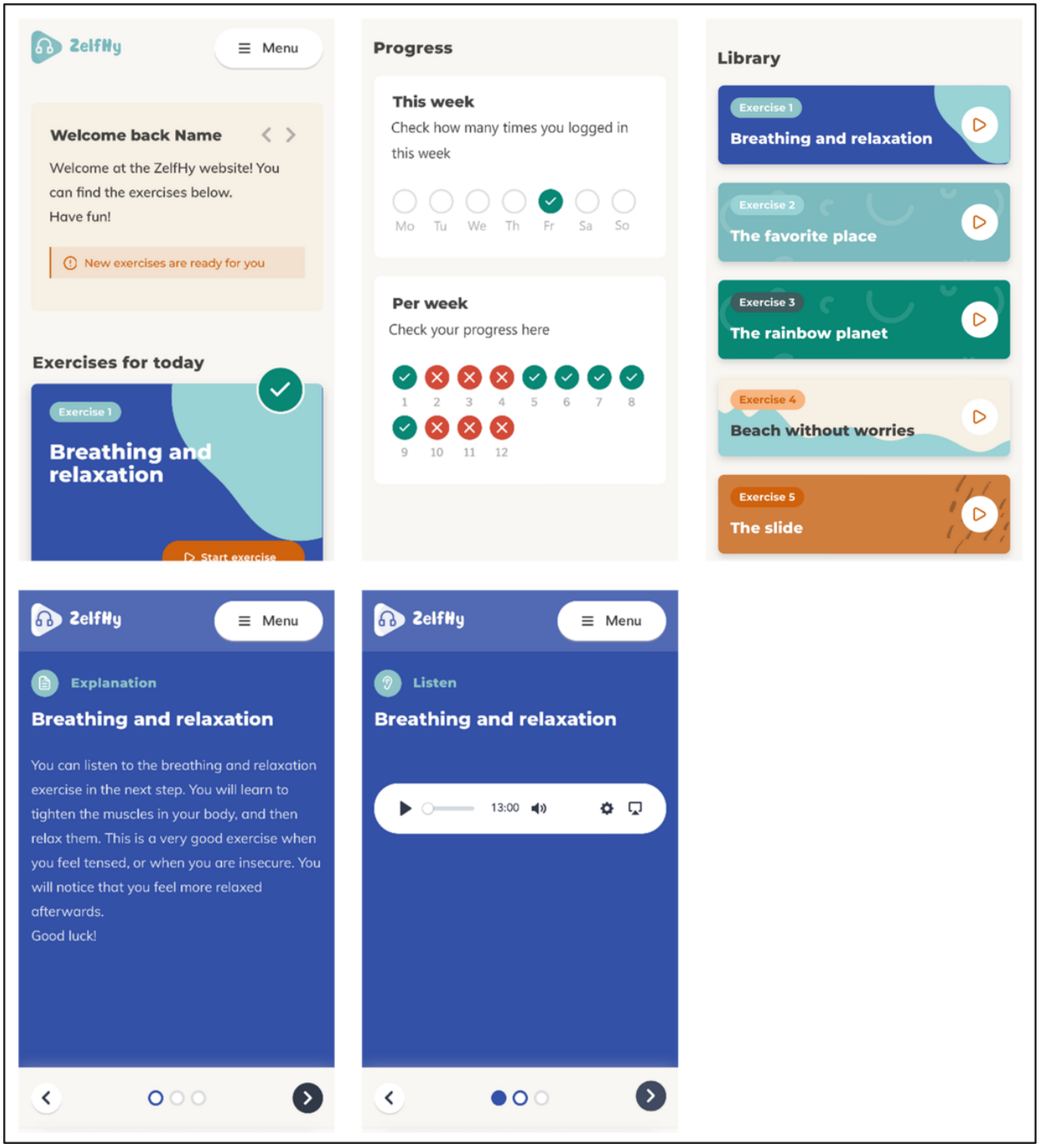
We followed the Consolidated Criteria for Reporting Qualitative Research [19].

Home-Based Guided Hypnotherapy Program

The children in the intervention group of the RCT received standard care and home-based guided hypnotherapy for 3 months. Before starting, a researcher explained hypnotherapy, its benefits for abdominal pain, and access methods during a video call with the child, parent, or both. They were also advised not to discuss the pain. The hypnotherapy program included 5 exercises: 1 breathing and relaxation exercise and 4 visualization exercises: “the favorite place” or “the favorite place+ rainbow” (age-dependent), “the rainbow planet” or “air balloon” (age-dependent), “the beach without worries,” and “the slide.” Two exercises comprised 2 versions with adjustments in language: for children aged <12 years and ≥12 years. Exercises were audio-recorded by a hypnotherapist. Instructions and exercises were hosted on a responsive website, as shown in Figure 1. All exercises were immediately available, but the children were guided to listen to the first 2 exercises for the first 2 weeks, adding new exercises every 1 to 2 weeks. They could choose and repeat exercises whenever they wanted. The children were encouraged to practice at least five times a week for 15 - 20 minutes daily for over 3 months. Automatic email reminders were sent after 14 and 28 days of inactivity to improve compliance.

XSL•FO
RenderX

Figure 1. Screenshots of the website taken from a smartphone.



Patient Participation

One mother of a girl aged 9 years and one male adolescent aged 19 years who both finished the intervention were engaged, and both received a voucher. Patient participation included attending 2 research team meetings and member checking the final results. The 2 research team meetings included discussion of the interview guide before the interviews, and discussion of topics, codes, and preliminary themes after the first interviews.

Recruitment and Participants

In this qualitative study, all the children and their parents in the intervention group of the RCT were included. Children aged 7 - 17 years with FAP or IBS according to their GP participated in the RCT. Exclusion criteria for participation in the RCT were a concomitant organic gastrointestinal disease, being managed for abdominal pain by a pediatrician, intellectual disability, psychotic disorders, a history of hypnotherapy in the past year, and poor comprehension of the Dutch language. Detailed information of recruitment methods for the ZelfHy study are described elsewhere [18].

All the children and their parents were invited to answer the questionnaire. Additional inclusion criteria for in-depth interviews for this study were that the children had to be within the 3-month intervention time frame at that time, and live in the

XSL•FO
RenderX

Northern or Middle part of the Netherlands because of travel convenience. Purposive sampling was used to achieve diversity in age, gender, and therapy adherence based on automatically logged data for the user interactions. The first author, a female primary care researcher, invited parent-child dyads for interviews via telephone approximately 6 weeks after they started the intervention. We assumed that halfway through the intervention, the children listened to all exercises and were able to recall and express their experiences. In practice, with time delay such as decision to participate and setting a date for the interview, interviews would be held in weeks 8 - 12. The authors believe that this was enough time to shape experiences.

Data Collection

Questionnaire data consisted of open-ended questions regarding what they liked and disliked generally, and for each exercise separately (Multimedia Appendix 1). Questionnaire data were collected through an electronic data capture system at 3 months follow-up between March 2021 and January 2024. The parents completed the questionnaire for the children aged <12 years, and the children aged ≥12 years completed the questionnaire themselves, with parental help as needed. Additionally, we collected log data from the intervention consisting of how long the children listened to each exercise per session. A session was defined as a log-in and start of at least one exercise. In accordance with a previous study on the effectiveness of hypnotherapy, we defined adequate use as starting at least four different exercises [18,20].

From May 2023 to December 2023, a female primary care researcher and trained interviewer (ING) and a female social scientist with expertise in qualitative research and trained interviewer (MAA) conducted semistructured interviews. The first author had contact via telephone with the parents for study procedures for the ZelfHy study before the interview. The interviews took place at the participant's home, except for the children with low adherence. For convenience, the parents of these children were interviewed by telephone and they did not necessarily have to live in the Northern or Middle part of the Netherlands. Interviews were recorded using a digital voice recorder and transcribed verbatim. Field notes and short memos were written during and after each interview.

To develop the semistructured interview guide, we used sensitizing concepts from literature and expert discussion with the research team which consisted of a female primary care researcher, a female primary care research assistant, one female epidemiologist, one female social scientist, and two female GPs. The interview guide consisted of open-ended questions about the children's and parents' experiences with the therapy (Multimedia Appendix 2). Interviews were performed until data saturation was reached (ie, interviews no longer generated relevant concepts). We completed 3 additional interviews with the children and their parents in which no new codes were found. Iterative meetings with the research group were held to evaluate and update the interview guide for new concepts and discuss data saturation.

Data Analysis

Thematic content analysis was conducted as proposed by Braun and Clarke for questionnaire data and interview transcripts [21]. First, all questionnaire data and 10 interview transcripts were read and inductively and independently coded by ING (both questionnaire data and interview transcripts), GAH (questionnaire data and female epidemiologist), and ALvdV (interview transcripts and female primary care research assistant). ING coded the remaining transcripts and ALvdV checked the coding of these transcripts. Inconsistencies between coders were discussed until consensus was reached. Consequently, emerging themes and subthemes were discussed and redefined with the research team until consensus was reached. In one of these meetings, a mother and adolescent were part of the research team. Illustrative quotes were translated from Dutch to English by a native English speaker and editor, and the first author checked whether their meaning was retained. All analyses were facilitated using Atlas.ti (version 23; ATLAS.ti Scientific Software Development GmbH) software.

Ethical Considerations

The Medical Ethics Review Committee of the University Medical Center Groningen, the Netherlands, confirmed that the Medical Research Involving Human Subjects Act which includes the Declaration of Helsinki, did not apply to this qualitative study (number 202200110). All the participants gave informed consent. Participant data were deidentified after the interviews. No compensation was provided.

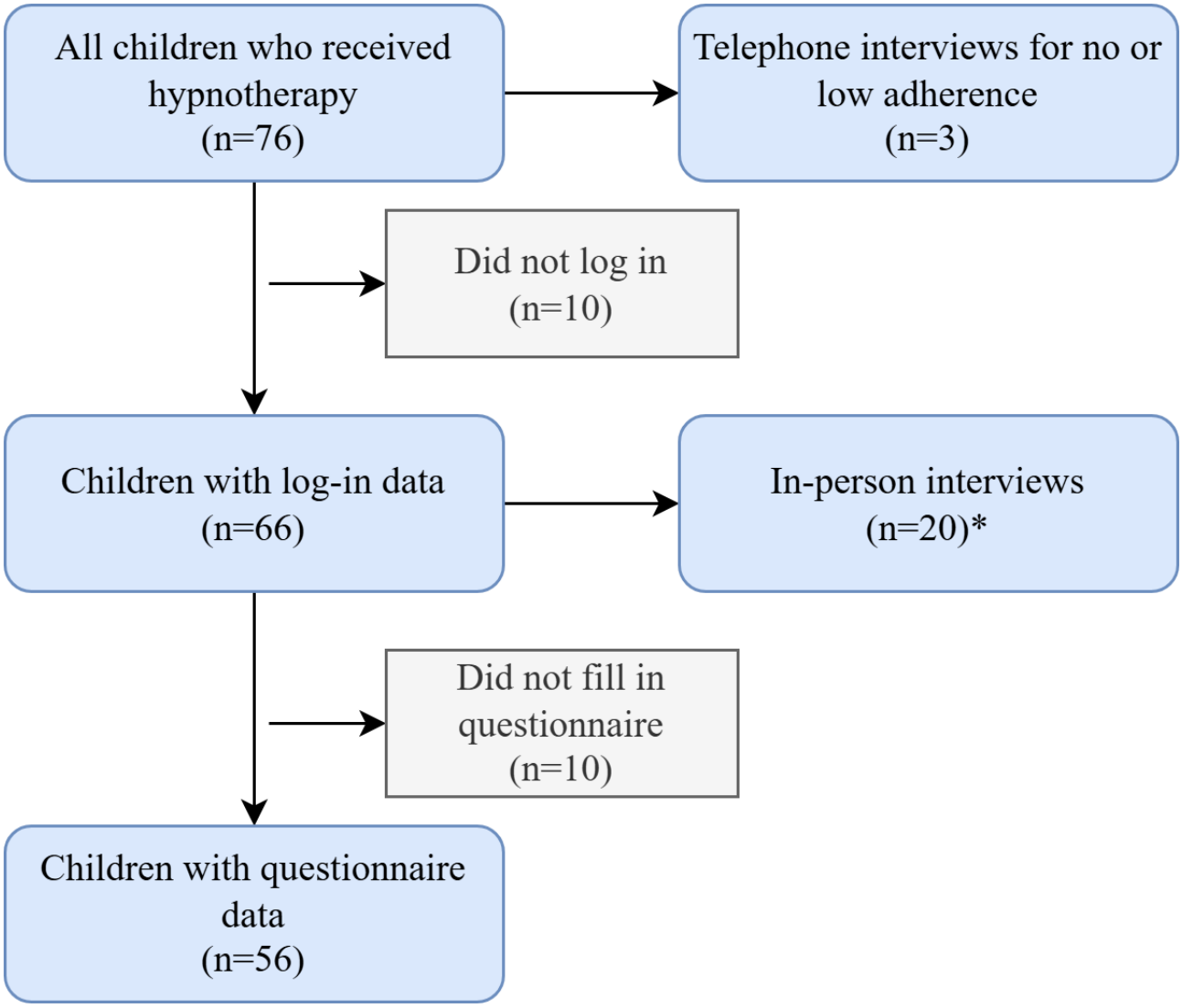
Results

Participants

In total, 76 children were eligible from the intervention group of the RCT. Their median age was 9.1 (IQR 8.1 - 11.2) years and 51 (67.1%) children were female. Of these 76 children, 20 children did not log in (n=10) or failed to complete the questionnaire for other reasons (n=10), resulting in questionnaire data from 56 children (Figure 2). For in-person interviews, 29 children were eligible because they were within the 3-month intervention period and lived in the Northern or Middle part of the Netherlands. We invited 19 children to participate in an in-person interview, of which 9 declined to participate because of personal circumstances (n=3), no interest (n=3), or no further reason (n=3). In addition, 3 parents of the children with low adherence were invited for a telephone interview. Interviews contained 13 children, of which 4 did not fill in the questionnaire. A total of 23 interviews were conducted, which lasted 19 - 63 minutes for in-person interviews and 5 - 11 minutes for telephone interviews. The in-person interviews included 10 children and 12 parents, of which 2 interviews were performed with both parents. The telephone interviews included 3 parents of the children with low adherence (Table 1).

XSL•FO
RenderX

Figure 2. Flowchart of participants. Asterisk (*) denotes that 20 in-person interviews were conducted: 10 with children and 10 with parents.



XSL•FO
RenderX

Table . Characteristics of interviewed participants.

ID	Gender	Age (years)	Gender of parent	Age of parent (years)	Parental educational level[a]	Sessions (n)[b]	Favorite exercise
1	Girl	8	Female	41	High	10	The rainbow planet
2	Girl	11	Female	36	High	31	The favorite place
3	Girl	12	Female	42	Low	12	The slide
4	Girl	11	Female and male	40 (mother) 45 (father)	High (mother) High (father)	46	The favorite place
5	Girl	13	Female	50	Intermediate	14	Beach without worries
6	Boy	9	Female	44	High	29	The slide
7	Girl	7	Female	37	High	63	The slide
8	Boy	13	Female	43	Intermediate	46	Beach without worries
9	Girl	9	Female	38	High	22	The favorite place
10	Girl	8	Female and male	46 (mother) 44 (father)	High (mother) High (father)	55	Beach without worries
11[c]	Girl	10	Female	Unknown	Unknown	0	Unknown
12[c]	Boy	12	Female	Unknown	Unknown	1	Unknown
13[c]	Girl	10	Female	Unknown	Unknown	8	Unknown

[a]Educational level was considered low (primary and lower secondary), intermediate (secondary vocational), or high (Bachelor's degree or higher).

[b]Number of sessions until the date of the interview.

[c]Telephone interviews were conducted with a parent only.

Adherence to Hypnotherapy

Of the 66 children that did log into the website, 3 children did 1 exercise, 3 children did 2 exercises, 8 did 3 exercises, 8 did 4 exercises, and 44 children did all 5. Consequently, 52 of 76 (68.4%) children adequately adhered to the intervention. The children did on average 25.5 (SD 23.2) sessions (median 17, range 1 - 89), and listened to more than one exercise in an average of 6.8 (SD 9.0) sessions (median 4, range 0 - 43). Log data per exercise are described in Table 2.

XSL•FO
RenderX

Table . Log data per exercise.

	Total	Exercise 1: breathing and relaxation	Exercise 2[a]: The favorite place	Exercise 2[b]: The favorite place and rainbow	Exercise 3[a]: The rainbow planet	Exercise 3[b]: The air balloon	Exercise 4: Beach without worries	Exercise 5: The slide
Duration (min:s)	—[c]	13:00	14:18	18:00	16:50	11:47	14:29	14:30
Duration listened, (min:s), median (minimum-maximum[d])	—	12:15 (00:05-26:30)	12:20 (00:05-28:40)	14:45 (00:05-22:15)	15:55 (00:05-34:20)	11:05 (00:05-13:40)	13:50 (00:05-31:00)	13:55 (00:05-36:50)
Children ever started (n)	66	66	50	11	46	10	51	51
Sessions per child, median (minimum-maximum)	17 (1 - 89)	4 (1-30)	5 (0 - 41)	2 (0 - 19)	5 (0 - 63)	3 (0 - 21)	3.5 (0 - 36)	3 (0 - 48)

[a]Exercise in the version for children aged <12 years.

[b]Exercise in the version for children aged ≥12 years.

[c]Not applicable.

[d]Maximum duration is higher than the exercise's length when children listened to the same exercise multiple times consecutively.

Experiences From Children and Their Parents

Overview

From questionnaire data and interviews, we found 6 themes that capture experiences from the children and their parents: impression of the exercises, not for everyone, influence of perceived effect, integrating exercises in daily life, content and practicalities of the website, and customization to personal preferences. For every quote, corresponding IDs from Table 1 are listed.

Impression of the Exercises

We found varying impressions of the therapy, ranging from nice, fun, and easy to stupid, boring, and difficult.

> *Then you have the feeling that you are really on a beach, and you can put all the feelings you don't want into a sand castle, so I really like that.* [Child 10]

> *The exercises themselves are a bit boring, because you have to keep doing the same thing every day.* [Child 2]

Most children felt relaxed during or after listening to an exercise and often had a positive association with a topic or liked the story in the exercises. The children enjoyed that they could choose what they wanted to see or do in their imagination.

> *And I really like the slide exercise because I like sliding a lot, and you can choose a color, and you can choose how fast you want to go.* [Child 1]

Although most of the children liked to visualize during the exercises, some of the children thought too little was happening. The children had conflicting ideas about exercises that required more physical activity such as stretching and relaxing muscles, or writing down colors and feelings.

> *I find the exercises boring because you just have to listen. I would rather have something to do, like filling in the colors of the rainbow planet.* [Child 1]

> *I liked just listening instead of having to actually do things.* [Child 5]

The children particularly enjoyed exercises in the beginning, when they were new and the children did not yet know what would happen. For some of the children, exercises became boring over time.

> *Because I know the exercise very well I can't really imagine anything different than what I do now when I listen to the exercise.* [Child 3]

The other children enjoyed knowing the exercises well.

> *Now I already know a few pieces by heart, so then I enjoy listening to them over and over again.* [Child 4]

Each exercise was experienced differently with diverse positive and negative aspects. An overview of impressions per exercise is presented in Multimedia Appendix 3.

Not for Everyone

From interviews with the parents it emerged that they expected both boys and girls with FAP or IBS to be suitable for hypnotherapy. However, some of the parents were more skeptical about a child's age or developmental level. Although children of all ages thought that the exercises were easy or somewhat childish, a few of the children noted that exercises were too difficult; they included difficult words or were spoken too fast. Some of the parents of children aged 7 or 8 years noted that their child was around the minimal age or level to remain focused for the entire exercise or understand why these exercises could help.

XSL•FO
RenderX

> *If she is just a bit older maybe then it might be a bit more effective. That she would understand it a bit better, and be better able to recall things in certain situations.* [Mother 7]

The parents also noted that certain characteristics could help the children in doing hypnotherapy successfully, such as being calm, creative, less rational, and having patience and high imaginary skills. The parents mentioned that energetic children might benefit most from relaxing but might need more time and practice. Indeed, some of the children did not like that they had to sit or lay still.

> *Because then I start thinking, shall I sneak and read something or just keep my eyes open, because I'm bored. I can't sit still. Look, I'm always fidgeting with my fingers.* [Child 1]

Some of the children needed time to become used to the exercises and understand how to follow instructions. A few of the children were never able to surrender to the exercises because, for example, they could not imagine the suggestion, they did not like the stories, or they felt something and could not give in to the feeling.

> *My child often strongly resisted doing the exercises because they made her sleepy and she didn't want to give in to that. "Because of them I can't hear my own dreams anymore."* [Mother of girl aged 8 years, 24 sessions, reported in the questionnaire]

The parents mentioned that sometimes when their child was too energetic or too stressed from events or stimuli, they could not concentrate and do the exercises in order to relax.

> *Now I had the idea that it even worked against her, that she first had to deal with her own things, and that hypnotherapy… that it wouldn't go together.* [Mother 1]

Influence of Perceived Effect

Feeling an effect of the therapy affected experiences of the children. Although a few of the children experienced less abdominal pain but did not like the exercises, most did. Primarily because it made their belly feel good, or because their pain decreased or disappeared. They also experienced other effects such as greater confidence, better sleep, more energy, more relaxation, a clearer mind, and more frequent school attendance.

> *I really like it, because you know that it relaxes you a lot.* [Child 3]

When the children experienced less abdominal pain either through the exercises or for another reason, some of the children and parents felt less need to continue the exercises and quit.

> *When she was in pain and started an exercise, it helped to reduce the pain. But when she did not have pain, she did not feel like doing the exercises or see the benefit of them.* [Mother 13]

Some of the children were not able to relax during the exercises, and felt that the exercises did not help to remove their pain. They felt stressed because it did not work for them. Doing hypnotherapy felt like an obligation; this resulted in resistance or discontinuation.

> *We have decided not to do the exercises anymore because they led to more frustration than success.* [Mother of girl aged 9 years, 9 sessions, reported in the questionnaire]

Integrating Exercises in Daily Life

Many of the children enjoyed doing the exercises on their own, without involvement of others who could distract them. A few of the children mentioned that they would not do hypnotherapy in the presence of friends, because they would not like to explain what it is, or be different from their friends or classmates. The other children sometimes listened together with their parents or siblings which made them feel more relaxed. The parents also played an important role by reminding their children to do the exercises, because they did not come up with it themselves, were not in the mood, or forgot it.

> *Stimulate her to do the exercises. She doesn't think to do them or ask for them. So I have to motivate her a bit.* [Mother 1]

Most of the children listened to exercises before going to sleep. Taking a device to their room was sometimes difficult for the parents because they usually withhold their children from screen time before bedtime. The children and parents appreciated that the exercises were easily accessible for the children to listen at home where they felt comfortable and at ease, such as on their bed.

> *I really like that you don't have to go anywhere. That you can just sit or lie down in your own house, in your comfort zone.* [Child 8]

Most of the children accomplished making it a routine in their daily schedule which made listening to the exercises easier and more fun.

> *He definitely doesn't want to skip it in the evening. It becomes a kind of evening ritual: tooth-brushing, pajamas on and listen, and then to bed.* [Mother 8]

The parents appreciated being able to use this as a tool when necessary, such as when their child was stressed or energized and needed to relax. Not all of the children and parents managed to integrate hypnotherapy into their routine. Some of the children were put off by doing hypnotherapy again because of the time constraint. A few of the parents noted that there is not enough time in a day to add 15 minutes of hypnotherapy, because it was not feasible to do it before school or before bedtime.

> *Because sometimes the exercises are long, you sometimes practice a bit less, or maybe even not at all.* [Mother 9]

The parents from the children with low adherence mentioned that they never started hypnotherapy because the children and their parents could not find a good moment in the first place.

> *Several times we thought of it, but then we thought, ah, we'll do it later. And every time that later never came.* [Mother 11]

XSL•FO
RenderX

Content and Practicalities of the Website

Information was perceived as clear and interesting, though there might have been somewhat too much information for younger children according to the parents. The distinction between exercises and explanation was not always clear on the website. The children thought that there was an extra exercise, but felt disappointed when they saw it was an explanation only.

Insight in log-in data (ie, a small red cross for not logging in, or a green check for logging in, both per day and weekly over the entire 3 months) was experienced both positively and negatively. For some of the children this insight motivated them to do the exercises and obtain more green checks, and for others this worked counterproductively; they felt frustrated, angry, or ashamed.

> *If I haven't practiced for a couple of weeks, for example, because I am busy, then I feel a bit, uh different, that I haven't done it right, that there will be red crosses.* [Child 3]

For most of the participants, the website functioned well technically. However, some of the children experienced that the exercise stopped when the screen automatically turned off. This got them out of their concentration and affected their experiences negatively.

> *So then she's totally caught up in the story, and then she has to turn all the way around, click on that thing and install herself again.* [Mother 1]

The children preferred using different devices, such as a smartphone, tablet, or computer. Many of the participants noted that a website was unpractical, since the children needed to fill in their log-in codes every time, were dependent on a parent nearby, or were unable to do it on the go. Sometimes, this made doing the exercises a barrier for the children. The parents suggested the use of an app instead of a website.

> *If he could just do it in an app, that you just use a password one time and then you can just turn it on, then it would have been easier and he would have done it more quickly.* [Mother 6]

Customization to Personal Preferences

The first aspect that the children would have liked to customize is appearance of the website and the exercises. The children and parents would have preferred to choose from different voices which can differ in speed. Overall, the children liked the looks of the website, but they had different ideas: some liked it simple as it is, others would have liked brighter colors such as pink and purple. The children would have liked to choose between colors on the website, change the background, and add illustrations to the exercises.

> *I thought that the colors could have been brighter. And just as with the iPad you can choose a background, I would like that you could also choose a background here. It really doesn't look so nice, so you think, now, I'm going to do some ZelfHy exercises.* [Child 1]

The second aspect that the children and parents would prefer to customize relates to the content. Most importantly, the participants would have liked more exercises. Only a few of the participants found 5 exercises sufficient. Animals, love, music, flowers, favorite animation, traveling, games, hobbies, and sports were recommended by the children as preferred topics to add more attractive exercises. According to the parents, topics should also be suitable for a child's age or level to be more effective.

> *Because I notice that not every exercise is suited for her. That you could better, yeah, make more personalized exercises. And with things going on in her own environment, because that is, of course, different for a 7-year-old than for a 17-year-old.* [Mother 7]

Additionally, choosing from exercises with different duration, particularly exercises of shorter duration (eg, between 5 and 10 min) is expected to enhance adherence. Shorter exercises would allow children to do an exercise quickly during a weekday, and to combine more exercises in 1 session. In contrast, a few of the parents hypothesized that shorter exercises might yield less effect than long exercises. The participants noted that a combination of shorter and longer exercises would be nice. Longer exercises are deemed useful in the beginning, and once children understand how they work, shorter exercises are expected to keep children more focused and satisfied.

> *I certainly think that the more often you practice, then I can imagine that at a certain point you want to go through such an exercise more quickly, because you have already formed a certain image of it, or you have given it certain colors, or you have associated a certain emotion with it. Then it doesn't have to take so much time.* [Mother 6]

Some of the participants noted that it would be more motivating if the website contained games, or if they could unlock new exercises. The parents also noted that a scoring or rewarding system could help to increase adherence.

> *You could attach a kind of gamification to it, so that the child gets a certain reward when she has done it, so that she wants to do the exercises.* [Father 4]

Discussion

Principal Results

Adherence to hypnotherapy varied greatly: some of the children never started hypnotherapy, some only logged in a handful of times, and most of the children adequately adhered to hypnotherapy by starting at least four exercises. The children experienced home-based guided hypnotherapy differently, both in general and per exercise. From interviews with the parents it emerged that hypnotherapy was sometimes difficult for those children who were young or had a low developmental level, could not sit still or surrender to the exercise, or were too energetic or stressed. Experiences were shaped by the influence of perceived effects, the ability to integrate exercises in daily life, and content and practicalities of the website. Ultimately, the children and parents would appreciate a therapy that can be customized to personal preferences for appearance and content.

XSL•FO
RenderX

Comparison With Prior Work

This is the first study to evaluate experiences of children and their parents with home-based guided hypnotherapy, other studies evaluated other self-guided interventions for children with abdominal pain. A mixed methods study assessing an online self-guided intervention found that children aged 9 - 15 years were satisfied with the intervention [22]. In our sample, we found more variation in the children's experiences, ranging from boring to fun. Possible explanations for this disparity could be that we included a larger sample, also included children with low adherence, and that children with questionnaire data had a broader age range, namely 7 - 17 years. Notably, it was a different intervention and this study showed that characteristics of the website or intervention also influence a child's experiences. The mixed methods study found that children learned to cope with their pain through relaxation or distraction and felt better in general [22]. This is consistent with our findings that experiences of children were influenced by a perceived effect.

In our study, a long duration of the exercises was one of the reasons why everyday adherence was difficult. Some children easily integrated the exercises into daily life, but others had difficulties to make it a routine. The parents who motivated and stimulated their child to listen to an exercise were helpful in integrating exercises in daily life. A mixed methods study assessing a guided imagery app also found no consensus on preferable exercise duration when asking children and parents [23]. In contrast, another study assessing guided imagery found that sessions lasting 10 to 25 minutes were enjoyable, children needed no help or reminders from parents, and most children listened to the exercises more often than instructed [24]. Our results add to the knowledge that preferences for duration of exercises are dependent on children's characteristics, ability to do the exercises, parental involvement and ability to integrate exercises in daily life. Home-based guided hypnotherapy that includes exercises with varying durations would allow that it is suitable and fitting for everyone, because it can be adjusted to children's preferences and time available at that moment.

The children and parents liked the look of the website in general, and a few experienced small technical issues that negatively affected their experience. Another study also mentioned small technical issues in an online intervention [25]. Consistent with a previous study using an app, the log-in procedure was easy [23]. However, in our study, the log-in procedure was also perceived as inconvenient, because it was not easy to use on the go. The parents suggested that an app could solve this inconvenience. A study assessing desirable components in a digital management app for children with long-term, chronic conditions found no agreement on preferences for either a website that is suitable on multiple devices versus an app [26]. This is consistent with our results and suggests that an app is favored, but flexibility of use on other devices should also be taken into account.

This study amplifies what has been found before, that children enjoy being able to do an intervention at home. eHealth interventions can increase adherence to treatment and improve outcomes which might influence effectiveness of the therapy [20,27]. Between the children and parents, there are many individual preferences regarding number and duration of exercises, topics, voices, and looks. Additionally, the child's age or level plays an important role. Consistent with prior literature, rewarding systems or gamification is important in eHealth interventions for children [23,28]. Our study emphasizes the importance of tailoring hypnotherapy to children's age or developmental level, customizing it according to their personal preferences regarding appearance and content, and incorporating gamification components to enhance engagement.

Strengths and Limitations

An important strength of this study is that we interviewed both children and their parents, with varying adherence ranging from zero adherence to daily adherence for 3 months. Interviews with the parents followed after interviews with children and allowed for more depth. Interviews were performed in their home environment, which allowed for a safe environment, and we therefore believe that we captured honest answers.

One limitation is that we primarily interviewed children and young adolescents (age range 7 - 13 y). Therefore, our results might not be generalizable to adolescents. We aimed to interview adolescents aged 14 to 17 years old, but failed because very few adolescents participated in the RCT. Although questionnaire data did include adolescents, and we included an adolescent for member checking, more research is needed on experiences of hypnotherapy among adolescents. Another limitation is that we failed to interview more fathers, as they were not at home during the interview. We believe that this minority of fathers did not influence our study results, because the 2 included fathers did not introduce new themes.

Clinical and Research Implications

This study highlights the importance of personalized home-based guided hypnotherapy to improve a child's experience, and possibly to increase adherence. This is of essence in eHealth, where patients themselves are responsible for following the therapy. Hypnotherapy that is fun to do at home and fitted to each child might be easy to adhere to and more prompting for GPs to promote. Primary care might be a beneficial setting for home-based guided hypnotherapy, as GPs manage most children with these complaints. Providing a self-managing intervention in this setting might prevent referrals to pediatric care and reduce costs [29,30].

Conclusions

The children's and parents' experiences varied greatly and were partly influenced by the topic or story in the exercise. For children who are young or have a low developmental level, cannot sit still, are unable to surrender to exercises, or are too energetic or stressed, home-based guided hypnotherapy might be difficult and needs optimization. Children liked hypnotherapy when they felt positive effects, could easily integrate the exercises in their daily life, or enjoyed the website's content and usability. Children who did not feel effects or found exercises too long often disliked hypnotherapy. A website or an app that is easily accessible and contains short exercises could increase its use. Hypnotherapy that is adaptable to personal preferences on appearance and content could boost the

XSL•FO
RenderX

experiences. In turn, positive experiences might lead to higher adherence, which potentially increases the effect of hypnotherapy and should be studied further.

Acknowledgments

The authors would like to thank all the respondents who took part in this study. We thank Quinten and Angelique for sharing their patient perspective and member checking our study results. We also thank Liesbeth AB, MD, for her general practitioner perspective during the entire research process, and JoAnn van Seventer, MA, for translating the quotations. This project was supported by the Dutch Organization for Health Research and Development, ZonMW (852002035).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Open-ended questions from the questionnaire.
[DOCX File, 14 KB - pediatrics_v8i1e58301_app1.docx]

Multimedia Appendix 2
Interview guides.
[DOCX File, 18 KB - pediatrics_v8i1e58301_app2.docx]

Multimedia Appendix 3
Impressions per exercise.
[DOCX File, 17 KB - pediatrics_v8i1e58301_app3.docx]

References

1. Rasquin A, Di Lorenzo C, Forbes D, et al. Childhood functional gastrointestinal disorders: child/adolescent. Gastroenterology 2006 Apr;130(5):1527-1537. [doi: 10.1053/j.gastro.2005.08.063] [Medline: 16678566]
2. Gieteling MJ, Lisman-van Leeuwen Y, van der Wouden JC, Schellevis FG, Berger MY. Childhood nonspecific abdominal pain in family practice: incidence, associated factors, and management. Ann Fam Med 2011;9(4):337-343. [doi: 10.1370/afm.1268] [Medline: 21747105]
3. Spee LAA, Lisman-Van Leeuwen Y, Benninga MA, Bierma-Zeinstra SMA, Berger MY. Prevalence, characteristics, and management of childhood functional abdominal pain in general practice. Scand J Prim Health Care 2013 Dec;31(4):197-202. [doi: 10.3109/02813432.2013.844405] [Medline: 24106821]
4. Albeda FW, Berger MY, Burgers JS, et al. NHG-standaard buikpijn bij kinderen. National healthcare guideline for abdominal pain in children. NHG-Richtlijnen. 2012. URL: https://richtlijnen.nhg.org/standaarden/buikpijn-bij-kinderen [accessed 2024-07-22]
5. Korterink JJ, Diederen K, Benninga MA, Tabbers MM. Epidemiology of pediatric functional abdominal pain disorders: a meta-analysis. PLoS One 2015;10(5):e0126982. [doi: 10.1371/journal.pone.0126982] [Medline: 25992621]
6. Scharff L. Recurrent abdominal pain in children: a review of psychological factors and treatment. Clin Psychol Rev 1997;17(2):145-166. [doi: 10.1016/s0272-7358(96)00001-3] [Medline: 9140713]
7. Lisman-van Leeuwen Y, Spee LAA, Benninga MA, Bierma-Zeinstra SMA, Berger MY. Prognosis of abdominal pain in children in primary care--a prospective cohort study. Ann Fam Med 2013;11(3):238-244. [doi: 10.1370/afm.1490] [Medline: 23690323]
8. Brodwall A, Brekke M. Children's and adolescents' experiences with functional abdominal pain: a qualitative study in Norway. BMJ Open 2021 Sep 13;11(9):e048949. [doi: 10.1136/bmjopen-2021-048949] [Medline: 34518260]
9. Brodwall A, Glavin K, Lagerløv P. Parents' experience when their child has chronic abdominal pain: a qualitative study in Norway. BMJ Open 2018 May 10;8(5):e021066. [doi: 10.1136/bmjopen-2017-021066] [Medline: 29748345]
10. Reid K, Lander J, Scott S, Dick B. What do the parents of children who have chronic pain expect from their first visit to a pediatric chronic pain clinic? Pain Res Manag 2010;15(3):158-162. [doi: 10.1155/2010/958792] [Medline: 20577658]
11. Bradshaw S, Brinkley A, Scanlan B, Hopper L. The burden and impact of recurrent abdominal pain - exploring the understanding and perception of children and their parents. Health Psychol Behav Med 2022;10(1):888-912. [doi: 10.1080/21642850.2022.2121710] [Medline: 36186891]
12. Abbott RA, Martin AE, Newlove-Delgado TV, et al. Psychosocial interventions for recurrent abdominal pain in childhood. Cochrane Database Syst Rev 2017 Jan 10;1(1):CD010971. [doi: 10.1002/14651858.CD010971.pub2] [Medline: 28072460]

XSL•FO
RenderX

13. Gordon M, Sinopoulou V, Tabbers M, et al. Psychosocial interventions for the treatment of functional abdominal pain disorders in children: a systematic review and meta-analysis. JAMA Pediatr 2022 Jun 1;176(6):560-568. [doi: 10.1001/jamapediatrics.2022.0313] [Medline: 35404394]
14. Rutten J, Korterink JJ, Venmans L, Benninga MA, Tabbers MM. Nonpharmacologic treatment of functional abdominal pain disorders: a systematic review. Pediatrics 2015 Mar;135(3):522-535. [doi: 10.1542/peds.2014-2123] [Medline: 25667239]
15. Schults J, Cooke M, Richards J, et al. mHealth applications for children and young people with persistent pain: a scoping review. Clin Nurs Res 2019 Sep;28(7):779-794. [doi: 10.1177/1054773818795078] [Medline: 30126292]
16. Lyszczyk M, Karkhaneh M, Gladwin KK, Funabashi M, Zorzela L, Vohra S. Adverse events of mind-body interventions in children: a systematic review. Children (Basel) 2021 Apr 29;8(5):358. [doi: 10.3390/children8050358] [Medline: 33947033]
17. Ossebaard HC, Van Gemert-Pijnen L. eHealth and quality in health care: implementation time. Int J Qual Health Care 2016 Jun;28(3):415-419. [doi: 10.1093/intqhc/mzw032] [Medline: 27029590]
18. Ganzevoort IN, Fokkema T, Mol-Alma HJ, et al. Home-based guided hypnotherapy for children with functional abdominal pain and irritable bowel syndrome in primary care: study protocol for a randomised controlled trial. BMJ Open 2023 May 8;13(5):e069653. [doi: 10.1136/bmjopen-2022-069653] [Medline: 37156587]
19. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007 Dec;19(6):349-357. [doi: 10.1093/intqhc/mzm042] [Medline: 17872937]
20. Rutten J, Vlieger AM, Frankenhuis C, et al. Home-based hypnotherapy self-exercises vs individual hypnotherapy with a therapist for treatment of pediatric irritable bowel syndrome, functional abdominal pain, or functional abdominal pain syndrome: a randomized clinical trial. JAMA Pediatr 2017 May 1;171(5):470-477. [doi: 10.1001/jamapediatrics.2017.0091] [Medline: 28346581]
21. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
22. Nieto R, Boixadós M, Hernández E, Beneitez I, Huguet A, McGrath P. Quantitative and qualitative testing of DARWeb: an online self-guided intervention for children with functional abdominal pain and their parents. Health Informatics J 2019 Dec;25(4):1511-1527. [doi: 10.1177/1460458218779113] [Medline: 29865899]
23. Hollier JM, Strickland TA, Fordis CM, van Tilburg MA, Shulman RJ, Thompson D. Children's and caregivers' review of a guided imagery therapy mobile app designed to treat children with functional abdominal pain disorders: leveraging a mixed methods approach with user-centered design. JMIR Form Res 2023 Apr 19;7:e41321. [doi: 10.2196/41321] [Medline: 37074773]
24. van Tilburg MAL, Chitkara DK, Palsson OS, et al. Audio-recorded guided imagery treatment reduces functional abdominal pain in children: a pilot study. Pediatrics 2009 Nov;124(5):e890-e897. [doi: 10.1542/peds.2009-0028] [Medline: 19822590]
25. Nieto R, Boixadós M, Ruiz G, Hernández E, Huguet A. Effects and experiences of families following a web-based psychosocial intervention for children with functional abdominal pain and their parents: a mixed-methods pilot randomized controlled trial. J Pain Res 2019;12:3395-3412. [doi: 10.2147/JPR.S221227] [Medline: 32099447]
26. Nightingale R, Hall A, Gelder C, Friedl S, Brennan E, Swallow V. Desirable components for a customized, home-based, digital care-management app for children and young people with long-term, chronic conditions: a qualitative exploration. J Med Internet Res 2017 Jul 4;19(7):e235. [doi: 10.2196/jmir.7760] [Medline: 28676470]
27. Hamine S, Gerth-Guyette E, Faulx D, Green BB, Ginsburg AS. Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. J Med Internet Res 2015 Feb 24;17(2):e52. [doi: 10.2196/jmir.3951] [Medline: 25803266]
28. Radovick S, Hershkovitz E, Kalisvaart A, Koning M, Paridaens K, Boulos MNK. Gamification concepts to promote and maintain therapy adherence in children with growth hormone deficiency. J 2018;1(1):71-80. [doi: 10.3390/j1010008]
29. Richardson PA, Harrison LE, Heathcote LC, et al. mHealth for pediatric chronic pain: state of the art and future directions. Expert Rev Neurother 2020 Nov;20(11):1177-1187. [doi: 10.1080/14737175.2020.1819792] [Medline: 32881587]
30. Stanic T, Saygin Avsar T, Gomes M. Economic evaluations of digital health interventions for children and adolescents: systematic review. J Med Internet Res 2023 Nov 3;25:e45958. [doi: 10.2196/45958] [Medline: 37921844]

Abbreviations

FAP: functional abdominal pain
GP: general practitioner
IBS: irritable bowel syndrome
RCT: randomized controlled trial

XSL•FO
RenderX

Edited by A Rossi; submitted 24.04.24; peer-reviewed by S Nilsson, T Soini; revised version received 31.07.24; accepted 16.11.24; published 27.01.25.

Please cite as:
Ganzevoort IN, van der Veen AL, Alma MA, Berger MY, Holtman GA
Children's and Their Parents' Experiences With Home-Based Guided Hypnotherapy: Qualitative Study
JMIR Pediatr Parent 2025;8:e58301
URL: https://pediatrics.jmir.org/2025/1/e58301
doi:10.2196/58301

© Ilse Nadine Ganzevoort, Adriëlla L van der Veen, Manna A Alma, Marjolein Y Berger, Gea A Holtman. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 27.1.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

eHealth Literacy and Adolescent Health in Japanese Female High School Students in Sendai: Cross-Sectional Study

Takashi Takeda[1], MD, PhD; Kana Yoshimi[1], MD, PhD; Sayaka Kai[1], MD; Fumi Inoue[1], BSc

Division of Women's Health, Research Institute of Traditional Asian Medicine, Kindai University, Osaka-Sayama, Japan

Corresponding Author:
Takashi Takeda, MD, PhD
Division of Women's Health
Research Institute of Traditional Asian Medicine
Kindai University
377-2 Ohno-Higashi, Osaka-Sayama
Osaka-Sayama, 589-8511
Japan
Phone: 81 72 366 0221 ext 3393
Fax: 81 72 366 6661
Email: take@med.kindai.ac.jp

Abstract

Background: In the digital age, adolescents increasingly rely on online sources for health-related information. eHealth literacy—defined as the ability to find, evaluate, and apply online health information—plays a crucial role in health outcomes. However, limited research exists on eHealth literacy among Japanese high school students, particularly on its association with menstrual health and psychological well-being.

Objective: This study aimed to assess the eHealth literacy of Japanese female high school students and examine its association with premenstrual symptoms, psychological distress, loneliness, and self-esteem.

Methods: A cross-sectional, web-based survey was conducted in December 2024 among 1607 female students from 2 public high schools in Sendai, Japan. A total of 909 students with regular menstrual cycles completed all survey items. The survey included the eHealth Literacy Scale (eHEALS), Premenstrual Symptoms Questionnaire, Kessler Psychological Distress Scale (K6), Revised UCLA Loneliness Scale, Rosenberg Self-Esteem Scale, and a numerical rating scale for menstrual pain. Statistical analyses, including Student t tests, chi-square tests, correlation analyses, and logistic regression analyses, were used to examine the relationships between eHealth literacy and various health outcomes.

Results: The mean eHEALS score was 22.8 (SD 7.3), with 32.1% (292/909) of participants classified as having high eHealth literacy (eHEALS≥26). Students with higher eHealth literacy reported significantly lower levels of loneliness and higher self-esteem. The severity of premenstrual symptoms, particularly feeling overwhelmed, was significantly lower in the high eHealth literacy group. Additionally, interpersonal difficulties related to premenstrual symptoms were less prevalent among students with high eHealth literacy. Pearson correlation analysis indicated negative associations between the eHEALS score and psychological distress (K6) and loneliness, whereas a positive association was observed with self-esteem. Logistic regression analysis showed that high self-esteem was significantly associated with high eHealth literacy.

Conclusions: This study highlights the importance of eHealth literacy in adolescent health care. Higher eHealth literacy is linked to lower levels of loneliness, higher self-esteem, and reduced premenstrual symptom severity, particularly feeling overwhelmed. Although the cross-sectional design limits causal conclusions, these findings suggest that higher eHealth literacy is associated with better mental and reproductive health in adolescents. Future research should adopt longitudinal designs, include more diverse populations—such as male adolescents—and explore additional contributing factors to better elucidate these associations.

(JMIR Pediatr Parent 2025;8:e73237) doi:10.2196/73237

KEYWORDS

female adolescents; mental health; premenstrual symptoms; self-esteem; eHealth

XSL•FO
RenderX

Introduction

Growing Role of eHealth in Adolescent Health

In recent years, many people have begun to use eHealth information to manage their own health [1]. As internet accessibility continues to expand globally, more individuals are obtaining health-related information online. Internet use is also high in Japan, standing at 86.2% in 2023, according to data from the Ministry of Internal Affairs and Communications [2]. The usage rate is particularly high among adolescents aged 13 years to 19 years (98.7%). Adolescence is an important transition period from childhood to adulthood, during which adolescents undergo many physical, cognitive, and psychosocial changes; establish their ego; build their own world; and develop healthy lifestyle habits. During this period, adolescents seek information on topics such as sexual health, nutrition, beauty, and infectious diseases through websites and social media [3].

Concept and Importance of eHealth Literacy

Health literacy is the ability to find, understand, and use health information to make informed decisions. These include reading medical instructions, understanding prescriptions, and evaluating health information from various sources. Good health literacy helps individuals manage diseases, correctly follow treatment, and effectively communicate with health care providers. It also involves numeracy skills such as understanding dosages and medical test results. Low health literacy can lead to poor health outcomes and medication errors. Therefore, promoting health literacy empowers individuals to take charge of their well-being and make healthier choices. Among digitally native adolescents, the internet has replaced traditional sources such as books for gathering health information [4,5].

Assessment of eHealth Literacy Among Adolescents

Given this shift, eHealth literacy—the ability to find, evaluate, and use health information from the internet to solve one's health problems—has become increasingly important [6]. The 6-item Lily Model of eHealth literacy, comprising traditional, health, information, scientific, media, and computer literacy, was previously proposed [6]. An 8-item rating scale called the eHealth Literacy Scale (eHEALS), based on this model, has been developed [7], translated into many languages, and used worldwide [8-11]. As adolescents continue to rely on the internet for health-related information, assessing their eHealth literacy is essential. However, despite increasing reliance on digital health information, research on eHealth literacy among adolescents remains scarce. Most studies have focused on university students or adults, leaving a significant knowledge gap regarding younger adolescents [4,12]. Moreover, global studies on adolescent eHealth literacy are sparse, with only a few investigations conducted in specific regions such as Turkey, Serbia, and Brazil [13-15]. These studies suggest variations in eHealth literacy levels among different populations, further highlighting the need for region-specific studies.

Premenstrual Symptoms and Psychological Well-Being

Premenstrual symptoms are characterized by unpleasant psychosomatic symptoms that impair the quality of life of many women from adolescence to adulthood [16-18]. Premenstrual syndrome (PMS) is characterized by various premenstrual symptoms and is classified as premenstrual dysphoric disorder when psychological symptoms become particularly severe [19]. Recently, the concept of premenstrual disorders was introduced, considering both conditions as part of a continuum [20]. Menstrual pain and premenstrual symptoms are correlated and, as menstrual symptoms, have a significant impact on performance [21,22]. In Japan, a study with working women found that those with higher health literacy reported lower presenteeism and better performance at managing menstrual symptoms [22]. However, this study did not examine premenstrual symptoms or social dysfunction in detail. In addition, few studies have examined the relationship between health literacy, including eHealth literacy, and menstrual symptoms in adolescents.

Psychological Distress, Loneliness, and Self-Esteem in Adolescents

High school students are at an increased risk of psychological distress, depression, anxiety, loneliness, and trauma [23]. Loneliness, the subjective feeling of isolation, has gained attention as a major public health concern owing to its strong association with mental health conditions such as depression and anxiety. It is also a key risk factor for poor mental health outcomes, particularly during adolescence [24-26]. A survey of Japanese high school students conducted in 2021 found that psychological distress was correlated with the severity of premenstrual symptoms, whereas loneliness was independently linked to both conditions. Self-esteem, which reflects an individual's overall sense of self-worth [27], is another critical factor affecting the mental health of adolescents. Low self-esteem is linked to depression, eating disorders, risky behaviors, and academic decline [28]. Additionally, it has a strong reciprocal relationship with loneliness [27,28]. Low self-esteem and loneliness are particularly concerning during adolescence, which is the formative period for developing self-identity [29]. As adolescents increasingly rely on online health information, eHealth literacy may play a role in their psychological well-being by influencing their access to and interpretation of health-related content.

Study Objectives

The purpose of this study was to assess the current level of eHealth literacy among Japanese female high school students, with a particular focus on examining its association with premenstrual symptoms. In addition, we investigated how eHealth literacy is related to other key aspects of adolescent health, including psychological distress, loneliness, and self-esteem. We hypothesized that students with higher eHealth literacy would report fewer premenstrual symptoms, lower levels of psychological distress and loneliness, and higher levels of self-esteem. These associations were examined to better understand the potential role of digital health literacy in promoting reproductive and mental well-being among adolescents.

XSL•FO
RenderX

Methods

Ethical Considerations

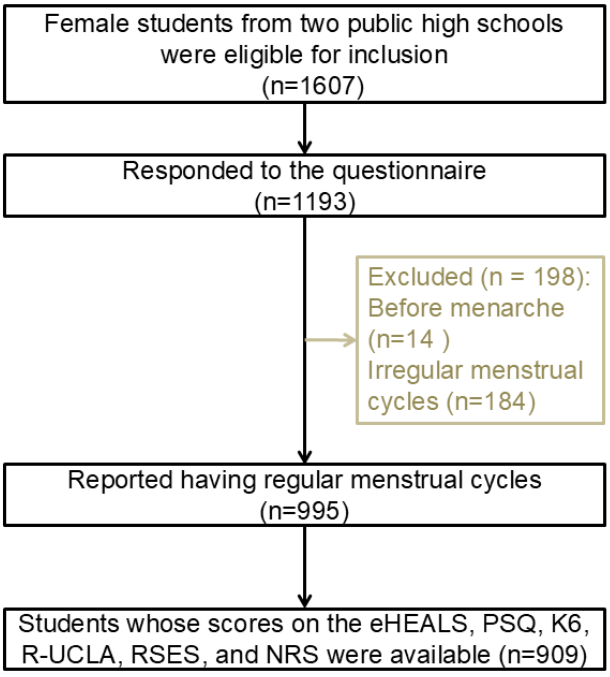
This study was conducted in accordance with the principles of the Declaration of Helsinki, and the Kindai University Ethics Committee approved the research protocol (approval number: R06-131; approval date: October 2, 2024). Students who participated in the study provided informed consent.

The Kindai University Ethics Committee approved the waiver of parental informed consent, and the students' consent and willingness to participate were considered sufficient. The omission of parental informed consent was in accordance with the Ethical Guidelines for Medical and Health Sciences Research Involving Human Subjects issued by the Ministry of Education, Culture, Sports, Science, and Technology, and the Ministry of Health, Labour and Welfare. The data were anonymized and did not contain identifiable information regarding the participants. Participants were not compensated.

Settings and Participants

In mid-December 2024, a school survey was conducted among 1607 female students attending 2 public high schools in Sendai, Japan. We conducted a web survey using Google Forms. The link to the self-administered survey form was distributed through school classes, and the survey was administered over the internet with consent. Given the sensitive nature of the questions, students were instructed to complete the survey independently at home after school hours, rather than during class time. A total of 1193 students responded to the survey. Of these, 995 had regular menstrual cycles of 25 days to 38 days (Figure 1). Because premenstrual symptoms appear solely during ovulatory cycles, only those with regular menstrual cycles were selected. Furthermore, 909 students who completed all items from the following measures were selected: eHEALS, Premenstrual Symptoms Questionnaire (PSQ), 6-item Kessler Psychological Distress Scale (K6), 3-item Revised UCLA Loneliness Scale (R-UCLA), Rosenberg Self-Esteem Scale (RSES), and numerical rating scale (NRS) for menstrual pain intensity.

Figure 1. Study flowchart. eHEALS: eHealth Literacy Scale; K6: 6-item Kessler Psychological Distress Scale; NRS: numerical rating scale; PSQ: Premenstrual Symptoms Questionnaire; R-UCLA: 3-item Revised UCLA Loneliness Scale; RSES: Rosenberg Self-Esteem Scale.



Questionnaires

eHEALS

The eHEALS is the only questionnaire that examines online health literacy [7]. In this study, we used the Japanese version, which has demonstrated validity and reliability [10]. The eHEALS is composed of 8 items and is scored on a 5-point scale (1=strongly disagree to 5=strongly agree). The total eHEALS score ranges from 8 to 40: the higher the score, the better the eHealth literacy. In this study, the Cronbach α coefficient for the scale was 0.935. Participants were divided into 2 groups—a high-scoring group (eHEALS≥26; n=292) and a low-scoring group (eHEALS<26; n=617)—according to criteria reported previously [29].

PSQ

The PSQ, previously used in research, was chosen for this study as a simple screening tool for premenstrual symptoms [18,30]. Its reliability and validity are well established [31]. The PSQ starts with: "In the past three months, have you experienced any premenstrual symptoms that start a week before menstruation and stop a few days after it begins?" It includes 11 items based on the Diagnostic and Statistical Manual of Mental Disorders–premenstrual dysphoric disorder criteria and assesses the impact of symptoms on (1) work and family responsibilities, (2) social activities, and (3) relationships. Severity and impact are rated on a 4-point scale (1=not at all to 4=severe). The total score (range: 14-56) indicates symptom severity. The Cronbach α was 0.936.

XSL•FO
RenderX

K6

The K6 was chosen for this study because it is a widely used screening tool for psychological distress in the general population [32,33]. Psychological distress was measured using the Japanese version of K6 [34], with established reliability and validity. The K6 consists of 6 items rated on a 5-point scale (0=not at all to 4=all). The total score ranges from 0 to 24, with higher scores indicating greater distress. The Cronbach α was 0.957.

R-UCLA

The R-UCLA was chosen for this study because it is a widely used and simple assessment tool for evaluating loneliness [35]. The Japanese version of the 3-item R-UCLA was used, and its reliability and validity have been well established [36]. This scale consists of 3 items rated on a 3-point scale (1=hardly ever, 2=sometimes, and 3=often), yielding a total score between 3 and 9. Higher scores indicate greater loneliness. The scale demonstrated strong internal consistency, with a Cronbach α of 0.913.

RSES

The RSES is a widely used self-esteem assessment tool that was selected for this study owing to its broad applicability [27]. The Japanese version of RSES (RSES-J) was used to measure self-esteem, and its reliability and validity have been confirmed [37]. The RSES-J consists of 10 items: 5 positive and 5 negative. Negative items are rated on a 4-point scale (1=strongly agree, 2=agree, 3=disagree, and 4=strongly disagree), whereas positive items are scored inversely. The total score ranges from 10 to 40, with higher scores indicating greater self-esteem. In this study, the Cronbach α for the RSES was 0.873.

NRS

Menstrual pain is closely linked to premenstrual symptoms [21,31]. In this study, pain severity was assessed using the NRS, a standard tool for measuring pain perception. Participants rate their pain on an 11-point scale ranging from 0 (no pain) to 10 (worst imaginable pain).

Participant data included age, school grade, weight, height, age at menarche, menstrual cycle length, internet usage time, and sleep duration. Menarche marks the onset of puberty and is linked to health issues such as early pregnancy, sexually transmitted diseases, depression, and anxiety [38,39]. It has been identified as a key factor in adolescent health. A regular cycle was defined as 25 days to 38 days. BMI was calculated by dividing weight by height squared (kg/m²). As obesity is associated with PMS, low self-esteem, and loneliness, BMI was included in the analysis [40,41].

Statistical Analysis

The Cronbach α coefficient was used to assess the reliability of each scale (eHEALS, PSQ, K6, 3-item R-UCLA, and RSES). We calculated the means and SDs for continuous variables and proportions for categorical variables. Differences in the background characteristics of the high and low eHealth literacy groups were compared using Student *t* tests and Pearson chi-square tests. The Steel-Dwass test was used to compare differences in eHEALS scores between school years. The exact Wilcoxon signed-rank test was used to compare the severity of 11 premenstrual symptoms and 3 social disability items on the PSQ between the high and low eHealth literacy groups. Correlations among the 5 psychological questionnaires (total eHEALS, PSQ, K6, 3-item R-UCLA, and RSES) were examined using Pearson correlation coefficients. The factors significantly associated with high eHealth literacy were determined using multivariable logistic regression analysis. A total of 10 items—age, BMI, age at menarche, menstrual pain intensity, duration of internet use, sleep duration, total PSQ score, total K6 score, R-UCLA, and RSES—were included in the model.

Statistical analyses were performed using JMP Pro 18.1.0 (SAS). A *P* value<.05 was considered statistically significant.

Results

Participant Characteristics

The characteristics of all participants are presented in Table 1. The mean eHEALS score was 22.8 (SD 7.3). Approximately one-third (292/909, 32.1%) of the participants belonged to the high eHealth literacy group. The high eHealth literacy group had lower R-UCLA scores and higher RSES scores than the low eHealth literacy group.

XSL•FO
RenderX

Table 1. Characteristics of the study participants.

Characteristic	Overall (N=909)	Low eHealth literacy group (eHEALS[a]<26; n=617)	High eHealth literacy group (eHEALS≥26; n=292)	*P* value
Age (years), mean (SD)	16.8 (0.9)	16.8 (0.9)	16.8 (1.0)	.88[b]
School year, n (%)				.58[c]
First year[d]	270 (29.7)	188 (69.6)	82 (30.3)	
Second year[e]	297 (32.7)	195 (65.7)	102 (34.3)	
Third year[f]	342 (37.6)	234 (68.4)	108 (31.6)	
BMI (kg/m^2), mean (SD)	20.5 (2.6)	20.5 (0.1)	20.3 (0.15)	.29[b]
Age at menarche (years), mean (SD)[g]	12.1 (1.3)	12.1 (0.1)	12.0 (0.1)	.12[b]
Menstrual pain intensity, mean (SD)	4.8 (2.6)	4.9 (0.1)	4.8 (0.2)	.52[b]
Duration of internet use (hours), mean (SD)[h]	3.1 (1.9)	3.2 (2.1)	3.1 (1.6)	.89[b]
Sleep duration (hours), mean (SD)[i]	6.1 (1.0)	6.0 (1.0)	6.1 (1.0)	.12[b]
Total PSQ[j] score, mean (SD)	26.8 (9.5)	27.0 (0.4)	26.3 (0.6)	.24[b]
K6[k], mean (SD)	7.4 (7.4)	7.5 (0.3)	7.0 (0.4)	.27[b]
R-UCLA[l], mean (SD)	5.8 (2.7)	6.0 (0.1)	5.5 (0.2)	.02[b]
RSES[m], mean (SD)	25.1 (6.1)	24.3 (0.2)	26.8 (0.4)	<.001[b]
eHEALS, mean (SD)	22.8 (7.3)	19.0 (5.2)	30.8 (4.1)	<.001[b]

[a]eHEALS: eHealth Literacy Scale.
[b]Student *t* test.
[c]Pearson chi-square test.
[d]Median age: 16 (IQR 15-16) years.
[e]Median age: 17 (IQR 16-17) years.
[f]Median age: 18 (IQR 17-18) years.
[g]Missing data: 7 (0.8%).
[h]Missing data: 24 (2.6%).
[i]Missing data: 4 (0.4%).
[j]PSQ: Premenstrual Symptoms Questionnaire.
[k]K6: 6-item Kessler Psychological Distress Scale.
[l]R-UCLA: 3-item Revised UCLA Loneliness Scale.
[m]RSES: Rosenberg Self-Esteem Scale.

Comparison of eHealth Literacy Between School Years

Differences in eHEALS scores between school years were analyzed in terms of the total score and each of the 8 items (Table 2). We found no differences in total eHEALS scores between school years. Of the 8 items, second-year students' scores were significantly higher than those for first-year students for Q6 (I find on the Internet, I know how to use the Internet to answer my questions about health) and Q7 (I can distinguish high-quality health resources from low-quality health resources on the Internet). This suggests that some aspects of eHealth literacy may improve with age or school experience, but the overall literacy level remains consistent across the years.

XSL•FO
RenderX

Table 2. Study participants' eHealth Literacy Scale (eHEALS) scores by school year level.

Question and total scores	First year, median (IQR)	Second year, median (IQR)	Third year, median (IQR)	*P* value (second vs first)[a]	*P* value (third vs first)[a]	*P* value (third vs second)[a]
Q1[b]	3 (2-3)	3 (2-4)	3 (2-4)	.48	.30	.90
Q2[c]	3 (2-3)	3 (2-3)	3 (2-3)	.35	.71	.82
Q3[d]	3 (2-4)	3 (2-4)	3 (2-4)	.41	.57	.97
Q4[e]	3 (2-4)	3 (2-4)	3 (2-4)	.54	.59	≥.99
Q5[f]	3 (2-4)	3 (2-4)	3 (2-4)	.40	.51	.98
Q6[g]	3 (2-3)	3 (2-3.5)	3 (2-4)	.02	.47	.33
Q7[h]	3 (2-3)	3 (2-4)	3 (2-4)	.02	.11	.82
Q8[i]	3 (2-3)	3 (2-4)	3 (2-4)	.08	.10	≥.99
Total eHEALS score	23 (16-26)	24 (19-28)	24 (18-28)	.10	.27	.88

[a]Steel-Dwass test.

[b]"I know what health resources are available on the Internet."

[c]"I know where to find helpful health resources on the Internet."

[d]"I know how to use the health information I find on the Internet to help me."

[e]"I know how to find helpful health resources on the Internet."

[f]"I have the skills I need to evaluate health resources."

[g]"I know how to navigate the Internet and use it to answer my questions about health."

[h]"I can distinguish high-quality health resources from low-quality health resources on the Internet."

[i]"I feel confident in using information from the Internet to make health decisions."

eHealth Literacy and Premenstrual Symptoms

Next, the differences in premenstrual symptoms and level of social impairment were examined according to the level of eHealth literacy (high and low literacy; Table 3). Of the 11 premenstrual symptoms listed in the PSQ, only feeling overwhelmed was significantly lower in the high eHealth literacy group than in the low eHealth literacy group. In terms of social life impairment, only interpersonal impairment was significantly lower in the high eHealth literacy group than in the low eHealth literacy group. However, there were no significant differences in work productivity nor participation in social activities between the 2 groups.

XSL•FO
RenderX

Table 3. Differences by eHealth literacy level (high [n=292] and low [n=617] literacy) in terms of premenstrual symptoms and level of social impairment.

Characteristic	Responses to questions				*P* value[a]
	Not at all, n (%)	Mild, n (%)	Moderate, n (%)	Severe, n (%)	
Premenstrual symptoms					
Depressed mood					.96
Low eHealth literacy[b]	231 (37.4)	189 (30.6)	149 (24.2)	48 (7.8)	
High eHealth literacy[c]	106 (36.3)	97 (33.2)	68 (23.3)	21 (7.2)	
Anxiety or tension					.27
Low eHealth literacy	166 (26.9)	211 (34.2)	183 (29.7)	57 (9.2)	
High eHealth literacy	93 (31.9)	89 (30.5)	87 (29.8)	23 (7.9)	
Tearful					.49
Low eHealth literacy	244 (39.6)	159 (25.8)	151 (24.5)	63 (10.2)	
High eHealth literacy	125 (42.8)	72 (24.7)	61 (20.9)	34 (11.6)	
Anger or irritability					.10
Low eHealth literacy	177 (28.7)	201 (32.6)	192 (31.1)	47 (7.6)	
High eHealth literacy	99 (33.9)	95 (32.5)	75 (25.7)	23 (7.9)	
Decreased interest in work, home, or social activities					.10
Low eHealth literacy	333 (54)	164 (26.6)	95 (15.4)	25 (4.1)	
High eHealth literacy	176 (60.3)	67 (23)	35 (12)	14 (4.8)	
Difficulty concentrating					.41
Low eHealth literacy	230 (37.3)	215 (34.9)	126 (20.4)	46 (7.5)	
High eHealth literacy	118 (40.4)	96 (32.9)	59 (20.2)	19 (6.5)	
Fatigue or lack of energy					.39
Low eHealth literacy	159 (25.8)	198 (32.1)	183 (29.7)	77 (12.5)	
High eHealth literacy	87 (29.8)	86 (29.5)	84 (28.8)	35 (12)	
Overeating or food cravings					.32
Low eHealth literacy	149 (24.2)	194 (31.4)	197(31.9)	77 (12.5)	
High eHealth literacy	84 (28.8)	85 (29.1)	86 (29.5)	37 (12.7)	
Insomnia or hypersomnia					.40
Low eHealth literacy	233 (37.8)	157 (25.5)	148 (24)	79 (12.8)	
High eHealth literacy	119(40.8)	72 (24.7)	66 (22.6)	35(12)	
Feeling overwhelmed					.03
Low eHealth literacy	343 (55.6)	172 (27.9)	78 (12.6)	24 (3.9)	
High eHealth literacy	189 (64.7)	58 (19.9)	33 (11.3)	12 (4.1)	
Physical symptoms					.86
Low eHealth literacy	298 (48.3)	190 (30.8)	95 (15.4)	34 (5.5)	
High eHealth literacy	144 (49.3)	77 (26.4)	56 (19.2)	15 (5.1)	
Interference with work, usual activities, or relationships					
Work efficiency, productivity, home responsibilities					.55
Low eHealth literacy	249 (40.4)	210 (34)	130 (21.1)	28 (4.5)	
High eHealth literacy	128 (43.8)	90 (30.8)	56 (19.2)	18 (6.2)	
Social activities					.15
Low eHealth literacy	422 (68.4)	127 (20.6)	52 (8.4)	16 (2.6)	

XSL•FO
RenderX

Characteristic	Responses to questions				*P* value[a]
	Not at all, n (%)	Mild, n (%)	Moderate, n (%)	Severe, n (%)	
High eHealth literacy	214 (73.3)	50 (17.1)	22 (7.5)	6 (2.1)	
Relationships with coworkers and family					.045
Low eHealth literacy	431 (69.9)	142 (23)	33 (5.4)	11 (1.8)	
High eHealth literacy	224 (76.7)	48 (16.4)	15 (5.1)	5 (1.7)	

[a]Exact Wilcoxon signed-rank test.

[b]eHealth Literacy Scale (eHEALS)<26.

[c]eHEALS≥26.

Correlations Between eHealth Literacy and Psychological Measures

Subsequently, we examined the correlations between the eHEALS and the 4 psychological questionnaires used in this study (Table 4). The Pearson correlation coefficient analyses showed that the eHEALS score was negatively associated with the K6 total score (*r*=–0.071) and the R-UCLA score (*r*=–0.086) and positively associated with the RSES score (*r*=–0.170).

Table 4. Correlations among eHealth literacy, premenstrual symptoms, psychological distress, loneliness, and self-esteem.

Characteristics	eHEALS[a]	Total PSQ[b]	Total K6[c]	R-UCLA[d]	RSES[e]
eHEALS					
r	—[f]	–0.023	–0.071	–0.086	0.170
P value	—	.49	.03	.01	<.001
Total PSQ					
r	–0.023	—	0.447	0.401	–0.358
P value	.49	—	<.001	<.001	<.001
Total K6					
r	–0.071	0.447	—	0.212	–0.285
P value	.03	<.001	—	<.001	<.001
R-UCLA					
r	–0.086	0.401	0.212	—	–0.468
P value	.01	<.001	<.001	—	<.001
RSES					
r	0.170	–0.358	–0.285	–0.468	—
P value	<.001	<.001	<.001	<.001	—

[a]eHEALS: eHealth Literacy Scale.

[b]PSQ: Premenstrual Symptoms Questionnaire.

[c]K6: 6-item Kessler Psychological Distress Scale.

[d]R-UCLA: 3-item Revised UCLA Loneliness Scale.

[e]RSES: Rosenberg Self-Esteem Scale.

[f]Not applicable.

Factors Associated With High eHealth Literacy

We performed multivariable logistic regression analysis to identify the factors significantly associated with high eHealth literacy (Table 5) and found that high self-esteem was significantly associated with high eHealth literacy.

XSL•FO
RenderX

Table 5. Factors associated with high eHealth literacy (eHealth Literacy Scale≥26; R2=0.04).

Factors	Odds ratio (95% CI)	*P* value
Age (years)	1.026 (0.880-1.197)	.74
BMI (kg/m^2)	0.954 (0.899-1.010)	.11
Age at menarche (years)	0.900 (0.801-1.091)	.07
Menstrual pain intensity	0.976 (0.917-1.040)	.46
Duration of internet use (hours)	1.015 (0.942-1.091)	.70
Sleeping duration (hours)	1.066 (0.929-1.224)	.36
Total PSQ[a]	1.010 (0.980-1.023)	.34
Total K6[b]	1.001 (0.979-1.023)	.94
R-UCLA[c]	0.996 (0.933-1.062)	.90
RSES[d]	1.076 (1.047-1.107)	<.001

[a]PSQ: Premenstrual Symptoms Questionnaire.

[b]K6: 6-item Kessler Psychological Distress Scale.

[c]R-UCLA: 3-item Revised UCLA Loneliness Scale.

[d]RSES: Rosenberg Self-Esteem Scale.

Discussion

Principal Findings

This study examined the eHealth literacy levels of female Japanese high school students and their associations with premenstrual symptoms, psychological distress, loneliness, and self-esteem. The findings highlight the importance of eHealth literacy in adolescent health and suggest that students with higher eHealth literacy tend to experience better mental and reproductive health outcomes. Additionally, this study contributes to the growing body of evidence indicating that digital health literacy plays a significant role in adolescent development and well-being—particularly as reflected in their health-related decision-making processes.

eHealth Literacy Level

The results showed that the mean eHEALS score among participants was 22.8, with 32.1% classified as having high eHealth literacy. Compared with eHEALS scores of 23.6 and 23.5 for university students and the general population in Japan, respectively [10,12], the values obtained in this study appear to be slightly lower. As the data on adolescents overseas in the same age group are limited, performing comparisons becomes challenging. However, among 702 high school students in Serbia (mean age: 16.5 years), the average eHEALS score was 26.0 [14], and among 260 high school students in Brazil (mean age: 15.6 years), the average eHEALS score was 28.1 [15]. Based on these values, Japanese students appear to have a lower eHEALS score. The eHealth literacy of Japanese high school students obtained in this study was lower than that of Japanese university students, adults, and overseas high school students, suggesting a need for further improvement. The results of this study showed that eHEALS scores increased for some items in the second year compared with those in the first year, but there was no difference in scores between the years when assessed as a whole. Therefore, it is difficult to expect an improvement in eHealth literacy during the natural course of events, and educational interventions may be necessary.

eHealth Literacy, Psychological Well-Being, and Social Connectedness

The negative association between eHealth literacy and loneliness suggests a potential link between digital health literacy and social connectivity. Adolescents with higher eHealth literacy may be more likely to engage with credible online health communities, which could help alleviate feelings of isolation. Additionally, the positive correlation between eHealth literacy and self-esteem indicates that adolescents with stronger digital health literacy may feel more empowered to make informed health decisions, potentially contributing to greater confidence and a more positive self-image.

Association Between eHealth Literacy and Menstrual Symptom Severity

The intensity of menstrual pain and premenstrual symptoms, as assessed using the total PSQ score, did not differ according to the level of eHealth literacy. In terms of premenstrual symptoms, the high eHealth literacy group reported significantly lower levels of “feeling overwhelmed” than the low eHealth literacy group. However, other PMS symptoms, such as mood swings, fatigue, and irritability, were not significantly different between the groups. This suggests that, although higher eHealth literacy may be related to better psychological resilience, its direct relationship with overall premenstrual symptom severity remains unclear. Further investigation is needed to determine whether increased eHealth literacy leads to improved symptom management or whether other factors, such as coping strategies and social support, mediate this relationship. It is possible that individuals with high eHealth literacy possess more accurate knowledge of premenstrual symptoms, which might help them manage symptoms more calmly and avoid feeling overwhelmed, potentially reducing interpersonal difficulties. These findings suggest that higher eHealth literacy may be associated with

XSL•FO
RenderX

improved psychological resilience and coping strategies for menstruation-related issues. Moreover, our results are consistent with those of prior research linking higher health literacy to improved management of menstrual symptoms among working women [22]. However, this study extends these findings by focusing on younger adolescents and exploring the relationship between eHealth literacy and premenstrual symptoms in relation to more detailed symptoms and details of social dysfunction, an area that has received less attention in previous studies.

Correlation Between eHealth Literacy and Psychological Measures

The Pearson correlation analysis revealed a negative association between eHEALS scores and psychological distress (K6: r=–0.071; P=.03), as well as loneliness (R-UCLA: r=–0.086; P=.01), whereas a positive association was observed between the eHEALS score and self-esteem (RSES: r=0.170; P<.001). Although these associations were statistically significant, the effect sizes were small, suggesting that eHealth literacy alone may not be a strong predictor of psychological well-being. Additional factors, such as social relationships and coping mechanisms, should be considered in future research. These results suggest that adolescents with higher eHealth literacy are better equipped to access and interpret mental health information, which may help explain the lower psychological distress and higher self-worth observed in this study. Future research should investigate the causal relationships between eHealth literacy and mental well-being using longitudinal data.

Factors Associated With High eHealth Literacy

The multivariate logistic regression analysis showed that high self-esteem was significantly associated with high eHealth literacy. These results align with previous findings among university students in the United Kingdom [42]. This finding highlights a strong link between self-esteem and eHealth literacy, suggesting that positive self-perception may be an important factor to consider in adolescent eHealth literacy programs.

Limitations and Future Directions

Despite its strengths, this study has some limitations. First, the cross-sectional design precludes causal inference; therefore, longitudinal studies are needed to establish temporal relationships between eHealth literacy and health outcomes. Second, the study sample was limited to female students from 2 public high schools in Sendai, which may limit the generalizability of the findings to other regions and populations. Future studies should include more diverse samples, including students from different geographic and socioeconomic backgrounds. Expanding this research to include male adolescents and individuals from rural areas would provide a more comprehensive understanding of how eHealth literacy affects various demographics. Third, this study used self-administered online questionnaires completed by participants in their home environments. Although this approach offers convenience and accessibility, it has the following limitations: (1) potential response bias, including social desirability bias and misinterpretation of questions resulting from lack of direct supervision; (2) the home setting, which may have allowed outside influences or noncompliance with instructions, potentially affecting the authenticity of responses; and (3) collecting sensitive psychological and health-related information in an uncontrolled environment, which raises concerns about data integrity. However, discussing reproductive health is often taboo worldwide, especially in Asia, including Japan, with its conservative cultural and religious background [43]. Openly discussing menstrual issues in Japanese school classrooms is very difficult, and online after-school surveys are more likely to reveal the true status of students. Fourth, the study did not evaluate other participant-related factors that may influence eHealth literacy, such as parental education level, family economic status, and participants' medical history [13,44-46]. Although the survey was administered online and completed by students after school, these questions were considered sensitive and difficult to ask. Therefore, it was challenging to include them in a study conducted as part of regular high school activities. Moreover, we acknowledge that other factors—such as access to internet resources, support from family and the community, and a family or maternal history of symptoms or gynecological or endocrine conditions—may also influence eHealth literacy and its related outcomes. Although these variables were not assessed in this study, their potential impact on health-related factors, such as self-esteem, should not be overlooked. These factors may interact with the psychosocial and reproductive health outcomes examined here. We recommend that future studies incorporate these elements to enhance the understanding of adolescent health in relation to eHealth literacy. Fifth, the logistic regression analysis in this study included 10 variables but did not account for potential confounders such as socioeconomic status, academic stress, home environment, and previous digital health education. As mentioned previously, items related to socioeconomic background and home environment were excluded because of ethical and practical limitations inherent in this school-based survey. Although past health education could have been included as a question, there are very few systematic digital health education programs for high school students in Japan. We judged that there was little variation in this factor and thus did not consider it meaningful as an analytical variable. Nevertheless, the omission of these factors may limit the comprehensiveness of the regression analysis, and future studies should include these variables as much as possible, depending on the circumstances.

Furthermore, this study focused only on specific health outcomes—namely, premenstrual symptoms, psychological distress, loneliness, and self-esteem. Future research should investigate additional physical and mental health outcomes to develop a more comprehensive understanding of how eHealth literacy influences adolescent health. Further research should explore potential interventions to enhance eHealth literacy and examine their long-term impact on adolescent health. In fact, a study with secondary school students in Spain demonstrated the educational impact of training sessions on eHealth literacy [47].

Conclusions

In conclusion, this study highlights the importance of eHealth literacy for adolescent well-being. We found that higher eHealth

XSL•FO
RenderX

literacy was associated with lower loneliness, higher self-esteem, and a reduced premenstrual symptom burden, particularly regarding feelings of being overwhelmed. These findings suggest that integrating eHealth literacy education into school programs could potentially benefit adolescents' mental and reproductive health, although this should be confirmed in future studies. Future studies should aim to include more diverse populations—such as male adolescents and students from various socioeconomic backgrounds—and adopt longitudinal approaches to better understand the causal relationships between eHealth literacy and adolescent health outcomes. Future research should also focus on developing and evaluating interventions aimed at improving eHealth literacy and its long-term impact on adolescent health outcomes. By prioritizing digital health literacy initiatives, educators, health care professionals, and policymakers may help cultivate a more informed and health-conscious future generation.

Acknowledgments

We would like to thank Editage (www.editage.com) for English language editing. We used DeepL Translate and DeepL Write (DeepL SE) to translate Japanese text into English. The authors report no funding for this work.

Data Availability

The data obtained in this study are available from the corresponding author upon request.

Authors' Contributions

TT, KY, SK, and FI designed the study. TT and FI collected the data. TT analyzed and interpreted the data and wrote the manuscript. KY, SK, and FI revised the manuscript. KY and SK supervised the study and provided conceptual assistance. All the authors read and approved the final version of the manuscript.

Conflicts of Interest

None declared.

References

1. Luo A, Qin L, Yuan Y, Yang Z, Liu F, Huang P, et al. The effect of online health information seeking on physician-patient relationships: systematic review. J Med Internet Res 2022 Feb 10;24(2):e23354 [FREE Full text] [doi: 10.2196/23354] [Medline: 35142620]
2. Part II: Current status and issues in the information and communications field. Ministry of Internal Affairs and Communications. URL: https://www.soumu.go.jp/johotsusintokei/whitepaper/ja/r06/html/nd21b120.html [accessed 2025-06-12]
3. Park E, Kwon M. Health-related internet use by children and adolescents: systematic review. J Med Internet Res 2018 Apr 03;20(4):e120 [FREE Full text] [doi: 10.2196/jmir.7731] [Medline: 29615385]
4. Stellefson M, Hanik B, Chaney B, Chaney D, Tennant B, Chavarria EA. eHealth literacy among college students: a systematic review with implications for eHealth education. J Med Internet Res 2011 Dec 01;13(4):e102 [FREE Full text] [doi: 10.2196/jmir.1703] [Medline: 22155629]
5. Freeman JL, Caldwell PHY, Bennett PA, Scott KM. How adolescents search for and appraise online health information: a systematic review. J Pediatr 2018 Apr;195:244-255.e1. [doi: 10.1016/j.jpeds.2017.11.031] [Medline: 29398062]
6. Norman CD, Skinner HA. eHealth literacy: essential skills for consumer health in a networked world. J Med Internet Res 2006 Jun 16;8(2):e9 [FREE Full text] [doi: 10.2196/jmir.8.2.e9] [Medline: 16867972]
7. Norman CD, Skinner HA. eHEALS: the eHealth literacy scale. J Med Internet Res 2006 Nov 14;8(4):e27 [FREE Full text] [doi: 10.2196/jmir.8.4.e27] [Medline: 17213046]
8. De Caro W, Corvo E, Marucci AR, Mitello L, Lancia L, Sansoni J. eHealth literacy scale: an nursing analisys and Italian validation. Stud Health Technol Inform 2016;225:949. [Medline: 27332425]
9. Paramio Pérez G, Almagro BJ, Hernando Gómez Á, Aguaded Gómez JI. [Validation of the eHealth Literacy Scale (eHEALS) in Spanish university students]. Rev Esp Salud Publica 2015;89(3):329-338 [FREE Full text] [doi: 10.4321/S1135-57272015000300010] [Medline: 26388346]
10. Mitsutake S, Shibata A, Ishii K, Okazaki K, Oka K. [Developing Japanese version of the eHealth Literacy Scale (eHEALS)]. Nihon Koshu Eisei Zasshi 2011 May;58(5):361-371. [Medline: 21905612]
11. Park H, Lee E. Self-reported eHealth literacy among undergraduate nursing students in South Korea: a pilot study. Nurse Educ Today 2015 Feb;35(2):408-413. [doi: 10.1016/j.nedt.2014.10.022] [Medline: 25466791]
12. Tsukahara S, Yamaguchi S, Igarashi F, Uruma R, Ikuina N, Iwakura K, et al. Association of eHealth literacy with lifestyle behaviors in university students: questionnaire-based cross-sectional study. J Med Internet Res 2020 Jun 24;22(6):e18155 [FREE Full text] [doi: 10.2196/18155] [Medline: 32579126]

XSL•FO
RenderX

13. Dağhan ?, Kalkim A, Unlu E, Sahin HK, Yuksel M. Factors affecting eHealth literacy of early adolescents: school-based research. Compr Child Adolesc Nurs 2022 Dec 26;45(4):383-394. [doi: 10.1080/24694193.2022.2056263] [Medline: 36440872]
14. Gazibara T, Cakic J, Cakic M, Pekmezovic T, Grgurevic A. eHealth and adolescents in Serbia: psychometric properties of eHeals questionnaire and contributing factors to better online health literacy. Health Promot Int 2019 Aug 01;34(4):770-778. [doi: 10.1093/heapro/day028] [Medline: 29800141]
15. Barbosa MCF, Baldiotti ALP, Resende JL, Perazzo MDF, Firmino RT, Granville-Garcia AF, et al. Assessment of the psychometric properties of the eHealth Literacy Scale for Brazilian adolescents. PLoS One 2024 Nov 25;19(11):e0314099 [FREE Full text] [doi: 10.1371/journal.pone.0314099] [Medline: 39585850]
16. Yonkers KA, Simoni MK. Premenstrual disorders. Am J Obstet Gynecol 2018 Jan;218(1):68-74. [doi: 10.1016/j.ajog.2017.05.045] [Medline: 28571724]
17. Takeda T. Premenstrual disorders: Premenstrual syndrome and premenstrual dysphoric disorder. J Obstet Gynaecol Res 2023 Feb;49(2):510-518. [doi: 10.1111/jog.15484] [Medline: 36317488]
18. Takeda T, Koga S, Yaegashi N. Prevalence of premenstrual syndrome and premenstrual dysphoric disorder in Japanese high school students. Arch Womens Ment Health 2010 Dec 21;13(6):535-537. [doi: 10.1007/s00737-010-0181-3] [Medline: 20857152]
19. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR). Washington, DC: American Psychiatric Association Publishing; 2022.
20. O'Brien PMS, Bäckström T, Brown C, Dennerstein L, Endicott J, Epperson CN, et al. Towards a consensus on diagnostic criteria, measurement and trial design of the premenstrual disorders: the ISPMD Montreal consensus. Arch Womens Ment Health 2011 Feb 12;14(1):13-21 [FREE Full text] [doi: 10.1007/s00737-010-0201-3] [Medline: 21225438]
21. Kitamura M, Takeda T, Koga S, Nagase S, Yaegashi N. Relationship between premenstrual symptoms and dysmenorrhea in Japanese high school students. Arch Womens Ment Health 2012 Apr 28;15(2):131-133. [doi: 10.1007/s00737-012-0266-2] [Medline: 22371098]
22. Imamura Y, Kubota K, Morisaki N, Suzuki S, Oyamada M, Osuga Y. Association of women's health literacy and work productivity among Japanese workers: a web-based, nationwide survey. JMA J 2020 Jul 15;3(3):232-239 [FREE Full text] [doi: 10.31662/jmaj.2019-0068] [Medline: 33150257]
23. Meunier S, Bouchard L, Coulombe S, Doucerain M, Pacheco T, Auger E. The association between perceived stress, psychological distress, and job performance during the COVID-19 pandemic: the buffering role of health-promoting management practices. Trends in Psychol 2022 Jan 26;30(3):549-569. [doi: 10.1007/s43076-021-00136-5] [Medline: 40477693]
24. Nochaiwong S, Ruengorn C, Thavorn K, Hutton B, Awiphan R, Phosuya C, et al. Global prevalence of mental health issues among the general population during the coronavirus disease-2019 pandemic: a systematic review and meta-analysis. Sci Rep 2021 May 13;11(1):10173 [FREE Full text] [doi: 10.1038/s41598-021-89700-8] [Medline: 33986414]
25. Takeda T, Kai S, Yoshimi K. Association between premenstrual symptoms and posttraumatic stress symptoms by COVID-19: a cross-sectional Study with Japanese high school students. Tohoku J Exp Med 2021 Sep;255(1):71-77 [FREE Full text] [doi: 10.1620/tjem.255.71] [Medline: 34588375]
26. Takeda T, Yoshimi K, Kai S, Inoue F. Association between loneliness, premenstrual symptoms, and other factors during the COVID-19 pandemic: a cross-sectional study with Japanese high school students. IJWH 2023 Apr;Volume 15:655-664. [doi: 10.2147/ijwh.s400818] [Medline: 37131359]
27. Rosenberg M. Rosenberg self-esteem scale (RSE). Acceptance and commitment therapy. Measures Package 1965;61(52):18. [doi: 10.1037/t01038-000]
28. Baumeister RF, Campbell JD, Krueger JI, Vohs KD. Does high self-esteem cause better performance, interpersonal success, happiness, or healthier lifestyles? Psychol Sci Public Interest 2003 May 01;4(1):1-44. [doi: 10.1111/1529-1006.01431] [Medline: 26151640]
29. Richtering SS, Hyun K, Neubeck L, Coorey G, Chalmers J, Usherwood T, et al. eHealth literacy: predictors in a population with moderate-to-high cardiovascular risk. JMIR Hum Factors 2017 Jan 27;4(1):e4 [FREE Full text] [doi: 10.2196/humanfactors.6217] [Medline: 28130203]
30. Takeda T, Tasaka K, Sakata M, Murata Y. Prevalence of premenstrual syndrome and premenstrual dysphoric disorder in Japanese women. Arch Womens Ment Health 2006 Jul 9;9(4):209-212. [doi: 10.1007/s00737-006-0137-9] [Medline: 16761114]
31. Takeda T, Yoshimi K, Yamada K. Psychometric testing of the premenstrual symptoms questionnaire and the association between perceived injustice and premenstrual symptoms: a cross-sectional study among Japanese high school students. IJWH 2020 Sep;Volume 12:755-763. [doi: 10.2147/ijwh.s269392] [Medline: 33061664]
32. Kessler RC, Barker PR, Colpe LJ, Epstein JF, Gfroerer JC, Hiripi E, et al. Screening for serious mental illness in the general population. Arch Gen Psychiatry 2003 Feb 01;60(2):184-189. [doi: 10.1001/archpsyc.60.2.184] [Medline: 12578436]
33. Kessler R, Andrews G, Colpe L, Hiripi E, Mroczek D, Normand S, et al. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychol. Med 2002 Sep 26;32(6):959-976. [doi: 10.1017/S0033291702006074] [Medline: 12214795]

XSL•FO
RenderX

34. Furukawa TA, Kawakami N, Saitoh M, Ono Y, Nakane Y, Nakamura Y, et al. The performance of the Japanese version of the K6 and K10 in the World Mental Health Survey Japan. Int J Methods Psychiatr Res 2008;17(3):152-158 [FREE Full text] [doi: 10.1002/mpr.257] [Medline: 18763695]
35. Russell DW. UCLA Loneliness Scale (Version 3): reliability, validity, and factor structure. J Pers Assess 1996 Feb;66(1):20-40. [doi: 10.1207/s15327752jpa6601_2] [Medline: 8576833]
36. Igarashi T. Development of the Japanese version of the three-item loneliness scale. BMC Psychol 2019 Apr 05;7(1):20 [FREE Full text] [doi: 10.1186/s40359-019-0285-0] [Medline: 30953545]
37. Mimura C, Griffiths P. A Japanese version of the Rosenberg Self-Esteem Scale: translation and equivalence assessment. J Psychosom Res 2007 May;62(5):589-594. [doi: 10.1016/j.jpsychores.2006.11.004] [Medline: 17467414]
38. Shen Y, Varma DS, Zheng Y, Boc J, Hu H. Age at menarche and depression: results from the NHANES 2005-2016. PeerJ 2019;7:e7150 [FREE Full text] [doi: 10.7717/peerj.7150] [Medline: 31223544]
39. Sequeira M, Lewis SJ, Bonilla C, Smith GD, Joinson C. Association of timing of menarche with depressive symptoms and depression in adolescence: Mendelian randomisation study. Br J Psychiatry 2017 Jan 02;210(1):39-46 [FREE Full text] [doi: 10.1192/bjp.bp.115.168617] [Medline: 27491534]
40. Bertone-Johnson ER, Hankinson SE, Willett WC, Johnson SR, Manson JE. Adiposity and the development of premenstrual syndrome. J Womens Health (Larchmt) 2010 Nov;19(11):1955-1962 [FREE Full text] [doi: 10.1089/jwh.2010.2128] [Medline: 20874240]
41. Rankin J, Matthews L, Cobley S, Han A, Sanders R, Wiltshire HD, et al. Psychological consequences of childhood obesity: psychiatric comorbidity and prevention. Adolesc Health Med Ther 2016;7:125-146 [FREE Full text] [doi: 10.2147/AHMT.S101631] [Medline: 27881930]
42. Holch P, Marwood JR. EHealth literacy in UK teenagers and young adults: exploration of predictors and factor structure of the eHealth Literacy Scale (eHEALS). JMIR Form Res 2020 Sep 08;4(9):e14450 [FREE Full text] [doi: 10.2196/14450] [Medline: 32897230]
43. Zainuddin AA, Cheung SC, Roos EJ. PAG in the Asia-Oceania region-taking little steps forward. J Pediatr Adolesc Gynecol 2025 Jun;38(3):306-307. [doi: 10.1016/j.jpag.2025.02.001] [Medline: 40345795]
44. Vozikis A, Drivas K, Milioris K. Health literacy among university students in Greece: determinants and association with self-perceived health, health behaviours and health risks. Arch Public Health 2014;72(1):15 [FREE Full text] [doi: 10.1186/2049-3258-72-15] [Medline: 24987522]
45. Elsborg L, Krossdal F, Kayser L. Health literacy among Danish university students enrolled in health-related study programmes. Scand J Public Health 2017 Dec;45(8):831-838. [doi: 10.1177/1403494817733356] [Medline: 29052485]
46. Yang S, Luo Y, Chiang C. The associations among individual factors, eHealth literacy, and health-promoting lifestyles among college students. J Med Internet Res 2017 Jan 10;19(1):e15 [FREE Full text] [doi: 10.2196/jmir.5964] [Medline: 28073739]
47. Hernández-Rabanal C, Vall A, Boter C. [Training, the key to improving eHealth literacy of upper secondary school students]. Gac Sanit 2018 Jan 21;32(1):48-53 [FREE Full text] [doi: 10.1016/j.gaceta.2016.12.005] [Medline: 28238342]

Abbreviations

eHEALS: eHealth Literacy Scale
K6: 6-item Kessler Psychological Distress Scale
NRS: numerical rating scale
OR: odds ratio
PMS: premenstrual syndrome
PSQ: Premenstrual Symptoms Questionnaire
R-UCLA: 3-item Revised UCLA Loneliness Scale
RSES: Rosenberg Self-Esteem Scale
RSES-J: Japanese version of the RSES

Edited by J Hagström; submitted 28.02.25; peer-reviewed by K Biswas, A Azizi, L Reid-Chassiakos; comments to author 14.04.25; revised version received 24.04.25; accepted 02.06.25; published 30.06.25.

Please cite as:
Takeda T, Yoshimi K, Kai S, Inoue F
eHealth Literacy and Adolescent Health in Japanese Female High School Students in Sendai: Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e73237
URL: https://pediatrics.jmir.org/2025/1/e73237
doi:10.2196/73237
PMID:

XSL•FO
RenderX

©Takashi Takeda, Kana Yoshimi, Sayaka Kai, Fumi Inoue. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 30.06.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Advice for Improving the Experience of Web-Based Patient Portals: Qualitative Interviews With Caregiver-Adolescent Dyads

Rachel E Granberg[1], MD, MPH; Jessica M Goldberg[2], BS; Alison L Antes[3], PhD; Christine Bereitschaft[1], MSW; Fabienne Bourgeois[4,5], MD, MPH; James DuBois[3], PhD, DSc; Bryan A Sisk[1,3], MD, MSCI

[1]Division of Hematology/Oncology, Department of Pediatrics, Washington University School of Medicine, St Louis, MO, United States

[2]Washington University School of Medicine, St Louis, MO, United States

[3]Bioethics Research Center, General Medical Sciences, Department of Medicine, Washington University School of Medicine, St Louis, MO, United States

[4]Division of General Pediatrics, Boston Children's Hospital, Boston, United States

[5]Department of Pediatrics, Harvard School of Medicine, Boston, MO, United States

Corresponding Author:
Bryan A Sisk, MD, MSCI
Division of Hematology/Oncology, Department of Pediatrics
Washington University School of Medicine
4523 Clayton Avenue
Campus Box 8005
St Louis, MO, 63110
United States
Phone: 1 314 273 9084
Email: siskb@wustl.edu

Abstract

Background: Web-based patient portals can benefit adolescents and their caregivers by increasing access and providing greater understanding of one's health information, enhancing communication with clinicians, and supporting caregiver influence. Despite these benefits, adolescent uptake has been low with high attrition rates. Feedback from adolescents and caregivers is essential to improve the uptake and usability of the web-based patient portal.

Objective: The aim of the study is to identify advice for medical informatics administrators and clinicians directed at improving the adolescent and caregiver experience with the web-based patient portal.

Methods: Caregivers completed a demographic survey followed by separate qualitative, semistructured interviews with adolescent-caregiver dyads with and without chronic illnesses. Caregivers and adolescents were interviewed separately regarding advice for administrators and clinicians on several topics, including (1) providing adolescent and caregiver portal access, (2) how doctors should discuss the portal with families and the content of their notes, and (3) what general advice they had to improve portal access for families. We performed thematic analysis to develop a codebook, and team members applied these codes to the transcripts and analyzed for overlaps and contrasts.

Results: We performed 102 interviews with 51 dyads of caregivers and adolescents (26 with chronic illness and 25 without chronic illness). The majority of adolescents and their caregivers were White (adolescents: n=28, 55% and caregivers: n=28, 55%) or Black (adolescents: n=21, 41% and caregivers: n=21, 41%) and female (adolescents: n=30, 59% and caregivers: n=50, 98%). The majority of caregivers had accessed their child's portal (n=33, 65%), whereas the majority of adolescents had not (n=17, 33%). We identified three themes related to adolescent and caregiver advice: (1) encouraging and supporting portal use, (2) recognizing the emotional experience of portal use, and (3) improving portal usability, understandability, and individualization. Adolescents and their caregivers provided specific recommendations regarding initial access or enrollment including improving resources and clinician encouragement as well as improving the usability in terms of user-friendly design, understandable language, and clear expectations. Finally, caregivers and adolescents had varied opinions on confidentiality and access but emphasized the importance of understanding the emotional impact and providing guidance to caregivers and adolescents.

Conclusions: Adolescents and caregivers outlined critical advice to medical informatics administrators and clinicians to improve the patient portal uptake and usability. Further research is required to determine the best application for these recommendations, including the potential use for advance technologies to simplify results and clinical documentation, strategies to improve the

XSL•FO
RenderX

user-friendly design, and how clinicians should communicate with families now that clinical documentation is viewable to patients and caregivers.

(JMIR Pediatr Parent 2025;8:e72134) doi:10.2196/72134

KEYWORDS

web-based patient portal; electronic health records; adolescent health care perspectives; qualitative research; adolescent; caregivers

Introduction

Web-based patient portals are resources that allow patients to access their electronic health information (EHI) and communicate with their clinicians through portal messages. Availability of portals has been bolstered by the 21st Century Cures Act, which was signed into US law on December 13, 2016. This law prohibits US health care systems and electronic health record (EHR) vendors from information blocking, "a practice [by a health care clinician or health IT developer, exchange, or network] that except as required by law or covered by an exception ... is likely to interfere with access, exchange, or use of EHI" [1]. This portion that expanded transparency in health care and access to EHI went into effect on April 5, 2021. Additionally, portal use surged during the COVID-19 pandemic when electronic communication, including video visits, increased, spurring uptake on a national scale [2].

In pediatrics, caregivers can access their child's EHI through a proxy version of the portal. When children reach the age of adolescence (ranging from 10 to 16 years, depending on the US state) [3], most health care systems also provide adolescents with the option to register for their own portal account. However, each US state has laws that dictate which adolescent health information must be protected, usually related to sexual and reproductive health, mental health, and substance use disorders [4]. Each pediatric health care system must determine how to comply with these laws, and caregiver access may be limited to varying degrees when a child becomes an adolescent. As such, the usefulness of the caregiver proxy portal is often in tension, with restrictions required to ensure confidentiality of the adolescent's sensitive, protected information.

Providing portal access can benefit both adolescents and their caregivers by improving understanding of one's health, empowering adolescent self-management and autonomy, enhancing communication with clinicians, and supporting caregiver influence [5]. These benefits of improved medical competency and autonomy are especially critical for adolescents who are beginning to transition to adulthood and self-management. However, many adolescents demonstrate limited interest in using their portal [5], and their use has been low with studies citing variable rates of uptake between 15% and 64% [6-10]. In those who do use the portal, there is a high attrition rate, with one study finding that over 50% of portal accounts were actively used for less than 1 year [8].

Health care systems and administrators must consider devising strategies to simultaneously increase the usefulness of adolescent and caregiver proxy portals, support adolescent interest in using the portal, and maintain confidentiality of sensitive information. Input from adolescents and caregivers will be essential to inform these strategies, but few studies have explored these perspectives in depth. Most of this literature has focused on protecting confidentiality and increasing enrollment [11-16]. In this analysis, we aimed to address this gap by identifying adolescent and caregiver advice for medical informatics administrators and clinicians directed at improving the web-based patient portal experience.

Methods

We report this study following the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines [17].

Participants and Recruitment

We conducted semistructured interviews with caregiver and adolescent dyads who received care in St Louis. We stratified sampling for adolescents with and without chronic illnesses and purposively sampled for racial and ethnic minorities and fathers. Adolescents with chronic illness were recruited from specialty clinics at a major academic medical center, including sickle cell disease (SCD), inflammatory bowel disease (IBD), and diabetes mellitus (DM). We chose these 3 chronic illnesses because they create lifelong medical complications and represent diverse racial and ethnic populations. Adolescents without chronic illness were recruited from 3 pediatric clinics and 1 adolescent medicine clinic associated with the academic medical center.

Patient Portal Policies

All clinics used the same patient portal (called MyChart) with the same requirements for creating portal accounts. This portal allows participants to view scheduled appointments, clinician notes, and diagnostic results, communicate with their providers or clinics, and request medication refills, among other functions. Children aged 11 years and younger cannot have their own MyChart account, and caregivers may obtain full access to a proxy account by completing a proxy access form. When a child turns 12 years, caregivers lose proxy access by default. Adolescents can create their own account if they call the help desk during business hours. To provide proxy access for parents of adolescents, caregivers need to obtain signed forms of approval by the adolescent and the patient's primary doctor. Every child in a family requires a separate proxy portal account with a unique password. There was no ability to link accounts of family members or to link accounts across institutions that used a different patient portal. There is no phone app available, though individuals can log in through an internet browser on their phone or computer.

Data Collection

As part of a larger qualitative study [5], we performed semistructured interviews, in which we asked adolescents and caregivers to provide advice for administrators and clinicians

XSL•FO
RenderX

regarding (1) providing adolescent and caregiver portal access, (2) how doctors should discuss the portal with families and write their notes, and (3) what general advice they had to improve portal access for families (Multimedia Appendix 1). This guide was informed by literature review, our prior work, and a stakeholder advisory board. BAS, CB, and another team member performed interviews between May and December 2022 via telephone or Zoom videoconferencing software (Zoom Video Communications) based on participant preference. Caregivers and adolescents were interviewed separately and privately. Interviews were audio-recorded and professionally transcribed. We collected demographics via a Qualtrics survey that was sent via email to caregiver participants.

Data Analysis

BAS, CB, and JMG developed a codebook following validated phases of thematic analysis [18]. Coding involved multiple iterative steps: (1) read transcripts to familiarize themselves, (2) descriptively coded 5 transcripts to formulate preliminary codes, (3) grouped codes into categories and collapsed categories into representative themes, and (4) refined definitions for themes through 3 cycles of independent coding and consensus meetings. After reviewing 20 adolescent transcripts and 19 caregiver transcripts, we reached saturation for representative themes.

CB and REG independently applied this codebook to all transcripts using Dedoose qualitative software, reviewed each other's application of codes, marked disagreements, and resolved disagreements via discussion. Subsequently, REG reviewed transcripts for each dyad, identifying overlaps and contrasts between caregivers and adolescents, as well as overlaps and contrasts for adolescents with a chronic medical condition and their caregivers compared to adolescent-caregiver dyads who do not have a chronic medical condition. Quantitative data on patient-reported demographics were analyzed using SPSS Statistics (version 29.0.2.0; IBM Corp).

Ethical Considerations

The institutional review board at Washington University approved this study (202203147). We obtained informed consent from caregivers and assent from adolescents. All transcripts were deidentified prior to analysis. Participants were provided with a US $40 electronic gift card for their participation in the interviews.

Positionality Statement

BAS is a pediatric oncologist and communication researcher with training in qualitative research. REG is a fellow in pediatric hematology/oncology with a master's degree in public health and prior training in qualitative research. CB is a research coordinator with a master's degree in social work and prior qualitative experience. Another team member who performed interviews has a master's degree in public health and qualitative methods experience. JMG was a medical student with training in qualitative research. All team members have prior experience in qualitative research.

Results

Demographics

There were 102 separate interviews performed with 51 dyads, averaging 25 (SD 11) minutes. The majority of adolescents and their caregivers were White (adolescents: n=28, 55% and caregivers: n=28, 55%) or Black or African American (adolescents: n=21, 41% and caregivers: n=21, 41%), non-Hispanic (adolescents: n=46, 90% and caregivers: n=47, 92%), and female (adolescents: n=30, 59% and caregivers: n=50, 98%). Many caregivers had accessed their child's portal (n=33, 65%), but fewer adolescents had accessed their portal (n=17, 33%; Table 1).

XSL•FO
RenderX

Table 1. Parent and adolescent dyad demographics.

Characteristics	No chronic illness (n=26)	Chronic illness (n=25)
Parent		
Age (years), mean (SD)	44 (4.8)	46 (6.1)
Sex, n (%)		
Female	26 (100)	24 (96)
Male	0 (0)	1 (4)
Race, n (%)		
Black or African American	9 (35)	12 (48)
Native Hawaiian or Pacific Islander	1 (4)	0 (0)
White	15 (57)	13 (52)
Other	1 (4)	0 (0)
Ethnicity, n (%)		
Hispanic	4 (15)	0 (0)
Non-Hispanic	22 (85)	25 (100)
Adolescent		
Age (years), mean (SD)	15 (1.33)	15 (1.26)
Sex, n (%)		
Female	16 (62)	14 (56)
Male	8 (31)	10 (40)
Nonbinary or third gender	2 (7)	1 (4)
Race, n (%)		
Black or African American	9 (35)	12 (48)
White	15 (57)	13 (52)
Other	2 (7)	0 (0)
Ethnicity, n (%)		
Hispanic	4 (15)	1 (4)
Non-Hispanic	22 (85)	24 (96)

Encouraging and Supporting Portal Use

Improving Accessibility

Caregivers reported significant challenges with the enrollment processes for the proxy portal. These caregivers advised that the entire procedure should be easier, stating that the experience was “confusing” and requesting that more information be provided. Both caregivers and adolescents reported that the login process could be easier, stating the requirements for adolescents to have their own email made accessing the portal difficult. In addition, the sign-up process for the adolescent proxy portal required the adolescent to call the help desk during business hours, which conflicted with school and sports schedules. Further, institutions had rules about required characteristics of passwords, such as numbers and symbols, that frustrated some participants. Adolescents and caregivers thought it would be beneficial to have increased resources to assist in the sign-up and usability of the portal platform, including a website, pamphlet, or an individual that could guide families through the process.

Clinician’s Role in Educating and Promoting Use

Caregivers and adolescents acknowledged that the portal should be “brought up more” (Adolescent 26, no chronic medical condition) by the clinician to encourage use, with one caregiver stating that it should be “a part of the visit every time” (Caregiver 26, no chronic medical condition). Only one respondent stated that they did not know “if that’s really a doctor’s responsibility to worry about the portal” (Caregiver 13, IBD). Some felt it would be useful for clinicians to “be more informational” (Caregiver 46, SCD) about the portal components and sign-up process, with one person stating that they felt the doctor should have experience using the portal to better understand the patient perspective. Others recommended that clinicians outline acceptable uses of the platform, including types of portal messages that are acceptable and how to best communicate with them.

XSL•FO
RenderX

Recognize the Importance of the Portal for Chronic Illness

Nearly all caregivers and adolescents acknowledged the importance of respecting and protecting adolescent confidentiality. However, many caregivers of children with chronic illness described the importance of retaining access to nonsensitive information in the portal, such as notes, appointments, laboratory results, and medication lists. These caregivers worried that limiting parental access to this actionable information could be "very detrimental" (Caregiver 51, SCD), especially because adolescents are often not mature enough to navigate health care on their own (Table 2).

XSL•FO
RenderX

Table 2. Illustrative participant quotes on encouraging and supporting portal use.

Theme and subtheme	Illustrative quote
Improving accessibility	
Easy sign-up	• "The sign-up process took a while. It was kind of confusing. I think I had to have a code or something and I didn't get it, so I remember that was kind of difficult. Making it just easier to actually get an account" [Caregiver 4, DM[a]].
Easy access	• "Just make it very simple to access it, not having to go through a lot of steps and give parents really good instructions on how to access it" [Caregiver 10, DM].
Improved resources	• "Maybe if it's your first time using it, you do a step-by-step page or whatnot to show you where everything is and the layout" [Adolescent 47, no chronic medical condition]. • "I think there needs to be better instruction and explanation on how to set it up, why it has to be set up that way. A lot of people just want you to, oh, set up the portal, but no one explains that you need a special code. You need consent. You need—so it's never explained very well" [Caregiver 45, no chronic medical condition]. • "If there's a place that could have helped us, like a phone number we could've called, someone that could have walked us through it besides the doctor's office themselves, that would've been more helpful too" [Caregiver 26, no chronic medical condition].
Clinician's role in educating and promoting use	
Educate	• "I think that my doctors have been very good about telling us about the medical records, but again, I think they should just give a more precise knowledge about how to access the records" [Adolescent 41, no chronic medical condition]. • "I think that they should just tell the family about it. Maybe they could show them on their phone. It's like a demo, so it doesn't show any personal stuff. Like they could show them on their phone, so they could see what the app looks like and show how user-friendly it is" [Adolescent 25, SCD[b]]. • "I'm not sure that doctors understand how to use it. I think they need to have used it themselves, logged in, checked it out, seen it from a patient view, and—I don't know—have better detailed description and notes of how to get in, who to call, what to do" [Caregiver 45, no chronic medical condition].
Promote	• "I would suggest the doctor tell the family that they should regularly look at the online medical records. Just so they know everything, all the information that's on there that they need to know. If there's something serious or even if there's not, just to make sure that everything's okay" [Adolescent 40, no chronic medical condition]. • "Oh, I think they should definitely encourage it with every patient because it is a useful tool, and I thought should be presented. It's not just information. It's a useful tool that you can use to help take an active part in the health of the child" [Caregiver 5, IBD[c]].
Outline acceptable uses	• "Educating parents and teenagers, this is how you access it, this is what it's good for, this is a positive use of it, and this is what you shouldn't use it for" [Adolescent 20, no chronic medical condition]. • "Just making clear how they prefer to communicate and how they want us as the patients to communicate with them or how they will choose to communicate. 'I will send you a message through MyChart.' We just recently went to our endocrine appointment and the nurse practitioner said, 'I will call you.' He did, he called and left a message because that was all clear. He told us how he was gonna communicate. Now that we do have MyChart, we have the phone, we have all these different ways and the after-hours communication just to be clear how they want, what method they would prefer, and what's most effective for them" [Caregiver 2, DM].
Recognize the importance of the portal for chronic illness	
—[d]	• "I think it's a good idea to let parents access it because they need to know what's going on with their child's health, and if they don't, then their child could worsen their own health without them knowing" [Adolescent 16, SCD]. • "I would tell them that these are minor children, and it is very important that parents are an integral role in the health of their children, and that they should have access to all of it" [Caregiver 12, IBD].

[a]DM: diabetes mellitus.

[b]SCD: sickle cell disease.

[c]IBD: inflammatory bowel disease.

[d]Not applicable.

XSL•FO
RenderX

Recognizing the Emotional Experience of Using the Portal

Mitigate Stress Through Discussion and Resources

To decrease stress, caregivers advised that clinicians discuss with families the maturity level of the adolescent prior to granting access to ensure that the adolescent is ready for access. Caregivers also recommended that adolescents should be walked through the portal at their first time of access. A few adolescents worried about portal access being problematic for parents who were "helicopter parents" or overbearing. These adolescents advised that clinicians discuss the types of information that might be released through the portal, prepare them for potentially stressful results, and encourage them not to become fixated on every abnormal result. One caregiver and one adolescent noted the importance of maintaining the option for verbal communication with clinicians outside of the portal, especially when worrisome test results are released.

Modify Note Content

Adolescents and caregivers advised that notes should be tailored to remove and protect confidential discussions that occurred between the adolescent and their clinician. Some adolescents and caregivers advised a collaborative discussion between clinicians and adolescents about what specifically should be excluded from the notes to ensure confidentiality tailored to the comfort level of that patient and the patient-caregiver dynamic. Another caregiver suggested the clinician inform the adolescent that the confidential portion would not be included in the note to build trust.

Caregivers and adolescents also had recommendations for the content and language that were included in the portal. Many caregivers and adolescents stated the importance of considering adolescents' emotions when writing notes, which involved using professional language and "stay[ing] positive and to stay just on facts. Maybe not put personal thoughts" (Caregiver 4, DM). A few participants discussed concerns that comments about the adolescent's weight could have a negative emotional effect. These participants advised clinicians to be "sensitive and mindful" (Caregiver 42, no chronic medical condition) and use "very gentle phrasing" (Adolescent 23, no chronic medical condition). One adolescent reflected that they had "a doctor make jokes about me in my medical notes before ... It just made me not trust the doctor really, and withhold information from them because I didn't wanna be judged about it" (Adolescent 10, DM) (Table 3).

XSL•FO
RenderX

Table 3. Illustrative participant quotes on recognizing the emotional experience of using the portal.

Theme and subtheme	Illustrative quote
Mitigate stress through discussion and resources	
Prepare parents	• "Then to the parents, be like, 'If you see something that's worrisome, don't become overbearing,' because I definitely think, especially with mental health, a step in the right direction is telling the doctor—maybe not your parent, but telling the doctor or someone else that you trust, and I definitely think if a parent becomes super overbearing or super controlling because they have access to these records, there's the chance that the child won't give that information and won't be very open with their doctor. Then that could spill out into a bigger problem down the road" [Adolescent 29, no chronic medical condition]. • "I think there's maybe a possibility with other teenagers of parents who are striving for those perfect numbers, and that can put a lot of stress on children, so I think maybe in terms of the parents' access, and it may not be restricting access to anything, but it could just be reminders that parents have lots of impact on their children, obviously, even if a child doesn't have a condition, but especially with children that have a medical condition. Parents have a very big impact on how their child will view their health, and so I think that could be a good reminder to parents as well" [Adolescent 2, DM[a]].
Communication of big news	• "A worry I would have is if they have this big disease or something, just something big, something that's a very big deal, it might be best to first tell them and then give the medical records" [Adolescent 23, no chronic medical condition]. • "I feel like if there's something that is detrimental, knowing that either an adolescent or a parent has access to that, that should be a verbal conversation versus seeing something like that written. You know what I mean? When you have that information, when you see that information, there are so many questions that go through your mind, and I think that would be unfair to the patient to have to read that and not be able to access the doctor immediately to have a discussion about that information" [Caregiver 27, no chronic medical condition].
Modify note content	
Protect confidentiality	• "I don't think they should be putting things that they ask the parents to leave the room for because if they had the parents leave the room, they're trying to get the teenager to be completely truthful and completely comfortable. Maybe I don't think it's the best idea for them to put that information in the Doctor's Note, unless maybe it's like a serious issue, and they got permission from the teenager during the doctor's appointment" [Adolescent 3, DM].
Sensitive language	• "Very gentle phrasing, not saying this child is overweight. They need to work out now, something like that. Not that way, but something more like kind, considering people's feelings and stuff" [Adolescent 23, no chronic medical condition]. • "I would hate to see in a doctor's note somethin' that could be hurtful by the patient, where they need to lose a certain amount of weight by this time or they're gonna have horrible—they're gonna develop diabetes" [Caregiver 1, DM].

[a]DM: diabetes mellitus.

Improving Portal Usability, Understandability, and Individualization

Improving Interpretation of Laboratory Results and Notes

For interpreting laboratory results, adolescents and their caregivers noted that having a dictionary, glossary of medical terms, or additional information such as reference values would be beneficial. Some specifically stated that without these resources, they resort to web-based searches to interpret results. Adolescents without chronic medical conditions did not have advice regarding improving laboratory understanding for individuals accessing the portal, presumably because they had few or no laboratory values in their medical records. Regarding clinician notes, many adolescents and caregivers described a "language barrier" (Adolescent 2, DM) due to the medical terminology and complexity of notes. They advised that notes should be understandable to the average person, with "everyday language instead of medical terms" (Adolescent 13, IBD). One caregiver specifically advised how clinicians' notes could be a "bridge from the labs or the records" (Caregiver 8, IBD), with notes providing an explanation for difficult-to-understand laboratory results. Others advised that the notes did not need to change but that clinicians should speak with adolescents and their caregivers about the readability of these notes. A few adolescents and caregivers had suggestions regarding the content of notes, stating that they should contain next steps, address the concerns of the caregiver and patient, and be transparent and detailed.

Improving Portal Design

Some adolescents and caregivers reflected that the patient portal should be overall "user-friendly" (Caregiver 30, SCD) and "making sure that everything is findable, that needs to be found" (Caregiver 28, no chronic medical condition) with an organized layout. Caregivers of children with a chronic medical condition noted the potential benefits of having the office and doctor's contact information "in case we need to get ahold of them quickly" (Caregiver 9, IBD). Several adolescents noted that "it would be more acceptable if it was an app" (Adolescent 46, no chronic medical condition).

XSL•FO
RenderX

Individualizing the Interface

Caregivers and adolescents recommended improving the level of customization of portal contents for adolescents and their caregivers. Suggestions included having a simpler interface for adolescents, having a more summarized note personalized to the adolescent, or personalizing the interface with users selecting for desired or undesired features.

Linking Accounts

Caregivers and adolescents recommended a feature by which portal accounts could be linked, such that caregivers could have one sign-in for all children or family members. Participants noted that this would ease usability and access, which can be hindered by requiring multiple logins and passwords. Caregivers also recommended an additional feature where records could be linked and shared across institutions, which would enable the streamlining of medical care (Table 4).

XSL•FO
RenderX

Table 4. Illustrative participant quotes on improving portal usability, understandability, and individualization.

Theme and subtheme	Illustrative quote
Improving interpretation of laboratory results and notes	
Dictionary	"In bloodwork, there are a lot of medical terms that teens might not know. Try to make it easier for people to access information on that ... Well, maybe by the term, like white blood cell count for example, you just have a little info button that you can press it and it pops up some information about what that is" [Adolescent 5, IBD[a]].
Understandable language in notes	"Just make it as simple and as easy to understand and follow as possible. Maybe if they're using medical terminology, to explain what that medical terminology means. What condition is going on, where it is affecting them physically, and treatment. Very specific and easy to understand" [Caregiver 10, DM[b]].
Note as a bridge to understand laboratory results	"I think they should be thorough and in layman's terms. I think the labs can be, obviously, more medical terms, but the doctor's notes should be the bridge from the labs or the records to better—to make it easier to understand" [Caregiver 8, IBD].
Prepare families for medical terminology	"I think they should write them according to how they were trained to write notes. I don't think they should alter how they were taught to write notes. Write 'em as they should, but also let families know that these—prep 'em they contains medical terminology" [Caregiver 32, no chronic medical condition].
Improving portal design	
User-friendly	"Probably go to a graphic designer, somebody that designs websites, and just make an easily accessible app. Also make it look clean, I guess, because that makes you want to use it more" [Adolescent 46, no chronic medical condition].
Organized layout	"Maybe if there's a way to organize it to where even if a teenager, even if I was there without my mom, I would be able to understand where to find things and just make it easier to understand where everything is. I think that would help" [Adolescent 13, IBD].
Contact information	"I think adding the doctors' contact information for their office right there with their name in case we need to get ahold of them quickly" [Caregiver 9, IBD].
App form	"If they can make an app that would be easier to use" [Adolescent 7, DM].
Individualizing the interface	
Individualized notes	"Maybe they can make like a note for the kid, the teen, and a note for the parent. The note for the parent could be more in detail and stuff, and the note for the kid could be more summarized so they understand" [Adolescent 25, SCD[c]].
Simpler interface	"When I open the website, it makes sense to me, but it would be overwhelming to a child. Looking at the menu and the visits and the messages, and test results, scheduling appointment, those are things that—maybe it would just be like a little more child-like. To say a smiley face, you're seeing your pediatrician in two weeks, how are you feeling? To be able to—instead of saying, 'Send a message' 'Is there anything you wanna ask your doctor?'" [Caregiver 15, no chronic medical condition].
Personalized interface	"I would consider is having multiple sign-ons for each patient. That way, my son could have his sign-on. I could have my sign-on. Then if, let's say, we both make it clear that he only wants to see certain things, his level could be set for that, but then I could see everything or vice versa. That way, it's specific to what each user needs to see" [Caregiver 5, IBD].
Linking accounts	
Caregivers can link family member accounts	"They should make it so that the parents could have one account. Then the kids can come out of that account, where the parent doesn't have to log in with the other kids. 'Cause in my family, I have four other siblings, so my mom is gonna have to deal with that and having four other accounts" [Adolescent 25, SCD].
Link across institutions	"That's confusing that every institution has their own MyChart. If there was a way to make 'em universal that they flow in together, that would be more helpful to the families and the patients" [Caregiver 53, no chronic medical condition].

[a]IBD: inflammatory bowel disease.

[b]DM: diabetes mellitus.

[c]SCD: sickle cell disease.

Discussion

Principal Findings

Using the technology acceptance model framework, we consider the 2 key factors of perceived ease of use and perceived usefulness that influence the attitude, behavioral intention, and actual portal system use [19]. Adolescents and caregivers provided advice on how to improve the perceived ease of use, including improving the accessibility of portal enrollment and access, the understandability of its contents, and mitigation methods for potential emotional distress that could result from portal use. Regarding its perceived usefulness, while some recognized the usefulness and importance of the portal, many

XSL•FO
RenderX

stressed that the perceived usefulness could be bolstered by clinician promotion of the portal and by improving the understandability and customization of its contents. There were three overarching themes that permeated the adolescent and caregiver recommendations: (1) encouraging and supporting portal use, (2) recognizing the emotional experience of portal use, and (3) improving portal usability, understandability, and individualization.

Increasing resources for accessing, using, and understanding the portal was nearly universally recommended. Areas that were identified to benefit from increased resources were establishing portal access and initial use as well as improving the understandability of laboratory results and clinician notes. This is particularly salient when discussing portal design for the adolescent age range, as the target audience's maturity level and reading skills evolve over time. Some resources could be standardized, such as handouts to understand the enrollment process, a tutorial to demonstrate display features, or a glossary that explains basic medical terms. Other aspects, such as interpreting radiology reports or understanding the potential impact of an abnormal laboratory result, may require a more nuanced and personalized approach. Improvement on these more nuanced aspects could involve efforts to improve communication with clinicians or the incorporation of advanced technologies, such as large language model (LLM)–powered chatbots. Prior work demonstrated that LLMs can improve the readability of radiology reports [20,21]. Another study found that LLMs were able to generate accurate and comprehensive responses with minimal risk of harm to radiation oncology patient care questions, though with a higher-than-recommended readability level [22]. Additionally, LLMs can provide inaccurate information or generate "hallucinations," which "include a vast array of failures of faithfulness and factuality" of the LLM [23]. More research, particularly in its application to the pediatric and adolescent population, is required to determine the safety, acceptability, and usefulness of LLMs in supporting portal use.

This study further emphasizes and expands on the idea that clinicians should be discussing patient portals with families. While clinician endorsement can influence portal engagement [24,25], this study is novel in identifying other important roles of clinician communication for the portal experience, including setting up parameters for confidentiality, alleviating emotional distress, and outlining expectations and communication preferences. Many caregivers and adolescents had recommendations for how clinicians may improve communication by way of their notes. These recommendations included using sensitive language that recognizes the potential emotional impact, using layman terms, and removing confidential information [26]. This research underscores the importance of clinician communication in promoting appropriate use and enhancing the effectiveness of the patient portal. Furthermore, it raises difficult questions about the purpose and audience of clinical notes. Should these notes primarily be written for medical documentation and communication with other clinicians, for understandable communication with caregivers and patients, or for liability or billing purposes? The same note might not be able to fulfill these divergent purposes [27].

Many caregivers and adolescents provided recommendations on improving the layout, as well as how EHR vendors could improve portal engagement and use by focusing on a user-centered design, which seeks to adapt the design and functionality of the portal based on user feedback and goals. Research in adult populations has found that identifying user goals and interests and then tailoring portal design and function to meet these needs improves engagement in the portal [28,29]. Furthermore, as research in adolescent and adult populations shows that portal engagement is associated with better medical adherence and understanding, as well as a better perception of control over one's health, this engagement could have significant downstream effects [30-33]. Given that many adolescents show limited interest in using the portal [5-8], engaging in user-centered design might increase the perceived usefulness and ease of use of portals, which are central drivers of uptake and acceptance of novel technologies [34].

Strengths and Limitations

This study had several limitations. First, while we purposively sampled for racial and ethnic minorities, as well as fathers, our study was limited by excluding non-English speakers and having few Hispanic participants and few fathers as participants. Therefore, these perspectives may not be appropriately reflective or generalizable to these populations. Second, adolescents with greater concerns about privacy and confidentiality might have been less inclined to participate in this study, which may result in a decreased emphasis on this aspect compared to a more generalized adolescent population. Third, as patients were recruited from a single health care system in St Louis, MO, using a single EHR platform, the results may not be generalizable to other regions of the United States or to other hospital systems using a different EHR platform.

This study also had several strengths. First, the unique perspective of this qualitative research evaluates not just the barriers and benefits of portal engagement for adolescents and their caregivers, but uniquely identifies potential solutions. Second, while the study was limited in having few fathers, few Hispanic participants, and excluding non-English speakers, it still represents a diverse population by including both adolescents and caregivers, those with and without chronic medical illnesses, and purposively sampling for racial and ethnic minorities. This improves generalizability by providing advice for clinicians and administrators that serves a broader group of patients and families, particularly when considering those with versus those without a chronic medical condition, who may have different priorities when using the portal.

Conclusions

Caregivers and adolescents had specific recommendations for administrators and clinicians to improve the usefulness of the patient portal. Adolescents and caregivers universally recommended more resources for accessing and using the portal, improved clinician communication regarding the portal, and enhanced user-centered design of the portal. Clinicians can take steps to better understand and inform families about portal

XSL•FO
RenderX

access and functions. However, the onus lies with administrators and EHR vendors to make structural changes to the portal user interface and functionalities that can improve the usefulness and usability of the portal. The advice provided in this study should guide these improvement efforts.

Acknowledgments

This study was funded by a Greenwall Foundation Making a Difference grant. Generative artificial intelligence was not used in any portion of the manuscript writing.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

REG participated in the formal analysis, drafted the initial manuscript, and reviewed and revised the manuscript. BAS participated in the conceptualization, design, and implementation of the study, participated in the formal analysis, and reviewed and revised the manuscript. JMG and CB participated in the design of the study, facilitated the acquisition of data, participated in formal data analysis, and reviewed and revised the manuscript. ALA, FB, and JD participated in the conceptualization, design, and implementation of the study, and reviewed and revised the manuscript. All authors approve the final manuscript as submitted and agreed to be accountable for all aspects of work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide.
[DOCX File , 37 KB - pediatrics_v8i1e72134_app1.docx]

References

1. 21st Century Cures Act: interoperability, information blocking, and the ONC Health IT Certification Program. Federal Register. 2020. URL: https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification [accessed 2025-08-16]
2. Maini I, Gilotra K, Sadigh G. Patient factors associated with the use of online portal health information in the postpandemic era: cross-sectional analysis of a national survey. J Med Internet Res 2025;27:e60472. [doi: 10.2196/60472] [Medline: 40179386]
3. Sisk BA, Antes AL, Bereitschaft C, Enloe M, Bourgeois F, DuBois J. Challenges to developing and implementing policies for adolescent online portal access. Pediatrics 2023;151(6). [doi: 10.1542/peds.2023-061213] [Medline: 37132339]
4. Sharko M, Jameson R, Ancker J, Krams L, Webber EC, Rosenbloom ST. State-by-state variability in adolescent privacy laws. Pediatrics 2022;149(6). [doi: 10.1542/peds.2021-053458] [Medline: 35531640]
5. Sisk BA, Antes AL, Bereitschaft C, Bourgeois F, DuBois JM. Providing adolescents with access to online patient portals: interviews with parent-adolescent dyads. J Pediatr 2024;270:114015. [doi: 10.1016/j.jpeds.2024.114015] [Medline: 38492914]
6. Calman N, Pfister HR, Lesnewski R, Hauser D, Shroff N. Electronic access to adolescents' health records: legal, policy, and practice implications. Fam Pract Manag 2015;22(2):11-14 [FREE Full text] [Medline: 25884967]
7. Krasowski MD, Grieme CV, Cassady B, Dreyer NR, Wanat KA, Hightower M, et al. Variation in results release and patient portal access to diagnostic test results at an academic medical center. J Pathol Inform 2017;8:45 [FREE Full text] [doi: 10.4103/jpi.jpi_53_17] [Medline: 29226008]
8. Steitz B, Cronin RM, Davis SE, Yan E, Jackson G. Long-term patterns of patient portal use for pediatric patients at an academic medical center. Appl Clin Inform 2017;08(03):779-793. [doi: 10.4338/aci-2017-01-ra-0005]
9. Szilagyi PG, Valderrama R, Vangala S, Albertin C, Okikawa D, Sloyan M, et al. Pediatric patient portal use in one health system. J Am Med Inform Assoc 2020;27(3):444-448 [FREE Full text] [doi: 10.1093/jamia/ocz203] [Medline: 31841146]
10. LeLaurin JH, Nguyen OT, Thompson LA, Hall J, Bian J, Cho HD, et al. Disparities in pediatric patient portal activation and feature use. JAMIA Open 2021;4(3):ooab086 [FREE Full text] [doi: 10.1093/jamiaopen/ooab086] [Medline: 34604712]
11. Elias J, Gossey JT, Xi W, Sharko M, Robbins L, Bostwick S, et al. Sharing clinical notes while protecting adolescent confidentiality and maintaining parental insight. Appl Clin Inform 2023;14(3):555-565 [FREE Full text] [doi: 10.1055/a-2084-4650] [Medline: 37130566]
12. Sethness JL, Golub S, Evans YN. Adolescent patient portals and concerns about confidentiality. Curr Opin Pediatr 2023;35(4):430-435. [doi: 10.1097/MOP.0000000000001252] [Medline: 37036289]

XSL•FO
RenderX

13. Ancker JS, Sharko M, Hong M, Mitchell H, Wilcox L. Should parents see their teen's medical record? Asking about the effect on adolescent-doctor communication changes attitudes. J Am Med Inform Assoc 2018;25(12):1593-1599 [FREE Full text] [doi: 10.1093/jamia/ocy120] [Medline: 30247699]
14. Xie J, McPherson T, Powell A, Fong P, Hogan A, Ip W, et al. Ensuring adolescent patient portal confidentiality in the age of the Cures Act Final Rule. J Adolesc Health 2021;69(6):933-939. [doi: 10.1016/j.jadohealth.2021.09.009] [Medline: 34666956]
15. Murugan A, Gooding H, Greenbaum J, Boudreaux J, Blanco R, Swerlick A, et al. Lessons learned from OpenNotes learning mode and subsequent implementation across a pediatric health system. Appl Clin Inform 2022;13(1):113-122 [FREE Full text] [doi: 10.1055/s-0041-1741483] [Medline: 35081655]
16. Sisk BA, Antes AL, Bereitschaft C, Enloe M, Lin S, Srinivas M, et al. Engaging adolescents in using online patient portals. JAMA Netw Open 2023;6(8):e2330483 [FREE Full text] [doi: 10.1001/jamanetworkopen.2023.30483] [Medline: 37610751]
17. Tong A, Sainsbury P, Craig J. Consolidated Criteria for Reporting Qualitative Research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007;19(6):349-357. [doi: 10.1093/intqhc/mzm042] [Medline: 17872937]
18. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
19. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS Q 1989;13(3):319-340. [doi: 10.2307/249008]
20. Butler JJ, Harrington MC, Tong Y, Rosenbaum A, Samsonov AP, Walls RJ, et al. From jargon to clarity: improving the readability of foot and ankle radiology reports with an artificial intelligence large language model. Foot Ankle Surg 2024;30(4):331-337. [doi: 10.1016/j.fas.2024.01.008] [Medline: 38336501]
21. Li H, Moon JT, Iyer D, Balthazar P, Krupinski EA, Bercu ZL, et al. Decoding radiology reports: potential application of OpenAI ChatGPT to enhance patient understanding of diagnostic reports. Clin Imaging 2023;101:137-141. [doi: 10.1016/j.clinimag.2023.06.008] [Medline: 37336169]
22. Yalamanchili A, Sengupta B, Song J, Lim S, Thomas TO, Mittal BB, et al. Quality of large language model responses to radiation oncology patient care questions. JAMA Netw Open 2024;7(4):e244630 [FREE Full text] [doi: 10.1001/jamanetworkopen.2024.4630] [Medline: 38564215]
23. Farquhar S, Kossen J, Kuhn L, Gal Y. Detecting hallucinations in large language models using semantic entropy. Nature 2024;630(8017):625-630 [FREE Full text] [doi: 10.1038/s41586-024-07421-0] [Medline: 38898292]
24. Irizarry T, DeVito Dabbs A, Curran CR. Patient portals and patient engagement: a state of the science review. J Med Internet Res 2015;17(6):e148 [FREE Full text] [doi: 10.2196/jmir.4255] [Medline: 26104044]
25. Sisk BA, Lin S, Balls-Berry JJE, Servin AE, Mack JW. Identifying contributors to disparities in patient access of online medical records: examining the role of clinician encouragement. JAMIA Open 2023;6(3):ooad049 [FREE Full text] [doi: 10.1093/jamiaopen/ooad049] [Medline: 37425488]
26. Lam BD, Dupee D, Gerard M, Bell SK. A patient-centered approach to writing ambulatory visit notes in the Cures Act era. Appl Clin Inform 2023;14(01):199-204. [doi: 10.1055/s-0043-1761436]
27. Blease C, Torous J, Hägglund M. Does patient access to clinical notes change documentation? Front Public Health 2020;8:577896 [FREE Full text] [doi: 10.3389/fpubh.2020.577896] [Medline: 33330320]
28. Reynolds TL, Ali N, Zheng K. What do patients and caregivers want? A systematic review of user suggestions to improve patient portals. AMIA Annu Symp Proc 2020;2020:1070-1079 [FREE Full text] [Medline: 33936483]
29. Nazi KM, Turvey CL, Klein DM, Hogan TP. A decade of veteran voices: examining patient portal enhancements through the lens of user-centered design. J Med Internet Res 2018;20(7):e10413 [FREE Full text] [doi: 10.2196/10413] [Medline: 29991468]
30. Delbanco T, Walker J, Bell SK, Darer JD, Elmore JG, Farag N, et al. Inviting patients to read their doctors' notes: a quasi-experimental study and a look ahead. Ann Intern Med 2012;157(7):461-470 [FREE Full text] [doi: 10.7326/0003-4819-157-7-201210020-00002] [Medline: 23027317]
31. Weinert C. Giving doctors' daily progress notes to hospitalized patients and families to improve patient experience. Am J Med Qual 2017;32(1):58-65. [doi: 10.1177/1062860615610424] [Medline: 26453323]
32. DesRoches CM, Bell SK, Dong Z, Elmore J, Fernandez L, Fitzgerald P, et al. Patients managing medications and reading their visit notes: a survey of OpenNotes participants. Ann Intern Med 2019;171(1):69-71. [doi: 10.7326/m18-3197]
33. Lam BD, Bourgeois F, DesRoches CM, Dong Z, Bell SK. Attitudes, experiences, and safety behaviours of adolescents and young adults who read visit notes: opportunities to engage patients early in their care. Future Healthc J 2021;8(3):e585-e592 [FREE Full text] [doi: 10.7861/fhj.2021-0118] [Medline: 34888446]
34. Venkatesh V, Morris MG, Davis GB, Davis FD. User acceptance of information technology: toward a unified view. MIS Q 2003;27(3):425-478. [doi: 10.2307/30036540]

Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
DM: diabetes mellitus

XSL•FO
RenderX

EHI: electronic health information
EHR: electronic health record
IBD: inflammatory bowel disease
LLM: large language model
SCD: sickle cell disease

Edited by S Badawy; submitted 04.02.25; peer-reviewed by R Dendere, A Noblin; comments to author 28.05.25; revised version received 22.07.25; accepted 13.08.25; published 11.09.25.

Please cite as:
Granberg RE, Goldberg JM, Antes AL, Bereitschaft C, Bourgeois F, DuBois J, Sisk BA
Advice for Improving the Experience of Web-Based Patient Portals: Qualitative Interviews With Caregiver-Adolescent Dyads
JMIR Pediatr Parent 2025;8:e72134
URL: https://pediatrics.jmir.org/2025/1/e72134
doi:10.2196/72134
PMID:

©Rachel E Granberg, Jessica M Goldberg, Alison L Antes, Christine Bereitschaft, Fabienne Bourgeois, James DuBois, Bryan A Sisk. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 11.09.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Increasing Vaccination Awareness for Italian Primary Care Pediatricians: Game Design and Usability Study

Federico Marchetti[1], MSc; Martino Barretta[2], MD; Antonio Di Mauro[3], MD; Marco Bona[4], BSc; Chiara Amerighi[4], MSc; Antonio D'Avino[5], MD

[1]GSK, Viale dell'Agricoltura 7, Verona, Italy

[2]Federazione Italiana Medici Pediatri, Crotone, Italy

[3]Federazione Italiana Medici Pediatri, Bari, Italy

[4]Choralia Comunicazione Interna e Formazione Srl, Milan, Italy

[5]Federazione Italiana Medici Pediatri, Naples, Italy

Corresponding Author:
Federico Marchetti, MSc
GSK, Viale dell'Agricoltura 7, Verona, Italy

Abstract

Background: Invasive meningococcal disease has a high fatality rate and can lead to severe long-term health issues. In Europe, serogroup B meningococcal disease (MenB) accounts for over half of invasive meningococcal disease cases. In Italy, MenB vaccination is recommended for all newborns, but the uptake is below the Ministry of Health Vaccination Plan target (uptake: 80.91%; target: 90%).

Objective: A vaccine-based digital educational tool, Meningioca, was designed to increase primary care pediatricians' (PCPs') knowledge on the value and proper timing of MenB vaccination and to support communication of this value to parents.

Methods: Meningioca was developed using Articulate, an authoring software, and released via the TalentLMS online platform. Players engaged in a sequence of activities and mini-games, taking on the role of a PCP and progressing through 7 modules. Each module corresponds to a different age group and follows a fixed sequence of topics, simulating typical discussions that might occur during health checks for each specific age group. At the launch, members of the Italian Federation of PCPs were invited to play the game via an email link and rated the game based on aspects such as overall enjoyment, the difficulty of modules, and usefulness of the game as a teaching tool.

Results: Between March 2023 and May 2024, 471 PCPs accessed Meningioca, completing 1206 modules and 482 hours of learning. Meningioca received a mean rating of 4.4/5 (5 being the highest score), with many participants noting that they would recommend Meningioca to a colleague. "Communicating with the parent" and "health checks" were voted as participants' favorite module topics; "general culture" and "child growth and development" were voted as the most difficult. At the end of Module 3, 75% (n/N=50/67) of players agreed that Meningioca was a teaching tool to refresh and strengthen knowledge to a high or very high extent.

Conclusions: User feedback from Meningioca's first year suggests that the game is enjoyable and a potentially valuable learning tool for increasing PCPs' knowledge on vaccination.

(JMIR Pediatr Parent 2025;8:e70049) doi:10.2196/70049

KEYWORDS

primary care pediatricians; health education; immunization; meningococcal serogroup B; vaccination

Introduction

Invasive meningococcal disease (IMD) is caused by *Neisseria meningitidis*. Despite its low incidence in Europe (0.1 cases per 100,000 individuals), IMD is a public health concern due to its high fatality rate (13% in infants aged <1 y) and severe long-term health implications [1].

In Europe, serogroup B meningococcal disease (MenB) is the leading cause of IMD, responsible for more than 50% of serogroup-documented cases. Recent national surveillance data from Italy also highlight MenB as the most common cause of IMD in the country [1,2]. MenB vaccination in Italy is offered as a 2-dose primary course (starting from ≥2 mo of age and subsequent dose 2 mo later) and 1 booster dose (at 13 - 14 mo of age; a 2+1 schedule) [3]. However, MenB vaccination is recommended, not mandatory, in Italy [4] and nonmandatory vaccinations may be viewed as less important than mandatory vaccinations by citizens and health workers [5].

XSL•FO
RenderX

Due to the high incidence of invasive MenB cases in individuals aged under 1 year, studies analyzing both Italian and UK cohorts have highlighted the importance of starting a vaccination schedule as early as possible [6-8]. In two retrospective, observational studies, MenB vaccination in children aged <6 years was shown to be highly effective at preventing the disease [7,8]. However, despite the proven efficacy of MenB vaccination, mean MenB vaccination coverage in Italy for the 2020 birth cohort was reported to be 80.91% and therefore, lower than the Italian Ministry of Health's target of 90% [3,9].

In Italy, primary care pediatricians (PCPs) are expected to perform scheduled health checks, recommend vaccinations, and verify the vaccination status of children. In a survey conducted by the Italian Federation of Pediatricians (FIMP) in 2019, out of over 1000 responses, approximately 80% of PCPs said they stress the importance of vaccinations during health checks, but nearly half said they do not proactively arrange such health checks [10]. Although it is widely understood that vaccination is important for disease prevention, parental vaccine hesitancy is a known barrier to adherence to childhood vaccinations, with reasons for vaccine hesitancy including concerns about the busy pediatric vaccination schedule, vaccine effectiveness, and vaccine safety [11]. Between below-target vaccination coverage and vaccine hesitancy among parents, there is a need for effective communication about the value of recommended vaccinations in order to increase vaccine uptake [12].

Serious games and gamification allow participants to learn in an experiential, learning-by-doing way through making content more engaging, facilitating improvement of knowledge, and offering a measure of progress to create healthy competition, encouraging participants to learn more [13]. The use of serious games to improve knowledge and skills of health care professionals has been shown to be as effective as traditional learning methods, such as learning from written text or lectures [13]. In the context of vaccines, digital gamification has been suggested to hold potential to increase vaccination knowledge and thereby coverage. The use of gamification to enhance vaccine uptake is a rapidly expanding field [14,15]; a scoping review published in 2020 found only 7 peer-reviewed articles evaluating gamified digital tools to increase vaccine knowledge; a similar study published in 2024 identified 28 such articles, a four-fold increase [14,15].

The aim of this project was to develop a digital gamified educational training tool, Meningioca, to inform PCPs of the value and proper timing of vaccination with a focus on MenB and to improve communication of this value to parents and caregivers.

Methods

Game Concept

Meningioca was designed in partnership with the FIMP, which comprises of over 5300 Italian PCPs (the target audience for Meningioca). Meningioca was designed by a multiprofessional core team comprised of family pediatricians (end-users), professionals with experience and skills in online or remote learning, and professionals with documented scientific expertise in vaccines and vaccinations, through a design-thinking approach [16].

For Meningioca, the design-thinking approach began with understanding the needs of the end-users (ie, PCPs). To ensure all required information was included, a map of topics discussed during health checks was generated (Textbox 1). Unique ideas to communicate this information to end-users in an innovative and engaging way were discussed, and gamification was identified as a potential solution. The map of health check topics was then adapted to suit a serious game, forming the basis of Meningioca's content.

XSL•FO
RenderX

Textbox 1. Contents discussed during each health check-up formed the basis of Meningioca's modules. Each health check is intended to occur at a specific age. The contents of each health check are in line with this age and aim to monitor the physiological development of children and inform parents about preventable diseases.

Health check 1

- Tasks to be done
- Vaccination status
- Meningitis B – characteristics and diagnosis
- Early autism diagnosis
- Communicate with the caregiver
- Nutrition and breastfeeding

Health check 2

- Tasks to be done
- General culture
- Vaccination status
- Hunger signals
- Meningitis B – lethality and disability
- Communicate with the caregiver

Health check 3

- Tasks to be done
- General culture
- Meningitis B – symptoms
- Vaccination status
- External body obstruction
- Communicate with the caregiver
- Weaning

Health check 4

- Tasks to be done
- Meningitis B – doses and serogroups
- Vaccination status
- Neurodevelopmental assessment of the child
- Communicate with the caregiver
- Babbling and language development

Health check 5

- Tasks to be done
- Child's oral hygiene
- Vaccination status
- Meningitis B – spread and transmission
- Risks of using digital devices
- Live attenuated virus vaccination
- Communicate with the caregiver

Health check 6

- Tasks to be done
- Scoliosis and posture

XSL•FO
RenderX

- Vaccination status
- Meningitis B – permanent disabilities
- Communicate with the caregiver
- Abilities at every age group

Health check 7

- Tasks to be done
- Sense of risk
- Vaccination status
- Meningitis B – contagion in adolescence
- General knowledge (adolescent language)
- Communicate with the caregiver
- Sexual experience

Game Design

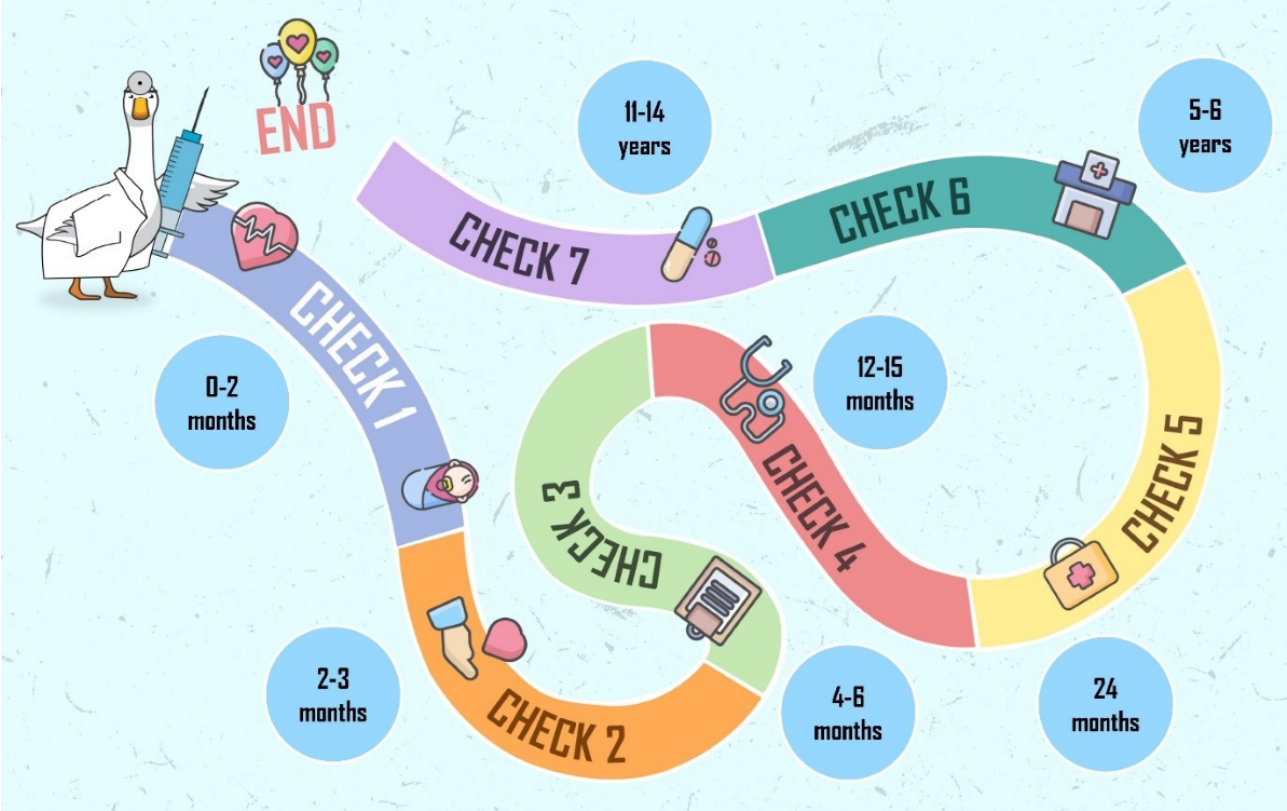
Meningioca was developed using Storyline 360 (a suite of Articulate 360), an authoring software, SCORM 1.2 (standard format), and TalentLMS, a learning management platform [17-19]. Participants play as an avatar of a goose, inspired by the Game of the Goose (a well-known board game that originated in Italy in the 15th century) and take on the role of a PCP. Using a narrative approach, players participate in a series of activities and mini-games, using and improving vaccination knowledge. Examples of the mini-games include a drag-and-drop activity, where users separate actions they would and would not carry out during health checks, as well as a quick-fire selection game, where users scroll through a video and click on correct answers to questions posed. Participants received points and feedback after each mini-game, with points gained the first time a module is played and players ranked against all other participants. Once each module had been unlocked, it was freely accessible for review or to refresh training. All data included in Meningioca are supported by a reference, either from scientific or gray literature, to ensure all information is confirmed with a reliable source.

Game Refinement and Structure

A prototype of one module was played by 10 PCPs. Feedback from these testers suggested that the game was enjoyable, and further modules were produced. At launch (March 2023), Meningioca was comprised of 6 modules, with each module focusing on a different age group (0 - 2, 2 - 3, 4 - 6, 12 - 15, 24, and 60 - 72 mo of age), selected to be in line with the Italian national immunization calendar. In April 2024, a 7th module focusing on adolescents (11 - 14 y of age) was added (Figure 1).

XSL•FO
RenderX

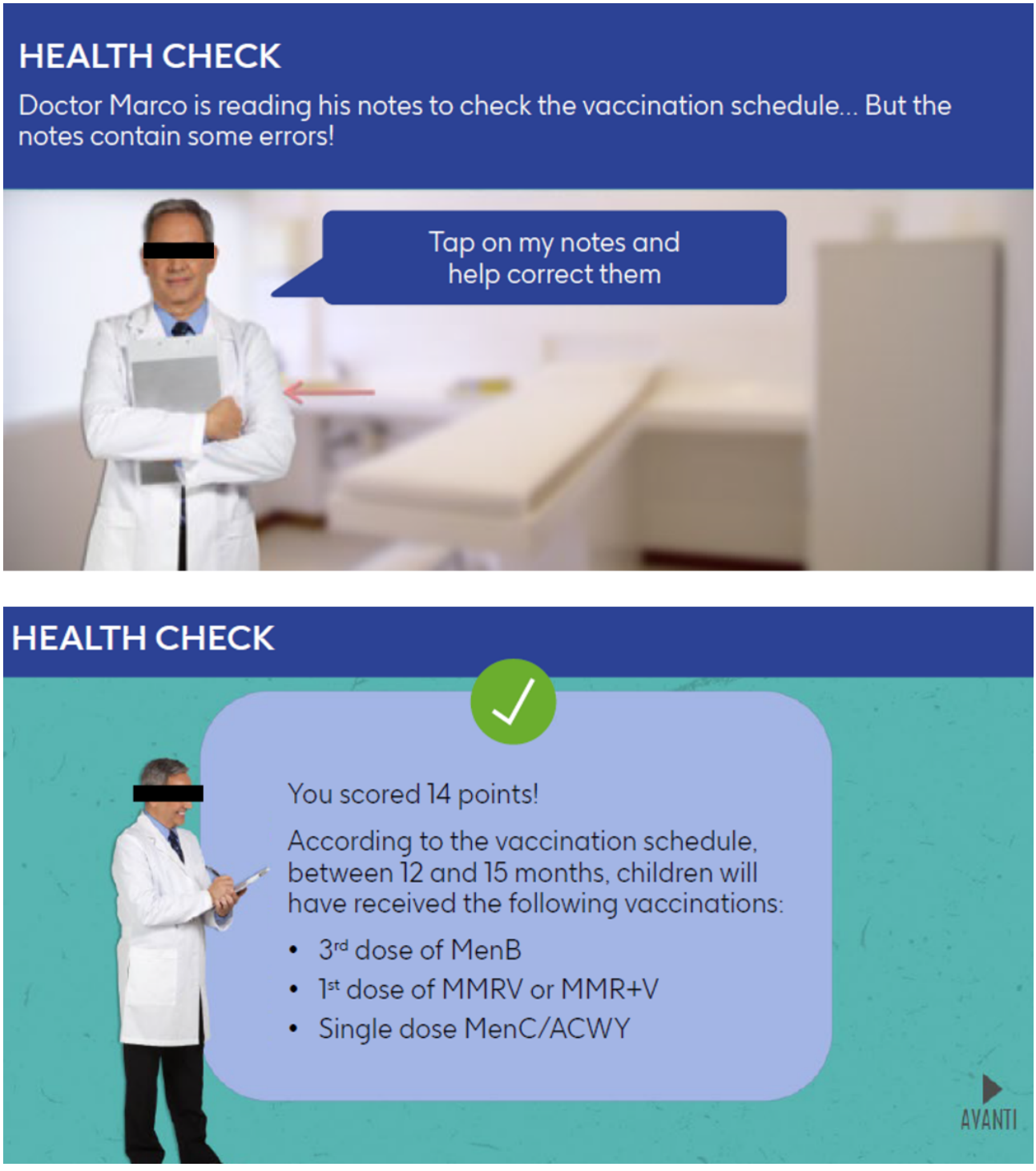
Figure 1. Meningioca modules.



All modules within Meningioca are based on a fixed sequence of topics, mirroring discussions that could be expected during health checks for each age group. In brief, the following main themes are covered: health checks in general, child growth or development, vaccination calendar and immunization status check, deepening MenB understanding, communicating with the parent, and Italian general culture. The modules use elements of surprise via quizzes and involve role-playing scenarios where users interact with avatars of colleagues (Figure 2) and caregivers (Figure 3).

XSL•FO
RenderX

Figure 2. Example scenes from Meningioca depicting interactions with colleagues. Text from the game has been translated from Italian into English.



XSL•FO
RenderX

Figure 3. Example scenes from Meningioca depicting interactions with caregivers. Text from the game has been translated from Italian into English.



Game Launch

At the launch of Meningioca in March 2023, members of the FIMP were invited to play the game via an email link. Members who subscribed to the game were notified of the launch of the module in April 2024. The effectiveness of Meningioca to educate PCPs on the value and proper timing of vaccination with a focus on MenB was measured via feedback questionnaires at the end of each module (Multimedia Appendix 1).

Ethical Considerations

Meningioca was an educational project, not involving a human subject scheme nor collecting human data. Therefore, this project did not require ethics review as per the Linea Guida per la classificazione e conduzione degli studi osservazionali sui farmaci (GU Serie Generale n.76 del 31-03-2008) [20].

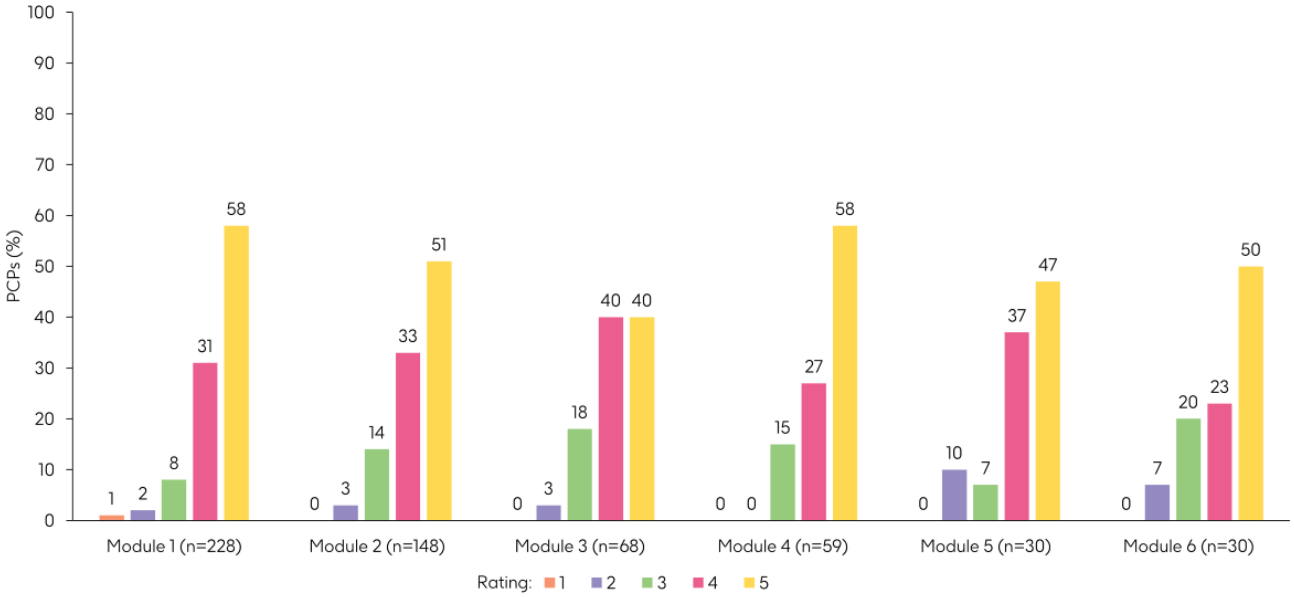
Results

Between March 2023 and May 2024, 471 PCPs accessed Meningioca and 1206 modules were completed, comprising 482 hours of learning. After Module 6, players were asked to

XSL•FO
RenderX

rate their enjoyment of Meningioca on a scale from 1 to 5, with 5 being the highest score. Meningioca received a mean rating of 4.4/5. Participants were also asked to rate individual modules at the end of Modules 1 - 6, and a breakdown of ratings is reported in Figure 4.

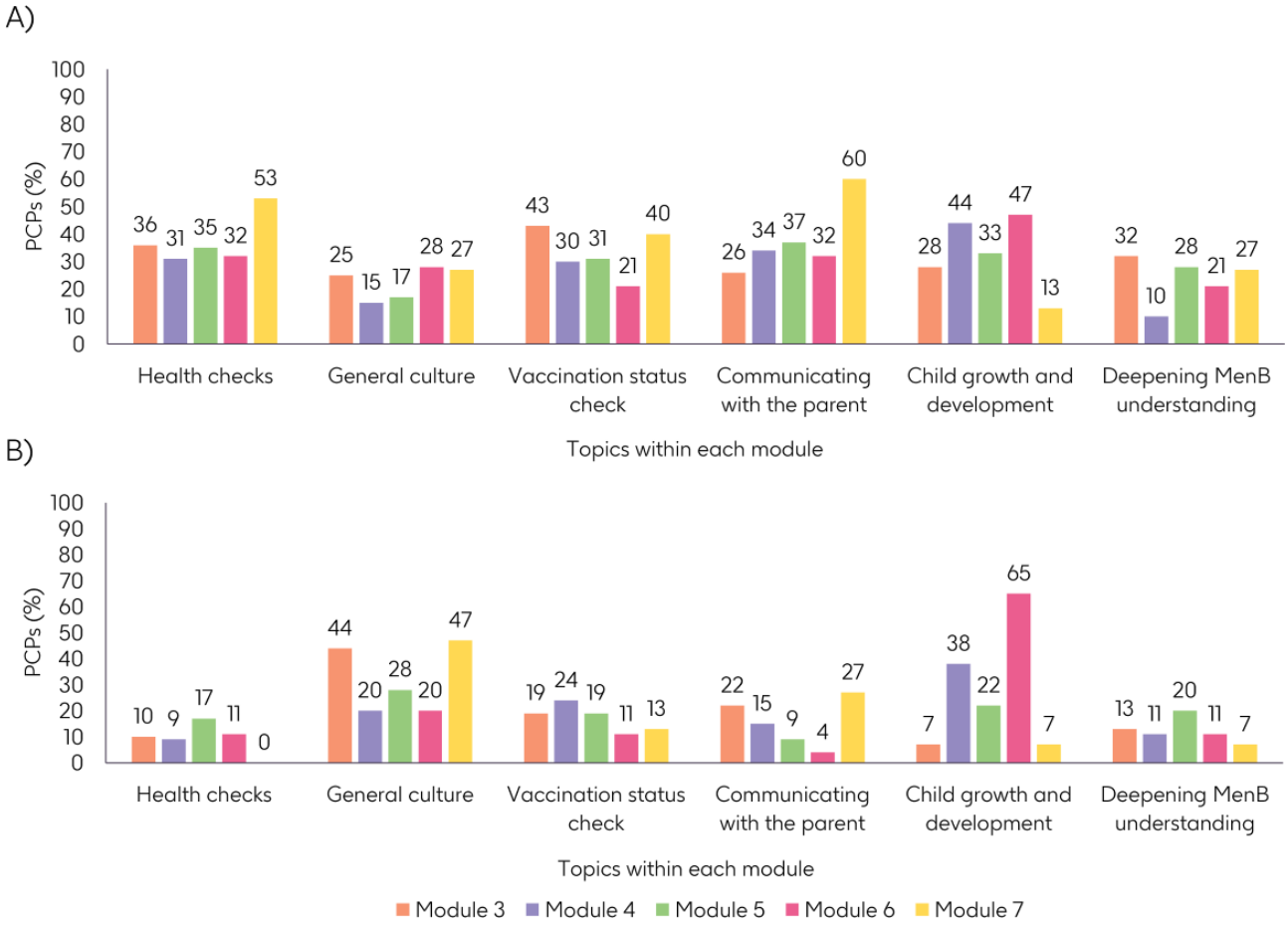
Figure 4. Proportion of PCPs rating each module on a scale of 1 - 5 from March 2023 to September 2023. At the end of each module, PCPs were asked to rate how much they liked the module on a scale of 1 - 5, with 5 as the highest score. PCP: primary care pediatrician.



After Modules 3 - 7, participants were asked to select their favorite topic and the topic that they found most difficult. There was a relatively even split regarding participants' favorite topics; "communicating with the parent" and "health checks" received the most votes and "general culture" received the fewest (Figure 5A). "General culture" and "child growth and development" were voted as the most difficult module topics (Figure 5B).

XSL•FO
RenderX

Figure 5. Proportion of PCPs that rated different topics within Meningioca as (**A**) the topic they liked the most and (**B**) the topic they found the most difficult. At the end of Modules 3 - 7, PCPs were asked to choose their favorite topic within the module and the topic they found most difficult. MenB: serogroup B meningococcal disease; PCP: primary care pediatrician.



On completion of certain modules, participants were asked whether they would recommend Meningioca to a colleague. Overall, 93% (n/N=63/68) answered "yes" at the end of Module 3, 90% (n/N=53/59) at Module 4, 90% (n/N=53/59) at Module 5, with the remaining participants answering "No." Additionally, at the end of Module 3, participants were asked to what extent Meningioca could be considered a teaching tool to refresh/strengthen knowledge, with a response scale from "very little" to "very much"; 43% (n/N=29/67) of participants answered "a lot" and 32% (n/N=21/67) of participants answered "very much".

Discussion

Principal Findings

To the best of our knowledge, Meningioca is the first gamified educational training tool developed within the field of vaccination, specifically designed for PCPs in Italy. The primary aim of Meningioca is to increase PCPs' knowledge on the importance of health checks within the context of childhood vaccination and, on a larger scale, boost the below-target MenB vaccination coverage in Italy and decrease general vaccine hesitancy among parents. Early results from the first 14 months of use indicate that Meningioca is not only an enjoyable game but also serves as an effective teaching tool to refresh and strengthen vaccination knowledge.

Comparison to Prior Work

Meningioca adds to the rapidly expanding field of digital vaccination-based serious gamification tools. Over the past 10 years, digital learning methods aimed at enhancing vaccination knowledge and programs have transitioned from being limited in use to becoming well established, with this evolution evidenced by the increasing number of these games available [14,15,21]. Meningioca, like many vaccine-based digital gamification tools, was aimed at a specific population [22,23]. Understanding the needs of the end-user is key for an engaging learning tool, and by focusing on one target group, the effectiveness of digital gamification tools can be maximized. PCPs were closely involved in the development of Meningioca, both as part of the initial multiprofessional design team and as testers of the pilot module. Involving the end-user from an early stage of development is a valuable strategy for tailoring the needs of a game and may have contributed to players' enjoyment of Meningioca [15]. Furthermore, Meningioca reinforces the idea that digital gamification tools can be effective even in cohorts with a high level of base knowledge, as demonstrated in a previous study involving antibiotics and vaccination games, where senior students' knowledge improved despite already possessing high baseline knowledge in these areas [22]. At present, the majority of vaccine-based digital gamification tools focus on one type of disease, such as influenza or human papillomavirus [15]. While Meningioca focuses on MenB vaccination, it also includes information on other childhood

XSL•FO
RenderX

vaccinations, topics discussed during health checks, and general Italian culture. By including information on multiple childhood vaccinations, Meningioca ensures PCPs gain interconnected knowledge between different vaccinations, which may lead to a more comprehensive understanding and an increased ability to apply this knowledge more broadly. The web-based nature of Meningioca enhances its ease of use, as no downloadable content or additional devices are required to participate. While the impact of the type of platform used to deliver the tools, eg, web-based, mobile, or virtual reality has not currently been evaluated in terms of user preference, this web-based approach aligns with the majority of vaccine-related digital gamified tools [15].

Feedback from Meningioca's first year indicated that the game is well-rated among players and enjoyable, as evidenced by Meningioca's mean rating of 4.4/5. The even split between players' favorite topics within modules suggests that the game offers a balanced experience, with each aspect developed to a high quality throughout. Enjoyment has been shown to have a positive effect on learning and memory, suggesting that Meningioca may be more effective at increasing knowledge if players enjoy it [24]. "Communicating with parents," consistently one of the PCPs' favorite topics, was voted as one of the least difficult, suggesting enjoyment and difficulty may be linked. As no single topic received an overwhelming majority of votes as the most difficult, it could be implied that players of a digital gamification tool need to experience a balanced level of challenge. This balance is crucial for effective learning, as players should feel challenged enough to engage in the game's content, but not too much that it becomes overwhelming. Overall, early results suggest Meningioca was well received and is an effective tool to increase vaccination knowledge.

In Italy, regular health checks from birth to the age of 14 years are recommended to monitor the physiological development of children and inform parents about preventable diseases, including raising awareness of these diseases and encouraging caregivers to ensure their children receive available vaccinations. Nonetheless, many PCPs do not proactively schedule these appointments, potentially leading to gaps in preventive care and lapses in vaccination schedule adherence, ultimately impacting the child's overall immunization profile [10]. Enhancing PCPs' knowledge on the importance of vaccination may not only encourage them to proactively arrange future health checks but also improve their ability to effectively communicate this information to parents, thereby reducing parental vaccine hesitancy, fostering increased vaccine adherence, and helping to prevent the spread of disease. While it is not possible to measure this directly, by encouraging both PCPs to carry out more health checks and parents to take their children to receive vaccinations, Meningioca could boost childhood vaccination uptake, potentially leading to Italy meeting its national MenB vaccination coverage target.

Strengths and Limitations

The ability of Meningioca to act as an effective teaching tool was strengthened by the inclusion of PCPs in its development. A large number of Italian PCPs were invited to play the game, improving the game's generalizability and aiming to ensure that the players accurately represent PCPs overall. Despite these strengths, Meningioca was associated with limitations. First, feedback questionnaires were not consistent across modules, leading to data gaps when synthesizing responses. Consistent questions across modules may help in building a more comprehensive view of the perceptions of end-users. Second, the impact of Meningioca, in terms of its ability to reduce caregiver vaccine hesitancy and increase vaccine uptake, cannot be directly measured. Surrogate measures such as enjoyment and Meningioca's use as a learning tool could instead be used as proxies.

Future Directions

Further feedback from users will be essential for the improvement of Meningioca as a tool to increase vaccine knowledge among Italian PCPs. Meningioca will continue to be a live game for PCPs to access, in order to increase their knowledge on health check activities as well as their knowledge on vaccinations. Specific questions that test PCPs' vaccine knowledge before and after using the training tool may help to quantify the effectiveness of Meningioca as a resource for increasing PCPs' knowledge. Further validation will need to be carried out to assess whether Meningioca could be effective in reducing caregiver vaccine hesitancy and increasing MenB vaccine uptake.

Conclusions

Digital gamification tools are an innovative and promising option for developing vaccination-related learning tools. Meningioca is an enjoyable and potentially effective educational resource for increasing PCP knowledge on the value and proper timing of vaccination, particularly MenB vaccination.

Acknowledgments

The authors thank Costello Medical for editorial assistance and publication coordination, on behalf of GSK, and acknowledge Hannah Russell, Costello Medical, UK, for medical writing and editorial assistance based on authors' input and direction.

Financial costs associated with this project were supported by GSK. Support for third-party writing assistance for this article, provided by Hannah Russell, Costello Medical, UK, was funded by GSK in accordance with Good Publication Practice (GPP 2022) guidelines [25].

XSL•FO
RenderX

Data Availability

Data available are those on which the manuscript is based. Files are stored in the GSK repository; no other data will be disclosed unless FIMP consider it of interest.

Authors' Contributions

Substantial contributions to study conception and design: FM, MBarretta, ADM, MBona, CA, ADA; substantial contributions to analysis and interpretation of the data: FM, MBarretta, ADM, MBona, CA, ADA; drafting the article or revising it critically for important intellectual content: FM, MBarretta, ADM, MBona, CA, ADA; final approval of the version of the article to be published: FM, MBarretta, ADM, MBona, CA, ADA.

Conflicts of Interest

FM: Employed by GSK and holds financial equities in GSK. ADM: Honoraria for AstraZeneca speaker/presentations and Angelini manuscript writing; unpaid GSK video interview contract, unpaid roles for Italian Society of Pediatrics (SIP) and Italian Federation of Primary Care Pediatricians (FIMP). MBarretta, ADA, MBona, CA: Nothing to disclose.

Multimedia Appendix 1
Questions that Meningioca users were asked following each module.
[DOCX File, 28 KB - pediatrics_v8i1e70049_app1.docx]

References

1. Invasive Meningococcal Disease: Annual Epidemiological Report for 2021-2023. : European Centre for Disease Prevention and Control URL: https://www.ecdc.europa.eu/sites/default/files/documents/MEN%20AER%202021.pdf [accessed 2024-02-20]
2. Sorveglianza nazionale delle malattie batteriche invasive (National Surveillance of Invasive Bacterial Diseases Data 2021-2023). Istituto Superiore di Sanità. 2024. URL: https://www.iss.it/documents/20126/6703853/RIS+2-2024.pdf/67f460ad-111b-9fd9-24bd-4e23160ad864?t=1727273034488 [accessed 2025-09-24]
3. Piano nazionale prevenzione vaccinale PNPV 2023-2025. Presidenza del Consiglio dei Ministri. 2023. URL: https://www.quotidianosanita.it/allegati/allegato1679488094.pdf [accessed 2025-09-24]
4. Italy: recommended vaccinations. European Centre for Disease Prevention and Control. URL: https://tinyurl.com/ynmpnffx [accessed 2025-09-24]
5. I presupposti culturali del counselling vaccinale. Istituto Superiore di Sanità. URL: https://www.epicentro.iss.it/vaccini/pdf/Presupposti_culturali_couns.pdf [accessed 2024-02-26]
6. Ladhani SN, Campbell H, Amin-Chowdhury Z, Lucidarme J, Borrow R, Ramsay ME. Timing of meningococcal vaccination with 4CMenB (Bexsero®) in children with invasive meningococcal group B (MenB) disease in England. Vaccine (Auckl) 2022 Mar 1;40(10):1493-1498. [doi: 10.1016/j.vaccine.2021.12.010] [Medline: 35148913]
7. Azzari C, Moriondo M, Nieddu F, et al. Effectiveness and impact of the 4CMenB vaccine against Group B meningococcal disease in two Italian regions using different vaccination schedules: a five-year retrospective observational study (2014-2018). Vaccines (Basel) 2020 Aug 22;8(3):469. [doi: 10.3390/vaccines8030469] [Medline: 32842669]
8. Lodi L, Barbati F, Amicizia D, et al. Four-component recombinant protein-based vaccine effectiveness against serogroup B meningococcal disease in Italy. JAMA Netw Open 2023 Aug 1;6(8):e2329678. [doi: 10.1001/jamanetworkopen.2023.29678] [Medline: 37594762]
9. Vaccinazioni dell'età pediatrica anno 2022 (coorte 2020). Ministero della Salute. URL: https://www.salute.gov.it/imgs/C_17_bancheDati_38_0_0_file.pdf [accessed 2025-09-24]
10. Biasci P, Barretta M, Conforti G, Doria M, Rosati GV. Bilanci di salute e vaccinazioni: risultati di una indagine conoscitiva condotta tra i Pediatri di Famiglia associati a FIMP [Article in Italian]. Il Medico Pediatra 2020;29(4):4-8. [doi: 10.36179/2611-5212-2020-33]
11. Napolitano F, D'Alessandro A, Angelillo IF. Investigating Italian parents' vaccine hesitancy: a cross-sectional survey. Hum Vaccin Immunother 2018 Jul 3;14(7):1558-1565. [doi: 10.1080/21645515.2018.1463943] [Medline: 29641945]
12. Ames HM, Glenton C, Lewin S. Parents' and informal caregivers' views and experiences of communication about routine childhood vaccination: a synthesis of qualitative evidence. Cochrane Database Syst Rev 2017 Feb 7;2(2):CD011787. [doi: 10.1002/14651858.CD011787.pub2] [Medline: 28169420]
13. Gentry SV, Gauthier A, L'Estrade Ehrstrom B, et al. Serious gaming and gamification education in health professions: systematic review. J Med Internet Res 2019;21(3):e12994. [doi: 10.2196/12994]
14. Montagni I, Mabchour I, Tzourio C. Digital gamification to enhance vaccine knowledge and uptake: scoping review. JMIR Serious Games 2020 May 18;8(2):e16983. [doi: 10.2196/16983] [Medline: 32348271]
15. Hakim H, Driedger SM, Gagnon D, et al. Digital gamification tools to enhance vaccine uptake: scoping review. JMIR Serious Games 2024 Feb 29;12:e47257. [doi: 10.2196/47257] [Medline: 38421688]

XSL•FO
RenderX

16. Design thinking. IDEOU. URL: https://www.ideou.com/pages/design-thinking [accessed 2025-09-24]
17. Storyline 360. Articulate. 2025. URL: https://www.articulate.com/lp/storyline-version-articulate-360/ [accessed 2025-09-24]
18. SCORM 12 overview for developers. SCORM.com. 2025. URL: https://scorm.com/scorm-explained/technical-scorm/scorm-12-overview-for-developers/ [accessed 2025-09-24]
19. TalentLMS. 2025. URL: https://www.talentlms.com/ [accessed 2025-09-24]
20. Agenzia italiana del farmaco: linee guida per la classificazione e conduzione degli studi osservazionali sui farmaci (GU serie generale n76 del 31-03-2008). Gazzetta Ufficiale. 2008. URL: https://www.gazzettaufficiale.it/eli/id/2008/03/31/08A02109/sg
21. Tozzi AE, Gesualdo F, D'Ambrosio A, Pandolfi E, Agricola E, Lopalco P. Can digital tools be used for improving immunization programs? Front Public Health 2016;4:36. [doi: 10.3389/fpubh.2016.00036] [Medline: 27014673]
22. Eley CV, Young VL, Hayes CV, Verlander NQ, McNulty CAM. Young people's knowledge of antibiotics and vaccinations and increasing this knowledge through gaming: mixed-methods study using e-bug. JMIR Serious Games 2019 Feb 1;7(1):e10915. [doi: 10.2196/10915] [Medline: 30707096]
23. Healy P, Lu C, Silk JS, et al. An exposure-based video game (dr. zoo) to reduce needle phobia in children aged 3 to 6 years: development and mixed methods pilot study. JMIR Serious Games 2023 Oct 16;11:e42025. [doi: 10.2196/42025] [Medline: 37843885]
24. Hernik J, Jaworska E. The effect of enjoyment on learning. Presented at: 12th International Technology, Education and Development Conference; Mar 5-7, 2018; Valencia, Spain. [doi: 10.21125/inted.2018.1087]
25. Good publication practice (GPP 2022) guidelines. International Society for Medical Publication Professionals. URL: https://www.ismpp.org/gpp-2022 [accessed 2025-09-29]

Abbreviations

FIMP: Italian Federation of Pediatricians
IMD: invasive meningococcal disease
MenB: serogroup B meningococcal disease
PCP: primary care pediatrician

Edited by S Badawy; submitted 13.12.24; peer-reviewed by IK Singgih, LE Bloomfield; revised version received 21.07.25; accepted 17.08.25; published 03.11.25.

Please cite as:
Marchetti F, Barretta M, Di Mauro A, Bona M, Amerighi C, D'Avino A
Increasing Vaccination Awareness for Italian Primary Care Pediatricians: Game Design and Usability Study
JMIR Pediatr Parent 2025;8:e70049
URL: https://pediatrics.jmir.org/2025/1/e70049
doi:10.2196/70049

© Federico Marchetti, Martino Barretta, Antonio Di Mauro, Marco Bona, Chiara Amerighi, Antonio D'Avino. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 3.11.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Evidence of Interventions for the Prevention of Unintentional Injuries: Scoping Review

Sheela Shetty[1*], MSc; Baby S Nayak[1*], PhD; Anice George[1*], PhD; Avinash Shetty[2*], MD; Vasudeva Guddattu[3*], PhD

[1]Department of Child Health Nursing, Manipal College of Nursing, Manipal Academy of Higher Education, Madhava Nagar, Manipal, Udupi District, Karnataka, India

[2]Kasturba Hospital, Manipal Academy of Higher Education, Manipal, Udupi District, Karnataka, India

[3]Department of Data Science, Prasanna School of Public Health, Manipal Academy of Higher Education, Manipal, Udupi District, Karnataka, India

[*]all authors contributed equally

Corresponding Author:
Baby S Nayak, PhD
Department of Child Health Nursing, Manipal College of Nursing, Manipal Academy of Higher Education, Madhava Nagar, Manipal, Udupi District, Karnataka, India

Abstract

Background: Unintentional injuries are the leading cause of death and disability among young children. Preventive strategies for unintentional injuries are mainly based on surveillance data and identifying risk factors.

Objective: This study aimed to review and synthesize published literature that determined the effectiveness of interventions for preventing unintentional injuries among children.

Methods: The methodological framework was supported by The Joanna Briggs Institute Reviewer's Manual – Methodology for JBI Scoping Reviews as well as the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines. The inclusion criteria to include the studies in the review were unintentional injuries in children, interventions to prevent injuries, a brief description of the intervention and the outcome of the intervention, and articles published in a peer-reviewed journal and written in the English language.

Results: In total, 21 articles were included in the review following the systematic search of key databases such as Web of Science, PubMed/MEDLINE, Scopus, ScienceDirect, and gray literature for studies published between July 2013 and May 2023. Of the 21 articles, 16 were randomized controlled trials, 4 were nonrandomized controlled trials, and 1 was a mixed method study. The findings of the review showed that interventions, either as a single measure (video-based teaching, testimonial story-based teaching, health education, storybook reading) or in combination (knowledge quiz and simulation test, module-based teaching along with personal counseling, and teaching with the help of video and poster), have shown a considerable decline in the number and severity of injuries. The studies included various target populations, including children and adolescents between 0 and 19 years old.

Conclusions: The review results indicate the need to plan, implement, and reinforce preventive measures and techniques to reduce unintentional injuries among children. They can also serve as a useful indicator for policymakers.

(JMIR Pediatr Parent 2025;8:e67877) doi:10.2196/67877

KEYWORDS

prevention; injury; education; health; child; children; unintentional injury; disability; youth; surveillance; surveillance data; risk factor; injury intervention; literature search; scoping review; scoping literature review; policymaker; preventative measure; preventive measure

Introduction

Background and Significance

Unintentional injuries among children are a major public health concern and result in significant childhood morbidity and mortality [1]. In addition to mortality risk, unintentional injuries can result in significant disability and disruption to quality of life [2,3]. Unfortunately, over 95% of all child injury deaths occur in low- and middle-income countries, resulting in a highly inequitable burden [4]. In India alone, unintentional injuries contribute to 9.1 deaths per 100,000 population, while transport injuries account for 2.8 deaths per 100,000 population [5].

Childhood encompasses different stages of emotional, physical, and brain development, ranging from newborn to adolescence. The age between birth and 5 years is a time of rapid changes in children's physical and cognitive abilities that can increase their

XSL•FO
RenderX

risk of unintentional injury [6]. Temperamental attributes such as increased activity level and impulsiveness in young children have been associated with proneness to injury [7]. Each of the new developmental stages in children brings changes in their physical, cognitive, or social development and the emergence of new injury hazards, thus emphasizing the importance of awareness of how injuries occur in certain populations to anticipate and avoid the risks [8].

Unintentional injuries were noted among children of younger mothers, overactive children, children belonging to extended or joint families, and children from urban dwellings, which assists in the identification of contributing risk factors to formulate strategies aimed at risk reduction and prevention of childhood injuries [9]. The environmental risk assessment found unsafe electrical points, unsafe stairs, unsafe kitchens with access to sharps, access to active fire, and unsafe furniture and objects as the most common risk factors leading to home injuries among young children [10]. Children left unsupervised or inadequately supervised may sustain negative physical, mental, or social outcomes [11].

The most challenging aspect for caregivers is to provide a safe environment for children to minimize injuries at home [12]. Toddlers and preschoolers are fragile as per their physical development and they spend most of their time at home compared to school-age children. This might impose a higher risk of developing unintentional injuries among children of this age [13]. The development of effective home hazard reduction educational materials could have a significant impact on the burden of home injuries in children, particularly in lower-income countries [14].

Studies are available on interventions to prevent unintentional injuries that are effective in improving various parameters such as knowledge, attitude, practice, and home environment.

Objectives

This scoping review aimed to review and synthesize published literature that determined the effectiveness of interventions for preventing unintentional injuries among children and the magnitude of the outcomes to support children and families. Additionally, it aims to provide an overview of the various interventions and understand those that are effective in preventing unintentional injuries. The results of this review can assist researchers and health care professionals in implementing injury prevention interventions and creating awareness among caregivers. The search question guiding this scoping review study was: what evidence exists that determines the implementation and effectiveness of interventions to prevent unintentional injuries in children? The review also focused on the most cost-effective interventions for the prevention of unintentional injuries for implementation in resource-limited settings.

Methods

Overview

This scoping review examined the relevant literature on interventions addressing unintentional injuries among children. The methodological framework was supported by the Joanna Briggs Institute Reviewer's Manual – Methodology for JBI Scoping Reviews, which builds on the framework introduced by Arksey and O'Malley [15] of Population, Concept, and Context, to create our search terms, with the population being parents or caregivers of children aged <12 years and children with age ranging from 0 to 19 years. The core concept is the prevention of unintentional injuries and includes interventions designed within the context of home, community, well-baby clinic, and preschool settings.

The review process followed 5 stages as outlines by Arksey and O'Malley [15]: stage 1, identifying the research question; stage 2, identifying relevant studies; stage 3, selecting studies; stage 4, charting the data; and stage 5, collating, summarizing, and reporting the results. The optional stage 6 is a consultation exercise to inform and validate the review findings with critical stakeholders, which was not carried out in this review. The methodological rigor of the individual studies was not assessed. However, each study was assessed for importance and coherence with the review question. We used the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines to enhance transparency in our approach to the scoping review study [16]. The PRISMA-ScR guidelines checklist is depicted in Checklist 1.

Stage 1: Identifying the Research Question

The review question was as follows: what evidence exists that determines the implementation and effectiveness of interventions to prevent unintentional injuries in children? The objectives of the review were (1) to provide a comprehensive overview of interventions to prevent unintentional injuries at home and (2) to identify the impact of interventions and outcomes on reducing the occurrence/incidence of unintentional injuries and improving the knowledge of parents/families regarding preventive strategies. The keywords used for the search were "injuries," "unintentional injuries," "children," "prevention," and "interventions."

Stage 2: Identifying Relevant Studies

The literature research included studies published between July 2013 and May 2023. Two independent reviewers (BSN and SS) searched the MEDLINE/PubMed, Scopus, ProQuest, Embase, and CINAHL databases for relevance. Search strategies specific to each database were developed. Any discrepancy in the extracted data was again rechecked by a third reviewer (AG) to resolve the discrepancy. AS provided subject expertise, and VG provided statistical input. The free-text terms and controlled vocabulary terms were combined via the relevant Boolean operators—AND, OR, and NOT. The bibliography and citations of the included studies were further searched to identify any additional studies pertinent to the review.

Stage 3: Selecting Studies

The articles identified through searches were exported to Rayyan software for duplicate removal and title and abstract screening. Concerns with data extraction were resolved in consultation with the team members. Based on the eligibility criteria, relevant articles were reviewed and selected.

XSL•FO
RenderX

We included peer-reviewed, free, full-text articles published in the English language. Narrative reviews, critical reviews, systematic reviews, and meta-analyses, as well as nonempiric publications like editorials, opinion pieces, case reports, conference abstracts, and commentaries, were excluded. Studies that reported any interventions targeting a reduction or prevention of the incidence/occurrence of unintentional injuries among children or improved knowledge or change in behavior of parents were included. Quantitative interventional studies such as randomized controlled trials (RCT), non-RCT studies, quasi-experimental studies, before-and-after design, crossover designs, and mixed methods studies, which include interventions, were included. Observational studies and qualitative studies were excluded from the scope of this review.

Stage 4: Charting the Data

The data extraction was carried out by 2 reviewers (BSN and SS), and any discrepancy in the extracted data was again rechecked by a third reviewer (AG). Data from the articles were extracted into an extraction table. The table included columns for authors, country of origin, year of publication, objectives, research design, sample size, target population, details of intervention, time frame of data collection, and main findings. Pilot testing of the data extraction framework was performed on 3 studies that were reviewed before the data extraction. No modifications were carried out in the data extraction framework. The summary of data extraction is depicted in Table 1.

XSL•FO
RenderX

Table . Description of data gathering measures of selected studies.

Author, year, country	Objective and study design	Target population	Intervention details	Measures and data collection	Findings and outcomes
Feng et al [17], 2023, China	To explore the mechanisms by which online social-network–based health education is effective in reducing unintentional injuries. RCT[a].	Parents of children aged 0-3 years (n=138)	Health education intervention to improve knowledge, skill, and behavior of parents regarding unintentional injuries through a WeChat account for 12 weeks, and communication of parents with each other and community childcare doctor for 9 months.	The knowledge, skills, and beliefs of parents regarding unintentional injuries in children were assessed before and after the intervention.	Of 76 parents in the intervention group, 49 (64.5%) demonstrated better understanding and effective communication compared to 11 (31.9%) parents of 66 in the control group. A positive impact on enhancing parents' knowledge, skills, and beliefs about unintentional childhood injuries was noted.
Ning et al [18], 2019, China	To assess the effectiveness of an app-based intervention to prevent unintentional injury. RCT.	Caregivers of preschool children aged 3-6 years (n=1980)	An app-based parenting education on unintentional injury prevention, with submodules to support interaction among users, surveys, and feedback.	Assessment of injury incidence, caregiver's attitude toward injury prevention, and safety behaviors measured at baseline and at 3- and 6-month follow-up visits.	No change in the incidence of injury and caregiver's attitude in either of the groups noted during the 6-month follow-up. Changes in injury prevention behavior were greater in the intervention group (B=.87, 95% CI 0.33 - 1.42).
Feng et al [19], 2022, China	To evaluate the effectiveness of an online social community–based parental health education intervention in preventing unintentional injuries in children between 0 and 3 years of age. RCT.	Parents of children aged 0-3 years (n=365)	WeChat Group and WeChat official account named, "Children Safety and Health." Thirty studies and 30 text messages on unintentional injury prevention and videos on first aid measures were produced and sent to the parents' WeChat group (intervention group).	Beliefs about unintentional injuries, skill in first aid measures for injuries, and behavior toward unintentional injuries were measured.	A significant difference in the occurrence of injuries was observed between the intervention and control groups (OR[b] 1.71, 95% CI 1.02 - 2.87; *P*=.04). The skill component showed a significant difference (*P*=.06) in the area of first aid for a tracheal foreign body.
Shen et al [20], 2016, China	To evaluate the efficacy of a testimonial-based video intervention in reducing drowning risk among school-aged children. RCT.	Children in third and fourth grade (n=280)	Testimonial-based intervention on drowning prevention; a 36-minute video of 4 testimonial stories about actual near-drowning experiences.	Safety knowledge on prevention of drowning, child-perceived vulnerability, and child-simulated behavior in and around the water measured at baseline and a week after the intervention.	A significant improvement was observed in children's safety knowledge of drowning risk ($F_{1,250}$[c]=7.04; *P*=.008) and safe, simulated behaviors ($F_{1,245}$=8.27; *P*=.004) related to playing in and near water. A minimal impact on children's perceived vulnerability to drowning risk was found.

XSL•FO
RenderX

Author, year, country	Objective and study design	Target population	Intervention details	Measures and data collection	Findings and outcomes
Wang et al [21], 2018, United States	To evaluate the effectiveness of an intervention grounded in social cognitive theory on the reduction of home safety problems. RCT.	Mother-toddler (12 - 32 months) dyad (n=277)	Safety intervention through health education, goal setting, and social support on fire and fall prevention, poison control, and car seat use.	Assessment of home safety problems and self-efficacy behavior measured at baseline and 6 and 12 months after the intervention.	There were fewer safety problems in the intervention group (between-group difference in change over time β=−0.54, 95% CI −0.05 to −1.03; *P*=.035) and decreased self-efficacy scores were noted at 12 months follow-up.
Weaver, et al [22], 2019, United States	To evaluate the effectiveness of a tailored parenting program on parenting behaviors. RCT.	Caregivers of children between 0 and 5 years (n=125)	RISE UP, a tailored parenting program to promote nurturing, child development, resiliency, social connection, and support within the context of unintentional injury prevention.	Safety behaviors of parents related to unintentional injury areas were assessed.	Postintervention follow-up showed a decrease in parenting injury risk scores (95% CI 25-42) and the intervention promoted positive parenting behaviors.
Swartz et al [23], 2013, United States	To evaluate the effectiveness of Keeping Baby Safe In and Around the Car, a video-based DVD on child safety seat installation and use. RCT.	Parent or custodian of a child aged 0-24 months (n=195)	Self-directed viewing of Keeping Baby Safe In and Around the Car, a video-based DVD lasting 45 minutes	Pre- and posttest assessment of vehicle safety knowledge quiz and child safety seat installation simulation test.	A significant improvement in parents' knowledge (*F*-value 103.71; *P*<.001) of car seats and their ability to discriminate the critical elements of correct car seat installation was found among the intervention group.
McKenzie, et al [24], 2021, United States	To evaluate the effect of a mobile technology–based health behavior change intervention on parental safety knowledge and behavior in preventing unintentional injuries. RCT.	Parents and caregivers of children aged between 0 and 12 years (n=5032)	The Make Safe Happen App was developed to help parents and caregivers learn about making their homes safer for children. It includes room-by-room safety checklists and links to purchase home safety products from Amazon.com.	Safety knowledge and safety actions of parents/caregivers were assessed during the pretest and posttest.	Mean knowledge score significantly increased between the pretest and posttest: intervention (8.45 - 10.32; *P*<.0001) and control participants (8.51 - 8.87; *P*=.0064). There was an increase in the percentage of participants who reported doing all repeated safety actions from 71.1% (pretest) to 77.3% (posttest) for the intervention group (*P*=.0001).
Banerjee et al [25], 2021, India	To evaluate the effectiveness of the child-to-child approach in preventing unintentional injuries in children. Non-RCT.	Children and adolescents from 0-19 years (n=397)	Older adolescents of the family were trained in first aid and CPR[d], road safety, traffic rules, injury prevention, and immediate care. They were made to disseminate the knowledge to their younger siblings and other family members.	The magnitude of injuries, time taken for recovery from injuries, knowledge of participants, and practice of the family were assessed during the pre- and postintervention period.	The postintervention measurement showed a significant reduction in the incidence of injuries (intervention: 16; 2.03, 0.06 - 4.0; control: 29; 3.62, 1.03 - 6.2; *P*<.001) and improvement in knowledge and practice on injuries in the intervention group. The total time taken for recovery was also evident in the intervention group (143 vs 95 days).

XSL•FO
RenderX

Author, year, country	Objective and study design	Target population	Intervention details	Measures and data collection	Findings and outcomes
George et al [26], 2021, India	To examine the effect of a home safety supervisory program on childhood safety, self-reported home hazards, and caregivers' supervisory attitude. RCT.	Caregivers of children aged between 2-5 years (n=130)	The Home Safety Supervisory Program consisted of a video and poster on "safe home, safe child" and individual home visits.	Injury patterns, home safety practices, and self-reported home hazard practices were assessed at baseline and 1 month after the intervention.	Significant difference in the mean baseline scores of caregivers' self-reported home hazard practices between the 2 groups (P<.001) and an improvement in the supervisory attitudes of caregivers in the intervention group (P<.001) were observed.
Holla et al [27], 2021, India	To evaluate the effectiveness of school-based interventions in promoting child safety and reducing unintentional injuries. RCT.	Children from classes 5 to 7 (n=1100)	A comprehensive pictorial child safety and injury prevention module was taught by 2 teachers on a regular basis (25 - 30 hours on average/school)	Incidences and types of unintentional injuries were assessed during the pretest and at follow-up visits at 3, 6, and 10 months after the intervention.	The incidence of unintentional injuries declined from baseline until the end of the study in the intervention and control groups. However, the decline in incidence was higher in the intervention group (50.4% vs 12.7%; P<.001).
Taylor et al [28], 2023, United Kingdom	To assess the effectiveness of systematically delivered, evidence-based home safety promotion for improving child home-safety practices. Non-RCT.	Families consisting of parents or caregivers of children between the ages of 2 and 7 months (n=361)	Stay One Step Ahead, a multievidence-based intervention for families, consisted of monthly safety messages through quizzes, posters, and flyers; home safety activities; home safety checklists; and educational safety weeks for families on common injuries.	Home safety outcomes measures were assessed at baseline and 12 and 24 months of follow-up.	The families in the intervention group showed significantly more improvement in storage of poisons out of reach (OR 1.81, 95% CI 1.06-3.07; P=.029). The total number of home safety measures used by the intervention families was significantly more than the control group families at 12 months (β=0.34, 95% 0.06-0.63; P=.019) and 24 months follow-up (β=0.46, 95% CI 0.13-0.79; P=.006).
Cowley et al [29], 2021, United Kingdom	To assess the impact of SafeTea on the knowledge and behavior of parents with regard to the prevention of scalds and first aid for burns. Mixed method design.	Parents or caregivers of children less than 5 years of age	SafeTea, a community-based intervention that provides information to parents regarding the risk factors for hot drink scalds and first aid for burns. The campaign included video clips, posters, leaflets, and charts distributed to schools, nurseries, and parent groups.	Knowledge and behavior of parents related to the prevention of scalds and first aid for burns were assessed.	Qualitative analysis under 4 themes: "reach," "engagement", "acceptability," and "impact/behavioural change." Reach and engagement declined after the first month due to decreased publicity and social media promotion. Changes in parents' behavior to minimize the risk of burns noted. Awareness of parents on the dangers of hot drinks and use of appropriate first aid measures improved.

XSL•FO
RenderX

Author, year, country	Objective and study design	Target population	Intervention details	Measures and data collection	Findings and outcomes
Morrongiello et al [30], 2013, Canada	To evaluate the efficacy of the Supervising for Home Safety program on mothers' supervision practices. RCT.	Caregivers of children between 2 and 5 years of age (n=186)	Watchful Parents, Safe Children video (20 minutes), followed by a structured discussion for 40 minutes. Mothers were given supervision diary recording forms for an 8-week baseline period.	Two time points of diary-based recording of postintervention practices—after 1 month and 3 months.	Significant decrease in time the children were unsupervised ($F_{1,83}$=4.81; *P*=.04), higher levels of supervision (t_{166}=2.99; *P*<.01), and an increase in attention to the child, immediately (t_{67}=5.22; *P*<.01) and 3 months (t_{67}=3.84; *P*<.01) after the intervention.
Morrongiello et al [31], 2021, Canada	To evaluate the effectiveness of a storybook about home safety on preschoolers' safety knowledge and injury risk behaviors. RCT.	Preschool children aged 3.5 to 5.5 years (n=59)	A storybook, "Careful Puppy Saves the Day," with information on different hazards in and around the home. Mothers were instructed to read the book with their children for 10 min/day, 4 times/week.	Knowledge about hazards and injury risk behavior was assessed at baseline and 4 weeks after the intervention.	Children in the intervention group were able to identify more hazards, showed fewer risky behaviors, and provided a more comprehensive explanation of safety (ηp2=0.13, 0.19, and 0.51, respectively).
Khan et al [32], 2023, Pakistan	To evaluate the effectiveness of the long-term effect of 2 injury prevention interventions on the prevalence of home injury hazards. Non-RCT.	Caregivers of children under the age of 5 years (n=312)	Two interventions were included: an educational pamphlet and a tutorial. Both consisted of information on injury hazards for children that are commonly found in homes along with the strategies to reduce or eliminate those hazards.	Reduction in home injury hazards was classified into 6 types: falls, burns, poisoning, drowning, cut injuries, and choking, which were assessed at baseline, 3 months after the intervention, and 2 years after the intervention.	The long-term outcome showed a significant reduction in injury hazards in the tutorial group when compared to the educational pamphlet group: falls (IRR[e] 0.24, 95% CI 0.08 - 0.71), drowning (IRR 0.45, 95% CI 0.85 - 0.98), burns (IRR 0.56, 95% CI 0.33 - 0.78), poisoning (IRR 0.53, 95% CI 0.44 - 0.77), and breakable objects within reach of child (IRR 0.62, 95% CI 0.39 - 0.99).
Tajiki et al [33], 2022, Pakistan	To examine the efficacy of a training program based on the health belief model in burn prevention knowledge in mothers of children aged 1-3 years. RCT.	Mothers of children aged between 1 and 3 years (n=64)	The educational intervention on preventing burns was delivered using lectures and PowerPoint slides, educational pamphlets, and illustrated books. It was a 45-minute session per week for a period of 6 weeks.	The questionnaire on the Health Belief Model for the prevention of burns in children was administered before the intervention, immediately after the intervention, and 2 months after the intervention.	There was a significant difference between the groups in terms of perceived susceptibility and severity during immediate and 2 months postintervention (control: 11.9, SD 0.53 vs 13.34, SD 0.82; intervention: 18.06, SD 0.24 vs 15.93, SD 0.24; *P*<.001). Significant difference in mean scores of perceived barriers and benefits (control: 9.78, SD 0.49; 9, SD 0; *P*=.6; intervention: 11, SD 0; 11.5, SD 1.04; *P*<.001).

XSL•FO
RenderX

Author, year, country	Objective and study design	Target population	Intervention details	Measures and data collection	Findings and outcomes
Choi and Ahn [34], 2021, Republic of Korea	To evaluate the effectiveness of mobile-based parental education programs in preventing unintentional childhood injuries. RCT.	Parents or relatives caring for infants and toddlers (n=167)	Two groups. First group: e-learning program for preventing unintentional injuries. Second group: electronic document distribution group, which received a PDF of e-learning content.	Safety knowledge and safety behavior regarding unintentional injuries were assessed during the pretest and 2 weeks after the intervention.	There was no significant difference found in the safety knowledge of the participants in both intervention groups. However, the safety behavior between the 3 groups showed statistically significant differences (F=10.09; P<.001).
van Beelen et al [35], 2014, the Netherlands	To evaluate the effectiveness of web-based, tailored safety information combined with personal counseling on parents' safety behaviors. RCT.	Parents with a child aged 5-8 months (n=1292)	E-health4Uth module, along with personal counseling on safety in and around the home on prevention of falls, poisoning, drowning, and burns in children aged between 12 and 24 months.	Parents' child safety behavior on prevention of falls, poisoning, drowning, and burns was assessed at baseline and 6 months after the intervention.	Parents in the intervention group showed significantly less unsafe behavior when compared with control group parents. Parents positively rated the E-health4Uth home safety intervention as an effective source of information (mean 4.05, SD 0.62).
Myers et al [36], 2022, Israel	To evaluate the effect of the intervention on injuries in children aged 0-4 years. Non-RCT.	Children aged 0-4 years and 5-17 years through home visits (n=6334)	The multifaceted intervention included a youth leadership program, workshops in well-baby clinics and preschools, home visits, and a media campaign.	Data on visits to the emergency room and hospitalization were obtained from the hospital records during the pre- and postintervention periods.	There was a significant reduction in emergency room visits (7.6%) in children between 0 and 3 years during postintervention period. Admissions to the hospital for burns and falls reduced. A greater reduction in emergency room visits (P=.038; P=.004) was observed for children aged 0-4 years in towns that started the intervention earlier.
Cheraghi et al [37], 2014, Iran	To assess the effect of the Health Belief Model on the education of mothers for promoting safety and preventing injury. RCT.	Mothers with at least 1 child below the age of 5 years (n=120)	Four sessions, 1 hour each, twice per week, on factors affecting mothers' knowledge and practices and Health Belief Model constructs.	Assessment of mother's knowledge, practice, Health Belief Model constructs, and injury history before and 2 months postintervention.	There was a significant mean difference in mothers' knowledge (3.98), practice (2.47), and Health Belief Model constructs in the intervention group (P<.001). The number of injuries decreased from 7 to 2 in the intervention group.

[a]RCT: randomized controlled trial.

[b]OR: odds ratio.

[c]*F*: analysis of variance.

[d]CPR: cardiopulmonary resuscitation.

[e]IRR: incidence risk ratio.

Stage 5: Collating, Summarizing, and Reporting the Results

Data extracted from the included studies were collated and textually summarized and findings were tabulated as key categories.

Results

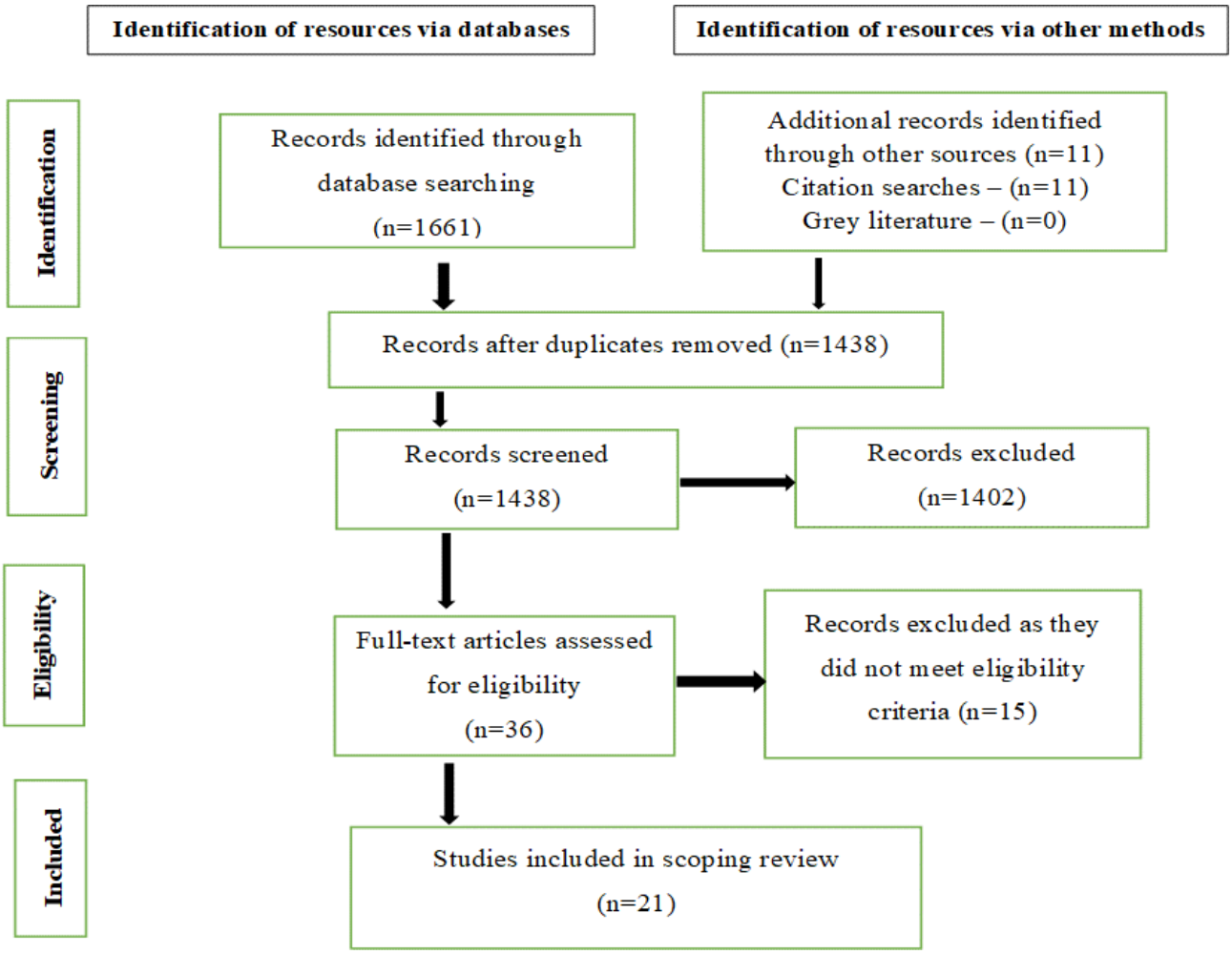
Overview

The database search identified 1683 articles, of which 245 (14.56%) were duplicates, so we screened the titles and abstracts

XSL•FO
RenderX

of 1438 (85.44%) articles. A total of 36 studies were evaluated for eligibility, and 21 studies were included in the review. Most studies that remained included parents or caregivers as participants (16/21, 76%), while some studies examined children specifically (5/21, 24%). Figure 1 provides an overview of the study selection process and the reasons for the exclusions of full-text articles.

Figure 1. PRISMA flowchart. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.



Study Characteristics

All 21 articles included were published in peer-reviewed journals. The review included 4 (19%) studies conducted in China [17-20], 4 (19%) in the United States [21-24], 3 (14%) in India [25-27], 2 (10%) in the United Kingdom [28,29], 2 (10%) in Canada [30,31], 2 (10%) in Pakistan [32,33], 1 (5%) in Korea [34], 1 (5%) in the Netherlands [35], 1 (5%) in Israel [36], and 1 (5%) in Iran [37]. The sample size of the studies ranged from 59 to 6334. The studies identified various target populations, including children and adolescents aged between 0 and 19 years. Diverse interventions such as teaching, training, workshops, technology-based training, storybooks, educational book–based training, and model-based training were identified. The target population included parents, caregivers, or family members, as well as children and adolescents with ages ranging from 0 to 19 years. Table 1 provides a detailed overview of the study characteristics.

Interventions Targeting Parents, Caregivers, and Family

Parents or caregivers supervise the activities of young children at home and are accountable for their environment. Hence, it is critical to assess their knowledge, attitudes, and practices regarding unintentional injuries and plan and implement effective interventions.

Parents or caregivers were the focus of intervention in 17 of 21 (81%) articles presented in this review. Caregivers of children below the age of 3 years were addressed in 8 of 17 (47%) articles [17,19,21,23,28,33-35], which focused on the knowledge of parents on vehicle safety, home safety, self-efficacy behaviors, and skill in first aid measures. Of the 17 articles, 6 (35%) highlighted interventions for parents of children aged less than 5 years [22,26,29,30,32,37], which assessed the levels of supervision and attention toward their children, and knowledge, practice, and safety behavior of parents regarding unintentional injuries. Two articles of 17 (12%) focused on caregivers of children between the ages of 3 and 6 years [18,31], and 1 article (6%) reported an intervention among caregivers of children younger than 12 years [24], which assessed the safety knowledge

XSL•FO
RenderX

and safety actions of parents/caregivers, knowledge about hazards, injury risk behavior, and attitude toward injury prevention.

Interventions Targeting Children as Change Agents

Injury prevention strategies, especially for individual-level factors, may be implemented using different learning approaches and theories. Approaches such as demonstrations, role-play, and simulation at the school level may help children understand how injury prevention interventions could work. Children learn about a health subject and share that information with their parents or the community, encouraging parents and others to enhance their knowledge and engage in health-promoting behaviors.

Of 21 articles, 3 (14%) focused on children of different age groups, evaluating the effectiveness of interventions to prevent unintentional injuries. Children in the third and fourth grades were assessed for their knowledge on the prevention of drowning, perceived vulnerability, and simulated behavior in and around the water [20]. Incidences and types of unintentional injuries were assessed among children in classes 5 to 7 [27]. In another study, through a child-to-child approach [25], adolescent children taught younger siblings and other family members regarding the prevention of unintentional injuries, whereby the knowledge of participants and the practices of the family were assessed.

Effectiveness of Educational Interventions

Education provides individuals with the necessary knowledge and awareness of the benefits and risks associated with certain behaviors. Education stands as a powerful catalyst for change, enabling people to acquire skills, information, and perspectives that shape their attitudes and perceptions.

This review found that 5 of 21 articles (24%) reported various educational interventions as a single strategy or in combination with other modalities to prevent unintentional injuries in children. RISE UP is a tailored parenting program to promote nurturing, child development, resiliency, social connection, and support to prevent unintentional injuries, which showed a decrease in parenting injury risk scores and promoted positive parenting behaviors [22].

Safety education prepares children for specific situations, whereas risk education prepares them for unanticipated or unknown situations, where they may have had no specific instruction or learning opportunity. The child-to-child approach [25] is one such method wherein the older adolescents of the family were trained in first aid and cardiopulmonary resuscitation, road safety, traffic rules, injury prevention, and immediate care. As a next step, they were made to transfer the information to their younger siblings and other family members. In another study, a comprehensive pictorial child safety and injury prevention module, as part of a school-based intervention to prevent injuries and promote child safety, was evaluated [27]. A significant reduction in the incidence of injuries in younger children and improvement in knowledge and practice regarding injury prevention were noted.

A multifaceted intervention with components such as a youth leadership program for adolescents, workshops in well-baby clinics and preschools, home visits, and a media campaign showed a greater reduction in emergency room visits in children between 0 and 3 years of age, as well as reduced hospital admission due to burns and falls injury [36]. A significant reduction in injury hazards was identified in a group that received tutorials when compared to an educational pamphlet [32].

Effectiveness of Home Safety Interventions

Home is a place where children spend lots of time during their younger days. It is the responsibility of the caregivers to ensure a safe place for the kids to learn, play, and explore. Home safety interventions are implemented to reduce the risk of accidents, injuries, and other hazards within households. In total, 4 of 21 articles (19%) reported on the effectiveness of home safety interventions.

Implementation of home-based injury prevention programs through the “Watchful Parents, Safe Children” video, “Safe Home, Safe Child” video, and a poster followed by a structured discussion with mothers and home visits showed a significant decrease in time during which the children were unsupervised, higher levels of supervision, an increase in attention to the child, a significant reduction in the injury pattern in children, and improved mean scores of caregivers’ home safety practices [26,30].

Implementation of innovative teaching strategies and playful approaches aimed at children can have a long-lasting effect in reducing unintentional injuries. A storybook, “Careful Puppy Saves the Day,” with information on different hazards in and around the home, read by mothers with their children beside them, was incorporated as a change agent. Significant changes were noted in the form of better identification of injury hazards, fewer risky behaviors, and a more comprehensive explanation of safety by the children [31]. Furthermore, Stay One Step Ahead, a multievidence-based intervention for families, incorporated monthly safety messages through quizzes, posters, and flyers; organized home safety activities; and educational safety weeks for families on common injuries. The findings showed a significant improvement in the storage of poisons out of children’s reach and improved use of home safety measures [28].

Technology-Based Interventions

Technology-based interventions can provide individualized and tailored interfaces enriched with interactive elements [38], which can be accessed anytime and anywhere. This review identified 9 articles that dealt with the effectiveness of technology-based interventions to prevent various forms of unintentional injuries in children.

A video-based DVD on child safety seat installation and use [23]; a web-based, E-health4Uth module along with personal counseling on the prevention of falls, poisoning, drowning, and burns [35]; a testimonial-based video intervention in reducing drowning risk among school-aged children [20]; and an app-based parenting education intervention to prevent unintentional injury [18] are a few of the studies that used

XSL•FO
RenderX

technology as a medium to disseminate the information to children and caregivers. The results of the studies show an improvement in their respective areas of assessment, which include the ability of caregivers to rightly install the car seat, less unsafe injury-prone behaviors, and children's safety knowledge of drowning risk.

SafeTea is a community-based intervention that incorporates video clips, posters, leaflets, and charts to educate parents regarding the risk factors for hot drink scalds and first aid for burns [29]. Choi and Ahn [34] conducted a mobile-based parental education program to prevent unintentional injuries in children, and McKenzie et al [24] studied the effectiveness of the Make Safe Happen App, which helped caregivers keep their homes safe and also provided links to purchase home safety products from Amazon.com. Two studies [17,19] used WeChat accounts for social-network–based health education to enhance the knowledge, skill, and beliefs of parents about unintentional injuries.

Interventions Based on Models and Theories

A theory is a comprehensive framework for explaining and predicting phenomena, while a model is a focused and practical tool that represents parts of a theory, helping to visualize or analyze specific aspects. We found that 3 of 21 articles (14%) reported on the effectiveness of interventions based on theories and models.

Two studies [33,37] evaluated the effect of training programs on mothers' knowledge regarding the prevention of unintentional injuries in children based on the Health Belief Model. Wang et al [21] assessed the effectiveness of an intervention grounded in social cognitive theory. The outcome of the reviewed article showed an improvement in the mothers' knowledge and practice, a decrease in the number of injuries, a significant difference in the Health Belief Model constructs, and fewer safety problems. Health education models can be used when planning educational programs at the individual or community levels.

Discussion

Principal Findings

The study aimed to answer the following scoping review question: what is known globally from the existing research literature about interventions to prevent unintentional injuries in children?

This review highlights the different areas of unintentional injuries, the interventions to prevent them, the outcomes of the interventions, and the diverse population on whom an intervention is being implemented. It provides an overview of how the interventions have been conceptualized and applied with the use of various data collection instruments measured at different timelines and their outcome measures. Of 21 studies considered for review, 16 (76%) studies were RCTs, 4 (19%) articles were non-RCTs, and 1 (5%) article had a mixed method design. Due to the heterogeneous nature of the included studies, the level of evidence of this review is considered as moderate.

Interventions Targeting Parents, Caregivers, and Family

In this review, 17 articles described interventions focusing on caregivers or parents to prevent unintentional injuries in children. Parents' or caregivers' involvement in educational interventions has been shown to improve safety knowledge and behaviors. In addition, the distribution of safety supplies to keep the home safe has improved the safety-related behavior of parents. Similar evidence was reported by the authors of a review [39] that interventions targeting parents are effective in reducing child injuries and that parenting interventions appeared to have a greater effect on home safety practices and the reduction of hazards at home. The findings of this review suggested that the beneficial effects were attributable to interventions targeting changes in parents' knowledge, attitude, and behavior.

Interventions Targeting Children as Change Agents

Three articles highlighted the interventions for preventing unintentional injuries in diverse modalities focusing on children of different age groups. The analysis showed improved knowledge and safety practices and a decrease in the incidence of injuries. However, there are fewer studies focused on children, who need to be considered further. There is a need to integrate appropriate and well-designed programs, especially focusing on children, such as school-based injury prevention modules, adolescent-targeted interventions, and simulation-based training. The cost of preventing unintentional injuries is much lower than the cost of treating their direct and indirect consequences [40]. In resource-limited settings, children can act as change agents to bring about change in their homes and neighborhoods. Future research on children should engage parents and teachers to develop, implement, and evaluate a more comprehensive and integrated intervention to prevent unintentional injuries.

Effectiveness of Educational Interventions

Five articles in this review addressed the effectiveness of educational interventions for both parents/caregivers and children. Educational interventions targeting changes in the behavior of parents and a hazard-free home environment were proven effective in reducing the incidence of unintentional injuries at home. The results of the studies demonstrate a positive outcome and ensure their feasibility of being implemented in low-income and resource-limited settings. Despite the high incidence of unintentional injuries among children in low- and middle-income countries, few interventional studies have been conducted in these countries. Multimodal educational interventions play a crucial role in sensitizing and creating awareness among children and caregivers to prevent unintentional injuries and injury hazards.

Effectiveness of Home Safety Interventions

Four articles reported on home safety interventions to prevent unintentional injuries. The analysis showed improved home safety practices, an increased level of supervision, and an environment free from injury hazards. Greater reductions in injury rates were found for interventions delivered in the home; however, there was a lack of evidence that home safety

XSL•FO
RenderX

interventions reduced rates of thermal injuries or poisoning [41]. It is particularly important that children in low-income families have close supervision, as the caregivers may have difficulty acquiring safety materials, and the presence of poor housing quality can impose an additional risk on children. Hence, the implementation of low-cost and locally available measures in an accessible and efficient manner could prove beneficial for both children and their caregivers to reduce the risk of injuries within the community context. Failure to invest in programs for preventing injuries among children will further increase the number of dependents in future generations and negatively impact society. Policymakers need to be involved in the evaluation and implementation of policies related to injury prevention, especially in resource-limited countries.

Technology-Based Interventions

Nine articles addressed the effectiveness of technology-based interventions in the prevention of unintentional injuries. Studies using interventions through mobile apps, web-based education, and social online health education provided an impactful result among the participants who used them effectively on a timely basis. Information and communication technologies can accelerate progress toward the achievement of the United Nations Sustainable Development Goals [42]. The use of technology-based interventions and an online platform can be adapted to deliver preventive health care information for large-scale community users. Nevertheless, the digital mode of interventions and app-based programs play a significant role in covering the large and diverse range of participants to create awareness, instill knowledge, improve their practice, and bring about a positive change in their behaviors. However, such interventions have drawbacks in low- and middle-income countries with a lack of resources and a lack of participant awareness of different gadgets.

Interventions Based on Models and Theories

This review highlighted 3 articles that used models and theories as a basis for interventions to prevent injuries. The Health Belief Model is a theoretical model used to guide health promotion and disease prevention programs, which explains and predicts changes in health behaviors [43]. Accordingly, the previously mentioned studies proved useful in applying a similar approach to evaluate the impact of interventions and thus bring about change in the practice and behavior of parents.

Strengths and Limitations

A strength of this review was that a comprehensive literature search of articles published from 2013 to 2023 was conducted using different databases that covered studies focusing on interventions to prevent unintentional injuries in children. A limitation of our review was that only articles published in the English language were included. Additionally, the present study area is an active field of research, so it is important to note that this scoping review is a snapshot at a particular point in time.

Conclusion

The articles included in this review addressed interventions of different magnitudes, data measurements taken at varying time points, and participants of a diverse nature. Cost-effective, accessible, and multifaceted interventions represent effective strategies to prevent unintentional injuries in children. Further studies in the form of online social networks and app-based interventions could be considered to reach out to the larger population with long-term outcome measurements.

Conflicts of Interest

None declared.

Checklist 1
PRISMA-ScR checklist.
[DOCX File, 49 KB - pediatrics_v8i1e67877_app1.docx]

References

1. Morrongiello BA. Caregiver supervision and child-injury risk: I. Issues in defining and measuring supervision; II. Findings and directions for future research. J Pediatr Psychol 2005;30(7):536-552. [doi: 10.1093/jpepsy/jsi041] [Medline: 16166243]
2. Peden M. World report on child injury prevention. World Health Organization. 2008. URL: https://iris.who.int/handle/10665/43851 [accessed 2024-10-13]
3. Sengoelge M, Leithaus M, Braubach M, Laflamme L. Are there changes in inequalities in injuries? A review of evidence in the WHO European Region. Int J Environ Res Public Health 2019 Feb 22;16(4):653. [doi: 10.3390/ijerph16040653] [Medline: 30813329]
4. Kumar M, Pathak VK, Tripathi S, Upadhyay A, Singh VV, Lahariya C. Burden of childhood injuries in India and possible public health interventions: a systematic review. Indian J Community Med 2023;48(5):648-658. [doi: 10.4103/ijcm.ijcm_887_22] [Medline: 37970167]
5. Pinheiro PS. World report on violence against children. : United Nations; 2006 URL: https://violenceagainstchildren.un.org/sites/violenceagainstchildren.un.org/files/document_files/world_report_on_violence_against_children.pdf [accessed 2025-04-19]
6. Sethi D, editor. European report on child injury prevention. : WHO Regional Office for Europe; 2008 URL: https://iris.who.int/bitstream/handle/10665/326500/9789289042956-eng.pdf [accessed 2025-04-19]

XSL•FO
RenderX

7. Schwebel DC, Gaines J. Pediatric unintentional injury: behavioral risk factors and implications for prevention. J Dev Behav Pediatr 2007 Jun;28(3):245-254. [doi: 10.1097/01.DBP.0000268561.80204.2a] [Medline: 17565295]
8. Flavin MP, Dostaler SM, Simpson K, Brison RJ, Pickett W. Stages of development and injury patterns in the early years: a population-based analysis. BMC Public Health 2006 Jul 18;6(1):187. [doi: 10.1186/1471-2458-6-187] [Medline: 16848890]
9. Sheriff A, Rahim A, Lailabi MP, Gopi J. Unintentional injuries among children admitted in a tertiary care hospital in North Kerala. Indian J Public Health 2011;55(2):125-127. [doi: 10.4103/0019-557X.85248] [Medline: 21941048]
10. Bhuvaneswari N, Prasuna JG, Goel MK, Rasania SK. An epidemiological study on home injuries among children of 0-14 years in South Delhi. Indian J Public Health 2018;62(1):4-9. [doi: 10.4103/ijph.IJPH_428_16] [Medline: 29512558]
11. Morrongiello BA, Schell SL. Child injury: the role of supervision in prevention. Am J Lifestyle Med 2010 Jan;4(1):65-74. [doi: 10.1177/1559827609348475]
12. Ablewhite J, Kendrick D, Watson M, Shaw I. Maternal perceptions of supervision in pre-school-aged children: a qualitative approach to understanding differences between families living in affluent and disadvantaged areas. Prim Health Care Res Dev 2015 Jul;16(4):346-355. [doi: 10.1017/S1463423614000218] [Medline: 24871079]
13. Harris VA, Rochette LM, Smith GA. Pediatric injuries attributable to falls from windows in the United States in 1990-2008. Pediatrics 2011 Sep;128(3):455-462. [doi: 10.1542/peds.2010-2687] [Medline: 21859909]
14. Chandran A, Khan UR, Zia N, et al. Disseminating childhood home injury risk reduction information in Pakistan: results from a community-based pilot study. Int J Environ Res Public Health 2013 Mar 15;10(3):1113-1124. [doi: 10.3390/ijerph10031113] [Medline: 23502323]
15. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005 Feb;8(1):19-32. [doi: 10.1080/1364557032000119616]
16. Tricco AC, Lillie E, Zarin W, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med 2018 Oct 2;169(7):467-473. [doi: 10.7326/M18-0850] [Medline: 30178033]
17. Feng Y, Li X, Ma X, et al. Using online social networks to provide a parental health-education intervention for preventing unintentional injuries among children aged 0-3 years: a randomized controlled trial and social network analysis in Shanghai, China. Front Public Health 2022;10:1049851. [doi: 10.3389/fpubh.2022.1049851] [Medline: 36711338]
18. Ning P, Cheng P, Schwebel DC, et al. An app-based intervention for caregivers to prevent unintentional injury among preschoolers: cluster randomized controlled trial. JMIR mHealth uHealth 2019 Aug 9;7(8):e13519. [doi: 10.2196/13519] [Medline: 31400105]
19. Feng Y, Ma X, Zhang Q, et al. Effectiveness of WeChat-group-based parental health education in preventing unintentional injuries among children aged 0-3: randomized controlled trial in Shanghai. BMC Public Health 2022 Nov 16;22(1):2086. [doi: 10.1186/s12889-022-14462-5] [Medline: 36380326]
20. Shen J, Pang S, Schwebel DC. Evaluation of a drowning prevention program based on testimonial videos: a randomized controlled trial. J Pediatr Psychol 2016 Jun;41(5):555-565. [doi: 10.1093/jpepsy/jsv104] [Medline: 26546476]
21. Wang Y, Gielen AC, Magder LS, Hager ER, Black MM. A randomised safety promotion intervention trial among low-income families with toddlers. Inj Prev 2018 Feb;24(1):41-47. [doi: 10.1136/injuryprev-2016-042178] [Medline: 28385953]
22. Weaver NL, Weaver TL, Loux T, Jupka KA, Lew D, Sallee H. The impact of RISE Up! in promoting positive parenting and safety behaviors of parents with young children. Child Youth Serv Rev 2019 Oct;105:104422. [doi: 10.1016/j.childyouth.2019.104422]
23. Swartz L, Glang A, Schwebel DC, GeigerWolfe EG, Gau J, Schroeder S. Keeping baby safe: a randomized trial of a parent training program for infant and toddler motor vehicle injury prevention. Accid Anal Prev 2013 Nov;60:35-41. [doi: 10.1016/j.aap.2013.07.026] [Medline: 24007755]
24. McKenzie LB, Roberts KJ, Collins CL, Clark RM, Smith KC, Manganello J. Maternal knowledge, attitudes, and behavioral intention after exposure to injury prevention recommendations in the news media. J Health Commun 2019;24(7-8):625-632. [doi: 10.1080/10810730.2019.1646357] [Medline: 31378155]
25. Banerjee B, Banerjee R, Ingle GK, Mishra P, Sharma N, Garg S. Effectiveness of child-to-child approach in preventing unintentional childhood injuries and their consequences: a non-randomized cluster-controlled trial. Indian Pediatr 2021 Jun 15;58(6):542-547. [Medline: 33612489]
26. George A, Renu G, Shetty S. Effect of a home safety supervisory program on occurrence of childhood injuries: a cluster randomized controlled trial. Indian Pediatr 2021 Jun 15;58(6):548-552. [Medline: 34176795]
27. Holla R, Darshan BB, Unnikrishnan B, et al. Effectiveness of school-based interventions in reducing unintentional childhood injuries: a cluster randomized trial. Indian Pediatr 2021 Jun 15;58(6):537-541. [doi: 10.1007/s13312-021-2236-0] [Medline: 33612490]
28. Taylor MJ, Orton E, Patel T, et al. Effectiveness of systematically delivered evidence-based home safety promotion to improve child home safety practices: a controlled before-and-after study. Inj Prev 2023 Jun;29(3):227-233. [doi: 10.1136/ip-2022-044745] [Medline: 36720631]
29. Cowley LE, Bennett CV, Brown I, Emond A, Kemp AM. Mixed-methods process evaluation of SafeTea: a multimedia campaign to prevent hot drink scalds in young children and promote burn first aid. Inj Prev 2021 Oct;27(5):419-427. [doi: 10.1136/injuryprev-2020-043909] [Medline: 33093127]

XSL•FO
RenderX

30. Morrongiello BA, Zdzieborski D, Sandomierski M, Munroe K. Results of a randomized controlled trial assessing the efficacy of the Supervising for Home Safety program: impact on mothers' supervision practices. Accid Anal Prev 2013 Jan;50:587-595. [doi: 10.1016/j.aap.2012.06.007] [Medline: 22771287]
31. Morrongiello BA, Marquis AR, Cox A. A RCT testing if a storybook can teach children about home safety. J Pediatr Psychol 2021 Aug 11;46(7):866-877. [doi: 10.1093/jpepsy/jsab002] [Medline: 33598702]
32. Khan UR, Ali A, Khudadad U, et al. Follow-up household assessment for child unintentional injuries two years after the intervention: a community-based study from Karachi, Pakistan. Injury 2023 Aug;54 Suppl 4:110519. [doi: 10.1016/j.injury.2022.11.062] [Medline: 36481051]
33. Tajiki I, Vizeshfar F, Keshtkaran Z. The effect of training program based on health belief model on burn prevention knowledge in mothers of children aged to 1-3 years: a randomized controlled. Burns 2022 Jun;48(4):808-815. [doi: 10.1016/j.burns.2021.11.001] [Medline: 34903403]
34. Choi Y, Ahn HY. Developing and evaluating a mobile-based parental education program for preventing unintentional injuries in early childhood: a randomized controlled trial. Asian Nurs Res (Korean Soc Nurs Sci) 2021 Dec;15(5):329-336. [doi: 10.1016/j.anr.2021.12.001] [Medline: 34915186]
35. van Beelen MEJ, Beirens TMJ, den Hertog P, van Beeck EF, Raat H. Effectiveness of web-based tailored advice on parents' child safety behaviors: randomized controlled trial. J Med Internet Res 2014 Jan 24;16(1):e17. [doi: 10.2196/jmir.2521] [Medline: 24463421]
36. Myers V, Malkin G, Nir N, Orr D, Baron-Epel O. Evaluation of an intervention to reduce child injury in Bedouin communities in Southern Israel. Inj Prev 2022 Feb;28(1):38-42. [doi: 10.1136/injuryprev-2020-044013] [Medline: 33712540]
37. Cheraghi P, Poorolajal J, Hazavehi SMM, Rezapur-Shahkolai F. Effect of educating mothers on injury prevention among children aged <5 years using the Health Belief Model: a randomized controlled trial. Public Health (Fairfax) 2014 Sep;128(9):825-830. [doi: 10.1016/j.puhe.2014.06.017]
38. Mouton A, Cloes M. Web-based interventions to promote physical activity by older adults: promising perspectives for a public health challenge. Arch Public Health 2013 Jul 2;71(1):16. [doi: 10.1186/0778-7367-71-16] [Medline: 23819885]
39. Kendrick D, Mulvaney CA, Ye L, Stevens T, Mytton JA, Stewart-Brown S. Parenting interventions for the prevention of unintentional injuries in childhood. Cochrane Database Syst Rev 2013 Mar 28;2013(3):CD006020. [doi: 10.1002/14651858.CD006020.pub3] [Medline: 23543542]
40. Salam RA, Arshad A, Das JK, et al. Interventions to prevent unintentional injuries among adolescents: a systematic review and meta-analysis. J Adolesc Health 2016 Oct;59(4S):S76-S87. [doi: 10.1016/j.jadohealth.2016.07.024] [Medline: 27664598]
41. Kendrick D, Young B, Mason-Jones AJ, et al. Home safety education and provision of safety equipment for injury prevention (review). Evid Based Child Health 2013 May;8(3):761-939. [doi: 10.1002/ebch.1911] [Medline: 23877910]
42. Digital technologies to achieve the UN SDGs. ITU. URL: https://www.itu.int/en/mediacentre/backgrounders/Pages/icts-to-achieve-the-united-nations-sustainable-development-goals.aspx [accessed 2025-04-07]
43. Alyafei A, Easton-Carr R. The Health Belief Model of Behavior Change: StatPearls; 2024. URL: http://www.ncbi.nlm.nih.gov/books/NBK606120 [accessed 2024-10-20]

Abbreviations

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
RCT: randomized controlled trial

Edited by S Badawy; submitted 24.10.24; peer-reviewed by D Joubert, H Li; revised version received 07.02.25; accepted 10.02.25; published 28.04.25.

Please cite as:
Shetty S, Nayak BS, George A, Shetty A, Guddattu V
Evidence of Interventions for the Prevention of Unintentional Injuries: Scoping Review
JMIR Pediatr Parent 2025;8:e67877
URL: https://pediatrics.jmir.org/2025/1/e67877
doi:10.2196/67877

© Sheela Shetty, Baby S Nayak, Anice George, Avinash Shetty, Vasudeva Guddattu. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 28.4.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The

XSL•FO
RenderX

complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

A Companion Robot for Children With Asthma: Descriptive Development and Feasibility Pilot Study

Jinnaphat Sangngam[1], PhD; Somsiri Rungamornrat[1], PhD; Rungnapa Santipipat[2], BNS; Kunchira Ponthanee[2], BNS

[1]Pediatric Nursing Department, Faculty of Nursing, Mahidol University, 2 Wang Lang Road, Siriraj, Bangkok Noi, Bangkok, Thailand

[2]Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand

Corresponding Author:
Somsiri Rungamornrat, PhD
Pediatric Nursing Department, Faculty of Nursing, Mahidol University, 2 Wang Lang Road, Siriraj, Bangkok Noi, Bangkok, Thailand

Abstract

Background: Consistent medication use and proper inhaler technique are essential in pediatric asthma, and young children require supportive tools to maintain these practices.

Objective: This study aimed to investigate the caregivers' ability to use a companion robot–assisted app for children with asthma, their attitudes toward the usage, and the characteristics that hinder or facilitate the implementation.

Methods: This study employed a descriptive design. The sample group consisted of 30 children with asthma aged 3 - 6 years who received treatment at an asthma clinic and their caregivers. The companion robot for children with asthma called "Pukkabot," which is an innovation that is developed to teach inhalation techniques and to raise awareness about consistent medication administration through positive reinforcement, was examined. Data collection included personal information questionnaires, the System Usability Scale (SUS) for evaluating usage and overall satisfaction, and interviews to gather attitudes toward apps and characteristics that hinder or facilitate. Data were analyzed with descriptive statistics and content analysis.

Results: The study revealed that the scores for usability and overall satisfaction were 80.6, which is above the standard threshold and rated at grade A or an excellent level. Additionally, caregivers stated that the companion robots were easy to use, not complicated, had appropriately sized screens, and demonstrated clear images and sounds. The detailed steps for inhalation were exhibited, and reminders included those of medication times. The children with asthma enjoyed the app and were very interested, making most caregivers want to continue their use.

Conclusions: Caregivers were generally satisfied with the usability, finding it easy to use and engaging, which successfully attracted the interest of the children with asthma. Therefore, the companion robot may be used further, with the following recommendations: improving its physical design, adding content, incorporating tracking and symptom assessment systems, and creating a downloadable mobile app for greater accessibility and convenience.

Trial Registration: Thai Clinical Trials Registry TCTR20240912001; https://www.thaiclinicaltrials.org/show/TCTR20240912001

(JMIR Pediatr Parent 2025;8:e68943) doi:10.2196/68943

KEYWORDS

companion robot; app; asthma; children; caregiver; model

Introduction

Asthma is a chronic respiratory condition that is characterized by bronchial tube inflammation, causing a heightened response to allergens and environmental factors. This causes symptoms, including bronchial hyperreactivity, bronchoconstriction, swelling, and increased mucus production [1]. Asthma affects individuals of any age, but it is particularly prevalent in children under 6 years of age, who are more susceptible to respiratory infections that worsen bronchial inflammation. Early detection and effective management of asthma exacerbations are crucial for preventing chronic inflammation and improving long-term health outcomes as children develop. The World Health Organization reported that approximately 262 million people globally experience difficulties from asthma, with a significant proportion being children from low- to middle-income countries, where the prevalence is increasing [2]. Approximately 2 million children with asthma are affected in Thailand, with 9.8% experiencing exacerbations annually and a significant cost associated with treatment [3].

The Global Initiative for Asthma (GINA) provides comprehensive guidelines for pediatric asthma management, focusing on symptom control through medication, decreasing environmental trigger exposure, and continuous symptom monitoring [4]. The key treatment goals include achieving satisfactory symptom control, minimizing acute exacerbations,

XSL•FO
RenderX

allowing normal daily activities, and maintaining optimal lung function. Children with asthma require both relief medications for acute symptoms and long-term controller medications to prevent future exacerbations and maintain symptom control [4]. However, many children face difficulties with consistent and correct inhaler use, which is crucial for effective medication delivery [5,6]. Literature emphasizes issues, such as incorrect inhaler techniques and irregular medication adherence, frequently stemming from caregivers's misconceptions about inhalers, fears of side effects, and concerns over costs [6,7]. Therefore, both children and their caregivers need to receive a thorough education on proper inhaler use and the significance of consistent medication adherence.

Environmental pollutants, particularly particulate matter (PM) with a diameter of <2.5 microns (PM 2.5), are significant triggers for asthma exacerbations, causing bronchial inflammation and irritation [8]. Children with asthma who are exposed to high air pollution levels may experience worsened symptoms, which impair lung function and require emergency medical interventions [9,10]. Various smartphone apps provide real-time air quality data, but challenges associated with accessibility and technological literacy among caregivers may limit their effectiveness in managing asthma triggers [11]. Effective asthma management requires collaboration between the pediatric patient and their caregiver, tailored to the child's developmental stage. Instilling health-promoting behaviors during this critical period facilitates the teaching of consistent inhaler use for preschool-aged children.

Recent technological advancements have resulted in the creation of devices aimed at improving inhaler use among children with asthma [12]. In particular, the JOE robot, which assists with demonstrating inhaler techniques, currently supports only English and French, limiting its accessibility for users who speak other languages [13]. Other innovations, such as the Whizz smart inhaler [14] and CapMeDicTM [15], provide various features to encourage proper inhaler utilization but may not fully engage young children or be widely available in Thailand. Hence, Thammasat University (Thailand) has developed the "Asthma Care" app, which provides comprehensive guidance on asthma management. However, further innovations that are specifically designed for preschool-aged children to meet their unique needs are highly warranted.

This study aimed to assess caregivers' ability to use "Pukkabot," a companion robot-assisted app designed to teach correct inhaler techniques and promote consistent medication adherence through positive reinforcement, considering the necessity for accessible and effective asthma management tools for young children. Additionally, the study investigated caregivers' attitudes toward "Pukkabot," determining features that may either facilitate or hinder its use. "Pukkabot" seeks to improve symptom control, reduce severe asthma attacks, and enhance overall treatment efficacy by fostering early awareness and proper inhaler techniques in children with asthma, ultimately minimizing hospitalizations and lowering the risk of severe complications. The results from this research provided valuable information into the development of effective and user-friendly asthma management tools for young children in Thailand, contributing to improved health outcomes and quality of life for children with asthma.

Methods

This descriptive study aimed to explore the feasibility of using "Pukkabot," and to explore barriers and facilitators to its use.

Recruitment Process

This study recruited caregivers and children with asthma from the Allergy and Immunology Clinic in the asthma clinic, Pediatric Outpatient Department of a tertiary hospital from February to September 2024. The children included were aged 3 - 6 years, physician-diagnosed with asthma of any severity for at least 6 months, receiving treatment with at least 1 inhaled medication, and without a history of uncertain clinical symptoms or learning disabilities. Caregivers were required to be ≥18 years old and related to the child.

A convenience sample of 30 children with asthma was recruited for this single-arm interventional trial. The sample size was guided by recommendations for pilot and feasibility studies [16]. According to Brooke [17], a general rule of thumb is to include at least 30 participants to allow for reasonable estimation of study parameters.

Study Design

The researcher instructed the caregiver and the child to interact with the companion robot. The process began with the caregiver setting a medication reminder (set for 5 min) and selecting an air quality monitoring option within the app, which displays the real-time Air Quality Index (AQI) to raise awareness about environmental triggers. Afterward, the child was invited to select a preferred pet (rabbit, dog, cat, bear, and dragon). When the reminder alarm was triggered, the child practiced medication administration steps by following on-screen instructions, using an empty inhaler device that contained no active medication. This activity was conducted solely as a demonstration to simulate proper inhaler technique, without actual medication use. The demonstration lasted approximately 5 minutes, during which the researcher provided verbal guidance and support. The entire process was completed within approximately 15 minutes.

Afterward, the caregivers were instructed to complete a 10-item System Usability Scale (SUS) regarding the companion robot. The caregivers completed the questionnaire, whereas the researcher recorded personal information from the patient's medical records.

Finally, the researcher interviewed the caregivers to gather their attitudes toward using the asthma management companion robot, as well as any perceived barriers or facilitators to its implementation. This aimed to determine areas for system improvement. The interview included 6 questions and lasted approximately 5 - 10 minutes.

Research Instruments

In this study, various instruments were used to gather data effectively, ensuring a comprehensive understanding of the participants' backgrounds and experiences. The instruments included personal information questionnaires, patient medical

XSL•FO
RenderX

record data forms, the SUS, and caregiver interviews focused on attitudes toward asthma management companion robot-assisted app for children with asthma.

Personal Information Questionnaires

The interview form designed for children with asthma collected vital information, including age, sex, age at diagnosis, prescribed medications, comorbid conditions, and asthma exacerbation-related hospitalization history. This comprehensive data helped develop a baseline profile of the pediatric participants, enabling a nuanced analysis of their health status and treatment history.

The personal information interview form for caregivers collected critical details, including age, sex, educational level, marital status, occupation, income, and relationship to the pediatric patient. Understanding the caregivers' backgrounds is crucial, as their socioeconomic status, educational level, and relationship to the child significantly affect asthma management strategies and the usage of health care resources.

Patient Medical Record Data Form

The Patient Medical Record Data Form was used to collect clinical data directly from the medical records of children with asthma. This form provided comprehensive information regarding asthma severity, which was classified according to the GINA guidelines by health care professionals, age at diagnosis, prescribed medications for symptom control and relief, other treatments received, comorbid conditions, and any asthma-related hospitalization history.

System Usability Scale (SUS)

The SUS, developed by John Brooke in 1986 [17], is a widely recognized tool for evaluating the usability and overall satisfaction of a companion robot-assisted app. The SUS consists of a 5-point Likert scale, with response options ranging from 1 ("strongly disagree") to 5 ("strongly agree"). The scale includes 10 items—5 positively worded and 5 negatively worded—that assess the usability of the asthma management app. Scoring involves assigning values from 1 to 5 for the positive items while applying reverse scoring for negative items. The total score is calculated and then multiplied by 2.5 to convert the range from 0 to 40 to a scale of 0 - 100. A score of ≥68 indicates acceptable usability, corresponding to the 50th percentile, whereas scores below this threshold indicate areas for improvement in design and usability [17-19].

Caregiver Interviews on Attitudes Toward Using a Companion Robot for Asthma Management

In-depth interviews were conducted with a semistructured format to gain information about caregivers' perceptions of the asthma management app and the pediatric asthma model. This approach facilitated a nuanced exploration of caregivers' attitudes, including barriers and facilitators to app. The interview consisted of 7 main questions developed to prompt discussion on previous experiences with similar technologies, willingness to use the asthma model, and opinions on the model's design. In particular, caregivers were asked the following questions: "Have you ever encountered a similar app or model before?"; "If not, after learning about or using this system, would you consider using this asthma model for your child?"; "What are the main reasons for your decision?" Another sample question included the following: "Which aspects of the model's design do you think are not well-developed or convenient for use?" The interviews were used to collect qualitative data that complemented the quantitative results, providing information on how to improve the effectiveness and user acceptance of asthma management tools.

In summary, the diverse range of research instruments used in this study—personal information questionnaires, patient medical record data forms, the SUS, and caregiver interviews—enabled a comprehensive assessment of both the clinical and experiential aspects of asthma management in children. The research aimed to provide actionable information for improving asthma care delivery and technology usage among caregivers and health care professionals by integrating quantitative and qualitative data.

Pukkabot

The tool used in this study is the companion robot-assisted app for children with asthma, named "Pukkabot," an innovative device designed to teach proper inhaler use and promote medication adherence through positive reinforcement (Figure 1). The design of the companion robot is tailored to each child's treatment plan, specifically focusing on those who require both inhaled controller medications and quick-relief medications. The app operates on the Android 13 platform, featuring a touch-sensitive screen that displays both video and audio content. The model, shaped like an animal, measures 23.5 cm in width, 23.1 cm in length, 21 cm in height, and 800 g in weight, including the screen. Its structure is composed of polylactic acid plastic, providing strength and lightweight durability during use. Polylactic acid is a form of plastic derived from natural sources, making it non-irritating during use. It can be cleaned with an alcohol spray. The model is developed to be placed on a flat surface, with the weight supported by its 2 legs and tail for balance while using the screen. The screen area is recessed by approximately 2 inches to prevent damage in case of impact or if it falls from a height. The main display screen provides the following 5 operational modes.

XSL•FO
RenderX

Figure 1. Appearance of the Pukkabot companion robot and screenshots of its mobile app interface designed to support caregivers of children with asthma.



1. My pet: the user must select a pet by tapping on the desired pet when entering for the first time. Afterward, the screen will display the virtual pet. This screen will enable the user to feed the pet, which receives 1 food item per completed inhaler use.
2. Timer: the screen displays a timer to remind the user of the medication inhalation schedule. The screen shows an image of the eyes when in standby mode. The screen changes to display the message "It's time to recharge" along with a cartoon sound alert as the scheduled inhalation time approaches. The timer can be set for 2 reminders per day.
3. Inhaler use: this displays images and step-by-step instructions for using the inhaler, with accompanying audio. Users navigate through the steps via control buttons, enabling them to administer medication in real time alongside the instructions displayed.
4. Rewards: this displays the rewards earned, with the virtual pet growing according to the number of completed inhaler uses and the food it receives. This is designed to motivate children to use their inhalers consistently.
5. Air quality: this displays the local air quality in terms of AQI levels. It is used along with the daily usage of inhalers to alert the user of the severity and provide information on avoiding triggers.

In total, 1 pediatric nurse with expertise in asthma care and 1 pharmacist with expertise in respiratory care validated the "Pukkabot" for content accuracy, structure, and language. Feedback from these experts was incorporated to refine and improve the system.

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board Committee of the Faculty of Nursing and the Faculty of Medicine, Siriraj Hospital, Mahidol University (MU-MOU CoA no. IRB-NS2023/824.1212, dated December 12, 2023). All caregivers and children were informed of the study's purpose and procedures and provided written informed consent before participation. Data were anonymized prior to analysis to protect the confidentiality and privacy of participants. No financial compensation was provided; however, caregivers received small tokens of appreciation in recognition of their time and participation.

Data Analysis

Personal data and usability assessment results were analyzed with descriptive statistics. Content analysis was conducted to assess the system's usability, determining both barriers and facilitators based on caregiver interviews.

Results

General Characteristics of Children With Asthma and Their Caregivers

Among the children with asthma, 63% (19/30) were male and 37% (11/30) were female, with an average age of 5.3 (SD 0.7) years. The onset of asthma occurred at an average age of 2.9 (SD 1.2) years, with 77% (23/30) of the children being diagnosed with allergic rhinitis. A majority (21/30, 70%) of children used both the controller and reliever inhaler medications. Only 7% (2/30) of the children had partly controlled asthma, whereas the majority (28/30, 93%) demonstrated well-controlled asthma. Asthma control was classified according to GINA guidelines, with "well-controlled" defined as symptoms occurring no more than twice per week, minimal nighttime symptoms, infrequent use of rescue medication, and no limitations on daily activities.

Of the caregivers of children with asthma, 80% (24/30) were female, with an average age of 40.7 (SD 6.8) years. A large proportion (22/30, 73%) were mothers, with only 7% (2/30) being grandmothers. Regarding educational background, 50% (15/30) completed a bachelor's degree, whereas 20% (6/30) completed a master's degree. Regarding occupations, 57% (17/30) were employed. Most caregivers (19/30, 63%) reported a monthly household income of > 20,000 (approximately US

XSL•FO
RenderX

$570), which is considered a moderate-income level and is above the country's median household income.

Usability and Overall Satisfaction

The average SUS score from the 30 caregivers was 80.6 (SD 12.2), with scores of 52.5 - 97.5 based on the results of the usability and satisfaction assessment, as measured by the SUS. These scores are higher than the standard benchmark of 68, indicating a level of usability above average. The SUS score is categorized in the grade A range, indicating a high level of usability and acceptability.

The highest rated aspects of usability and overall satisfaction in reviewing the individual items were item 7, "I believe others will quickly understand how to use this app," and item 3, "I find this app easy to use." In contrast, the lowest rated aspect was item 4, "I believe I need assistance to use this app," indicating that most users did not feel the need for additional help and could use the app independently.

Attitudes Toward Using a Companion Robot for Asthma Management

The results in this section depend on interviews about attitudes toward the use of the companion robot-assisted app for children with asthma, as well as user behavior observations. The results are categorized into 3 main areas: attitudes toward use, barriers and facilitators, and improvement suggestions.

Attitudes Toward the Use of the Companion Robot

Caregivers' experiences and perspectives on the tools were largely positive.

There was a lack of previous experience. None of the caregivers had previous experience with similar apps for asthma management, although 3 had learned about inhaler use through videos or YouTube.

There were also positive reactions to the companion robot. After being introduced to the tools, 26 (87%) caregivers expressed an interest in using them. They considered the tools easy to use and believed they could motivate their children to use their inhalers regularly. The cute, pet-themed design was particularly appealing to the children, making the process more engaging.

> *I've never used it before, but I would like to. My child and I have used the inhaler for a long time, but this doll could motivate my child to want to use it more. I like that it has a pet, which makes it fun for my child and serves as good motivation.* [Mother, aged 38 years]

> *I haven't used it, but I've watched videos on how to utilize the inhaler and have an app that monitors air quality, although I rarely check it. This seems useful, and my child seems interested. It may help motivate my child to use the inhaler properly, as they frequently avoid it. I like the presence of a cartoon pet to capture their attention.* [Mother, aged 30 years]

Barriers and Facilitators in the Use of Companion Robot

Caregivers identified both positive aspects and challenges to the use of the companion robot. The feedback is categorized into 2 sub-themes: (1) external features of the companion robot and (2) usability.

External Features of the Companion Robot

In terms of facilitators, 9 (30%) caregivers felt that the model's design was appealing and stable, with a pet-like appearance that caught children's interest.

In terms of barriers, 21 (70%) caregivers emphasized several design issues, including that the model was too large to be portable, its surface was not smooth, and the colors were not vibrant.

> *It demonstrates a complete range of functions, but the size is a drawback. It is too large to carry around, and an app would be more convenient. I think the app would only be initially engaging for children unless additional features are added.* [Mother, aged 43 years]

Usability

In terms of facilitators, all caregivers reported that the app was easy to use. The content, images, and audio instructions were concise and suitable for young children, enabling them to follow the steps independently. The cute cartoons and pet-care game kept the children motivated to regularly use their inhalers. Additionally, the app included helpful features, such as medication reminders, air quality monitoring, and health guidelines. Most (26/30, 87%) caregivers felt that the light, colors, and sounds of the app exhibited no negative effect on children's eyesight due to the short usage duration.

In terms of barriers, some (3/30, 10%) caregivers stated that the medication preparation steps were too long and that users had to manually advance through the inhaler steps. In total, 4 caregivers (4/30, 13%) expressed concerns about screen addiction from using the app frequently.

> *I like the reminder feature for medication timing, as it helps us not forget. The model's large size is inconvenient to move, and I would prefer it as a mobile app. I'd also like a feature to count the number of doses administered.* [Mother, aged 38 years]

> *I like the cartoon that captures my child's attention, and the images and sounds are clear. I appreciate the advice on when to use emergency inhalers according to breathing difficulty. A mobile app would be more convenient.* [Father, aged 37 years]

Suggestions for Improving the Companion Robot

Caregivers provided recommendations to improve both the companion robot for asthma management:

- App development: a majority (27/30, 90%) of caregivers recommended developing the app into a smartphone-compatible version for easier access.
- Model design: a smaller group (3/30, 10%) indicated retaining the model but making it more portable by adjusting the design to be rectangular and flat for easier storage.
- Functional enhancements: several additional features were proposed, including (1) instructions for cleaning the inhaler device, (2) tracking inhaler use and remaining medication

XSL•FO
RenderX

doses, (3) an action plan for asthma exacerbations, (4) videos showing asthma symptoms, (5) videos demonstrating nasal irrigation techniques, (6) notifications about environmental triggers (eg, high dust levels), and (7) contact channels for health care teams.

Discussion

Principal Findings

The study revealed that caregivers reported an average post-use satisfaction score of 80.6 (SD 12.2) on the SUS, which exceeds the standard threshold and falls within the "Grade A" category. This high score indicates that caregivers of children with asthma were highly satisfied after their initial trial of the companion robot. Such a positive reception may affect their decision to continue using these tools in the future. Further analysis revealed that most caregivers expressed satisfaction due to the app's ease of use, its simplicity, and because they did not require assistance during the operation.

Interviews with caregivers indicated that none had previous experience using an app or model specifically designed for children with asthma, although some had learned inhalation techniques from videos or web-based media primarily intended for adults. However, all caregivers considered the app user-friendly, with a comprehensive set of functions. The content, audio, and animated illustrations of inhaler usage were deemed suitable for young children, enabling them to independently follow the steps. Additionally, the pet-care game included in the app helped motivate children to consistently use their inhalers. The app can reduce disease severity and improve treatment outcomes, enabling children to live healthy, normal lives, by encouraging early asthma control and fostering self-discipline in inhaler use. Motivation in children under 6 years of age is significantly improved through interactive and engaging tools. Research reveals that interactive learning media, such as game-based learning and multimedia presentations, foster intrinsic motivation by providing dynamic learning experiences that cater to diverse learning styles [20].

A majority of caregivers indicated that the app could be optimized for use on mobile platforms, but the design of the companion robot for children with asthma, "Pukkabot," in this study specifically aimed to provide preschool-aged children (ages 3 - 6 y) with a tangible companion during inhalation therapy. The model functions as a motivator for consistent inhaler use to help control asthma symptoms. Familiar toy-like designs in therapeutic devices improve children's emotional connections, thereby increasing treatment engagement and adherence, as evidenced by positive feedback from children and parents regarding the respiratory aid for inhalers (RAFIhaler) experience [21].

Caregivers stated that the asthma inhaler details provided in "Pukkabot" aligned well with their requirement for managing children with asthma. This result aligns with research by Lio et al [22], who developed an app for children with asthma aged 2 - 12 years. Their study revealed that children and caregivers were more likely to use the app when it was engaging, easy to use, and contained essential content, including disease pathophysiology, self-care practices, and asthma management strategies [22]. Similarly, Li et al [23] established an app for asthma self-management in children that featured symptom evaluation, treatment planning, inhaler usage, and communication with doctors in emergencies, further improving asthma management. Together, these studies emphasize the importance of user-friendly, comprehensive apps in enhancing asthma care for children and their caregivers.

The ability of apps to set multiple reminders for inhaler use significantly benefits children with asthma, particularly those requiring frequent medication doses. A study revealed that setting multiple alarms ensures timely medication adherence, which is crucial for asthma management in children who may require varying inhaler schedules based on the severity of their condition [24]. Additionally, the inclusion of the AQI monitoring function enables both caregivers and children to be vigilant about daily air quality changes. PM 2.5 significantly affects respiratory health, especially in children with asthma [9]. Children with asthma are particularly vulnerable to air pollution such as ozone and PM 2.5, which have been associated with increased respiratory symptoms, hospitalizations, and long-term impairment in lung function [25]. Therefore, it is essential for children and their caregivers to stay informed and take precautions based on daily air quality. This feature enables children and caregivers to make informed decisions about daily activities, including staying indoors, wearing masks to prevent exposure, or adjusting outdoor routines.

In this study, most (22/30, 73%) caregivers were mothers, and 50% (15/30) held a bachelor's or master's degree. Furthermore, 20% (6/30) of them were employed, and 57% (17/30) reported a household income higher than the national minimum wage, with 63% (19/30) exhibiting a family income above the country's median. A study of parental attitudes towards artificial intelligence in children with asthma found that socioeconomic factors influenced technology adoption, with parents from disadvantaged backgrounds more likely to be reluctant to adopt technology [26]. Therefore, socioeconomic factors may affect caregivers' readiness to adopt technology for health management. Moreover, this research was conducted at a tertiary hospital with access to high-standard care and advanced medical technology. Most caregivers had received ongoing training and education on asthma management for children, which may have contributed to their interest in using technology, such as this app, for at-home care.

Raising awareness and educating caregivers on asthma management in children remains crucial, and health care professionals must prioritize this. Based on the study's recommendations, additional features, such as instructions for cleaning inhalers, tracking medication usage and remaining doses, establishing action plans for asthma exacerbations, videos demonstrating key symptoms and nasal irrigation techniques, and alerts for environmental triggers, such as air pollution levels, along with direct communication with health care teams, can improve asthma care tools. These improvements will increase the treatment efficacy.

This study highlights the importance of health care professionals in prioritizing caregiver education, emphasizing that improved

XSL•FO
RenderX

asthma care tools—with features such as inhaler cleaning instructions, medication tracking, action plans for exacerbations, videos demonstrating key symptoms, and alerts for environmental triggers—can significantly enhance asthma management. These improvements will boost treatment adherence and overall effectiveness, causing better health outcomes for children with asthma, although continuous monitoring remains necessary as they grow older.

Limitations

One limitation of this study is that it primarily focused on establishing tools for asthma management without fully addressing the individual variability in caregiver readiness and technological literacy. Additionally, the generalizability of the results may be limited due to the specific demographic and technological context of the study participants.

Suggestions for Future Study

Special attention should be given to the design of these tools for future research, ensuring that they are engaging for children, portable, and nontriggering to prevent exacerbating asthma symptoms. Studies should focus on the long-term effectiveness of these tools and the way they can be seamlessly integrated into routine clinical practice. Additionally, further investigation into the effect of technological innovations on caregiver engagement, particularly across diverse populations and health care settings, is crucial. These tools may improve asthma management, but recognizing that children with asthma will still require continuous monitoring and treatment as they grow older remains important. Therefore, future studies should prioritize establishing adaptable and dynamic educational content that supports asthma care for children across all stages of development.

Data Availability

The datasets used or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

JS initiated the concept of the innovation, and SR collaborated in planning and supervising the study. JS conducted the primary investigation, while RS and KP assisted in data development and collection. All authors contributed to, revised, approved, and are accountable for the final manuscript.

Conflicts of Interest

None declared.

References

1. Quirt J, Hildebrand KJ, Mazza J, Noya F, Kim H. Asthma. Allergy Asthma Clin Immunol 2018;14(Suppl 2):50. [doi: 10.1186/s13223-018-0279-0] [Medline: 30275843]
2. Asthma. World Health Organization. URL: http://www.who.int/news-room/fact-sheets/detail/asthma [accessed 2024-05-06]
3. Benjaponpitak S. Clinical outcomes research report quality of life and economics of long-term care in pediatric asthma in Thailand [Web page in Thai]. Digital Research Information Center. 2012. URL: https://dric.nrct.go.th/index.php?/Search/SearchDetail/286246 [accessed 2024-07-15]
4. 2022 GINA main report. Global Initiative for Asthma. 2022. URL: https://ginasthma.org/gina-reports [accessed 2024-07-15]
5. Carpenter DM, Roberts CA, Sage AJ, George J, Horne R. A review of electronic devices to assess inhaler technique. Curr Allergy Asthma Rep 2017 Mar;17(3):17. [doi: 10.1007/s11882-017-0684-3] [Medline: 28290015]
6. Trojanowska A, Emeryk A, Zarzycka D. Adherence to therapy regimen by children with asthma and their parents. Postepy Dermatol Alergol 2022 Apr;39(2):258-264. [doi: 10.5114/ada.2022.115886] [Medline: 35645686]
7. Kassa E, Kebede RA, Habte BM. Perceptions towards childhood asthma and barriers to its management among patients, caregivers and healthcare providers: a qualitative study from Ethiopia. BMC Pulm Med 2022 May 8;22(1):184. [doi: 10.1186/s12890-022-01984-2] [Medline: 35527248]
8. Lu X, Li R, Yan X. Airway hyperresponsiveness development and the toxicity of PM2.5. Environ Sci Pollut Res Int 2021 Feb;28(6):6374-6391. [doi: 10.1007/s11356-020-12051-w] [Medline: 33394441]
9. Zhang Y, Guo Z, Zhang W, et al. Effect of acute PM2.5 exposure on lung function in children: a systematic review and meta-analysis. J Asthma Allergy 2023;16:529-540. [doi: 10.2147/JAA.S405929] [Medline: 37193111]
10. Fan J, Li S, Fan C, Bai Z, Yang K. The impact of PM2.5 on asthma emergency department visits: a systematic review and meta-analysis. Environ Sci Pollut Res Int 2016 Jan;23(1):843-850. [doi: 10.1007/s11356-015-5321-x] [Medline: 26347419]
11. Kim S, Park Y, Ackerman MK. Designing an indoor air quality monitoring app for asthma management in children: user-centered design approach. JMIR Form Res 2021 Sep 22;5(9):e27447. [doi: 10.2196/27447] [Medline: 34550080]
12. Hakizimana A, Devani P, Gaillard EA. Current technological advancement in asthma care. Expert Rev Respir Med 2024 Jul;18(7):499-512. [doi: 10.1080/17476348.2024.2380067] [Medline: 38992946]
13. An innovative digital medical device for asthmatic children. Ludocare. 2022. URL: https://www.ludocare.com/wp-content/uploads/2023/08/Press-release-11-14-2022-3.pdf [accessed 2024-10-17]
14. Meracle. URL: https://meraclehealth.com/ [accessed 2025-03-20]

XSL•FO
RenderX

15. Paronyan E, Landon C, Biswas R, Wicklund H, Wallace K, Thompson A. Utilizing capmedic electronic device to measure and improve inhaler technique in clinic. Presented at: American Thoracic Society 2020 International Conference; May 15-20, 2020; Philadelphia, PA. [doi: 10.1164/ajrccm-conference.2020.201.1_MeetingAbstracts.A4786]
16. Whitehead AL, Julious SA, Cooper CL, Campbell MJ. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. Stat Methods Med Res 2016 Jun;25(3):1057-1073. [doi: 10.1177/0962280215588241] [Medline: 26092476]
17. Brooke J. SUS: A quick and dirty usability scale. In: Usability Evaluation In Industry 1996, Vol. 189:4-7. [doi: 10.1201/9781498710411-35]
18. Bangor A, Kortum P, Miller J. Determining what individual SUS scores mean: adding an adjective rating scale. J Usability Stud 2009;4:114-123. [doi: 10.7717/peerj-cs.1918/supp-1]
19. Lewis JR, Sauro J. The factor structure of the System Usability Scale. In: Kurosu M, editor. Human Centered Design: Springer; 2009:94-103. [doi: 10.1007/978-3-642-02806-9_12]
20. Alotaibi MS. Game-based learning in early childhood education: a systematic review and meta-analysis. Front Psychol 2024;15:1307881. [doi: 10.3389/fpsyg.2024.1307881] [Medline: 38629045]
21. Aslam TM, Shakir S, Murray C. Feasibility study of interactive game technologies to improve experience with inhaler spacer devices in young children. Pulm Ther 2016 Dec;2(2):189-197. [doi: 10.1007/s41030-016-0023-1]
22. Iio M, Sato M, Narita M, et al. Development and feasibility of a mobile asthma app for children and their caregivers: mixed methods study. JMIR Form Res 2022 May 20;6(5):e34509. [doi: 10.2196/34509]
23. Li X, Wyatt TH, Velur Rajashekaran P, Bayless AK, Odom L. Using a systems engineering approach to design an interactive mobile health application for improving asthma self-management. Comput Inform Nurs 2020 Dec 4;39(4):221-228. [doi: 10.1097/CIN.0000000000000691]
24. De Simoni A, Fleming L, Holliday L, et al. Electronic reminders and rewards to improve adherence to inhaled asthma treatment in adolescents: a non-randomised feasibility study in tertiary care. BMJ Open 2021 Oct 29;11(10):e053268. [doi: 10.1136/bmjopen-2021-053268] [Medline: 34716166]
25. Bignier C, Havet L, Brisoux M, et al. Climate change and children's respiratory health. Paediatr Respir Rev 2025 Mar;53:64-73. [doi: 10.1016/j.prrv.2024.07.002] [Medline: 39107182]
26. Abdoul C, Cros P, Coutier L, et al. Parents' views on artificial intelligence for the daily management of childhood asthma: a survey. J Allergy Clin Immunol Pract 2021 Apr;9(4):1728-1730. [doi: 10.1016/j.jaip.2020.11.048] [Medline: 33290917]

Abbreviations

AQI: Air Quality Index
GINA: Global Initiative for Asthma
PM: particulate matter
SUS: System Usability Scale

Edited by S Badawy; submitted 19.11.24; peer-reviewed by D Drummond; revised version received 31.03.25; accepted 14.04.25; published 23.06.25.

Please cite as:
Sangngam J, Rungamornrat S, Santipipat R, Ponthanee K
A Companion Robot for Children With Asthma: Descriptive Development and Feasibility Pilot Study
JMIR Pediatr Parent 2025;8:e68943
URL: https://pediatrics.jmir.org/2025/1/e68943
doi:10.2196/68943

© Jinnaphat Sangngam, Somsiri Rungamornrat, Rungnapa Santipipat, Kunchira Ponthanee. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 23.6.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Guided Inhalation via Electronic Monitoring in Children With Uncontrolled Asthma (the IMAGINE Study): Randomized Controlled Trial

Esther Sportel[1], PharmD; Kris Movig[1], PhD; Bernard Thio[2,3], PhD; Mattienne Van der Kamp[2,3], PhD; Job Van der Palen[4,5], Prof Dr; Marjolein Brusse-Keizer[4,6], PhD

[1]Department of Clinical Pharmacy, Medisch Spectrum Twente, Enschede, The Netherlands
[2]Department of Pediatrics, Medisch Spectrum Twente, Enschede, The Netherlands
[3]Biomedical Signals and System Department, University of Twente, Enschede, The Netherlands
[4]Department of Epidemiology, Medisch Spectrum Twente, Enschede, The Netherlands
[5]Section Cognition, Data and Education, University of Twente, Enschede, The Netherlands
[6]Health Technology and Services Research, University of Twente, Enschede, The Netherlands

Corresponding Author:
Esther Sportel, PharmD
Department of Clinical Pharmacy
Medisch Spectrum Twente
Koningsplein 1
Enschede 7512 KZ
The Netherlands
Phone: 31 534872000
Email: e.sportel@mst.nl

Abstract

Background: Pediatric asthma is the most common chronic illness among children in the Netherlands. Scheduled hospital visits provide limited insight into therapy adherence and inhalation technique, which are critical for disease control. Smart inhalers that provide immediate feedback may offer a solution for monitoring and improving these parameters at home, leading to better asthma control.

Objective: This study aimed to improve asthma control through immediate feedback on therapy adherence and inhalation technique, with the use of a smart inhaler.

Methods: The IMAGINE (Improving Adherence by Guiding Inhalation via Electronic Monitoring) study was a randomized controlled trial consisting of 3 phases: an observational run-in phase in which adherence and technique were recorded, a randomized phase with feedback for the intervention group and recording for the control group, followed by an observational phase with only recording for both groups. Asthma control was measured with clinical outcomes including predicted forced expiratory volume in 1 second, lung function reversibility, lung function variability, the Asthma Control Test, and the Childhood Asthma Control Test.

Results: Between October 2019 and October 2023, a total of 34 children were enrolled and randomized. Overall, improvements were observed at the end of phase 2 in clinical parameters (reversibility, lung function variability, Asthma Control Test, and Childhood Asthma Control Test), except for predicted forced expiratory volume in 1 second. However, no significant differences between the intervention and control groups over time were observed. At the end of phase 2, 87% (13/15) of control participants and 78% (10/13) of intervention participants met one or more predefined clinical criteria. Inhalation technique and therapy adherence did not differ over time between the groups (P=.70 and P=.14, respectively).

Conclusions: While smart inhaler feedback did not lead to better outcomes compared with no feedback, clinical improvements were observed in both groups. Future studies should explore how adaptive smart inhaler interventions can be optimized to support personalized care and enhance patient ownership in asthma management.

Trial Registration: International Clinical Trials Registry Platform NL-OMON50093; https://tinyurl.com/yws24rxy

International Registered Report Identifier (IRRID): RR2-10.1186/s13063-020-04694-4

XSL•FO
RenderX

(JMIR Pediatr Parent 2025;8:e78526) doi:10.2196/78526

KEYWORDS

clinical outcomes; inhalation technique; adherence; smart inhaler; pediatrics; eHealth; asthma

Introduction

Pediatric asthma is the most prevalent chronic disease among children in the Netherlands, affecting between 5% and 10% of children up to 12 years of age [1]. Asthma is defined as a chronic inflammatory disorder of the airways resulting in airflow limitation and is characterized by bronchial hyperresponsiveness to a variety of stimuli [2]. The initial management of asthma is guided by the activity of the disease [3,4], requiring ongoing monitoring of asthma control to determine whether current therapies should be maintained or adjusted [3,5,6]. Accordingly, international guidelines [3,7] recommend that physicians reassess therapy adherence, the quality of inhalation technique, environmental factors, and associated comorbidities before considering escalation of pediatric asthma therapy [5,6,8,9].

The two prevalent factors leading to asthma control failure in children are poor therapy adherence and an inadequate inhalation technique, as evidenced by multiple studies [9-12]. Approximately 50% of children exhibit poor adherence to asthma medication, a factor linked to an increased frequency of exacerbations [13-17]. Good adherence has been significantly associated with improved asthma control [18]. Additionally, a substantial proportion of incorrect inhaler handling has been reported among children with asthma, with appropriate use remaining low, which may lead to incomplete drug delivery and increased asthma morbidity [19].

Given that therapy adherence and the inhalation technique followed at home cannot be reliably assessed during a hospital visit [20], home-based monitoring using smart inhalers offers a promising solution [21]. A randomized controlled trial demonstrated that electronic adherence monitoring with daily reminder alarms can enhance adherence, reduce the need for oral steroids, and decrease hospital admissions [22]. Other systematic reviews have emphasized that education combined with repeated feedback on inhaler technique is critical for improving proper device use [19,23].

In this context, AMIKO developed the Respiro device [24], an innovative add-on for conventional inhalers that measures both therapy adherence and inhalation technique by recording vibration patterns. The device captures key parameters including the time of use per inhalation, dosing intervals, peak inspiratory flow, inhalation duration, and the orientation of the device during medication administration. Connected to a patient app, Respiro delivers immediate smart feedback on adherence and technique. The first randomized controlled trial using this device, known as Improving Adherence by Guiding Inhalation via Electronic Monitoring (IMAGINE), was designed to evaluate its impact on asthma control in children [25,26].

The primary hypothesis of this study was that participants assigned to the feedback group would more often demonstrate clinical improvement—defined by 7 pediatric clinical criteria related to predicted forced expiratory volume in 1 second ($predFEV_1$), lung function reversibility, lung function variability (LFV), and Childhood Asthma Control Test (C-ACT)—compared with participants assigned to the control (no feedback) group. Secondary aims included the assessment of therapy adherence and inhalation technique across both study groups.

Methods

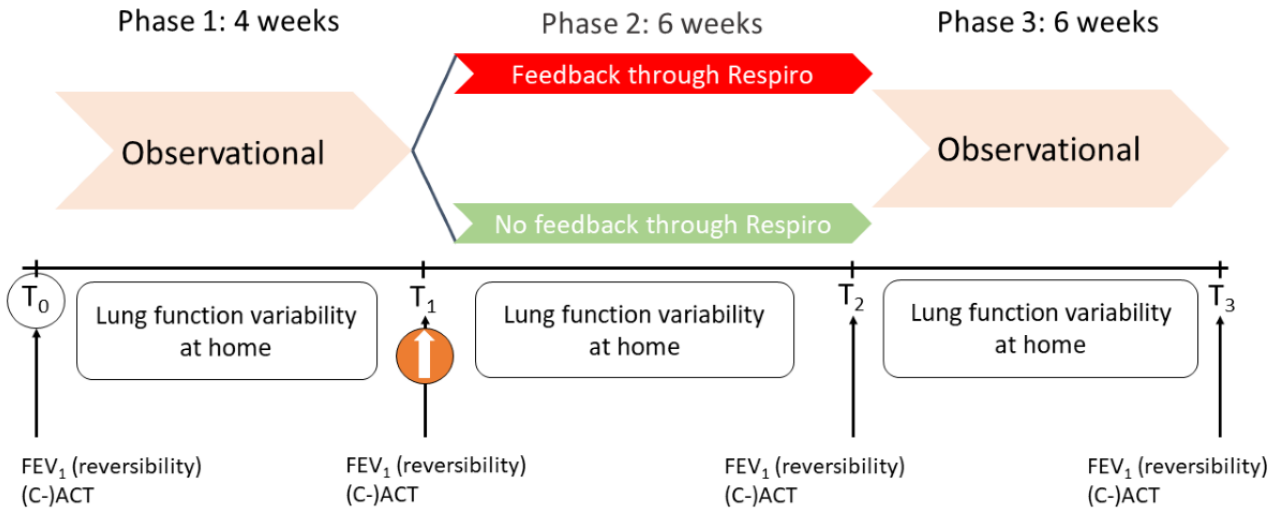
Study Design

The IMAGINE study was a 3-phase randomized controlled interventional study (Figure 1). For more detailed information, see the published protocol by Sportel et al [27]. The CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) guideline (version 1.6.1) was followed (Multimedia Appendix 1) [28]. Recruitment took place from October 2019 through October 2023.

Phase 1 was a 4-week observational period in which adherence and technique were measured by the Respiro device, without providing any feedback to children. At T1, randomization to feedback or no feedback took place (1:1). The randomization at T1 was a 1:1 blocked randomization, performed by an independent researcher. In addition, the randomization was stratified by age (≥12 years vs <12 years) and the use of nasal corticosteroids (prescribed vs nonprescribed). Patients in the intervention group received feedback from their smart device, while patients in the control group received no feedback. This interventional phase (phase 2) lasted 6 weeks. Blinding was not possible for either the participants or the staff due to the nature of this study. Phase 3 consisted of a 6-week observational follow-up during which adherence and technique were measured by the Respiro device but none of the patients received feedback. Treating physicians did not have access to adherence or inhalation technique data at T1 or T2, and no feedback based on these data was provided to patients.

XSL•FO
RenderX

Figure 1. Study design and outcome measurements. The measurements were done at 4 points: T0, the start of the study; T1, the start of phase 2; T2, the start of phase 3; and T3, the end of the study. At T1, the participants were randomized. C-ACT: Childhood Asthma Control Test; FEV1: forced expiratory volume in 1 second.



Ethical Considerations

The protocol was approved by the medical ethics committee of the University of Twente (P19-09), registered in Clinical Trials Registry Platform (trial number NL-OMON50093), was conducted in accordance with the Declaration of Helsinki, and was consistent with International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use and Good Clinical Practice and the applicable regulatory requirements. Written consent was obtained from all children and their parents. In case participants were younger than 12 years, both parents or guardians signed the informed consent, for participants aged between 12 and 16 years both the child and the parents or guardians signed the informed consent, and for participants older than 16 years, the child was allowed to sign independently. The ethics committee approved the informed consent procedure, including the provision that participants aged 16 years and older could provide written consent independently, without requiring parental or legal guardian consent.

All research activities were conducted in accordance with ethical standards, including strict adherence to the principles of privacy and confidentiality to safeguard participants' data and identities. No compensation was offered for participation in the study.

Recruitment

All participants were aged between 6 and 18 years, had uncontrolled moderate to severe asthma, and were outpatients at a large teaching hospital in the Netherlands. Asthma was considered uncontrolled when the C-ACT score was below 20 or lung function reversibility on short-acting bronchodilator of at least 12% [6]. The diagnosis of moderate or severe asthma was made by the same pediatric pulmonologist for every child based on recommendations in the Global Initiative for Asthma (GINA) guidelines [29].

The Respiro device had to be compatible with the controller medication of the participants, which was possible for the Nexthaler (Chiesi Farmaceutici SpA). Switching from a metered dose inhaler to a dry powder inhaler was allowed, as long as the medication remained the same. Participants were instructed in the use of the new inhaler before entering the study and were required to use this device for at least 1 month before inclusion. If children, or their parents (if aged <12 years), were unable to speak or understand the Dutch language, they were excluded from participating in this study. The same applied to children with other chronic conditions that could potentially influence lung function.

The Respiro Add-On Device

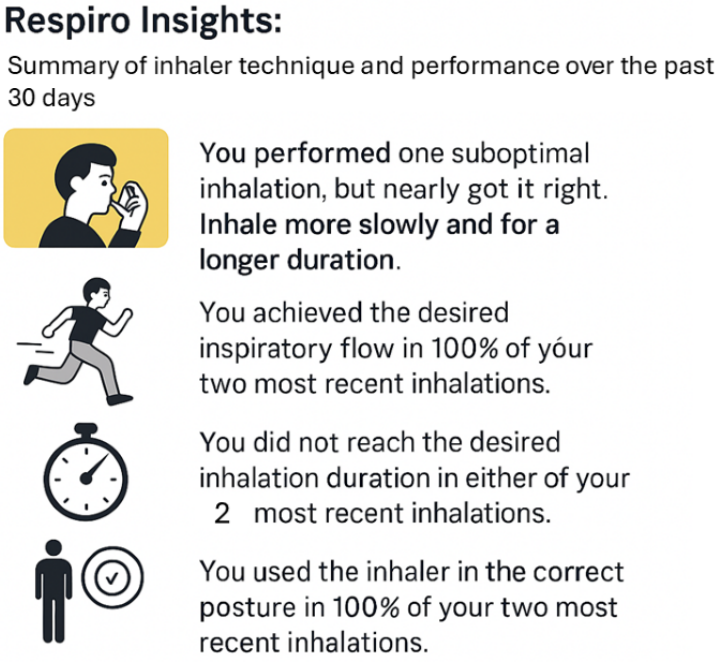
The Respiro add-on device is an attachment to the patient's controller medication inhaler. This add-on device automatically tracks the generated flows of the user through the inhaler. The device uses an accelerometer that measures acceleration forces to determine orientation relative to gravity. It analyzes vibration patterns associated with inhaler use, which allows the identification of critical inhalation errors, such as failing to reach a sufficient peak flow, insufficient inhalation duration, and incorrect orientation of the inhaler. Respiro is connected via Bluetooth to an app on the patient's smartphone, named the Respiro Mobile (Amiko Digital Health) app, and can be used for synchronizing the Respiro device. No major content changes were made to the system during the study.

Intervention

Participants in the intervention group received the Respiro Mobile app, which reminded them when it was time to inhale a dose. The app also provided personalized feedback to help participants optimize their inhalation technique. The feedback included motivational push messages immediately after each inhalation and provided feedback on inhalation quality trends with visuals and text (see Figure 2 for examples of messages, translated into English). The control group received an adapted Respiro Mobile app without reminders or feedback on the inhalation technique; it only registered inhalation use and technique observationally.

XSL•FO
RenderX

Figure 2. Examples of Respiro insights, motivational feedback messages, and visuals.



Measurements

The children visited the hospital before the study began and after every phase. During the first appointment, the C-ACT and FEV_1 reversibility tests were performed by a trained researcher to check if the children were eligible for the study. After being included, the following parameters were measured at fixed time points throughout the study duration (Figure 1). Baseline lung function reversibility and C-ACT were measured at the start of phase 1 to determine asthma control, and at the end of each phase. Lung function reversibility was determined by performing spirometry before and after administration of a short-acting beta-agonist and calculated using equation 1 (Multimedia Appendix 2). The C-ACT is a self-report, internationally accepted questionnaire assessing the patient's perception of asthma complaints and asthma control for the previous 4 weeks. The regular Asthma Control Test was used for children 12 years and older and consisted of 5 questions. The C-ACT was used for children aged below 12 years and consisted of 4 questions for the child and 3 additional questions for the parents.

All participants received a handheld NuvoAir spirometer (Air Next, NuvoAir) [30] to perform spirometry at home. This device is connected via Bluetooth with the Air MD app (NuvoAir) on a mobile phone of the participant to register the spirometry results. The participants were trained and instructed to perform spirometry twice a week at home for the entire duration of the study. If deviations from the protocol were noticed regarding adherence to the twice-weekly home spirometry, the researcher actively contacted participants to encourage and maintain adherence as much as possible. In addition, each participant attended 4 scheduled study visits at the hospital, during which spirometry was performed together with the researcher. This ensured that reliable measurement points were consistently obtained throughout the study. After each phase, LFV was determined using the minimum and maximum value of the home FEV_1 measurements of a specific participant during a particular phase using equation 2 (Multimedia Appendix 2).

Asthma Control

The primary outcome of the IMAGINE study was the degree of asthma control, measured at the end of phase 2 [27]. Asthma control was evaluated based on 4 clinical parameters: FEV_1, C-ACT, lung function reversibility, and LFV. Additionally, 7 predefined criteria were used to specifically assess pediatric asthma control. Clinical improvement in asthma control was defined as the fulfillment of one or more of these criteria. Criteria 3 and 5 were excluded from the primary outcome if they had already been met at baseline. An overview of these criteria and the corresponding categories for clinical improvement is provided in Multimedia Appendix 3.

The 7 criteria were as follows [6,31]:

1. A relative FEV_1 increase of ≥10% at the end of phase 2, compared with the baseline value measured at the start of phase 1
2. An absolute C-ACT score increase of ≥3 points at the end of phase 2, compared with the baseline C-ACT score measured at the start of phase 1
3. A C-ACT score of ≥20 at the end of phase 2
4. A relative lung function reversibility decrease of ≥9% at the end of phase 2, compared with the baseline lung function reversibility measured at the start of phase 1
5. A lung function reversibility of <12% after administration of salbutamol at the end of phase 2
6. A relative LFV decrease of ≥10% during phase 2, compared with the LFV of phase 1
7. An LFV of ≤15% measured during the entire phase 2

Therapy Adherence and Inhalation Technique

Therapy adherence and inhalation technique were considered secondary outcome measures. Therapy adherence was assessed as the actual medication intake during a specific phase divided

XSL•FO
RenderX

by the prescribed medication intake per day, multiplied by the number of days during that phase (equation 3 in Multimedia Appendix 2). In addition, the percentage of adherence was qualified as insufficient (<75%) or good (≥75%).

The quality of the inhalation technique was assessed using two critical errors: (1) the peak inspiratory flow of less than 30 L/min [32] and (2) the inhalation duration was less than 1 second [33]. An inhalation was classified as incorrect when at least one of these 2 critical errors occurred. The overall inhalation technique was calculated as the percentage of correct inhalations (not containing a critical error) divided by the total number of inhalations during a specific phase (equation 4 in Multimedia Appendix 2). Inhalation technique was qualified as poor when ≥25% of the inhalations contained a critical error.

Statistical Analysis

Baseline characteristics were presented as means with SD or medians with IQR for continuous variables depending on the distribution of the variable; categorical variables were presented as numbers with corresponding percentages. First, baseline characteristics were compared between the 2 groups. Continuous variables were tested with the independent 2-tailed *t* test or Wilcoxon rank-sum test, depending on distribution, and categorical variables were tested with a chi-square or Fisher exact test as appropriate.

Second, the mean changes over time for the continuous variables (the predFEV$_1$, C-ACT scores, lung function reversibility, and LFV) were assessed using mixed model repeated measures analysis with fixed effects. A mixed model was created for each of these variables using the optimal covariance structure. Baseline values were subtracted from the follow-up values to obtain normally distributed values. The main parameter of interest was not only the group-by-time interaction but also the time and group effect that was assessed. All participants enrolled at baseline were included in the analyses.

Third, between-group analyses were performed to assess differences in performance for each of the 7 criteria by the Wilcoxon rank-sum test. Percentages of participants reaching the thresholds for improvement per criterion were compared with Fisher exact test.

Percentages of therapy adherence and critical inhalation errors were also assessed with a mixed model repeated measures analysis. For this, the mean percentage of therapy adherence and the mean percentage of inhalations containing critical errors for each participant in every phase were calculated. Percentages of adherence and critical errors during phase 1 were subtracted from the values of the following phases to obtain normally distributed values. In addition, a between-group comparison of participants achieving good therapy adherence and a proper inhalation technique in phases 1 and 2 was performed using the Fisher exact test.

As detailed in our published protocol (Sportel et al [27]), the sample size was calculated based on a 2-sample comparison of independent proportions (2-sided *Z* test), assuming improvement in asthma control in 10% of controls versus 40% of the intervention group, with 80% power; calculations were performed in PASS 11 (NCSS LLC). An interim analysis at 50% information was planned using O'Brien-Fleming spending (target final α=.049), with stopping for futility if the observed difference was ≤10% and early stopping for efficacy if P<.005; participants already enrolled completed all study phases. The resulting minimum required sample was 62, inflated by 10% for anticipated attrition to a recruitment target of 68 participants.

All these analyses were performed according to the intention-to-treat principle. The data were analyzed using SPSS (IBM Corp). P<.05 was considered statistically significant.

Results

Overview

Between October 2019 and October 2023, a total of 62 children with presumed uncontrolled asthma were approached to participate in the study, of whom 34 (55%) children were included and randomized (Figure 3). At T0, the children had a mean age of 11.7 (SD 2.7) years, 24 (71%) were male children, and the median C-ACT score was 18 (IQR 15-21). All demographic and baseline characteristics are presented in Table 1. These characteristics did not differ significantly between the control and intervention groups (Table 1). No significant difference in lung function reversibility at baseline was observed between the groups.

XSL•FO
RenderX

Figure 3. Participant flow graph.

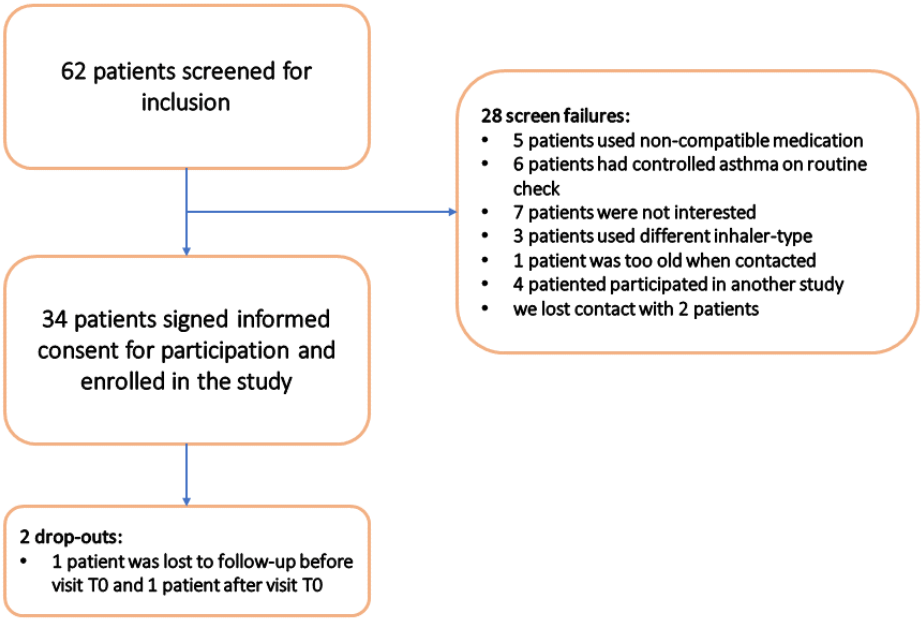


Table 1. Demographic characteristics and measurements at T0 of the 33 study participants.

Demographic characteristics and baseline measures	Control group (n=15)	Intervention group (n=18)	*P* value
Age (years), mean (SD)	11.1 (2.6)	12.2 (2.7)	.28
Height (cm), mean (SD)	147.7 (13.6)	156.9 (18.8)	.12
Gender (male), n (%)	13 (87)	10 (56)	.13
Nasal corticosteroid use, n (%)	11 (73)	10 (56)	.28
C-ACT[a] score, median (IQR)	17.0 (16.0-19.0)	20.0 (10.8-22.3)	.48
C-ACT score >20, n (%)	2 (13)	9 (50)	.06
Predicted FEV_1[b] pre-SABA[c] (%), median (IQR)	83.55 (73.0-94.3)	89.5 (70.0-103.5)	.45
FEV_1 reversibility (%), median (IQR)	13.5 (8.8-24.3)	13.5 (4.0-19.0)	.54
FEV_1 reversibility ≤12, n (%)	5 (33)	5 (28)	>.99

[a]C-ACT: Childhood Asthma Control Test.

[b]FEV_1: forced expiratory volume in 1 second.

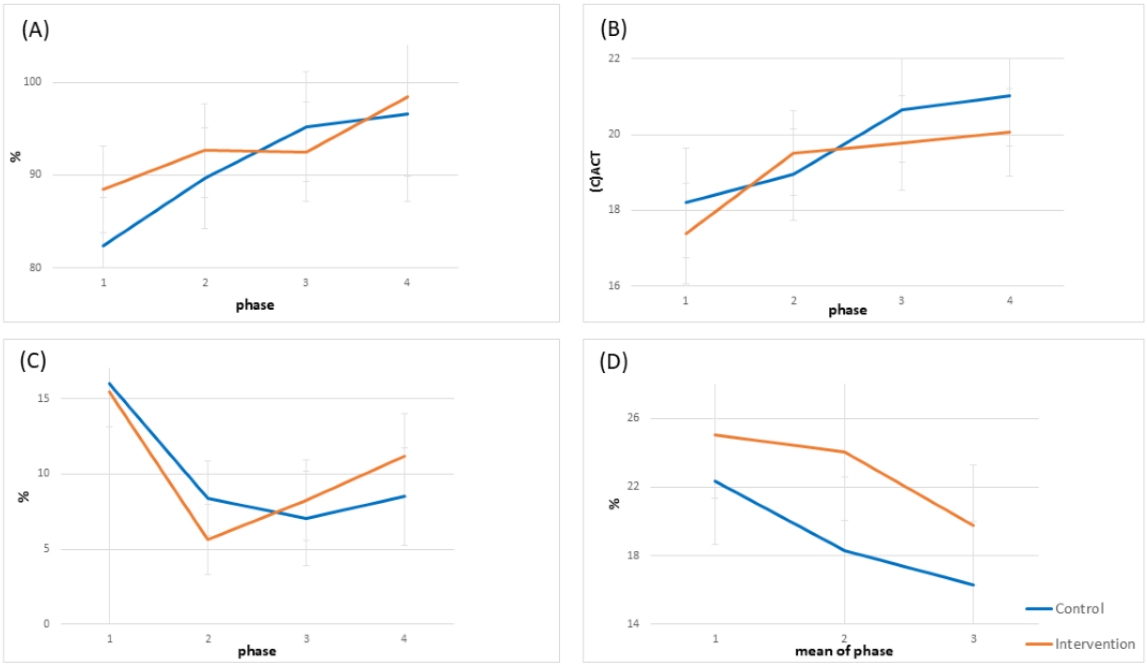
[c]SABA: short-acting beta-agonist.

Clinical Parameters of Asthma Control

In Figure 4A to 4D, the trends in the clinical parameters of asthma control over time for both groups are presented, with estimated means and standard errors.

XSL•FO
RenderX

Figure 4. Time-by-group interaction of the mean change with reference to the baseline measure. (A) Predicted forced expiratory volume in 1 second percentage. (B) Asthma Control Test scores. (C) Lung function reversibility. (D) Lung function variability. The estimated marginal means of the mixed model with repeated measures are presented for each study visit measure per group: T0 (1) is the start of the study. T1 (2) is the start of phase 2, etc. In D, 1 is the mean of phase 1, 2 is the mean of phase 2, and 3 is the mean of phase 3.



Predicted Forced Expiratory Volume per Second

Both groups exhibited a nonsignificant upward trend in predFEV$_1$ percentage over time (P=.13 for the control group and P=.10 for the intervention group; Figure 4A). The between-group difference in the change in predFEV$_1$ percentage over time did not reach statistical significance either (P=.36).

Asthma Control Test

Both groups showed a significant increase in the C-ACT score over time (P=.01 for the control group and P=.04 for the intervention group), as shown in Figure 4B. The between-group difference in the absolute change in C-ACT score over time was not significant (P=.57).

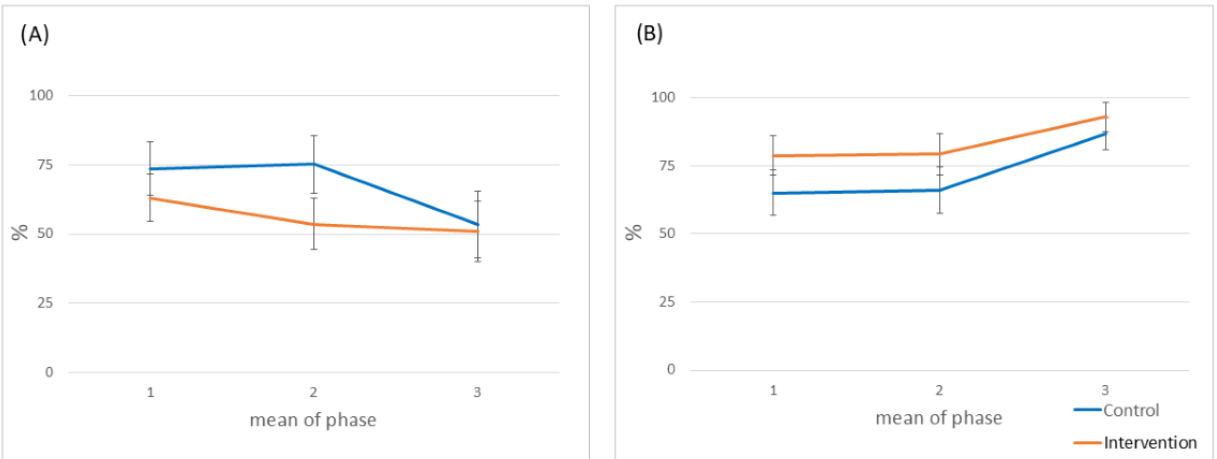
Lung Function Reversibility

The lung function reversibility for both groups showed a decrease over time (P=.02 for the control group and P=.12 for the intervention group). The between-group difference over time was not significant (P=.71; Figure 4C).

Lung Function Variability

A decrease in LFV for both groups was observed over time. The decrease was significant in the intervention group (P=.02) but not in the control group (P=.28; Figure 4D). The between-group difference in change in variability over time was not significant (P=.84; Figure 5D).

Figure 5. Time-by-group interaction of the mean change with reference to the baseline measure. (A) Adherence per phase. (B) Correct inhalations per phase. The estimated marginal means of the mixed model with repeated measures are presented for each phase per group: 1 is the mean of phase 1, 2 is the mean of phase 2, and 3 is the mean of phase 3.



XSL•FO
RenderX

Clinical Improvement

Multimedia Appendix 4 displays both the actual scores (performance) as well as the percentages of children fulfilling each of the 7 clinical criteria at the end of phase 2 in a table. Overall, no significant differences were observed between the control and intervention groups.

Criteria 4 and 5, which pertain to lung function reversibility, exhibited the highest fulfillment rates. A relative lung function reversibility decrease of ≥9% by the end of phase 2 was achieved in 73% of the participants in both the control (8/11) and intervention (11/15) groups. Furthermore, the criterion requiring a lung function reversibility of ≤12% following salbutamol administration at the end of phase 2 was met by 91% (10/11) of cases in the control group and 73% (11/15) in the intervention group. This criterion was already met at baseline, with 55% (6/11) and 53% (8/15) of the patients achieving this criterion during phase 2 (Multimedia Appendix 3).

In contrast, criteria related to LFV (criteria 6 and 7) demonstrated the lowest fulfillment rates in both groups, together with C-ACT score of ≥20 at the end of phase 2 (criterion 3). The criterion specifying an LFV of ≤15% throughout phase 2 was met by 27% (3/11) of participants in the control group versus 31% (4/13) in the intervention group. Furthermore, 36% (4/11) versus 46% (6/13) of the patients in the control and intervention groups, respectively, met the criterion for a relative LFV decrease of ≥10% during phase 2 compared with phase 1. Criterion 3 was met by 33% (4/12) and (5/15) of the participants in both groups, not including the children who had already fulfilled this criterion at baseline.

In total 87% (n/N) of the patients in the control group showed clinical improvement (ie, fulfilling one or more criteria at the end of phase 2) versus 78% (n/N) in the intervention group; this difference was not statistically significant (P=.52). The mean number of fulfilled criteria at the end of phase 2 in the control group was 2.33 (SD 1.54) versus 2.61 (SD 1.79) in the intervention group (P=.64). Criteria that were already completed at baseline were not included in the total percentage of fulfillment per criterion.

Therapy Adherence and Inhalation Technique

Figure 5A shows that, overall, both groups demonstrated a significant declining trend in adherence—significant in the control group (P=.03) and borderline significant in the intervention group (P=.05). The between-group difference over time was not significant (P=.14).

Both groups exhibited an upward trend in correct inhalations, with statistical significance in the control group (P=.005) and a similar borderline significant trend in the intervention group (P=.07). This overall improvement was particularly evident after phase 2. The between-group difference in change in correct inhalations over time was not significant (P=.70; Figure 5B).

The percentages of children who had good adherence (75%-125%) and a correct inhalation technique (≥75% correct inhalations) were calculated for each phase. Good adherence was observed in 57% (8/14) of participants in the control group and 50% (9/18) in the intervention group in phase 1. In phases 2 and 3, adherence remained relatively stable in the control group (54% and 50%, respectively). In the intervention group, it declined to 33% in phase 2 before returning to 50% in phase 3.

In phase 1, 43% (6/14) of participants in the control group and 72% (13/18) in the intervention group demonstrated good inhaler technique. In phase 2, these proportions increased to 62% (8/13) in the control group and remained relatively stable at 67% (10/15) in the intervention group. In phase 3, these increased to 90% (9/10) and 85% (11/13), respectively.

Discussion

Principal Findings

In this study, both the control and intervention groups demonstrated improvement over time in the clinical parameters—predFEV$_1$ percentage, C-ACT, LFV, and lung function reversibility; however, there was no difference between the groups at the end of phase 2. In accordance with the study protocol, an interim analysis indicated futility, leading to early termination of the trial.

This is the first study that investigates the effects of smart immediate feedback and monitoring on objective and subjective clinical end points, providing valuable insights into patient and group characteristics and behavior in relation to pediatric asthma. Both the control and the intervention groups exhibited a high rate of clinical improvement at the end of phase 2 (87% vs 78% fulfilling one or more clinical criteria). Although we identified a clinical improvement for both groups at the end of phase 2, we did not observe improvement in adherence or inhalation technique during phase 2. Adherence declined during phase 2, which we believe reflects a component that is less related to skill acquisition and more to behavior. It is likely that adherence was overestimated at the start of the study—possibly due to participants initially demonstrating more favorable behavior than was truly representative—which then gradually decreased over time. Interestingly, a more notable improvement in inhalation technique emerged in phase 3 in the control group. This delayed effect may reflect the time required for a skill acquisition change to take hold, as is known from the stages of change in adherence and other health settings [34,35]. Initial exposure to feedback in phase 2 may have laid the foundation, known as the contemplation or preaction phase, with actual skill acquisition becoming evident only later. Participants may also have needed time to become familiar with the smart inhaler and its feedback mechanisms, leading to more effective use and readiness for the feedback over time [36]. However, this also raises the question of whether the feedback system was sufficiently intuitive for children. In our study, we used a system designed suitable for both adults and children, incorporating clear pictograms as part of the feedback. Nevertheless, a more child-specific and intuitive design might have facilitated faster adaptation. In addition, the auditory reminders used in the system may have elicited resistance, potentially leading participants to disable them. Although we were unable to monitor the exact frequency of reminder deactivation in our study, prior research by Knauer et al [37] in a different population suggests that social acceptance in this context is a

XSL•FO
RenderX

critical factor in pediatric settings. Furthermore, the lack of an observed effect on inhalation technique and adherence suggests that other important factors may influence clinical asthma control beyond the parameters measured in this study, such as lifestyle, allergic exposure, or parental and environmental smoking habits. Standard care was not fully represented in our study, as both groups received a smart monitoring device—one group with active feedback and the control group with monitoring data transferred only to the researcher. Therefore, improvements observed in both groups may partly be explained by the monitoring principle itself, especially for adherence. This observation may also be partially attributable to the Hawthorne effect, in which improvements in observable behaviors, such as inhalation technique or adherence, are driven by the awareness of being observed [38]. However, these effects were not consistently observed in our study. It is possible that the Hawthorne effect instead manifested through other behavioral changes, such as lifestyle adjustments, which were not directly measured but may have contributed to the observed clinical improvements.

Given the episodic nature of asthma, patients experience fluctuations in symptoms throughout the year, with considerable interindividual variability. These dynamics underscore the potential value of continuous digital monitoring and feedback mechanisms. By capturing real-time changes in symptoms and behavior, such systems may support more personalized and responsive care. Moreover, a model based on objective monitoring to identify pitfalls could facilitate focused interventions and could potentially lead to more effective care. As part of a decision support tool, the smart inhaler must be able to work under various conditions, inconsistencies, and different patient needs [39]. More extensive monitoring may be used for a short period at the start of an eHealth strategy to identify personal cues that disrupt asthma control and to develop a personalized eHealth treatment strategy. Thereafter, monitoring intensity could be personalized to prevent alert fatigue, as observed in other decision support systems [40], while continuing the monitoring of the personal disrupting cues to allow timely short-term detection of asthma control deterioration. This resembles a just-in-time approach, in which the device is delivering when the need is high and receptiveness is likely [41,42], thereby empowering patients to take greater ownership of their condition [43,44].

A key strength of this study is the continuous use of the Respiro smart add-on device, which enabled objective assessment of both adherence and inhalation technique in an ambulatory, real-world setting. This approach enhanced the validity of our findings, ensuring that the results were representative of actual inhaler use in daily clinical practice. Another strength is the comprehensive approach to defining the clinical end points of asthma. The C-ACT questionnaire is the current validated gold standard in modern Dutch health care for assessing asthma control in children. However, the C-ACT comes with several drawbacks [45-47]. Asthma control in children fluctuates greatly, and the C-ACT questionnaire fails to account for this variability. The C-ACT score tends to underestimate asthma control, as defined by GINA [48,49]. However, to compensate for the drawbacks of the C-ACT questionnaire, other objective parameters, such as predFEV$_1$, lung function reversibility after intake of medication, and LFV, were included.

Limitations

Several limitations must be acknowledged. A substantial number of participants already met one or more of the criteria (eg, ACT score or lung function reversibility) at baseline, potentially limiting the scope for observable improvement. Additionally, for both groups, adherence to protocol, particularly concerning home measurements, was suboptimal, which may have affected the reliability of LFV as an outcome measure and should therefore be considered when interpreting its suitability as a parameter. The auditory warning signals provided by the smart inhaler were sometimes disabled by the participants in the feedback group, although no exact data on this were available. Although the intervention group initially demonstrated a significantly higher absolute FEV$_1$ (in liters), no substantial effect was expected from this baseline difference, as predFEV$_1$ percentage values were comparable between both groups. The study was limited by reduced statistical power, generalizability, and therefore by a limited ability to detect smaller effects. However, according to the stopping rule in the protocol, an effect size of less than 10% compared with the control group indicated futility, and therefore no substantial changes in outcomes were to be expected from including additional participants.

Comparison With Prior Work and Future Perspectives

We believe that adding a smart monitoring feedback device (eg, Respiro) to the arsenal of asthma management provides a clearer view into patient behavior and presents an opportunity to enhance the efficiency and precision of asthma management strategies. Data from the observational phase of the IMAGINE study show that adherence and the inhalation technique are distinct and separate pitfalls in asthma care, each representing independent challenges [50]. In our study, adherence declined significantly in both groups, a finding similar to the Outcomes following Tailored Education and Retraining: Studying Performance and Adherence (OUTERSPACE) study, in which the intervention group showed a similar decline in adherence over time [51]. The authors explained this decline by the improvement in inhalation technique, which might reduce the need for strict adherence as the effectiveness of each inhalation increases. Furthermore, the absence of auditory reminders may also partly explain the decline in adherence observed in the OUTERSPACE study, a finding that could likewise apply to our study [51]. The INCA Sun study reported better adherence in the group treated with a digital inhaler compared with the control group. Similar to our study, the Inhaler Compliance Assessment (INCA) device measured data on treatment use and the inhaler technique in both study groups. However, feedback was not provided immediately, and therefore did not closely resemble our intervention [52]. In the Connected Electronic Inhalers Asthma Control Trial (CONNECT) 1 and 2 studies, the smart inhaler provided direct feedback on adherence and the inhalation technique through a patient-facing app. Both studies demonstrated improvements in clinical outcomes. Two key differences from our study are that the CONNECT trials included participants aged 13 years and older, and that their

XSL•FO
RenderX

control groups received standard care without monitoring, whereas our control group was also monitored. Consequently, these differences in design and population may explain the contrasting findings regarding the impact of feedback on clinical outcomes [53,54]. Future research should focus on the optimal form of feedback, particularly adaptive and real-time interventions. As a first step, a prospective study could be designed in which a cohort of children with moderate to severe asthma is provided with a smart inhaler for an extended period [55]. At predefined moments—specifically when asthma control deteriorates or issues with adherence and the inhalation technique arise—additional tailored support could be offered to the intervention group, in contrast to standard nonadaptive care in the control group. Key questions include whether a just-in-time approach can improve outcomes, prevent exacerbations, and enhance self-management and user experience; an example of a protocol with this design is the Mobile Health for Kids With Asthma study [56]. Current clinical guidelines addressing pitfalls in asthma management may be too generic in mitigating issues of adherence and inhalation technique [55,57]. In contrast, objective monitoring and targeted attention to inhalation technique and adherence appear to contribute to more effective and efficient care. Such approaches not only improve outcomes but also enable a more personalized focus, fostering patient ownership in disease management [58].

Ultimately, this could pave the way for a study in which multicomponent adaptive interventions are delivered in a personalized manner, providing care for the right patient at the right time.

This creates a whole new opportunity to offer patient-tailored advice, enabling individuals to take responsible ownership of their condition while allowing health care providers to make optimal use of the just-in-time resources and opportunities for this disease with an episodic nature in the current health care landscape.

Conclusions

In summary, this study investigated both objective and subjective clinical end points in the context of smart immediate feedback and monitoring for pediatric asthma management. Although the intervention did not lead to superior outcomes compared with the control group, the overall clinical improvements observed across both groups suggest that increased awareness and objective monitoring positively influence asthma control in children with uncontrolled asthma. The integration of smart monitoring feedback devices (eg, Respiro) offers valuable insights into patient behavior, thereby highlighting opportunities for more personalized and effective asthma management strategies. Based on our findings, we propose that future research should focus on refining assessment criteria and exploring the potential benefits of more targeted, personalized adaptive feedback interventions in asthma management.

Acknowledgments

The authors thank Michiel Lookeren Campagne for his assistance with the recruitment phase.

The add-on devices for this study were provided by AMIKO.

Figure 2, including the translation from Dutch to English, was generated with assistance from the generative AI tool ChatGPT (OpenAI) [59].

Data Availability

The dataset generated or analyzed during this study is available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1256 KB - pediatrics_v8i1e78526_app1.pdf]

Multimedia Appendix 2
Equations 1 to 4.
[DOCX File , 20 KB - pediatrics_v8i1e78526_app2.docx]

Multimedia Appendix 3
Four domains divided into 7 clinical criteria for pediatric asthma control.
[DOCX File , 76 KB - pediatrics_v8i1e78526_app3.docx]

Multimedia Appendix 4

XSL•FO
RenderX

Performance and fulfillment per criterion. The performance on the 7 criteria for both groups is displayed as median and IQR, while the fulfillment of the criteria is displayed as percentage of subjects who fulfilled the criteria within the group. If criteria 3 and 5 were already fulfilled at baseline, they were not accounted for in the total percentage of fulfillment per criterion.
[DOCX File , 22 KB - pediatrics_v8i1e78526_app4.docx]

References

1. Boeschoten SA, Buysse CM, Merkus PJ, van Wijngaarden JM, Heisterkamp SG, de Jongste JC, et al. Children with severe acute asthma admitted to Dutch PICUs: a changing landscape. Pediatr Pulmonol 2018 Jul;53(7):857-865 [FREE Full text] [doi: 10.1002/ppul.24009] [Medline: 29635844]
2. Asthma. World Health Organization. URL: https://www.who.int/news-room/fact-sheets/detail/asthma [accessed 2025-10-31]
3. Reddel HK, Bacharier LB, Bateman ED, Brightling CE, Brusselle GG, Buhl R, et al. Global Initiative for Asthma Strategy 2021: executive summary and rationale for key changes. Am J Respir Crit Care Med 2022 Jan 01;205(1):17-35 [FREE Full text] [doi: 10.1164/rccm.202109-2205PP] [Medline: 34658302]
4. Devonshire AL, Kumar R. Pediatric asthma: principles and treatment. Allergy Asthma Proc 2019 Dec 01;40(6):389-392. [doi: 10.2500/aap.2019.40.4254] [Medline: 31690377]
5. Licari A, Brambilla I, Marseglia A, De Filippo M, Paganelli V, Marseglia GL. Difficult vs. severe asthma: definition and limits of asthma control in the pediatric population. Front Pediatr 2018 Jun 19;6:170 [FREE Full text] [doi: 10.3389/fped.2018.00170] [Medline: 29971223]
6. Dinakar C, Chipps BE, Section on Allergy and Immunology, Section on Pediatric Pulmonology and Sleep Medicine. Clinical tools to assess asthma control in children. Pediatrics 2017 Jan;139(1):20163438. [doi: 10.1542/peds.2016-3438] [Medline: 28025241]
7. Chung KF, Wenzel SE, Brozek JL, Bush A, Castro M, Sterk PJ, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J 2014 Mar;43(2):343-373 [FREE Full text] [doi: 10.1183/09031936.00202013] [Medline: 24337046]
8. Tesse R, Borrelli G, Mongelli G, Mastrorilli V, Cardinale F. Treating pediatric asthma according guidelines. Front Pediatr 2018 Aug 23;6:234 [FREE Full text] [doi: 10.3389/fped.2018.00234] [Medline: 30191146]
9. Chipps BE, Corren J, Israel E, Katial R, Lang DM, Panettieri RAJ, et al. Asthma yardstick: practical recommendations for a sustained step-up in asthma therapy for poorly controlled asthma. Ann Allergy Asthma Immunol 2017 Mar;118(2):133-42.e3. [doi: 10.1016/j.anai.2016.12.010] [Medline: 28153079]
10. Rodriguez-Martinez CE, Sossa-Briceño MP, Sinha IP. When adherence and inhalation technique matter: difficult-to-control pediatric asthma in low- to middle-income countries. Pediatr Pulmonol 2021 Jul;56(6):1366-1373. [doi: 10.1002/ppul.25342] [Medline: 33684267]
11. Can C, Akkelle E, Gökmirza Özdemir P, Yazıcıoğlu M, Süt N. Assessment of regular drug use and inhaler technique skills in asthmatic children. Allergol Immunopathol (Madr) 2020;48(2):124-129. [doi: 10.1016/j.aller.2019.06.009] [Medline: 31627970]
12. Capanoglu M, Dibek Misirlioglu E, Toyran M, Civelek E, Kocabas CN. Evaluation of inhaler technique, adherence to therapy and their effect on disease control among children with asthma using metered dose or dry powder inhalers. J Asthma 2015 Oct;52(8):838-845. [doi: 10.3109/02770903.2015.1028075] [Medline: 26037396]
13. Ménard S, Jbilou J, Lauzier S. Family caregivers' reported nonadherence to the controller medication of asthma in children in Casablanca (Morocco): extent and associated factors. J Asthma 2018 Dec;55(12):1362-1372. [doi: 10.1080/02770903.2017.1414235] [Medline: 29336706]
14. Desager K, Vermeulen F, Bodart E. Adherence to asthma treatment in childhood and adolescence - a narrative literature review. Acta Clin Belg 2018 Oct;73(5):348-355. [doi: 10.1080/17843286.2017.1409684] [Medline: 29228891]
15. Booster GD, Oland AA, Bender BG. Treatment adherence in young children with asthma. Immunol Allergy Clin North Am 2019 May;39(2):233-242. [doi: 10.1016/j.iac.2018.12.006] [Medline: 30954173]
16. Spaulding SA, Devine KA, Duncan CL, Wilson NW, Hogan MB. Electronic monitoring and feedback to improve adherence in pediatric asthma. J Pediatr Psychol 2012;37(1):64-74 [FREE Full text] [doi: 10.1093/jpepsy/jsr059] [Medline: 21852340]
17. Moore A, Preece A, Sharma R, Heaney LG, Costello RW, Wise RA, et al. A randomised controlled trial of the effect of a connected inhaler system on medication adherence in uncontrolled asthmatic patients. Eur Respir J 2021 Jul 17;57(6):2003103 [FREE Full text] [doi: 10.1183/13993003.03103-2020] [Medline: 33334936]
18. Basharat S, Jabeen U, Zeeshan F, Bano I, Bari A, Rathore AW. Adherence to asthma treatment and their association with asthma control in children. J Pak Med Assoc 2018 May;68(5):725-728. [Medline: 29885170]
19. Gillette C, Rockich-Winston N, Kuhn JA, Flesher S, Shepherd M. Inhaler technique in children with asthma: a systematic review. Acad Pediatr 2016 Sep;16(7):605-615. [doi: 10.1016/j.acap.2016.04.006] [Medline: 27130811]
20. van der Kolk A, Lammers N, Brusse-Keizer M, van der Palen J, Faber J, Spenkelink-Visser R, et al. Comparison of inhalation technique with the Diskus and Autohaler in asthmatic children at home. ERJ Open Res 2021 Apr 19;7(2):00215-2019 [FREE Full text] [doi: 10.1183/23120541.00215-2019] [Medline: 33898617]
21. Lam WY, Fresco P. Medication adherence measures: an overview. Biomed Res Int 2015;2015:217047 [FREE Full text] [doi: 10.1155/2015/217047] [Medline: 26539470]

XSL•FO
RenderX

22. Morton RW, Elphick HE, Rigby AS, Daw WJ, King DA, Smith LJ, et al. STAAR: a randomised controlled trial of electronic adherence monitoring with reminder alarms and feedback to improve clinical outcomes for children with asthma. Thorax 2017 May;72(4):347-354 [FREE Full text] [doi: 10.1136/thoraxjnl-2015-208171] [Medline: 27815524]
23. Rau JL. The inhalation of drugs: advantages and problems. Respir Care 2005 Mar;50(3):367-382. [Medline: 15737247]
24. Amiko: upgrading respiratory care. Amiko. URL: https://amiko.io/ [accessed 2025-02-10]
25. Bonini M. Electronic health (e-Health): emerging role in asthma. Curr Opin Pulm Med 2017 Jan;23(1):21-26. [doi: 10.1097/MCP.0000000000000336] [Medline: 27763999]
26. van der Kamp M, Reimering Hartgerink P, Driessen J, Thio B, Hermens H, Tabak M. Feasibility, efficacy, and efficiency of eHealth-supported pediatric asthma care: six-month quasi-experimental single-arm pretest-posttest study. JMIR Form Res 2021 Jul 26;5(7):e24634 [FREE Full text] [doi: 10.2196/24634] [Medline: 34309568]
27. Sportel ET, Oude Wolcherink MJ, van der Palen J, Lenferink A, Thio BJ, Movig KL, et al. Does immediate smart feedback on therapy adherence and inhalation technique improve asthma control in children with uncontrolled asthma? A study protocol of the IMAGINE I study. Trials 2020 Oct 17;21(1):801 [FREE Full text] [doi: 10.1186/s13063-020-04694-4] [Medline: 32943094]
28. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of web-based and mobile health interventions. J Med Internet Res 2011 Dec 31;13(4):e126 [FREE Full text] [doi: 10.2196/jmir.1923] [Medline: 22209829]
29. Report- Global Initiative for Asthma. Global Initiative for Asthma. URL: https://ginasthma.org/reports [accessed 2024-03-14]
30. NuvoAir. URL: https://nuvoair.com/outcomes [accessed 2025-11-07]
31. van der Kamp MR, Klaver EC, Thio BJ, Driessen JM, de Jongh FH, Tabak M, et al. WEARCON: wearable home monitoring in children with asthma reveals a strong association with hospital based assessment of asthma control. BMC Med Inform Decis Mak 2020 Aug 14;20(1):192 [FREE Full text] [doi: 10.1186/s12911-020-01210-1] [Medline: 32795352]
32. Laube BL, Janssens HM, de Jongh FH, Devadason SG, Dhand R, Diot P, et al. What the pulmonary specialist should know about the new inhalation therapies. Eur Respir J 2011 Jul;37(6):1308-1331 [FREE Full text] [doi: 10.1183/09031936.00166410] [Medline: 21310878]
33. Holmes MS, D'arcy S, Costello RW, Reilly RB. Acoustic analysis of inhaler sounds from community-dwelling asthmatic patients for automatic assessment of adherence. IEEE J Transl Eng Health Med 2014;2:1-10. [doi: 10.1109/jtehm.2014.2310480]
34. Dekhuijzen R, Lavorini F, Usmani OS, van Boven JF. Addressing the impact and unmet needs of nonadherence in asthma and chronic obstructive pulmonary disease: where do we go from here? J Allergy Clin Immunol Pract 2018;6(3):785-793 [FREE Full text] [doi: 10.1016/j.jaip.2017.11.027] [Medline: 29339126]
35. Genberg BL, Lee Y, Rogers WH, Willey C, Wilson IB. Stages of change for adherence to antiretroviral medications. AIDS Patient Care STDS 2013 Oct;27(10):567-572 [FREE Full text] [doi: 10.1089/apc.2013.0126] [Medline: 24093810]
36. Willey C, Redding C, Stafford J, Garfield F, Geletko S, Flanigan T, et al. Stages of change for adherence with medication regimens for chronic disease: development and validation of a measure. Clin Ther 2000 Jul;22(7):858-871. [doi: 10.1016/s0149-2918(00)80058-2] [Medline: 10945512]
37. Knauer J, Baumeister H, Schmitt A, Terhorst Y. Acceptance of smart sensing, its determinants, and the efficacy of an acceptance-facilitating intervention in people with diabetes: results from a randomized controlled trial. Front Digit Health 2024;6:1352762 [FREE Full text] [doi: 10.3389/fdgth.2024.1352762] [Medline: 38863954]
38. McCambridge J, Witton J, Elbourne DR. Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects. J Clin Epidemiol 2014 Mar;67(3):267-277 [FREE Full text] [doi: 10.1016/j.jclinepi.2013.08.015] [Medline: 24275499]
39. Kocsis O, Lalos A, Arvanitis G, Moustakas K. Multi-model short-term prediction schema for mHealth empowering asthma self-management. Electron Notes Theor Comput Sci 2019 May 4;343:3-17 [FREE Full text] [doi: 10.1016/j.entcs.2019.04.007]
40. Fallon A, Haralambides K, Mazzillo J, Gleber C. Addressing alert fatigue by replacing a burdensome interruptive alert with passive clinical decision support. Appl Clin Inform 2024 Jan;15(1):101-110 [FREE Full text] [doi: 10.1055/a-2226-8144] [Medline: 38086417]
41. Hardeman W, Houghton J, Lane K, Jones A, Naughton F. A systematic review of just-in-time adaptive interventions (JITAIs) to promote physical activity. Int J Behav Nutr Phys Act 2019 May 03;16(1):31 [FREE Full text] [doi: 10.1186/s12966-019-0792-7] [Medline: 30943983]
42. Nahum-Shani I, Smith SN, Spring BJ, Collins LM, Witkiewitz K, Tewari A, et al. Just-in-time adaptive interventions (JITAIs) in mobile health: key components and design principles for ongoing health behavior support. Ann Behav Med 2018 May 18;52(6):446-462 [FREE Full text] [doi: 10.1007/s12160-016-9830-8] [Medline: 27663578]
43. Gönül S, Namlı T, Coşar A, Toroslu İ. A reinforcement learning based algorithm for personalization of digital, just-in-time, adaptive interventions. Artif Intell Med 2021 May;115:102062. [doi: 10.1016/j.artmed.2021.102062] [Medline: 34001322]
44. Lentferink A, Noordzij ML, Burgler A, Klaassen R, Derks Y, Oldenhuis H, et al. On the receptivity of employees to just-in-time self-tracking and eCoaching for stress management: a mixed-methods approach. Behav Inf Technol 2021 Feb 02;41(7):1398-1424. [doi: 10.1080/0144929x.2021.1876764]

XSL•FO
RenderX

45. Kopel SJ, Walders-Abramson N, McQuaid EL, Seifer R, Koinis-Mitchell D, Klein RB, et al. Asthma symptom perception and obesity in children. Biol Psychol 2010 Apr;84(1):135-141 [FREE Full text] [doi: 10.1016/j.biopsycho.2009.11.007] [Medline: 19941934]
46. Yoos HL, Kitzman H, McMullen A, Sidora K. Symptom perception in childhood asthma: how accurate are children and their parents? J Asthma 2003 Mar;40(1):27-39. [doi: 10.1081/jas-120017204] [Medline: 12699209]
47. Banzett RB, Dempsey JA, O'Donnell DE, Wamboldt MZ. Symptom perception and respiratory sensation in asthma. Am J Respir Crit Care Med 2000 Oct 01;162(3 Pt 1):1178-1182. [doi: 10.1164/ajrccm.162.3.9909112] [Medline: 10988151]
48. Pocket guide for asthma management and prevention. Global Initiative for Asthma. URL: https://ginasthma.org/pocket-guide-for-asthma-management-and-prevention/ [accessed 2025-10-31]
49. Bourdin A, Halimi L, Vachier I, Paganin F, Lamouroux A, Gouitaa M, et al. Adherence in severe asthma. Clin Exp Allergy 2012 Dec;42(11):1566-1574. [doi: 10.1111/j.1365-2222.2012.04018.x] [Medline: 23106657]
50. Sportel E, Thio B, Movig K, van der Palen J, Brusse M. The correlation between the level of therapy adherence and inhalation technique in children with uncontrolled asthma using a smart inhaler: the IMAGINE study. Ther Adv Respir Dis 2025;19:17534666251346363 [FREE Full text] [doi: 10.1177/17534666251346363] [Medline: 40476634]
51. Dierick BJ, Achterbosch M, Eikholt AA, Been-Buck S, Klemmeier T, van de Hei SJ, et al. Electronic monitoring with a digital smart spacer to support personalized inhaler use education in patients with asthma: the randomized controlled OUTERSPACE trial. Respir Med 2023 Dec;218:107376 [FREE Full text] [doi: 10.1016/j.rmed.2023.107376] [Medline: 37549796]
52. Hale EM, Greene G, Mulvey C, Mokoka MC, van Boven JF, Cushen B, et al. Use of digital measurement of medication adherence and lung function to guide the management of uncontrolled asthma (INCA Sun): a multicentre, single-blinded, randomised clinical trial. Lancet Respir Med 2023 Jul;11(7):591-601. [doi: 10.1016/S2213-2600(22)00534-3] [Medline: 36963417]
53. Hoyte FC, Mosnaim GS, Rogers L, Safioti G, Brown R, Li T, et al. Effectiveness of a digital inhaler system for patients with asthma: a 12-week, open-label, randomized study (CONNECT1). J Allergy Clin Immunol Pract 2022 Oct;10(10):2579-2587 [FREE Full text] [doi: 10.1016/j.jaip.2022.08.023] [Medline: 36038131]
54. Mosnaim GS, Hoyte FC, Safioti G, Brown R, Hill TD, Li T, et al. Effectiveness of a maintenance and reliever Digihaler system in asthma: 24-week randomized study (CONNECT2). J Allergy Clin Immunol Pract 2024 Mar;12(2):385-95.e4 [FREE Full text] [doi: 10.1016/j.jaip.2023.11.037] [Medline: 38040117]
55. Ruuls T, Sprengers R, Hengeveld V, Thio B, Tabak M, Zagers D, et al. Cohort multiple randomized controlled trial in pediatric asthma to assess the long- and short-term effects of eHealth interventions: protocol of the CIRCUS study. Ther Adv Respir Dis 2025 Mar 12;19:17534666251323192 [FREE Full text] [doi: 10.1177/17534666251323192] [Medline: 40071339]
56. Nyirimanzi N, Bransi M, Counil FP, Drouin O, Gravel J, Hicks A, et al. Using mHealth to predict asthma exacerbations in children and adolescents (Mobile Health for Kids with Asthma): protocol for an observational study. JMIR Res Protoc 2025 Oct 11;14:e70517 [FREE Full text] [doi: 10.2196/70517] [Medline: 40934499]
57. 2022 GINA main report. Global Initiative for Asthma. URL: https://ginasthma.org/gina-reports/ [accessed 2024-04-16]
58. Rhee H, Love T, Wicks MN, Tumiel-Berhalter L, Sloand E, Harrington D, et al. Long-term effectiveness of a peer-led asthma self-management program on asthma outcomes in adolescents living in urban areas: a randomized clinical trial. JAMA Netw Open 2021 Dec 01;4(12):e2137492 [FREE Full text] [doi: 10.1001/jamanetworkopen.2021.37492] [Medline: 34874404]
59. ChatGPT. URL: https://chatgpt.com/ [accessed 2025-05-04]

Abbreviations

ACT: Asthma Control Test
C-ACT: Childhood Asthma Control Test
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
FEV1: forced expiratory volume in 1 second
GINA: Global Initiative for Asthma
IMAGINE: Improving Adherence by Guiding Inhalation via Electronic Monitoring
LFV: lung function variability
predFEV1: predicted forced expiratory volume in 1 second

XSL•FO
RenderX

Edited by S Badawy; submitted 04.06.25; peer-reviewed by M Gholamzadeh, D Drummond; comments to author 10.09.25; revised version received 17.09.25; accepted 14.10.25; published 14.11.25.

Please cite as:
Sportel E, Movig K, Thio B, Van der Kamp M, Van der Palen J, Brusse-Keizer M
Guided Inhalation via Electronic Monitoring in Children With Uncontrolled Asthma (the IMAGINE Study): Randomized Controlled Trial
JMIR Pediatr Parent 2025;8:e78526
URL: https://pediatrics.jmir.org/2025/1/e78526
doi:10.2196/78526
PMID:

©Esther Sportel, Kris Movig, Bernard Thio, Mattienne Van der Kamp, Job Van der Palen, Marjolein Brusse-Keizer. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 14.11.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Exploring the Impact of Perceived Parental Oversight on Problematic Smartphone Use Among Adolescents in the Digital Age: Database Analysis

Mary Ho[1,2*], MS; Peter Johannes Schulz[1,3*], PhD; Angela Chang[4], PhD

[1]Institute of Communication and Public Policy, Faculty of Communication, Culture and Society, Università della Svizzera Italiana, Lugano, Switzerland
[2]Department of Public Health and Medical Administration, Faculty of Health Sciences, University of Macau, Taipa, Macao, China
[3]Wee Kim Wee School of Communication and Information (WKWSCI), Nanyang Technological University, Singapore, Singapore
[4]Department of Communication, Faculty of Social Sciences, University of Macau, E21-2056, Avenida da Universidade, Taipa, Macao, China
[*]these authors contributed equally

Corresponding Author:
Angela Chang, PhD
Department of Communication, Faculty of Social Sciences, University of Macau, E21-2056, Avenida da Universidade, Taipa, Macao, China

Abstract

Background: The proliferation of smartphones raises worries over their impact on adolescent development, especially problematic smartphone use. This research investigates the intricacies of problematic smartphone usage in adolescents, particularly in light of significant increases in screen time, from a developmental psychology perspective.

Objective: This study aimed to examine the association between adolescent-perceived parental monitoring strategies and problematic smartphone use in Taiwan, while also exploring variations across age, gender, and socioeconomic status.

Methods: A nationwide dataset from Taiwan's annual survey (n=1673; aged 10 - 18 y) was analyzed using descriptive analysis and moderated multiple serial mediation regression. In total, 3 parental mediation styles—restrictive monitoring, evaluative mediation, and unfocused monitoring—were examined for their effects on smartphone usage.

Results: Rigorous surveillance is more beneficial for younger adolescents (aged 10 - 12 y), significantly reducing smartphone addiction. Conversely, as teenagers mature, the efficacy of restrictive approaches wanes. Adolescents aged 16-18 years benefit more from parental mediation strategies that foster autonomy and encourage appropriate digital conduct. Restrictive monitoring significantly diminishes addiction by constraining internet access; yet, the diverse outcomes of assessment methods highlight the importance of qualitative engagement. Conversely, unfocused surveillance is ineffective, necessitating the use of targeted parental strategies.

Conclusions: This study highlights the significance of developmentally suitable parental strategies to mitigate digital addiction and enhance teenage self-regulation. We urge policymakers to implement age-specific, evidence-based methods to improve digital literacy and overall well-being in youth. Future research should investigate the enduring psychological and behavioral impacts of parental mediation and analyze cross-cultural differences in digital parenting methodologies.

(JMIR Pediatr Parent 2025;8:e75837) doi:10.2196/75837

KEYWORDS

problematic smartphone use; parental monitoring strategies; adolescent digital behavior; developmental differences; socioeconomic factors; mobile phone

Introduction

Background

In the digital era, smartphones have become indispensable tools for communication, education, and entertainment. Among adolescents, smartphone penetration is rapidly increasing, with more than 80% of individuals aged 12-17 years owning such devices [1]. While digital access fosters connectivity and learning, it also presents growing concerns about problematic smartphone use (PSU), characterized by compulsive checking, excessive screen time, and withdrawal symptoms upon separation [2,3]. PSU has been associated with disrupted sleep, impaired academic performance, and hindered emotional development, establishing it as a pressing public health issue.

Previous studies suggest rising smartphone addiction among adolescents, with prevalence rates ranging from 10% in the United Kingdom to more than 30% in South Korea [4,5]. Moreover, the COVID-19 pandemic significantly reshaped

XSL•FO
RenderX

digital media usage. Remote learning, physical distancing, and prolonged home confinement have intensified adolescents' reliance on digital devices for social interaction and emotional coping [6]. This shift has sparked increased risks of excessive use and internet addiction, with adolescents turning to social media and gaming to alleviate pandemic-induced stress and loneliness [7,8]. These behavioral shifts are particularly concerning given adolescents' developmental vulnerabilities, such as immature impulse control and heightened sensitivity to peer influence [9].

Parental mediation is a critical factor influencing adolescent digital engagement and well-being. Empirical evidence consistently demonstrates that parental involvement is associated with a reduction in adolescents' risky online behaviors and problematic media use [10,11]. Specifically, studies have established a significant, although complex, association between various parental mediation strategies (eg, restrictive, active, and technical mediation) and attitudes, as well as reduced levels of adolescent problematic media habits [12-15]. Strategies such as screen-time limits, content monitoring, and open communication are commonly used, yet the effectiveness of these measures may be mediated by adolescents' perceptions of control and autonomy [15]. Thus, the parent-adolescent dynamic and the child's perception of mediation are crucial variables determining its success.

Theoretical models like parental mediation theory emphasize that youth interpretations of parental actions, whether perceived as autonomy-supportive or controlling, determine their behavioral responses [16,17]. Recent studies continue to apply these models to examine how evolving parental strategies shape adolescents' online experiences [18]. Although pioneering work has begun to effectively incorporate adolescent perspectives on parental mediation, particularly concerning social media use [19,20], research on smartphone-specific problematic use (PSU) continues to rely more heavily on parents' self-reported practices. Consequently, the adolescent's subjective experience of mediation strategies applied to the unique challenges of smartphone use remains less explored. This limits the development of tailored, context-sensitive approaches to digital well-being.

Goal of This Study

This study aims to examine the association between perceived parental oversight and PSU among adolescents, guided by parental mediation theory. By integrating quantitative assessments of PSU with adolescents' subjective interpretations of parental strategies, the research seeks to illuminate how different mediation styles influence digital behavior. The findings will inform interventions that align more closely with youths' psychological needs, especially in contexts shaped by increased digital dependency, such as during public health crises. In doing so, this study positions parental oversight as a dynamic and influential factor in designing effective interventions for adolescent digital well-being.

Literature Review

Adolescent media use significantly influences psychological well-being, with excessive screen exposure linked to body dissatisfaction, anxiety, and distraction [21-23]. During the COVID-19 pandemic, digital reliance intensified, exacerbating emotional vulnerability and compulsive behaviors [6,7]. While mobile technology offers educational and social benefits, unregulated use can harm development, particularly in environments lacking effective parental mediation [24,25]. Cross-national studies reveal varied addiction rates, underscoring sociocultural and familial influences [5]. Despite the known risks, few studies integrate youth perceptions of parental oversight into intervention frameworks. To address this, this study draws on 2 complementary theoretical frameworks. First, family systems theory posits that individual behavior, including media use, is shaped within the dynamics of the family unit. Parent-child interactions, including monitoring strategies, are seen as bidirectional and mutually influential, making parental mediation a relational, rather than merely regulatory, process [26,27]. Also, the positive youth development (PYD) framework emphasizes the importance of nurturing environments and adult support in fostering adolescents' internal assets, such as self-regulation and resilience [28]. From this view, autonomy-supportive parental involvement can help adolescents build healthy digital habits. The existing research attempts to bridge the research gap by synthesizing family systems theory with PYD, positioning parental supervision as a dynamic moderator of self-regulated smartphone engagement (SRSE) [16,17]. Their approach reframes oversight not as a static constraint but as a modifiable factor that shapes the efficacy of SRSE-based interventions.

PSU and Adolescent Health Risks

The increasing ubiquity of smartphones has reshaped adolescent behavior and well-being. While moderate digital engagement can foster social connection and access to diverse information [29,30], excessive and unregulated use contributes to a range of psychosocial challenges. PSU refers to a behavioral pattern characterized by compulsive use, impaired control, and continued use despite experiencing negative consequences in daily functioning [24,25,31]. Common manifestations include preoccupation with the device, withdrawal symptoms (eg, anxiety when separated from it), tolerance (needing increased use for satisfaction), and a significant disruption to academic, social, or sleep routines [32,33].

Adolescents are a particularly vulnerable population for PSU. Empirical studies have consistently linked PSU to adverse outcomes, including diminished mental well-being, reduced self-esteem, sleep disturbances, academic difficulties, and increased feelings of loneliness [23,34-37]. The COVID-19 pandemic intensified digital reliance, especially among youth, exacerbating digital overexposure and mental health strains [6,7]. In Taiwan, smartphone usage surpasses 94.9% [38], raising significant concerns about youth digital addiction. The prevalence of smartphone addiction in adolescents much surpasses that in adults, with estimates suggesting that 1 in 3 teenagers is at risk [38].

Previous studies explore the implications of smartphone use among different age groups, highlighting the associated health risks of PSU among adolescents. Park and Park [39] introduce a conceptual model of smartphone addiction specifically

XSL•FO
RenderX

targeting early childhood, discussing factors that contribute to the development of compulsive smartphone behaviors and their potential impacts on young children's social and cognitive development. In contrast, 1 study [40] conducted a cross-sectional survey focusing on middle- and high-school students in China, revealing the prevalence of PSU within this demographic and identifying significant correlations with mental health issues, academic performance, and social interactions. Together, these studies underscore the need for targeted interventions to mitigate the risks associated with excessive smartphone use and promote healthier digital habits among adolescents.

Sex-based differences also shape PSU patterns. While males more frequently engage in compulsive gaming and exposure to violent content [41], females report higher levels of internalizing symptoms, such as anxiety and depression, due to screen overuse [36,37]. These variations suggest the importance of tailored strategies in addressing PSU across demographic groups.

In addition, adolescents' perceptions of parental oversight, whether controlling or autonomy-supportive, can significantly moderate the outcomes of interventions targeting smartphone habits [16,17]. As such, understanding PSU requires a multifaceted perspective that incorporates developmental, behavioral, and social determinants. Effective responses should consider not only individual behaviors but also relational factors, particularly the evolving role of parents in managing adolescents' digital environments.

Predicting Digital Behaviors

Parental monitoring has emerged as a key factor influencing adolescents' digital engagement and their susceptibility to PSU [10,11]. Parental monitoring is traditionally defined as parental efforts to supervise and regulate children's activities, including digital media use [42,43], and updated with reduced exposure to online risks such as violent content, gambling, and inappropriate interactions in the current digital era [44,45]. Scholars commonly categorize parental mediation into 3 distinct types. The first category is restricted mediation. This involves setting rules and limits governing screen time or access to specific apps and content [10,43]. Evaluative mediation, often referred to as educational or active mediation, involves parent-child discussions about media content aimed at fostering critical understanding and resilience [10,43,46]. Unfocused mediation describes co-use without explicit educational or restrictive intent, often characterized by shared but unsupervised media consumption [43]. One of the research gaps in the existing research usually relies on parents' self-reported practices, overlooking the impact of adolescents' subjective perceptions.

Recent studies highlight that the effectiveness of parental supervision hinges not only on behavioral enforcement but also on how adolescents interpret these efforts. Perceived overcontrol may elicit resistance, while autonomy-supportive practices foster self-regulation [16,17]. For instance, research in Taiwan found no significant association between parental monitoring and adolescent smartphone addiction, suggesting that the mere presence of supervision does not guarantee behavioral change [47]. Furthermore, some data show that heightened parental control may paradoxically increase digital risk-taking when perceived as intrusive [48,49].

Given the inconsistencies across contexts and measurement approaches, this study centers on adolescents' perceived parental monitoring rather than parental self-report. By capturing children's subjective experiences, this research seeks to clarify how parental regulation interacts with psychological factors to shape digital behavior, offering a more dynamic understanding of preventive strategies in adolescent technology use. Thus, the first hypothesis is raised, which states that adolescents' perceptions of higher restrictive, evaluative, and unfocused parental supervision will be associated with lower levels of (1) daily internet usage and (2) PSU.

Family Structures

Sex

Parents are anticipated to use distinct regulatory approaches with male as opposed to female children in accordance with the sex roles established within their society. Research suggests that parents use distinct control tactics based on the gender of their children, and the degree to which this occurs varies between fathers and mothers. For instance, research has shown that parents give less independence to their girls and protect them more than boys [50]. Moreover, research on adolescents' media use of several kinds revealed that females were more likely than boys to have phone-using restrictions [51]. However, some research reported that parents tend to supervise their male children to a somewhat higher degree compared with their female children [52]. Some others have discovered that there is no discernible disparity in parental supervision based on the gender of the child [53].

Currently, there is a scarcity of evidence and inconclusive findings about the impact of parental mediation on cell phone addiction in children, specifically in relation to gender disparities. Based on the discussions made in the previous research, the objective of this study is to investigate the following research question (RQ) and propose one hypothesis to guide our analysis.

RQ1 was to examine how adolescents' genders impact parental supervision and the prevalence of internet use and mobile phone addiction among teenagers.

Hypothesis 2 states that parental monitoring has a greater impact on girls' intention to use the internet and their levels of mobile phone addiction compared with boys.

Age

Monitoring by parents elicits varied responses from children of different age groups. Not surprisingly, evidence regularly demonstrates that parents supervise the television and media consumption of their younger children to a greater extent than they do with their older children [54]. Furthermore, due to the concern that younger children are more prone to acquiring mobile phone addiction, research suggests that parents are more inclined to implement restrictive mediation and evaluative mediation with their younger children [39,53,55].

XSL•FO
RenderX

To go deeper into the studies of specific ages and the effect of parental monitoring differences, 1 study [56] done in Korea in 2015 proved that parents usually use restrictive mediation to monitor their kids in elementary school. A later study [57] in 2018 highlights that higher restrictive parental monitoring is correlated with a lower risk of mobile phone addiction among adolescents aged 11-13 years. Similar results were also found from a study by Chang and other researchers [47] who surveyed 2621 kids and 2468 parents from the main cities of Taiwan. They indicated that only the restrictive parental monitoring mediation could effectively decrease smartphone addiction risks among fifth-grade kids (aged 10-11 y). Accordingly, similar results are also found among middle-school and high-school kids (age range from 14 to 19 y old) in China, Japan, Thailand, and Portugal; their results suggested that parental neglect was significantly positively associated with adolescents' mobile phone addiction, and perceived parental monitoring of smartphones was negatively related to adolescent mobile phone addiction [58-61].

The study investigates the threshold at which the efficacy of parental monitoring starts to decline or vanish to discover whether age is a significant mediator. Thus, RQ2 and another hypothesis (hypothesis 3) of the effectiveness of parental monitoring are raised:

RQ2 seeks an answer to whether parental monitoring has universal effectiveness across adolescents of varying ages, and at what age does the effectiveness of parental monitoring begin to diminish or disappear.

Hypothesis 3 states that younger adolescents experience higher levels of parental monitoring regarding their internet usage and mobile phone addiction compared with older adolescents.

Income and Parental Educational Level

Family socioeconomic status, particularly parental income and education, plays a significant role in shaping adolescents' vulnerability to smartphone addiction. Previous research demonstrates that lower household income and parental education are associated with higher risks of problematic mobile phone use in adolescents [62,63]. A scoping review [64], synthesizing findings from 67 studies, supports this trend by identifying socioeconomic disadvantage as a consistent predictor of mobile phone addiction. Parents with limited education may lack awareness of the psychological risks associated with excessive smartphone use, increasing the likelihood of early and unrestricted access [65]. Financial constraints may also reduce parental capacity to offer alternative recreational or social resources, leading to greater screen dependence among youth [66]. Without access to structured extracurricular activities or supervised community spaces, adolescents from lower-income households may rely more heavily on smartphones for entertainment and socialization, thereby increasing their risk of problematic use.

The connection between socioeconomic status and parental mediation remains inconclusive. Previous studies suggest that adolescents from higher socioeconomic backgrounds may exhibit elevated levels of digital dependency, driven by feelings of isolation or pressure to remain socially connected via advanced devices [65,67]. This duality highlights the need for a nuanced understanding of how different economic and cultural contexts shape digital behaviors. While some research reports no significant association [68], others suggest that low-income families may favor restrictive or evaluative mediation strategies [69,70]. These inconsistencies underscore the complex interplay between structural constraints and parenting styles, emphasizing the need to account for family background when designing interventions for adolescent smartphone addiction. Thus, 2 RQs (RQ 3 and RQ 4) and 2 hypotheses are raised.

RQ3 aims to examine whether there is a relationship between household income and the practice of parental monitoring styles, and how this relationship affects adolescent mobile phone addiction. RQ4 aims to examine whether there is a relationship between parental education levels and the practice of parental monitoring styles, and how this relationship affects adolescent mobile phone addiction.

Hypothesis 4 states that higher household income is associated with more effective parental monitoring styles, which in turn reduces the vulnerability to mobile phone addiction among Taiwanese adolescents aged 10-18 years. Hypothesis 5 states that higher parental education levels are associated with more effective parental monitoring styles, which in turn reduces the vulnerability to mobile phone addiction among Taiwanese adolescents aged 10-18 years.

Methods

Ethical Considerations

Our study is a secondary data analysis based on the Taiwan Communication Survey (TCS), a nationally representative dataset administered by the Institute of Sociology, Academia Sinica (Taipei, Taiwan). The dataset was fully anonymized before public release and made available for academic research. The Academia Sinica Humanities and Social Science Research Ethics Committee reviewed and approved the project "Taiwan Communication Survey – Phase II, Year 4-5" under approval AS-IRB-HS-19027. This study used data from this approved project.

During the original data collection, written informed consent was obtained from all adolescent participants and their legal guardians before participation. To protect participants' privacy, personally identifiable information was anonymized and restricted to use only during the implementation period of the TCS. Upon study completion, all physical and digital contact lists were destroyed and archived on record. Furthermore, participant information was strictly handled in an anonymized form and used solely for academic research purposes.

Participants received a gift card worth NT $100 (approximately US $3.2) upon completion of the survey as a token of appreciation. No additional compensation, insurance, or risk-related arrangements were deemed necessary due to the minimal risk nature of school-based data collection.

XSL•FO
RenderX

Research Design

The predicted number of smartphone users in Taiwan is expected to reach 20.81 million by 2029, representing an increase of 0.7 million individuals [71].

The TCS project has been using structured questionnaire surveys and interview methods at the national level since 2012. The data used in this study were extracted from the TCS database available through the website [72] to learn the trend of media usage, social engagement, and social capital concern. TCS is a research program supported by the Government's Ministry of Science and Technology to conduct an annual survey of the population with representative samples. It centers on monitoring shifts in consumption media patterns. Besides media use data analysis, the survey uses several specialized modules to discover current trends in health communication.

Procedure

The TCS cohort project used a mixed methods approach, combining quantitative and qualitative interviews to comprehensively examine young users' online information-seeking behaviors. The TCS report indicates that the sample selection included a multistage and stratified random methodology to guarantee a representative cross-section of participants [73]. The approach involved a substantial number of students who completed a survey, offering insights into their preferences, sources, and motivations for accessing online knowledge. In a subsequent study, certain respondents were invited to participate in qualitative interviews, facilitating a more profound examination of their experiences and perceptions regarding online information.

The TCS project and data collection received approval from the members of the Taiwan Institutional Review Board before implementation. All data were gathered from September to October 2020. Trained supervisors who conducted the survey were mandated to visit the sampling classes at 62 schools across the nation.

A total of 1696 respondents aged 9-18 years included 19 elementary schools with 446 valid surveys and 20 junior high schools with 582 valid responses. A total of 15 secondary schools and 8 technical high schools were selected for sampling from high school students. A total of 668 surveys were completed. Data from participants aged 9-18 years in the 2020 TCS project were collected. To maintain analytical consistency aligned with the study's objective, individuals aged 10-18 years were examined in this research (n=1673). The research achieved a confidence level of 95%, with a sampling error not exceeding 2.38%.

Measurements

Parental Monitoring

This analysis examines the potential influences on the relationship between parental monitoring and mobile phone addiction, focusing on PSU, parental monitoring, and demographic factors. Parental mediation consists of 3 components: restrictive mediation (questions 1 to 3, Cronbach α coefficient=0.761), evaluative mediation (questions 5 and 6, Cronbach α coefficient=0.674), and unfocused mediation (question 4). Restrictive mediation encompasses parental limitations on specific websites, regulations regarding media consumption, and imposed time constraints. Evaluative mediation entails parents engaging with media and subsequently discussing their usage and experiences with their children. Unfocused mediation denotes a parental approach in which children are encouraged to use media without any form of guidance or limitations.

PSU

The evaluation of mobile phone addiction was conducted using 5 questions that used a 5-point scale, ranging from "I strongly disagree" to "I strongly agree." The final PSU score represents the average (mean) of the 5 items, where higher scores indicate greater levels of mobile phone addiction. These questions were designed to evaluate the participants' behavior and their views on the use of mobile phones. Items assessed loss of control, functional impairment, and preoccupation (eg, "You daydream about your phone"). The formation of these 5 questions was done following previous studies on PSU [74]. The purpose of these questions was to assess the participants' behaviors and views regarding mobile phones. The Cronbach α coefficient for 5 questions is 0.769, and the McDonald omega is 0.788.

Sociodemographic Characteristics

The demographic data included age, gender, school grade, parental educational achievement, family income level, and marital status. In addition to descriptive results, multiple linear regression analysis and moderated multiple serial mediation analyses unveiled the substantial predictive capacity of sociodemographic characteristics and general parental supervision in shaping internet usage and effects on mobile phone addiction. Concretely, the regression models explained how and to what extent each of the demographic variables influenced the relationship between parental monitoring and mobile phone addiction. Demographic variables like age, gender, parents' education levels, and household income were identified as significant factors influencing individuals' internet usage, PSU, and parent monitoring.

This comprehensive methodology, involving meticulous sampling, data collection over various time periods in 2020, and advanced statistical analysis, serves as the foundation for understanding the intricate relationship between demographic factors and online information-seeking behavior within the context of the specified information categories. The complete list of variables, their descriptions, question phrasing, and scaling details can be found in Multimedia Appendix 1.

Data Processing

The statistical software IBM SPSS 29 was used to perform both descriptive and regression analyses of the collected data. Descriptive statistics were used as measures of overview tendencies to give general information regarding the frequencies and general patterns regarding internet usage, mobile phone addiction, and parental supervision among adolescents.

Besides descriptive analysis, multiple linear regression analysis, and moderated multiple serial mediation analyses unveiled the substantial predictive capacity of sociodemographic

XSL•FO
RenderX

characteristics and general parental supervision in shaping internet usage and effects on smartphone addiction. Concretely, the regression models explained how and to what extent each of the demographic variables—age, gender, parents' education levels, and household income—influenced the relationship between parental monitoring and smartphone addiction.

Results

Descriptive Statistics

An analysis of internet and digital device usage patterns was performed among children and teenagers in 2020. A total of 1673 valid data were evaluated. It is found that 92.3% (n=1545) of children and teenagers accessed the internet in Taiwan, among the respondents, with a mean age of 13.31 (SD 2.294) years. Out of the total number of respondents, 51.8% (n=867) were male and 48.2% (n=806) were female. A significant proportion of the participants' parents possessed a high school diploma or a higher level of education, specifically 29.2% (n=488) and 27% (n=451), respectively, with a total sample size of 939. Approximately 73.7% of respondents, namely 1233 individuals, believe that their household income level is relatively affluent. Among adolescents, 83.9% (n=1423) own mobile phones and 92% (n=1561) use their mobile phones to access the internet. The mean score of PSU was 3.29 (SD 0.84). The descriptive results for parental monitoring revealed that restrictive mediation had a mean score of 2.39 (SD 0.90), followed by evaluative mediation with a mean of 2.22 (SD 0.86), and unfocused mediation with a mean of 2.11 (SD 0.95). Multimedia Appendix 2 provides the statistical information for adolescent respondents from Taiwan in 2020.

Effects of Parental Monitoring

Among the 3 types of parental monitoring, restrictive monitoring was the most effective. This approach had a significant indirect effect on mobile phone addiction through decreased internet usage (b=−0.029, SE 0.007, 95% CI −0.044 to −0.017). The direct effect of restrictive monitoring on phone addiction (controlling for internet use) was significant (b=−0.154, SE 0.024, P<.001). Further analysis showed that restrictive monitoring significantly decreased internet usage (b=−0.338, SE 0.036, P<.001). These findings confirm that reducing screen time is a key pathway by which strict parental rules help lower mobile phone dependency.

In contrast, evaluative monitoring, which involves discussing media use with teens, had mixed effects. It was associated with slightly higher internet use (b=0.090, SE 0.038, P=.02), but its direct effect on phone addiction was not statistically significant (b=−0.037, SE 0.024, P=.13). This suggests that while open communication may encourage greater digital engagement, it does not necessarily reduce problematic mobile phone use.

Unfocused monitoring, where parents offer little structure or guidance, was linked to higher internet use (b=0.145, SE 0.035, P<.001) but showed no significant effect on mobile phone addiction (b=−0.010, SE 0.022, P=.66). This indicates that inconsistent or vague monitoring is ineffective at managing digital behavior.

These findings partially support the first hypothesis that parental monitoring helps prevent mobile phone addiction among adolescents. Concretely, restrictive monitoring was the most effective in reducing both internet use and phone addiction. While restrictive monitoring was protective, both evaluative and unfocused monitoring were associated with increased internet use, which in turn was linked to higher levels of PSU. Table 1 provides the details of the regression analysis illustrating the impact of parental monitoring and internet usage on mobile phone addiction.

XSL•FO
RenderX

Table . The bootstrap results of the moderated multiple serial mediation model.

Path	Mobile phone addiction (Y), b (SE)	*t* (*df*)	*P* value	Bootstrapped 95% CI
Parent monitor_ restrictive (X) n=1584				
Direct effect (X→Y)	−0.154 (0.024)	−6.477 (1582)	<.001	−0.201 to −0.108
Direct effect (X→internet use)	−0.338 (0.036)	−9.340 (1582)	<.001	−0.408 to −0.267
Indirect effect (X→internet use→Y)	−0.029 (0.007)	—[a]	—	−0.044 to −0.017
Parent monitor_ evaluative (X) n=1584				
Direct effect (X→Y)	−0.037 (0.024)	−1.515 (1582)	.13	−0.084 to 0.011
Direct effect (X→internet use)	0.090 (0.038)	2.365 (1582)	.02	0.015 to 0.165
Indirect effect (X→internet use→Y)	0.010 (0.005)	—	—	0.001 to 0.020
Parent monitor_ unfocused (X) n=1584				
Direct effect (X→Y)	−0.010 (0.022)	−0.445 (1582)	.66	−0.053 to 0.034
Direct effect (X→internet use)	0.145 (0.035)	4.207 (1582)	<.001	0.078 to 0.213
Indirect effect (X→internet use→Y)	0.016 (0.005)	—	—	0.008 to 0.026

[a]Not applicable.

Variable of Sex

Sex does not moderate the effect of any form of parental monitoring; for instance, restrictive monitoring, internet use, and mobile phone addiction (b=0.0008, SE 0.009, 95% CI −0.019 to 0.019). When sex was introduced into the analysis, it was revealed that it had no effect on the relationship between the level of parental monitoring, internet use, and mobile phone addiction. Thus, it was found that there was a lack of sex differences in terms of perceived parental monitoring, internet use, and mobile phone addiction. This result, illustrated in Table 2, failed to reject the null hypothesis of the second hypothesis, which proposed that girls were likely to experience more parental monitoring than boys in the use of the internet and mobile phone addiction.

Table . The bootstrap results of the moderated multiple serial mediation of sex and age for mobile phone addiction.

Path	Mobile phone addiction (Y), b (SE)	*t* (*df*)	*P* value	Bootstrapped 95% CI
Parent monitor_ restrictive (X)[a] n=1584				
Direct effect	−0.163 (0.036)	−4.522 (1582)	<.001	−0.2234 to −0.092
Indirect effect (X→internet use→Y)	0.0008 (0.009)	—[b]	—	−0.019 to 0.019
Parent monitor_ evaluative (X)[c] n=1584				
Direct effect	−0.101 (0.038)	−2.633 (1582)	.008	−0.177 to −.026
Indirect effect (X→internet use→Y)	0.019 (0.013)	—	—	−0.007 to 0.046
Parent monitor_ unfocused (X)[d] n=1584				
Direct effect	−0.053 (0.033)	−1.588 (1582)	.11	−0.120 to 0.012
Indirect effect (X→internet use→Y)	0.019 (0.011)	—	—	−0.003 to 0.043

[a]X* Gender (W): R^2=0.001, *P*=.14, *F*=2.164.

[b]Not applicable.

[c]X* Gender (W): R^2=0.0002, *P*=.60, *F*=0.282.

[d]*X* Gender (W):* R^2=0.001, *P*=.18, *F*=1.830.

XSL•FO
RenderX

Variable of Age

The influence of internet usage on PSU differed depending on the age group. Internet use was found to be a significant predictor of mobile phone addiction among teenagers aged 10-14 years. However, this prediction was not significant for those aged 15-18 years. Among 10-year-olds, heightened unfocused parental monitoring had a significant negative effect on mobile phone addiction (b=−0.333, SE 0.160, t_{51}=−2.084, *P*=.04). This indicates that unfocused parental monitoring can lower mobile phone addiction, but it did not have a significant influence on internet usage.

Concomitantly, 11-year-old users' heightened restrictive parental monitoring led to a substantial decrease in internet usage and mobile phone addiction (b=−0.066, SE 0.028, 95% CI −0.129 to −0.019). Furthermore, restrictive monitoring also has a negative direct impact on the development of mobile phone addiction (b=−0.185, SE 0.085, t_{189}=−2.173, *P*=.03). Additionally, evaluative monitoring negatively correlated with mobile phone addiction (b=−0.164, SE 0.071, t_{189}=−2.322, *P*=.02). In contrast, unfocused mediation did not exert a substantial direct impact on mobile phone addiction.

Among 12-year-olds, implementing stricter parental monitoring (restrictive monitoring) resulted in a substantial decrease in internet usage (b=−0.033, SE 0.017, 95% CI −0.073 to −0.038). However, restrictive parental monitoring did not have a significant effect on mobile phone addiction. On the other hand, when parents are using unfocused monitoring, there is a substantial rise in internet usage. Additionally, higher levels of internet usage are associated with a greater likelihood of developing mobile phone addiction (b=0.042, SE 0.018, 95% CI 0.011-0.083).

Among 13-year-olds, stricter parental monitoring (restrictive monitoring) was found to be directly linked to a decrease in mobile phone addiction (b=−0.240, SE 0.073, t_{226}=−3.288, *P*=.001). Users among 16-year-olds with heightened unfocused parental monitoring have a significant negative impact on internet usage. However, unfocused did not have a significant effect on mobile phone addiction (b=−0.004, SE 0.007, 95% CI −0.022 to 0.008).

The findings support hypothesis 3, indicating that younger adolescents benefit more from restrictive parental monitoring in reducing both internet usage and mobile phone addiction, while older adolescents are less affected by such monitoring techniques. The results imply that there are differences in various types of parental supervision regarding the age of the child. The effects of parental oversight are not uniform on both internet use and mobile phone dependency, which answered the RQ2. Table 3 displays the overview of results for the significant result of synergy of the mediation effects for age groups 10 to 13 and 16 as identified in this study.

XSL•FO
RenderX

Table . Overview of the bootstrap results of the moderated multiple serial mediation for mobile phone addiction.

Path	Mobile phone addiction (Y), b (SE)	*t* (*df*)	*P* value	Bootstrapped 95% CI
10-year-old (n=53)				
Parent monitor_Restrictive (X)				
Direct effect	−0.174 (0.164)	−1.064 (51)	.29	−0.504 to 0.155
Indirect effect (X→internet use→Y)	−0.092 (0.072)	—[a]	—	−0.246 to 0.046
Parent monitor_Evaluative (X)				
Direct effect	−0.153 (0.168)	−0.908 (51)	.37	−0.492 to 0.185
Indirect effect (X→internet use→Y)	0.084 (0.104)	—	—	−0.029 to 0.364
Parent monitor_Unfocused (X)				
Direct effect	−0.333 (0.160)	−2.084 (51)	.04	−0.655 to −0.012
Indirect effect (X→internet use→Y)	0.077 (0.063)	—	—	−0.070 to 0.188
11-year-old (n=191)				
Parent monitor_Restrictive (X)				
Direct effect	−0.185 (0.085)	−2.173 (189)	.03	−0.354 to −0.017
Indirect effect (X→internet use→Y)	−0.066 (0.028)	—	—	−0.129 to −0.019
Parent monitor_Evaluative (X)				
Direct effect	−0.164 (0.071)	−2.322 (189)	.02	−0.304 to 0.024
Indirect effect (X→internet use→Y)	0.0004 (0.021)	—	—	−0.042 to 0.046
Parent monitor_Unfocused (X)				
Direct effect	0.008 (0.066)	0.122 (189)	.90	−0.122 to 0.139
Indirect effect (X→internet use→Y)	0.036 (0.023)	—	—	−0.0008 to 0.089
12-year-old (n=303)				
Parent monitor_Restrictive (X)				
Direct effect	−0.076 (0.073)	−1.045 (301)	.30	−0.221 to 0.067
Indirect effect (X→internet use→Y)	−0.033 (0.017)	—	—	−0.073 to −0.003
Parent monitor_Evaluative (X)				
Direct effect	−0.089 (0.063)	−1.397 (301)	.16	−0.214 to 0.036
Indirect effect (X→internet use→Y)	0.011 (0.012)	—	—	−0.010 to 0.038
Parent monitor_Unfocused (X)				
Direct effect	−0.133 (0.063)	−2.112 (301)	.04	−0.258 to 0.009
Indirect effect (X→internet use→Y)	0.042 (0.018)	—	—	0.011 to 0.083

XSL•FO
RenderX

Path	Mobile phone addiction (Y), b (SE)	*t* (*df*)	*P* value	Bootstrapped 95% CI
13-year-old (n=228)				
Parent monitor_Restrictive (X)				
Direct effect	−0.240 (0.073)	−3.288 (226)	.001	−0.384 to −0.096
Indirect effect (X→internet use→Y)	−0.013 (0.014)	—	—	−0.047 to 0.010
Parent monitor_Evaluative (X)				
Direct effect	−0.102 (0.080)	−1.275 (226)	.20	−0.259 to 0.055
Indirect effect (X→internet use→Y)	0.019 (0.019)	—	—	−0.010 to 0.068
Parent monitor_Unfocused (X)				
Direct effect	−0.004 (0.069)	−0.060 (226)	.95	−0.141 to 0.132
Indirect effect (X→internet use→Y)	0.023 (0.014)	—	—	−0.0003 to 0.054
16-year-old (n=281)				
Parent monitor_Restrictive (X)				
Direct effect	−0.069 (0.069)	−0.993 (279)	.32	−0.206 to 0.068
Indirect effect (X→internet use→Y)	−0.003 (0.007)	—	—	−0.020 to 0.010
Parent monitor_Evaluative (X)				
Direct effect	−0.065 (0.058)	−1.129 (279)	.26	−0.180 to 0.048
Indirect effect (X→internet use→Y)	0.0003 (0.004)	—	—	−0.007 to 0.009
Parent monitor_Unfocused (X)				
Direct effect	0.026 (0.052)	0.500 (279)	.62	−0.076 to 0.128
Indirect effect (X→internet use→Y)	−0.004 (0.007)	—	—	−0.022 to 0.008

[a]Not applicable.

Household Income and Parents' Education

Parental use of restrictive monitoring is influenced by 2 main factors: household income and the mother's education level. Higher-income families are more likely to adopt restrictive strategies, which effectively reduce adolescent smartphone addiction. The analyses revealed that the mediator (restrictive mediation) and income (X) were significant predictors of mobile phone addiction (b=−0.022, SE 0.010, 95% CI −0.043 to −0.003). It is found that households with higher incomes tend to use restrictive control measures, which successfully reduce the likelihood of cell phone addiction among adolescents.

The findings also show that higher-income families are more likely to use evaluative mediation, which involves discussing phone use with their children. This approach was positively associated with wealth (b=0.189, SE 0.037, t_{1582}=5.060, P<.001). Similarly, there was a positive association between higher household income (b=0.092, SE 0.041, t_{1582}=2.228, P=.03) and increased use of unfocused mediation. The findings indicate that specific socioeconomic characteristics have an impact on the evaluative and unfocused type of parental supervision used, but they do not have an indirect influence on the decreasing probability of adolescent mobile phone addiction. The third RQ delves into the intricate relationship between income, mobile phone addiction, and internet usage patterns. Table 4 displays the results of the third RQ and fourth hypothesis, which answered the mediation relationship between income, mobile phone addiction, and restrictive parental monitoring.

XSL•FO
RenderX

Table . The bootstrap results of income of the moderated multiple serial mediation model.

Path (income [X], n=1584)	Mobile phone addiction (Y), b (SE)	*t* (*df*)	*P* value	Bootstrapped 95% CI
PM_restrictive				
Direct effect (X →Y)	−0.087 (0.040)	−2.154 (1582)	.03	−0.166 to −0.078
Direct effect (X →PM_restrictive)	0.092 (0.038)	2.395 (1582)	.02	0.016 to 0.168
Indirect effect (X →PM_restrictive→Y)	−0.022 (0.10)	—[a]	—	−0.043 to −0.003
PM_evaluative				
Direct effect (X →Y)	−0.100 (0.041)	−2.394 (1582)	.02	−0.182 to −0.018
Direct effect (X →PM_restrictive)	0.189 (0.037)	5.060 (1582)	<.001	0.115 to 0.262
Indirect effect (X →PM_evaluative→Y)	−0.009 (0.006)	—	—	−0.022 to 0.001
PM_unfocused				
Direct effect (X →Y)	−0.110 (0.041)	−2.666 (1582)	.007	−0.192 to −0.029
Direct effect (X →PM_restrictive)	0.092 (0.041)	2.228 (1582)	.03	0.011 to 0.173
Indirect effect (X →PM_unfocused→Y)	0.001 (0.002)	—	—	−0.004 to 0.007

[a]Not applicable.

Mother's education was found to influence adolescent smartphone addiction. Higher maternal education was linked to lower phone addiction (b=−0.001, SE 0.0007, t_{1582}=−2.709, *P*=.006), and it also predicted greater use of restrictive parental monitoring (b=0.001, SE 0.0006, t_{1582}=2.879, *P*=.004). Thus, it is reported that mothers who have greater levels of education tend to use restrictive meditation practices, which successfully reduce the likelihood of kids developing cell phone addiction. Also, children of mothers with greater levels of education are less likely to develop mobile phone addiction (b=−0.0004, SE 0.0002, 95% CI −0.008 to −0.0001). RQ4 was solved based on this finding, and the result is presented in Table 5.

XSL•FO
RenderX

Table . The bootstrap results of parental education of the moderated multiple serial mediation model.

Path	Mobile phone addiction (Y), b (SE)	*t* (*df*)	*P* value	Bootstrapped 95% CI
PM_restrictive				
Father education (X) n=1584				
Direct effect (X →Y)	−0.0004 (0.0006)	−.6404 (1582)	.52	−0.001 to 0.0008
Direct effect (X →PM_restrictive)	0.002 (0.0006)	4.384 (1582)	<.001	0.001 to 0.003
Indirect effect (X →PM_restrictive→Y)	−0.0006 (0.0002)	—[a]	—	−0.001 to 0.0003
Mother education (X) n=1584				
Direct effect (X →Y)	−0.001 (0.0007)	−2.709 (1582)	.006	−0.003 to 0.0005
Direct effect (X →PM_restrictive)	0.001 (0.0006)	2.879 (1582)	.004	0.0006 to 0.003
Indirect effect (X →PM_restrictive→Y)	−0.0004 (0.0002)	—	—	−0.008 to −0.0001
PM_evaluative				
Father education (X) n=1584				
Direct effect (X →Y)	−0.001 (0.0007)	−1.909 (1582)	.06	−0.002 to 0.0001
Direct effect (X →PM_ evaluative)	−0.003 (0.0006)	−5.063 (1582)	<.001	−0.004 to −0.001
Indirect effect (X →PM_evaluative→Y)	0.0002 (0.0001)	—	—	−0.0001 to 0.0004
Mother education (X) n=1584				
Direct effect (X →Y)	−0.002 (0.0007)	−3.343 (1582)	<.001	−0.003 to −0.001
Direct effect (X →PM_ evaluative)	−0.002 (0.0006)	−4.181 (1582)	<.001	−0.003 to −0.001
Indirect effect (X →PM_evaluative→Y)	0.0002 (0.0001)	—	—	0.0001 to 0.0004
PM_unfocused				
Father education (X) n=1584				
Direct effect (X →Y)	−0.001 (0.0007)	−1.597 (1582)	.11	−0.002 to .0002
Direct effect (X →PM_ unfocused)	−0.002 (0.0006)	−3.406 (1582)	<.001	−0.003 to −0.0009
Indirect effect (X →PM_ unfocused→Y)	0.0001 (0.0001)	—	—	−0.0001 to 0.0001
Mother education (X) n=1584				
Direct effect (X →Y)	−0.002 (0.0007)	−3.207 (1582)	.001	−0.003 to −0.0009
Direct effect (X →PM_ unfocused)	−0.001 (0.0007)	−2.624 (1582)	.008	−0.003 to −0.0004
Indirect effect (X →PM_ unfocused→Y)	0.0001 (0.0001)	—	—	−0.0001 to 0.0001

[a]Not applicable.

The data also showed that parents with lower education levels, both fathers (b=−0.003, SE 0.0006, t_{1582}=−5.063, *P*<.001) and mothers (b=−0.002, SE 0.0006, t_{1582}=4.181, *P*<.001) were more likely to use evaluative mediation. Nevertheless, this type of mediation also had a measurable impact on reducing smartphone addiction. Meanwhile, lower parental education levels were associated with the use of unfocused mediation, both for fathers (b=−0.002, SE 0.0006, t_{1582}=−3.406, *P*<.001) and mothers (b=−0.001, SE 0.0007, t_{1582}=−2.624, *P*=.008). However, this technique was found to have little or no predictive value for cell phone addiction.

Hence, the study partially supports hypothesis 5, which hypothesizes that household income and parental education are

XSL•FO
RenderX

the 2 main factors that influence the style of monitoring by parents, with only restrictive monitoring as being effective in preventing addiction to mobile phone use. However, the sociodemographic variables, such as income and parent education level, are often linked to evaluative and unfocused monitoring but have little impact on the likelihood of mobile phone addiction.

Discussion

Principal Results

This study examined the complex interplay between parental monitoring, adolescent development, and PSU. Findings demonstrated a strong association between parental supervision strategies and digital behaviors, corroborating previous research that links monitoring to reduced internet addiction [75,76]. Notably, restrictive mediation was more effective among younger adolescents, significantly curbing internet and smartphone use for those aged 10 - 12 years. This supports earlier findings that younger children are more responsive to parental authority [53,55]. However, as adolescents matured, restrictive strategies proved less effective. According to past studies, older adolescents, particularly those aged 15 - 18 years, demonstrated greater resistance to control [48,49,77]. With advanced problem-solving skills and critical thinking, they are able to manage their digital lives independently and evade parental detection [78].

Evaluative mediation, characterized by open dialogue and critical reflection, was associated with increased internet use; however, it did not significantly reduce problematic mobile phone use. Unfocused monitoring yielded inconsistent outcomes: among 11 - 12-year-olds, it increased internet use, but by age 16, it was linked to reduced usage. These results underscore the developmental dimension of digital behavior regulation and emphasize the need for age-sensitive parental strategies.

Age emerged as a key moderator in the relationship between parental oversight and adolescent smartphone behavior. As cognitive maturity develops, adolescents increasingly prioritize peer affiliation and autonomy over parental control [79,80].

Consequently, the study reinforces that while restrictive strategies may work for younger cohorts, autonomy-supportive and collaborative forms of oversight are more effective for older adolescents. These findings directly inform SRSE-based interventions by identifying parental style as a modifiable determinant that mediates their effectiveness.

Developmentally Adaptive Parental Mediation

The developmental trajectory of adolescence demands flexible parental mediation strategies [81]. Research findings suggest that parental oversight functions not merely as a passive background variable, but as a dynamic moderator that either enhances or inhibits SRSE-based interventions. When adolescents perceive parental control as autonomy-supportive, emphasizing trust, communication, and shared decision-making, they are more likely to internalize self-regulatory behaviors. In contrast, controlling or punitive oversight may provoke psychological reactance and lead to resistance, especially in older adolescents [48,49,77].

This aligns with parental mediation theory, which positions parenting as an adaptive, interactive process shaped by both the parent's approach and the adolescent's developmental stage. Integrating this with the PYD framework allows for a more holistic understanding of adolescent digital well-being. Rather than viewing smartphone use as inherently problematic, this perspective emphasizes fostering competencies, such as critical thinking and emotional regulation, that enable responsible digital engagement. Parental mediation strategies that evolve in tandem with adolescent cognitive and social maturity can effectively bridge these models, guiding healthier digital development.

Socioeconomic Influences and Theoretical Implications

While the developmental stage significantly shaped the effectiveness of parental strategies, our findings also illuminated how socioeconomic variables influenced smartphone addiction and mediation style. Consistent with previous research, adolescents from low-income and lower-education households demonstrated higher levels of smartphone addiction [63-65]. These families often lack alternative recreational resources or digital literacy [66], which may lead to greater reliance on smartphones as surrogate caregivers. In contrast, high-income families, benefiting from greater resources and parental availability, implemented more diverse and effective mediation approaches, thereby reducing smartphone dependency.

Interestingly, while parental education was inversely related to adolescent smartphone addiction, it also influenced the choice of monitoring strategy. Parents with higher education tended to favor restrictive mediation, while parents with lower education leaned toward evaluative or unfocused approaches [69]. These findings indicate that effective digital parenting is shaped not only by knowledge and resources but also by attitudes and awareness regarding digital risks. Importantly, this supports the argument that interventions must account for both perceptual and structural determinants of parenting behavior.

Contrary to some earlier assumptions, this study found no significant sex differences in parental monitoring or smartphone use. Both male and female adolescents were subject to similar levels of parental oversight, aligning with research that documents diminishing sex-based parenting distinctions in the digital age [52,82]. This neutrality in parental response further emphasizes the relevance of focusing on developmental and contextual factors rather than demographic stereotypes when designing digital well-being interventions.

These results advance theoretical integration by situating parental mediation within a bidirectional model of digital development. The convergence of parental mediation theory with SRSE and PYD frameworks underscores the importance of tailoring interventions to the evolving cognitive, emotional, and environmental realities of adolescents. Parental oversight should be understood not as a fixed constraint but as an evolving, context-dependent factor with the potential to amplify or hinder the success of digital health initiatives.

This study used a nationally representative dataset from Taiwan, where adolescents aged 10 - 18 years encounter one of the highest rates of digital saturation in East Asia. Its

XSL•FO
RenderX

Confucian-influenced parenting norms and academic pressures create a culturally unique yet regionally relevant context.

Insights obtained from the Taiwanese context can therefore enhance the comprehension of parental mediation in other industrialized East Asian nations, namely South Korea, Japan, and Singapore, which possess analogous sociocultural and educational attributes. In both settings, the efficacy of parental mediation measures is significantly affected by developmental stage and perceived autonomy, rendering Taiwan a crucial case study for comparative digital parenting research.

Limitations

Despite offering valuable insights into adolescent digital behavior and parental supervision, this study has several limitations. Primarily, the data were self-reported, which introduces potential biases such as social desirability and recall errors [83,84]. Previous research involving 3401 participants shows that only one-third of respondents accurately report internet usage, while 42% (n=1428) overestimate and 26% (n=884) underestimate it [85]. Heavy users tend to underreport, whereas light users often overreport [86]. Such inaccuracies can distort key behavioral metrics, especially when relying on survey-based primary data.

Furthermore, the COVID-19 pandemic likely influenced both adolescent behavior and parental monitoring. Shifting family routines, including remote work and increased household responsibilities, may have altered parents' capacity to supervise screen time effectively [87]. As families transitioned back to prepandemic structures, supervision patterns likely changed, complicating interpretations of consistency over time.

This study did not directly measure smartphone ownership, which recent research suggests can be a significant moderator of parental mediation efficacy and associated child outcomes [88]. In our high-penetration context (94.9%), ownership variance was minimal, likely limiting its moderating effect within our sample. However, this limits the generalizability of our findings to cultures or socioeconomic contexts where smartphone access among adolescents is not near-universal. Future studies should include this variable to better elucidate its role across different environments.

Additionally, the measurement of parental mediation was constrained by the limited number of items in each subdimension, especially unfocused mediation. This restricts the internal consistency of the overall scale and limits the interpretive power of the unfocused mediation category, which cannot yield a reliability estimate.

Future research should incorporate both subjective and objective digital usage metrics, include perspectives from both adolescents and parents, and consider cultural and demographic contexts. Longitudinal approaches would better capture evolving behavioral dynamics and improve the reliability of assessments across diverse environments.

Conclusions

This study investigated how parental monitoring shapes adolescents' digital well-being in Taiwan, using data from the nationwide survey. The findings highlight the critical role of age-specific parental strategies in mitigating excessive internet use and mobile phone addiction. Restrictive monitoring proved effective for younger adolescents, but its influence declined with age, emphasizing the need for adaptive, communication-centered approaches as adolescents develop greater autonomy.

As digital devices become integral to education and social interaction, especially in the postpandemic context, balancing screen use with psychosocial health is increasingly complex. Our results suggest that instead of relying solely on rigid restrictions, parents should promote constructive digital engagement, particularly among older adolescents. Equipping adolescents with self-regulatory skills through open dialogue and guidance may prove more effective in fostering responsible smartphone use.

While this research focuses on Taiwanese adolescents, its findings may resonate across culturally similar East Asian contexts. Taiwan's high smartphone penetration, academic intensity, and Confucian-rooted family dynamics make it a meaningful case study for digital parenting in developed Asian societies. Thus, the insights gained from this study are not only locally relevant but regionally informative, contributing to broader comparative understandings of adolescent digital regulation in Asia.

This research carries implications for families, educators, and policymakers. Awareness campaigns and parental support programs—particularly targeting lower-income and less-educated households—are essential in promoting effective mediation strategies. Community institutions, such as schools, can serve as platforms for delivering digital literacy interventions that empower families to navigate adolescents' digital lives with confidence and care. Future efforts should aim to develop developmentally sensitive, culturally attuned tools that support both youth well-being and healthy digital integration.

Acknowledgments

We thank the editors and anonymous reviewers for their careful reading of our manuscript and many insightful comments.

Data analyzed in this study were collected by the research project of the Taiwan Communication Survey (TCS), which is supported by the Ministry of Science and Technology of Taiwan, Republic of China, and available from Survey Research Data Archive, Academia Sinica [89]. The authors appreciate the assistance in providing data by the institute aforementioned. The views expressed herein are the authors' own.

XSL•FO
RenderX

Funding

This study is funded by the University of Macau (MYRG-GRG2023-00132-FSS) and (MYRG-GRG2024-00083-FSS).

Authors' Contributions

MH, PJS, and AC contributed to methodology and data curation. MH designed the main concepts, as well as conducted the investigation and formal analysis. MH and AC were involved in data interpretation. MH wrote the original draft. PJS and AC reviewed and edited the manuscript. All authors reviewed, approved, and promoted the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Detailed information about measurements.
[DOCX File, 23 KB - pediatrics_v8i1e75837_app1.docx]

Multimedia Appendix 2
Descriptive statistics of Taiwanese adolescent respondents in 2020.
[DOCX File, 23 KB - pediatrics_v8i1e75837_app2.docx]

References

1. Vaterlaus JM, Aylward A, Tarabochia D, Martin JD. “A smartphone made my life easier”: an exploratory study on age of adolescent smartphone acquisition and well-being. Comput Human Behav 2021 Jan;114:106563. [doi: 10.1016/j.chb.2020.106563]
2. Nawaz S. Distinguishing between effectual, ineffectual, and problematic smartphone use: a comprehensive review and conceptual pathways model for future research. Computers in Human Behavior Reports 2024 May;14:100424. [doi: 10.1016/j.chbr.2024.100424]
3. Nawaz S, Bhowmik J, Linden T, Mitchell M. Validation of a modified problematic use of mobile phones scale to examine problematic smartphone use and dependence. Heliyon 2024 Jan 30;10(2):e24832. [doi: 10.1016/j.heliyon.2024.e24832] [Medline: 38312683]
4. Lopez-Fernandez O, Honrubia-Serrano L, Freixa-Blanxart M, Gibson W. Prevalence of problematic mobile phone use in British adolescents. Cyberpsychol Behav Soc Netw 2014 Feb;17(2):91-98. [doi: 10.1089/cyber.2012.0260] [Medline: 23981147]
5. Cha SS, Seo BK. Smartphone use and smartphone addiction in middle school students in Korea: prevalence, social networking service, and game use. Health Psychol Open 2018;5(1):2055102918755046. [doi: 10.1177/2055102918755046] [Medline: 29435355]
6. Ni MY, Yang L, Leung CMC, et al. Mental health, risk factors, and social media use during the COVID-19 epidemic and cordon sanitaire among the community and health professionals in Wuhan, China: cross-sectional survey. JMIR Ment Health 2020 May 12;7(5):e19009. [doi: 10.2196/19009] [Medline: 32365044]
7. Breaux R, Cash AR, Lewis J, Garcia KM, Dvorsky MR, Becker SP. Impacts of COVID-19 quarantine and isolation on adolescent social functioning. Curr Opin Psychol 2023 Aug;52:101613. [doi: 10.1016/j.copsyc.2023.101613] [Medline: 37364468]
8. Steinberg L. Cognitive and affective development in adolescence. Trends Cogn Sci (Regul Ed) 2005 Feb;9(2):69-74. [doi: 10.1016/j.tics.2004.12.005]
9. Yu Y, Mo PKH, Zhang J, Li J, Lau JTF. Impulsivity, self-control, interpersonal influences, and maladaptive cognitions as factors of internet gaming disorder among adolescents in China: cross-sectional mediation study. J Med Internet Res 2021 Oct 27;23(10):e26810. [doi: 10.2196/26810] [Medline: 34704960]
10. Nielsen P, Favez N, Liddle H, Rigter H. Linking parental mediation practices to adolescents’ problematic online screen use: a systematic literature review. J Behav Addict 2019 Dec 1;8(4):649-663. [doi: 10.1556/2006.8.2019.61] [Medline: 31786936]
11. Fam JY, Männikkö N, Juhari R, Kääriäinen M. Is parental mediation negatively associated with problematic media use among children and adolescents? A systematic review and meta-analysis. Canadian Journal of Behavioural Science / Revue canadienne des sciences du comportement 2023;55(2):89-99. [doi: 10.1037/cbs0000320]
12. Soyoof A, Reynolds BL, Neumann M, Scull J, Tour E, McLay K. The impact of parent mediation on young children’s home digital literacy practices and learning: a narrative review. Computer Assisted Learning 2024 Feb;40(1):65-88 [FREE Full text] [doi: 10.1111/jcal.12866]
13. Domoff SE, Radesky JS, Harrison K, Riley H, Lumeng JC, Miller AL. A naturalistic study of child and family screen media and mobile device use. J Child Fam Stud 2019 Feb;28(2):401-410. [doi: 10.1007/s10826-018-1275-1] [Medline: 31105418]

XSL•FO
RenderX

14. Lukavská K, Hrabec O, Lukavský J, Demetrovics Z, Király O. The associations of adolescent problematic internet use with parenting: a meta-analysis. Addict Behav 2022 Dec;135:107423. [doi: 10.1016/j.addbeh.2022.107423] [Medline: 35933287]
15. Livingstone S, Helsper EJ. Parental mediation of children's internet use. J Broadcast Electron Media 2008 Nov 7;52(4):581-599. [doi: 10.1080/08838150802437396]
16. Clark LS. Parental mediation theory for the digital age. Commun Theory 2011 Nov;21(4):323-343. [doi: 10.1111/j.1468-2885.2011.01391.x]
17. Jiow HJ, Lim SS, Lin J. Level up! Refreshing parental mediation theory for our digital media landscape. Commun Theor 2017 Aug;27(3):309-328 [FREE Full text] [doi: 10.1111/comt.12109]
18. Qin Y, Musetti A, Omar B. Flow experience is a key factor in the likelihood of adolescents' problematic TikTok use: the moderating role of active parental mediation. Int J Environ Res Public Health 2023 Jan 23;20(3):2089. [doi: 10.3390/ijerph20032089] [Medline: 36767464]
19. Valkenburg PM, Piotrowski JT, Hermanns J, de Leeuw R. Developing and validating the perceived parental media mediation scale: a self-determination perspective. Hum Commun Res 2013 Oct;39(4):445-469 [FREE Full text] [doi: 10.1111/hcre.12010]
20. Geurts SM, Vossen HGM, Van den Eijnden R, Koning IM. Bidirectional within-family effects of restrictive mediation practices and adolescents' problematic social media use. J Youth Adolesc 2024 Aug;53(8):1928-1938. [doi: 10.1007/s10964-024-01990-z] [Medline: 38700825]
21. Primack BA, Shensa A, Escobar-Viera CG, et al. Use of multiple social media platforms and symptoms of depression and anxiety: a nationally-representative study among U.S. young adults. Comput Human Behav 2017 Apr;69:1-9. [doi: 10.1016/j.chb.2016.11.013]
22. Twenge JM, Campbell WK. Associations between screen time and lower psychological well-being among children and adolescents: evidence from a population-based study. Prev Med Rep 2018 Dec;12:271-283. [doi: 10.1016/j.pmedr.2018.10.003] [Medline: 30406005]
23. Richter A, Adkins V, Selkie E. Youth perspectives on the recommended age of mobile phone adoption: survey study. JMIR Pediatr Parent 2022 Oct 31;5(4):e40704. [doi: 10.2196/40704] [Medline: 36315219]
24. Billieux J. Problematic use of the mobile phone: a literature review and a pathways model. Curr Psychiatry Rev 2012;8(4):299-307. [doi: 10.2174/157340012803520522]
25. Lopez-Fernandez O. Short version of the Smartphone Addiction Scale adapted to Spanish and French: towards a cross-cultural research in problematic mobile phone use. Addict Behav 2017 Jan;64:275-280. [doi: 10.1016/j.addbeh.2015.11.013] [Medline: 26685805]
26. Cox MJ, Paley B. Families as systems. Annu Rev Psychol 1997;48(1):243-267. [doi: 10.1146/annurev.psych.48.1.243] [Medline: 9046561]
27. Minuchin S. Families and Family Therapy, 2nd edition: Harvard University Press; 2020. [doi: 10.4159/9780674041127]
28. Lerner RM, Almerigi JB, Theokas C, Lerner JV. Positive youth development a view of the issues. J Early Adolesc 2005 Feb;25(1):10-16. [doi: 10.1177/0272431604273211]
29. Chen L, Yan Z, Tang W, Yang F, Xie X, He J. Mobile phone addiction levels and negative emotions among Chinese young adults: the mediating role of interpersonal problems. Comput Human Behav 2016 Feb;55:856-866. [doi: 10.1016/j.chb.2015.10.030]
30. Lapierre MA, Zhao P, Custer BE. Short-term longitudinal relationships between smartphone use/dependency and psychological well-being among late adolescents. J Adolesc Health 2019 Nov;65(5):607-612. [doi: 10.1016/j.jadohealth.2019.06.001] [Medline: 31477510]
31. Lin YH, Pan YC, Lin SH, Chen SH. Development of short-form and screening cutoff point of the Smartphone Addiction Inventory (SPAI-SF). Int J Methods Psychiatr Res 2017 Jun;26(2):e1525. [doi: 10.1002/mpr.1525] [Medline: 27658956]
32. Layte R, Brannigan R, Stanistreet D. Digital engagement and adolescent depression: a longitudinal mediation analysis adjusting for selection. Computers in Human Behavior Reports 2023 May;10:100293. [doi: 10.1016/j.chbr.2023.100293]
33. Marty-Dugas J, Ralph BCW, Oakman JM, Smilek D. The relation between smartphone use and everyday inattention. Psychology of Consciousness: Theory, Research, and Practice 2018;5(1):46-62. [doi: 10.1037/cns0000131]
34. Mei S, Yau YHC, Chai J, Guo J, Potenza MN. Problematic internet use, well-being, self-esteem and self-control: data from a high-school survey in China. Addict Behav 2016 Oct;61:74-79. [doi: 10.1016/j.addbeh.2016.05.009] [Medline: 27249805]
35. Zhang H, Li D, Li X. Temperament and problematic internet use in adolescents: a moderated mediation model of maladaptive cognition and parenting styles. J Child Fam Stud 2015 Jul;24(7):1886-1897. [doi: 10.1007/s10826-014-9990-8]
36. Rutter LA, Thompson HM, Howard J, Riley TN, De Jesús-Romero R, Lorenzo-Luaces L. Social media use, physical activity, and internalizing symptoms in adolescence: cross-sectional analysis. JMIR Ment Health 2021 Sep 15;8(9):e26134. [doi: 10.2196/26134] [Medline: 34524096]
37. Sohn SY, Rees P, Wildridge B, Kalk NJ, Carter B. Prevalence of problematic smartphone usage and associated mental health outcomes amongst children and young people: a systematic review, meta-analysis and GRADE of the evidence. BMC Psychiatry 2019 Nov 29;19(1):356. [doi: 10.1186/s12888-019-2350-x] [Medline: 31779637]
38. Kemp S. Digital 2024: Taiwan. DataReportal. 2024 Feb 23. URL: https://datareportal.com/reports/digital-2024-taiwan [accessed 2024-06-18]

XSL•FO
RenderX

39. Park C, Park YR. The conceptual model on smart phone addiction among early childhood. IJSSH 2014;4(2):147-150. [doi: 10.7763/IJSSH.2014.V4.336]
40. Tai Z, Chen H, Li Y. Problematic smartphone use among middle school and high school students in China: a cross-sectional survey study. Int J Ment Health Addiction ;2024:1-16. [doi: 10.1007/s11469-024-01326-9]
41. Lee J. Mental health effects of school closures during COVID-19. Lancet Child Adolesc Health 2020 Jun;4(6):421. [doi: 10.1016/S2352-4642(20)30109-7] [Medline: 32302537]
42. Borawski EA, Ievers-Landis CE, Lovegreen LD, Trapl ES. Parental monitoring, negotiated unsupervised time, and parental trust: the role of perceived parenting practices in adolescent health risk behaviors. J Adolesc Health 2003 Aug;33(2):60-70. [doi: 10.1016/s1054-139x(03)00100-9] [Medline: 12890596]
43. Valkenburg PM, Krcmar M, Peeters AL, Marseille NM. Developing a scale to assess three styles of television mediation: "instructive mediation," "restrictive mediation," and "social coviewing". J Broadcast Electron Media 1999 Jan;43(1):52-66. [doi: 10.1080/08838159909364474]
44. Weiss HA, Bonell C. Smartphone use and mental health: going beyond school restriction policies. Lancet Reg Health Eur 2025 Apr;51:101237. [doi: 10.1016/j.lanepe.2025.101237] [Medline: 40007887]
45. Gong J, Zhou Y, Wang Y, et al. How parental smartphone addiction affects adolescent smartphone addiction: the effect of the parent-child relationship and parental bonding. J Affect Disord 2022 Jun 15;307:271-277. [doi: 10.1016/j.jad.2022.04.014] [Medline: 35398105]
46. Austin EW. Exploring the effects of active parental mediation of television content. J Broadcast Electron Media 1993 Mar;37(2):147-158. [doi: 10.1080/08838159309364212]
47. Chang FC, Chiu CH, Chen PH, et al. Children's use of mobile devices, smartphone addiction and parental mediation in Taiwan. Comput Human Behav 2019 Apr;93:25-32. [doi: 10.1016/j.chb.2018.11.048]
48. Yu L, Zhou X. Social media addiction among Hong Kong adolescents before and after the pandemic: the effects of parenting behaviors. Comput Human Behav 2024 Jul;156:108233. [doi: 10.1016/j.chb.2024.108233]
49. Liu YL. Maternal mediation as an act of privacy invasion: the association with internet addiction. Comput Human Behav 2020 Nov;112:106474. [doi: 10.1016/j.chb.2020.106474]
50. Mills R, Mann MJ, Smith ML, Kristjansson AL. Parental support and monitoring as associated with adolescent alcohol and tobacco use by gender and age. BMC Public Health 2021 Nov 4;21(1):2000. [doi: 10.1186/s12889-021-12119-3] [Medline: 34736436]
51. Corcoran E, Gabrielli J, Wisniewski P, Little TD, Doty J. A measurement model of media parenting: differences across parent and child reports and youth age and sex. J Psychopathol Behav Assess 2022 Sep;44(3):898-912. [doi: 10.1007/s10862-022-09962-y]
52. Endendijk JJ, Groeneveld MG, Bakermans-Kranenburg MJ, Mesman J. Gender-differentiated parenting revisited: meta-analysis reveals very few differences in parental control of boys and girls. PLoS ONE 2016;11(7):e0159193. [doi: 10.1371/journal.pone.0159193] [Medline: 27416099]
53. Wallace LN. Differences in social media monitoring practices based on child and parent gender. Fam Relat 2021 Dec;70(5):1412-1426 [FREE Full text] [doi: 10.1111/fare.12568]
54. Top N. Socio-demographic differences in parental monitoring of children in late childhood and adolescents' screen-based media use. J Broadcast Electron Media 2016 Apr 2;60(2):195-212. [doi: 10.1080/08838151.2016.1164168]
55. Barkin S, Ip E, Richardson I, Klinepeter S, Finch S, Krcmar M. Parental media mediation styles for children aged 2 to 11 years. Arch Pediatr Adolesc Med 2006 Apr;160(4):395-401. [doi: 10.1001/archpedi.160.4.395] [Medline: 16585485]
56. Hwang Y, Jeong SH. Predictors of parental mediation regarding children's smartphone use. Cyberpsychol Behav Soc Netw 2015 Dec;18(12):737-743. [doi: 10.1089/cyber.2015.0286] [Medline: 26544162]
57. Lee EJ, Kim HS. Gender differences in smartphone addiction behaviors associated with parent–child bonding, parent–child communication, and parental mediation among Korean elementary school students. J Addict Nurs 2018;29(4):244-254. [doi: 10.1097/JAN.0000000000000254] [Medline: 30507820]
58. Kwak JY, Kim JY, Yoon YW. Effect of parental neglect on smartphone addiction in adolescents in South Korea. Child Abuse Negl 2018 Mar;77:75-84. [doi: 10.1016/j.chiabu.2017.12.008]
59. Martins MV, Formiga A, Santos C, et al. Adolescent internet addiction - role of parental control and adolescent behaviours. Int J Pediatr Adolesc Med 2020 Sep;7(3):116-120. [doi: 10.1016/j.ijpam.2019.12.003] [Medline: 33094139]
60. Sun R, Gao Q, Xiang Y. Perceived parental monitoring of smartphones and problematic smartphone use in adolescents: mediating roles of self-efficacy and self-control. Cyberpsychol Behav Soc Netw 2022 Dec;25(12):784-792. [doi: 10.1089/cyber.2022.0040] [Medline: 36409521]
61. Tangmunkongvorakul A, Musumari PM, Tsubohara Y, et al. Factors associated with smartphone addiction: a comparative study between Japanese and Thai high school students. PLoS ONE 2020;15(9):e0238459. [doi: 10.1371/journal.pone.0238459] [Medline: 32898191]
62. Her ES, Lee S, Yang SJ, et al. Lower-income predicts increased smartphone use and problematic behaviors among schoolchildren during COVID-19 related school modification: a longitudinal study. J Korean Med Sci 2022 Jul 18;37(28):e225. [doi: 10.3346/jkms.2022.37.e225] [Medline: 35851864]

XSL•FO
RenderX

63. Yoo C. Longitudinal comparison of cohorts concerning sense of community of adolescents. Child Ind Res 2024 Jun;17(3):1023-1044. [doi: 10.1007/s12187-024-10122-9]
64. de Freitas B, Gaíva MAM, Bernardino FBS, Diogo PMJ. Smartphone addiction in adolescents, part 2: scoping review—prevalence and associated factors. Trends in Psychol 2021 Mar;29(1):12-30. [doi: 10.1007/s43076-020-00040-4]
65. Chou HL, Chou C. A quantitative analysis of factors related to Taiwan teenagers' smartphone addiction tendency using a random sample of parent-child dyads. Comput Human Behav 2019 Oct;99:335-344. [doi: 10.1016/j.chb.2019.05.032]
66. Siwiak A, Suris JC, Chok L, Stadelmann S, Corre T, Barrense-Dias Y. Are vulnerable adolescents more prone to smartphone and internet addiction? A cross-sectional study among adolescents in Switzerland. Vulnerable Child Youth Stud 2023 Oct 2;18(4):570-580. [doi: 10.1080/17450128.2023.2253511]
67. Huang D, Luo Y, He X, Hong L, Zhang B. A qualitative study on parental mediation of rural‐to‐urban migrant children's smartphone use in China: concerns, strategies and challenges. Child Fam Soc Work 2024 Feb;29(1):195-204 [FREE Full text] [doi: 10.1111/cfs.13062]
68. Hoffner C, Buchanan M. Parents' responses to television violence: the third-person perception, parental mediation, and support for censorship. Media Psychol 2002 Aug;4(3):231-252. [doi: 10.1207/S1532785XMEP0403_02]
69. Nagy B, Kutrovátz K, Király G, Rakovics M. Parental mediation in the age of mobile technology. Children & Society 2023 Mar;37(2):424-451. [doi: 10.1111/chso.12599]
70. Adigwe I, van der Walt T. Parental mediation of online media activities of children in Nigeria: a parent-child approach. Computers in Human Behavior Reports 2020 Aug;2:100041. [doi: 10.1016/j.chbr.2020.100041]
71. Slotta D. Number of smartphone users in Taiwan 2018-2029. Statista. 2025 Jan 30. URL: https://www.statista.com/statistics/1258283/taiwan-smartphone-users [accessed 2024-12-20]
72. Taiwan Communication Survey. 2012. URL: https://crctaiwan.dcat.nycu.edu.tw [accessed 2025-01-20]
73. Chang C, Tao CC. Taiwan communication survey: new communication technologies & life boundary expansion [data set] second phase, fourth wave ed. : Academia Sinica; 2021. [doi: 10.6141/TW-SRDA-D00216-2]
74. Chang C, Tao CC. Report of the 2020 Taiwan communication survey: new communication technologies & life boundary expansion second phase, fourth wave ed. : Academia Sinica; 2021. [doi: 10.6141/TW-SRDA-D00216-1]
75. Lin CH, Lin SL, Wu CP. The effects of parental monitoring and leisure boredom on adolescents' internet addiction. Adolescence 2009;44(176):993-1004. [Medline: 20432612]
76. Zhou N, Liang Y, Cao H, et al. Chinese adolescents' problematic cellphone use: exploring the implications of configuration profiles of cellphone-specific parenting behaviors. Comput Human Behav 2022 Dec;137:107408. [doi: 10.1016/j.chb.2022.107408]
77. Symons K, Ponnet K, Walrave M, Heirman W. A qualitative study into parental mediation of adolescents' internet use. Comput Human Behav 2017 Aug;73:423-432. [doi: 10.1016/j.chb.2017.04.004]
78. Bluth K, Campo RA, Futch WS, Gaylord SA. Age and gender differences in the associations of self-compassion and emotional well-being in a large adolescent sample. J Youth Adolesc 2017 Apr;46(4):840-853. [doi: 10.1007/s10964-016-0567-2] [Medline: 27632177]
79. Albert D, Chein J, Steinberg L. Peer influences on adolescent decision making. Curr Dir Psychol Sci 2013 Apr;22(2):114-120. [doi: 10.1177/0963721412471347] [Medline: 25544805]
80. Branje S. Development of parent–adolescent relationships: conflict interactions as a mechanism of change. Child Dev Perspectives 2018 Sep;12(3):171-176 [FREE Full text] [doi: 10.1111/cdep.12278]
81. Padilla-Walker LM, Coyne SM, Fraser AM, Dyer WJ, Yorgason JB. Parents and adolescents growing up in the digital age: latent growth curve analysis of proactive media monitoring. J Adolesc 2012 Oct;35(5):1153-1165. [doi: 10.1016/j.adolescence.2012.03.005] [Medline: 22507383]
82. Swim JK, Aikin KJ, Hall WS, Hunter BA. Sexism and racism: old-fashioned and modern prejudices. J Pers Soc Psychol 1995;68(2):199-214. [doi: 10.1037//0022-3514.68.2.199]
83. Krumpal I. Determinants of social desirability bias in sensitive surveys: a literature review. Qual Quant 2013 Jun;47(4):2025-2047. [doi: 10.1007/s11135-011-9640-9]
84. Stone AA, Shiffman S. Capturing momentary, self-report data: a proposal for reporting guidelines. Ann Behav Med 2002;24(3):236-243. [doi: 10.1207/S15324796ABM2403_09] [Medline: 12173681]
85. Scharkow M. The accuracy of self-reported internet use—a validation study using client log data. Commun Methods Meas 2016 Jan 2;10(1):13-27. [doi: 10.1080/19312458.2015.1118446]
86. Araujo T, Wonneberger A, Neijens P, de Vreese C. How much time do you spend online? Understanding and improving the accuracy of self-reported measures of internet use. Commun Methods Meas 2017 Jul 3;11(3):173-190. [doi: 10.1080/19312458.2017.1317337]
87. Parenting children in the age of screens. Pew Research Center. 2020 Jul 28. URL: https://www.pewresearch.org/internet/2020/07/28/parenting-children-in-the-age-of-screens [accessed 2024-06-16]
88. Martín-Cárdaba M, Martínez Díaz MV, Lafuente Pérez P, García Castro J. Smartphone ownership, minors' well-being, and parental mediation strategies. An analysis in the context of social media influencers. J Youth Adolesc 2024 Oct;53(10):2202-2218. [doi: 10.1007/s10964-024-02013-7] [Medline: 38782845]

XSL•FO
RenderX

89. The 2019 Taiwan communication survey (phase two, year three): the utility and impacts of media use II. SRDA. URL: https://srda.sinica.edu.tw/search/metadata/detail/D00184 [accessed 2025-12-01]

Abbreviations

PSU: problematic smartphone use
PYD: positive youth development
RQ: research question
SRSE: self-regulated smartphone engagement
TCS: Taiwan Communication Survey

Edited by J Hagström; submitted 12.04.25; peer-reviewed by E Lau, J Garcia-Castro, K Lukavska; revised version received 04.10.25; accepted 15.10.25; published 04.12.25.

Please cite as:
Ho M, Schulz PJ, Chang A
Exploring the Impact of Perceived Parental Oversight on Problematic Smartphone Use Among Adolescents in the Digital Age: Database Analysis
JMIR Pediatr Parent 2025;8:e75837
URL: https://pediatrics.jmir.org/2025/1/e75837
doi:10.2196/75837

© Mary Ho, Peter Johannes Schulz, Angela Chang. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 4.12.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Novel Profiles of Family Media Use: Latent Profile Analysis

Nicole Hamp[1], MD, MPA; Jenny Radesky[1], MD; Heidi M Weeks[2], PhD; Alison L Miller[2], PhD; Niko Kaciroti[2], PhD

[1]Division of Developmental Behavioral Pediatrics, University of Michigan Medical School, D2204 CS Mott Children's Hospital, 1500 E. Medical Ctr Dr, Ann Arbor, MI, United States

[2]University of Michigan School of Public Health, Ann Arbor, MI, United States

Corresponding Author:
Nicole Hamp, MD, MPA
Division of Developmental Behavioral Pediatrics, University of Michigan Medical School, D2204 CS Mott Children's Hospital, 1500 E. Medical Ctr Dr, Ann Arbor, MI, United States

Abstract

Background: Over the past 3 decades, digital and screen media have evolved from broadcast, stationary platforms to a complex environment of interactive, omnipresent, mobile media. Thus, clinical guidance centered around unidimensional concepts such as "screen time" must be modernized to help families navigate the intricate digital ecosystems of readily available entertainment and information.

Objective: This study aimed to identify and examine distinct latent profiles of media use in families with young children. We hypothesized that latent profile analysis (LPA) would identify different media use profiles characterized by more heavy, reactive, individual, and permissive media use and more intentional, regulated, or shared uses of media.

Methods: We analyzed data from 398 preschool-aged children. English-speaking parents were recruited through community settings. Participants completed surveys regarding several aspects of family media use, such as child device use or activities, parent concerns and attitudes, limit setting and mediation, parent media use, and technology interference, examined in an LPA. The number of latent media profiles was determined using Bayesian Information Criteria. Parents also completed validated scales of parenting stress, depression symptoms, parenting style, child behavior, child sleep, and household disorganization. Multivariable logistic regression was used to examine parent, child, and household predictors of group membership.

Results: The LPA yielded 2 distinct groups that differed in the duration of media used by parents and children, to calm children or help them fall asleep. Statistically significant differences between groups included: families in group 1 (n=236, which we termed social-emotional drivers) had parents who preferred interactions via text or email to in-person (P=.01) and were more likely to use media to calm their children (P=.03); in contrast, families in group 2 (n=162, intentional media) used more task-oriented media, like audio and nongame apps (P=.01), had more concerns about effects of media on child language development (P=.04), and used more media restrictions (P=.01). In regression models, female sex of the parent respondent, greater number of siblings, and later child sleep midpoint independently predicted group 1 membership.

Conclusions: Findings suggest divergent family media use patterns that can be categorized into 2 main media user groups: those using media to buffer social situations or regulate emotions and those planning mobile device use around functional purposes and concerns around media exposure. Profiles were associated with household size and child sleep. More research is needed to examine the impact of social and emotional uses of media on child outcomes.

(JMIR Pediatr Parent 2025;8:e59215) doi:10.2196/59215

KEYWORDS

preschool; child; digital media; mobile media; media use; latent profile analysis; computer use; LPA; technology use; survey; questionnaire; pediatrics

Introduction

Background

The landscape of digital technology use has changed dramatically over the past few decades. Digital and screen media have evolved from broadcast, stationary platforms, where screens stay put, plugged into the wall, and messages are transmitted broadly in a one-to-many model, to a world of interactive, mobile media, where screens can follow users wherever they go and interact in a bidirectional manner. For this reason, researchers have questioned whether clinical guidance centered around unidimensional concepts such as "screen time" are helpful to parents trying to navigate digital ecosystems of readily available entertainment and information [1], particularly considering families' increased technologic dependence during and following the COVID-19 pandemic.

Distinctions between traditional (eg, television [TV]) and mobile, interactive media are important for several reasons.

XSL•FO
RenderX

First, the portability and easy accessibility of mobile media inherently allows for more spontaneous and reactive use patterns in which the technology becomes increasingly integrated into daily routine and activities [2,3]. Second, small, handheld screens are more difficult for parents to monitor [4]. And third, mobile media use has rapidly become exceedingly common, even in infants and toddlers. As of 2017, 98% of homes of children 0 - 8 years old had a mobile device, and one third of all screen time in that same age group, who use on average almost 2.5 hours of screen media per day, was mobile [5].

Previous Work

In light of modern technologic advances, new ways of studying, conceptualizing, and framing media use guidance have been proposed. Young children's media use has been conceptualized as the "3 Cs", that is, content, context, and the individual child given the important role each of these factors plays in shaping child responses to media [6]. However, pervasive use of mobile media by families with young children requires new concepts such as use of devices for on-demand calming and keeping children occupied during daily activities.

To capture holistic patterns of family media use, it is also important to consider parents' mobile device use, which interrupts parent-child interaction [7] and is associated with less responsiveness [8], but is an important part of parent social connection, work-life, and day-to-day functioning [9]. Parents' mediation behaviors (practices such as coviewing, teaching children about media content, or setting limits) also shape children's responses to media [10]. Finally, child and parent media use are highly correlated [11], yet are usually studied in isolation. One previous attempt to describe family-level media behaviors [12] primarily focused on viewing duration and type of media use, rather than the several contextual variables or social-emotional drivers of media use in the current digital environment.

Goal of This Study

The current study aims to identify patterns that include the aforementioned concepts, examined through latent profile analysis, to try to identify patterns and concepts that might generate insights for clinical guidance and future research. Specifically, we sought to identify novel patterns of family media use that consider child duration and frequency of media activities; child use to keep occupied, regulate behavior, or fall asleep; parent attitudes about child use; limit setting and mediation; parent media use; and "technoference" (ie, technology interference in parent-child activities). We hypothesized that latent profile analysis (LPA) would identify different media use profiles characterized by more reactive, heavy, individual, and permissive media use; and more intentional, regulated, or shared uses of media. We examined these patterns and their associations with parent, child, and household characteristics within a large cohort of preschool-aged children, as early childhood is an important time of establishing media use habits [13].

Methods

Overall Study Design

We analyzed data from the Preschooler Tablet Study, a longitudinal cohort study (NICHD R21HD094051) examining associations between early childhood digital media use and social-emotional development. The present analysis used REDCap (Research Electronic Data Capture) [14] and Qualtrics survey data from the baseline data collection wave (August 2018-May 2019).

Ethical Considerations

The study was approved by the University of Michigan Institutional Review Board (HUM00131980). Parents provided electronic informed consent for themselves and on behalf of their young children. Participants were informed that they could opt out of the study at any time. Data downloaded from REDCap and Qualtrics were stored on secure password-protected servers at the University of Michigan. Data was not de-identified prior to analysis; all participants were assigned a study ID number that only linked to identifying information on REDCap, a HIPAA-secure database to which only approved study personnel had access. Participants received $40 for completing data collection procedures.

Participants

Parents of young children were recruited through flyers posted in community centers, preschools, childcare centers, and pediatric clinics in southeast Michigan, as well as our university's online participant registry and social media advertisements. Interested parents who contacted the study team were emailed a link to an eligibility questionnaire. Eligibility criteria is shown in Textbox 1. To improve generalizability, participating children did not need to regularly use mobile devices to be included in the study.

Textbox 1. Study inclusion and exclusion criteria.

Inclusion criteria:

- Parent was legal guardian of a 3 - to 4.99-year-old child.
- Parent lived with the child at least 5 days per week.
- Parent understood English sufficiently enough to complete questionnaires and provide consent.
- The family owned at least 1 Android or iOS tablet or smartphone.

Exclusion criteria:

- Child developmental delays.
- Use of psychotropic medication.

XSL•FO
RenderX

Survey Measures: Child, Parent, and Household Characteristics

After providing electronic informed consent, respondent parents completed web-based surveys with a variety of questionnaires to assess characteristics of the child, parent, and household, as well as family media use practices. Demographic characteristics were collected for children's age, sex, race, ethnicity (investigator-defined categories shown in Table 1), daycare or preschool enrollment, average sleep pattern (sleep onset and wake time, from which duration and midpoint were calculated, as well as sleep latency and overnight awakenings), prematurity, and whether they were an only child; parent age, gender, educational attainment, marital status, and employment status. We also used validated questionnaires to assess parent depression symptoms (Centers for Epidemiologic Studies-Depression Scale) [15], parenting stress (Parenting Stress Index-Short Form) [16], and parenting styles (laxness and harshness subscales of The Parenting Scale) [17]; as well as household income, size, composition, and disorganization (Chaos, Hubbub, and Order Scale) [18]. Child self-regulation abilities were assessed with the Emotional Reactivity subscale of the Child Behavior Checklist-Preschool [19], the Surgency subscale of the Rothbart Child Behavior Questionnaire-Very Short Form [20], and the Behavior Rating Inventory of Executive Function-Preschool [21].

XSL•FO
RenderX

Table . Participant sociodemographic characteristics.

Characteristics			Values
Parent			
	Age, mean (SD)		34 (4.7)
	Sex, n (%)		
		Male	25 (6.3%)
		Female	373 (93.7%)
	Education, n (%)		
		≤High school or GED[a]	25 (6.3%)
		Some college or a 2-year degree	126 (31.7%)
		4-year college degree	100 (25.1%)
		Advanced degree	147 (36.9%)
	Marital status, n (%)		
		Married or has a partner	360 (90.9%)
		Single, separated, or divorced	36 (9.1%)
	Employment, n (%)		
		Unemployed	110 (27.6%)
		Part-time	76 (19.1%)
		Full-time	185 (46.5%)
		Multiple jobs	27 (6.8%)
	Scales, mean (SD)		
		Depression symptoms (CES-D[b] score)	9.32 (8.87)
		Parenting Stress Index percentile	44.6 (32.9)
		Parenting Scale – Laxness Subscale	2.61 (0.76)
		Parenting Scale – Overreactivity Subscale	2.56 (0.74)
Child			
	Age, mean (SD)		3.85 (0.54)
	Sex, n (%)		
		Female	186 (46.7%)
		Male	212 (53.3%)
	Race/ethnicity, n (%)		
		Asian or Pacific Islander	11 (2.8%)
		Black or African American, non-Hispanic	20 (5.1%)
		Hispanic, any race	26 (6.6%)
		Multiple races, non-Hispanic	32 (8.1%)
		Native American or Alaska Native	5 (1.3%)
		White, non-Hispanic	302 (76.3%)
	Only child, n (%)		
		Yes	69 (17.3%)
		No	329 (82.7%)
	Child gestational age, n (%)		
		<37 weeks (premature)	32 (8%)

XSL•FO
RenderX

Characteristics		Values
	37 weeks or later	366 (92%)
Child preschool or child care, n (%)		
	Center-based child care	250 (65.8%)
	Home-based child care	30 (7.9%)
	Stays home with parent or caregiver	100 (26.3%)
Sleep, mean (SD)		
	Sleep duration	10.8 (0.8)
	Sleep midpoint (number of hours after 12 AM)	1.87 (0.82)
	Sleep latency >30 min	106 (26.6)
	Overnight awakenings	226 (60.4)
Scales, mean (SD)		
	CBQ-VSF[c] Surgency Subscale	4.40 (0.86)
	BRIEF-P[d] General Executive Composite	49.2 (12)
	CBCL-P[e] – Emotional Reactivity Subscale	3.69 (2.82)
Household, mean (SD)		
	Income-to-needs ratio	2.95 (1.71)
	CHAOS[f] score	3.29 (2.93)

[a]GED: General Educational Development.
[b]CES-D: Centers for Epidemiologic Studies-Depression
[c]CBQ-VSF: Child Behavior Questionnaire Very Short Form
[d]BRIEF-P: Behavior Rating Inventory of Executive Function-Preschool
[e]CBCL-P: Child Behavior Checklist–Preschool
[f]CHAOS: Chaos, Hubbub, and Organizational Scale

Survey Measures: Media Use

Parents also completed a 75-item questionnaire about family media use derived from the CAFE (Comprehensive Assessment of Family Exposure) Consortium Qualtrics Survey, which has been described elsewhere [22]. This survey asks about technology and device ownership, content and context of media use, parent media use, and mediation practices (refer to Textbox 2 for constructs assessed). Questions on the survey addressed types of devices in the home and locations of those devices, parent attitudes toward media and concerns regarding child use of media, duration of use on weekdays versus weekends, time of use and environmental context of use (for example while falling asleep or while in transit), usual content (for example streaming video versus playing games), family interactions around media, and media-use functions.

XSL•FO
RenderX

Textbox 2. Media-related constructs assessed through the CAFE (Comprehensive Assessment of Family Exposure) questionnaire.

A. Child ownership and frequency of activities

A1. Child ownership of mobile media device

A2. Child keeps device in bedroom

Frequency of mobile device use for specific activities:

(A3. Watch TV; A4. Watch movies; A5. Play games; A6. Use apps that are not games; A7. Read electronic books; A8. Listen to music or audiobooks; A9. Take photos; A10. View photos/videos)

B. Child instrumental or regulatory uses of media

B1. Use of media during travel in car or public transit

B2. Use of TV to calm when upset

B3. Use of mobile devices to calm when upset

Use of all types of screen media by parent for specific purposes related to child:

(B4. To educate child; B5. Calm child down; B6. Keep child busy; B7. Communicate with family and friends; B8. Because child enjoys it)

B9. Use of devices at bedtime

B10. Use of devices while falling asleep

C. Parent media knowledge and attitudes

Parent concerns that child will:

(C1. Be exposed to inappropriate content; C2. Become inattentive as a result of using screen media; C3. Become addicted to screen media; C4. Miss out on other important opportunities that are more valuable than screen media; C5. Be exposed to harmful electromagnetic waves; C6. Have poorer language development).

D. Mediation strategies

Presence of media content limits:

(D1. Parents blocks specific media content on TV/devices; D2. Parent uses web blockers/controls; D3. Parent only allows child to watch “child-friendly” content; D4. Parent uses ratings to decide what child will watch; D5. Child media use only allowed if parent is in the room).

D6. Media time limits are consistently enforced

D7. Media content limits are consistently enforced

D8 – D22: Valkenburg Mediation Scale (Social Coviewing, Instructive Mediation, and Restrictive Mediation)

E. Parent media use

Outside of work hours, parent feels:

(E1. The need to stay connected to work almost constantly; E2. The need to stay connected to friends and social media almost constantly; E3. It is easy to multitask between children and using a phone or mobile device; E4. Sometimes overwhelmed by how much they have to do on their phone or mobile device; E5. That they prefer to interact with others via texting, email, or social media, rather than in person; E6. Using their phone or mobile device allows them to “escape” a little bit while they’re with their children; E7. Sometimes “addicted” to mobile media like smartphones or tablet devices).

Frequency of specific activities during a typical weekday (Monday-Friday):

(E8. Watch TV; E9. Use the computer; E10. Read traditional books; E11. Read electronic books; E12. Play videogames on console game player; E13. Use an iPad, iTouch, or similar device (not including a smartphone); E14. Use a smartphone for things like texting, playing games, watching videos, checking email, or surfing the internet).

Frequency of specific activities during a typical weekend day (Saturday-Sunday):

(E15. Watch TV; E16. Use the computer; E17. Read traditional books; E18. Read electronic books; E19. Play videogames on console game player; E20. Use an iPad, iTouch, or similar device (not including a smartphone); E21. Use a smartphone for things like texting, playing games, watching videos, checking email, or surfing the internet).

F. Technoference

Frequency of parent phone use during specific activities:

(F1. During meals; F2. While getting child(ren) ready for school; F3. During playtime; F4. During bedtime routine; F5. While driving child(ren) to or from activities or when riding on public transportation; F6. At the playground).

XSL•FO
RenderX

Data Analysis

Of the 423 participants who provided consent and completed surveys, we excluded participants who did not complete (n=19) or had substantial missing data (n=6) on the media use questionnaire. This left 398 participants in this study available for the LPA. All media variables were included in LPA, a person-centered statistical method to identify distinct groups of participants with similar median profiles within each group. Using Bayesian Information Criteria (BIC), the LPA with the lowest BIC value yielded 2 distinct groups.

Wilcoxon Mann-Whitney tests were used to compare media use questionnaire items between the groups identified by the LPA. Then separate multivariable logistic regression models were built to estimate the odds of being in group 1 versus group 2 for each set of parent (Model I), child (Model II), and household (Model III) predictors. As our approach was exploratory, we started with including all parent, child, or household characteristics in each respective model and conducted backward elimination, resulting in the most parsimonious model that retained only variables showing significant associations at a *P* value of <.05. For all characteristics significantly associated with group membership in Models I, II, or III, we built a combined Model IV to test which characteristics were independently associated with group membership.

Results

Participant Demographics

Parents were 93.7% female (373/398), 34 (SD 4.7) years old, and 62% (247/398) had a 4-year college degree or more; children were 3.8 (SD 0.54) years old, 76.3% (302/398) were White and non-Hispanic, and 82.7% (329/398) had siblings in the household (Table 1).

Evaluation Outcomes

Latent profile analysis yielded 2 distinct groups of media users (Figure 1). Families in group 1 (n=236) were more likely to prefer interactions through text, email, or social media rather than those in person (*P*=.01) and more likely to use TV shows or DVDs to calm their children (*P*=.03). Parents in group 1 used their mobile device more frequently during the week to read electronic books (*P*=.04). In contrast, group 2 (n=162) used more task-oriented media, including more audio and nongame apps (*P*=.01), had more concerns about effects of media on language development (*P*=.04), and used more media restrictions (*P*=.01).

XSL•FO
RenderX

Figure 1. Latent Profile Analysis: media use profiles. Standardized means by variable for group 1 versus group 2. Lettering describes variable type: A. child ownership and frequency of activities; B. child instrumental or regulatory uses of media; C. parent media knowledge and attitudes; D. mediation strategies; E. parent media use; F. technoference.

XSL•FO
RenderX

As shown in Figure 1, several additional variables approached significance (P<.20) that warrant mention. Parents in group 1 were more likely to feel overwhelmed by how much they have to do on their phone or mobile device (P=.12) and reported that using the phone or mobile device allowed them to "escape" a little bit while with their children (P=.14). They were more likely to watch TV or DVDs (P=.15) or use the computer (P=.10) over the weekend than were families in group 2. Group 1 families also reported using more content restrictions for what their children see in the media with internet filters, parental controls, or apps to block certain websites (P=.11) , as well as use of parental media websites (eg, common sense media) to decide what types of programs are appropriate for their child. Finally, group 1 families were more likely to use their mobile device to take photos (P=.11).

Group 2 families preferred using their mobile devices to view photos or home videos (P=.13) in addition to the other task-oriented media described above. They also noted concerns that children will become inattentive as a result of using screen media (P=.11) and more frequently restrict the amount of child viewing (P=.06).

In logistic regression models (Table 2), the only parent characteristic that was significantly associated with group 1 membership (vs group 2) in Model I was female parent sex. In Model II, children with longer duration of sleep had lower odds of group 1 membership, while those with later sleep midpoint and prematurity showed increased odds of group 1 membership. Households with more siblings had a borderline increased odds of group 1 membership in Model III. With all characteristics considered in the same model (IV), independent associations remained for female parent sex, greater number of siblings, and later child sleep midpoint.

Table . Multivariable logistic regression models predicting group assignment.

Model and variable		Group 1 (social-emotional drivers) versus group 2 (intentional media), aOR[a] (95% CI)
Model I: parent characteristics		
	Parent sex (male vs female)	0.36 (0.16-0.84)
Model II: child characteristics		
	Sleep duration (per 1 hour)	0.72 (0.55-0.95)
	Sleep midpoint (per 1 hour)	1.5 (1.13-1.98)
	Prematurity (no vs yes)	2.26 (1.06-4.8)
Model III: household characteristics		
	Number of siblings (per sibling)	1.23 (0.998-1.5)
Model IV: all characteristics		
	Parent sex (male vs female)	0.3 (0.12-0.76)
	Number of siblings (per sibling)	1.27 (1.02-1.57)
	Sleep midpoint (per 1 hour)	1.51 (1.1-2.07)

[a] aOR: adjusted odds ratio

Discussion

Principal Findings

This study used a wide range of questions about child, parent, and household context of media use to identify coherent patterns of media use that are relevant to pediatric research or clinical intervention. Latent profile analysis results suggest that people may be predisposed to different media-use patterns based on individual motivations. Group 1 preferred text and email interactions to those in-person and used media to calm their children. These behaviors may be interpreted as use of media based on social-emotional drivers. In contrast, group 2 used media for more functional purposes. This group preferred more nongame and audio applications. They seemed warier of media, placed more restrictions around child media use, and had more concerns about the effect of media on child development. Though these findings in some way confirmed our initial hypothesis, that some types of media users are predisposed to more reactive-use patterns (group 1), while others are more predisposed to intentional and regulated uses of media (group 2), the tendency to use media as a sort of social-emotional buffer was not a factor we considered in our initial hypothesis.

When examining the overall patterns of media use between groups, a few theoretically coherent concepts arise. In group 1, described as using media based on social-emotional drivers, there appeared to be more parent use of media as an "escape" from childrearing demands, such as more parental media during the weekends, which is typically time families are together during the day. In previous qualitative work, parents have described using mobile devices and social media as a "virtual escape" when their child stresses them out [9], when they want to avoid parenting tasks [23], or when intentionally not wanting to engage with difficult child behavior [24]. Furthermore, compared with parents in group 2 who were more likely to view, but not take, photos or home videos on a mobile device, group 1 families took photos on their device more frequently, an action that by definition interrupts a social moment and introduces a

XSL•FO
RenderX

physical barrier between the individual taking the photograph and the subjects.

In group 2, parent media use appeared more goal oriented, and more limits and restrictions were placed on child media use, which may be related to greater concerns about media's effects on child wellbeing. This pattern of device usage has been described as "instrumental" (ie, goal directed and purposeful) rather than "ritualistic" in previous work [25], and is hypothesized to be related to the individual motivations for engaging with technology. In this study, we describe this pattern of device usage as intentional, similarly noting that this type of media use is meant to fulfill a purpose rather than for pleasure or distraction. Though we did not observe increased odds of group 2 membership based on measures of parental mental health or child behavior, a recent study using latent class analysis found stronger well-being indicators for "family-engaged adolescents" who live in families with family-owned devices, positive parent relationships, and lower parental social media use [26]. Higher wellbeing also occurred in teens who placed lower importance on technology and were expected to follow household technology rules. Future research may therefore examine the relationship between these multiple classes of media users in a longitudinal manner to determine if "intentional" media-use families who set early boundaries around child media use are more likely to have "family-engaged adolescents" with better social-emotional outcomes.

It is surprising that socioeconomic status, parenting stress, household disorganization, and child behavioral difficulties were not associated with membership in group 1. In previous research, longer screen time duration and higher parent technology interference have been linked with higher parenting stress [27-29]. Recent work has also suggested that children's screen time is a marker of family distress due to multiple psychosocial factors [30]. However, these studies only examined the variable of screen time, while our approach identified larger family media use patterns that appear independent of socioeconomic factors in this cohort.

We did find that mothers are more likely to use media as a social-emotional buffer and that this type of media use is more common in larger families. It is possible that mothers or parents of larger families may experience higher caregiver burden and, as a result, are using media for more self-regulatory purposes and to calm or manage child behavior more frequently. Indeed, use of digital technology as a "babysitter," to provide caregiver respite or allow parents time to tend to other tasks, is a concept that is well-described in research literature and mainstream news, albeit with some differences in acceptance across cultures [31-35]. Evidence suggests that use of media to occupy children may be especially relevant in homes where children require more attention or behavioral management due to temperament differences [36], or where there is limited support for the primary caregiver. One study found that parents who lack support from a partner or who are uncertain about their parenting skills were more likely to use media as a distractor and concluded that "media are thus especially used as a distractor in the family when parents feel that it is difficult to keep the household going by themselves" [34].

Another correlate of group membership was later sleep midpoint (ie, the calculated midpoint between reported average sleep onset and wake time), with group 1 having later sleep midpoints than group 2. This may be explained by the fact that group 2, despite any significant difference in overall parenting style, seemed more prone to limit setting. What is perhaps most surprising about our study findings are the variables that did not predict group membership including parent education, marital status, employment, and child behavior variables such as emotional reactivity and surgency. Although human-computer interaction research has identified individual predictors of smartphone usage habits such as personality [37], attachment style [38], and executive functioning [39], we found no associations of parenting style (such as laxness vs harshness), parenting stress, or depression symptoms with group membership.

Limitations

Our study was limited in generalizability due to our study population which included mostly White, non-Hispanic, higher-educated, and female-parent responders. While our cohort reflected the racial and ethnic diversity of our local area, results may not be generalizable to other populations. In addition, the data we analyzed on media use was all from self-report questions, which can lead to single-reporter bias. We also reported on several associations that did not achieve significance, but were near significant, that we included in our results as we felt the data helped to demonstrate an overall trend. Greater insight into the reasons for media use may have been gleaned from a mixed methods approach, where follow up semistructured interviews could have explored themes related to media as a social-emotional buffer versus to fulfill a desired goal.

Conclusions

Results of our study suggest that people likely do have different motivations behind their use of digital media that may be reflected in their usage patterns. The significance of these different media usage patterns for the long-term outcomes of children and families is yet to be determined. It is possible, and in fact likely, that each pattern of media use may be considered adaptive in certain situations and maladaptive in others. By having a better understanding of why and how different families use media in their daily lives, pediatric care providers can provide more individualized anticipatory guidance regarding technology use by the whole family, including limit setting, use of media for calming, and how devices impact family dynamics. For example, by understanding that a parent is more prone to using mobile media to calm their child, a pediatrician might suggest that such a parent reflect on the frequency with which they use such calming techniques to ensure that they are also providing their child opportunities to practice frustration tolerance using techniques that go beyond distraction with media.

The research implications of our study may allow us to classify the media use patterns of families to better examine the long-term effects of media use on child health and development. Follow up studies could examine trajectories of profiles over childhood to determine their stability and how they relate to

XSL•FO
RenderX

child outcomes over time. Future research directions should also include nationally representative populations, objective device use data, or reports from multiple household members (eg, parents and children).

Acknowledgments

All phases of this study were supported by the National Institute of Child Health and Human Development grant (#1R21HD094051-01; Radesky, PI). The National Institute of Child Health and Human Development had no role in the design and conduct of the study.

Authors' Contributions

NH conceptualized and contributed to the design of the study, reviewed all data, participated in the statistical analysis, drafted the initial manuscript, and reviewed and revised the manuscript. JR was the primary investigator on the grant award for the original study, contributed to the conceptualization of the current study, advised on study design, reviewed data, participated in the statistical analysis, and reviewed and revised the manuscript. HMW advised on study design, conducted the statistical analysis, summarized the study data, developed related figures and tables, and contributed to, reviewed, and revised the manuscript. ALM advised on study design, reviewed data and outcomes, reviewed and revised the manuscript. NK advised on study design, directed and oversaw the statistical analysis, reviewed study data, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Conflicts of Interest

NH has ownership interest in Arbor Autism Centers LLC. In the past year, JR received fees from Melissa & Doug LLC and research funding from Common Sense Media. HMW reported receiving grants from the National Institute of Child Health and Human Development outside the submitted work. ALM reported receiving grants from the National Institutes of Health outside the submitted work. NK reported receiving grants from the National Institutes of Health outside the submitted work.

References

1. Hiniker A, Radesky JS, Livingstone S, Blum-Ross A. Moving beyond “the great screen time debate” in the design of technology for children. Presented at: CHI ’19; May 4-9, 2019; Glasgow, Scotland, United Kingdom. [doi: 10.1145/3290607.3311745]
2. Raman S, Guerrero-Duby S, McCullough JL, et al. Screen exposure during daily routines and a young child’s risk for having social-emotional delay. Clin Pediatr (Phila) 2017 Nov;56(13):1244-1253. [doi: 10.1177/0009922816684600] [Medline: 28952333]
3. Radesky JS, Weeks HM, Ball R, et al. Young children’s use of smartphones and tablets. Pediatrics 2020 Jul;146(1):e20193518. [doi: 10.1542/peds.2019-3518] [Medline: 32482771]
4. Domoff SE, Radesky JS, Harrison K, Riley H, Lumeng JC, Miller AL. A naturalistic study of child and family screen media and mobile device use. J Child Fam Stud 2019 Feb;28(2):401-410. [doi: 10.1007/s10826-018-1275-1] [Medline: 31105418]
5. Rideout V, Robb MB. The common sense census: media use by kids age zero to eight. Common Sense Media. 2020. URL: https://www.commonsensemedia.org/sites/default/files/uploads/research/2020_zero_to_eight_census_final_web.pdf [accessed 2025-02-13]
6. Guernsey L. Into the Minds of Babes: How Screen Time Affects Children from Birth to Age Five: Basic Books; 2007.
7. Reed J, Hirsh-Pasek K, Golinkoff RM. Learning on hold: cell phones sidetrack parent-child interactions. Dev Psychol 2017 Aug;53(8):1428-1436. [doi: 10.1037/dev0000292] [Medline: 28650177]
8. Wolfers LN, Kitzmann S, Sauer S, Sommer N. Phone use while parenting: an observational study to assess the association of maternal sensitivity and smartphone use in a playground setting. Comput Human Behav 2020 Jan;102:31-38. [doi: 10.1016/j.chb.2019.08.013]
9. Radesky JS, Kistin C, Eisenberg S, et al. Parent perspectives on their mobile technology use: the excitement and exhaustion of parenting while connected. J Dev Behav Pediatr 2016;37(9):694-701. [doi: 10.1097/DBP.0000000000000357] [Medline: 27802256]
10. Collier KM, Coyne SM, Rasmussen EE, et al. Does parental mediation of media influence child outcomes? A meta-analysis on media time, aggression, substance use, and sexual behavior. Dev Psychol 2016 May;52(5):798-812. [doi: 10.1037/dev0000108] [Medline: 26914217]
11. Jago R, Thompson JL, Sebire SJ, et al. Cross-sectional associations between the screen-time of parents and young children: differences by parent and child gender and day of the week. Int J Behav Nutr Phys Act 2014;11(1):54. [doi: 10.1186/1479-5868-11-54]
12. Wartella E, Rideout V, Lauricella A, Connell S. Parenting in the age of digital technology: a national survey. : Northwestern University; 2013.

XSL•FO
RenderX

13. McArthur BA, Browne D, Tough S, Madigan S. Trajectories of screen use during early childhood: predictors and associated behavior and learning outcomes. Comput Human Behav 2020 Dec;113:106501. [doi: 10.1016/j.chb.2020.106501]
14. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381. [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
15. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Appl Psychol Meas 1977;1(3):385-401. [doi: 10.1177/014662167700100306]
16. Abidin RA. Parenting Stress Index, 3rd edition: Psychological Assessment Resources; 1995.
17. Arnold DS, O'Leary SG, Wolff LS, Acker MM. The Parenting Scale: a measure of dysfunctional parenting in discipline situations. Psychol Assess 1993;5(2):137-144. [doi: 10.1037//1040-3590.5.2.137]
18. Matheny AP, Wachs TD, Ludwig JL, Phillips K. Bringing order out of chaos: psychometric characteristics of the confusion, hubbub, and order scale. J Appl Dev Psychol 1995 Jul;16(3):429-444. [doi: 10.1016/0193-3973(95)90028-4]
19. Achenbach T, Rescorla L. Manual for the ASEBA Preschool Forms & Profiles: An Integrated System of Multi-Informant Assessment; Child Behavior Checklist for Ages 1 1/2-5; Langauge Development Survey; Caregiver-Teacher Report Form: University of Vermont; 2000.
20. Rothbart MK, Ahadi SA, Hershey KL, Fisher P. Investigations of temperament at three to seven years: the Children's Behavior Questionnaire. Child Dev 2001;72(5):1394-1408. [doi: 10.1111/1467-8624.00355] [Medline: 11699677]
21. Gioia G, Espy K, Isquith P. BRIEF-P: Behavior Rating Inventory of Executive Function–Preschool Version: Psychological Assessment Resources; 2003.
22. Barr R, Kirkorian H, Radesky J, et al. Beyond screen time: a synergistic approach to a more comprehensive assessment of family media exposure during early childhood. Front Psychol 2020;11:1283. [doi: 10.3389/fpsyg.2020.01283] [Medline: 32754078]
23. Oduor E, Neustaedter C, Odom W, et al. The frustrations and benefits of mobile device usage in the home when co-present with family members. Presented at: DIS '16; Jun 4-8, 2016; Brisbane, Australia. [doi: 10.1145/2901790.2901809]
24. Torres C, Radesky J, Levitt KJ, McDaniel BT. Is it fair to simply tell parents to use their phones less? A qualitative analysis of parent phone use. Acta Paediatr 2021 Sep;110(9):2594-2596. [doi: 10.1111/apa.15893] [Medline: 33905125]
25. Hiniker A, Patel SN, Kohno T, Kientz JA. Why would you do that? Predicting the uses and gratifications behind smartphone-usage behaviors. Presented at: UbiComp '16; Sep 12-16, 2016; Heidelberg, Germany. [doi: 10.1145/2971648.2971762]
26. Moreno MA, Binger K, Zhao Q, Eickhoff J, Minich M, Uhls YT. Digital technology and media use by adolescents: latent class analysis. JMIR Pediatr Parent 2022 May 4;5(2):e35540. [doi: 10.2196/35540] [Medline: 35507401]
27. McDaniel BT, Radesky JS. Technoference: longitudinal associations between parent technology use, parenting stress, and child behavior problems. Pediatr Res 2018 Aug;84(2):210-218. [doi: 10.1038/s41390-018-0052-6] [Medline: 29895837]
28. Brauchli V, Sticca F, Edelsbrunner P, von Wyl A, Lannen P. Are screen media the new pacifiers? The role of parenting stress and parental attitudes for children's screen time in early childhood. Comput Human Behav 2024 Mar;152:108057. [doi: 10.1016/j.chb.2023.108057]
29. Shin E, Choi K, Resor J, Smith CL. Why do parents use screen media with toddlers? The role of child temperament and parenting stress in early screen use. Infant Behav Dev 2021 Aug;64:101595. [doi: 10.1016/j.infbeh.2021.101595] [Medline: 34153781]
30. Hartshorne JK, Huang YT, Lucio Paredes PM, Oppenheimer K, Robbins PT, Velasco MD. Screen time as an index of family distress. Current Research in Behavioral Sciences 2021 Nov;2:100023. [doi: 10.1016/j.crbeha.2021.100023]
31. Morley D. Family Television: Cultural Power and Domestic Leisure, 1st edition: Routledge; 1986.
32. Evans CA, Jordan AB, Horner J. Only two hours? A qualitative study of the challenges parents perceive in restricting child television time. J Fam Issues 2011;32(9):1223-1244. [doi: 10.1177/0192513X11400558]
33. Beyens I, Eggermont S. Putting young children in front of the television: antecedents and outcomes of parents' use of television as a babysitter. Commun Q 2014 Jan;62(1):57-74. [doi: 10.1080/01463373.2013.860904]
34. Nikken P. Parents' instrumental use of media in childrearing: relationships with confidence in parenting, and health and conduct problems in children. J Child Fam Stud 2019 Feb;28(2):531-546. [doi: 10.1007/s10826-018-1281-3]
35. Elias N, Sulkin I. YouTube viewers in diapers: an exploration of factors associated with amount of toddlers' online viewing. Cyberpsychology (Brno) 2017;11(3). [doi: 10.5817/CP2017-3-2]
36. Nabi RL, Krcmar M. It takes two: the effect of child characteristics on U.S. parents' motivations for allowing electronic media use. J Child Media 2016 Jul 2;10(3):285-303. [doi: 10.1080/17482798.2016.1162185]
37. Stachl C, Au Q, Schoedel R, et al. Predicting personality from patterns of behavior collected with smartphones. Proc Natl Acad Sci U S A 2020 Jul 28;117(30):17680-17687. [doi: 10.1073/pnas.1920484117] [Medline: 32665436]
38. Eichenberg C, Schott M, Schroiff A. Comparison of students with and without problematic smartphone use in light of attachment style. Front Psychiatry 2019;10:681. [doi: 10.3389/fpsyt.2019.00681] [Medline: 31620031]
39. Warsaw RE, Jones A, Rose AK, Newton-Fenner A, Alshukri S, Gage SH. Mobile technology use and its association with executive functioning in healthy young adults: a systematic review. Front Psychol 2021;12:643542. [doi: 10.3389/fpsyg.2021.643542] [Medline: 33815229]

XSL•FO
RenderX

Abbreviations:

BIC: Bayesian Informed Criteria
CAFE: Comprehensive Assessment of Family Exposure
DVD: digital versatile disc
LPA: latent profile analysis
REDCap: Research Electronic Data Capture
TV: television

Edited by S Badawy; submitted 13.06.24; peer-reviewed by HG Holmgren, MM Papamichael; revised version received 19.11.24; accepted 28.11.24; published 06.03.25.

Please cite as:
Hamp N, Radesky J, Weeks HM, Miller AL, Kaciroti N
Novel Profiles of Family Media Use: Latent Profile Analysis
JMIR Pediatr Parent 2025;8:e59215
URL: https://pediatrics.jmir.org/2025/1/e59215
doi:10.2196/59215

© Nicole Hamp, Jenny Radesky, Heidi M Weeks, Alison L Miller, Niko Kaciroti. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 6.3.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Parental Perspectives on the Use of Smartwatch Activity Trackers by Young Children: Qualitative Study

Raymond J Davey[1,2], PhD; Amity Campbell[1,2], PhD; Amber Beynon[1,2], PhD; Charlotte Lund Rasmussen[1,2], PhD; Danica Hendry[1,2], PhD; Sarah Stearne[1,2], PhD; Courtenay Harris[1,2], PhD; Leon Straker[1,2], PhD; Juliana Zabatiero[1,2], PhD

[1]Curtin School of Allied Health, Faculty of Health Sciences, Curtin University, Bentley, Australia

[2]ARC Centre of Excellence for the Digital Child, Perth, Australia

Corresponding Author:
Raymond J Davey, PhD
Curtin School of Allied Health
Faculty of Health Sciences
Curtin University
Kent Street
Bentley, 6102
Australia
Phone: 61 8 9266 9123
Fax: 61 8 9266 3699
Email: ray.davey@curtin.edu.au

Abstract

Background: Smartwatch activity trackers are devices that measure physical activity levels with features that aim to encourage physically active behaviors. These devices have shown promise for increasing physical activity levels and reducing sedentary behaviors among school-aged children, adolescents, and adults. Recently, commercially available products have been adapted so that they are suitable for use by preschool-aged children. However, it is unclear whether the intended use of these devices is feasible and effective in young children.

Objective: The purpose of this study was to explore parents' perspectives on the use of smartwatch activity trackers by young children.

Methods: Semistructured interviews were conducted with 22 parents (17/22, 77% female) of children aged 3-5 years. Interviews explored perspectives on the feasibility of their children wearing the devices, implications of use by young children, and how families could make use of these devices to support their children's physically active behaviors. Interviews were audio-recorded, transcribed verbatim, and data analyzed using thematic analysis.

Results: Parents perceived that the use of these devices by young children is feasible, with developmental stage or abilities and personality or temperament being important individual determinants of feasibility. However, parents expressed concerns related to the devices providing extrinsic motivation to move, being disruptive or distracting, being a burden on parents, and for the safety and privacy of their child's information. Most parents believed that young children are inherently active and do not need devices to support physical activity. Furthermore, most parents expressed an interest in knowing how physically active their children were and thought that there may be a role for these devices for children who are less physically active.

Conclusions: Parents reported developmental stage or abilities and temperament as relevant considerations related to the feasibility of smartwatch activity tracker use by young children. Parents also indicated that there is a potential role for these devices in young, less active children.

(JMIR Pediatr Parent 2025;8:e79851) doi:10.2196/79851

KEYWORDS

wearable activity tracker; smartwatch; preschool children; physical activity; qualitative research

XSL•FO
RenderX

Introduction

Higher levels of physical activity are associated with reduced adiposity and better cognitive and motor skill development, psychosocial health, bone and skeletal health, and cardiometabolic health in preschool children [1,2]. Furthermore, in this age group, participation in physical activity helps to offset the risks of excessive sedentary behavior, with higher levels of sitting associated with increased adiposity and reduced psychosocial health and cognitive development [3,4]. Establishing physically active behaviors at this age also influences engagement in physical activity throughout childhood, adolescence, and adulthood [5].

International health guidelines recommend that preschool children (aged 3 to 5 years) spend at least 180 minutes per day in a variety of physical activities at any intensity, of which, at least 60 minutes is moderate to vigorous physical activity [6,7]. In addition, replacing restrained sedentary behaviors and sedentary screen time with physical activity is suggested to provide additional health benefits [6,7]. Unfortunately, many preschool children in developed countries do not meet current physical activity recommendations [8-10] and spend significant proportions of their waking time sitting or inactive [10,11]. Therefore, a current public health priority is to develop intervention programs that aim to increase physical activity levels among young children, when these formative experiences can shape future behaviors.

Smartwatch activity trackers are wrist-worn devices that incorporate accelerometers to provide measures of physical activity such as the number of steps taken, distance travelled, time spent active or inactive, and the intensity of activity. This information is typically shared with the user via a small digital interface on the wearable device itself and additionally via synchronization to mobile or web-based apps that collect and summarize the physical activity data. These devices also include features that aim to encourage physically active behaviors and disrupt sedentary behaviors. For instance, users can set daily physical activity goals and receive notifications about their progress. These devices have been shown to provide valid and reliable estimates of physical activity in children [12]. They have also shown promise for increasing physical activity levels and reducing sedentary behaviors among school-aged children, adolescents, and adults [13,14]. Specifically, interventions that incorporate these activity trackers have shown small to moderate favorable effects on physical activity minutes per day, steps per day, and moderate to vigorous physical activity levels in children and adults [13-17]. However, it is unknown whether smartwatch activity trackers can have similarly favorable effects on physical activity in preschool children. In a recent systematic review, we showed that while the use of these devices may be feasible in preschool children, to date, no studies have evaluated their efficacy for increasing physical activity in this age group [18].

With the increase in commercially available smartwatch activity trackers designed for use in preschool-aged children, evidence is needed on the feasibility and efficacy of influencing the physical activity of young children. Given the important role parents would have in mediating the use of this technology by preschool children, this study aimed to explore parents' perspectives on the feasibility of young children wearing activity trackers, potential implications of young children using these devices, such as advantages, disadvantages, and unintended consequences of use, and possible roles for activity trackers in this age group.

Methods

The description of the methodology follows established Standards for Reporting Qualitative Research [19].

Study Design

This qualitative study used single time-point semistructured interviews, following an exploratory, cross-sectional, observational design [20]. An interpretive description approach was chosen, where the perceptions and experiences of the participants were explored by analyzing concepts, themes, and patterns in the interview data, with the view to generating practically useful outcomes [21]. This follows a constructivist or interpretivist paradigm, with our rationale being that the perspectives and experiences of our participants are necessary to meet our study aims. This approach may limit the transferability of our research findings to people in different contexts to those of the participants of this study.

Participants

The participants were parents or primary caregivers of children aged 3 to 5 years. Parents or primary caregivers were defined as the primary person providing support to the child over a long period of time and involved in daily care routines such as feeding, hygiene, play, sleep, or health. Participants were recruited through purposive and snowball sampling from existing networks of the Curtin Healthy Digital Child research team including the networks of their community advisory groups [22]. In addition, recruitment flyers were distributed nationally using the Australian Research Council Centre of Excellence for the Digital Child social media [23]. The recruitment material provided links to the participant information statement and consent form. Once informed consent was obtained, the participants were provided with a link to an online preinterview questionnaire (Qualtrics XM). Following this, the participants completed an interview either in person or online using videoconferencing technology.

Preinterview Questionnaire

The preinterview questionnaire (Multimedia Appendix 1) included questions on sociodemographic characteristics (eg, age of participant and age and sex of child, number of children, suburb of residence, occupation, and highest education level). This information was used to tailor each participant's semistructured interview and support data analysis.

Qualitative Semistructured Interview

The interviews followed a semistructured format guided by open-ended questions to allow parents to express a broad range of perspectives openly and honestly without their responses being directed by the question itself. The researcher (RJD) who conducted the interviews is the father of a preschool child with a background in health research and education. Although the

XSL•FO
RenderX

questions were designed to allow free expression, it is possible that these interviewer characteristics may have introduced biases or influenced the relationship with the participants through shared experiences. The interview questions related to the use of wrist-worn smartwatch activity trackers by 3- to 5-year-old children. In particular, the questions explored their perspectives on the feasibility of young children wearing these devices, the potential implications of young children using these devices, and the potential roles or applications for these devices in the lives of young children. The questions were developed by a multidisciplinary team of researchers in consultation with the Curtin Healthy Digital Child Parent and Professional Advisory Groups. Each question was mapped to at least one of the three themes directly aligned with the research aims: (1) feasibility, (2) implications of use, and (3) potential roles. The average duration of interviews was 33 (SD 8; range 20-53) minutes. Each interview was audio-recorded (with consent), and the recordings were professionally transcribed verbatim.

Feasibility has been defined as the extent to which the devices are suitable for the target population, can be successfully delivered to the target population, or show promise of being successful within the intended population [12]. Based on this definition, the following open-ended questions were posed to the participants to capture their perceptions of the feasibility of activity tracker use by young children: Does your child use an activity tracker? Do you think young children could use these devices? Do you see a role for activity trackers in your child's life?

Implications were broadly defined as any advantages, disadvantages, or unintended consequences of use that may or may not be related to the device's primary purpose of physical activity monitoring. The open-ended questions that were posed to the participants to capture their perceptions of the implications of activity tracker use by young children included the following: What issues do you think parents might raise? Can you think of any other considerations for young children using activity trackers?

Potential roles included any application for smartwatch activity trackers identified by the participants in either their child's life or the lives of other 3- to 5-year-old children. The open-ended questions that were posed to the participants to capture these potential roles included the following: Do you see a role for activity trackers in your child's life? Do you think parents have a good sense of how much physical activity their child does? Would you be interested to know?

Data Analysis

Data from the preinterview questionnaire were analyzed using descriptive statistics, reported as counts and percentages, to provide a summary of participants' characteristics. The audio recordings of the open-ended questions were transcribed verbatim, and transcriptions were then analyzed by inductive thematic analysis [24] using NVivo (Lumivero). Data collection and analysis were conducted simultaneously to allow the research team to respond to evolving study findings. This iterative process also allowed the research team to identify saturation of emergent themes [22], which informed the decision to stop recruitment and data collection naturally.

Ethical Considerations

This study was approved by the Curtin University Human Research Ethics Office (approval: HRE2023-0608). Prospective participants were provided with a detailed information sheet describing the purpose of the study; the benefits, risks, and expected outcomes of the study; and the research team. Following this, the participants provided informed consent before completing a questionnaire, and an interview was conducted either in person or using secure videoconferencing software. At the beginning of each interview, the participants were asked to provide verbal confirmation of their consent for the interview to be audio-recorded. The interview questions were not sensitive in nature and open-ended to allow free expression of perspectives. The participants were reminded that they were not obliged to answer the questions and that they could stop the interview at any stage. To ensure participant privacy, the data collected were either deidentified or coded and stored on secure Curtin University research drives, accessible by the research team only. The participants were not paid for their involvement in the study but were offered a US $32.7 gift card for their time.

Results

Participant Characteristics

The participant characteristics are presented in Table 1. In total, 22 parents aged 31 to 43 years (mean 36.5, SD 3.6 years) of children aged 3 to 5 years, inclusive (mean 4.3, SD 0.9 years) completed this study. This included 17 mothers and 5 fathers of 1 to 3 (mean 2.1, SD 0.6) children. The most common occupations were health professionals (5/22, 23%), academics (4/22, 18%), clerical and administrative workers (3/22, 14%), education professionals (3/22, 14%), and stay-at-home parents (3/22, 14%), with 18/22 (82%) who had completed tertiary education. Most participants lived in Western Australia (16/22, 73%), with others located in Victoria (3/22, 14%), New South Wales (2/22, 9%), and South Australia (1/22, 5%).

XSL•FO
RenderX

Table 1. Participant characteristics (N=22).

Characteristic	Values, n (%)
Age (years)	
18-24	0 (0)
25-34	8 (36)
35-44	14 (64)
>45	0 (0)
Sex	
Female	17 (77)
Male	5 (23)
Children	
1 child	3 (14)
2 children	13 (59)
3 children	6 (27)
Age of child (years)	
3 to <4	10 (45)
4 to <5	7 (32)
5 to <6	5 (23)
Occupation	
Manager	1 (5)
Academic	4 (18)
Health professional	5 (23)
Education professional	3 (14)
Social and welfare professional	2 (9)
Clerical and administrative worker	3 (14)
Stay-at-home parent	3 (14)
Defense	1 (5)
Highest education level	
High school or equivalent	1 (5)
Postsecondary, nontertiary	3 (14)
Bachelor degree or equivalent	7 (32)
Postgraduate degree	11 (50)
Location	
Western Australia	16 (73)
New South Wales	2 (9)
Victoria	3 (14)
South Australia	1 (5)

Feasibility

Overview

When parents considered the feasibility of smartwatch activity tracker use by young children, the following subthemes were identified: age and developmental abilities, personality and temperament, capacity for independent use, novelty and maintenance of use, and wearability. Supporting quotes for each of the subthemes are presented in Table 2.

XSL•FO
RenderX

Table 2. Parental perspectives on the feasibility of smartwatch activity tracker use by young children.

Subthemes	Supporting quotes
Age and developmental abilities (17/22, 77%)	• "I think there's a big difference between a three-year-old and a five-year-old" [Participant 2, mother of 3 children including a 3-year-old]. • "I think definitely a five-year-old would probably be more engaged and have more of an understanding of the device" [Participant 2, mother of 3 children including a 3-year-old]. • "... as a three-year-old, I just don't think that she would make the link yet" [Participant 2, mother of 3 children including a 3-year-old]. • "I think for [my 5-year-old child] I think she'd definitely be capable in appreciating—I guess engaging with it, and I think that she would interact with it and understand and equate the game with moving more. [My 3-year-old child] I'm not so sure about just because of his age. I don't think [my 3-year-old-child] would be at that level to make that connection" [Participant 3, father of 3 children including a 3-year-old and a 5-year-old].
Personality and temperament (16/22, 73%)	• "... it would depend on the child and what motivates them" [Participant 21, mother of 2 children including a 4-year-old]. • "... he has that kind of personality where he responds really well to challenges or to goals" [Participant 1, mother of 2 children including a 5-year-old]. • "I think for kids that are really rewards-focused or goal-oriented, it could be really valuable to them to motivate them to do a bit more" [Participant 1, mother of 2 children including a 5-year-old].
Capacity for independent use (21/22, 95%)	• "I feel like he would need quite a bit of help still ... I think at this age; you'd probably need to make good use of those incentives and those rewards and walk him through that. And then once he gets the hang of it, I think he'd probably be okay, but it would take a bit of work" [Participant 11, mother of a 3-year-old child]. • "I think it would be pretty led by the parents. I think they're probably still too young to do it independently, I would think" [Participant 7, mother of 2 children including a 5-year-old].
Novelty and maintenance of use (15/22, 68%)	• "... maybe initially they would find it really exciting and they would use it like a toy, and then I think the novelty would probably wear off if they weren't that engaged with it and it ... prompted them to do something and they didn't want to, it would become a chore and not a game anymore" [Participant 15, mother of 2 children including a 4-year-old]. • "I wonder whether the novelty of it would wear quickly, so I'm not sure how long-term it would make changes for either parents or as a family unit" [Participant 15, mother of 2 children including a 4-year-old].
Wearability (11/22, 50%)	• "I think the biggest thing would be keeping it on them and having them wear it all the time. Because even just getting her to keep shoes on can be a bit of a hassle, so I imagine something that's around her wrist, I think that she wouldn't necessarily want to keep on" [Participant 18, mother of 2 children including a 3-year-old]. • "I think that actually wearing it would be the biggest hurdle for her" [Participant 18, mother of 2 children including a 3-year-old]. • "... she might find wearing a watch to be uncomfortable or irritating" [Participant 2, mother of 3 children including a 3-year-old]. • "... going in the sandpit, sand caught under it, hot and sweaty in summer ... not tolerated from a sensory perspective" [Participant 2, mother of 3 children including a 3-year-old].

Subtheme: Age and Developmental Abilities

This subtheme relates to perspectives that 3 to 5 years is a developmentally diverse age range with children at different stages of cognitive development and having varied literacy, understanding of the purpose or intention of the device (including the rewards and prompts), and abilities to respond to it. Most parents (17/22, 77%) reported this as a key determinant of feasibility.

Subtheme: Personality and Temperament

This subtheme relates to perspectives that individual differences would influence the uptake and maintenance of use of these devices. Most parents (16/22, 73%) reported that these devices would suit children who are goal- or reward-focused, competitive, or compliant.

Subtheme: Capacity for Independent Use

This subtheme relates to perspectives on the capacity of children to use and engage with the device independently as intended, for example, receive and respond to information, purposefully aim to achieve movement goals, and understand and seek rewards. Almost all parents (21/22, 95%) expressed a view related to this subtheme, but their perspectives were mixed, with the child's age, abilities, and personality being key determinants of their capacity for independent use and their need for support.

Subtheme: Novelty and Maintenance of Use

Many parents (15/22, 68%) reported that novelty may encourage uptake and engagement by young children, but that the maintenance of use would be limited in this age range, as interest might diminish over time.

Subtheme: Wearability

Half of the parents (11/22, 50%) also indicated that issues related to wearability (eg, tolerance to wear and comfort) would impact the feasibility of use of these devices by their children.

XSL•FO
RenderX

Implications

Overview

When considering the implications of smartwatch activity tracker use by young children, the following subthemes were identified: the potential negative influence of extrinsically motivating physical activity, disrupting positive behaviors, the burden on parents, and the safety and privacy of information. Supporting quotes for each of the subthemes are presented in Table 3.

Table 3. Parental perspectives on potential implications of smartwatch activity tracker use by young children.

Subthemes	Supporting quotes
Extrinsically motivating physical activity (17/22, 77%)	• "... kids would then place emphasis on rewards for activity rather than just enjoying and initiating activity of their own accord" [Participant 14, mother of 2 children including a 5-year-old]. • "I think the games are a good motivator, but whether or not this is going to affect their overall intrinsic motivation for exercise in the long term, I'm not sure" [Participant 2, mother of 3 children including a 3-year-old]. • "I like the idea that it can help foster better physical activity, but I just wonder whether it comes at the expense of driving an implicit and internal motivation to engage in exercise, whether it's going to the playground for enjoyment, engaging with friends, playing sport" [Participant 3, father of 3 children including a 3-year-old and a 5-year-old]. • "I'd like them to engage in physical activity and exercise because they enjoy the activity, not because they're motivated by what's on their wrist" [Participant 3, father of 3 children including a 3-year-old and a 5-year-old].
Disrupting positive behaviors (16/22, 73%)	• "Will they stop what they are currently so intently focused on to do what this thing is telling them to do?" [Participant 13, mother of 2 children including a 3-year-old]. • "... these ones are very visible, so that sense of being almost a distraction at times, or intrusive to what's going on in the present" [Participant 6, father of 3 children including a 3-year-old and a 5-year-old]. • "I do have concerns about the interactive nature of it ... as much as they would use them, I wouldn't want them to overuse them" [Participant 12, mother of 3 children including a 3-year-old and a 4-year-old]. • "I do fear that it would be more a case of them sitting on the lounge looking at their watch, rather than actually getting up and doing stuff" [Participant 12, mother of 3 children including a 3-year-old and a 4-year-old].
The burden on parents (18/22, 82%)	• "... has the potential to just be another source of guilt that we're not doing enough as parents" [Participant 10, mother of 2 children including a 4-year-old]. • "... you're adding to parents' burden and that feeling that we're never doing enough" [Participant 12, mother of 3 children including a 3-year-old and a 4-year-old]. • "I think if the information goes to the parent or the parent is managing that feedback, it would be up to the parent to be careful in the way they—what they do with that information in relation to the child and how much information they want to share with their child especially if there's a need for improvement" [Participant 11, mother of a 3-year-old child].
Safety and privacy of information (14/22, 64%)	• "Can people find out where my child is or what they're doing?" [Participant 16, mother of 2 children including a 4-year-old]. • "... some parents would be concerned about the tracking of their children's movements and whether or not that could be hacked" [Participant 18, mother of 2 children including a 3-year-old]. • "I think maybe the privacy stuff around the data and how secure that is, and where it goes and what it's used for" [Participant 6, father of 3 children including a 3-year-old and a 5-year-old].

Subtheme: Extrinsically Motivating Physical Activity

This subtheme relates to perspectives that activity trackers are a source of extrinsic motivation (eg, rewarding achievement) that may displace children's intrinsic motivation to move simply for fun and enjoyment. Most parents (17/22, 77%) reported this implication of use.

Subtheme: Disrupting Positive Behaviors

This subtheme relates to perspectives that the device may be intrusive and disrupt children from positive behaviors including physical activity itself, as well as immersive, creative play, or rest. Most parents (16/22, 73%) reported this concern.

Subtheme: The Burden on Parents

Most parents (18/22, 82%) expressed the concern that the use of these devices by young children would impose a burden on parents because of their essential role in interpreting and delivering the information from the devices to their children, together with the guilt parents may feel when recommendations or goals are not met.

Subtheme: The Safety and Privacy of Information

Two-thirds of parents (14/22, 64%) indicated that safety and privacy of information is a concern, primarily related to the security of identifiable data and location information as well as the possibility of companies gathering information about children's behaviors and lives.

Potential Roles

Overview

When the possible roles for smartwatch activity trackers for young children were considered, the following subthemes were identified: a limited need for a device to encourage physical activity in young children because they are inherently active; benign activity tracking to measure, but not influence, physical activity levels to improve parents' awareness of their child's

XSL•FO
RenderX

physical activity behaviors; creating opportunities to discuss physical activity in a family setting; as a means to encourage physical activity in children who are less active, and as a supporting tool that is part of a broader program to increase physical activity levels in young children. Supporting quotes for each of the subthemes are presented in Table 4.

Table 4. Parental perspectives on the potential roles of smartwatch activity tracker use by young children.

Subthemes	Supporting quotes
Limited—young children are inherently active (20/22, 91%)	• "... she's motivated to move her body regardless of the activity tracker or not. I think intrinsically as a three-year-old, she does a lot of activity without even thinking about it or without even really knowing, comprehending what it is and what it means" [Participant 2, mother of 3 children including a 3-year-old]. • "... it wouldn't ever cross my mind that a typical preschooler would need one only because of how much my own child loves sport and movement already. It's hard to get him to rest" [Participant 11, mother of a 3-year-old child]. • "I'm not too concerned because I just have a general impression that she's busy and she's active and she's enthusiastic and she's happy to be active when we are. So, I'm not particularly worried" [Participant 5, mother of 3 children including a 3-year-old].
Increase awareness of physical activity levels (20/22, 91%)	• "I would be super interested to ... see how much he actually does" [Participant 1, mother of 2 children including a 5-year-old]. • "... it would be interesting ... to know how much (her child) is doing and when he's active, maybe the circumstances" [Participant 1, mother of 2 children including a 5-year-old]. • "Yeah, so it would be interesting to know how much she really is moving during the day" [Participant 14, mother of 2 children including a 5-year-old]. • "I would definitely be interested to know exactly how much physical activity she's doing and when, and then how that might potentially affect other things like sleep and things like that" [Participant 2, mother of 3 children including a 3-year-old].
Opportunities to discuss physical activity (13/22, 59%)	• "You can have little discussions with them about, what did you do today? Did you feel puffed afterwards? Was it fun?" [Participant 4, mother of 2 children including a 3-year-old]. • "How many steps have I done? And how many steps have you done? And what's yours saying? And what's mine saying?' So, that social element of it I think would bring more interest, rather than it being a personal thing" [Participant 6, father of 3 children including a 3-year-old and a 5-year-old].
Special circumstances (17/22, 77%)	• "I think that activity trackers could play a role for those sorts of kids who don't or don't have an interest in being active" [Participant 3, father of 3 children including a 3-year-old and a 5-year-old]. • "I mean, maybe if there was an obvious problem and the specific child didn't get enough physical activity, or they were really against going to the park and doing all those things" [Participant 2, mother of 3 children including a 3-year-old]. • "I think if I was worried that I had a really sedentary kid ..." [Participant 5, mother of 3 children including a 3-year-old]. • "I can imagine that if you lived in a flat or an apartment and you only had a very small space and not much access to outdoors, you might also be worried" [Participant 5, mother of 3 children including a 3-year-old]. • "I think there are plenty of situations where these trackers would be beneficial and would potentially help kids and families [without adequate] education, knowledge, and background [related to the benefits of physical activity to health]" [Participant 10, mother of 2 children including a 4-year-old].
Part of a broader program (10/22, 45%)	• "I can see that (it) would be another tool in their belt on how to help a family" [Participant 15, mother of 2 children including a 4-year-old]. • "I think it's probably best to have a range of approaches. So this could be one of a package of—if you're looking to increase activity in young children, have this as part of a broader package, not the only thing that we're relying on" [Participant 14, mother of 2 children including a 5-year-old].

Subtheme: Limited—Young Children Are Inherently Active

This subtheme relates to perspectives that there may not be a role for these devices in this age range because young children are naturally physically active without encouragement or support and parents are generally not concerned about their children's physical activity levels. Almost all parents (20/22, 91%) reported this view.

Subtheme: Increase Awareness of Physical Activity Levels

This subtheme relates to perspectives that there may be a role for these devices to support parents' awareness of their children's physical activity levels and the settings or circumstances that either facilitated or constrained this behavior. Almost all parents (20/22, 91%) reported that they would be interested in using these devices for this purpose.

Subtheme: Opportunities to Discuss Physical Activity

This subtheme relates to perspectives that the use of activity trackers may facilitate discussions about physical activity between parents and their children. Some parents (13/22, 59%)

XSL•FO
RenderX

indicated that there may be a role for activity trackers to prompt conversations about physical activity with their children to both encourage the behavior and educate their children on its benefits.

Subtheme: Special Circumstances

This subtheme relates to possible applications for activity trackers in circumstances where the ability or opportunity to participate in physical activity may be limited. Most parents (17/22, 77%) could see a potential benefit in instances where children are not getting enough physical activity due to health issues, a natural inclination to be physically inactive, or other family, social, or environmental factors.

Subtheme: Part of a Broader Program

Almost half of the parents (10/22, 45%) suggested that there may be an application for activity trackers as an adjunct or supporting strategy to encourage physical activity levels but not the sole strategy.

Discussion

Principal Findings

The purpose of this study was to explore parents' perspectives related to the feasibility, potential implications, and possible roles for smartwatch activity tracker use by young children. While the parents in this study perceived the use of smartwatch activity trackers by young children as feasible, the potential negative influence of extrinsic motivation to physical activity, disruption of positive behaviors, parental burden on parents to mediate the information from the device, and the safety and privacy of their child's information are important implications to consider. These implications, together with the pervasive view that young children are naturally physically active, could explain why these parents did not see a broad role for smartwatch activity trackers to promote physical activity in this age group. However, these parents indicated that there may be a role for the use of these devices to increase parents' awareness of their child's physical activity levels and patterns, to create opportunities to discuss physical activity, and in specific circumstances when children may not be getting enough physical activity for individual or family or social or environmental reasons.

Feasibility

The overarching view from parents was that the use of smartwatch activity trackers by young children is feasible. This view is supported by findings of recent systematic reviews that report 80% to 100% adherence to wear by young users (aged 3-7 years) as a proxy measure of feasibility [12,18]. However, parents reported that child characteristics related to their age, developmental abilities, and temperament, as well as the potential need for parental support to use the device and interpret its information, are likely to be key determinants of uptake and ongoing use by young children. Aligned with these perceptions is the observation that a sense of competence and self-efficacy are drivers of engagement in physical activity [25]. This could explain why individual factors that influence this sense of competence, including age or development or abilities and personality or temperament, are key in determining the feasibility of activity tracker use by young children. Smartwatch activity trackers incorporate behavior change techniques, including goal setting, action planning, and behavioral practice or rehearsal, which have been developed based on frameworks derived from theories of adolescent or adult motivation. Although such frameworks may not be the most relevant for young children, they have shown some promise in interventions to increase physical activity in children younger than 6 years of age [26]. However, the degree to which these devices influence a sense of competence and other key tenets of self-determination theory that support motivation for physical activity may depend on individual factors in addition to developmental stage [25]. For instance, goal setting and self-monitoring may support competence and self-efficacy in some children [27-29] but perhaps not in others who do not place as much value on goal achievement. Furthermore, parent involvement and support may be important for promoting relatedness, which also underpins intrinsic motivation for physical activity behaviors [27,30]. This may be particularly relevant for younger users who rely on the involvement of their parents.

Parents also indicated that the novelty of using an activity tracker may encourage uptake initially, but ongoing use may be limited in this age range. This view is consistent with findings in older children (aged 5 to 19 years), where adherence to wear declines after 2 to 4 weeks of use [31]. Poor maintenance of activity tracker use over time has also been reported in young children [18]. Furthermore, the view that comfort and wearability would also influence feasibility has been previously reported by parents of preschool children [32,33] and is corroborated by studies in young children [18] and older children (aged 5 to 19 years) [31,34]. This may be an important consideration for practical applications including intervention studies.

Implications

While parents in this study could see the positive intention of the devices to encourage or support physically active behaviors, they also raised some relevant considerations about this approach. These included that the device may be a source of extrinsic motivation for physical activity that could displace intrinsic desires to simply move and play for fun and enjoyment. Specifically, many devices include certain features designed to motivate movement (eg, prompts or reminders to move, daily physical activity goals with updates on progress, and rewards for achieving certain milestones or targets). In support of this implication raised by the parents, extrinsic rewards for completing tasks or activities have been shown to reduce subsequent intrinsic interest and motivation for these behaviors in young children [35,36]. Furthermore, intrinsic motivation has been shown to be the only type of motivation that is associated with physical activity behavior in children, and it has been recommended that interventions to increase physical activity in children should aim to optimize enjoyment and inherent satisfaction in being active rather than relying on forms of extrinsic motivation [37]. Thus, the extrinsic motivation theory basis for activity trackers may not be appropriate for young children. Additionally, the potential for the feedback from the device to be misinterpreted or create feelings of

XSL•FO
RenderX

pressure to achieve physical activity goals or guilt associated with not meeting goals has been reported in school-aged children and adolescents [38]. Relatedly, some parents indicated that how the information from the activity trackers was interpreted by young children has the potential to shape their involvement in physical activity (eg, children interpret low numbers or missed goals as failures, not being good enough, or being naughty). However, the potential negative effect of smartwatch activity trackers on intrinsic motivation to be active and feelings of pressure or guilt associated with meeting goals have not been specifically investigated in young children.

Parents also indicated that the devices could disrupt or distract positive behaviors, with the potential to interrupt learning or immersive play. This perception may be related to the importance that parents place on opportunities for immersive, enriching play that contributes to learning, socialization, and emotional and physical development [39,40]. It may also reflect parents' reluctance to overuse technology. It has been reported that parents have mixed perceptions of young children engaging with digital technologies with both perceived benefits (eg, supporting learning and education) and risks (eg, detrimental to cognitive and social development) [41]. It is possible that parents may be reluctant to use these devices if they do not perceive a clear benefit to their use. This possibility is supported by the parents' view that young children are naturally active and do not need a device to support physical activity behaviors.

Another commonly reported implication was that the information provided by the devices is a potential burden on parents since they see the mediation and messaging of this information as their responsibility, and this information may also be a source of guilt for parents in instances where their child's physical activity targets or recommendations are not met. Parents believe that in younger users, they would play a key role in interpreting and delivering feedback to the child and that they have a responsibility to deliver this information in a manner that is positive and encouraging. Some parents suggested that the opportunity for parents to present the feedback positively (eg, "let's go outside for a walk") or negatively (eg, "you have not met your goals, you need to do more") would influence the child's engagement in physical activity. Given that parents are integral to shaping early childhood physical activity behaviors [42], how parents respond to and deliver this information to their child has the potential to affect the child's sense of achievement, self-worth, and relationship with physical activity. Activity tracker use could therefore have unintended consequences if parental framing of the information provided is not helpful. When reflecting on the intention of the smartwatch activity trackers to promote physical activity, some parents indicated that they see this as their role through modeling, providing opportunities, and expressing family values. This perspective is supported by studies that show strong associations between parental support of physical activity and their child's participation in physical activity [43,44]. Parents believe that this role is particularly important in this age range, given the limited autonomy of young children (eg, ability to control their environment). In agreement with this view is the observation that the relationship between physical activity levels of parents and their children is strongest when their children are preschool-aged [45].

Potential Roles

The perception by parents that young children are naturally active is consistent with previous findings and could explain why parents in this and other studies have reported that their children are sufficiently active, and they are not concerned about their children's physical activity levels [33,46-49]. However, this view is not supported by population studies that show that many preschool children in developed countries do not meet current physical activity guidelines [8-10]. It is possible that parents overestimate the physical activity levels of their children compared to objective measures of physical activity, which has been reported in parents of less active children [49,50]. However, it has also been reported that while young children are perceived to be sufficiently active overall, their levels of moderate to vigorous physical activity may be low [48]. This observation is consistent with objectively measured physical activity levels in preschool children [51]. In this study, all children aged 3 to 5 years met the recommended 180 minutes per day of total daily physical activity, but only one-third of children met the 60 minutes per day of energetic play component of the guideline [51]. This could explain the incongruence between parents' perceptions of their children's physical activity levels and population data and suggests that strategies to support young children to achieve 60 minutes of energetic play per day are needed. While there may be a role for smartwatch activity trackers to support this goal, this remains to be investigated.

Despite the view that young children do not need a device to support their engagement in physical activity, many parents indicated that they would be interested to know how and when their children were physically active and that there may be a role for smartwatch activity trackers to increase their awareness of their children's physical activity. This awareness of their child's physical activity could inform decisions about their child's physical activity as well as challenge the perception that increasing physical activity requires significant effort and instead can occur with small changes with little or no preparation. Thus, there could be a role for smartwatch activity tracker use in changing attitudes toward physical activity and helping to identify opportunities for increasing physical activity [52]. However, as discussed previously, some parents indicated that how the information was received by parents and delivered to children would shape the potential benefit of this opportunity. Furthermore, some parents indicated that there may be a role for smartwatch activity trackers to prompt conversations about physical activity with their children to both encourage the behavior and educate their children on the benefits of this behavior. In support of this view, it has been reported that short-term use of smartwatch activity trackers in families of preschool-aged children may encourage physical activity by prompting discussions about physical activity [52].

The perspective of most parents that the use of these devices may be beneficial for increasing physical activity levels in physically inactive children is supported by previous findings in school-aged children where programs that incorporated wearable activity trackers were more effective in inactive

XSL•FO
RenderX

children [13]. Some parents indicated that smartwatch activity trackers may have a role as a supplementary tool in a toolkit of resources that encourage physical activity or address inactivity in children. These parents suggested that smartwatch activity trackers could be used as an adjunct or supporting strategy to encourage physical activity but not the only strategy. This may reflect the importance of mediating how the information the devices capture is received and interpreted by the children. Programs that incorporate wearable activity trackers in school-aged children have been shown to have a greater effect on physical activity when complementary strategies are used [13].

Limitations

The participants included a high representation of well-educated parents in health and education professions located in Australia (primarily Western Australia) with access to parks and gardens, low-density living, and a favorable climate for engaging in outdoor physical activities. For these reasons, the perspectives reported in this study may not be transferable to other socioeconomic and geographical contexts.

Conclusions

For most parents, the potentially negative implications of the use of these devices, together with the pervasive view that most young children are inherently physically active, meant that they see a limited role for the use of smartwatch activity trackers for supporting physically active behaviors in active young children. However, parents indicated that there may be a role for these devices to increase awareness of and promote discussions about physical activity, as well as encourage physical activity in children who are less active.

Acknowledgments

This project was partly funded by a Curtin School of Allied Health 2023 Teaching and Research Grant (A0000001575) and the ARC Centre of Excellence for the Digital Child.

Data Availability

The data generated or analyzed during this study are available from the corresponding author upon request.

Authors' Contributions

Conceptualization: RJD (lead), AC (equal), LS (equal), JZ (equal), AB (supporting), CLR (supporting), DH (supporting), SS (supporting), CH (supporting)
Data curation: RJD (lead), JZ (supporting)
Formal analysis: RJD (lead), JZ (supporting)
Funding acquisition: RJD (lead), AC (equal), LS (equal), JZ (equal), AB (supporting), CLR (supporting), DH (supporting), SS (supporting), CH (supporting)
Investigation: RJD (lead), JZ (supporting)
Methodology: RJD (lead), AC (equal), LS (equal), JZ (equal), AB (supporting), CLR (supporting), DH (supporting), SS (supporting), CH (supporting)
Project administration: RJD (lead), AC (supporting), LS (supporting), JZ (supporting)
Resources: RJD (lead), AC (supporting), LS (supporting), JZ (supporting)
Supervision: JZ (lead), AC (supporting), LS (supporting)
Validation: JZ (lead), AC (supporting), LS (supporting)
Visualization: RJD (lead), AC (equal), LS (equal), JZ (equal), AB (supporting), CLR (supporting), DH (supporting), SS (supporting), CH (supporting)
Writing—original draft: RJD (lead), AC (supporting), LS (supporting), JZ (supporting)
Writing—reviewing and editing: RJD (lead), AC (supporting), LS (supporting), JZ (supporting), AB (supporting), CLR (supporting), DH (supporting), SS (supporting), CH (supporting)

Conflicts of Interest

None declared.

Multimedia Appendix 1
Preinterview questionnaire.
[DOCX File , 67 KB - pediatrics_v8i1e79851_app1.docx]

References

1. Carson V, Lee E, Hewitt L, Jennings C, Hunter S, Kuzik N, et al. Systematic review of the relationships between physical activity and health indicators in the early years (0-4 years). BMC Public Health 2017;17(Suppl 5):854. [doi: 10.1186/s12889-017-4860-0] [Medline: 29219090]

XSL•FO
RenderX

2. Timmons BW, Leblanc AG, Carson V, Connor Gorber S, Dillman C, Janssen I, et al. Systematic review of physical activity and health in the early years (aged 0-4 years). Appl Physiol Nutr Metab 2012;37(4):773-792. [doi: 10.1139/h2012-070] [Medline: 22765840]
3. LeBlanc AG, Spence JC, Carson V, Connor Gorber S, Dillman C, Janssen I, et al. Systematic review of sedentary behaviour and health indicators in the early years (aged 0-4 years). Appl Physiol Nutr Metab 2012;37(4):753-772. [doi: 10.1139/h2012-063] [Medline: 22765839]
4. Poitras VJ, Gray CE, Janssen X, Aubert S, Carson V, Faulkner G, et al. Systematic review of the relationships between sedentary behaviour and health indicators in the early years (0-4 years). BMC Public Health 2017;17(Suppl 5):868. [doi: 10.1186/s12889-017-4849-8] [Medline: 29219092]
5. Telama R, Yang X, Leskinen E, Kankaanpää A, Hirvensalo M, Tammelin T, et al. Tracking of physical activity from early childhood through youth into adulthood. Med Sci Sports Exerc 2014;46(5):955-962. [doi: 10.1249/MSS.0000000000000181] [Medline: 24121247]
6. Guidelines on physical activity, sedentary behaviour and sleep for children under 5 years of age. World Health Organization. 2019. URL: https://www.who.int/publications/i/item/9789241550536 [accessed 2025-10-23]
7. Willumsen J, Bull F. Development of WHO guidelines on physical activity, sedentary behavior, and sleep for children less than 5 years of age. J Phys Act Health 2020;17(1):96-100 [FREE Full text] [doi: 10.1123/jpah.2019-0457] [Medline: 31877559]
8. Chaput J, Colley RC, Aubert S, Carson V, Janssen I, Roberts KC, et al. Proportion of preschool-aged children meeting the Canadian 24-Hour Movement Guidelines and associations with adiposity: results from the Canadian Health Measures Survey. BMC Public Health 2017;17(Suppl 5):829. [doi: 10.1186/s12889-017-4854-y] [Medline: 29219075]
9. Cliff DP, McNeill J, Vella SA, Howard SJ, Santos R, Batterham M, et al. Adherence to 24-Hour Movement Guidelines for the Early Years and associations with social-cognitive development among Australian preschool children. BMC Public Health 2017;17(Suppl 5):857. [doi: 10.1186/s12889-017-4858-7] [Medline: 29219104]
10. Hesketh KD, Booth V, Cleland V, Gomersall SR, Olds T, Reece L, et al. Results from the Australian 2022 Report Card on physical activity for children and young people. J Exerc Sci Fit 2023;21(1):83-87 [FREE Full text] [doi: 10.1016/j.jesf.2022.10.006] [Medline: 36408206]
11. Pereira JR, Cliff DP, Sousa-Sá E, Zhang Z, Santos R. Prevalence of objectively measured sedentary behavior in early years: systematic review and meta-analysis. Scand J Med Sci Sports 2019;29(3):308-328. [doi: 10.1111/sms.13339] [Medline: 30456827]
12. Phillips SM, Summerbell C, Hobbs M, Hesketh KR, Saxena S, Muir C, et al. A systematic review of the validity, reliability, and feasibility of measurement tools used to assess the physical activity and sedentary behaviour of pre-school aged children. Int J Behav Nutr Phys Act 2021;18(1):141. [doi: 10.1186/s12966-021-01132-9] [Medline: 34732219]
13. Casado-Robles C, Viciana J, Guijarro-Romero S, Mayorga-Vega D. Effects of consumer-wearable activity tracker-based programs on objectively measured daily physical activity and sedentary behavior among school-aged children: a systematic review and meta-analysis. Sports Med Open 2022;8(1):18. [doi: 10.1186/s40798-021-00407-6] [Medline: 35099630]
14. Gal R, May AM, van Overmeeren EJ, Simons M, Monninkhof EM. The effect of physical activity interventions comprising wearables and smartphone applications on physical activity: a systematic review and meta-analysis. Sports Med Open 2018;4(1):42 [FREE Full text] [doi: 10.1186/s40798-018-0157-9] [Medline: 30178072]
15. Brickwood K, Watson G, O'Brien J, Williams AD. Consumer-based wearable activity trackers increase physical activity participation: systematic review and meta-analysis. JMIR Mhealth Uhealth 2019;7(4):e11819. [doi: 10.2196/11819] [Medline: 30977740]
16. Ringeval M, Wagner G, Denford J, Paré G, Kitsiou S. Fitbit-based interventions for healthy lifestyle outcomes: systematic review and meta-analysis. J Med Internet Res 2020;22(10):e23954. [doi: 10.2196/23954] [Medline: 33044175]
17. Tang MSS, Moore K, McGavigan A, Clark RA, Ganesan AN. Effectiveness of wearable trackers on physical activity in healthy adults: systematic review and meta-analysis of randomized controlled trials. JMIR Mhealth Uhealth 2020;8(7):e15576. [doi: 10.2196/15576] [Medline: 32706685]
18. Davey RJ, Zabatiero J, Beynon A, Wood G, Sy S, Rasmussen CL, et al. It is feasible for 3 to 5-year-old children to use smartwatch activity trackers: a systematic review. Acta Paediatr 2025;114(9):2133-2147. [doi: 10.1111/apa.70137] [Medline: 40377501]
19. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med 2014;89(9):1245-1251 [FREE Full text] [doi: 10.1097/ACM.0000000000000388] [Medline: 24979285]
20. Burkett GL. Classifying basic research designs. Fam Med 1990;22(2):143-148. [Medline: 2182361]
21. Thompson Burdine J, Thorne S, Sandhu G. Interpretive description: a flexible qualitative methodology for medical education research. Med Educ 2021;55(3):336-343. [doi: 10.1111/medu.14380] [Medline: 32967042]
22. Rapley T, Flick U. Sampling Strategies in Qualitative Research. London: SAGE Publications Limited; 2014:49-63.
23. Digital Child. URL: https://digitalchild.org.au/ [accessed 2025-10-18]
24. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2008;3(2):77-101. [doi: 10.1191/1478088706qp063oa]

XSL•FO
RenderX

25. Deci EL, Ryan RM. Handbook of Self-Determination Research. Rochester, NY: University of Rochester Press; 2002.
26. Al-Walah MA, Donnelly M, Cunningham C, Heron N. Which behaviour change techniques are associated with interventions that increase physical activity in pre-school children? A systematic review. BMC Public Health 2023;23(1):2013. [doi: 10.1186/s12889-023-16885-0] [Medline: 37845721]
27. Beauchamp MR, Crawford KL, Jackson B. Social cognitive theory and physical activity: mechanisms of behavior change, critique, and legacy. Psychol Sport Exerc 2019;42:110-117. [doi: 10.1016/j.psychsport.2018.11.009]
28. Knittle K, Nurmi J, Crutzen R, Hankonen N, Beattie M, Dombrowski SU. How can interventions increase motivation for physical activity? A systematic review and meta-analysis. Health Psychol Rev 2018;12(3):211-230. [doi: 10.1080/17437199.2018.1435299] [Medline: 29385950]
29. McEwan D, Harden SM, Zumbo BD, Sylvester BD, Kaulius M, Ruissen GR, et al. The effectiveness of multi-component goal setting interventions for changing physical activity behaviour: a systematic review and meta-analysis. Health Psychol Rev 2016;10(1):67-88. [doi: 10.1080/17437199.2015.1104258] [Medline: 26445201]
30. Ntoumanis N, Ng JYY, Prestwich A, Quested E, Hancox JE, Thøgersen-Ntoumani C, et al. A meta-analysis of self-determination theory-informed intervention studies in the health domain: effects on motivation, health behavior, physical, and psychological health. Health Psychol Rev 2021;15(2):214-244. [doi: 10.1080/17437199.2020.1718529] [Medline: 31983293]
31. Creaser AV, Clemes SA, Costa S, Hall J, Ridgers ND, Barber SE, et al. The acceptability, feasibility, and effectiveness of wearable activity trackers for increasing physical activity in children and adolescents: a systematic review. Int J Environ Res Public Health 2021;18(12):6211 [FREE Full text] [doi: 10.3390/ijerph18126211] [Medline: 34201248]
32. Phillips SM, Summerbell C, Hesketh KR, Saxena S, Hillier-Brown FC. Parental views on the acceptability and feasibility of measurement tools used to assess movement behaviour of pre-school children: a qualitative study. Int J Environ Res Public Health 2022;19(6):3733 [FREE Full text] [doi: 10.3390/ijerph19063733] [Medline: 35329419]
33. Visier-Alfonso ME, Sánchez-López M, Rodríguez-Martín B, Ruiz-Hermosa A, Bartolomé-Gutiérrez R, Sequí-Domínguez I, et al. Parents' perceptions of children's and adolescents' use of electronic devices to promote physical activity: systematic review of qualitative evidence. JMIR Mhealth Uhealth 2023;11:e44753. [doi: 10.2196/44753] [Medline: 37471127]
34. Ridgers ND, McNarry MA, Mackintosh KA. Feasibility and effectiveness of using wearable activity trackers in youth: a systematic review. JMIR Mhealth Uhealth 2016;4(4):e129 [FREE Full text] [doi: 10.2196/mhealth.6540] [Medline: 27881359]
35. Deci EL, Koestner R, Ryan RM. A meta-analytic review of experiments examining the effects of extrinsic rewards on intrinsic motivation. Psychol Bull 1999;125(6):627-668; discussion 692-700. [doi: 10.1037/0033-2909.125.6.627] [Medline: 10589297]
36. Greene D, Lepper MR. Effects of extrinsic rewards on children's subsequent intrinsic interest. Child Dev 1974;45(4):1141-1145. [Medline: 4143868]
37. Sebire SJ, Jago R, Fox KR, Edwards MJ, Thompson JL. Testing a self-determination theory model of children's physical activity motivation: a cross-sectional study. Int J Behav Nutr Phys Act 2013;10:111. [doi: 10.1186/1479-5868-10-111] [Medline: 24067078]
38. Kerner C, Goodyear VA. The motivational impact of wearable healthy lifestyle technologies: a self-determination perspective on Fitbits with adolescents. Am J Health Educ 2017;48(5):287-297. [doi: 10.1080/19325037.2017.1343161]
39. Moon-Seo SK, Munsell SE. Play as a medium for children's learning from parents' perspectives. Educ Res Theory Pract 2022;33(2):23-31 [FREE Full text]
40. Moon-Seo SK, Munsell SE, Kim N. Mothers’ and fathers’ perceptions of children’s play. Early Child Educ J 2023;52(1):373-385. [doi: 10.1007/s10643-022-01439-7]
41. Hinkley T, McCann JR. Mothers' and father's perceptions of the risks and benefits of screen time and physical activity during early childhood: a qualitative study. BMC Public Health 2018;18(1):1271 [FREE Full text] [doi: 10.1186/s12889-018-6199-6] [Medline: 30453927]
42. Xu H, Wen LM, Rissel C. Associations of parental influences with physical activity and screen time among young children: a systematic review. J Obes 2015;2015:546925 [FREE Full text] [doi: 10.1155/2015/546925] [Medline: 25874123]
43. Loprinzi PD, Trost SG. Parental influences on physical activity behavior in preschool children. Prev Med 2010;50(3):129-133. [doi: 10.1016/j.ypmed.2009.11.010] [Medline: 19962397]
44. Trost SG, Sallis JF, Pate RR, Freedson PS, Taylor WC, Dowda M. Evaluating a model of parental influence on youth physical activity. Am J Prev Med 2003;25(4):277-282. [doi: 10.1016/s0749-3797(03)00217-4] [Medline: 14580627]
45. Alderman BL, Benham-Deal TB, Jenkins JM. Change in parental influence on children's physical activity over time. J Phys Act Health 2010;7(1):60-67. [doi: 10.1123/jpah.7.1.60] [Medline: 20231756]
46. Bentley GF, Jago R, Turner KM. Mothers' perceptions of the UK physical activity and sedentary behaviour guidelines for the early years (Start Active, Stay Active): a qualitative study. BMJ Open 2015;5(9):e008383 [FREE Full text] [doi: 10.1136/bmjopen-2015-008383] [Medline: 26351186]
47. Hinkley T, Salmon J, Okely A, Crawford D, Hesketh K. Influences on preschool children's physical activity: exploration through focus groups. Fam Commun Health 2011;34(1):39-50. [doi: 10.1097/FCH.0b013e31820590d6] [Medline: 21135627]

XSL•FO
RenderX

48. Ek A, Sandborg J, Delisle Nyström C, Lindqvist A, Rutberg S, Löf M. Physical activity and mobile phone apps in the preschool age: perceptions of teachers and parents. JMIR Mhealth Uhealth 2019;7(4):e12512. [doi: 10.2196/12512] [Medline: 30994465]
49. Kesten JM, Jago R, Sebire SJ, Edwards MJ, Pool L, Zahra J, et al. Understanding the accuracy of parental perceptions of child physical activity: a mixed methods analysis. J Phys Act Health 2015;12(12):1529-1535. [doi: 10.1123/jpah.2014-0442] [Medline: 25872227]
50. Hesketh KR, McMinn AM, Griffin SJ, Harvey NC, Godfrey KM, Inskip HM, et al. Maternal awareness of young children's physical activity: levels and cross-sectional correlates of overestimation. BMC Public Health 2013;13:924 [FREE Full text] [doi: 10.1186/1471-2458-13-924] [Medline: 24090173]
51. Christian HE, Adams EK, Moore HL, Nathan A, Murray K, Schipperijn J, et al. Developmental trends in young children's device-measured physical activity and sedentary behaviour. Int J Behav Nutr Phys Act 2024;21(1):97 [FREE Full text] [doi: 10.1186/s12966-024-01645-z] [Medline: 39223658]
52. Sharaievska I, Battista RA, Zwetsloot J. Use of physical activity monitoring devices by families in rural communities: qualitative approach. JMIR Pediatr Parent 2019;2(1):e10658 [FREE Full text] [doi: 10.2196/10658] [Medline: 31518327]

Edited by S Badawy; submitted 30.06.25; peer-reviewed by L Ardigò, F Loureiro; comments to author 10.09.25; revised version received 06.10.25; accepted 14.10.25; published 11.11.25.

Please cite as:
Davey RJ, Campbell A, Beynon A, Rasmussen CL, Hendry D, Stearne S, Harris C, Straker L, Zabatiero J
Parental Perspectives on the Use of Smartwatch Activity Trackers by Young Children: Qualitative Study
JMIR Pediatr Parent 2025;8:e79851
URL: https://pediatrics.jmir.org/2025/1/e79851
doi:10.2196/79851
PMID:41217801

©Raymond J Davey, Amity Campbell, Amber Beynon, Charlotte Lund Rasmussen, Danica Hendry, Sarah Stearne, Courtenay Harris, Leon Straker, Juliana Zabatiero. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 11.11.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Challenges and Opportunities in Recruiting a Very Large Sample of Pregnant Individuals: Secondary Analysis of an Online Nationwide Randomized Controlled Trial

Breanne Laird[1], PhD; Sara Moyer[2], PhD; Jennifer Huberty[3], PhD; Susan Bodnar-Deren[4], PhD; Patricia Kinser[2], PhD

[1]College of Health Solutions, Arizona State University, 500 North 3rd Street, Tempe, AZ, United States

[2]Family and Community Health Nursing, School of Nursing, Virginia Commonwealth University, Richmond, VA, United States

[3]Fit Minded, Inc, Phoenix, AZ, United States

[4]Department of Sociology and Institute for Women's Health, College of Humanities and Sciences, Virginia Commonweath University, Richmond, VA, United States

Corresponding Author:
Breanne Laird, PhD
College of Health Solutions, Arizona State University, 500 North 3rd Street, Tempe, AZ, United States

Abstract

Background: It is challenging to recruit vulnerable populations such as pregnant individuals, particularly during the perinatal period, which involves significant life changes and stressful situations that may create barriers to participation. Barriers to participation are even more prominent in historically marginalized populations, such as minoritized and low-income populations. Current literature is limited on recruitment methods, and specific activities may be best to recruit diverse pregnant individuals into online studies for the promotion of perinatal mental health.

Objective: The aim of this paper is to describe recruitment methods and strategies used to recruit a large sample (n=1953) of diverse pregnant individuals to an online nationwide large-scale randomized controlled trial, the Mamma Mia Study.

Methods: The Mamma Mia study is a multisite randomized controlled trial of an online- and mobile-based intervention for preventing and reducing perinatal depressive symptoms, based in the United States. The study intended to ensure a diverse national representation in the study population, with internal team demographic goals of at least 50% of participants identifying as a race or ethnicity other than White and at least 25% low-income (defined as a household income of less than US $50,000). Institutional review board–approved active and passive recruitment methods, both online nationally and in-person locally, were used to recruit eligible pregnant individuals.

Results: Combining local and in-person with national and online recruitment methods allowed for successful recruitment of a large and diverse sample of pregnant individuals, despite the necessity for several pivots due to national events (eg, the COVID-19 pandemic). In addition, this layered approach allowed the study to continue during an unplanned world event and be responsive to pivoting to meet recruitment goals. Recruitment approaches and methods that were the most successful were establishing community partnerships both online nationally and in-person locally, dedicated research time to focus on recruiting historically marginalized groups for a more representative sample, allocation of study time and resources to recruitment preparation, and dedicated internal research team recruitment planning and tracking.

Conclusions: Researchers should continue to publish and disseminate specific details about recruitment efforts and results, highlighting both aspects of success and lessons learned, as well as the pivot points in their recruitment methods for shared learning.

Trial Registration: ClinicalTrials.gov NCT04300894; https://www.clinicaltrials.gov/study/NCT04300894

(JMIR Pediatr Parent 2025;8:e72580) doi:10.2196/72580

KEYWORDS

recruitment; digital health; perinatal health; mental health; maternal health

Introduction

Studies that promote mental health and well-being in pregnant populations are often statistically underpowered due to small sample sizes that fail to meet recruitment goals [1-3]. It is challenging to recruit vulnerable populations such as pregnant women, particularly during the perinatal period, which involves significant life changes and stressful situations that create barriers to participation [1]. Barriers to participation are even more prominent in historically marginalized populations, such as minoritized and low-income populations [4,5]. Low

XSL•FO
RenderX

recruitment rates in these groups are commonly associated with reported issues such as access to research sites due to location, time commitment required, hesitancy due to lack of trust and knowledge in the research process due to misinformation, and concerns for privacy and confidentiality [1-4]. Other extenuating circumstances, such as time of year (eg, holidays) and world events (eg, COVID-19 pandemic), can intensify these challenges to an even greater extent. Participation of underrepresented groups in perinatal mental health research is necessary to understand and mitigate health disparities and to have findings that are generalizable to the population at large [4]. Research teams must be strategic about their study design and recruitment methodologies to ensure an adequate and representative sample of pregnant individuals is obtained.

Conducting online and mobile-based interventions that promote mental health and well-being for pregnant women during pregnancy and postpartum may be a way to decrease barriers to participation associated with in-person research [2]. The use of digitally delivered mental health programs reduces participation barriers related to travel costs, access, time, and the potential health risks of the public [2]. However, online and mobile-based studies with pregnant populations still struggle to be representative of historically marginalized groups [6,7]. A commonly used recruitment method, in general, is face-to-face in-person local recruitment that uses recruitment methods such as printed recruitment materials (eg, flyers, brochures, and postcards) that can be used both actively (eg, flyer handed to potential participant) and passively (eg, potential participant sees a posted flyer) [1-9]. Online recruitment is another recruitment method that has been increasing in popularity due to digital advancements. Online recruitment methods commonly used to recruit study participants, including pregnant individuals, are digital flyer postings through social media, email, and digital newsletters. These online methods promote greater reach and dissemination of the study participation opportunity [2]. Preliminary studies suggest online recruitment methods may help researchers successfully reach pregnant women [2], but there are still challenges to recruiting individuals who are traditionally underrepresented in research, such as historically marginalized populations by race, ethnicity, income, geolocation, and education [6,7].

It is unclear what general recruitment methods (ie, in-person, online, active, and passive) and associated specific recruitment methods for each strategy are best to recruit diverse groups of pregnant people into online studies for the promotion of perinatal mental health. It is timely and important for researchers to share with each other best practices for ensuring appropriate recruitment of diverse pregnant individuals. Transparency about challenges and opportunities is critical, whereby researchers can share their experiences and lessons learned to better equip future research with the strategies and tools needed to conduct studies with samples of participants that are representative of the target population effectively and credibly. Therefore, the purpose of this paper is to describe recruitment methods and strategies used to recruit a large sample of diverse pregnant individuals to an online nationwide large-scale randomized controlled trial (RCT). We explore methods and strategies used for recruitment and the successes and failures of these over the course of 4 years.

Methods

Study Design

The Mamma Mia study is a multisite randomized controlled trial of an online- and mobile-based intervention for preventing and reducing perinatal depressive symptoms that was conducted in the United States. The Mamma Mia study protocol and methods were published elsewhere [10]

Participant recruitment for the Mamma Mia Study occurred in the United States and used nationwide and local recruitment efforts. Local recruitment occurred at 2 geographical hubs: the central east coast region of the United States (East Central [EC] hub in Richmond, Virginia, led by study authors affiliated with Virginia Commonwealth University) and the southwestern region of the United States (Southwest hub, led by study authors affiliated with Arizona State University).

The study intended to ensure a diverse representation in the study population, with internal team demographic goals of at least 50% of participants who identified as Black or African American, Asian or Pacific Islander, Native American or Alaska Native, other or 2 or more races, or Latino or Hispanic and at least 25% low-income (as defined as a household income of less than US $50,000). Local active and passive recruitment was used to complement national recruitment efforts, given that online recruitment can have varying success in reaching individuals from historically marginalized populations [11,12]. We sought to recruit 1950 pregnant individuals who were: (1) less than 25 weeks gestation, (2) at least 18 years of age, (3) able to speak, read, and understand English as the intervention was available in English, and (4) had the ability to access an internet- or mobile-based program (via computer, tablet, or smartphone), and had access to a phone number and email address for study-related and safety protocol–related check-ins. All data collection occurred via digital platforms (eg, REDCap; Research Electronic Data Capture) via participant self-report survey, including the data about demographic questions (eg, race, ethnicity, income, and geolocation) and recruitment method (eg, “How did you hear about this study?”).

Recruitment Plan

This study was designed to integrate nationwide online recruitment alongside local passive and active recruitment at both the EC Hub and Southwest Hub. Based on our team’s experience with previous studies [13-16] in combination with extant literature [17,18], we expected that online recruitment may not accurately represent the diverse pregnant populations in the United States. Therefore, the recruitment plan for this study was intentionally designed to incorporate passive and active recruitment at local hubs in a layered recruitment plan.

In this study, we conceptualized “community” and “partnerships” as layered and dynamic, extending beyond formal health care and research settings. Consistent with frameworks for authentic community engagement [19], we understood “community” to include formal organizations (eg, Women Infants and Children clinics, community health resource centers,

XSL•FO
RenderX

Birth in Color) as well as informal networks (eg, community health workers, peer advocates) embedded within the lived realities of pregnant individuals, particularly those from historically marginalized groups. "Partnerships" were not limited to advisory or consultative relationships; rather, they reflected shared efforts to co-develop culturally relevant recruitment strategies, build trust, and foster mutual investment in the study's goals. By adopting this layered and relational approach, we sought to create a more inclusive, trust-centered recruitment model, better positioned to reach diverse pregnant populations across geographic regions.

Recruitment Preparation

Recruitment preparation included: (1) developing a recruitment plan and strategy, (2) building credibility and trust with an online presence, and (3) a recruitment tracking plan. Recruitment methods in our recruitment plan included where recruitment should take place (eg, online, in-person, and specific locations), who might have access to the target population (community partners), contact strategies for potential partners (email, phone, and social media), and developing recruitment materials (eg, flyers and recruitment scripts for both in-person and online communication). Community partner outreach and support included connecting with potential online community partners who would be willing to share about the study via their own established online platforms (eg, listserv emails and social media postings). Other recruitment preparation methods included developing a study website and developing social media accounts. These study-specific websites and accounts were used as landing pages to build credibility and trust with an online presence. Recruitment tracking was set up using the data collection tool REDCap, a secure web-based data collection and management system. Our recruitment tracking collected data related to the type of recruitment method each enrolled participant endorsed (eg, how did you hear about this study) in addition to tracking data about the type of recruitment material (eg, which flyer) was used throughout the recruitment period.

Recruitment Methods

Internal Team Recruitment Strategies and Tracking

Internal team strategies for planning and tracking recruitment methods used included weekly team meetings for brainstorming, planning, and goal setting, as well as constant consideration of feedback from the community. Additional internal team methods included internal team accountability, such as weekly and monthly data updates to monitor progress and recruitment tracking (inclusive of our internal diversity benchmarks, how participants heard about the study, etc). Study team members also attended webinars and training focused on health equity and social justice to be able to design recruitment strategies and material most appropriate for collaborating with community partners and recruiting our target demographics.

Study Eligibility and Intake Procedures

An essential aspect of data integrity for studies that use online recruitment methods is data integrity and sample validity by ensuring that enrolled study participants are a potential human research participant (eg, not a bot) and they are accurately representing themselves during the enrollment screening process [8,20]. Therefore, we implemented the following layered strategies. First, we posted the link to our study-specific website (rather than the direct survey link) in public open forum online spaces. Second, we activated a reCAPTCHA (Completely Automated Public Turing test to tell Computers and Humans Apart) tool on the eligibility screening form on REDCap. Third, we required an enrollment phone call during which the research team reviewed the consent form and had participants verify several free-text items from the enrollment form, including where they heard about the study. This allowed us to track our recruitment efforts, including snowball recruitment. Fourth, we cross-referenced each new enrollment participant's email address with our recent enrolled database to screen for multiple concurrent enrollments by the same individual.

Ethical Considerations

This study, including all recruitment materials and study plans, was approved by the Virginia Commonwealth University Institutional Review Board (IRB; HM20017197), with reliance on the VCU IRB by the Arizona State University IRB. All participants provided electronic consent prior to participating in the study. To protect privacy and confidentiality, all data collected were deidentified, with personal information securely stored and accessible only to authorized personnel. Financial compensation was offered to all study participants (up to US $140 in gift cards) and provided for each study task (eg, survey completion).

Results

Overview

Our final sample consisted of n=1953 participants. The study sample included participants who self-identified as African American or Black (367/1953, 18.8%), Asian or Pacific Islander (95/1953, 4.9%), Native American or Alaska Native (14/1953, 0.7%), White (1255/1953, 64.3%), Other (61/1953, 3.1%), and Latino or Hispanic (158/1953, 8.1%). In addition, this sample consisted of at least one participant from each of the 50 states and the District of Columbia, and participants were distributed across the nation with regional representation as follows: 17% from the Northeast, 20.6% from the Midwest, 38.9% from the South, and 23.6% from the West. The majority of participants were recruited from Virginia (611/1953, 31.3%), California (132/1953, 6.8%), North Carolina (86/1953, 4.4%), Texas (74/1953, 3.8%), and New York (71/1953, 3.6%). Our sample is comparable to the US Census population data of women of reproductive age (15-44 years) as of July 2023 (13.4% Black or African American, 6.8% Asian or Pacific Islander, 1.2% Native American or Alaska Native, 51.8% White, 13.7% two or more races, and 22.2% Latino or Hispanic) [21].

As mentioned previously, the team identified internal benchmarks for race, ethnicity, and income to track as a metric of study sample diversity. In addition, the team tracked how many participants heard about the study from each recruitment method (see Table 1): online and national recruitment (including social media posts and email blasts from community partner organizations), in-person local recruitment (including active and passive recruitment methods surrounding each regional hub), and snowball recruitment (including participants that

XSL•FO
RenderX

actively spread the word to their connections regarding the study).

Our team began recruitment on October 15, 2020 (Y 1 Q3) and ended on September 1, 2023 (Y 4 Q2). Figure 1 depicts overall recruitment data for this RCT, along with world events and pivots during recruitment, and benchmark details by year/quarter.

Table . Recruitment timeline.

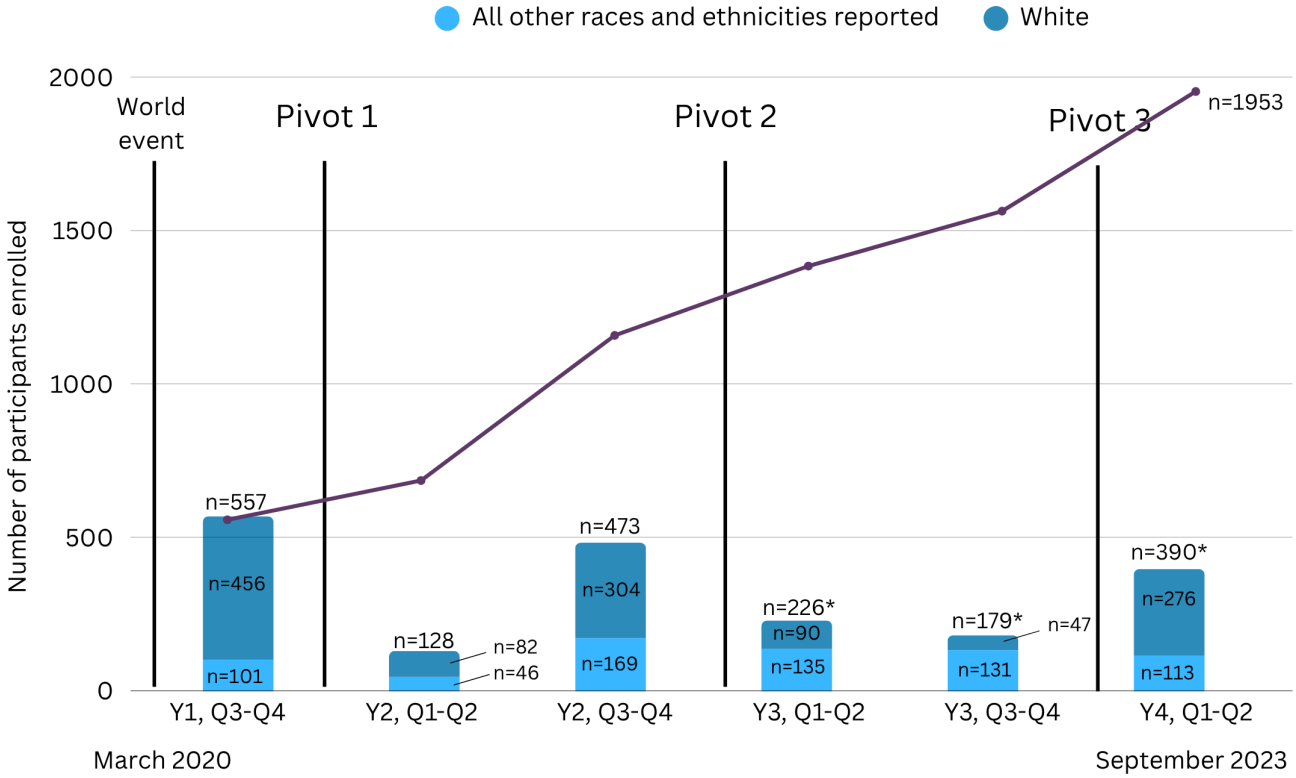
Grant year	Year 1		Year 2		Year 3		Year 4	Total
Quarters	1-2	3-4	1-2	3-4	1-2	3-4	1-2	—
Recruitment goals, n (%)	—[a]	162 (8.3)	366 (18.8)	366 (18.8)	366 (18.8)	366 (18.8)	324 (16.6)	1950 (100)
Recruitment actual, n (%)	—	557 (28.5)	128 (6.6)	473 (24.3)	226 (11.6)	179 (9.2)	390 (20)	1953 (100.2)
Internal team benchmark tracking								
Race/ethnicity, n (%)								
Any race or ethnicity reported other than White	—	101 (18.1)	46 (35.9)	169 (35.7)	135 (59.7)	131 (73.2)	113 (29)	695 (35.6)
White	—	456 (81.9)	82 (64.1)	304 (64.3)	90 (39.8)	47 (26.3)	276 (70.8)	1255 (64.3)
Missing	—	—	—	—	1 (0.4)	1 (0.6)	1 (0.31)	3 (0.2)
Income, n (%)								
<US $50,000/year	—	78 (14)	22 (17.2)	105 (22.2)	95 (42)	97 (54.2)	73 (18.7)	470 (24.1)
>US $50,000/year	—	469 (84.2)	104 (81.3)	364 (77.0)	126 (55.8)	80 (44.7)	312 (80)	1455 (74.5)
Missing	—	10 (1.8)	2 (1.5)	4 (0.8)	5 (2.2)	2 (1.1)	5 (1.3)	28 (1.4)
Recruitment strategies, n (%)								
National	—	403 (72.4)	74 (57.8)	35 (7.4)	70 (31)	29 (16.2)	239 (61.3)	850 (43.5)
Southwest hub	—	1 (0.2)	0 (0)	3 (0.6)	13 (5.8)	8 (4.5)	1 (0.3)	26 (1.3)
EC hub[b]	—	83 (14.9)	41 (32)	158 (33.4)	132 (58.4)	124 (69.3)	117 (30)	655 (33.5)
Snowball	—	70 (12.6)	13 (10.2)	277 (58.6)	11 (4.9)	18 (10.1)	33 (8.5)	422 (21.6)

[a]Not applicable.

[b]EC hub: East Coast region local hub.

XSL•FO
RenderX

Figure 1. Overall recruitment data. *: n=1 with missing race and ethnicity data.



World Event

Of note, this study launched in the Spring of 2020, which co-occurred with the major world event of the SARS-CoV-2 (COVID-19) pandemic; this is noted as "World Event" in Figure 1. As such, no direct in-person recruitment was possible in local clinics and community events. However, because our recruitment plan included a dual approach of online and in-person recruitment, the study was able to continue operating when many research studies had to completely suspend operation.

Pivots in Recruitment Approaches

Pivot 1: After deploying online recruitment methods (eg, social media) that yielded high recruitment and enrollment numbers initially, we noticed a majority of these participants identified as White and reported higher income brackets. The team had originally planned to integrate in-person recruitment at each of our local hubs to account for this potential issue; however, due to pandemic-related restrictions, that was not possible. To be able to reach our diversity goals, as a team, we enacted Pivot 1. In this pivot, we aimed to focus our online recruitment efforts on potential participants who identified as a person of color by (1) connecting with online community partners on social media who specifically focused their content on pregnant individuals identifying as people of color, (2) updating our recruitment materials and images, and (3) adding language adjustments to our recruitment materials and study website specifically highlighting the study's goal of including pregnant individuals identifying as people of color.

Pivot 2: As pandemic-related restrictions shifted, our team enacted Pivot 2. In this pivot, we allocated intentional time and efforts toward in-person recruitment at both local hubs in addition to continued online and national efforts. Continuing the focus to recruit a diverse and representative sample, we intentionally focused on posting recruitment materials and attending in-person events in a variety of community-based locations. For example, our study teams attended community events such as powwows for local indigenous tribes in rural areas of Virginia and multicultural festivals in several urban areas in central Virginia. We also collaborated with our local community partners who held community baby showers and other celebratory events for the pregnant and postpartum community in Virginia (eg, Black Maternal Mental Health Week). We activated our professional and clinical network to engage in active recruitment through presence at our academic clinical partner sites. Specific to our academic clinical partner site, we obtained a waiver of consent through the IRB for prescreening of medical records. In this prescreening process, no data was recorded about potential participants. This process allowed team members to actively engage with potential participants who met the team's internal benchmarks for race, ethnicity, and income.

Also, during this pivot, we mentioned that participants were welcome to share about the study with their communities or other pregnant individuals during the enrollment phone call. This was an organic process that arose after several participants asked permission to share with friends or family, or even via private social media groups (eg, Reddit). At the time of Pivot 2, we intentionally integrated this discussion into the enrollment call script with every newly enrolled participant with a simple offering of, "Also, you are welcome to share about this study with anyone else who may want to hear about it. You can share our website or are welcome to give them my (the research coordinator's) contact info if they would like additional information." Having an easily shareable study-specific website

XSL•FO
RenderX

that served as a direct way to share the study was critical to this process.

Pivot 3: Throughout the study, our team tracked enrollment by state, given an internal team goal to have representation across the nation. As our team neared our goal completion date for recruitment, we completed a final overall review of our study enrollment progress to date and noticed that we had minimal representation from the Midwest region of the United States. As such, we engaged with an online community partner who had tailored social media content for pregnant women in the Midwest to share study recruitment materials. In addition, to meet total enrollment goals, we re-engaged with study partners about re-sharing recruitment materials.

Discussion

Overview

The purpose of this paper was to describe recruitment methods and strategies used to recruit a large sample (n=1953) of diverse pregnant individuals to an online nationwide large-scale RCT. The intent of sharing these details is to inform other research studies intending to conduct similar large-scale online studies. The study was successful in meeting total enrollment goals and partially successful in meeting goals of enrolling participants identifying as Black or African American, Asian or Pacific Islander, Native American or Alaska Native, other or two or more races, or Latino or Hispanic, and low-income. We discuss our experiences and future considerations for researchers below.

A combination of in-person and local, online and national, and passive and active recruitment, combined with internal team recruitment planning and tracking strategies, helped us reach our recruitment goals in a timely manner. The most successful recruitment methods were: (1) establishing community partnerships both in-person locally and online nationwide, (2) ensuring team-wide dedication to recruiting individuals from historically marginalized groups, and (3) maintaining a nimble internal team approach. Recruitment approaches that did not yield many participants included mailed postcards, newsletters, and "boosted" posts on Facebook (Meta Inc) and Instagram (Meta Inc). In line with extant literature, mailed postcards and newsletters often result in low response rates (typically <10%) and overrepresent older, White, and more educated populations compared to more active approaches [22]. Similarly, "boosted" social media posts may yield high traffic but produce lower eligibility and completion rates [23,24].

We established community partnerships by engaging with physicians and perinatal-focused organizations in person and by working with individuals and organizations online nationally who had large followings and were willing to share information about our study. Given our experiences and the extant literature, we believe that research teams should strive for sustained, bi-directional engagement when building relationships with community partners both in person and online; intentionally focusing on relationships based on aligned missions that can grow toward true engagement and collaboration through a program of research rather than a one-time recruitment engagement. We ensured team-wide dedication to recruitment goals through internal team recruitment strategies, including (1) intentional dedication to recruiting diverse participants, (2) recruitment preparation through website and social media development, (3) online and social media community partner feedback collaborations, and (4) remaining flexible and open to pivoting recruitment efforts and goals based on recruitment performance and community feedback.

In-Person and Local Recruitment

In-Person and Local Methods

In-person and local recruitment methods included building collaborations with community partners such as practitioners (eg, clinic partnerships), researchers (eg, other research teams working with perinatal populations), businesses or individuals (eg, local and regional organizations or members focused on perinatal health), events, and mailed postcards. For community partners who were a part of the study team, financial compensation was provided for their time and efforts. Although funding was not available for every community partner, some other ideas for extending gratitude to community partners who were interested included adding their logo on the study website with a clickable link; the research team collaborating to create educational content to be shared through the organization (eg, website, blog, and social media); and sharing the community partner's content or social media posts as mutually agreed upon and appropriate by both the study team and the community partner.

The use of purposeful in-person recruitment allows for focused recruitment of diverse populations in the community via community partnerships and professional networks. In-person methods that were most successful included the presence of research personnel in community and clinical settings commonly attended by pregnant individuals. Our research team established new relationships and expanded existing relationships with local primary care and obstetric clinics and organizations (eg, Women Infants and Children Program, Birth in Color RVA, Postpartum Support Virginia, Urban Baby Beginnings, Huddle Up Moms). These methods are consistent with previous literature suggesting that obstetrician and midwife support is essential for introducing patients to research studies for patients to feel comfortable participating in clinical research while pregnant [25]. When applicable, research team presence in clinic settings and taking the time to meet with clinic professionals to present study methods and answer questions gave our team the opportunity to be fully integrated in prenatal clinical settings.

Most importantly, this study included collaboration with a local community partner as a part of the research team, and this community partnership was an essential part of recruitment planning, recruitment material development, and community engagement planning at the local EC hub. For example, our primary community partner, "Birth in Color," provides a myriad of services to pregnant women of color—from community baby showers, to parenting classes, to prenatal yoga, including events held in public housing communities. In addition, the study team sought additional community partner relationships with organizations serving pregnant women at the local level, developing relationships for bidirectional support, including supporting community events with volunteers. Research team

XSL•FO
RenderX

members' presence alongside community partners in community spaces is a first step toward community engagement and collaboration to develop research that is integrated into the community. In this way, research teams can include individuals who may not have been included in research through more typical clinical avenues; team members can answer questions in real-time and build relationships with potential participants [25].

Online and National Recruitment

Online national recruitment methods included engaging with community partners online to build relationships, credibility, and trust with influencers and leaders of online communities that engage with diverse pregnant individuals in the United States. Online community partners included nonprofit organizations that shared our recruitment materials via their email listservs or websites and social media sharing by individuals or groups with large followings on various social media platforms. Additional recruitment strategies included paying for advertisements and "boosted" posts, as well as creating a study website for interested individuals to access information about the study and engage in enrollment activities. The study website included research team and study funding transparency, study coordinator contact information for questions, and information about community partners to support credibility and trust.

The greatest benefit of online recruitment methods we observed was being able to connect with community partners who treat, advocate for, or serve the target population nationwide. These methods allowed us to reach diverse populations and increase the generalizability of research findings. Online community partner outreach and support can begin during the project planning phase, grant development phase, and during the IRB approval stage. Preparation support includes letters of support or verbal (eg, email) agreement and receiving feedback on recruitment language and images and referrals to other potential community partners. Asking community partners to follow the study's social media accounts can be a first step to begin establishing rapport in the community the research is targeting. Once community partners agree to collaborate, logos made clickable to partners' websites or social media accounts can be uploaded to the study website. Securing online relationships with community partners is important for trust and credibility to be felt by the potential participant [21]. For example, multiple participants communicated they had signed up for our study because a trusted health care provider or public figure had shared the Mamma Mia study on their social media account. Our study website and social media presence allowed the community partners to direct potential participants to places online where they could learn more about the study, find contact information to ask questions, and see other community partners and followers who support the research. Researchers should consider following credible individuals in their field of study on their study social media accounts and ask community partners to follow the account back, effectively creating a well-integrated online community. Of note, some larger, national groups and organizations as well as nonprofits that serve both pregnant individuals and underserved groups were less likely to share via online platforms than smaller regional or local groups for a myriad of reasons; for example, some had multiple other concurrent social media campaign priorities or other research they were supporting, while others had a mission that did not align with the current recruitment goals, and some never responded or stopped responding to our outreach. Research teams may consider this when planning for engaging with online and social-media partners, as local and regional organizations with an online presence may be more impactful for study recruitment purposes.

The use of the internet for both recruitment of study participants and tracking recruitment efforts can be a cost-effective and high-yield strategy [2,8,20,26]. More specifically, the use of social media, email list-servs, websites, and online data collection tools can be highly effective online recruitment methods [8,20]. However, the technology literacy of team members and partners can impact the success of these strategies. Study teams who use online and digital recruitment strategies must be educated on social marketing and how a social media platform works (eg, how the algorithm works), how to best communicate with potential partners via email versus direct messages on social media, how to design and manage a website, and how to track recruitment efforts digitally for insight into what is working and what is not. Researchers should be aware of the level of experience and technology literacy of their teams and consider training team members in online strategies before study recruitment begins, even if they are experienced in study recruitment. Further, if the target population of a research study is historically marginalized populations, it is critical to ensure teams are trained in health equity and social justice concepts before starting recruitment activities. This training is essential for all health research professionals.

Partnering with individuals and organizations who already have established large followings can help spread the word about the study opportunity to a greater degree, effectively reaching the target potential participant population much more effectively than sharing via the research-specific accounts. In addition, when working with pregnant individuals, it is important to acknowledge that many participants wanted to share with others in their own communities about the research participation opportunity, leading to a snowball recruitment effect. Having relationships with community partners nationwide can increase recruitment reach, leading to more diverse samples that are more representative of the general population.

Recruitment Materials

IRB-approved recruitment materials were used for both in-person and online recruitment, as well as for our active and passive recruitment methods. Recruitment materials included, but were not limited to, flyers, brochures, email scripts, images optimized for digital use, short videos, and social media post-scripts. Graphic design software was used to create study flyers, brochures, and digital graphics. All recruitment materials included inclusive images intended to reflect the many types of pregnant individuals. All recruitment materials, including emails without images, presented appropriate IRB-approved wording that had been cocreated with a consulting community partner. Recruitment materials were then updated and improved based

XSL•FO
RenderX

on feedback from community partners, participants, and potential participants.

Recruitment material design and recruitment language are essential to successful study enrollment. The content of both paper and online recruitment materials must be professional, eye-catching, and well-received by the intended population [2]. Research teams should also be flexible when working with social media partners and consider methods to effectively and efficiently meet the needs of both the partners and the IRB to streamline this process. For example, simple techniques such as flexibility around the color scheme of the digital graphic used can be impactful, allowing the social media partner to keep their posts "on brand." Researchers should seek feedback from their community partners during the design phase of recruitment materials.

Collaboration with community partners should occur regarding the recruitment flyers and digital graphics, email and social media wording used, as well as the design and information on a study's website. For example, we collaborated with the community partner on our team to develop study recruitment materials and integrated their valuable feedback before launching study recruitment. This is particularly important when recruiting vulnerable and historically marginalized populations. Researchers must acknowledge historical exclusion and well-earned mistrust by medical and research communities and move toward language and images in recruitment materials that are intentionally inclusive [27]. Researchers should make sure that all study materials appropriately disclose the study purpose, personnel, and funding to support transparency and trust between the researchers and potential participants, and they should be open to constructive feedback from the community.

Internal Team Support

Study recruitment cannot be successful without internal team strategies that emphasize training and accountability [28]. Researchers should consider frequent team meetings that include planning and goal-setting that align with the study timeline, recruitment data reporting based on goals, accountability for meeting goals, and being open and flexible to pivoting recruitment strategies as needed. Our internal team strategies are consistent with the literature that demonstrates recruiting historically marginalized pregnant women is most successful when studies combine in-person and remote recruitment with internal team coordination methods [17,18]. Recruitment management that includes preparation, training, and tracking will also ensure that various strategies are being used correctly and are providing the results intended. Insights from those who have recruited participants during pregnancy underscore that training in recruitment strategies can reduce gatekeeping and enable flexible adaptation [29].

Recruitment Cost

Community partners often prefer and sometimes require financial support for their efforts. Although in-person recruitment has been found to be less cost-effective than online methods [2,30], we found that the typical cost for social media partners to advertise about the study through a website, social media post, or series ranged from US $150-US $7000. Studies planning to incorporate online advertising as part of their recruitment strategies should plan for this expenditure in the budget planning phase. Because this type of recruitment funding is often limited or not included in grant proposals at all, other forms of compensation should also be considered. For example, potential partners may find it valuable if direct links to their website or social media accounts are included on the study website; partners may also appreciate having their information shared with study participants through newsletters, blogs, and study landing pages. These strategies may allow researchers to reciprocate support with partners despite limited funding. We recommend that researchers plan ahead for and justify these costs for recruitment preparation time, active efforts, and costs in grant proposals.

Protecting Data Integrity and Sample Validity

Ensuring sample validity, and therefore protecting data integrity, is of paramount concern for online studies using online recruitment strategies. Online studies should have systems in place to detect both robotic or spam involvement as well as deceptive enrollment (eg, human participants who do not meet the study enrollment criteria that may use deception in eligibility screening in order to participate in the study). In this study, useful strategies included sharing a study-specific website rather than the direct enrollment survey link via social media, implementing a reCAPTCHA tool on the eligibility screening survey, and requiring an enrollment and consent verification phone call before confirming enrollment, where participants were required to verify free-text items from the eligibility screener. Although not done in our study, we suggest that researchers may consider additional approaches such as (1) adding hidden fields to eligibility surveys that will be "seen" and filled out by robotic or spam respondents but not human participants, (2) activating a timestamp on online surveys to evaluate time spent completing each survey, and (3) requiring a video call for enrollment and consent verification [8,20]. Future studies should consider the tension between data integrity and ensuring that study enrollment procedures are not overly burdensome for participants.

Our findings confirm and extend previous work demonstrating the value of a multiapproach, community-engaged recruitment strategies that integrate both digital and in-person methods to reach underserved populations. While previous studies have suggested the efficacy of social media in perinatal research recruitment [31], our findings suggest the use of online methods alone, without community partners, may not be sufficient to meet diversity goals [31]. These findings align with concerns in recent literature of a digital divide and underrepresentation of marginalized populations in digital health research [20,32].

Limitations and Future Considerations

While we were partially successful in recruiting a diverse sample, we did not fully achieve all of our internal benchmark goals. This study encountered several limitations to recruitment that are important to consider when interpreting the findings and planning for future research. First, using a low-income benchmark of US $50,000 may have been too high for some US regions, potentially limiting the generalizability of our findings for low-income individuals. Second, the study was

XSL•FO
RenderX

conducted exclusively online and in English, which may have been a barrier to participation from non-English speaking populations or low-income individuals who may not have access to a tablet, smartphone, or computer. Future research should consider providing materials in multiple languages, offering tech support, or providing study devices to increase accessibility. Third, the recruitment period overlapped with the COVID-19 pandemic, which limited the ability to conduct in-person recruitment activities during the early phases of the study. Although the pivot to online recruitment was successful, the inability to rely on traditional in-person methods may have impacted the diversity and reach of the study sample. Fourth, our team encountered several barriers associated with online community partnerships. We recommend that research teams engage with online and social media partners early on, particularly in the grant budget planning phase, to allocate adequate budget line items for successful partnership compensation. Future research should consider the demographics of their local communities, resources for supporting local entities in assisting in recruitment, as well as the intended goals for the study and how dissemination of findings will directly impact the population being studied when deciding where and how to recruit.

Fifth, despite our efforts to recruit a geographically diverse sample, representation from some regions, such as the Midwest, was lower than anticipated. While we adapted our recruitment strategies to targeted community partnerships and online outreach, this imbalance highlights the ongoing need for tailored region-specific approaches to recruitment. Finally, we used multiple approaches to prevent fraudulent or duplicate enrollments, and this may add administrative burden that may not be feasible for all research teams. Additional research into scalable, automated approaches to ensure data integrity is needed.

Conclusion

Recruiting participants to research studies is a complex and ever-changing process due to the importance of sample size and diversity, as well as advancements in technology. Best recruitment results for recruiting very large samples of historically marginalized groups to online and mobile-based RCTs are achieved with an integration of both in-person and online recruitment. This paper aimed to describe the recruitment plan, inclusive of recruitment methods, approaches, and strategies, used to recruit a large sample of diverse pregnant individuals to an online mobile-based RCT. Combining local and in-person with national and online recruitment methods allowed for successful recruitment of a large sample of pregnant individuals. In addition, this layered approach allowed the study to continue during an unplanned world event and be responsive to pivoting to meet recruitment goals. Recruitment approaches and methods that were the most successful were establishing community partnerships both online nationally and in-person locally, dedicated research time to focus on recruiting historically marginalized groups for a more representative sample, allocation of study time and resources to recruitment preparation, and a dedicated internal research team for recruitment planning and tracking. Researchers should continue to publish and disseminate their recruitment efforts and results, highlighting both aspects of success and lessons learned, as well as the pivot points in their recruitment methods for shared learning. As such, future studies may reach their intended sample sizes with appropriate, diverse representation of the population intended to benefit from the study findings.

Acknowledgments

We would like to thank Molly Robinson Schwartz for the graphic design for the logo included in this manuscript. This study is funded by the National Institutes of Health/Eunice Kennedy Shriver National Institute of Child Health and Human Development (R01HD100395; PI: Kinser). The use of REDCap for data collection and management is supported by Clinical and Translational Science Award (CTSA) award number UL1TR000058 from the National Center for Advancing Translational Sciences. Its contents are solely the responsibility of the authors and do not necessarily represent official views of the National Center for Advancing Translational Sciences or the National Institutes of Health.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

PK and JH were responsible for funding acquisition for the intervention. PK, JH, SM, and BL contributed to the conceptualization of the manuscript. PK, JH, SM, and BL contributed to the recruitment into the intervention. SM and BL contributed to data curation of the recruitment results. SM and SBD contributed to the recruitment analysis. BL and SM reviewed the literature review to support the perspectives put forth and contributed to drafting the manuscript. BL and SM contributed to writing the original draft. PK, JH, and SBD contributed to writing by reviewing and editing the original draft. All authors discussed the ideas, revised the manuscript for intellectual content, and approved the final version for publication.

Conflicts of Interest

None declared.

XSL•FO
RenderX

References

1. Frew PM, Saint-Victor DS, Isaacs MB, et al. Recruitment and retention of pregnant women into clinical research trials: an overview of challenges, facilitators, and best practices. Clin Infect Dis 2014 Dec 15;59 Suppl 7(Suppl 7):S400-S407. [doi: 10.1093/cid/ciu726] [Medline: 25425718]
2. Cochrane KM, Hutcheon JA, Karakochuk CD. Strategies for improving recruitment of pregnant women to clinical research: an evaluation of social media versus traditional offline methods. Digit Health 2022;8:20552076221095707. [doi: 10.1177/20552076221095707] [Medline: 35531089]
3. Hulsbosch LP, Nyklíček I, Potharst ES, Meems M, Boekhorst M, Pop VJM. Online mindfulness-based intervention for women with pregnancy distress: design of a randomized controlled trial. BMC Pregnancy Childbirth 2020 Mar 13;20(1):159. [doi: 10.1186/s12884-020-2843-0] [Medline: 32169030]
4. Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research, Committee on Women in Science, Engineering, and Medicine, Policy and Global Affairs, National Academies of Sciences, Engineering, and Medicine. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. National Academies Press 2022. [doi: 10.17226/26479] [Medline: 36137057]
5. Louis-Jacques AF, Heuberger AJ, Mestre CT, et al. Improving racial and ethnic equity in clinical trials enrolling pregnant and lactating individuals. J Clin Pharmacol 2023 Jun;63 Suppl 1:S21-S33. [doi: 10.1002/jcph.2263] [Medline: 37317498]
6. Turner BE, Steinberg JR, Weeks BT, Rodriguez F, Cullen MR. Race/ethnicity reporting and representation in US clinical trials: a cohort study. Lancet Reg Health Am 2022 Jul;11:100252. [doi: 10.1016/j.lana.2022.100252] [Medline: 35875251]
7. Krukowski RA, Ross KM, Western MJ, et al. Digital health interventions for all? Examining inclusivity across all stages of the digital health intervention research process. Trials 2024 Jan 30;25(1):98. [doi: 10.1186/s13063-024-07937-w] [Medline: 38291539]
8. Pozzar R, Hammer MJ, Underhill-Blazey M, et al. Threats of bots and other bad actors to data quality following research participant recruitment through social media: cross-sectional questionnaire. J Med Internet Res 2020 Oct 7;22(10):e23021. [doi: 10.2196/23021] [Medline: 33026360]
9. Rider A, Aubry C, Moyer S, Kinser P. Perspectives on successes and challenges in the recruitment and retention of pregnant women in a research study. Clin Res (Alex) 2019 Sep;33(8):6-14. [Medline: 32832581]
10. Kinser P, Jallo N, Huberty J, et al. Study protocol for a multisite randomized controlled trial of an internet and mobile-based intervention for preventing and reducing perinatal depressive symptoms. Res Nurs Health 2021 Feb;44(1):13-23. [doi: 10.1002/nur.22092] [Medline: 33319443]
11. Lee EW, Denison FC, Hor K, Reynolds RM. Web-based interventions for prevention and treatment of perinatal mood disorders: a systematic review. BMC Pregnancy Childbirth 2016 Feb 29;16(1):38. [doi: 10.1186/s12884-016-0831-1] [Medline: 26928898]
12. Andersson G, Titov N, Dear BF, Rozental A, Carlbring P. Internet-delivered psychological treatments: from innovation to implementation. World Psychiatry 2019 Feb;18(1):20-28. [doi: 10.1002/wps.20610] [Medline: 30600624]
13. Huberty J, Matthews J, Leiferman JA, Lee C. Use of complementary approaches in pregnant women with a history of miscarriage. Complement Ther Med 2018 Feb;36:1-5. [doi: 10.1016/j.ctim.2017.11.003] [Medline: 29458913]
14. Huberty J, Puzia M, Green J, Stecher C. Mental health and meditation practices of pregnant women during COVID-19. Obstet Gynecol Res 2021;04(1):1-6. [doi: 10.26502/ogr048]
15. Green J, James D, Larkey L, et al. A qualitative investigation of a prenatal yoga intervention to prevent excessive gestational weight gain: a thematic analysis of interviews. Complement Ther Clin Pract 2021 Aug;44:101414. [doi: 10.1016/j.ctcp.2021.101414] [Medline: 33989862]
16. Green J, Neher T, Puzia M, Laird B, Huberty J. Pregnant women's use of a consumer-based meditation mobile app: a descriptive study. Digit Health 2022;8:20552076221089098. [doi: 10.1177/20552076221089098] [Medline: 35371532]
17. Rokicki S, Gobburu A, Weidner M, et al. Barriers and strategies for recruitment of pregnant women in contemporary longitudinal birth cohort studies. BMC Med Res Methodol 2025 Apr 28;25(1):117. [doi: 10.1186/s12874-025-02570-w] [Medline: 40295914]
18. Goldstein E, Bakhireva LN, Nervik K, et al. Recruitment and retention of pregnant women in prospective birth cohort studies: a scoping review and content analysis of the literature. Neurotoxicol Teratol 2021;85:106974. [doi: 10.1016/j.ntt.2021.106974] [Medline: 33766723]
19. Blumenthal DS. A community coalition board creates a set of values for community-based research. Prev Chronic Dis 2006 Jan;3(1):A16. [Medline: 16356369]
20. Loebenberg G, Oldham M, Brown J, et al. Bot or not? Detecting and managing participant deception when conducting digital research remotely: case study of a randomized controlled trial. J Med Internet Res 2023 Sep 14;25:e46523. [doi: 10.2196/46523] [Medline: 37707943]
21. NST-EST2023-POPCHG2020-2023: Annual estimates of resident population change for the United States, states, District of Columbia, and Puerto Rico and state rankings: April 1, 2020 to July 1, 2023. : Census Bureau, Population Division; 2023 URL: https://www2.census.gov/programs-surveys/popest/technical-documentation/file-layouts/2020-2023/NST-EST2023-POPCHG2020_2023.pdf [accessed 2025-10-12]

XSL•FO
RenderX

22. Ley C, Duan H, Parsonnet J. Recruitment into antibody prevalence studies: a randomized trial of postcards vs. letters as invitations. BMC Med Res Methodol 2023 Jul 22;23(1):170. [doi: 10.1186/s12874-023-01992-8] [Medline: 37481522]
23. Pekarsky C, Skiffington J, Leijser LM, Slater D, Metcalfe A. Social media recruitment strategies to recruit pregnant women into a longitudinal observational cohort study: usability study. J Med Internet Res 2022 Dec 12;24(12):e40298. [doi: 10.2196/40298] [Medline: 36508244]
24. Childers-Rockey ZA, Flesher EA, Stephens JI, Barton NK, Waldron ME, Rioux C. Recruitment through social media ads and videocalls: cost, effectiveness, and lessons from the experiences of pregnancy study. Am J Epidemiol 2025 Mar 17:kwaf061. [doi: 10.1093/aje/kwaf061] [Medline: 40098473]
25. Sutton EF, Cain LE, Vallo PM, Redman LM. Strategies for successful recruitment of pregnant patients into clinical trials. Obstet Gynecol 2017 Mar;129(3):554-559. [doi: 10.1097/AOG.0000000000001900] [Medline: 28178062]
26. Surdam J, Daly B, Fulton S, et al. Recruitment strategies for nurse enrollment in an online study. Nurs Res 2020;69(1):69-73. [doi: 10.1097/NNR.0000000000000393] [Medline: 31804433]
27. Israel BA, et al. Critical issues in developing and following CBPR principles. In: Wallerstein N, Duran B, Oetzel JG, Minkler M, editors. Community-Based Participatory Research for Health, 3rd edition 2017:32-35.
28. Cranfill JR, Freel SA, Deeter CE, et al. Development and evaluation of a novel training program to build study staff skills in equitable and inclusive engagement, recruitment, and retention of clinical research participants. J Clin Transl Sci 2022;6(1):e123. [doi: 10.1017/cts.2022.456] [Medline: 36259068]
29. Hanrahan V, Gillies K, Biesty L. Recruiters' perspectives of recruiting women during pregnancy and childbirth to clinical trials: a qualitative evidence synthesis. PLoS One 2020;15(6):e0234783. [doi: 10.1371/journal.pone.0234783] [Medline: 32559236]
30. Ellington M, Connelly J, Clayton P, et al. Use of Facebook, Instagram, and Twitter for recruiting healthy participants in nutrition-, physical activity-, or obesity-related studies: a systematic review. Am J Clin Nutr 2022 Feb 9;115(2):514-533. [doi: 10.1093/ajcn/nqab352] [Medline: 34669955]
31. Frampton GK, Shepherd J, Pickett K, Griffiths G, Wyatt JC. Digital tools for the recruitment and retention of participants in randomised controlled trials: a systematic map. Trials 2020 Jun 5;21(1):478. [doi: 10.1186/s13063-020-04358-3] [Medline: 32498690]
32. National Academies of Sciences, Engineering, and Medicine, Policy and Global Affairs, Committee on Women in Science, Engineering, and Medicine, Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups: The National Academies Press; 2022. [doi: 10.17226/26479]

Abbreviations

CAPTCHA: Completely Automated Public Turing test to tell Computers and Humans Apart
EC: East Central
IRB: Institutional Review Board
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
VCU: Virginia Commonwealth University

Edited by S Badawy; submitted 12.02.25; peer-reviewed by A Sheon, B Afolabi, L Uscher-Pines, R Singh; revised version received 31.07.25; accepted 17.08.25; published 24.10.25.

Please cite as:
Laird B, Moyer S, Huberty J, Bodnar-Deren S, Kinser P
Challenges and Opportunities in Recruiting a Very Large Sample of Pregnant Individuals: Secondary Analysis of an Online Nationwide Randomized Controlled Trial
JMIR Pediatr Parent 2025;8:e72580
URL: https://pediatrics.jmir.org/2025/1/e72580
doi:10.2196/72580

© Breanne Laird, Sara Moyer, Jennifer Huberty, Susan Bodnar-Deren, Patricia Kinser. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 24.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Impact of COVID-19 on Dutch General Practitioner Prenatal Primary Care: Retrospective, Observational Cohort Study Using an Interrupted Time-Series Approach

Wikje Berends-Hoekstra[1,2,3], MSc; Maarten Homburg[1], MD; Anke Oenema[4], PhD; Matthijs Simeon Berends[1,5,6], PhD; Lilian Peters[1,2,3], PhD

[1]Department of Primary and Long-term Care, University of Groningen, University Medical Center Groningen, Home Post Code FA21, PO Box 196, Groningen, The Netherlands

[2]Department of Midwifery Science, Vrije Universiteit Amsterdam, Amsterdam University Medical Centre, Amsterdam, The Netherlands

[3]Midwifery Academy Amsterdam Groningen, Inholland University of Applied Sciences, Amsterdam, The Netherlands

[4]Department of Health Psychology, Open Universiteit, Heerlen, The Netherlands

[5]Department of Medical Microbiology and Infection Prevention, University of Groningen, University Medical Center Groningen, Groningen, The Netherlands

[6]Department of Medical Epidemiology, Certe Foundation, Groningen, The Netherlands

Corresponding Author:
Wikje Berends-Hoekstra, MSc
Department of Primary and Long-term Care, University of Groningen, University Medical Center Groningen, Home Post Code FA21, PO Box 196, Groningen, The Netherlands

Abstract

Background: The COVID-19 pandemic significantly impacted primary health care–seeking behavior of the general population. The extent to which health care–seeking behavior of pregnant women in general practitioner (GP) care was affected remains largely unknown. The unique health care needs of pregnant women necessitate regular monitoring and care to ensure the well-being of expectant mothers, fetuses, and neonates, as timely interventions and screenings can profoundly influence the long-term health outcomes. Understanding how pandemic-related changes have influenced pregnant women's primary health care–seeking behavior is essential for developing targeted interventions and informing policy decisions to improve health outcomes for expectant mothers, fetuses, and neonates, both during public health emergencies and in routine health care settings.

Objective: This study aims to examine the impact of different COVID-19 pandemic phases on health care–seeking behavior among pregnant women in Dutch GP practices throughout 2020 and 2021. By analyzing clinical electronic health record (EHR) GP data, we aim to evaluate the health care consumption, occurrence of pregnancy-relevant symptoms and diagnoses, and types of contact (ie, regular consultations, phone consultations, home visits, and digital consultations) during different pandemic phases.

Methods: Using a retrospective cohort design, EHRs of selected pregnant women from 3 Dutch GP networks between 2019 and 2021 were analyzed, comparing 6 pandemic phases divided into 13 subphases with a prepandemic phase. Contact rates were analyzed by interrupted time-series analyses, pregnancy-relevant symptoms, and diagnoses by comparing the frequency of pregnancy-relevant International Classification of Primary Care (ICPC) code registrations and type of contact by descriptive statistics.

Results: In total, 10,985 pregnant women were included, yielding 39,023 patient-GP contacts. Contact rates fluctuated significantly across pandemic phases, with the sharpest declines at the onset and the end of the pandemic. Pregnancy-relevant symptoms and diagnosis in the category related to pregnancy showed the highest variability across the pandemic phases, such as an increase in the frequency of health care consumption concerning gestational diabetes mellitus and nausea or vomiting of pregnancy. Detailed statistical results are reported in the main text. Contacts for symptoms and diagnosis like digestive or urinary tract problems did not fluctuate across the pandemic phases. The number of physical contacts decreased, while telephone contacts increased.

Conclusions: By analyzing EHR data from over 10,000 pregnant women, this study highlights the pandemic's impact on pregnant women's GP health care–seeking behavior, including declining health care consumption trends during the initial and end phases of the pandemic (2020 - 2021). The observed increase in GDM and its potential long-term effects underscore the need for enhanced public health strategies within GP practices, ensuring continuous access to prenatal care and striving for improved outcomes of expectant mothers, their fetuses, and neonates during times of pandemics and in routine health care settings.

(JMIR Pediatr Parent 2025;8:e64831) doi:10.2196/64831

XSL•FO
RenderX

KEYWORDS

pregnant women; COVID-19 pandemic; general practitioner; GP; health care–seeking behavior; interrupted time-series analysis; health policy; primary care

Introduction

The COVID-19 pandemic has caused profound changes in health care–seeking behavior globally, especially within primary general practitioner (GP) care settings, where a significant decline in use was observed following the outbreak of the pandemic [1-5]. This decline in GP health care visits was shown to be driven by factors such as lockdown measures and heightened fears of viral transmission [1]. These shifts have resulted in reduced experienced accessibility and continuity of GP care, leading to postponed chronic care and increased interactions with unfamiliar health care providers [6].

Prenatal health care is managed collaboratively by midwives and obstetricians in secondary health care, and by midwives and GPs in primary health care. In the Netherlands, every citizen is registered with a GP who serves as a gatekeeper to secondary care [7]. Midwives and GPs typically oversee low-risk pregnancies in primary care, while obstetricians handle high-risk cases in secondary hospital care. GPs play a pivotal role in prenatal health care, providing comprehensive support that encompasses health promotion (eg, advices concerning diet and exercise in the case of diabetes mellitus, smoking cessation, and COVID-19 infection and vaccination), timely interventions for routine health care problems (eg, treatment of urine tract infections and mental health problems) and specialist referrals [8-10]. In addition, pregnant women can rely on GPs for certain medication needs (eg, antibiotics, thyroid medication, and mental health medication), especially since midwives do not have prescription authority in the Netherlands. A previous national study showed that before the pandemic, pregnant women typically consulted their GPs around 6 times on average during pregnancy and the postpartum period [10]. Common reported symptoms and diagnoses included intercurrent diseases, vomiting, urogenital problems, mental health issues, and work-related concerns [10,11]. Most pregnant women saw their GP, alongside their midwife or obstetrician, as an essential prenatal care provider, fostering long-term trusted health relationships with their registered GPs [10]. Therefore, GPs play an important role in providing additional prenatal health care for pregnant women.

Postponing or cancelling this important prenatal care may lead to negative consequences for maternal, fetal, or neonatal health [12-14]. Pregnant individuals are inherently vulnerable and susceptible to both physical and psychological illness, which may be exacerbated if the necessary prenatal GP care is not provided. Therefore, sustainable GP care for pregnant women, in addition to regular perinatal care, is needed for a robust public health care system [2].

Consequently, understanding the impact of the COVID-19 pandemic on health care–seeking behavior among pregnant women in GP practices is imperative. However, the extent to which the pandemic influenced pregnant women's health care–seeking behavior within Dutch GP practices across different pandemic phases remains largely unknown. For that reason, this study aims to examine the impact of different COVID-19 pandemic phases on health care consumption among pregnant women in Dutch GP practices throughout 2020 and 2021. By analyzing routine clinical electronic health record (EHR) data registered by GPs, this study aims to evaluate health care consumption, the occurrence of pregnancy-relevant symptoms and diagnoses, and the types of contact (ie, regular consultations, phone calls, home visits, digital consultations) during different pandemic phases. It is important for informing policymakers, health care providers, and expectant mothers to understand how external factors such as a pandemic and associated restrictive measures influence health care–seeking behaviors among pregnant women. By providing these insights, this study ultimately aims to contribute to the improvement of prenatal GP care delivery, impacting public health in both pandemic and routine health care settings.

Methods

Study Design and Population

This retrospective observational cohort study used data retrieved from routinely registered clinical EHRs from GP practices from 2019 (prepandemic) to 2021 (pandemic). Data from 3 regional Dutch GP research networks were used: (1) the northern Academic General Practitioner Development Network (Academisch Huisartsen Ontwikkel Netwerk, AHON), including 59 GP practices managed by the University Medical Center Groningen (UMCG) [15]; (2) the eastern Family Medicine Network including 6 practices managed by Radboud University Medical Centre Nijmegen [16]; and (3) the southern Research Network Family Medicine Maastricht, including 28 practices managed by Maastricht University Medical Centre [17]. The network populations are a good reflection of the population in these regions [15,17,18]. The dataset included anonymized EHR data from approximately 410,000 patients, encompassing patients' medical history, clinical findings, diagnoses, types of contact, and demographic characteristics [1].

In the Netherlands, GPs are required to assign an International Classification of Primary Care (ICPC) code to each patient contact [19]. Contacts were defined as either a physical consultation (at the clinic or at home), a telephone consultation, or any type of digital contact between a patient and a GP or practice nurse, with registration of a free text note (physician's note) and at least 1 ICPC code.

Selection of Pregnant Women

Women in the reproductive age (20 - 45 y) with a confirmed pregnancy status in their EHR were selected for inclusion in the study. To select pregnant women, all EHR records of women of reproductive age were screened to determine pregnancy status during the studied period, using 3 methods. First, pregnancy status was determined based on the registration of at least one of the 24 pregnancy and childbearing related ICPC codes, such

XSL•FO
RenderX

as W78 (“pregnancy, confirmed”), see Multimedia Appendix 1. Second, to identify pregnant and postpartum women without pregnancy-relevant ICPC codes, physician’s notes (free text notes) were screened for text patterns indicating pregnancy, using a regular expression (see Multimedia Appendix 2). To enhance validity, this regular expression was reviewed by a data scientist. Third, physician’s notes of contacts of potentially pregnant women selected by the aforementioned methods were manually assessed by the study team (WB-H and MH) to confirm pregnancy status (see Multimedia Appendix 3). Only contacts where pregnancy status was confirmed at the time of the contact were included irrespective of their pregnancy duration.

Women miscarrying were also retrospectively labelled as being pregnant. If neither of these 3 methods were irrefutable about pregnancy status, women were excluded. Registrations of the ICPC code W90 (“normal delivery liveborn”) were excluded for data integrity reasons, as some of these were identified as false registrations from previous pregnancies. Women were excluded when they had died during the study period, were deregistered from one of the included practices, had a reason for deregistration without deregistration date, had an unknown date of birth, were registered less than 3 months, or had missing data that hindered pseudonymization (eg, zip code). Only dates of weekdays were included. Weekend days, holidays, and consults outside of regular office hours were excluded from the analysis (see Multimedia Appendix 4).

Outcome Variables

The primary outcome variables included pandemic health care consumption (ie, contact rates), pregnancy-relevant symptoms and diagnoses, and type of contact (ie, regular, phone, home visit, or digital contact), and were compared with the prepandemic baseline (2019). Pregnancy-related symptoms and diagnoses were determined by listing pregnancy-relevant ICPC codes that represented symptoms or diagnoses that commonly occur during pregnancy or require clinical attention in pregnant women. The selection was based on relevant ICPC codes from previous research [10], and supplemented with manual evaluation of all ICPC codes for their relevance in pregnancy. To validate the list of pregnancy-relevant ICPC codes, a general practitioner (MH) and a midwife evaluated the relevance of each code to pregnancy (see Multimedia Appendix 5). Contacts could involve one or more ICPC codes.

Pandemic Phases and Subphases

Previous research showed that health care consumption fluctuated during the pandemic in response to both changes in COVID-19 incidence rates and the implementation or relaxation of restrictive measures in the general population [1]. Therefore, this study is conducted in accordance with a previously described framework that divides the pandemic into 6 main phases based on the restrictive measures mandated by the Dutch government [1,20]. These phases were subdivided into subphases based on turning points in the national COVID-19 incidence rates within each main phase (Table 1), using data from the National Institute for Public Health and Environment (Rijksinstituut voor Volksgezondheid en Milieu). In the general population, for example, health care consumption initially decreased in phase 1 and then increased again midway through phase 1 as incidence rates declined, leading people to gradually visit their GPs more often again [1].

XSL•FO
RenderX

Table . COVID-19 pandemic phases in the Netherlands based on infection rates and restrictive measures, and subphases based on highest and lowest infection rates.

Phase and subphase		Year	Week within year	Description of COVID-19 infection rates and containment measures
Phase 0				• No confirmed COVID-19 infections in the Netherlands.
	Phase 0	2019	1 - 52	
	Phase 0	2020	1 - 8	
Phase 1				• First wave of COVID-19 infections. • First lockdown (ie, hand hygiene, social distancing, working at home, and schools, restaurants, amusement and industry closed). • Highest infection rates: week 15.
	Phase 1a	2020	9 - 13	
	Phase 1b	2020	14 - 22	
Phase 2				• Decrease in infection rates. • Gradual relaxation of restrictive measures. • Lowest infection rates: week 28.
	Phase 2a	2020	23 - 28	
	Phase 2b	2020	29 - 40	
Phase 3				• Second wave of COVID-19 infections. • Stricter containment measures, start of a partial lockdown followed by a strict lockdown (ie, curfew, schools, stores, and sport facilities closed). • Highest infection rates: week 44 and 52.
	Phase 3a	2020	41 - 44	
	Phase 3b	2020	45 - 53	
	Phase 3c	2021	1 - 3	
Phase 4		2021	4-17	• Emergence of the Alpha variant (B1.1.7) of concern, further increase in infection rates, and continued lockdown measures. • Highest infection rates: week 16.

XSL•FO
RenderX

Phase and subphase		Year	Week within year	Description of COVID-19 infection rates and containment measures
Phase 5				• Decrease in infection rates. • Gradual opening-up of society and only minor restrictions. • Lowest infection rates: week 26.
	Phase 5a	2021	18 - 26	
	Phase 5b	2021	27 - 43	
Phase 6				• Epidemic rise with the Delta variant (B.1.617.2) of concern and a steep increase in infection rates. • Lockdown measures reintroduced. • Highest infection rates: week 48.
	Phase 6a	2021	44 - 48	
	Phase 6b	2021	49 - 52	

Data Analysis

Overview

Descriptive statistics were performed to describe the study population characteristics for each studied year (2019, 2020, and 2021). This included the total number of included pregnant women per (pre)pandemic year and region, the total number of contacts, the mean number of contacts per patient with SD, the mean number of ICPC code registrations per contact, and the mean age with SDs. Statistical differences between the studied years were tested using a G-test for goodness-of-fit.

All statistical analyses with a $P<.05$ were considered significant. All data were analyzed using R (version 4.0.5; R Foundation for Statistical Computing).

Analysis of Health Care Consumption

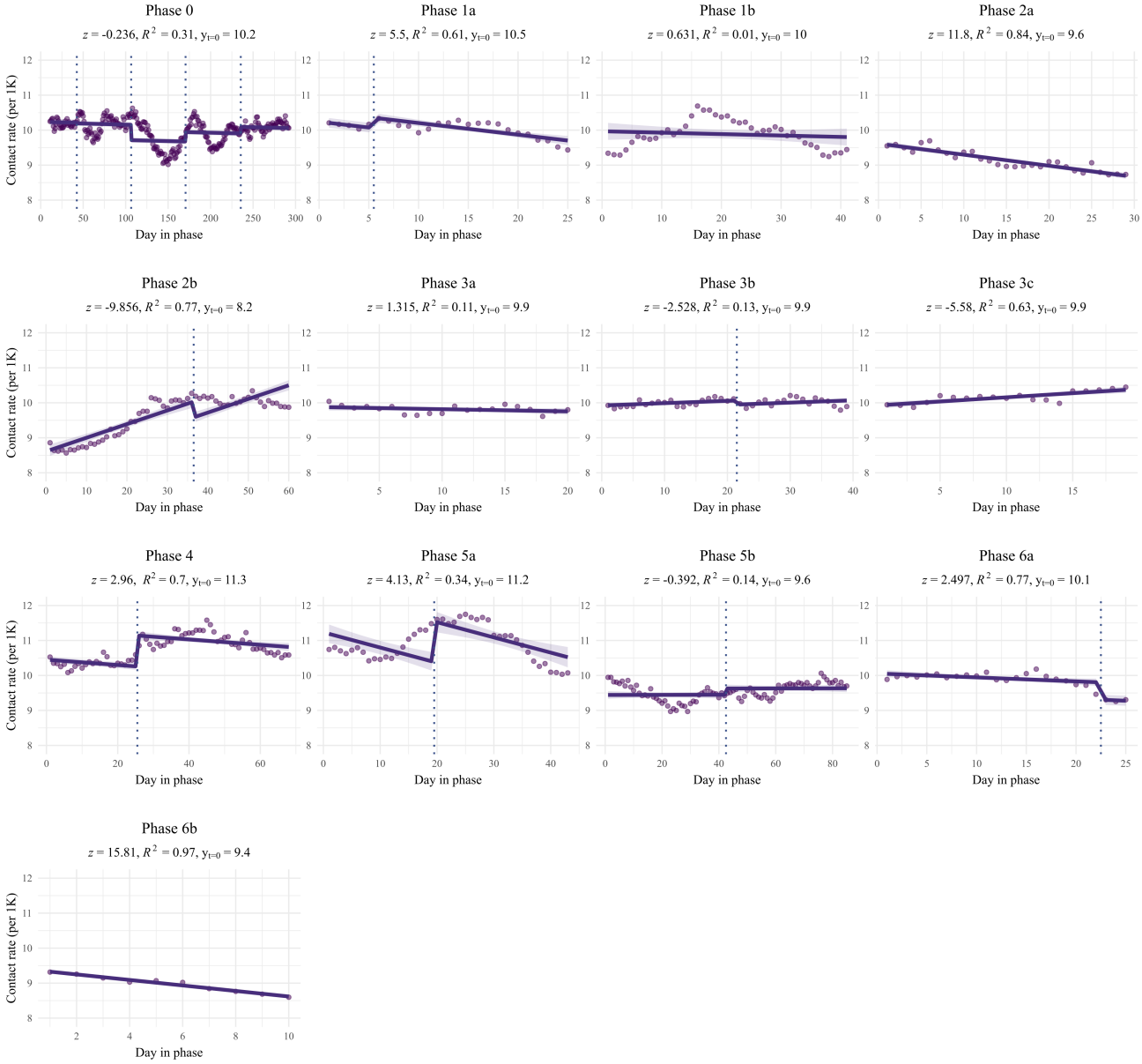
Health care consumption was calculated by normalizing daily contact rates per 1000 registered pregnant patients. An interrupted time-series analysis was conducted using a segmented linear regression model to assess the impact of the COVID-19 incidence rates and societal measures on health care consumption during each pandemic subphase. For each (pre)pandemic subphase, a linear regression model was used, assuming a linear relationship between time and the contact rates within each subphase and fitted to generate a least squares regression line. Linearity was checked through visual inspection of the fitted models, while autocorrelation was assessed visually using autocorrelation plots. To enhance the stability of contact rates, a 3-week centered moving average was applied before modeling. Seasonality was accounted for by adding seasonal intercepts to the model, with spring as the baseline. For each subphase P, the linear regression model was described mathematically (Equation 1).

$$(1) YT(P)=\beta 0+\beta 1\cdot T+\beta 2\cdot S1+\beta 3\cdot S3+\beta 4\cdot S4$$

In this equation, Y_T represents the contact rate at time T, P the phase being modelled (ranging from 0 to 6b), β_0 the intercept value at the start (t=0) of phase P, β_1 the slope of the linear model during phase P, and T the time variables (in days within phase P). β_2, β_3, and β_4 are the seasonal intercepts. S_1, S_3, S_4 are dummy variables indicating the season (Winter, Spring, Summer, and Autumn), taking value 1 if the season is within the studied phase, and value 0 otherwise (see Figure 1). S_2 was considered the baseline, always having value 0. This model captures the variation in the health care consumption during each phase, considering both the overall time trend ($\beta_0 + \beta_1 \cdot T$) and the seasonal effects introduced by the dummy variables $\beta_2 \cdot S_1 + \beta_3 \cdot S_3 + \beta_4 \cdot S_4$, taking spring S_2 as the baseline.

XSL•FO
RenderX

Figure 1. Linear models of health care consumption per phase, shown by day in phase and per 1000 registered pregnant patients. The *z* scores represent the comparison of the slope of each pandemic phase as compared to the slope of the prepandemic phase (Phase 0) along with their significance. As the prediction models for health care consumption were adjusted for seasonality, the linear regression lines may shift within a phase; these shifts are marked by vertical dashed lines at the seasonal transitions. The distributions of the x-axes are not equal for each phase, as phases did not consist of an equal number of days.



Beta coefficients (ie, intercept β_0 and slope β_1) were computed for each subphase. Intercept values and their SEs were calculated at the start of each subphase (t=0) to determine immediate effects at the start of a new subphase. In addition, slopes and their SEs were computed to model and assess the trend in health care consumption within each subphase, where a negative slope indicated a decrease, and a positive slope indicated an increase in health care consumption. To compare intercept values and slopes of pandemic subphases to the prepandemic baseline, *z*-scores of the β-coefficients and their accompanying *P* values were calculated. Coefficients of determination (R^2) and adjusted R^2 were calculated to describe the proportion of variance that was explained by the independent variables within each model. Differences between a pandemic subphase and the prepandemic baseline were considered significant if the *P* value of the *z* score of either the intercept or the slope was <.05.

Analysis of Pregnancy-Relevant Symptoms and Diagnoses

The changes in the most prevalent pregnancy-related symptoms and diagnoses were examined by identifying the 10 most frequently registered ICPC codes from the created list of pregnancy-relevant ICPC codes (ie, symptoms and diagnoses) within the studied population during the studied period. Focusing on the most prevalent conditions allowed for a structured analysis of variation over time while maintaining analytical feasibility. The number of ICPC code registrations was calculated by normalizing the number of ICPC code registrations per 1000 contacts. To assess whether these proportions differed substantially between each pandemic subphase and the prepandemic baseline, statistical analysis through Fisher Exact tests for each specific ICPC code was conducted.

XSL•FO
RenderX

Analysis of Type of Contact

The type of contact was visualized as a percentage of the total number of contacts within each phase. Visualization was done using a centered moving average of 3 weeks and smoothed using Locally Estimated Scatterplot Smoothing. This nonparametric smoothing technique uses locally weighted polynomial regression to fit a smooth curve through points in a scatter plot, providing a visual trend of the data without assuming a specific parametric model.

Ethical Considerations

Ethical approval for the collection and analysis of COVID-19 EHR data was conducted by the Medical Ethics Committee of the UMCG (2020/309). In this study, no patients were directly involved, and thus, this research was ruled not to be subject to the Medical Research Involving Human Subjects Act (Article 9, paragraph 2, EU-GDPR 2016/679). The EHR data were anonymized and deidentified before being made available to the researchers.

Results

Population Characteristics

A total of 975,545 contacts of 78,941 women in the reproductive age (20 - 45 y) were screened for pregnancy status, of which 10,985 women (13.9%) were labelled as pregnant and had 39,023 contacts with the GP (see Table 2). Pregnant women had a mean age of 30.4 (SD 4.6) years during the total studied period. These women had an average of 2.8 (SD 2.6) contacts in 2019, 2.8 (SD 2.6) in 2020, and 2.9 (SD 2.8) in 2021.

Table . Demographic characteristics of the study population of pregnant women per year (2019 - 2021; n=10,985).

	Total population[a] (N=10,985)	Population in 2019 (n=4414)	Population in 2020 (n=4553)	Population in 2021 (n=4836)	*P* value
Pregnant women, n	10,985	4414	4553	4836	<.001
Age (years), mean (SD)	30.4 (4.6)	30.5 (4.6)	30.3 (4.6)	30.5 (4.5)	≥.99
Total contacts, n	39,023	12,384	12,686	13,953	<.001
Number of contacts per patient, mean (SD)	3.6 (3.5)	2.8 (2.6)	2.8 (2.6)	2.9 (2.8)	.99
Number of ICPC[b] code registrations per contact, mean (SD)	1.13 (0.38)	1.14 (0.39)	1.13 (0.37)	1.12 (0.37)	≥.99

[a]Populations partly overlap in the 3 studied years.

[b]ICPC: International Classification of Primary Care.

Changes in Health Care Consumption

Health care-seeking behavior differed significantly in each pandemic subphase compared to Phase 0 (see Figure 1 and Table 3). At the onset of the pandemic (Phase 1a), an immediate significant increase in health care consumption was observed (β_0=10.54; *P*=.04), evident from the elevated intercept value compared to Phase 0. During Phase 1a, there was a substantial and significant decrease in health care consumption following the initial peak intercept value (β_1=–0.03; *P*<.001), indicating reduced contacts with the GP at the beginning of the pandemic. In Phase 1b, an immediate effect was noted, with a significantly lower intercept value (β_0=9.97, *P*<.001). However, the subsequent period did not significantly differ from Phase 0, indicating consistently lower health care consumption during Phase 1b, though this model was unable to explain most of the variance (R^2=0.02).

XSL•FO
RenderX

Table . Interrupted time series analysis of health care consumption for the different pandemic subphases (2020 and 2021) compared to the prepandemic year 2019 (phase 0) of the total studied population of pregnant women, showing intercepts (β_0) with SE, slopes with SEs (β_1), *z* scores, and *P* values for intercepts.

Phase	Intercept of the linear model			Slope of the linear model			Model's goodness of fit	
	Intercept β_0 (SE)	*z* score, intercepts	*P* value, intercepts	Slope β_1 (SE)	*z* score, slopes	*P* value, slopes	R^2	Adjusted R^2
0 (baseline)	10.22 (0.04)	—[a]	—	−0.00 (0.00)	—	—	0.31	0.30
1a	10.54 (0.10)	–4.10	.04	–0.03 (0.00)	5.50	<.001	0.61	0.57
1b	9.97 (0.13)	0.97	<.001	–0.00 (0.01)	0.63	.53	0.02	0.01
2a	9.62 (0.05)	7.83	.33	−0.03 (0.00)	11.80	<.001	0.85	0.84
2b	8.16 (0.20)	9.33	<.001	0.04 (0.00)	−9.86	<.001	0.77	0.76
3a	9.88 (0.05)	3.31	<.001	−0.01 (0.00)	1.32	.19	0.11	0.06
3b	9.92 (0.04)	3.05	.001	0.01 (0.00)	−2.53	.01	0.13	0.08
3c	9.92 (0.05)	2.74	.002	0.02 (0.00)	−5.58	<.001	0.63	0.61
4	11.34 (0.11)	−10.13	.006	−0.01 (0.00)	2.96	.003	0.70	0.69
5a	11.23 (0.14)	−7.61	<.001	−0.04 (0.01)	4.13	<.001	0.34	0.31
5b	9.62 (0.14)	3.33	.001	0.00 (0.00)	−0.39	.70	0.14	0.11
6a	10.06 (0.06)	0.59	.56	−0.01 (0.00)	2.50	.01	0.77	0.75
6b	9.41 (0.03)	13.26	<.001	−0.08 (0.01)	15.81	<.001	0.97	0.97

[a]Not applicable.

The start of Phase 2a did not significantly differ from Phase 0 (β_0=9.62; *P*=.33). Nevertheless, a significant negative slope indicated a sustained decline in health care consumption during this phase (β_1=–0.03; *P*<.001). Phase 2b marked the lowest intercept value in health care consumption in the studied period (β_0=8.16; *P*<.001). Subsequently, there was a significant increase in health care consumption during Phase 2b (β_1=0.04; *P*<.001).

In Phase 3, all subphases (3a, 3b, and 3c) exhibited significantly lower intercept values (respectively, β_0=9.88, *P*<.001; β_0=9.92, *P*=.001; and β_0=9.92, *P*=.002). Health care consumption remained stable during Phase 3a (β_1=–0.01; *P*=.19), while significant increases occurred during Phases 3b and 3c (β_1=0.01, *P*=.01 and β_1=0.02, *P*<.001, respectively), though the models of Phase 3a and 3b were unable to explain most of the variance (R^2=0.11, and R^2=0.13, respectively).

The onset of Phase 4 marked the highest intercept value since the beginning of 2019 (β_0=11.34; *P*=.006). However, health care consumption significantly declined during Phase 4 (β_1=–0.01; *P*=.003).

Phase 5a began with a significantly higher intercept value (β_0=11.23; *P*<.001). During Phase 5a, health care consumption declined significantly (β_1=–0.04; *P*<.001). This decline led to a significantly lower intercept value at the beginning of Phase 5b (β_0=9.62; *P*=.001), with health care consumption remaining relatively stable during Phase 5b. Phase 6a initiated with an intercept value comparable to Phase 0 (β_0=10.06; *P*=.56). However, health care consumption declined significantly during Phase 6a (β_1=–0.01; *P*=.01), resulting in a significantly lower intercept value of Phase 6b (β_0=9.41; *P*<.001), followed by a further significant decline during Phase 6b (β_1=–0.08; *P*<.001).

Pregnancy-Relevant Symptoms and Diagnoses

Most Frequent Registered Symptoms and Diagnoses

The top 10 pregnancy-relevant symptoms and diagnoses (ie, ICPC codes) presented by pregnant women to their GP during the studied period were examined (see Multimedia Appendix 6). These symptoms and diagnoses were (1) pregnancy confirmed (ICPC W78), (2) cystitis or other urine infection (U71), (3) vomiting or nausea of pregnancy (W05), (4) abortion spontaneous (W82), (5) unwanted pregnancy confirmed (W79) (6) frequent or urgent urination, (U02), (7) urogenital candidiasis (X72), (8) GDM (W84.02), (9) other localized abdominal pain (D06), and (10) constipation (D12). Contacts related to these top 10 symptoms and diagnosis covered 65.6% (n=25,587) of all contacts of pregnant women during the studied period.

Changes in Pregnancy-Relevant Symptoms and Diagnosis

The normalized and absolute number of contacts concerning the top 10 symptoms and diagnoses per phase were examined (Multimedia Appendix 6). Health care consumption concerning pregnancy-related symptoms and diagnoses changed statistically significant in multiple pandemic phases compared to Phase 0. Specifically, health care consumption for vomiting or nausea of pregnancy was significantly higher during Phase 2a, 2b, 3b, 3c, 4, 5b, and 6b compared to Phase 0. Conversely, confirmed pregnancy was significantly lower in Phase 1a, 1b, 4, and 6a compared to Phase 0. Confirmed unwanted pregnancy was significantly lower in Phase 2b, 3b, 4, 5a, 5b, and 6a compared to Phase 0. Spontaneous abortion was found to be significantly

XSL•FO
RenderX

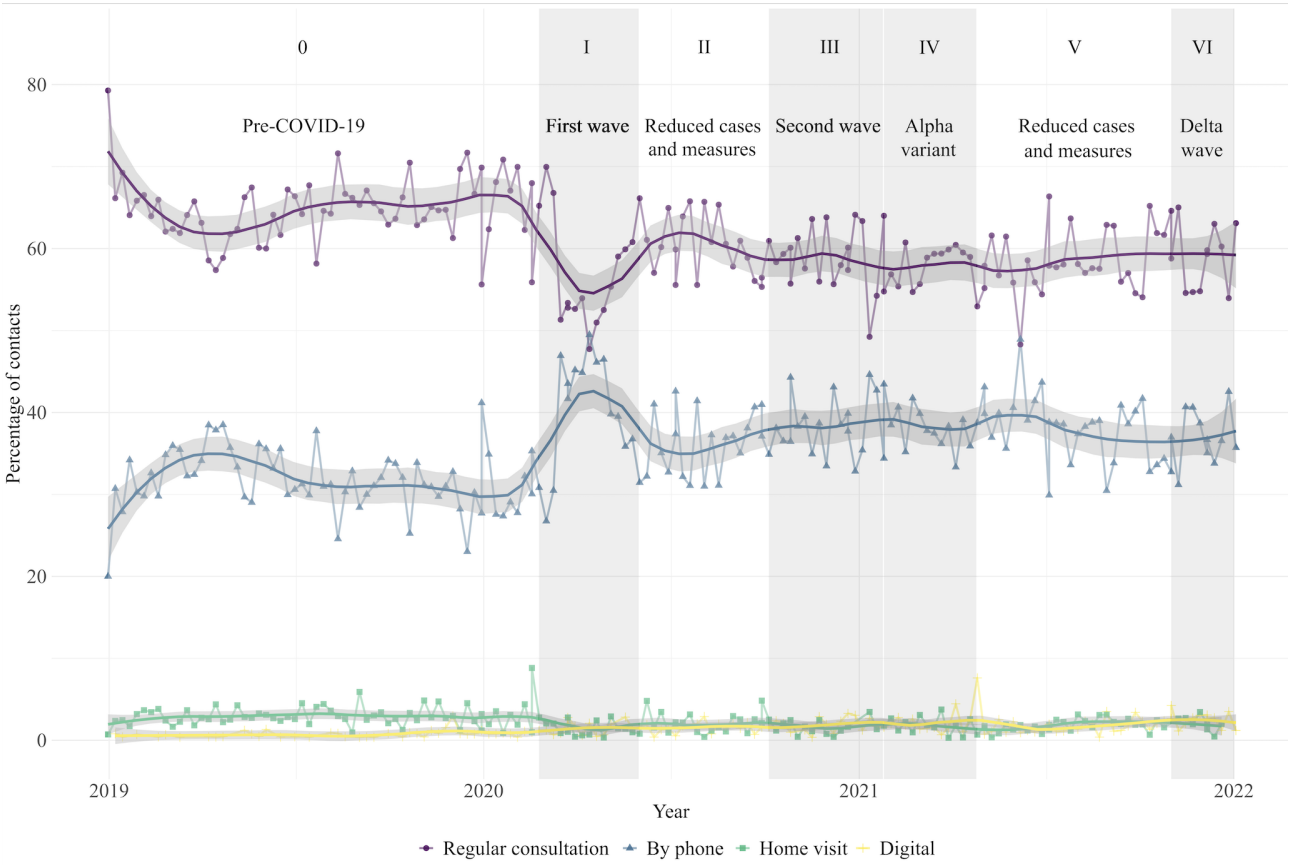
higher in Phase 2a and 3b compared to Phase 0 (P=.04 and P=.048, respectively). GDM was significantly higher in the Phase 2a, 4, 5a, and 5b compared to Phase 0.

Notably, among general health symptoms and diagnoses, health care consumption for localized abdominal pain did not change significantly during the pandemic phases compared to Phase 0. Constipation declined significantly in Phase 5a compared to Phase 0 (P=.02). Frequent or urgent urination declined significant in Phase 3c compared to Phase 0 (P=.02). Cystitis or other urine infection was significantly higher in Phase 5b and lower in Phase 6a compared to Phase 0 (P<.001 and P=.04, respectively). Urogenital candidiasis showed a significant increase in Phase 5b compared to Phase 0 (P=.002).

Changes in Type of Contact

Figure 2 shows the percentages of type of contact (ie, regular consultations, telephone consultations, home visits, and digital consultations). During the initial pandemic phase, regular consultations declined, and telephone consultations increased. From Phase 2 until Phase 6, regular consultations increased, but did not reach the prepandemic baseline of 64.9% (n=9281). After the sharp increase in telephone consultations, there was a decline during the following pandemic phases. However, the percentage of telephone consultations remained higher than the prepandemic baseline of 31.7% (n=4529). Digital consultations remained comparable to the prepandemic baseline throughout the pandemic phases.

Figure 2. The proportion of types of contact for pregnant women across prepandemic and pandemic phases, with raw and smoothed percentages shown by contact date. Contact types were visualized as a percentage of the total number of contacts within each subphase, using a centered moving average of 3 weeks.



Discussion

Principal Findings

To the best of our knowledge, this is the first study examining pregnancy-relevant symptoms and diagnoses in GP practices in relation to the COVID-19 pandemic. By analyzing routine clinical EHR data registered by GPs, this study revealed statistically significant fluctuations in health care consumption among over 10,000 studied pregnant women during various pandemic phases, defined by infection rates and restrictive measures. In addition, this study demonstrated significant increases in GDM and vomiting or nausea of pregnancy, while contacts concerning confirmed pregnancies declined.

The deployed interrupted time-series analysis is a highly effective design for studying effects of interventions [21], such as the restrictive measures mandated by the government and changes in COVID-19 incidence rates during the pandemic phases. Furthermore, our combined method of selecting pregnant women led to the inclusion of a large sample of a wide range of pregnant women in the Netherlands. This comprehensive analysis of contacts, symptoms, and diagnoses of pregnant women provided valuable insights into prenatal GP care and changes in health care–seeking behavior of these vulnerable women during the COVID-19 pandemic.

XSL•FO
RenderX

Population Characteristics

Our study showed a statistically significant increase in the number of pregnancies registered at the GP practice and absolute number of contacts in 2021, which is in accordance with national birth rates [22]. The mean age of the pregnant women studied (30.4 y, SD 4.6) is slightly lower than the mean maternal age at the date of delivery of the total Dutch population (31.6 y). Our study illustrated that, if pregnant women contacted their GP, the mean number of contacts in the prepandemic year 2019 was 2.8 (SD 2.6) and remained comparable in the pandemic years 2020 and 2021.

Health Care Consumption

We show primarily declining health care consumption during the initial phases of the pandemic. The hesitation of pregnant women to seek GP care may have been influenced by the lack of knowledge about the consequences of a COVID-19 infection on both mother and fetus along with related news messages, fear of contamination, societal recommendations to stay home, or limited child care availability [23-25]. The declining trend also aligns with findings from other studies among the general population, which observed a pandemic-induced decrease in primary health care consumption initially [1-5,26]. Recent research has further highlighted a more pronounced decline in health care–seeking behavior among women compared with men during these initial pandemic phases, indicating that women may have been particularly hesitant to seek medical care amidst the pandemic [27]. Furthermore, a previously published systematic review revealed notable shifts in pregnant women's health care–seeking behavior in other health care settings such as obstetric hospital and prenatal clinic care, including a substantial decline in both routine and unscheduled prenatal care visits at their maternal health care providers [28]. This decline may indicate that important prenatal care was missed during this period, potentially resulting in delayed adverse effects on mother, fetus, and neonate. Future research should elaborate on these long-term consequences.

After reaching the lowest point of GP health care consumption in the studied period (2020 - 2021) in July 2020, health care consumption mainly increased until January 2021 and remained statistically significantly higher than the prepandemic level until mid 2021, suggesting a rebound after the initial decline. The observed increase mid-2020 may be explained by the declining infection rates and the gradual reopening of society. Furthermore, the increasing health care consumption among pregnant women may be indicative of an increased demand for GP health care, potentially compensating for earlier missed care. Other research illustrated similar fluctuating trends in health care–seeking behavior worldwide during these pandemic phases [1,27,29]. Despite this temporary rebound of health care consumption, the World Health Organisation identified a continued disruption of access to prenatal and primary health care services worldwide during this period [29].

Notably, from mid-2021 until the end of the year, a recurrent steep decline in health care consumption was observed, despite declining infection rates, minimal restrictions, and the gradual reopening of society. Possibly, pregnant women sought care with their primary care midwife again. However, the hesitation in contacting the GP may also be explained by news messaging highlighting an increased risk of serious illness from COVID-19 infection for pregnant women during this period, which was based on related published research [30]. This implies a negative impact of the rise of the Delta variant and reintroduced lockdown measures on prenatal health care, potentially resulting in recurrent missed prenatal care.

Overall, the declining trends in health care consumption during the start and end phases of the pandemic among pregnant women suggest a substantial impact on health care consumption during the pandemic, influenced by the COVID-19 incidence rates, restrictive measures, and news messaging related to COVID-19. Previous studies found that factors such as the fear of infection during health care contacts, limited understanding of the effects of COVID-19 on maternal and fetal health, and societal restrictions probably influenced this declining trend in health care consumption [1,23]. This could potentially lead to delayed adverse pregnancy outcomes, and physical and mental health problems [23,28]. Future studies should elaborate on these long-term consequences of the pandemic and on additional factors contributing to variation in health care consumption.

Pregnancy-Relevant Symptoms and Diagnoses

Building upon these fluctuating trends in health care consumption, we also explored changes in presented pregnancy-relevant symptoms and diagnoses. We show that 83.8% (n=21,621) out of the top 10 most frequently registered symptoms and diagnoses were related to pregnancy, which largely aligns with prepandemic research among Dutch pregnant women in GP care [10]. Interestingly, most changes between pandemic phases and the prepandemic baseline were found in pregnancy-related symptoms and diagnoses, while fewer changes were observed in categories related to routine health care symptoms and diagnoses. Most symptoms and diagnoses consistently declined or consistently increased in frequency, independent of pandemic phases. This suggests that changes in frequency of presented symptoms and diagnoses were driven by the nature of the specific complaint or diagnosis, rather than being influenced by the prevailing measures or incidence rates during each phase.

We have underlined a noteworthy increase in health care consumption concerning GDM during different pandemic phases, consistent with previous research [31-34]. This might be attributed to a rise in pregnancy-related weight gain, as was shown by other studies [32,35]. We speculate that this consequential increase in GDM could be due to physical limitations, sedentary behavior, and emotional distress following the severely restrictive lockdown measures [35-37]. Therefore, pandemics can be a risk factor for developing GDM. This is an important finding given the results of a recent review underlining that GDM increases risks of adverse maternal and perinatal outcomes, such as hypertensive disorders of pregnancy, induction of labor, caesarean section, large-for-gestational-age neonates, preterm birth, and neonatal intensive care unit admission [38]. Furthermore, the increase in GDM may have contributed to the statistically significant increase in cystitis or other urine infection and urogenital candidiasis in some pandemic phases.

XSL•FO
RenderX

In addition, we speculate that the previously reported decreased physical behavior [37,39], increased sedentary behavior, and emotional distress may have also contributed to the observed increase of vomiting or nausea of pregnancy. Furthermore, previous reviews underlined a negative influence of the pandemic on eating behavior, influenced by emotions, mood, cravings, and environmental factors [40,41], which could have further worsened symptoms of vomiting and nausea. Nevertheless, no previous research was found regarding this increased complaint. Further research is needed to examine these notable increases in GDM and nausea or vomiting of pregnancy, and their impact on long-term health outcomes for both mother and child. This could enable the development of appropriate lifestyle interventions for pregnant women to be provided as part of routine prenatal GP care, with a positive impact on outcomes during future pandemics.

Furthermore, our study brought to light notable declines in the registration of confirmed wanted and unwanted pregnancies during various pandemic phases, despite consistent national birth rates in 2020, and even higher rates in 2021 [22]. This implicates a decline in women reporting pregnancies to their GP or a decline in routine contacts where these codes are registered, aiming to prevent strain on GP care for what may seem like trivial reasons for care. Consequently, an important proportion of pregnant women did not consult their GP and were, therefore, not included in the study. The pandemic led to changes in the organization of prenatal health care provision by maternal health care professionals (midwives and obstetricians) and GPs, and probably contributed to a decline in the number of pregnant women consulting their GP. Further studies should elaborate on these suggestions. Yet, contacting the GP about pregnancy is important, as GPs provide essential prenatal care, including health promotion, timely interventions for general health care problems, management of medication needs, and referrals [8,9,11,42]. Furthermore, women with unwanted pregnancies experience more psychosocial problems than those with wanted pregnancies and often rely on GPs for care, highlighting the importance of contacting the GP [43].

Type of Contact

Considering the types of contact, our study showed a decrease in the proportion of regular physical contacts at the onset of the pandemic among pregnant women, accompanied by an increase of phone contacts. In line with previous research among the general population, while the proportion of regular physical contacts increased during subsequent phases, it did not return to the prepandemic levels during the studied years [1,28]. The pandemic accelerated the adoption of telehealth technologies, mainly through telephone contacts, in prenatal health care, facilitating more individualized and efficient health care [44,45]. A potential long-term shift toward a greater reliance on telehealth among pregnant women and GPs seems to have taken place. Nevertheless, further research should elaborate on whether this shift persisted postpandemic.

Limitations

There are also some limitations to this study. EHR data are not specifically intended for scientific purposes, but rather for informing other physicians. Therefore, important information could be overlooked when assessing presented symptoms and diagnoses. Despite this, it is imperative to analyze such data as they represent one of the few available sources that provide real time, longitudinal insights into patient's health care–seeking behavior. In addition, we could not assess the impact of other external factors, such as COVID-19-related news messaging and changes in other health care provision by maternal health care providers on health care consumption, due to limited data availability and the scope of the study design. However, these factors may have contributed to the limited explanation of the variation in health care consumption by the modeled independent variables across certain subphases. Future research should explore the influence of such factors. Furthermore, the endpoint of our data collection in 2021 limits our ability to assess the long-term effects or follow-up of pregnancy outcomes. To address this limitation, we recommend linking GP registration data with birth registration data over a longer term to comprehensively track the entire course of pregnancy and its outcomes. Finally, while the data are a reliable reflection of the Dutch general population, it should be noted that the results may not be fully generalizable to countries with different health care systems for pregnant women. Despite these constraints, it remains essential to analyze real-life EHR data to understand immediate trends and outcomes within the context of the health care system.

Conclusions

In conclusion, this study highlights the impact of the pandemic on pregnant women's health care–seeking behavior among more than 10,000 studied pregnant women. By analyzing routine clinical EHR data registered by GPs, we have underlined declining health care consumption trends during the initial and end phases of the pandemic (2020 - 2021), the increase in pregnancy-related symptoms and diagnosis, such as GDM and nausea or vomiting of pregnancy, and the (temporary) adoption of a renewed way of providing health care to pregnant women through telehealth. Changes in frequency of presented symptoms and diagnoses were likely driven by the nature of the specific complaint or diagnosis. Physical limitations, sedentary behavior, and emotional distress following the severely restrictive lockdown measures may have attributed to the increased presentation of certain conditions, such as GDM and nausea or vomiting of pregnancy.

Given the potential adverse long-term effects of GDM on mother, fetus, and neonate, the urgent need for enhanced public health strategies within GP practices for pregnant women is undeniable. It is crucial for health care policymakers, providers, and pregnant women to recognize the risks associated with avoiding GP health care during this vulnerable period and work collaboratively to ensure safe and high-quality care during future pandemics, but also in routine health care settings. Implementing proactive measures to address these challenges could enhance the protection of the health and well-being of expectant mothers, fetuses, and neonates during times of crisis and beyond.

XSL•FO
RenderX

Acknowledgments

The authors express their gratitude for the valuable work provided by data scientist Thijmen Kupers and midwife Dr Esther Feijen-De Jong within the Department of Primary and Long-Term Care (University Medical Center Groningen; UMCG), and general practitioners (GPs) Prof Jean Muris (Maastricht University Medical Centre; MUMC+) and Dr Tim Olde Hartman (Radboud University Medical Centre Nijmegen; RUMC) for the consortium collaboration and data. This study was funded by the Netherlands Organisations for Health Research and Development (Zorgonderzoek Nederland Medische Wetenschappen; reference 10430022010006) and was conducted as part of the COVID-GP project, "COVID-19 program") [46]. This project is a collaborative alliance between the UMCG, Nivel, and the academic GP research networks of RUMC and MUMC+. The current study was conducted within the Department of Primary and Long-Term Care at UMCG. The funder was not involved in the study design, data collection, data analysis and interpretation, or manuscript writing.

Data Availability

The datasets analyzed during this study are not publicly available due to the inclusion of sensitive and confidential patient health information and access restrictions imposed by the steering committees of the participating general practitioner (GP) networks, but are available via the corresponding author after formal permission, which may involve associated fees.

Authors' Contributions

WB-H, MH, AO, and LP initiated the study. LP performed data curation. TK, MSB, and WB-H conducted data gathering and cleaning. WB-H, MSB, and TK developed the regular expression. WB-H conducted the selection of pregnant women, with MH serving as medical advisor. WB and MSB initiated data analyses methods, which WB-H subsequently conducted and MSB assessed. WB-H and MH drafted the manuscript, which was critically reviewed by all authors.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Used International Classification of Primary Care (ICPC) codes for defining pregnant and postpartum women.
[DOCX File, 22 KB - pediatrics_v8i1e64831_app1.docx]

Multimedia Appendix 2
Regular expression for textual analysis of general practitioner (GP) texts for defining pregnancy.
[DOCX File, 23 KB - pediatrics_v8i1e64831_app2.docx]

Multimedia Appendix 3
Assumptions met during manual labelling of general practitioner (GP) texts for defining pregnancy.
[DOCX File, 23 KB - pediatrics_v8i1e64831_app3.docx]

Multimedia Appendix 4
Flowchart of patient inclusion and exclusion.
[DOCX File, 480 KB - pediatrics_v8i1e64831_app4.docx]

Multimedia Appendix 5
Pregnancy-relevant International Classification of Primary Care (ICPC) codes used for the analysis of symptoms and diagnoses.
[DOCX File, 26 KB - pediatrics_v8i1e64831_app5.docx]

Multimedia Appendix 6
Distribution of the top 10 pregnancy-related International Classification of Primary Care (ICPC) code registrations.
[DOCX File, 29 KB - pediatrics_v8i1e64831_app6.docx]

References

1. Homburg M, Berger M, Berends M, et al. Dutch GP healthcare consumption in COVID-19 heterogeneous regions: an interregional time-series approach in 2020–2021. BJGP Open 2024 Jul;8(2):BJGPO. [doi: 10.3399/BJGPO.2023.0121]
2. Huston P, Campbell J, Russell G, et al. COVID-19 and primary care in six countries. BJGP Open 2020 Oct;4(4):bjgpopen20X101128. [doi: 10.3399/bjgpopen20X101128]

XSL•FO
RenderX

3. Ramerman L, Rijpkema C, Bos N, Flinterman LE, Verheij RA. The use of out-of-hours primary care during the first year of the COVID-19 pandemic. BMC Health Serv Res 2022 May 21;22(1):679. [doi: 10.1186/s12913-022-08096-x] [Medline: 35597939]
4. Sutherland K, Chessman J, Zhao J, et al. Impact of COVID-19 on healthcare activity in NSW, Australia. Public Health Res Pract 2020 Dec 9;30(4):3042030. [doi: 10.17061/phrp3042030] [Medline: 33294906]
5. Moynihan R, Sanders S, Michaleff ZA, et al. Impact of COVID-19 pandemic on utilisation of healthcare services: a systematic review. BMJ Open 2021 Mar 16;11(3):e045343. [doi: 10.1136/bmjopen-2020-045343] [Medline: 33727273]
6. Homburg M, Brandenbarg D, Olde Hartman T, et al. Patient experiences during the COVID-19 pandemic: a qualitative study in Dutch primary care. BJGP Open 2022 Dec;6(4):BJGPO.2022.0038. [doi: 10.3399/BJGPO.2022.0038] [Medline: 36270671]
7. Perdok H, Jans S, Verhoeven C, van Dillen J, Mol BW, de Jonge A. Intrapartum referral from primary to secondary care in the Netherlands: a retrospective cohort study on management of labor and outcomes. Birth 2015 Jun;42(2):156-164. [doi: 10.1111/birt.12160] [Medline: 25846937]
8. Frayne J, Hauck Y. Enjoying a healthy pregnancy: GPs' essential role in health promotion. Aust Fam Physician 2017;46(1):20-25. [Medline: 28189126]
9. Knowing more: a better start: better and faster collaboration to improve maternity care [Report in Dutch]. : Rijksinstituut voor Volksgezondheid en Milieu; 2020 URL: https://www.rivm.nl/bibliotheek/rapporten/2020-0140.pdf [accessed 2023-11-23]
10. Feijen-de Jong EI, Baarveld F, Jansen D, Ursum J, Reijneveld SA, Schellevis FG. Do pregnant women contact their general practitioner? A register-based comparison of healthcare utilisation of pregnant and non-pregnant women in general practice. BMC Fam Pract 2013 Jan 16;14(10):10. [doi: 10.1186/1471-2296-14-10] [Medline: 23324253]
11. Damen K, Haga P, Meijer S, et al. Zwangerschap en kraamperiode [Web page in Dutch]. NHG-Richtlijnen. URL: https://richtlijnen.nhg.org/standaarden/zwangerschap-en-kraamperiode#volledige-tekst-algemeen-huisartsgeneeskundige-zorg-voor-de-zwangere-en-kraamvrouw [accessed 2023-11-23]
12. Buekens P, Alger J, Bréart G, Cafferata ML, Harville E, Tomasso G. A call for action for COVID-19 surveillance and research during pregnancy. Lancet Glob Health 2020 Jul;8(7):e877-e878. [doi: 10.1016/S2214-109X(20)30206-0] [Medline: 32333854]
13. Larki M, Sharifi F, Roudsari RL. Models of maternity care for pregnant women during the COVID-19 pandemic. East Mediterr Health J 2020 Sep 24;26(9):994-998. [doi: 10.26719/emhj.20.097] [Medline: 33047788]
14. Kotlar B, Gerson EM, Petrillo S, Langer A, Tiemeier H. The impact of the COVID-19 pandemic on maternal and perinatal health: a scoping review. Reprod Health 2021 Jan 18;18(1):10. [doi: 10.1186/s12978-021-01070-6] [Medline: 33461593]
15. Twickler R, Berger MY, Groenhof F, et al. Data resource profile: registry of electronic health records of general practices in the north of the Netherlands (AHON). Int J Epidemiol 2024 Feb 14;53(2):dyae021. [doi: 10.1093/ije/dyae021] [Medline: 38389286]
16. Structured episode of care registration in primary care. Family Medicine Network. URL: https://famenet.nl [accessed 2024-04-25]
17. RNFM maastricht: research network family medicine [Web page in Dutch]. Maastricht University Vakgroep Huisartsgeneeskunde. URL: https://www.huisartsgeneeskundemaastricht.nl/onderzoek/rnfm/ [accessed 2024-04-25]
18. Schers H, van Weel C, van Boven K, Akkermans R, Bischoff E, olde Hartman T. The COVID-19 pandemic in Nijmegen, the Netherlands: changes in presented health problems and demand for primary care. Ann Fam Med 2021;19(1):44-47. [doi: 10.1370/afm.2625] [Medline: 33431391]
19. NHG-richtlijn: adequate dossiervorming met het elektronisch patiëntdossier (ADEPD) [Web page in Dutch]. Nederlands Huisartsen Genootschap. 2019. URL: https://www.nhg.org/wp-content/uploads/2022/11/NHG-Richtlijn-ADEPD-2019.pdf [accessed 2023-11-26]
20. Rijksinstituut voor volksgezondheid en milieu [Web page in Dutch]. Coronadashboard. 2023. URL: https://coronadashboard.rijksoverheid.nl/landelijk/positieve-testen [accessed 2023-11-05]
21. Schaffer AL, Dobbins TA, Pearson SA. Interrupted time series analysis using autoregressive integrated moving average (ARIMA) models: a guide for evaluating large-scale health interventions. BMC Med Res Methodol 2021 Mar 22;21(1):58. [doi: 10.1186/s12874-021-01235-8] [Medline: 33752604]
22. Geboorte; kerncijfers [Web page in Dutch]. StatLine. URL: https://opendata.cbs.nl/statline/#/CBS/nl/dataset/85722NED/table?ts=1704881396887 [accessed 2024-01-10]
23. Chmielewska B, Barratt I, Townsend R, et al. Effects of the COVID-19 pandemic on maternal and perinatal outcomes: a systematic review and meta-analysis. Lancet Glob Health 2021 Jun;9(6):e759-e772. [doi: 10.1016/S2214-109X(21)00079-6]
24. Chaudhry S, Aboudawoud O, Hardy G. A history of COVID-19 in pregnancy: a narrative review. J Clin Med 2023 Sep 1;12(17):17. [doi: 10.3390/jcm12175722] [Medline: 37685788]
25. Splinter MJ, Velek P, Ikram MK, et al. Prevalence and determinants of healthcare avoidance during the COVID-19 pandemic: a population-based cross-sectional study. PLOS Med 2021 Nov;18(11):e1003854. [doi: 10.1371/journal.pmed.1003854] [Medline: 34813591]

XSL•FO
RenderX

26. Lambooij M, Heins M, Meijer M, Vader S, Jong J, Janssen L. Het mijden van huisartsenzorg tijdens de coronapandemie. Inzicht in verminderde huisartsenzorg tijdens de coronapandemie [Article in Dutch]. Rijksinstituut voor Volksgezondheid en Milieu 2022 May. [doi: 10.21945/RIVM-2021-0227]
27. Frey A, Tilstra AM, Verhagen MD. Inequalities in healthcare use during the COVID-19 pandemic. Nat Commun 2024 Feb 29;15(1):1894. [doi: 10.1038/s41467-024-45720-2] [Medline: 38424038]
28. Townsend R, Chmielewska B, Barratt I, et al. Global changes in maternity care provision during the COVID-19 pandemic: a systematic review and meta-analysis. EClinicalMedicine 2021 Jul;37:100947. [doi: 10.1016/j.eclinm.2021.100947] [Medline: 34195576]
29. Interim report 2021: second round of the national pulse survey on continuity of essential health services during the COVID-19 pandemic. : World Health Organization; 2021 URL: https://iris.who.int/bitstream/handle/10665/340937/WHO-2019-nCoV-EHS-continuity-survey-2021.1-eng.pdf?sequence=1 [accessed 2021-04-22]
30. Overtoom EM, Rosman AN, Zwart JJ, et al. SARS-CoV-2 infection in pregnancy during the first wave of COVID-19 in the Netherlands: a prospective nationwide population-based cohort study (NethOSS). BJOG 2022 Jan;129(1):91-100. [doi: 10.1111/1471-0528.16903] [Medline: 34494694]
31. Zanardo V, Tortora D, Sandri A, Severino L, Mesirca P, Straface G. COVID-19 pandemic: impact on gestational diabetes mellitus prevalence. Diabetes Res Clin Pract 2022 Jan;183:109149. [doi: 10.1016/j.diabres.2021.109149] [Medline: 34808282]
32. Rhou YJJ, Elhindi J, Melov SJ, Cheung NW, Pasupathy D, Western Sydney COVID-19 Pregnancy Study Group. Indirect effects of the COVID-19 pandemic on risk of gestational diabetes and factors contributing to increased risk in a multiethnic population: a retrospective cohort study. BMC Pregnancy Childbirth 2023 May 12;23(1):341. [doi: 10.1186/s12884-023-05659-6] [Medline: 37173638]
33. Garrow J, Fan I, Lilly C, et al. The COVID-19 pandemic and its impact on the development of gestational diabetes mellitus (GDM) in West Virginia. Diabetes Res Clin Pract 2024 Feb;208:111126. [doi: 10.1016/j.diabres.2024.111126] [Medline: 38311246]
34. Rolnik DL, Matheson A, Liu Y, et al. Impact of COVID-19 pandemic restrictions on pregnancy duration and outcome in Melbourne, Australia. Ultrasound Obstet Gynecol 2021 Nov;58(5):677-687. [doi: 10.1002/uog.23743] [Medline: 34309931]
35. La Verde M, Torella M, Riemma G, et al. Incidence of gestational diabetes mellitus before and after the COVID-19 lockdown: a retrospective cohort study. J Obstet Gynaecol Res 2022 May;48(5):1126-1131. [doi: 10.1111/jog.15205] [Medline: 35199420]
36. Mendez Y, Alpuing Radilla LA, Delgadillo Chabolla LE, Castillo Cruz A, Luna J, Surani S. Gestational diabetes mellitus and COVID-19: the epidemic during the pandemic. World J Diabetes 2023 Aug 15;14(8):1178-1193. [doi: 10.4239/wjd.v14.i8.1178] [Medline: 37664480]
37. Park S, Marcotte RT, Staudenmayer JW, Strath SJ, Freedson PS, Chasan-Taber L. The impact of the COVID-19 pandemic on physical activity and sedentary behavior during pregnancy: a prospective study. BMC Pregnancy Childbirth 2022 Dec 3;22(1):899. [doi: 10.1186/s12884-022-05236-3] [Medline: 36463119]
38. Greco E, Calanducci M, Nicolaides KH, Barry EVH, Huda MSB, Iliodromiti S. Gestational diabetes mellitus and adverse maternal and perinatal outcomes in twin and singleton pregnancies: a systematic review and meta-analysis. Am J Obstet Gynecol 2024 Feb;230(2):213-225. [doi: 10.1016/j.ajog.2023.08.011]
39. Kołomańska-Bogucka D, Pławiak N, Mazur-Bialy AI. The impact of the COVID-19 pandemic on the level of physical activity, emotional state, and health habits of women in late pregnancy and early puerperium. Int J Environ Res Public Health 2023 Jan 19;20(3):1852. [doi: 10.3390/ijerph20031852] [Medline: 36767219]
40. Johnson AN, Clockston RLM, Fremling L, et al. Changes in adults' eating behaviors during the initial months of the COVID-19 pandemic: a narrative review. J Acad Nutr Diet 2023 Jan;123(1):144-194. [doi: 10.1016/j.jand.2022.08.132] [Medline: 36075551]
41. Shimpo M, Akamatsu R, Kojima Y. Impact of the COVID-19 pandemic on food and drink consumption and related factors: a scoping review. Nutr Health 2022 Jun;28(2):177-188. [doi: 10.1177/02601060221078161] [Medline: 35171054]
42. Houben E, Swart KM, Steegers EA, Elders PJ, Herings RM. GPs' awareness of pregnancy: trends and association with hazardous medication use. Br J Gen Pract 2023 Jul;73(732):e493-e501. [doi: 10.3399/BJGP.2022.0193] [Medline: 37385759]
43. Dijkstra CI, Dalmijn EW, Bolt SH, Groenhof F, Peters LL, Jansen D. Women with unwanted pregnancies, their psychosocial problems, and contraceptive use in primary care in Northern Netherlands: insights from a primary care registry database. Fam Pract 2023 Dec 22;40(5-6):648-654. [doi: 10.1093/fampra/cmad036] [Medline: 37029597]
44. van den Berg L, Thomson G, de Jonge A, et al. "Never waste a crisis": a commentary on the COVID-19 pandemic as a driver for innovation in maternity care. BJOG 2022 Jan;129(1):3-8. [doi: 10.1111/1471-0528.16996] [Medline: 34758179]
45. Kasaven LS, Saso S, Barcroft J, et al. Implications for the future of obstetrics and gynaecology following the COVID-19 pandemic: a commentary. BJOG 2020 Oct;127(11):1318-1323. [doi: 10.1111/1471-0528.16431] [Medline: 32716588]
46. Changes in the use and organization of care in general practices and out-of-hours services: lessons learned from the COVID-19 pandemic. ZonMw. URL: https://projecten.zonmw.nl/nl/project/changes-use-and-organization-care-general-practices-and-out-hours-services-lessons-learned [accessed 2023-08-29]

XSL•FO
RenderX

Abbreviations

AHON: Academic General Practitioner Development Network
EHR: electronic health record
GDM: gestational diabetes mellitus
GP: general practitioner
ICPC: International Classification of Primary Care
UMCG: University Medical Center Groningen

Edited by S Badawy; submitted 28.07.24; peer-reviewed by A Debbarma, Y Chai; revised version received 28.02.25; accepted 18.03.25; published 27.05.25.

Please cite as:
Berends-Hoekstra W, Homburg M, Oenema A, Berends MS, Peters L
Impact of COVID-19 on Dutch General Practitioner Prenatal Primary Care: Retrospective, Observational Cohort Study Using an Interrupted Time-Series Approach
JMIR Pediatr Parent 2025;8:e64831
URL: https://pediatrics.jmir.org/2025/1/e64831
doi:10.2196/64831

© Wikje Berends-Hoekstra, Maarten Homburg, Anke Oenema, Matthijs Simeon Berends, Lilian Peters. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 27.5.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

COVID-19 Vaccine Uptake, Sources of Information and Side Effects Reported by Pregnant Women in Western Australia: Cross-Sectional Cohort Survey

Nicole Catalano[1,2*], BSc, MPhil; Shailender Mehta[2,3,4*], MD, FRACP, PhD

[1]Neonatal Research Team, Fiona Stanley Hospital, 11 Robin Warren Drive, Murdoch, Australia

[2]School of Medicine, Curtin University, Perth, Australia

[3]Neonatal Unit, Fiona Stanley Hospital, Murdoch, Australia

[4]The Kids Research Institute Australia, Perth, Australia

[*]all authors contributed equally

Corresponding Author:
Nicole Catalano, BSc, MPhil
Neonatal Research Team, Fiona Stanley Hospital, 11 Robin Warren Drive, Murdoch, Australia

Abstract

Background: Pregnant women are a priority group for COVID-19 vaccination due to their vulnerability as a high-risk cohort. However, the currentCOVID-19 vaccine uptake rate for COVID-19 vaccination among pregnant women in Western Australia remains largely unknown.

Objective: This study aimed to explore pregnant women's vaccination uptake rates, information sources, and experiences regarding COVID-19 vaccination during pregnancy. We hypothesized that uptake of vaccination among pregnant women is higher than indicated in previous studies, given differences in disease burden and public health restrictions at the time when data was collected.

Methods: A cross-sectional survey was administered electronically to maternity patients at a single tertiary metropolitan hospital in Perth, Western Australia.

Results: A total of 520 women participated in the study. Overall, the antenatal COVID-19 vaccination rate was 79% (n=398). Approximately, 51% (n=256) of the women felt well-informed about the vaccine, and information was sourced primarily from their general practitioner (n=301, 60%), midwives (n=174, 35%), and obstetric doctors (n=64, 13%). Compared to Caucasian women, those of non-Caucasian ethnicity (n=332, 66% vs n=170, 34%; *P*=.07) and those born outside Australia (n=235, 47%) reported lower rates of vaccine information provision by the hospital staff (n=22, 34% vs n=42, 66%; *P*=.04).

Conclusions: The COVID-19 vaccine uptake among pregnant women was encouragingly high in our study, with favorable attitudes and acceptance for the vaccine observed in the majority of pregnant women. This self-reported study also identified opportunities for enhanced cultural competence and further education and training for hospital staff regarding COVID-19 vaccine information provision to ethnically diverse women. Further studies examining such interventions are warranted.

(JMIR Pediatr Parent 2025;8:e66645) doi:10.2196/66645

KEYWORDS

pregnancy; COVID-19 vaccination; COVID-19; uptake; vaccine uptake; side effects; pregnant; Australia; public health; maternity

Introduction

Vaccination against SARS-CoV2 is a key public health strategy to combat the pandemic [1,2]. Pregnant women are a priority group for vaccination against SARS-CoV2, and therefore require education, encouragement, and adequate opportunities to receive vaccinations antenatally [1,3]. Pregnancy puts women in a state of immune deficiency, and therefore increases vulnerability to infection [1], with unvaccinated pregnant women experiencing increased severity of symptoms and higher death rates compared to their vaccinated peers [2,4-6]. Along with increased risk of stillbirth, unvaccinated women also have an increased likelihood of premature birth and neonatal death if they contract SARS-CoV-2 virus during pregnancy [7,8].

At the time of initial vaccination rollout, there was limited evidence regarding the safety of the COVID-19 vaccine in pregnancy [9]. Ongoing real-world studies are adding to the body of evidence, confirming vaccine safety and effectiveness during pregnancy [9-11]. According to advice from the Australian Government and recently completed safety and effectiveness studies, the most widely used mRNA vaccines

XSL•FO
RenderX

(eg, Pfizer and Moderna) are safe to be administered throughout pregnancy and the breastfeeding period [1,10].

Worldwide research has demonstrated a hesitancy among women to receive the COVID-19 vaccination during pregnancy, being less likely than any other high-risk cohort to do so [10,12]. Several worldwide studies demonstrate that this uptake remains inadequate, indicating the vaccine acceptance is significantly lower for pregnant women than in nonpregnant women [7,12,13]. An Australian study conducted in 2020 surveyed pregnant women and various maternity health care providers during the early stages of the pandemic and found that pregnant women were the least likely group to accept vaccination [2]. At the time of the study, only 14% of pregnant women had been vaccinated, and 48% of pregnant women indicated they had definite intentions to be vaccinated [2]. Similarly, a large survey questioning vaccine confidence spanning 16 countries reported that only 52% of pregnant women intended to receive the vaccine [10].

Based on worldwide trends, pregnant women are assumed to be an undervaccinated cohort [14]. A 2021 survey of doctors and midwives in Australia reported that 60% - 70% of pregnant women had received their first dose, while an estimated two-thirds had been double vaccinated [15]. A recent study based on data from Western Australia (WA) demonstrated a vaccination uptake rate of only 44% in their pregnant participants [15]. At the time of that study, there was no community transmission of COVID-19, and this was potentially an influencing factor for the surveyed women [15].

There remains a paucity of knowledge regarding Australian pregnant women's attitudes and their vaccination uptake rate, particularly since the emergence of COVID-19 infections within the Western Australian community and the introduction of proof of vaccination requirements and associated social mandates within WA [15]. Understanding pregnant women's attitudes toward COVID-19 vaccination may be useful in optimization of vaccination uptake rates, development of educational strategies, and identifying areas for potential interventions such as standing vaccination orders.

Methods

Study setting and design

The study's objective was to determine pregnant women's perceptions, attitudes, and knowledge regarding vaccination against COVID-19 during pregnancy, and to ascertain the uptake of COVID-19 vaccines during pregnancy within a maternity cohort in a tertiary care setting. We also aimed to explore the effect of various demographic factors on vaccine uptake and vaccine information provision to pregnant women.

This prospective cross-sectional study was conducted at a tertiary metropolitan maternity hospital over a three-month period from January 12, 2022, to April 30, 2022. All pregnant and immediate postpartum women who attended the hospital were eligible to participate in the anonymous survey. Women were approached in the antenatal clinic or the postnatal ward or recruited via a text message containing a link to the optional survey, due to many appointments being transitioned to telehealth as COVID-19 spread across WA. Women who elected to join the study accessed the survey link via a QR code or text link on their own smartphones.

Demographic data collected included gestation and open-text responses for age, ethnicity, country of birth, postal code, and religion. Other multiple-choice questions included education level and sources of information, including various health care providers. The participants were asked at what point during pregnancy information was given, using multiple-choice options for trimesters, and how well-informed they felt, using a Likert scale. In addition to demographic data, the respondents were asked about vaccination status, the number of doses received, the type of vaccine, and the time points in pregnancy when the vaccine was administered. We also gathered information on any side effects using an open-text field for reporting. The unvaccinated participants were invited to describe their reasoning; their responses were a combination of multiple-choice options and a free-text response, allowing women to choose as may answers as desired.

Statistics

Descriptive statistics were reported using mean and ranges for continuous data and frequency distributions for categorical data. Statistical analysis was performed using χ^2 test for categorical variables. SPSS statistical software (version 24.0; IBM Corp) was used for analysis. P values<.05 were considered statistically significant.

Ethical Considerations

The study was approved by the South Metropolitan Health Service Human Research Ethics Committee (RGS 5201). Written informed consent was obtained from all participants before commencing the survey. All participants were over 18 years of age and able to provide consent. Data was deidentified upon commencement of the survey, with participants being assigned a unique number. No compensation was provided to the participants.

Results

A total of 502 eligible women completed the survey in its entirety. Mean age of participants was 31 (SD 5.08; range 18 - 46) years.

Overall, 79.2% (n=398) of the pregnant population were vaccinated with at least one dose. Of the study participants, 60.0% (239/398) were double vaccinated and 35.1% (140/398) were triple vaccinated. The majority (328/398, 82.4%) of these women received their vaccinations during pregnancy, while the remaining received them before the pregnancy was identified. A total of 92.4% (368/398) of vaccinated women received the Pfizer, 3.2% (13/398) received AstraZeneca, and 3.2% (13/398) received Moderna vaccines.

Ethnicity was categorized into eight broad groups based on the state maternity database. A majority (332/502, 66.1%) of women identified themselves as Caucasian. Additionally, 2.1% (11/502) identified as Aboriginal, 11.1% (56/502) as Asian, 6.7% (34/502) as Indian, 2.9% (15/502) as Maori, and 2.7% (14/502) as African. An additional 7.9% (n=40/502) women chose to

XSL•FO
RenderX

identify as "other" ethnicity. Approximately over half (n=267/502, 53.1%) of the women were born in Australia.

Of the 502 women surveyed, 301 (59.9%) women reported receiving information from their general practitioner (GP) regarding the vaccination, and while the others received it from alternate sources (Table 1). Eighteen percent (89/502) of all participants reported that no one had given them any information about the vaccine, and 5.9% (30/502) of women reported receiving information only in the third trimester of pregnancy.

Table . Reported sources of vaccine information.

Source of information[a]	Number of respondents (N=502), n (%)
GP	301 (60%)
Midwife	174 (34.6)
Obstetric doctor	64 (12.7)
Other	55 (10.9)
No one	89 (17.7)

[a]These sources were mutually exclusive.

The GPs provided information to 59.9% (301/502) of all women in our study. Of these, 66.1% were Caucasian and 33.9% were non-Caucasian (odds ratio [OR] 0.961, 95% CI 0.66-1.40; *P*=.85). A total of 174 women reported receiving information from their midwives, and of whom 72.9% (127/174) were Caucasian and 27.1% (47/174) were non-Caucasian (*P*=.22 (OR 1.62, 95% CI 1.08-2.43; *P*=.22). Only 12.7% (64/502) of the women reported receiving information from an obstetric doctor within the hospital system. Of these 64 women, 79.6% (51/64) were Caucasian and 20.3% (13/64) were of minority ethnicity (OR 2.2, 95% CI 1.15-4.15; *P*=.02). Of the 12.7% (64/502) of women who reported receiving information from an obstetric doctor, 65.6% (42/64) were born in Australia and 34.3% (22/64) self-reported as being born elsewhere (OR 1.8, 95% CI 1.04-3.13; *P*=.04).

Sources of information had no significant effect on the uptake rate of the vaccination, whether information was obtained from a GP (OR 1.2, 95% CI 0.78-1.88; *P*=.43), midwife (OR 0.23, 95% CI 0.14-3.6; *P*<.001), obstetric doctor (OR 0.368, 95% CI 0.21-0.64; *P*=.01), other sources (OR 1.59, 95% CI 0.72-3.48; *P*=.29), or from no one (OR 1.63, 95% CI 0.86-3.07; *P*=.15).

Overall, 50.9% (256/502) of women felt well-informed. 39.2% (97/502) women reported feeling somewhat informed, and 9.5% (48/502) reported feeling not well-informed. However, the perceived level of being informed did not statistically affect the uptake rate of the vaccination.

Religion was self-reported by majority of the women and did not have a statistically significant association with vaccine uptake rates (OR 0.9, 95% CI 0.6-1.5; *P*≥.99).

The majority of women (194/398, 48.7%) received two doses of the vaccine in the second trimester of pregnancy. Table 2 shows the side effects profile reported by the participants. Of the vaccinated women, 63.3% (252/398) reported experiencing some side effects from the vaccine, most commonly fatigue (n=81, 55%)), sore arm (n=65, 44%), headaches (n=51, 35%), body aches (n=39, 26%), fever (n=31, 21%), and nausea or vomiting (n=24, 16%). There was no difference in the frequency or type of side effects among women under or over 30 years, (OR 1.14, CI 95% 0.75-1.75; *P*=.59] or across various ethnic groups: Caucasian (n=334, 67%); Aboriginal (n=11, 2%); Asian (n=56, 11%); Indian (n=34, 7%); Maori (n=15, 3%); African (n=14, 3%); Polynesian (n=2, 0.4%); Middle Eastern (n=4, 1%), and other ethnic groups (n=31, 6%) *(P*=.82).

Among the unvaccinated women, 405 reasons were cited. "Safety concerns" was the main reason for women opting not to receive the vaccination (137/405, 33.8%). Additionally, 21.2% (n=86) of the women were concerned about adverse effects on the baby, 12.5% (n=51) were concerned about effects on themselves, while 16.0% (65/405) opted to wait until after their baby was born (Table 3).

Table . Vaccination side effects profile reported by participants.

Vaccination side effects[a]	Number of respondents (N=252), n (%)
Fatigue	81 (55)
Sore Arm	65 (44)
Headaches	51 (35)
Fever	31 (21)
Nausea/Vomiting	24 (16)

[a]The side effects were not mutually exclusive.

XSL•FO
RenderX

Table . Reasons for women not receiving the vaccine.

Reasons for not receiving vaccine[a]	Number of respondents (n=405), n (%)
Adverse effect on myself	51 (12.5)
Adverse effect on baby	86 (21.2)
I am waiting until after baby is born	65 (16.0)
No immediate COVID-19 threat in WA[b]	14 (3.4)
Upcoming booking	23 (5.6)
Not getting the vaccine	14 (3.4)
Other	8 (1.5)

[a]These effects are not mutually exclusive.

[b]WA: Western Australia.

The respondents' education levels varied widely: high-school diploma (n=172, 35%); a postgraduate degree (n=224, 45%); a master's degree (n=53, 11%); a trade qualification (n=31, 61%); a doctorate (n=8, 2%); and no education (n=10, 2%). The level of education had no significant impact on the vaccine uptake rates *(P*>.05).

Discussion

Overall, the rate of the COVID-19 vaccination within our study's pregnant population was encouragingly high, although it lagged behind the state average of >95% double vaccination in the general population [15]. The diverse demographic of the cohort at our hospital reportedly had an equal uptake of the vaccination regardless of age, ethnicity, education level, or country of birth. To our knowledge, this is among the highest vaccination rates in a pregnant population globally, although a deficit of research on this topic remains [6,12,15-17].

Every two out of three women received COVID-19 vaccine information from their GPs. Although this number is higher than that of women receiving vaccine information from the hospital staff, given the context of a pandemic and pregnancy being a vulnerability, it would be reasonable to aim for all women to receive information on COVID-19 vaccine during their first consultation with GPs, midwives, or obstetric doctors. Workload pressures on GP clinics and hospitals during the pandemic undoubtedly placed strain on service and information delivery but also highlighted missed opportunities to prioritize vaccine information at the earliest opportunity. The pandemic may also have affected the ability of pregnant women to have timely appointments with their GPs due to restrictions and increased burden on practices [18,19]. In our study, 10% (n=48) of women reported that they did not feel well-informed about the vaccination, reiterating the need to educate pregnant women. Some women (n=30, 6%) reported receiving information for the first time only in the third trimester of pregnancy.

Eighteen percent (n=89) of women reported not receiving any information at all, which is a public health concern. These data were not influenced by age, ethnicity, or religion of the women. Encouraging multiple open conversations surrounding vaccination between all health care providers and pregnant women may possibly decrease the number of women who reported not receiving any information [20].

Australia's historically strong population growth is drawn from both natural increase and net overseas migration. In 2020, there were over 7.6 million migrants living in Australia, accounting for 29.8% of the population who were born overseas [21]. It was reassuring to see that there was no difference in responses on receiving information from GPs across various ethnic groups or countries of birth. However, the significantly high proportion of women from minor ethnic groups or those born outside Australia who reported receiving no information from the hospital staff is highly concerning. Potentially, language barriers, inadequate use of interpreters, or lack of cultural competence may contribute to this number in our culturally diverse study population; however, these factors were not investigated further in our study. Ensuring a diversified workforce in hospitals may benefit women through the dispersion of information from culturally diverse health care professionals.

A recent, similar study conducted within WA by Ward et al [22] explored women's vaccine uptake rate and attitudes surrounding vaccination. While similar information was obtained from the pregnant population, the results contrasted significantly between the two studies; this could potentially be attributed to differences in community transmission as well as the vaccination-related social restrictions and introduction of state government vaccine mandates within WA. The uptake rate in the aforementioned study was only 44%, compared to 79% in our study. Additionally, one-third of their study population reported not being given any information regarding the vaccine, whereas our numbers, although still concerning, were much lower at 18%. This difference may likely be attributed to increased awareness and education as the pandemic evolved in WA, along with real-time evidence of vaccine safety in pregnancy being reported worldwide. At the commencement of our study, there was no community spread of COVID-19, and therefore, no imminent urgency was experienced within WA. However, the opening of borders was announced soon after the vaccine mandates were introduced, and eventually, the interstate and international WA borders were opened during the course of our study. Both studies discovered that women's safety concerns regarding their baby and themselves were primary factors behind declining or delaying the vaccine administration.

Our study had various strengths and limitations. It was conducted throughout the community COVID-19 transmission

XSL•FO
RenderX

in WA, making our findings unique and relevant to the current pandemic situation. Our study population reflects the health status and demographic status of WA's pregnant population. It incorporated multiple ethnicities, wide age range, and both low- and high-risk pregnancies. The results are generalizable to the WA pregnant population, as a variety of ethnicities, education levels, and ages were incorporated, along with a large sample size. The limitations of our study include restriction to a single-center experience, lack of information on primary spoken languages by the women, and reliability on the self-reported responses by the pregnant women.

In conclusion, COVID-19 vaccination was widely accepted among our study population, in contrast to previously reported data. Western Australia has demonstrated a high uptake of the vaccination across all age, social, religious, and ethnic groups attending our center. There were minimally reported and mild side effects due to the vaccine. In the exploration of women's attitudes, safety concerns led to vaccine hesitancy. Optimizing the uptake rate remains a priority for this vulnerable cohort to improve maternal and neonatal outcomes. The information gained from this study can be used to encourage hesitant women by providing the positive data. The discrepancy in information provided between the groups may indicate a need to address cultural competency among staff, furthering staff education, and ensuring a diverse workforce. Further studies examining such interventions are warranted to confirm the influence of these strategies on the vaccine uptake among pregnant women.

Data Availability

The datasets generated or analyzed during this study are not publicly available due to confidentiality, but are available from the corresponding author upon reasonable request.

Authors' Contributions

Conceptualization: NC
Data curation: NC
Formal analysis: NC
Methodology: NC, SM
Project administration: SM
Supervision: SM
Writing – original draft: NC
Writing – review & editing: SM

Conflicts of Interest

None declared.

References

1. Australian Government Department of Health, Disability, and Ageing. COVID-19 vaccination – shared decision making guide for women who are pregnant, breastfeeding or planning pregnancy. 2021. URL: https://www.health.gov.au/resources/publications/covid-19-vaccination-shared-decision-making-guide-for-women-who-are-pregnant-breastfeeding-or-planning-pregnancy [accessed 2025-06-13]
2. A message for pregnant women and their families. RANZCOG. 2021. URL: https://wirf.com.au/about-us/news-and-events/news/covid-19-statement-for-pregnant-women/accessed 20/3/2022 [accessed 2025-06-13]
3. Pregnant and recently pregnant people at increased risk for severe illness from COVID-19. Centers for Disease Control and Prevention. 2022. URL: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnant-people.html [accessed 2025-06-12]
4. Pregnant and recently pregnant people at increased risk for severe illness from COVID-19. Centers for Disease Prevention and Control. 2022. URL: https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/need-extra-precautions/pregnant-people.html accessed 25/03/2022 [accessed 2025-06-12]
5. Theiler RN, Wick M, Mehta R, Weaver AL, Virk A, Swift M. Pregnancy and birth outcomes after SARS-CoV-2 vaccination in pregnancy. Am J Obstet Gynecol MFM 2021 Nov;3(6):100467. [doi: 10.1016/j.ajogmf.2021.100467] [Medline: 34425297]
6. Stock SJ, Carruthers J, Calvert C, et al. SARS-CoV-2 infection and COVID-19 vaccination rates in pregnant women in Scotland. Nat Med 2022 Mar;28(3):504-512. [doi: 10.1038/s41591-021-01666-2] [Medline: 35027756 accessed 30/03/2022]
7. Morgan JA, Biggio JR Jr, Martin JK, et al. Maternal outcomes after Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection in vaccinated compared with unvaccinated pregnant patients. Obstet Gynecol 2022 Jan 1;139(1):107-109. [doi: 10.1097/AOG.0000000000004621] [Medline: 34644272]
8. COVID-19 linked to complications during pregnancy: research. Express Healthcare. 2022. URL: http://expresshealthcare.in/news/covid-19-linked-to-complications-during-pregnancy-research/433045/
9. Zauche LH, Wallace B, Smoots AN, et al. Receipt of mRNA COVID-19 vaccines and risk of spontaneous abortion. N Engl J Med 2021 Oct 14;385(16):1533-1535. [doi: 10.1056/NEJMc2113891] [Medline: 34496196]

XSL•FO
RenderX

10. Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary findings of mRNA Covid-19 vaccine safety in pregnant persons. N Engl J Med 2021 Jun 17;384(24):2273-2282. [doi: 10.1056/NEJMoa2104983] [Medline: 33882218]
11. De Rose DU, Salvatori G, Dotta A, Auriti C. SARS-CoV-2 vaccines during pregnancy and breastfeeding: a systematic review of maternal and neonatal outcomes. Viruses 2022 Mar 5;14(3):539. [doi: 10.3390/v14030539] [Medline: 35336947]
12. Blakeway H, Prasad S, Kalafat E, et al. COVID-19 vaccination during pregnancy: coverage and safety. Am J Obstet Gynecol 2022 Feb;226(2):236. [doi: 10.1016/j.ajog.2021.08.007] [Medline: 34389291]
13. Liotta M. Concerns for under-vaccinated pregnant population. RACGP. 2022. URL: https://www1.racgp.org.au/newsgp/clinical/concerns-of-under-vaccinated-pregnant-population
14. Skjefte M, Ngirbabul M, Akeju O, et al. COVID-19 vaccine acceptance among pregnant women and mothers of young children: results of a survey in 16 countries. Eur J Epidemiol 2021 Feb;36(2):197-211. [doi: 10.1007/s10654-021-00728-6] [Medline: 33649879]
15. Carroll L, Dow A. Vaccination for pregnant women lags national average. : Sydney Morning Herald; 2021 URL: https://www.smh.com.au/national/vaccination-for-pregnant-women-lags-national-average-20211112-p598d1.html [accessed 2022-04-04]
16. Pairat K, Phaloprakarn C. Acceptance of COVID-19 vaccination during pregnancy among Thai pregnant women and their spouses: a prospective survey. Reprod Health 2022 Mar 24;19(1):74. [doi: 10.1186/s12978-022-01383-0] [Medline: 35331263]
17. Galanis P, Vraka I, Siskou O, Konstantakopoulou O, Katsiroumpa A, Kaitelidou D. Uptake of COVID-19 vaccines among pregnant women: a systematic review and meta-analysis. Vaccines (Basel) 2022 May 12;10(5):766. [doi: 10.3390/vaccines10050766] [Medline: 35632521]
18. Brew BK, Gibberd A, Marks GB, et al. Maternal asthma in Australian indigenous women and perinatal outcomes: a whole population-linked study. Int J Gynaecol Obstet 2023 Feb;160(2):653-660. [doi: 10.1002/ijgo.14363] [Medline: 35869950]
19. Javanparast S, Roeger L, Kwok Y, Reed RL. The experience of Australian general practice patients at high risk of poor health outcomes with telehealth during the COVID-19 pandemic: a qualitative study. BMC Fam Pract 2021 Apr 8;22(1):69. [doi: 10.1186/s12875-021-01408-w] [Medline: 33832422]
20. Razzaghi H, Kahn KE, Masalovich S, et al. COVID-19 vaccination and intent among pregnant women, United States, April 2021. Public Health Rep 2022;137(5):988-999. [doi: 10.1177/00333549221099244] [Medline: 35699596]
21. Migration, Australia. Australian Bureau of Statistics. 2021. URL: https://www.abs.gov.au/statistics/people/population/migration-australia/2019-20#cite-window1
22. Ward C, Megaw L, White S, Bradfield Z. COVID‐19 vaccination rates in an antenatal population: a survey of women's perceptions, factors influencing vaccine uptake and potential contributors to vaccine hesitancy. Aust NZ J Obst Gynaeco 2022 Oct;62(5):695-700. [doi: 10.1111/ajo.13532]

Abbreviations

GP: general practitioner
WA: Western Australia

Edited by S Badawy; submitted 18.09.24; peer-reviewed by JH Mohamoud; revised version received 23.04.25; accepted 20.05.25; published 23.06.25.

Please cite as:
Catalano N, Mehta S
COVID-19 Vaccine Uptake, Sources of Information and Side Effects Reported by Pregnant Women in Western Australia: Cross-Sectional Cohort Survey
JMIR Pediatr Parent 2025;8:e66645
URL: https://pediatrics.jmir.org/2025/1/e66645
doi:10.2196/66645

© Nicole Catalano, Shailender Mehta. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 23.6.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Usability and Acceptability of a Pregnancy App for Substance Use Screening and Education: A Mixed Methods Exploratory Pilot Study

Haley Fitzgerald[1], BA; Madison Frank[2], BSc; Katelyn Kasula[2], MA, MSc; Elizabeth E Krans[2,3], MD, MSc; Tamar Krishnamurti[4], PhD

[1]University of Pittsburgh School of Medicine, Pittsburgh, PA, United States

[2]Magee-Womens Research Institute, Pittsburgh, PA, United States

[3]Department of Obstetrics, Gynecology, and Reproductive Sciences, University of Pittsburgh School of Medicine, Pittsburgh, PA, United States

[4]Division of General Internal Medicine, University of Pittsburgh School of Medicine, 230 McKee Place, Suite 600, Pittsburgh, PA, United States

Corresponding Author:
Tamar Krishnamurti, PhD
Division of General Internal Medicine, University of Pittsburgh School of Medicine, 230 McKee Place, Suite 600, Pittsburgh, PA, United States

Abstract

Background: Increasing opioid and other substance use has led to a crisis of epidemic proportions, with substance use now recognized as a leading cause of maternal morbidity and mortality in the United States. Interventions will only be effective if those who would benefit are identified early and connected to care. Apps are a ubiquitous source of pregnancy information, but their utility as a platform for evaluating substance use during pregnancy is unknown.

Objective: This study aims to explore the usability and acceptability of a pregnancy app for opioid and other substance use screening and education.

Methods: This mixed methods, exploratory pilot study examined adult pregnant people with a history of substance use who were recruited from outpatient and inpatient settings at a tertiary care obstetric hospital. After completing a baseline survey collecting demographics, substance use, and technology use, participants accessed an existing pregnancy support app for 4 weeks. Qualitative methods were used to measure the acceptability of embedding substance use screening, education, and information within the tool. App use frequency and access to substance use educational content and treatment referral information were evaluated.

Results: The 28 female participants had a mean (SD) age of 31 (0.46) years; most were White (21/28, 75%) and Medicaid insured (26/28, 93%), with an annual household income of <US $30,000 (16/28, 57%). The mean gestational age at enrollment was 22 weeks. Almost half (13/28, 46%) were taking medication for opioid use disorder (methadone or buprenorphine). Other substances used included tobacco (22/28, 79%), marijuana (20/28, 71%), illicit opioids (9/28, 32%), alcohol (6/28, 21%), and stimulants (4/28, 14%), including cocaine, amphetamines, and benzodiazepines (2/28, 7%). Most (19/28, 68%) reported previously using one or more prenatal apps and 11% (3/28) cited prenatal apps as their most frequently used source of pregnancy information. After approximately 4 weeks of app exposure, 71% (20/28) logged in at least weekly, 89% (25/28) were satisfied with the app, and 96% (27/28) reported that the app was a helpful source of support. In cognitive interviews, participants reported that app-based disclosure of substance use could be easier than disclosing in person due to reduced stigma. However, participants expressed concerns about not knowing who would have access to this information.

Conclusions: Incorporating substance use supports into a pregnancy app was found to be acceptable among those using substances. Participants reported frequent baseline use of prenatal apps, showed a high level of engagement with the pregnancy app during the study, and demonstrated interest in expanding the substance use support elements of this app. Embedding substance use screening, information, and connection to care into a tool with wide-scale use during pregnancy has the potential to identify at-risk individuals who may otherwise not be identified during routine prenatal care. It also has the potential to connect individuals, who might otherwise be hesitant to disclose their substance use, to recovery or harm reduction resources.

(JMIR Pediatr Parent 2025;8:e60038) doi:10.2196/60038

KEYWORDS

substance use disorder; substance use screening; mHealth; mobile health apps; pregnancy; technology

XSL•FO
RenderX

Introduction

Substance use during pregnancy has increased significantly over the past two decades [1-4], with almost 3% of pregnant people having a formal substance use disorder diagnosis [5]. Opioid use disorder during pregnancy has more than quadrupled in the past 20 years and is now a leading cause of maternal death in the United States [6-12]. Observed rates of other substance use during pregnancy have also increased in recent years, including cannabis, alcohol, sedatives, and stimulants. Actual numbers may be higher due to lack of reporting [5]. Additionally, concurrent substance use, such as marijuana use paired with opioid use, can further increase the risk of preterm birth and low birth weight infants [13] and may impact infant development and longer-term learning, memory, and impulsivity [10,11]. This increase in the prevalence of substance use is concerning and suggests an increased need for effective screening and resource provision to pregnant people.

Early identification and intervention are critical for reducing adverse maternal and neonatal outcomes associated with substance use [14]. As a result, major professional organizations, including the American College of Obstetricians and Gynecologists, recommend that all pregnant people be verbally screened for substance use with a validated tool at least once during pregnancy [15,16]. Despite this, 20% - 30% of obstetric providers do not routinely screen for substance use, and less than half routinely refer patients with a positive screen to substance use treatment resources [17,18]. Moreover, due to stigma, judgment, and fear of mandated reporting requirements, many pregnant people are hesitant or choose not to disclose substance use to their health care providers [12,19-21]. In a study of 422 pregnant people who presented for their first obstetric appointment, 46% of those who had a urine drug test positive for a nonprescribed substance chose to not disclose their substance use when verbally screened by their provider [22].

Mobile health (mHealth) technology has been successfully used to evaluate and deliver interventions related to tobacco, alcohol, and illicit substances, including opioid use, in nonpregnant populations [23-25]. In a study evaluating interest in using digital platforms to monitor recovery trajectories among 259 patients in substance use treatment, 70% of participants expressed interest in using a relapse prevention app [26]. Additionally, a study of 202 individuals using a recovery support app demonstrated high levels of usage of the app and articulated that further expanding the app to provide additional recovery-related resources could increase the likelihood of continuing to use the app in the future [27]. Further, in an evaluation of 316 patients engaged in a Veteran's Affairs (VA) substance use treatment program, more substance use was disclosed through an indirect method (self-completed questionnaire), as opposed to a direct method (verbal disclosure), suggesting that creating an accessible space for indirect disclosure may be beneficial for people who use substances [28].

Pregnancy apps are a common information source used by patients during pregnancy and allow for intimate, self-guided touchpoints for those seeking health-related resources, guidance, and information outside of clinical care settings [29,30]. As such, the American College of Obstetricians and Gynecologists supports mHealth as a suitable means for supplementing obstetric health care [31]. Due to their frequent use, mHealth tools may be an additional way to identify patients who are unwilling to disclose their substance use in traditional, in-person health care settings by mitigating stigma and bias associated with in-person substance use evaluations [29,32].

The purpose of this study was to explore the usability and acceptability of an existing prenatal mHealth app, MyHealthyPregnancy, as a tool in which substance use screening, education, and information could be provided as part of routine prenatal care among pregnant people with substance use. For an mHealth app to be acceptable, the patient population of interest must generally engage with mobile technology during their pregnancy, demonstrate interest in accessing information from the app, and importantly, trust the app as a setting for substance use disclosure [33-36]. Therefore, the specific objectives of this study were to understand, among pregnant people with a history of opioid or other addictive substance use, (1) general technology and mobile app usage, (2) willingness to disclose substance use through a pregnancy app, (3) interest in obtaining substance use education and information through a prenatal app, and (4) perspectives regarding how a pregnancy app could assist with substance use–related needs.

Methods

Study Sample

From April to August 2021, we conducted a mixed methods, exploratory pilot study to understand the usability and acceptability of a prenatal support app for substance use screening, education, and information during pregnancy. Pregnant people with substance use were recruited from inpatient and outpatient settings at an academic, tertiary care women's hospital including prenatal clinics, substance use treatment programs, and inpatient antepartum hospital units. Participants were eligible if they were pregnant, at least 18 years of age, less than 37 weeks gestation, had regular access to a smartphone (Android or iOS), and had a history of substance use during or within 3 months prior to their pregnancy, as determined through either self-report, *ICD-10* (*International Classification of Diseases, Tenth Revision*) diagnoses coding cord or evidence of substance use on urine drug testing in the electronic health record. In prior research, a sample size of approximately 30 participants has been determined to be sufficient to understand app usability and acceptability [37].

Ethical Considerations

The study was reviewed by the University of Pittsburgh institutional review board (STUDY18120026). Participants provided written informed consent. All audio and transcribed materials were stored on a secure, password- and firewall-protected university network drive or server, and all data were deidentified prior to analysis. Participants received US $25 for their participation in this study.

XSL•FO
RenderX

MyHealthyPregnancy mHealth App

The MyHealthyPregnancy app is a pregnancy mHealth tool that offers evidence-based, prenatal educational content organized by the user's weeks of gestation, a diary to document the user's pregnancy experiences, a fetal movement counter, a contraction timer, and routine screenings for symptoms and psychosocial risks. The app also functions as a risk assessment tool that may use patient-entered data (eg, symptoms, language, mood, sleep, and psychosocial screeners) to identify possible risks during pregnancy (eg, intimate partner violence, depression, and pre-eclampsia) and resources tailored to the risks identified. When users start the onboarding process to begin using the app, they are asked, "Do you currently use any of the following?" for various substances, including alcohol, tobacco (and vaping), marijuana, narcotics or opioids, heroin or fentanyl, benzodiazepines, cocaine or amphetamines, and other drugs. Depending on the substance disclosed, the user will be directed to substance-specific local, regional, and national recovery resources.

Educational content about substance use (eg, content regarding the risks of substance use during pregnancy, information on substance use treatment resources) is accessible to users through the app's "Learning Center" and "Resources" sections. These resources and articles were designed, in collaboration with clinical experts, to offer the same information as would be provided in routine prenatal care if substance use was disclosed to a provider. MyHealthyPregnancy was launched for beta-test evaluation at the University of Pittsburgh Medical Center health system in September 2019, with research demonstrating its effectiveness as a complementary tool to prenatal care [38-42].

Study Procedures

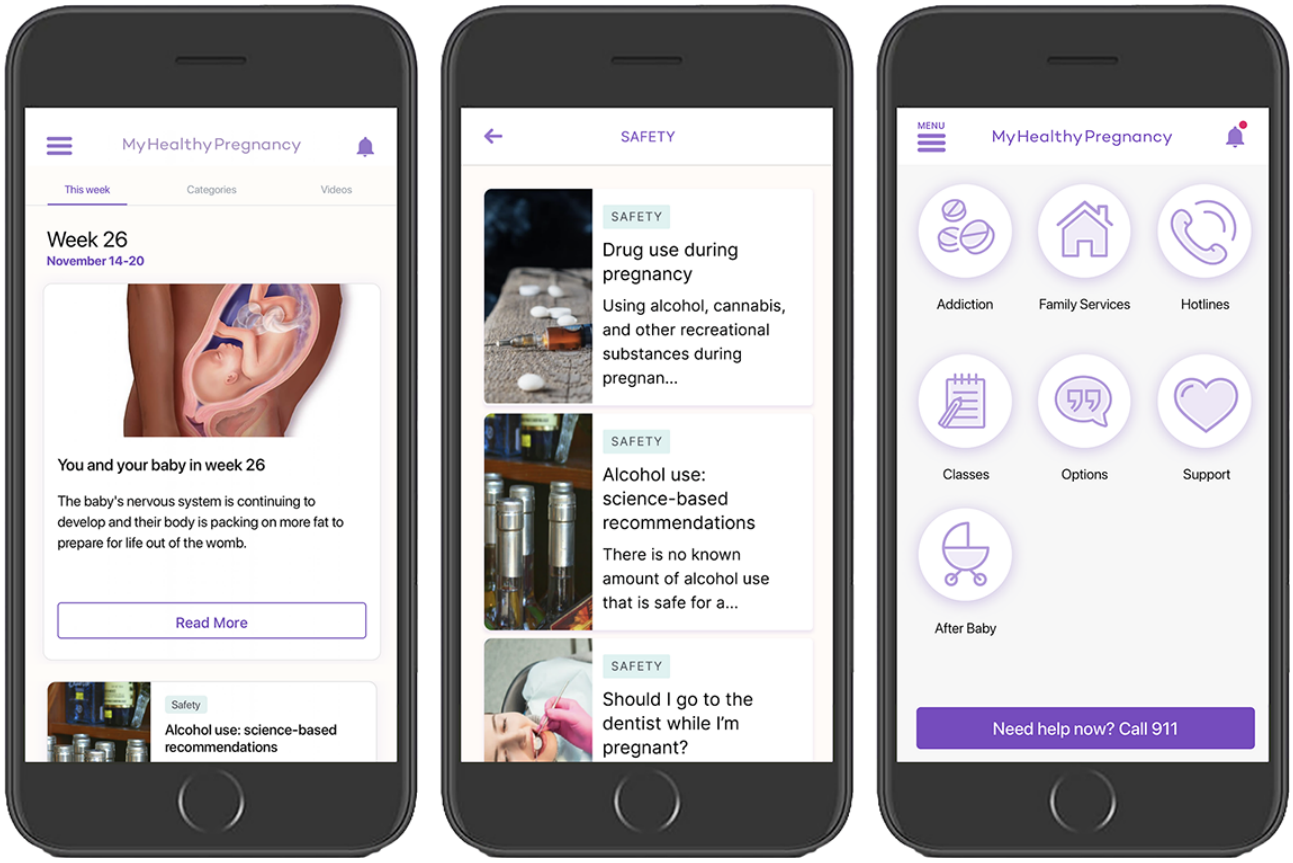
After signing a written informed consent, participants completed a baseline survey assessing demographics, substance use, pregnancy history, and technology and app use behaviors (Multimedia Appendix 1). Research staff then assisted participants with downloading the app on their smartphones and provided an overview of the sections of the MyHealthyPregnancy app before having participants self-navigate through the app on their phones. At this time, participants additionally consented to the sharing of identifiable data for research purposes and the publication of anonymized aggregate data through the app. Figure 1 shows sample screens from the app.

After navigating through each section of the app, research staff asked participants to relay their thoughts regarding the app and substance use–related content through a "think-aloud" technique [43-46]. Following the think-aloud sessions, participants engaged in a cognitive interview to further understand the acceptability of the app for substance screening and evaluation [47-51]. Examples of questions used during the cognitive interview included, "If you were actively using a substance, how do you think that you may feel about disclosing substance use on an app?", "How do you feel about tracking substance use–related information in an app?", and "Is there information you feel more comfortable sharing through the app compared to when you are talking directly to your provider?" Participants also completed a usability survey regarding the app's features (Multimedia Appendix 2) [52,53]. Participants were then encouraged to use the app as much or as little as they wished over the next 4 weeks.

At-home app usage was measured and transmitted through a secure HIPAA (Health Insurance Portability and Accountability Act)-compliant server to the research staff. For privacy protection, access to the app was protected by a password set up by the individual user. The password reset function required app users to provide their unique user ID and then complete instructions on resetting their password via a personalized SMS text message sent to their own, prespecified contact number. For sensitive questions embedded in the app (eg, substance use, reports of intimate partner violence), an icon was displayed that reminded users that information they shared might be transmitted to their health care provider. Participants were then recontacted by research staff by phone or in person to complete a brief follow-up survey regarding their impressions of independently using the app and any additional feedback or suggestions (Multimedia Appendix 3). The think-aloud sessions, cognitive interviews, and follow-up interviews were audio-recorded.

XSL•FO
RenderX

Figure 1. MyHealthyPregnancy sample screens offering substance use–related content and resources.



Data Analyses

Quantitative Analyses of Usability and Acceptability

Preliminary analyses evaluated survey and app usage data for completeness and accuracy and addressed any issues with data quality. Summary statistics were used to describe the participant characteristics, technology and mobile app use behaviors, assessments of app usability and acceptability, and participant-endorsed options for how a pregnancy app could assist with substance use. These statistics include means and standard deviations (or medians and quartiles for skewed distributions) for continuous variables and frequencies and proportions for categorical variables. Where appropriate, 95% CIs are included for means and proportions. IBM SPSS Statistics for Windows version 26 was used for quantitative statistical analysis [54].

Qualitative Analyses of Usability and Acceptability

Audio recordings from think-aloud sessions, cognitive interviews, and follow-up interviews were transcribed verbatim. Qualitative analyses were conducted using the Consolidated Framework for Implementation Research (CFIR)-based deductive analysis approach (directed content analysis), which is a rapid qualitative analytic method [53]. Prior to conducting the interviews, a preliminary codebook (in Microsoft Excel, version 16.54) was created by the research team. After the interviews were conducted, HF reviewed the transcripts using notes taken during the interviews to identify any additional codes or themes focused on understanding participants' experiences and perceptions of the app. The revised codebook was then used to code the transcripts for perspectives regarding the incorporation of substance use information in a pregnancy mHealth app.

Results

Study Sample

Over a 4-month enrollment period, 66 pregnant individuals were screened for eligibility, 24 declined to participate, and 6 did not meet study eligibility criteria. Among those that declined, the reasons provided were lack of interest in the study and limited time to attend study debriefs. Among those who did not meet the eligibility criteria, 5 participants did not have access to a smartphone due to rehabilitation facility or sober community living rules, and 1 participant was more than 37 weeks pregnant. Among the 36 participants who enrolled, 3 participants chose not to continue the study prior to using the app, 3 participants were unable to be reached for follow-up assessments, and 2 participants were found to no longer meet eligibility criteria due to fetal demise or lack of consistent access to a smartphone. Thus, 28 participants completed all study tasks and created the analytic sample.

Table 1 describes the characteristics of study participants. Most participants were White (21/28, 75%), Medicaid insured (26/28, 93%), and had an annual household income of less than US $30,000 (16/28, 57%). For 18% (5/28) of participants, this was their first pregnancy. The mean (SD) gestational age of participants at the time of enrollment was 22 (7.3) weeks. Substances used among participants consisted of tobacco (22/28, 79%), marijuana (20/28, 71%), illicit opioids (9/28, 32%),

XSL•FO
RenderX

alcohol (6/28, 21%), stimulants (4/28, 14%), including either cocaine or amphetamines, and benzodiazepines (2/28, 7%). Approximately 46% (13/28) of participants were currently taking medication for opioid use disorder (eg, methadone or buprenorphine). Some individuals (4/28, 14%) used marijuana only. All remaining participants used a combination of 2 or more substances.

Table . Participant characteristics (n=28).

Demographics			Values
Age (years), mean (SD)			31 (4.6)
Race, n (%)			
	White		21 (75)
	Multiracial		5 (18)
	Black or African American		2 (7)
Ethnicity, n (%)			
	Hispanic or Latino		2 (7)
Marital status, n (%)			
	Married		7 (25)
Insurance, n (%)			
	Medicaid		26 (93)
Highest level of completed education, n (%)			
	Some high school		7 (25)
	High school or general equivalency diploma		8 (29)
	Some college, trade school, or associate's degree		11 (39)
	Bachelor's degree		1 (4)
	Master's degree		1 (4)
Employment, n (%)			
	Full- or part-time employed		9 (32)
Income (US $), n (%)			
	<30,000		16 (57)
	30,000 - 60,000		3 (11)
	60,000 or more		4 (14)
	Unsure		4 (14)
Pregnancy history			
	Gestational age at enrollment (weeks), mean (SD)		22 (7.3)
	Primiparous, n (%)		5 (18)
Substance use history,[a] n (%)			
	Tobacco		22 (79)
	Marijuana		20 (71)
	Opioids		15 (54)
		MOUD[b]	13 (46)
		Illicit opioid use	9 (32)
	Alcohol		6 (21)
	Stimulants (ie, cocaine and amphetamines)		4 (14)
	Benzodiazepines		2 (7)

[a]Type of substances used within 3 months prior to pregnancy or during pregnancy.

[b]MOUD: medication for opioid use disorder.

XSL•FO
RenderX

Table 2 describes the technology behaviors and mobile app usage of participants. Texting (27/28, 96%) was the most commonly reported mode of communication, followed by phone (22/28, 79%), email (18/28, 64%), and social media (16/28, 57%). Health care providers (20/28, 71%) and mHealth apps (3/28, 11%) were the most frequently reported sources of pregnancy-related information followed by the internet or websites, family members, and friends. Health care providers were also noted to be the most trusted source of pregnancy-related information (27/28, 96%). mHealth apps were commonly used by participants, with 68% (19/28) reporting the use of a pregnancy app at the time of their enrollment and 26% (5/19) reporting that they used 2 or more pregnancy apps.

Table . Technology and mobile app use behaviors (n=28).

Technology use and communication during pregnancy		Values, n (%)
Source *most frequently* used for pregnancy information		
	Health care provider	20 (71)
	mHealth[a] apps	3 (11)
	Internet or websites	2 (7)
	Family members	2 (7)
	Friends	1 (4)
Source *most trusted* for accurate pregnancy information		
	Health care provider	27 (96)
	mHealth apps	1 (4)
Preferred methods of communication		
	Texting	27 (96)
	Phone	22 (79)
	Email	18 (64)
	Social media platforms	16 (57)
	Video calling or conferencing	11 (39)
	Apps	2 (7)
Smartphone ownership		28 (100)
Pregnancy app use (yes/no)		19 (68)
	Use of 2 or more pregnancy apps	5 (26)

[a]mHealth: mobile health.

Quantitative Analyses of Usability and Acceptability

Table 3 describes participants' experiences with the app. Measurements of the *usability* of the MyHealthyPregnancy app include participants' level of satisfaction with the ease of using the app and satisfaction with the time it took to use the app. Measurements of the app's *acceptability* include participants' overall satisfaction with the app, satisfaction with the interface, and how helpful the app was as a source of support. During the 4-week period, daily app use was the most common (12/28, 43%), and educational materials related to substance use were engaged with by the majority of participants (19/28, 68%). Acceptability and usability were generally high.

XSL•FO
RenderX

Table . MyHealthyPregnancy usability and acceptability (n=28).

	Values, n (%)
Acceptability	
The app was a helpful source of support in pregnancy	27 (96)
Liked the way the app looks	27 (96)
Overall, I am satisfied with the interface of the app	25 (89)
Overall, I am satisfied with the app in general	25 (89)
Usability	
I am satisfied with the ease of using the app	23 (82)
I am satisfied with the time it took to use the app	22 (79)
It was easy to navigate through the app	27 (96)
Engagement[a]	
Daily	12 (43)
Weekly	8 (29)
Monthly	5 (18)
Substance use resource utilization	
Participants who browsed substance use educational materials	19 (68)
Participants who accessed substance use treatment referral information	2 (7)

[a]Frequency of app logins within a 4-week period.

Participant-endorsed options for how a pregnancy app could assist with substance use–related behaviors are described in Table 4. Almost all participants (27/28, 96%) expressed a desire to use an app to block phone calls or SMS text messaging from people who had a negative effect on substance use behavior, while more than half desired the ability to track substance use, cravings, or treatment medications. The least endorsed options included information on infectious disease prevention (5/28, 18%), harm reduction (4/28, 14%), or intimate partner violence (3/28, 11%).

Table . Participant endorsed options for how a pregnancy app could assist with substance use (n=28).

Options	Values, n (%)
Blocking phone calls or SMS text messaging from people who have had a negative effect on recovery	27 (96)
Tracking incidences of substance use or cravings	19 (68)
Receiving reminders to take substance use treatment medications (eg, MOUD)[a]	16 (57)
Information about support groups for parents with substance use disorders	12 (43)
Neonatal opioid withdrawal syndrome information	9 (32)
Infectious disease prevention information	5 (18)
Harm reduction information	4 (14)
Intimate partner violence resources	3 (11)

[a]MOUD: medication for opioid use disorder (eg, methadone or buprenorphine)

Qualitative Analyses of Usability and Acceptability

In cognitive interviews, participants shared their perspectives regarding substance use disclosure through a pregnancy app and how a pregnancy app could be useful for people using substances or with a substance use disorder. Five major themes were identified from these debriefs (Table 5). Participants felt that substance use disclosure on an app may be associated with less stigma than in-person disclosure (theme 1). However, they also noted that their comfort with disclosure would vary by the type and legality of the substance (theme 2). Participants expressed concerns related to who could access substance use information (eg, health care professionals and social services providers) on a pregnancy app and concerns related to being permanently labeled as someone with an addiction (theme 3). Despite concerns, participants did believe that pregnancy apps could be a useful source of substance use information and education (theme 4) and felt that combining pregnancy and substance use information on a single app was the most desirable approach (theme 5).

XSL•FO
RenderX

Table . Participant perspectives regarding disclosure and incorporation of substance use information in a pregnancy mobile health app.

Theme	Example quote
Theme 1: Substance use disclosure on an app may be associated with less stigma than in-person disclosure	"I would feel a little more comfortable if I put it in the app than talking to an individual. The app doesn't judge you, like a human being would"
Theme 2: Disclosure comfort varies by type and legality of substance	"I definitely felt more comfortable disclosing legal drug use. For example, I do have my medical marijuana card, that is something I have no problem sharing, or alcohol and cigarettes, but yes, the non-legal ones, I would be a little nervous."
Theme 3: Concerns related to who could access disclosed substance use information	"Depending on what information I divulged, what would happen to that information? For example, would that be sent to a doctor? If it would be sent to a doctor or another professional or even a social worker… even though it would be confidential, I would just be worried I'd be labeled...and I will never be able to get away from my past addiction."
Theme 4: Prenatal apps could be a useful source of substance use information, education, and resources	"For the women who have no support or anyone to talk to, I really do think it is an effective tool to give them a little bit of encouragement and accurate information or just a guide: here are some resources, here is someone you could talk to."
Theme 5: Combining pregnancy and substance use information on a single app is desired	"Having it within a pregnancy app is kind of better personally just because it is all in one place...I've had recovery apps before, and I have fallen off of them. Actually, I completely forgot about them. So, like with pregnancy and having a kid and like getting ready for stuff, the simpler the better. So, if I don't have to go to multiple apps, that is great."

Discussion

Principal Results

Opioid use and the use of other addictive or illicit substances remain a significant and growing public health crisis in the United States. One significant barrier to providing early intervention during pregnancy is identifying individuals at risk and connecting them to care in a way that feels comfortable to them and through a mechanism which is engaging. One solution to identifying and engaging with pregnant individuals using opioids and other substances is through prenatal care apps. However, reaching pregnant individuals who use substances through more holistic prenatal care apps requires that the prenatal app be engaging and that app users who use substances must be willing to share their substance use through the app and act upon the information provided to them about recovery.

In this mixed methods, exploratory pilot study, incorporating substance use screening, information, education, and support into an existing prenatal app was found to be acceptable among pregnant people with substance use. Overall, participants showed high levels of interest in and engagement with MyHealthyPregnancy. Moreover, they reported being generally supportive of using an mHealth app as a means to access nonjudgmental resources for substance use during pregnancy. Our findings also indicate that there are multiple ways that an app could support individuals who use substances including blocking phone calls or SMS text messaging, providing information about recovery-oriented support groups, and offering resources regarding common co-occurring conditions (infectious disease acquisition, intimate partner violence, and harm reduction) [55].

Consistent with prior research demonstrating a high level of mHealth app usage among pregnant people (greater than 50%), most participants (19/28, 68%) reported that they had already used a prenatal app before starting the study, with some participants reporting the use of multiple prenatal apps [30,56-58]. In our study, apps were also identified, more generally, as a trustworthy, and easy-to-access source of pregnancy-related information, second only to health care providers. This aligns with other research findings demonstrating pregnant patients' appreciation for the accessibility and reliability of information found in prenatal apps [59]. Our study demonstrated a high level of engagement with our prenatal app, with 71% (20/28) logging in on a daily or weekly basis, similar to engagement levels that are considered high among other prenatal apps[60]. Together these findings suggest that a prenatal app-based intervention could be a beneficial strategy for information sharing between pregnant people who use substances and their providers, as this population already engages with and trusts this type of technology.

Our findings also indicate a high level of acceptability with incorporating substance use–related information into a pregnancy app. App usage data indicated that many participants browsed recovery-related educational materials on the app. These data align with other research demonstrating that people generally do not like moving between different apps to achieve their goals and prefer integrated technology tools, as well as prior findings showing that substance use screening and intervention in an app-based format has high acceptability and usability among patients [61,62]. Our participants expressed their interest in an expansion of substance use support capacity of the prenatal app, in alignment with prior research demonstrating that mHealth interventions are effective in areas including smoking cessation and addressing substance use during pregnancy[63]. Finally, many participants volunteered that disclosing substance use on an app may be easier than disclosing substance use in person, aligning with the current literature suggesting that self-report questionnaires and eHealth screenings could assist in creating more opportunities for disclosure than in-person evaluations alone [28,29,64].

XSL•FO
RenderX

However, many participants expressed concerns about disclosing substance use on an app because they would not know who might have access to this information, similar to prior research demonstrating patient concern about data security even in general prenatal apps [58]. Concerns about prosecution and child welfare involvement are previously reported barriers to substance use disclosure, which can lead to delays in seeking prenatal care and engaging in substance use treatment [65,66]. Mandatory reporting laws and the potential for child protective services involvement are major barriers to seeking treatment among pregnant people with opioid use disorder [67]. Any app that collects sensitive patient health information is required to comply with HIPAA. Moreover, any app that offers a substance use disorder treatment service must comply with the Opioid Addiction Recovery Fraud Prevention Act of 2018, which requires transparent and fair practices around how private health information is shared [68]. However, concerns about seeking and engaging in substance use treatment during pregnancy legitimately extend to disclosure and substance use treatment seeking through digital health means. In prior qualitative research, parents note that mandatory reporting regulations are biased, unjust, and stigmatizing and assert that stress stemming from the potential involvement of child welfare agencies has had a pronounced and detrimental impact on their families [67,69,70]. Moreover, since the 2022 *Dobbs v. Jackson* Supreme Court decision that ended federal protections for abortion, there have been increasing reports of digital health data being subpoenaed to criminalize pregnant individuals, further legitimizing caution around disclosure of certain health behaviors, especially during pregnancy [71,72].

Given both the concerns and interest voiced by our participants regarding embedding substance use screening and connection to care into a prenatal app, providers should familiarize themselves with any prenatal or substance use support apps available to patients prior to recommending them, including evaluating the evidence base, equity focus, and HIPAA protections afforded to such tools [73]. We additionally suggest that any providers discussing such apps with patients also educate patients about their rights and privacy related to disclosing substance use or other sensitive information in these apps. Providers can also encourage patients to share feedback about which apps they have found useful (or not) to support provider recommendations.

Limitations

There were several study limitations. First, approximately 36% (24/66) of those approached for study participation declined to enroll. Because many of those who declined to participate lacked interest in study participation, our sample may have been biased toward those who are more willing to use mHealth technology for health engagement or toward those with fewer reservations about disclosing substance use. In addition, all participants enrolled in the study had a known history of substance use. As such, their behaviors and perspectives may not be generalizable to pregnant people who have never disclosed their substance use within a health care setting. Next, our study sample was small and consisted of predominantly non-Hispanic White individuals, which limits the degree to which we can generalize our findings. Opioid overdose rates among Black individuals exceed those of White individuals by 4-6 times, and there are significant disparities in the receipt and use of medication for opioid use disorder between non-Hispanic White and Black and Hispanic pregnant individuals [74,75]. Thus, our findings cannot be generalized to those who may be at highest risk of not receiving adequate care. While the sample size for this exploratory pilot study was aligned with norms for thematic saturation for qualitative interview feedback to offer initial data on acceptability, a larger randomized trial with intentional demographic sampling would be required to adequately test implementation or intervention effects of incorporating substance use screening and content into the mHealth tool [76-78].

Conclusions

In this study, pregnant people with substance use found an existing pregnancy app to be an acceptable means of incorporating substance use supports and screening. Participants were already frequent users of prenatal apps and showed a high level of engagement with the prenatal support app in the study. At the completion of the study, participants expressed positive feelings about the usability of the app and interest in expanding the of the substance use support features of this app although some notable concerns relating to data privacy were raised. Given the prevalence of technology and app usage among pregnant people and the rise in substance use during pregnancy, mHealth technology should be considered a complement to in-person prenatal substance use screening and evaluation. Providing opportunities for substance use disclosure and resource provision through an acceptable digital platform that people are already using for pregnancy could result in earlier treatment engagement, along with improved outcomes among those who use substances. Our findings highlight this as an acceptable and desirable approach.

There is an ethical imperative for any prenatal app incorporating substance use–related content to clearly communicate both the confidentiality constraints of the tool and the potential consequences of disclosure prior to screening. As a way to address app users' concerns, developers should consider designing data collection so that any sensitive data are deleted as soon as possible or are only stored locally and not in a location that could be at risk of subpoena. App developers should also be sure to communicate clearly to app users about privacy and seek active consent for the collection or storage of any sensitive data. Finally, app developers should consider instating a policy prohibiting engagement in third-party data sharing, with the exception of HIPAA-compliant data sharing with the health care provider. Policy makers should ensure clear communication with providers about their rights related to substance use disclosure during pregnancy and potential legal repercussions. Health care providers considering using pregnancy apps, particularly for substance use screening or treatment referral, should evaluate whether the apps are evidence-based and adherent to strict policies around data protections. This may include being proactive about self-education regarding HIPAA privacy rules, as well as the state and institutional protections in place, so that they can communicate these clearly to their patients when recommending that patients share sensitive information through these tools.

XSL•FO
RenderX

Lastly, additional research is needed to prospectively evaluate and test patient-centered substance use screening and connection to recovery resources within pregnancy apps, as well as to understand and measure the rates of disclosure rates across substances. We recommend that any individuals involved in the development, use, or evaluation of pregnancy tools, which may provide these services, draw on established frameworks that center the needs and values of the target population, while proactively addressing health disparities as a strategy to advance health equity and improve health outcomes [73]. Through a personalized approach to health care, prenatal health apps can play a role in identifying and supporting pregnant people with substance use.

Acknowledgments

The authors thank Samantha Rodriguez and Laila Hayani for their support in facilitating secure app data exchange.

Conflicts of Interest

EEK is an investigator on grants to Magee-Womens Research Institute from the National Institutes of Health, Gilead, and Merck outside of the submitted work. TK is an investigator on grants to the University of Pittsburgh from the National Institutes of Health outside of the submitted work. TK is a cofounder of Naima Health, which provided app usage data for this study. The other authors report no conflicts of interest.

Multimedia Appendix 1
Baseline survey questions.
[DOCX File, 26 KB - pediatrics_v8i1e60038_app1.docx]

Multimedia Appendix 2
Usability survey questions.
[DOCX File, 19 KB - pediatrics_v8i1e60038_app2.docx]

Multimedia Appendix 3
Follow-up survey questions.
[DOCX File, 17 KB - pediatrics_v8i1e60038_app3.docx]

References

1. Admon LK, Bart G, Kozhimannil KB, Richardson CR, Dalton VK, Winkelman TNA. Amphetamine- and opioid-affected births: incidence, outcomes, and costs, United States, 2004-2015. Am J Public Health 2019 Jan;109(1):148-154. [doi: 10.2105/AJPH.2018.304771] [Medline: 30496001]
2. Denny CH, Acero CS, Terplan M, Kim SY. Trends in alcohol use among pregnant women in the U.S., 2011-2018. Am J Prev Med 2020 Nov;59(5):768-769. [doi: 10.1016/j.amepre.2020.05.017] [Medline: 33011009]
3. Hirai AH, Ko JY, Owens PL, Stocks C, Patrick SW. Neonatal abstinence syndrome and maternal opioid-related diagnoses in the US, 2010-2017. JAMA 2021 Jan 12;325(2):146-155. [doi: 10.1001/jama.2020.24991] [Medline: 33433576]
4. White A, Lundahl B, Bryan MA, et al. Pregnancy and the opioid crisis: heightened effects of COVID-19. J Addict Med 2022;16(1):e2-e4. [doi: 10.1097/ADM.0000000000000822] [Medline: 34282083]
5. Ndanga M, Sulley S, Saka AK. Trend analysis of substance use disorder during pregnancy. Cureus 2022 Mar;14(3):e23548. [doi: 10.7759/cureus.23548] [Medline: 35494976]
6. Bada HS, Das A, Bauer CR, et al. Low birth weight and preterm births: etiologic fraction attributable to prenatal drug exposure. J Perinatol 2005 Oct;25(10):631-637. [doi: 10.1038/sj.jp.7211378] [Medline: 16107872]
7. Viteri OA, Soto EE, Bahado-Singh RO, Christensen CW, Chauhan SP, Sibai BM. Fetal anomalies and long-term effects associated with substance abuse in pregnancy: a literature review. Am J Perinatol 2015 Apr;32(5):405-416. [doi: 10.1055/s-0034-1393932] [Medline: 25486291]
8. Almario CV, Seligman NS, Dysart KC, Berghella V, Baxter JK. Risk factors for preterm birth among opiate-addicted gravid women in a methadone treatment program. Am J Obstet Gynecol 2009 Sep;201(3):326. [doi: 10.1016/j.ajog.2009.05.052] [Medline: 19631928]
9. Cleary BJ, Eogan M, O'Connell MP, et al. Methadone and perinatal outcomes: a prospective cohort study. Addiction 2012 Aug;107(8):1482-1492. [doi: 10.1111/j.1360-0443.2012.03844.x] [Medline: 22340442]
10. Richardson GA, Ryan C, Willford J, Day NL, Goldschmidt L. Prenatal alcohol and marijuana exposure: effects on neuropsychological outcomes at 10 years. Neurotoxicol Teratol 2002;24(3):309-320. [doi: 10.1016/s0892-0362(02)00193-9] [Medline: 12009486]
11. Richardson GA, Day NL, Goldschmidt L. Prenatal alcohol, marijuana, and tobacco use: infant mental and motor development. Neurotoxicol Teratol 1995;17(4):479-487. [doi: 10.1016/0892-0362(95)00006-d] [Medline: 7565494]

XSL•FO
RenderX

12. Minkoff H, Paltrow LM. Melissa Rowland and the rights of pregnant women. Obstet Gynecol 2004 Dec;104(6):1234-1236. [doi: 10.1097/01.AOG.0000146289.65429.48] [Medline: 15572482]
13. Shah DS, Turner EL, Chroust AJ, Duvall KL, Wood DL, Bailey BA. Marijuana use in opioid exposed pregnancy increases risk of preterm birth. J Matern Fetal Neonatal Med 2022 Dec;35(25):8456-8461. [doi: 10.1080/14767058.2021.1980532] [Medline: 34582287]
14. Krans EE, Kim JY, Chen Q, et al. Outcomes associated with the use of medications for opioid use disorder during pregnancy. Addiction 2021 Dec;116(12):3504-3514. [doi: 10.1111/add.15582] [Medline: 34033170]
15. Center for Substance Abuse Treatment. A Guide to Substance Abuse Services for Primary Care Clinicians: Substance Abuse and Mental Health Services Administration (US); 1997.
16. American College of Obstetricians and Gynecologists. Committee opinion no. 633: Alcohol abuse and other substance use disorders: ethical issues in obstetric and gynecologic practice. Obstet Gynecol 2015;125(6):1529-1537. [doi: 10.1097/01.AOG.0000466371.86393.9b]
17. Friedmann PD, McCullough D, Saitz R. Screening and intervention for illicit drug abuse: a national survey of primary care physicians and psychiatrists. Arch Intern Med 2001 Jan 22;161(2):248-251. [doi: 10.1001/archinte.161.2.248] [Medline: 11176739]
18. Ko JY, Tong VT, Haight SC, et al. Obstetrician-gynecologists' practices and attitudes on substance use screening during pregnancy. J Perinatol 2020 Mar;40(3):422-432. [doi: 10.1038/s41372-019-0542-3] [Medline: 31666646]
19. Oni HT, Drake JA, Dietze P, Higgs P, Islam MM. Barriers to women's disclosure of and treatment for substance use during pregnancy: a qualitative study. Women Birth 2022 Nov;35(6):576-581. [doi: 10.1016/j.wombi.2021.12.009] [Medline: 34969637]
20. Lennox R, Patel T, Marmel A, Shaw E. Prenatal care outcomes in women with substance use disorders: a retrospective cohort study. J Obstet Gynaecol Can 2021 Jul;43(7):850-855. [doi: 10.1016/j.jogc.2020.10.021] [Medline: 33301956]
21. Simmons E, Austin AE. Association of prenatal substance use with prenatal and postpartum care: evidence from the Pregnancy Risk Assessment Monitoring System, 2016–2019. Prev Med 2022 Jun;159:107065. [doi: 10.1016/j.ypmed.2022.107065]
22. Chang JC, Holland CL, Tarr JA, et al. Perinatal illicit drug and marijuana use. Am J Health Promot 2017 Jan;31(1):35-42. [doi: 10.4278/ajhp.141215-QUAL-625]
23. Whittaker R, McRobbie H, Bullen C, Rodgers A, Gu Y. Mobile phone-based interventions for smoking cessation. Cochrane Database Syst Rev 2016;4(4):CD006611. [doi: 10.1002/14651858.CD006611.pub4]
24. Tofighi B, Nicholson JM, McNeely J, Muench F, Lee JD. Mobile phone messaging for illicit drug and alcohol dependence: a systematic review of the literature. Drug Alcohol Rev 2017 Jul;36(4):477-491. [doi: 10.1111/dar.12535]
25. Kazemi DM, Li S, Levine MJ, Auten B, Granson M. Systematic review of smartphone apps as a mHealth intervention to address substance abuse in adolescents and adults. J Addict Nurs 2021;32(3):180-187. [doi: 10.1097/JAN.0000000000000416] [Medline: 34473447]
26. Ashford RD, Lynch K, Curtis B. Technology and social media use among patients enrolled in outpatient addiction treatment programs: cross-sectional survey study. J Med Internet Res 2018 Mar 6;20(3):e84. [doi: 10.2196/jmir.9172] [Medline: 29510968]
27. Fleddermann K, Molfenter T, Vjorn O, et al. Patient preferences for mobile health applications to support recovery. J Addict Med 2023;17(4):394-400. [doi: 10.1097/ADM.0000000000001137] [Medline: 37579096]
28. Rosen CS, Henson BR, Finney JW, Moos RH. Consistency of self-administered and interview-based Addiction Severity Index composite scores. Addiction 2000 Mar;95(3):419-425. [doi: 10.1046/j.1360-0443.2000.95341912.x] [Medline: 10795362]
29. Silang K, Sanguino H, Sohal PR, Rioux C, Kim HS, Tomfohr-Madsen LM. eHealth interventions to treat substance use in pregnancy: a systematic review and meta-analysis. Int J Environ Res Public Health 2021 Sep 22;18(19):9952. [doi: 10.3390/ijerph18199952] [Medline: 34639252]
30. Lee Y, Moon M. Utilization and content evaluation of mobile applications for pregnancy, birth, and child care. Healthc Inform Res 2016 Apr;22(2):73-80. [doi: 10.4258/hir.2016.22.2.73] [Medline: 27200216]
31. American College of Obstetricians and Gynecologists. ACOG committee opinion no. 736: optimizing postpartum care. Obstet Gynecol 2018;131(5):e140-e150. [doi: 10.1097/AOG.0000000000002633]
32. Wouldes TA, Crawford A, Stevens S, Stasiak K. Evidence for the effectiveness and acceptability of e-SBI or e-SBIRT in the management of alcohol and illicit substance use in pregnant and post-partum women. Front Psychiatry 2021;12:634805. [doi: 10.3389/fpsyt.2021.634805] [Medline: 34025470]
33. Kenny R, Dooley B, Fitzgerald A. Feasibility of "CopeSmart": a telemental health app for adolescents. JMIR Ment Health 2015 Aug 10;2(3):e22. [doi: 10.2196/mental.4370] [Medline: 26552425]
34. Yang C, Linas B, Kirk G, et al. Feasibility and acceptability of smartphone-based ecological momentary assessment of alcohol use among African American men who have sex with men in Baltimore. JMIR Mhealth Uhealth 2015 Jun 17;3(2):e67. [doi: 10.2196/mhealth.4344] [Medline: 26085078]

XSL•FO
RenderX

35. Chen E, Moracco KE, Kainz K, Muessig KE, Tate DF. Developing and validating a new scale to measure the acceptability of health apps among adolescents. Digit Health 2022;8:20552076211067660. [doi: 10.1177/20552076211067660] [Medline: 35154802]
36. Rothstein JD, Jennings L, Moorthy A, et al. Qualitative assessment of the feasibility, usability, and acceptability of a mobile client data app for community-based maternal, neonatal, and child care in rural Ghana. Int J Telemed Appl 2016;2016:2515420. [doi: 10.1155/2016/2515420] [Medline: 28070186]
37. Guest G, Namey E, McKenna K. How many focus groups are enough? Building an evidence base for nonprobability sample sizes. Field Methods 2017 Feb;29(1):3-22. [doi: 10.1177/1525822X16639015]
38. Krishnamurti T, Davis AL, Rodriguez S, Hayani L, Bernard M, Simhan HN. Use of a smartphone app to explore potential underuse of prophylactic aspirin for preeclampsia. JAMA Netw Open 2021 Oct 1;4(10):e2130804. [doi: 10.1001/jamanetworkopen.2021.30804] [Medline: 34714341]
39. Krishnamurti T, Davis AL, Quinn B, Castillo AF, Martin KL, Simhan HN. Mobile remote monitoring of intimate partner violence among pregnant patients during the COVID-19 shelter-in-place order: quality improvement pilot study. J Med Internet Res 2021 Feb 19;23(2):e22790. [doi: 10.2196/22790] [Medline: 33605898]
40. Krishnamurti T, Davis AL, Wong-Parodi G, Fischhoff B, Sadovsky Y, Simhan HN. Development and testing of the MyHealthyPregnancy app: a behavioral decision research-based tool for assessing and communicating pregnancy risk. JMIR Mhealth Uhealth 2017 Apr 10;5(4):e42. [doi: 10.2196/mhealth.7036] [Medline: 28396302]
41. Allen K, Rodriguez S, Hayani L, et al. Digital phenotyping of depression during pregnancy using self-report data. J Affect Disord 2024 Nov 1;364:231-239. [doi: 10.1016/j.jad.2024.08.029] [Medline: 39137834]
42. Krishnamurti T, Rodriguez S, Wilder B, Gopalan P, Simhan HN. Predicting first time depression onset in pregnancy: applying machine learning methods to patient-reported data. Arch Womens Ment Health 2024 Dec;27(6):1019-1031. [doi: 10.1007/s00737-024-01474-w] [Medline: 38775822]
43. Chi MTH. Quantifying qualitative analyses of verbal data: a practical guide. J Learn Sci 1997 Jul;6(3):271-315. [doi: 10.1207/s15327809jls0603_1]
44. Güss CD. What is going through your mind? Thinking aloud as a method in cross-cultural psychology. Front Psychol 2018;9:1292. [doi: 10.3389/fpsyg.2018.01292] [Medline: 30150948]
45. Eccles DW, Arsal G. The think aloud method: what is it and how do I use it? Qual Res Sport Exerc Health 2017 Aug 8;9(4):514-531. [doi: 10.1080/2159676X.2017.1331501]
46. Anders Ericsson K, Simon HA. Protocol Analysis: Verbal Reports as Data (Revised Edition): MIT Press; 1984.
47. Beatty PC, Willis GB. Research synthesis: the practice of cognitive interviewing. Public Opin Q 2007;71(2):287-311. [doi: 10.1093/poq/nfm006]
48. Miller K, Willson S, Chepp V. In: Padilla JL, editor. Cognitive Interviewing Methodology: John Wiley & Sons; 2014. [doi: 10.1002/9781118838860]
49. Willis GB, Artino AR. What do our respondents think we're asking? Using cognitive interviewing to improve medical education surveys. J Grad Med Educ 2013 Sep;5(3):353-356. [doi: 10.4300/JGME-D-13-00154.1] [Medline: 24404294]
50. Collins D. Cognitive Interviewing Practice: SAGE Publications; 2015. [doi: 10.4135/9781473910102]
51. Willis GB. Cognitive Interviewing: A Tool for Improving Questionnaire Design: SAGE Publications; 2005.
52. Lewis JR. IBM computer usability satisfaction questionnaires: psychometric evaluation and instructions for use. Int J Hum Comput Interact 1995 Jan;7(1):57-78. [doi: 10.1080/10447319509526110]
53. Knafl K, Deatrick J, Gallo A, et al. The analysis and interpretation of cognitive interviews for instrument development. Res Nurs Health 2007 Apr;30(2):224-234. [doi: 10.1002/nur.20195] [Medline: 17380524]
54. IBM SPSS Statistics for Windows. : IBM Corp; 2014.
55. Nevedal AL, Reardon CM, Opra Widerquist MA, et al. Rapid versus traditional qualitative analysis using the Consolidated Framework for Implementation Research (CFIR). Implement Sci 2021 Jul 2;16(1):67. [doi: 10.1186/s13012-021-01111-5] [Medline: 34215286]
56. Tripp N, Hainey K, Liu A, et al. An emerging model of maternity care: smartphone, midwife, doctor? Women Birth 2014 Mar;27(1):64-67. [doi: 10.1016/j.wombi.2013.11.001] [Medline: 24295598]
57. Frid G, Bogaert K, Chen KT. Mobile health apps for pregnant women: systematic search, evaluation, and analysis of features. J Med Internet Res 2021 Oct 18;23(10):e25667. [doi: 10.2196/25667] [Medline: 34524100]
58. Goetz M, Müller M, Matthies LM, et al. Perceptions of patient engagement applications during pregnancy: a qualitative assessment of the patient's perspective. JMIR Mhealth Uhealth 2017 May 26;5(5):e73. [doi: 10.2196/mhealth.7040] [Medline: 28550005]
59. Bailey E, Nightingale S, Thomas N, et al. First-time mothers' understanding and use of a pregnancy and parenting mobile app (the Baby Buddy app): qualitative study using appreciative inquiry. JMIR Mhealth Uhealth 2022 Nov 21;10(11):e32757. [doi: 10.2196/32757] [Medline: 36409530]
60. Zhang P, Chen H, Shang J, et al. Mobile phone app use among pregnant women in China and associations between app use and perinatal outcomes: retrospective study. JMIR Form Res 2022;6(1):e29644. [doi: 10.2196/29644]
61. Krebs P, Duncan DT. Health app use among US mobile phone owners: a national survey. JMIR Mhealth Uhealth 2015 Nov 4;3(4):e101. [doi: 10.2196/mhealth.4924] [Medline: 26537656]

XSL•FO
RenderX

62. O'Grady M, Kapoor S, Gilmer E, et al. Point-of-care mobile application to guide health care professionals in conducting substance use screening and intervention: a mixed-methods user experience study. ACI Open 2019 Jan;03(01):e1-e12. [doi: 10.1055/s-0039-1684002]
63. Ameyaw EK, Amoah PA, Ezezika O. Effectiveness of mHealth apps for maternal health care delivery: systematic review of systematic reviews. J Med Internet Res 2024 May 29;26:e49510. [doi: 10.2196/49510] [Medline: 38810250]
64. Elertson KM, Schmitt CA. Ask them all: self-report universal prenatal substance use screening in the United States. J Subst Use 2019 Sep 3;24(5):520-523. [doi: 10.1080/14659891.2019.1614233]
65. Lander LR, Marshalek P, Yitayew M, Ford D, Sullivan CR, Gurka KK. Rural healthcare disparities: challenges and solutions for the pregnant opioid-dependent population. W V Med J 2013;109(4):22-27. [Medline: 23930558]
66. Kremer ME, Arora KS. Clinical, ethical, and legal considerations in pregnant women with opioid abuse. Obstet Gynecol 2015 Sep;126(3):474-478. [doi: 10.1097/AOG.0000000000000991] [Medline: 26244538]
67. Work EC, Muftu S, MacMillan KDL, et al. Prescribed and penalized: the detrimental impact of mandated reporting for prenatal utilization of medication for opioid use disorder. Matern Child Health J 2023 Dec;27(Suppl 1):104-112. [doi: 10.1007/s10995-023-03672-x] [Medline: 37253899]
68. Opioid Addiction Recovery Fraud Prevention Act of 2018. Federal Trade Commission. URL: https://www.ftc.gov/legal-library/browse/statutes/opioid-addiction-recovery-fraud-prevention-act-2018 [accessed 2025-01-21]
69. Proulx D, Fantasia HC. The lived experience of postpartum women attending outpatient substance treatment for opioid or heroin use. J Midwifery Womens Health 2021 Mar;66(2):211-217. [doi: 10.1111/jmwh.13165] [Medline: 33314604]
70. Martin CE, Almeida T, Thakkar B, Kimbrough T. Postpartum and addiction recovery of women in opioid use disorder treatment: a qualitative study. Subst Abus 2022;43(1):389-396. [doi: 10.1080/08897077.2021.1944954] [Medline: 34214405]
71. Torchinsky R. How period tracking apps and data privacy fit into a post-Roe v. Wade climate. NPR. 2022 Jun 24. URL: https://www.npr.org/2022/05/10/1097482967/roe-v-wade-supreme-court-abortion-period-apps [accessed 2025-01-21]
72. Kaste M. Nebraska cops used Facebook messages to investigate an alleged illegal abortion. NPR. 2022 Aug 12. URL: https://www.npr.org/2022/08/12/1117092169/nebraska-cops-used-facebook-messages-to-investigate-an-alleged-illegal-abortion [accessed 2025-01-21]
73. Krishnamurti T, Birru Talabi M, Callegari LS, Kazmerski TM, Borrero S. A framework for femtech: guiding principles for developing digital reproductive health tools in the United States. J Med Internet Res 2022 Apr 28;24(4):e36338. [doi: 10.2196/36338] [Medline: 35482371]
74. Gao YA, Drake C, Krans EE, Chen Q, Jarlenski MP. Explaining racial-ethnic disparities in the receipt of medication for opioid use disorder during pregnancy. J Addict Med 2022;16(6):e356-e365. [doi: 10.1097/ADM.0000000000000979] [Medline: 35245918]
75. Gondré-Lewis MC, Abijo T, Gondré-Lewis TA. The opioid epidemic: a crisis disproportionately impacting Black Americans and urban communities. J Racial Ethn Health Disparities 2023 Aug;10(4):2039-2053. [doi: 10.1007/s40615-022-01384-6] [Medline: 36068482]
76. Moore CG, Carter RE, Nietert PJ, Stewart PW. Recommendations for planning pilot studies in clinical and translational research. Clin Transl Sci 2011 Oct;4(5):332-337. [doi: 10.1111/j.1752-8062.2011.00347.x] [Medline: 22029804]
77. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. Field Methods 2006;18(1):59-82. [doi: 10.1177/1525822X05279903]
78. Kuzel AJ. Sampling in qualitative inquiry. In: Crabtree BF, Miller WL, editors. Doing Qualitative Research: SAGE Publications; 1992:31-44.

Abbreviations

CFIR: Consolidated Framework for Implementation Research
HIPAA: Health Insurance Portability and Accountability Act
***ICD-10*:** *International Classification of Diseases, Tenth Revision*
mHealth: mobile health
VA: Veterans Affairs

Edited by S Badawy; submitted 29.04.24; peer-reviewed by D Patel; revised version received 13.11.24; accepted 26.11.24; published 13.02.25.

Please cite as:
Fitzgerald H, Frank M, Kasula K, Krans EE, Krishnamurti T
Usability and Acceptability of a Pregnancy App for Substance Use Screening and Education: A Mixed Methods Exploratory Pilot Study
JMIR Pediatr Parent 2025;8:e60038
URL: https://pediatrics.jmir.org/2025/1/e60038
doi:10.2196/60038

XSL•FO
RenderX

© Haley Fitzgerald, Madison Frank, Katelyn Kasula, Elizabeth E Krans, Tamar Krishnamurti. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 13.2.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Simulation of Contraceptive Access for Adolescents and Young Adults Using a Pharmacist-Staffed e-Platform: Development, Usability, and Pilot Testing Study

Kayla Knowles[1], MPH; Susan Lee[1,2,3], MPH; Sophia Yapalater[4], MD; Maria Taylor[5], RPh; Aletha Y Akers[6], MPH, MD; Sarah Wood[1,2,3,7], MSHP, MD; Nadia Dowshen[1,2,3,7], MSHP, MD

[1]PolicyLab, Children's Hospital of Philadelphia, Philadelphia, PA, United States

[2]Clinical Futures, Children's Hospital of Philadelphia, Philadelphia, PA, United States

[3]Craig Dalsimer Division of Adolescent Medicine, Children's Hospital of Philadelphia, Philadelphia, PA, United States

[4]Division of General Internal Medicine, Department of Medicine, University of Pennsylvania, Philadelphia, PA, United States

[5]Stellar Pharmacy Services Inc, Avondale, PA, United States

[6]Guttmacher Institute, New York, NY, United States

[7]Department of Pediatrics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, United States

Corresponding Author:
Kayla Knowles, MPH
PolicyLab
Children's Hospital of Philadelphia
3401 Civic Center Blvd
Philadelphia, PA, 19104
United States
Phone: 1 267 425 1449
Email: knowlesk1@chop.edu

Abstract

Background: Offering contraceptive methods at pharmacies without a prescription is an innovative solution to reduce the incidence of unintended pregnancies among adolescents and young adults (AYA). Pharmacy-prescribed contraception may increase the convenience, simplicity, and affordability of contraceptives.

Objective: The aim of this study was to develop, pilot test, and evaluate the acceptability and feasibility of a telemedicine electronic platform app simulating pharmacist prescribing of contraceptives to AYA as well as assess agreement between pharmacist-simulated contraceptive approvals and contraception as prescribed in routine clinic visits.

Methods: This study was conducted in two phases: (1) development and usability testing of a prototype app to simulate pharmacists prescribing contraceptives to AYA and (2) pilot testing the app in a simulation for AYA requesting contraception from a pharmacist with pharmacist review and request approval or rejection. Eligibility criteria in both phases included the following: assigned female sex at birth, age 15-21 years, seeking contraceptive services at an academic adolescent medicine clinic, prior history of or intention to have penile-vaginal intercourse in the next 12 months, smartphone ownership, and English language proficiency. Phase 1 (usability) involved a video-recorded “think aloud” interview to share feedback and technical issues while using the app prototype on a smartphone and the completion of sociodemographic, sexual history, and perception of the prototype surveys to further develop the app. Phase 2 (pilot) participants completed phase 1 surveys, tested the updated app in a simulation, and shared their experiences in an audio-recorded interview. Descriptive analyses were conducted for quantitative survey data, and thematic analyses were used for interview transcripts.

Results: Of the 22 participants, 10 completed usability testing, with a mean age of 16.9 (SD 1.97) years, and 12 completed pilot testing, with a mean age of 18.25 (SD 1.48) years. Three issues with the prototype were identified during “think aloud” interviews: challenges in comprehension of medical language, prototype glitches, and graphic design suggestions for engagement. Usability testing guided the frontend and backend creation of the platform. Overall, participants agreed or strongly agreed that using an app to receive contraceptives would make it easier for teens to access (n=19, 86%) and make contraceptive use less stigmatizing (n=19, 86%). In addition, participants agreed that receiving contraception prescriptions from a pharmacist without a clinic visit would be safe (n=18, 82%), convenient (n=19, 86%), acceptable (n=18, 82%), and easy (n=18, 82%). Pharmacists and medical providers had 100% agreement on the prescribed contraceptive method for pilot participants.

XSL•FO
RenderX

Conclusions: AYA found contraceptive prescription by a pharmacist via an app to be highly acceptable and provided critical feedback to improve the design and delivery of the app. Additionally, pharmacist contraceptive approvals and contraception as prescribed in routine clinic visits were identical.

(JMIR Pediatr Parent 2025;8:e60315) doi:10.2196/60315

KEYWORDS

adolescent; contraception; telemedicine; user-centered design; young adult; reproductive; design; usability; experience; mHealth; mobile health; app; youth; teenager; drug; pharmacology; pharmacotherapy; pharmaceutics; medication; pharmacy; digital health; platform; access

Introduction

Pregnancy rates among adolescents and young adults (AYA) 15-19 years old have dropped from 61.8 births per 1000 in 1991 to 13.5 in 2022, while AYA 20-24 years old reported a record low pregnancy rate of 60.4 births per 1000 [1]. For 2010-2019, pregnancy rates declined the most for youth 19 years old and younger, a 50% decrease, followed by a 29% drop for 20-24 year olds [2]. Evidence suggests the decline in pregnancy rates may be attributed to increased access to comprehensive sex education, use of contraceptives and health care, and not due to decreased sexual activity [3]. However, sexually active AYA, aged 15-24 years, were the most likely age group to experience unintended pregnancies in the United States [2,4]. Despite evidence showing the value of access to sex education and contraceptive services in reducing pregnancy rates among AYA, laws restricting access to both are increasingly being introduced and passed in US state legislatures. Legal restrictions intensify barriers, such as cost, attending appointments, stigma, and more to accessing contraceptives [5,6], which disproportionately affects low-income, disabled, racial or ethnic minorities, and other marginalized women and other birthing people [7]. Pharmacist-prescribed contraception—a strategy already used in high-income and many low- and middle-income countries but rarely in the United States—is one such strategy. In 2019, the American College of Obstetricians and Gynecologists recommended pharmacist-prescribed contraception without age restrictions as a necessary step to increase over-the-counter access to hormonal contraception and reduce the rate of inconsistent or nonuse of contraception [8].

In prior research, women and other birthing people voiced “convenience, simplicity, [and] affordability” as primary benefits of pharmacist-prescribed contraception [9]. In a study in California among 426 women and other birthing people, pharmacy access for emergency hormonal contraceptive (EHC) was preferred to clinician prescription as it was perceived to be faster (54%) and more convenient (47%) than seeking physician prescription [10]. Another study found that 68% of women who were at risk for unintended pregnancy reported they would prefer to obtain the contraceptive pill, patch, ring, or EHC from a pharmacy rather than a clinic if pharmacist prescribing was an option [9]. Moreover, 41% of those not currently using contraception reported they would start a contraceptive method via pharmacist prescribing if available [10]. Provision of EHC via community pharmacies has increased the use of EHCs; moreover, expanding access in this way is estimated to prevent almost half (1.3 million) of the 3 million unintended pregnancies annually [11]. Centering patient priorities for access, as well as patient preferences for method choice, is a key tenet of reproductive justice and high-quality contraceptive care.

Historically, women and other birthing peoples’ safety has been the most common concern regarding contraception delivery without a clinician-provided prescription [9]. However, multiple studies demonstrate that patients can accurately self-screen for contraindications to contraceptive use using medical checklists [12,13]. One study found greater than 93% of 328 patient-physician concordance for risk factor identification [12]. In another study, self-screening by patients using a medical checklist of contraindications was found to have greater sensitivity (83.2%) and specificity (88.8%) than a patient self-completed clinician questionnaire, which asked them to simply consider their medical history to determine the presence of contraindications (56.2% sensitivity; 57.6% specificity) [13]. This means when using a medical checklist of contraindications, women were able to accurately self-screen for contraindications to combined hormonal contraception [13]. Given the consistency of evidence supporting patient ability to medical self-screen for contraceptive contraindications, the American College of Obstetricians and Gynecologists endorses patient use of self-screening tools to determine eligibility for over-the-counter access to hormonal contraception [8].

Pharmacist-prescribed contraception innovations will need to develop strategies for successful implementation prior to widespread scaling [14]. Implementing screening tools has proved challenging for non-sexual health services for select populations, like youth [14]. Developing outreach strategies for youth and other vulnerable populations may require careful consideration. Attention to the training of point-of-service staff may facilitate service delivery and uptake. Studies of pharmacy staff indicate greater hesitancy and a desire for more intense training before providing sexual health services compared to non-sexual health services [15]. Attention to training and post-training support services may be necessary to ease implementation challenges. Newer technologies, like telemedicine, that allow skilled providers to deliver services across a distance may be valuable in bridging this gap until larger numbers of pharmacists are comfortable delivering pharmacist-prescribed sexual health services. Combining innovations such as telehealth and pyxis machines can allow pharmacists who are trained and comfortable providing sexual health services to AYA to do so.

There is limited research on pharmacist-prescribed contraception for US adolescents [4]. This study sought to develop an e-platform app called Birth Control Pass (BCPass) to simulate

XSL•FO
RenderX

pharmacists prescribing contraceptives to AYA, test the acceptability and feasibility of pharmacist-delivered contraception among AYA as a proof of concept, and determine the concordance between pharmacists and providers on the appropriate contraceptive method(s) to be prescribed to participants.

Methods

Overview

This study occurred in 2 phases. In Phase I, the e-platform was developed, and participants were recruited to engage in usability testing. In Phase 2, participants pilot-tested the e-platform.

Participants and Setting

Eligible participants for both study phases were patients seeking contraceptive initiation services at a subspecialty academic adolescent medicine clinic, ages 15-21 years old, assigned female sex at birth, with a prior history of or intention to have penile-vaginal intercourse in the next 12 months, owned a smartphone and could read and speak English. Usability testing of the prototype was completed in April of 2021. Modifications were made to the app to address participants' concerns and implement suggestions through iterative usability testing between developers and the study team. Pilot testing of the final prototype occurred between October 2021 and August 2022.

Ethical Considerations

Institutional Review Board approval was granted by the Children's Hospital of Philadelphia (20-017957). Participants received a $20 US gift card for their time and effort. Precautions were taken to secure participants' personal information to ensure confidentiality including, the use of study identification numbers that were assigned to participants and used in place of participants' name and other private information on data collection forms.

Recruitment Strategy

For both study phases, the study team reviewed clinic schedules daily to identify patients with contraceptive appointments on the same day or the following clinic day. Clinic staff also referred patients for recruitment. Patients were approached in person at their medical appointment, by phone call, or via SMS text message. Consent was obtained via wet-ink signature on paper forms or electronic consent (e-consent) on Children's Hospital of Philadelphia's Research Electronic Data Capture (REDCap) [16,17] data collection application. Consent was provided either by legal guardians who attended clinic visits with patients 17 years old and younger or by the patients themselves, who were legally eligible to consent for themselves if they attended clinic visits alone [18] or were older than 18 years old. Participants were informed that by engaging in the research study, they would be testing the e-platform interface that simulated pharmacist prescribing but that they would not receive contraception as part of the study activities. Participants understood that contraception would be provided by their clinician during their scheduled medical visit, as per usual clinical care guidelines. Participants engaged with the e-platform either before or after their scheduled medical visit.

Study Procedures

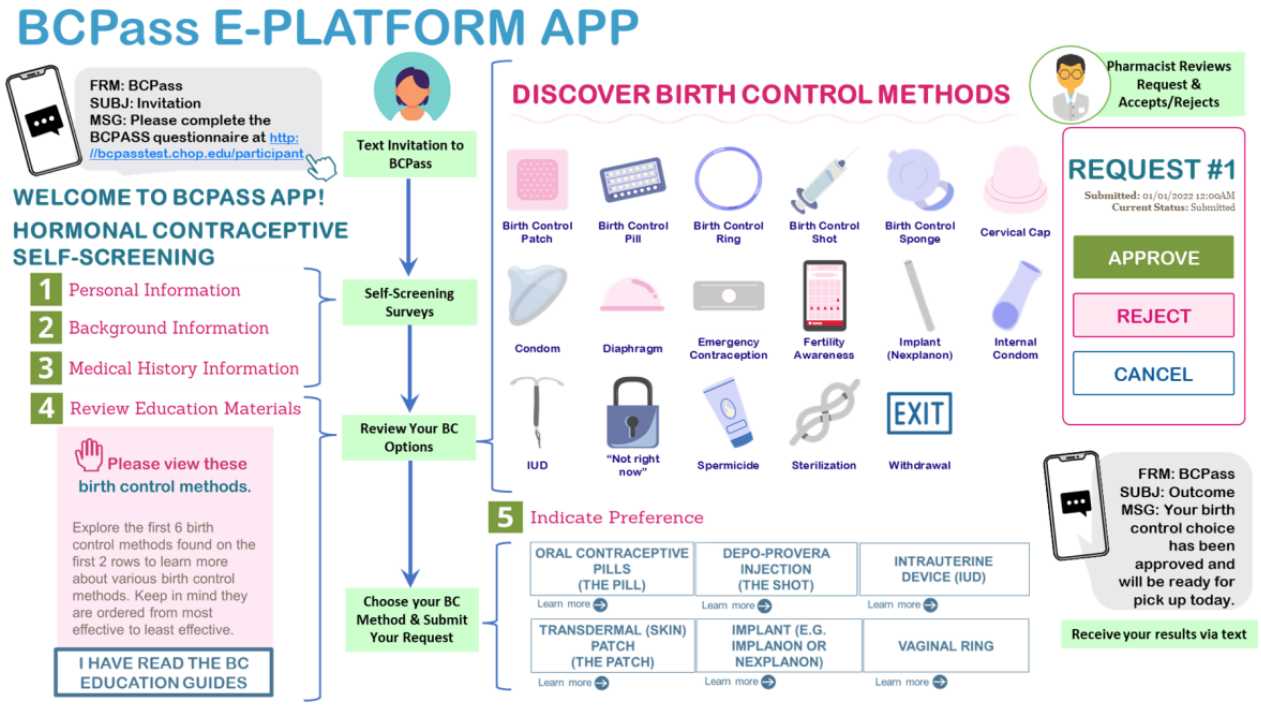
Phase 1: Development and Usability Testing

We created the BCPass prototype by modifying a large pediatric hospital system's app for employee COVID symptom check-in. The goal of the prototype was to simulate patient medical screening, patient contraceptive choice, and pharmacist contraceptive prescribing. The prototype first collected contact and self-screening information related to background and medical history. Next, participants were instructed to review content about contraceptive methods using a direct link to the educational website bedsider.org [19] and indicate their preferred method. Responses on the self-screening form were linked directly to medical contraindications to contraceptive prescribing per the Centers for Disease Control and Prevention US Medical Eligibility Criteria to facilitate rapid prescribing decision-making [20]. The prototype app included only a front-end interface for usability testing participants, but there was no backend personal health information data storage or pharmacist involvement. The study team explained to participants how the final app would work, including that if the participant had questions during the simulation, they had the option to call a pharmacist via the app ("Ask a Pharmacist" call button). Additionally, once the request for the preferred contraceptive method was submitted, a pharmacist would review and complete a "Pharmacist Approval Assessment Form" indicating if they would prescribe the contraceptive and approve dispensing or reject the request.

Participants completed web-based multiple-choice and short-answer surveys regarding their sociodemographic, sexual history, and attitudes regarding pharmacist-prescribed and app-delivered contraception. Next, they tested the prototype in a video-recorded "think aloud" interview [21], capturing the participants' initial impressions of the prototype, technical issues, and feedback while they actively engaged with the app prototype on their own smartphones. Studies using the "think aloud" methodology have proven to be successful at identifying usability problems without requiring a large number of subjects [21]. Participants were prompted to remark on ease of use, design aspects that are confusing or that slow task completion, and graphical elements, such as font size, ratios of images to words, and color schemes. The study team observed this process and took structured notes to capture information regarding domains from the sociotechnical model to ensure the optimization of service delivery [22]. Following prototype testing, participants' attitudes toward receiving contraception from a pharmacist and an app were assessed on a 5-point Likert scale: 1=strongly disagree, 2=disagree, 3=unsure, 4=agree, and 5=strongly agree. A 7-point Likert scale was used to evaluate the usefulness, ease of use, effectiveness, reliability, and satisfaction with the prototype (1=strongly disagree, 2=disagree, 3=somewhat disagree, 4=neither agree nor disagree, 5=somewhat agree, 6=agree, 7=strongly agree). Analyzed usability testing data was presented to the study team and app developers to inform the development of the app frontend and backend, along with iterative testing and weekly meetings (Figure 1). Special care was taken to thoroughly test each "click" on the app, and automated messages were reviewed to ensure ease of access and fluidity.

XSL•FO
RenderX

Figure 1. Birth Control Pass (BCPass) e-platform app overview. Overview of the BCPass app, invite link, participant-entered information, education information review [19], preferred contraception option, and the pharmacist review and outcome. "Discover Birth Control Methods" was adapted from the bedsider.org birth control dashboard webpage [19].



Phase 2: Pilot Testing

Once a fully functional app was developed, a study pharmacist was trained to implement the study protocol, and AYAs were recruited to pilot test the intervention. Pilot participants completed web-based surveys regarding their sociodemographic, sexual history, and attitudes toward receiving contraception from an app and a pharmacist. Next, participants completed a simulation exercise, which included completing a medical history form to identify contraindications to contraception, learning about contraceptive options via bedside.org [19], and selecting a contraceptive method. As part of the simulation, a text or email was sent to their smartphone with a link to the app. After they submitted their request for a contraceptive method, the study pharmacist accessed the request on the backend to review and complete the "Pharmacist Approval Assessment Form." Participants then received an automated SMS text message to confirm if the pharmacist accepted (prescribed the contraceptive and approved dispensing), rejected (shared information to call the clinic that provides contraceptive care), or requested additional information (when participants requested methods unavailable for pharmacist prescribing, such as long-acting reversible contraceptives and injectable medroxyprogesterone acetate).

Following the simulation, pilot participants completed a web-based survey to evaluate the usefulness, ease of use, effectiveness, reliability, and satisfaction on 5-point and 7-point Likert scales. Participants then engaged in a brief audio-recorded interview that solicited feedback on the app and participants' decision-making process in selecting a contraceptive method. After participants completed their clinic visit, the contraceptive method prescribed during their routine appointment was abstracted from their electronic medical record.

Analysis

Data analysis was conducted at two time points following phase 1 and phase 2, respectively. Deidentified survey demographics, sexual history, and Likert responses were exported from REDCap to Microsoft Excel for analysis. Descriptive analysis was computed for demographics and sexual history (proportions), and mean score and standard deviation were calculated for Likert questions. Audio from the "think aloud" video interview (usability) and feedback interview (pilot) were transcribed and manually coded by two coders until a 95% agreement regarding the themes was reached. For usability testing, participant comments and suggestions were categorized based on the type of modifications needed to the app (ie, wireframe, self-screening comprehension, and graphics). Interview data from the pilot testing was similarly thematically coded to reflect perceptions about the app's effectiveness, acceptability, feasibility, and participants' contraceptive decision-making. Effectiveness was defined as the e-platform success in simulating a birth control prescription. Acceptability or satisfaction with the e-platform was defined as participants' perceptions when using BCPass. Feasibility (BCPass practicality for learning about and accessing birth control) was defined by BCPass's usability or ease of use in navigating the e-platform and submitting a request for birth control. Lastly, birth control decision-making was based on participants' considerations made when indicating their birth control preference before and after using BCPass. Using the codebook, two coders not involved in usability qualitative analysis (one assisted with e-platform modifications and data collection, and the other helped with qualitative analysis only) classified statements in each thematic

XSL•FO
RenderX

area as positive, neutral, or negative. Finally, we assessed concordance between the contraceptive method selected at the medical visit (electronic medical record data) and the pharmacists' decision to approve or reject the participant's request for a contraceptive method.

Results

Participant Characteristics

In total, 22 AYA participated: 10 in phase 1 (usability testing) and 12 in phase 2 (pilot testing). On average, participants were 17.64 (1.50) years old, had some high school education (n=13), graduated from high school (n=4) or had some college (n=5), and had previously used contraception (n=17). See Table 1 for participant demographics and sexual history.

XSL•FO
RenderX

Table 1. Usability and pilot testing participant demographic and sexual history.

Characteristics	Usability testing (n=10)	Pilot testing (n=12)	Totals (N=22)
Age (years), n (%)			
15-16	3 (30)	1 (8)	4 (18)
17-18	7 (70)	7 (58)	14 (64)
19-21	0 (0)	4 (34)	4 (18)
Race or ethnicity, n (%)			
Black or African American	Unknown[a]	6 (50)	Unknown[a]
Hispanic or Latinx	Unknown[a]	1 (8)	Unknown[a]
White (non-Hispanic or Latinx)	Unknown[a]	5 (42)	Unknown[a]
Education, n (%)			
Not graduated high school	8 (80)	5 (42)	13 (59)
High school degree or General Education Development	1 (10)	3 (25)	4 (18)
Some college	1 (10)	4 (33)	5 (23)
Number of sex partners, n (%)			
None	4 (40)	2 (17)	6 (27)
Less than 3	3 (30)	8 (66)	11 (50)
Between 3 and 5	2 (20)	0 (0)	2 (9)
More than 5	0 (0)	2 (17)	2 (9)
Preferred not to say	1 (10)	0 (0)	1 (5)
Ever taken a pregnancy test, n (%)			
No	6 (60)	6 (50)	12 (55)
Yes	4 (40)	6 (50)	10 (45)
Ever been pregnant, n (%)			
No	10 (100)	12 (100)	22 (100)
Yes	0 (0)	0 (0)	0 (0)
Used birth control to prevent pregnancy, n (%)			
No	3 (30)	2 (17)	5 (23)
Yes	7 (70)	10 (83)	17 (77)
Ever used condoms during sex, n (%)			
No	3 (30)	2 (17)	5 (23)
Yes	7 (70)	10 (83)	17 (77)
Frequency of condom use[b,c], n (%)			
Never	0 (0)	1 (10)	1 (6)
Sometimes	2 (29)	6 (60)	8 (47)
Always	4 (57)	3 (30)	7 (41)
Unknown	1 (14)	0 (0)	1 (6)
Ever had a sexually transmitted infection[b], n (%)			
No	8 (80)	8 (67)	16 (73)
Yes	2 (20)	3 (25)	5 (23)
Unknown	0 (0)	1 (8)	1 (4)

[a]Race or ethnicity was not self-reported by usability participants in this phase of the study. Electronic medical record race and ethnicity data is not self-reported and may misidentify participants. Therefore, this study only reports self-reported information collected during the pilot testing phase.

XSL•FO
RenderX

[b]Due to rounding, some totals may not correspond with the sum of the separate figures.

[c]Participants were only asked about their frequency of condom use if they answered yes to using condoms during sex. Participants could have responded yes to ever using condoms, but they may not currently be using them.

Quantitative Survey: Acceptability and Feasibility of Pharmacist- and App-Delivered Contraception

Pharmacist-Prescribed Contraceptives

Usability and pilot participants (N=22) agreed receiving a contraceptive prescription from a pharmacist without a clinic visit would be safe (mean 4.27, SD 0.88), convenient (mean 4.50, SD 0.74), easy (mean 4.32, SD 0.89), and acceptable (mean 4.27, SD 1.08; Table 2). If they had the option to receive contraception from a pharmacist without a clinic visit, 14 of 22 participants reported they were likely or very likely to do so.

Table 2. Perceptions of pharmacist and app-delivered contraception (N=22, Likert Scale 1-5).

	Mean (SD)
Safety, convenience, acceptability, and ease receiving birth control	
Getting birth control prescribed by a pharmacist would be safe	4.27 (0.88)
Getting birth control from a pharmacist would be convenient	4.50 (0.74)
Getting birth control from a pharmacist would be acceptable to me	4.27 (1.08)
I think it would be easy to receive birth control from a pharmacist	4.32 (0.89)
Getting birth control from an app would be safe	3.82 (1.14)
Getting birth control from an app would be convenient	4.45 (1.01)
Getting birth control from an app would be acceptable to me	3.95 (1.17)
I think it would be easy to use an app to get birth control	4.36 (1.00)
Advantages of using an app to receive birth control	
It would be easier for teenagers to get oral contraceptives	4.55 (0.74)
It would feel less embarrassing	4.27 (0.98)
It is less stigmatizing, meaning more normal to use	4.45 (0.86)
Fewer teenagers would get pregnant	4.32 (0.99)
It would be more confidential	3.82 (1.30)
Disadvantages of using an app to receive birth control	
Teenagers might not use condoms to protect against sexually transmitted diseases	3.91 (0.87)
Teenagers need a doctor to decide if oral contraceptives are safe for them	3.73 (1.12)
Teenagers might have sex at a younger age	3.14 (1.32)
Teenagers might use oral contraceptives incorrectly	3.36 (1.05)
Teenagers might not get tested for sexually transmitted diseases	3.55 (1.26)
Oral contraceptives might cost more over the counter	3.50 (0.86)
Teenagers might not talk to their parents about birth control	4.00 (0.87)
I have no worries (concerns) about teens using a medication dispensing machine to get birth control	3.09 (1.11)
Social approval	
Most people who are important to me would approve of me using an app to get birth control	3.64 (1.14)
Most teens like me would use an app to get birth control	4.27 (0.77)
Teens my age would use an app to get birth control	4.23 (0.97)
Parents or family would support me using an app to get birth control	3.32 (1.30)
My romantic partner(s) would support me using an app to get birth control	4.09 (1.06)
The decision to use an app to get birth control would be totally up to me	4.18 (1.10)
I am confident that I could use an app to get birth control	4.09 (1.19)

XSL•FO
RenderX

Receive Contraceptives Through an e-Platform App

Usability and pilot participants (N=22) agreed that receiving contraception using an app would be safe (mean 3.82, SD 1.14), convenient (mean 4.45, SD 1.01), easy (mean 4.36, SD 1.00), and acceptable (mean 3.95, SD 1.17) (Table 2). Additionally, participants were confident they would be able to use an app to get contraception (mean 4.09, SD 1.19) and agreed most teens would use an app to get contraception (mean 4.27, SD 0.77). A potential advantage recognized by participants of using an app would include fewer teenagers experiencing an unintended pregnancy (mean 4.32, SD 0.99), getting contraception would be less embarrassing (mean 4.27, SD 0.98), and less stigmatizing (mean 4.45, SD 0.86). Participants agreed a potential disadvantage of receiving birth control from an app is that it may lead teens to not talk to their parents about birth control (mean 4.00, SD 0.87) or a possible decrease in condom use and an increase in sexually transmitted infections among teens (mean 3.91, SD 0.87). See Table 2 for additional insight into participants' attitudes toward pharmacists and app-delivered contraceptives.

E-Platform App Survey Feedback

Overall feedback on the BCPass app simulation during prototype and final productive testing was positive (Table 3). Participants agreed that BCPass was simple to use (mean 6.33, SD 1.24) and pleasant to interact with (mean 6.00, SD 1.64). Additionally, participants felt the app could do everything they would want it to be able to do for contraceptive delivery (mean 6.15, SD 1.23) and agreed they would use it again (mean 6.29, SD 1.54).

Table 3. BCPass app simulation feedback (N=22, Likert scale 1-7).

	Mean (SD)
BCPass was simple to use	6.33 (1.24)
BCPass was easy to learn and use	6.43 (1.02)
I believe I could become productive quickly using BCPass	6.05 (1.51)
The way I interact with BCPass is pleasant	6.00 (1.64)
I like using BCPass	6.00 (1.44)
BCPass can do everything I would want it to be able to do	6.15 (1.23)
I would use BCPass again	6.29 (1.54)

Clinician- and Pharmacist-Prescribed Contraception Concordance

A comparison of piloting participants who indicated a contraceptive preference (n=9) and what was prescribed revealed pharmacist contraceptive decisions and contraception methods as prescribed in routine clinic visits were identical. One of the 8 participant requests was rejected by the pharmacist because of a contraindication. This participant noted in their feedback interview that they requested a method they knew was contraindicated because it was their first choice over the contraception method they were prescribed. Three participants selected "I don't know" at the end of the simulation. One remained undecided following their clinic appointment. Another selected "I don't know" because they had an IUD at the time of the study but knew their first-choice method was contraindicated. The third selected a method at their clinic appointment. Of the 12 participants, one did not attend their clinic appointment, so it is unknown what they would be prescribed.

Qualitative Feedback

Usability Testing Think Aloud Data and Resultant e-Platform App Modifications

In an analysis of usability testing phase data, participants identified modifications related to addressing prototype wireframe glitches, self-screening comprehension, educational resource engagement, and app aesthetics. The prototype's wireframe glitches were anticipated as it was designed as a temporary test environment, and once the production frontend, patient-facing screen, backend, and developer view were created, the issues were resolved.

While navigating the prototype, participants requested clarification on the medical history questionnaire, indicating comprehension concerns. For example, participants asked if the transdermal skin patch was the same patch with which they were familiar. Additionally, participants asked what constitutes prolonged immobility or a bad reaction to hormonal contraception. The study team revised any questions that were identified as confusing and may be perceived as confusing to participants' peers. Examples and lay language were used for questions that required more medical terminology, such as including the more popular names for contraceptive methods in parentheses next to the full names (ie, oral contraceptive pill ["the pill"], transdermal hormonal patch ["the patch"], and injectable medroxyprogesterone acetate ["the shot"]).

Participants' feedback on the lack of educational material and the app's aesthetics were closely associated concerns. Numerous participants noted they skipped the mandatory contraceptive method educational website, explaining they did not see the link or felt it was not important. The color palette and ambiguity of the "Ask a Pharmacist" call button and bedsider.org weblink were noted as weaknesses. The team determined adding color and images was a solution to attract participants' attention to educational materials. A welcome page was created to introduce the purpose of BCPass and provide written instructions on how to contact the study pharmacist via the "Ask a Pharmacist" call button.

XSL•FO
RenderX

Pilot Testing Interview Feedback

The following four primary themes emerged during the coding process: (1) the perceived effectiveness of the BCPass app, (2) AYA's perceptions of using BCPass (usefulness as a standalone or compared to the standard of care), (3) BCPass practicality for learning about and accessing contraception via an app, and (4) AYA's considerations when selecting a contraceptive method before and after the BCPass simulation.

Of the 12 pilot participants, one interview was not completed because the study team could not reach the participant; thus, the results reflect 11 of the 12 participants. A quarter of the 11 pilot participants commented on receiving contraceptive prescriptions through BCPass from a pharmacist easily in the simulation. One participant expressed that BCPass may be unrealistic outside of the simulation due to safety concerns they had in making contraception more accessible to AYA without additional educational discussions with a provider. Due to the nature of the simulation, participants understood they would not receive a method as part of the study; therefore, the perceived effectiveness of BCPass was minimally mentioned.

> *"The only thing that surprised me was that um you can literally just just get it. Like you don't like need any doctor's approval like just being able to get it"* [Participant 1, selected implant in BCPass]

BCPass was highly acceptable among the 11 AYA pilot participants. The majority of pilot participants (73%) found BCPass to be quick, easy, convenient, and accessible. More than half (64%) found the process to be enjoyable and a good accessible option for other AYAs to request contraception compared to the standard of care of receiving contraception from a clinician after a medical appointment. Many participants stated they liked receiving contraception information from BCPass as well as avoiding a trip to a clinic and potentially uncomfortable conversation with a clinician (55%). Yet 18% of participants expressed they would also like the option to talk to a clinician by phone or in person in addition to the option they were given to talk to a pharmacist through BCPass. Some participants (18%) felt BCPass may not be adequate for AYA due to the possible need for more direct clinician oversight for young people and those with complex care needs.

> *"I also really liked the idea of not having to go to the doctor and have an awkward conversation about getting birth control"* [Participant 2, selected oral contraceptives in BCPass]

> *"I like that it was fast and convenient and I didn't have to go see a doctor. I could do it right on my phone. Um, I liked that it like also gave me a little feel about all the different kinds of birth control methods because I think that we are not often given information about all of them"* [Participant 3, selected IUD in BCPass]

A majority of the 11 pilot participants (91%) reported that BCPass was easy, quick, and convenient to use, with straightforward instructions and easy-to-answer questions. A third (36%) stated the information they received as part of the BCPass simulation was comparable to what they received at a medical appointment, including a participant stating the BCPass questions and education materials helped them determine what contraceptive method was best for them. While many usability concerns were addressed in the first phase of the study, 64% of participants shared feedback to further improve the experience for AYA. Suggestions included shortening the questionnaire, clarifying questions, deleting repetitive questions, and improving the delivery of educational materials.

> *"I liked how, I enjoyed how easy and self-explanatory a lot of the questions get… Sorry about that. I enjoyed mostly the descriptive questions that I was asked so that I was more sure about the pathway I would like to take while using that"* [Participant 4, selected Depo-Provera injection in BCPass]

Finally, participants were asked about their preferred contraceptive method selected using BCPass. Most of the 11 (82%) pilot participants reported prior use of the method they chose in the BCPass simulation. More than half (64%) cited their medical history and side effects associated with their preferred method when explaining their decision. Additional considerations participants noted were the delivery of contraception (eg, shot, long-acting reversible contraceptives, daily oral pill) (27%) as well as discussions they have had with family and friends (27%).

> *"I felt like it [the patch] was the easiest one to remember and it was something I didn't have to take every day and was something I only have to remember once a week. I feel like it would be easy on my time and my hobbies I tend to forget about stuff"* [Participant 5, selected transdermal patch in BCPass]

Prior to the BCPass simulation, two of the 11 (18%) pilot participants stated they did not have a single preferred contraceptive method in mind. After completing the simulation, they were able to more confidently select the method that they felt would work best for them. These participants credited the BCPass simulation questionnaire and educational materials in their decision-making process.

> *"Um I would definitely say that like IUD now. Originally, I would say 50-50 percent, like I would've leaned either way. But now using the app I would definitely say that I would have rather used the IUD because it's more, I don't want to say more protective. But like, it's better, it's like safer, better protection"* [Participant 3, selected IUD in BCPass]

Discussion

Principal Findings

We found that an app for pharmacist delivery of contraception, BCPass, was acceptable and usable for AYA. Participants liked how easy, convenient, and fast BCPass was to request contraception. Once the concerns addressed in the usability phase were incorporated, there were no glitches experienced, and few participants felt the app survey was too long or had confusing questions. Also, more education may be needed to ensure AYAs feel safe requesting contraception from a pharmacist. Finally, we identified 100% agreement between

XSL•FO
RenderX

pharmacist contraceptive approvals in the simulation and contraception as prescribed in routine clinic visits.

Our findings are consistent with prior research on this topic in older adult women. In one survey study, women and other birthing people (≥18 years) reported receiving contraception from a pharmacist may be more convenient, faster, and easier compared to getting contraception from a clinician [10], which mirrors AYA's beliefs in this study. Additionally, this study found AYA-reported advantages of using an app included improving access to contraception by reducing the stigma and embarrassment of using contraception, reducing the burden of scheduling and attending clinic visits, and reducing the number of teenagers who become pregnant. In our study's feedback interview, most pilot participants emphasized their favorite aspect of BCPass was how quick and convenient it was compared to the standard of care while still receiving the contraceptive information they desired.

We did not identify any discordance between simulated pharmacist approvals and clinicians, as prescribed in clinic visits, suggesting the safety of having youth self-screen for medical contraindications. Women and other birthing people have previously been shown to safely and accurately complete self-screening medical history questionnaires and identify contraindications [12,13]. Like the older cohort, this study has shown AYA were capable of reporting their medical history, reviewing education materials, and selecting a contraceptive method they wish to use without forgoing a medical professional's review. While this study made edits, such as including more lay language and providing examples to some questions, to the medical contraindications to contraceptive prescribing per the Centers for Disease Control and Prevention US Medical Eligibility Criteria [20], once these changes were made to accommodate AYA's readability and comprehension level, they were able to successfully communicate their own medical history with a pharmacist through the app. A few pilot participants noted in their feedback interview they were surprised how easy completing the simulation was because questions regarding medical history were primarily all yes or no with an option to write in additional information for context with the study pharmacist. Some participants even found questions on their contraception preferences and reviewing educational materials more helpful in picking their preferred contraception than speaking to a clinician. Additionally, the feedback from the pilot phase reflected AYA's thoughtful consideration and awareness of their medical history, as well as side effects when planning to request contraception.

Of note, only one participant expressed concerns that contraception prescription without a clinician's oversight could be dangerous for AYA by making contraception too accessible, but several felt that they would prefer to discuss it with a provider. This data suggests the BCPass educational materials and access to call a pharmacist were not as effective as they needed to be to assure safety. While most participants liked the educational materials, a few did not feel it was enough to educate AYA on side effects. This finding suggests a need to include multimodal educational material, including more visual and audio materials. Additionally, participants who questioned the safety of BCPass also did not view pharmacists as being as knowledgeable as clinicians in prescribing contraception, which contrasts with physicians and midlevel practitioners in other studies who have supported pharmacist-initiated access to contraceptives [15]. Safety concerns indicated educational information presented needs to not only address contraception concerns but also inform AYA of the pharmacist's credibility and remind future users that pharmacists provide medical care already, such as vaccine delivery and drug interaction information [23].

Limitations of this study include the small sample size, single-city site, and limited rounds of usability testing. In addition, current state policy allows only for the simulation of pharmacist prescriptions. Following usability testing and additional app modifications, the platform was not retested again in another usability round before it was launched in the pilot testing phase. We focused on contraceptive methods for pregnancy prevention only and did not include the myriad of other reasons AYA may use contraception (eg, menstruation management, acne treatment, gender-affirming care, and medical conditions such as endometriosis). In addition, some participants completed the BCPass simulation following their medical appointment, which was not documented but is an important consideration for future larger-scale testing of the simulation. Future studies should further inform apps' usefulness in improving access to contraception for a broad range of indications via pharmacist prescription. Additionally, future research should explore the acceptability and feasibility of BCPass for key populations, including but not limited to girls, women, and other birthing people who are low income, living with disabilities, and sexual and gender minorities, to navigate barriers to accessing contraception. At the time of this study, pharmacist dispensing of contraceptives was not legal in the state of Pennsylvania, where this study took place, and 29 other US states. During a time with increasingly restrictive laws on connecting AYAs to contraceptives and other family planning resources, implementing methods to increase access to contraception is more important than ever because AYAs are particularly vulnerable to these restrictions.

Conclusions

Our results indicate that the BCPass app has the potential to be a valuable tool to improve access to contraception more equitably by facilitating contraceptive education, person-centered decision-making, and convenient delivery. BCPass and other electronic health solutions can supplement traditional care models and can be easily scalable, time-efficient, and cost-effective to assist AYA with navigating barriers to accessing contraceptives. Our results, demonstrating high acceptability and usability, suggest the potential of apps as supplemental effective tools to expand access to contraception for AYA during this time of increasing restrictive laws and policies impacting AYA reproductive health.

XSL•FO
RenderX

Acknowledgments

The authors thank the AYA participants, the study team (James Adams, Ava Skolnik, and Hannah Lee), and the app developers (Daniel Atkins, David Schlich, and Lindsay Cowen). This research was supported by the Children's Hospital of Philadelphia Clinical Futures (formerly Center for Pediatric Clinical Effectiveness) Pilot Grant and National Institutes of Health, K23 (NIH K23MH119976-01A, SW).

Conflicts of Interest

None declared.

References

1. Hamilton BE, Martin JA, Osterman MJK. Births: Provisional Data for 2022, in Vital Statistics Rapid Release. Centers for Disease Control and Prevention. Hyattsville, MD: National Center for Health Statistics; 2023. URL: https://www.cdc.gov/nchs/data/vsrr/vsrr028.pdf [accessed 2024-11-25]
2. Rossen LM, Hamilton BE, Abma JC. Updated Methodology to Estimate Overall and Unintended Pregnancy Rates in the United States. Centers for Disease Control and Prevention. Hyattsville, MD: NCHS Vital and Health Statistics Series; 2023. URL: https://stacks.cdc.gov/view/cdc/124395 [accessed 2023-07-23]
3. Lindberg L, Santelli J, Desai S. Understanding the decline in adolescent fertility in the United States, 2007-2012. J Adolesc Health 2016;59(5):577-583 [FREE Full text] [doi: 10.1016/j.jadohealth.2016.06.024] [Medline: 27595471]
4. Finer LB. Unintended pregnancy among U.S. adolescents: accounting for sexual activity. J Adolesc Health 2010;47(3):312-314. [doi: 10.1016/j.jadohealth.2010.02.002] [Medline: 20708573]
5. Swan LET. The impact of US policy on contraceptive access: a policy analysis. Reprod Health 2021;18(1):235 [FREE Full text] [doi: 10.1186/s12978-021-01289-3] [Medline: 34809673]
6. Grindlay K, Grossman D. Prescription birth control access among U.S. women at risk of unintended pregnancy. J Womens Health (Larchmt) 2016;25(3):249-254. [doi: 10.1089/jwh.2015.5312] [Medline: 26666711]
7. Mercier AM, Carter SR, Manning N. Racial and ethnic disparities in access to gynecologic care. Curr Opin Anaesthesiol 2022;35(3):267-272. [doi: 10.1097/ACO.0000000000001130] [Medline: 35671011]
8. NA. Over-the-counter access to hormonal contraception: ACOG committee opinion summary, number 788. Obstet Gynecol 2019;134(4):886-887. [doi: 10.1097/AOG.0000000000003474] [Medline: 31568359]
9. Landau SC, Tapias MP, McGhee BT. Birth control within reach: a national survey on women's attitudes toward and interest in pharmacy access to hormonal contraception. Contraception 2006;74(6):463-470. [doi: 10.1016/j.contraception.2006.07.006] [Medline: 17157103]
10. Greene D, Sharon F, Landau C, Monastersky N, Chung F, Kim N, et al. Pharmacy access to emergency contraception in California. Perspect Sexual Reprod Health 2006;38(1):46-52. [doi: 10.1111/j.1931-2393.2006.tb00058.x]
11. Lloyd K, Gale E. Provision of emergency hormonal contraception through community pharmacies in a rural area. J Fam Plann Reprod Health Care 2005;31(4):297-300 [FREE Full text] [doi: 10.1783/jfp.31.2.297] [Medline: 16274553]
12. Doshi JS, French RS, Evans HER, Wilkinson CL. Feasibility of a self-completed history questionnaire in women requesting repeat combined hormonal contraception. J Fam Plann Reprod Health Care 2008;34(1):51-54 [FREE Full text] [doi: 10.1783/147118908783332203] [Medline: 18201408]
13. Grossman D, Fernandez L, Hopkins K, Amastae J, Garcia SG, Potter JE. Accuracy of self-screening for contraindications to combined oral contraceptive use. Obstet Gynecol 2008;112(3):572-578 [FREE Full text] [doi: 10.1097/AOG.0b013e31818345f0] [Medline: 18757654]
14. Dabrera G, Pinson D, Whiteman S. Chlamydia screening by community pharmacists: a qualitative study. J Fam Plann Reprod Health Care 2011;37(1):17-21 [FREE Full text] [doi: 10.1136/jfprhc.2010.0003] [Medline: 21367698]
15. Rafie S, Kelly S, Gray EK, Wong M, Gibbs S, Harper CC. Provider opinions regarding expanding access to hormonal contraception in pharmacies. Womens Health Issues 2016;26(2):153-160. [doi: 10.1016/j.whi.2015.09.006] [Medline: 26549241]
16. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, REDCap Consortium. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208 [FREE Full text] [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]
17. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
18. Minors' Consent to Medical, Dental and Health Services. 1970. URL: https://casetext.com/statute/pennsylvania-statutes/statutes-unconsolidated/title-35-ps-health-and-safety/chapter-51-minors-consent-to-medical-dental-and-health-services [accessed 2024-06-06]
19. Birth Control. Bedsider. 2020. URL: https://www.bedsider.org/birth-control [accessed 2023-07-05]

XSL•FO
RenderX

20. Tepper NK, Curtis KM, Cox S, Whiteman MK. Update to U.S. medical eligibility criteria for contraceptive use, 2016: updated recommendations for the use of contraception among women at high risk for HIV infection. MMWR Morb Mortal Wkly Rep 2020;69(14):405-410 [FREE Full text] [doi: 10.15585/mmwr.mm6914a3] [Medline: 32271729]
21. Nielsen J. Estimating the number of subjects needed for a thinking aloud test. Int J Hum Comput Stud 1994;41(3):385-397. [doi: 10.1006/ijhc.1994.1065]
22. Sittig DF, Singh H. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. Qual Saf Health Care 2010;19 Suppl 3(Suppl 3):i68-i74 [FREE Full text] [doi: 10.1136/qshc.2010.042085] [Medline: 20959322]
23. Strand MA, Bratberg J, Eukel H, Hardy M, Williams C. Community pharmacists' contributions to disease management during the COVID-19 pandemic. Prev Chronic Dis 2020;17:E69 [FREE Full text] [doi: 10.5888/pcd17.200317] [Medline: 32701431]

Abbreviations

AYA: adolescents and young adults
BCPass: Birth Control Pass
EHC: emergency hormonal contraceptive
REDCap: Research Electronic Data Capture

Edited by S Badawy; submitted 09.07.24; peer-reviewed by E de La Rochebrochard; comments to author 15.11.24; revised version received 27.11.24; accepted 28.11.24; published 19.02.25.

Please cite as:
Knowles K, Lee S, Yapalater S, Taylor M, Akers AY, Wood S, Dowshen N
Simulation of Contraceptive Access for Adolescents and Young Adults Using a Pharmacist-Staffed e-Platform: Development, Usability, and Pilot Testing Study
JMIR Pediatr Parent 2025;8:e60315
URL: https://pediatrics.jmir.org/2025/1/e60315
doi:10.2196/60315
PMID:

©Kayla Knowles, Susan Lee, Sophia Yapalater, Maria Taylor, Aletha Y Akers, Sarah Wood, Nadia Dowshen. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 19.02.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Quality of First Prenatal Consultations in Malemba Nkulu, Democratic Republic of Congo: Challenges and Opportunities in a Cross-Sectional Study

Fiston Ilunga Mbayo[1,2], MPH, MD; Pascal Geri Madragule[3], MPH, MD; Pacifique Kanku wa Ilunga[3], MPH, MD; Ignace Bwana Kangulu[3], MD, PhD; Dalau Nkamba Mukadi[1], MPH, MD, PhD

[1]School of Public Health, Faculty of Medicine, University of Kinshasa, Kinshasa, the Democratic Republic of the Congo

[2]Department of Public Health, General Referral Hospital of Malemba Nkulu, Malemba Nkulu, the Democratic Republic of the Congo

[3]Faculty of Medicine, University of Kamina, Kamina, the Democratic Republic of the Congo

Corresponding Author:
Fiston Ilunga Mbayo, MPH, MD
School of Public Health
Faculty of Medicine
University of Kinshasa
PO Box 11850
Kinshasa
the Democratic Republic of the Congo
Phone: 243 995716784
Email: ilungambayofiston@gmail.com

Abstract

Background: Maternal mortality remains alarmingly high in the Democratic Republic of Congo (DRC), particularly in rural areas where access to quality prenatal care is limited. Despite global efforts to improve maternal health, systemic gaps persist in the delivery of antenatal services.

Objective: The objective of this study is to assess the quality of first antenatal consultations in the Malemba Nkulu health zone and identify structural and procedural factors contributing to substandard care.

Methods: A cross-sectional descriptive study was conducted in November 2023 across 8 health facilities selected through simple random sampling. Data were collected from 248 pregnant women attending their first prenatal visit and from 14 health care providers. Quality indicators were assessed using a structured checklist based on World Health Organization (WHO) standards. Variables included provider qualifications, availability of diagnostic tools, and completeness of clinical assessments.

Results: Only 2% (5/248) of first antenatal consultations met the minimum quality standards. Major deficiencies included lack of physical examinations 78% (193/248), absence of essential laboratory tests 92% (228/248), and inadequate counseling 85% (212/248). Facilities lacked basic equipment such as blood pressure monitors and hemoglobin tests. Provider training was inconsistent, and community awareness of prenatal care remained low.

Conclusions: The quality of first antenatal consultations in Malemba Nkulu is critically poor, reflecting broader systemic challenges in rural maternal health care. Strengthening provider training, improving infrastructure, and enhancing community engagement are essential to reduce maternal mortality and improve outcomes in resource-limited settings.

(JMIR Pediatr Parent 2025;8:e78511) doi:10.2196/78511

KEYWORDS

quality; antenatal; consultation; maternal health; Democratic Republic of Congo

Introduction

Background

Maternal mortality remains a major public health concern in low-resource settings, particularly in sub-Saharan Africa. According to the World Health Organization (WHO), nearly 99% of maternal deaths occur in countries with limited access to quality care [1]. In the Democratic Republic of Congo (DRC), the maternal mortality ratio is estimated at 473 deaths per

XSL•FO
RenderX

100,000 live births [2], a figure that reflects persistent gaps in the health system and the urgent need for targeted interventions.

Antenatal care (ANC) is widely recognized as a key strategy to reduce maternal and neonatal morbidity and mortality. The WHO recommends at least 8 prenatal visits, with the first ideally occurring before 12 weeks of gestation [3]. Early and high-quality ANC enables timely screening, prevention of complications, and health education. However, in the DRC, fewer than 8% of pregnant women initiate ANC in the first trimester [4], and many consultations are conducted by providers lacking formal medical training [5].

The Malemba Nkulu health zone, located in the rural province of Haut-Lomami, exemplifies these challenges. It was selected for this study due to its high maternal risk profile, limited access to qualified health personnel, and absence of recent data on ANC quality. Preliminary data from this region reveal that over half of pregnant women (52.4%) attend their first ANC visit in the third trimester, limiting the effectiveness of preventive measures. Additionally, nearly 43% of consultations are conducted by traditional birth attendants without advanced medical qualifications, and more than 60% of health facilities lack essential equipment for complete prenatal assessments, including tests for anemia and maternal infections [6]. These findings suggest that the quality of the first antenatal consultation (ANC1) may be a critical determinant of maternal outcomes. While previous studies in West Africa have linked ANC quality to provider training, infrastructure, and community engagement [7], few have examined this issue in depth within the DRC. Evidence from Rwanda and Ethiopia shows that integrating ANC into community health programs and investing in provider capacity can significantly improve maternal care [8].

Objective

This study aims to assess the quality of the first antenatal consultation in the Malemba Nkulu health zone using national and international standards as benchmarks. It seeks to identify structural, procedural, and contextual factors that influence care quality and to inform strategies for improving maternal health in rural Congolese settings.

Methods

Study Design and Setting

This study used a descriptive cross-sectional design to assess the quality of ANC1s in the Malemba Nkulu health zone. The study was conducted over a 2-month period from November to December 2023. This design was selected to provide a snapshot of service delivery and identify gaps in compliance with national and WHO standards.

Study Site

This study took place in the Malemba Nkulu health zone, located in the rural province of Haut-Lomami in southeastern DRC. The area is characterized by limited access to qualified health personnel, inadequate infrastructure, and high maternal risk indicators, making it a relevant setting for evaluating ANC quality.

Sampling and Methodological Justification

This study used a mixed sampling approach, combining probabilistic and nonprobabilistic techniques to ensure both representativeness and feasibility in a resource-limited rural context.

Health Facilities

Eight facilities were selected using simple random sampling from the official list of centers providing ANC services within the Malemba Nkulu health zone. This method ensured equal probability of selection and minimized selection bias.

Pregnant Women

A total of 248 pregnant women were recruited through consecutive sampling, including all eligible participants attending their ANC1 during the study period. This approach captured real-time practices without interruption or subjective filtering.

Health Care Providers

Fourteen providers were included through exhaustive sampling, meaning all active personnel involved in ANC1 services at the selected facilities were enrolled, provided they had at least 6 months of experience in antenatal care. This ensured a comprehensive representation of professional profiles and practices.

Methodological Rationale

This sampling strategy was chosen to maximize data representativeness in a heterogeneous rural environment, minimize bias related to participant availability and provider selection, and facilitate logistical implementation under field conditions.

Study Population and Eligibility Criteria

Pregnant Women

The inclusion criteria for pregnant women included those (1) attending their ANC1 during the study period, (2) receiving care in one of the selected facilities, and (3) providing informed consent after explanation of study objectives. Pregnant women were excluded if their ANC1 was previously conducted in another facility or if they refused to participate.

Health Care Providers

The inclusion criteria for health care providers included those (1) actively involved in delivering ANC services in the selected facilities and (2) with a minimum of 6 months' experience in antenatal care provision. Health care providers were excluded if they were absent during the study period due to leave or reassignment or refused to participate.

Sampling Strategy and Justification

Health facilities were selected using simple random sampling to ensure equal probability of inclusion and reduce selection bias. Pregnant women were recruited consecutively, including all eligible women presenting for ANC1 during the study period. Health care providers were included exhaustively from the selected facilities, based on availability and direct involvement in ANC.

XSL•FO
RenderX

This mixed sampling approach was chosen to maximize representativeness and feasibility. The final sample included 248 pregnant women and 14 health care providers, reflecting the diversity of practices and qualifications across the zone.

Data Collection Procedures

Data were collected using a standardized observation grid adapted from national guidelines and WHO recommendations. Ten key dimensions of ANC1 were assessed, as outlined in Table 1.

Each consultation was directly observed by trained data collectors. Medical records were reviewed to confirm procedures, and structured interviews were conducted with pregnant women to assess their perceptions of care.

XSL•FO
RenderX

Table 1. A summary for the measurement of the first antenatal consultation (ANC1) quality variable. The maximum total ANC1 quality score is 100, with each domain contributing up to 10 points.

Domains and their objects	Measure	Percentage rating per object
History of pregnant women		
Age of the pregnant woman	1=Requested, 0=No	2.5
Medications that the pregnant woman takes	1=Requested, 0=No	2.5
Date of start of the pregnant woman's last menstrual period	1=Requested, 0=No	2.5
Number of previous pregnancies the pregnant woman has had	1=Requested, 0=No	2.5
Aspects of previous pregnancies		
Previous stillbirth(s)	1=Requested, 0=No	1
Infant(s) who died during the first week of life	1=Requested, 0=No	1
Heavy bleeding during or after childbirth	1=Requested, 0=No	1
Previous assisted delivery (eg, cesarean, vacuum, or forceps)	1=Requested, 0=No	1
Previous spontaneous abortions	1=Requested, 0=No	1
Previous multiple pregnancies	1=Requested, 0=No	1
Previous prolonged work	1=Requested, 0=No	1
Hypertension induced by previous pregnancy	1=Requested, 0=No	1
Seizures related to a previous pregnancy	1=Requested, 0=No	1
High fever or infection in previous pregnancies	1=Requested, 0=No	1
Danger signs of ongoing pregnancy		
Vaginal bleeding	1=Requested, 0=No	1.43
Fever	1=Requested, 0=No	1.43
Headache or blurred vision	1=Requested, 0=No	1.43
Swollen face, hands, or extremities	1=Requested, 0=No	1.43
Fatigue or shortness of breath	1=Requested, 0=No	1.43
Cough or difficulty breathing for 3 weeks or more	1=Requested, 0=No	1.43
Any other symptoms or problems related to this pregnancy	1=Requested, 0=No	1.43
Physical examination		
Taking the pregnant woman's blood pressure	1=Executed, 0=No	1.25
Weighing the pregnant woman	1=Executed, 0=No	1.25
Examine the conjunctiva or palms for anemia	1=Executed, 0=No	1.25
Examine legs, feet, and hands for edema	1=Executed, 0=No	1.25
Examine any swollen lymph nodes or glands	1=Executed, 0=No	1.25
Palpate or measure the pregnant woman's abdomen for fundal height	1=Executed, 0=No	1.25
Examine the pregnant woman's breasts	1=Executed, 0=No	1.25
Perform a vaginal examination or perineal examination	1=Executed, 0=No	1.25
Routine examinations		
Hemoglobin test	1=Executed, 0=No	2.5
Blood typing	1=Executed, 0=No	2.5
Any urine test	1=Executed, 0=No	2.5
Syphilis test	1=Executed, 0=No	2.5
HIV testing and counseling		
Asked if the pregnant woman knew her HIV status	1=Requested, 0=No	2
Provide or refer for advice related to HIV testing	1=Executed, 0=No	2

XSL•FO
RenderX

Domains and their objects	Measure	Percentage rating per object
Perform or refer for an HIV test	1=Executed, 0=No	2
Providing posttest counseling	1=Executed, 0=No	2
Discussion on partner testing	1=Discussed, 0=No	2
Maintaining a healthy pregnancy		
Discussed nutrition (ie, food to eat) during pregnancy	1=Discussed, 0=No	3.33
Informing the pregnant woman about the progress of the pregnancy	1=Executed, 0=No	3.33
Discussed the importance of at least 4 prenatal visits	1=Executed, 0=No	3.33
Iron and folate supplementation		
Prescribed or given iron or folic acid tablets or both	1=Executed, 0=No	2.5
Explained the purpose of iron or folic acid	1=Executed, 0=No	2.5
Explained how to take iron or folic acid tablets	1=Executed, 0=No	2.5
Explanation of the side effects of iron or folic acid tablets	1=Executed, 0=No	2.5
Tetanus toxoid injection		
Prescribed or administered a TAT[a] injection	1=Executed, 0=No	3.33
Explained the purpose of TAT injection	1=Executed, 0=No	3.33
TAT card verified or ANC[b] card	1=Executed, 0=No	3.33
Preparation for childbirth		
Asked the pregnant woman where she will deliver	1=Requested, 0=No	2
Advised the pregnant woman to prepare for delivery	1=Recommended, 0=No	2
Advised the pregnant woman to seek the assistance of a qualified health worker for delivery	1=Recommended, 0=No	2
Indicate what items to have on hand in case of emergency	1=Recommended, 0=No	2
Advised the pregnant woman to give birth in a health facility	1=Recommended, 0=No	2

[a]TAT: tetanus toxoid.

[b]ANC: antenatal care.

Variables

Independent variables included the following: (1) type of health facility (health center or general hospital), (2) provider profile (level of qualification and professional experience), (3) patient characteristics (age, education level, parity, and trimester of pregnancy at the time of ANC1), (4) availability of resources (medical equipment and access to laboratory tests), and (5) accessibility of care (distance from home to facility and consultation cost).

Dependent variables included the following: (1) overall conformity of the consultation (compliant or noncompliant), (2) completion of clinical and laboratory examinations, (3) quality of information provided to the patient (nutrition, danger signs, and birth planning), (4) preventive and curative interventions (prescription of iron or folic acid, tetanus vaccination, and malaria treatment), and (5) patient satisfaction (reception, waiting time, cost, and quality of counseling received).

Handling of Missing Data

Missing data were identified through systematic review of observation grids and medical records. Completely missing data were excluded from the analysis, and partially missing data were imputed using weighted averages and predictive modeling. Sensitivity analyses were conducted to assess the impact of missing data on key indicators.

Data Analysis

Data were entered and analyzed using SPSS version 25.0 (IBM Corporation). Descriptive statistics were used to calculate frequencies, proportions, means, and SDs. The results were stratified by facility type and provider qualification, and 95% CIs were calculated for key indicators. *P* values were reported where applicable, with statistical significance set at $P<.05$.

Ethical Considerations

This study was conducted in full compliance with the ethical principles outlined in the Declaration of Helsinki and the guidelines of the National Ethics Committee of the Democratic Republic of Congo. Ethical approval was obtained from the Ethics Committee of the School of Public Health at the University of Kinshasa, under reference number ESP/CE/099/2023, in accordance with institutional procedures.

Before any data collection, written informed consent was obtained from each pregnant woman included in the study,

XSL•FO
RenderX

following a clear explanation of the study's objectives and participation procedures. Participation was entirely voluntary, with no form of pressure or financial or material incentive.

Data confidentiality was ensured through anonymized records and the use of secure identification codes. All data were stored in protected files, accessible only to authorized members of the research team.

The authors declare no conflicts of interest related to this research. The study is part of a broader effort to strengthen local maternal public health capacities and to promote medical practices in rural settings.

Results

The distribution of pregnant women by the quality of the ANC1, according to the criteria defined by national and international standards, is shown in Table 2. It shows the percentage of consultations that meet quality standards and highlights gaps in care.

Table 2. Distribution of pregnant women according to the quality of the first prenatal consultation (ANC1) received (N=248).

Quality of ANC1	Pregnant women, n (%)	95% CI
Good quality	5 (2)	1.86-2.16
Poor quality	243 (98)	3.51-5.36

The study found that 61% (151/248) of health facilities lacked the necessary equipment to perform a comprehensive prenatal checkup. Essential laboratory tests such as syphilis screening and anemia assessment were systematically absent in 45% (112/248) of cases. Table 3 illustrates the availability and performance of essential laboratory tests at the first antenatal visit. It highlights gaps in screening, including the absence of hemoglobin tests, blood typing, and syphilis screening.

A significant proportion of consultations did not include all of the recommended examinations or adequate advice on pregnancy management.

Our analysis highlighted several constraints affecting the quality of ANC1. Among the limiting factors, 43% (107/248) of consultations were conducted by midwives without advanced medical training. Furthermore, 52% (129/248) of women had their first ANC in the third trimester, which significantly reduces the impact of preventive measures.

Table 4 describes the characteristics of the prenatal care providers who performed the consultations. It highlights their education level, average age, and sex distribution. Notably, a majority of providers did not have advanced medical training.

Table 3. Assessment of the quality of prenatal consultations according to laboratory tests.

Laboratory tests received	Pregnant women (N=248), n (%)
Hemoglobin test	
No	215 (86.7)
Yes	33 (13.3)
Blood typing	
No	240 (96.8)
Yes	7 (2.8)
Urine test	
No	218 (87.9)
Yes	30 (12.1)
Syphilis test	
No	243 (98)
Yes	5 (2)

XSL•FO
RenderX

Table 4. Distribution of prenatal care providers according to their sociodemographic characteristics.

Features	Providers (N=14)
Age (years), mean (SD)	49.3 (6)
Educational level, n (%)	
Nurse A2	8 (57.1)
None	6 (42.9)
Sex, n (%)	
Female	14 (100)
Male	0 (0)

Analysis of interactions between providers and pregnant women showed that only 37% (149/248) of consultations included in-depth education on nutrition, danger signs, and childbirth preparation. The average consultation duration was less than 15 (SD 3) minutes in 68% (169/248) of cases, limiting the quality of support.

Table 5 summarizes pregnant women's opinions on various aspects of their first prenatal visit, including cost, distance, reception by health workers, and waiting time. It provides insight into pregnant women's perceptions of the quality of care received.

Table 5. Assessment of the quality of prenatal consultation on the judgment of pregnant women.

Judgement	Pregnant women (N=248), n (%)
Cost	
Affordable	100 (40.3)
Pupil	114 (46)
Lower	22 (8.9)
Higher	12 (4.8)
Distance	
Short	59 (23.8)
Long	66 (26.6)
Normal	88 (35.5)
Too short	24 (9.7)
Too long	11 (4.4)
Welcoming health workers during ANC1 [a]	
Not satisfactory	40 (16.1)
Satisfying	158 (63.7)
Very satisfactory	50 (20.2)
Waiting times for prenatal consultations	
Long	138 (55.6)
Not long	97 (39.1)
Too long	13 (5.2)

[a]ANC1: first antenatal consultation.

Less than 50% (124/248) of women received necessary nutritional supplements, such as iron and folic acid. Vaccination coverage and the administration of antimalarial drugs were also limited, compromising the prevention of maternal and neonatal complications.

Table 6 details the elements covered during the prenatal consultation related to maternal and newborn health. It analyzes nutrition awareness, the importance of prenatal monitoring, the prescription of nutritional supplements and vaccines, as well as information on pregnancy management.

XSL•FO
RenderX

Table 6. Assessment of the quality of prenatal consultation on maintaining a healthy pregnancy.

Aspects discussed for maintaining a healthy pregnancy	Pregnant women (N=248), n (%)
Nutrition discussion	
No	93 (37.5)
Yes	155 (62.5)
Information on the progress of the pregnancy	
No	95 (38.3)
Yes	152 (61.3)
Discussion of the importance of at least 4 prenatal visits	
No	93 (37.5)
Yes	155 (62.5)
Prescription of iron tablets	
No	36 (14.5)
Yes	212 (85.5)
Explanation of the purpose of iron	
No	217 (87.5)
Yes	31 (12.5)
Explanation of how to take iron	
No	40 (16.1)
Yes	208 (83.9)
Prescription or injection of tetanus vaccines	
No	34 (13.7)
Yes	214 (86.3)
Explanation of the purpose of the tetanus vaccine injection	
No	68 (27.4)
Yes	180 (72.6)

Discussion

Principal Findings

The findings of this study revealed that only 2% of ANC1s met minimum quality standards in the Malemba Nkulu health zone. This reflects broader systemic challenges in rural maternal health care, including limited provider training, lack of diagnostic tools, and delayed access to care.

Similar challenges have been documented in other Central and West African contexts. In Lubumbashi, DRC, a study found that only 0.2% of pregnant women initiated ANC in the first trimester, and most consultations were conducted by nurses with limited qualifications [9]. In Mali, research conducted in Sélingué highlighted gaps in counseling and continuity of care, despite satisfactory physical examinations and reception [10]. Another study in Bougouni emphasized the importance of integrating ANC into reproductive health programs and strengthening provider training [11].

These regional findings reinforce the relevance of our results and suggest that targeted interventions—such as community-based outreach, provider certification, and subsidized diagnostic services—could improve ANC quality across similar settings. They also support evidence from Rwanda and Ethiopia, where continuous training and integration of ANC into community health systems have led to measurable improvements in maternal outcomes [12,13].

The results obtained in this study are consistent with those reported in other research in sub-Saharan Africa. For example, a study conducted in Nigeria showed that more than 60% of antenatal consultations were carried out by unqualified personnel, leading to insufficient follow-up [14]. Research in Ghana has shown a direct link between the quality of antenatal consultations and obstetric complication rates [15]. Additionally, in Rwanda and Ethiopia, the quality of antenatal care has improved considerably thanks to policies targeting continuous training of providers and integration of antenatal services into community care [12,13]. These successes suggest that adapted strategies could be implemented in the DRC to improve the effectiveness of prenatal consultations and reduce maternal morbidity [16].

Factors Influencing the Quality of Care

Among the main causes of the insufficient quality of prenatal consultations in the health zone studied, the following elements stand out:

XSL•FO
RenderX

1. Training of providers: 43% (107/248) of consultations were carried out by midwives without advanced medical training, which limits the application of standardized protocols [17].
2. Late access to care: 52% (129/248) of women had their first prenatal consultation in the third trimester, thus reducing the impact of preventive interventions [18].
3. Lack of medical equipment: 61% (151/248) of health facilities did not have the necessary tools to carry out a complete prenatal assessment, compromising the quality of monitoring [19].
4. Cost of services: the high cost of consultations and additional examinations is a barrier to pregnant women's adherence to medical recommendations [16].

Implications for Health Policy

These results highlight the urgency of implementing strategies to strengthen the quality of prenatal care. Among the possible measures, several recommendations can be made, including:

1. Strengthening the training of providers, particularly through practical workshops and certifications in prenatal monitoring [12,13].
2. Subsidy of prenatal services to improve accessibility to care [14,15].
3. Community awareness to encourage pregnant women to consult from the first trimester [17].
4. Integration of prenatal care into maternal health programs to ensure comprehensive and effective monitoring [18,19].

Practical Implications of the Results

The study highlights several challenges related to the quality of antenatal consultations in the Malemba Nkulu health zone. These findings underscore the need for concrete interventions to improve the effectiveness of maternal care and reduce maternal and neonatal mortality. In particular, we highlight 4 measures that may contribute to a lasting improvement in the care of pregnant women and a significant reduction in maternal morbidity and mortality:

1. Capacity building for service providers: this involves organizing continuing education for prenatal care providers, with an emphasis on diagnostic examinations and management protocols, as well as establishing a skills assessment system, ensuring compliance with WHO recommendations.
2. Improving access to prenatal care: this involves developing community programs to raise awareness among pregnant women about the importance of early monitoring and reducing financial barriers by subsidizing essential medical consultations and examinations.
3. Strengthening medical infrastructure: this involves ensuring the availability of medical equipment in health facilities and implementing a policy for the distribution of essential medicines for the prevention and management of maternal complications.
4. Monitoring and evaluation of interventions: this involves integrating a monitoring system to measure the impact of improvements on prenatal consultations and encouraging further studies to refine strategies and adjust maternal health policies.

Limitations and Potential Sources of Bias

This study has several methodological limitations that must be taken into account.

Selection Bias

The sample studied is based on pregnant women who consulted in the 8 selected health structures, which may introduce a representativeness bias. In particular, this study could overestimate or underestimate the quality of prenatal care depending on the specific characteristics of the institutions selected. Notably, however, the magnitude of selection bias is low since there was no stratification that could have favored certain subgroups. This means that the results are generally representative of the study population, although random variations may remain.

Information Bias

Some variables, including the pregnant women's medical history and provider protocols, are based on medical records and self-reports from pregnant women; therefore, there is a risk of overestimating compliance with care, as some information may be incomplete or influenced by recall bias. We consider the magnitude of bias to be moderate because the data were collected by direct observation and validation of medical records, reducing potential errors.

Missing Data and Statistical Treatment

Although imputation methods were used, some missing data regarding laboratory tests and provider training could affect the accuracy of the results, leading to potential overestimation or underestimation of the quality of services based on missing data. We consider the magnitude of bias to be low to moderate as sensitivity analyses confirmed the robustness of the results.

Despite these limitations, this study provides a vital assessment of the quality of prenatal consultations and highlights priority areas for improvement. However, further research, particularly longitudinal, would be needed to refine the analysis and strengthen the generalizability of the results.

Generalizability of the Study Results

The study sample was selected by simple random sampling, ensuring an equal probability of inclusion for each patient. This methodological choice strengthens external validity, as it limits selection bias and improves the ability to generalize the results to all pregnant women attending health facilities in the Malemba Nkulu health zone. However, some constraints may affect generalizability. For example, the sample size, although statistically sufficient for analysis, might not capture all the nuances present in the entire target population. Additionally, women who did not attend the health facilities studied were excluded, which limits the applicability of the results to pregnant women who do not have access to prenatal care. The results obtained are consistent with similar studies conducted in sub-Saharan Africa, notably in Nigeria, Ghana, Rwanda, and Ethiopia, where comparable problems have been observed in terms of access to prenatal care and the training of providers.

Specific local factors may also limit the generalizability of the results, such as structural differences in the organization of care

XSL•FO
RenderX

(some countries have implemented targeted reforms, significantly improving access to prenatal care) and variability of prenatal monitoring protocols (national recommendations can influence the application of quality standards).

The issues identified in this study, notably, the limits of training providers in environments where traditional midwives play a dominant role and financial and geographical barriers that restrict access to early prenatal consultations, are broadly representative of the challenges encountered in several health zones in the DRC. However, local adaptations would be necessary to replicate these findings in urban contexts, where medical infrastructure is more developed and pregnant women have better access to specialized care.

The external validity of this study is moderately high, as simple random sampling enhances the representativeness of the results. However, certain contextual specificities must be taken into account before extrapolating these findings to other regions of the DRC or to other African countries.

Conclusions

This study reveals the poor quality of ANC1s in the Malemba Nkulu health zone, with only 2% meeting established standards. The findings underscore critical gaps in provider training, limited access to essential diagnostic tests, and insufficient awareness among pregnant women regarding the importance of early and comprehensive prenatal care. Addressing these deficiencies requires targeted interventions to strengthen health worker capacity, improve service availability, and enhance community engagement in maternal health.

Among the challenges identified, 43% of consultations were conducted by midwives without advanced medical qualifications, compromising the quality of follow-up. Furthermore, 52.4% of women had their ANC1 in the third trimester, limiting the impact of preventive measures.

To improve the quality of prenatal care, several recommendations can be made, including (1) strengthening the training of service providers through practical sessions and adapted certifications, (2) subsidy for prenatal services to ensure better access to care, (3) community awareness to encourage early consultations, and (4) integration of prenatal care into maternal health programs. These measures could contribute to a significant reduction in maternal morbidity and mortality. Further research is needed to evaluate the impact of the proposed interventions and ensure effective management.

Acknowledgments

All authors declared that they had insufficient funding to support open access publication of this manuscript, including from affiliated organizations or institutions, funding agencies, or other organizations. JMIR Publications provided article processing fee (APF) support for the publication of this article.

Authors' Contributions

FIM conceived the study, supervised data analysis, and drafted the manuscript. PGM contributed to data collection and supported the interpretation of results. PKwI participated in field data collection and contributed to contextual analysis. IBK reviewed the scientific content and validated the consistency of the findings. DNM provided methodological corrections and ensured the scientific rigor of the study protocol. All authors reviewed and approved the final version of the manuscript and agree to be accountable for the integrity of the work.

Conflicts of Interest

None declared.

References

1. Say L, Chou D, Gemmill A, Tunçalp Ö, Moller A, Daniels J, et al. Global causes of maternal death: a WHO systematic analysis. Lancet Glob Health 2014 Jun;2(6):e323-e333. [doi: 10.1016/s2214-109x(14)70227-x]
2. Ministry of Public Health, DRC |. Annual Report on Maternal and Child Health. Annual Report on Maternal and Child Health. Kinshasa: MSP; 2022. URL: https://www.sante.gouv.cd [accessed 2025-09-15]
3. WHO recommendations on antenatal care for a positive pregnancy experience. National Library of Medicine. 2016. URL: https://www.ncbi.nlm.nih.gov/books/NBK409110/ [accessed 2025-09-15]
4. Tunçalp , Pena-Rosas JP, Lawrie T, Bucagu M, Oladapo O, Portela A, et al. WHO recommendations on antenatal care for a positive pregnancy experience-going beyond survival. BJOG 2017 May;124(6):860-862 Reference used for the analysis of prenatal care practices in Malemba Nkulu | [FREE Full text] [doi: 10.1111/1471-0528.14599] [Medline: 28190290]
5. Gage A, Guirlène CM. Effects of the quality of prenatal care on neonatal mortality in Haiti. Population Health Metrics 2006;4(1):1-10 Reference used to support the link between ANC quality and neonatal outcomes in low-resource settings | [FREE Full text]
6. Cissé C, Faye P, Ba M, Diouf A, Sylla A. Quality of antenatal care in West Africa: challenges and perspectives. African Journal of Public Health 2018;12(2):135-142 Reference used for the analysis of prenatal care practices in Malemba Nkulu |.

XSL•FO
RenderX

7. Bhutta ZA, Das JK, Bahl R, Lawn JE, Salam RA, Paul VK, et al. Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost? Lancet 2014 Jul 26;384(9940):347-370 [FREE Full text] [doi: 10.1016/s0140-6736(14)60792-3]
8. McDonagh M. Is antenatal care effective in reducing maternal morbidity and mortality? Health Policy and Planning 1996 Mar 01;11(1):1-15 [FREE Full text] [doi: 10.1093/heapol/11.1.1] [Medline: 10155875]
9. Baleke B, Kabanza P. Quality of prenatal consultations in the DRC: challengesopportunities. Pan African Medical Journal 2021;38:213 Reference used for the analysis of prenatal care practices in Malemba Nkulu | [FREE Full text] [doi: 10.11604/pamj.2021.38.213.27890] [Medline: 34394235]
10. Traoré A. Évaluation de la qualité des soins prénatals au CSRéf de Sélingué. Thèse de médecine, Université de Bamako 2019:1 Reference consulted in print; used to support local analysis of prenatal care quality in Mali.
11. Coulibaly M. Analyse des pratiques de suivi prénatal à Bougouni. Santé Reprod Afrique. 2020;? 2020;14(2):94 Reference consulted in print; used to support regional analysis of prenatal follow-up practices in Mali.
12. Nsereko E, Tuyisenge G. Strengthening community-based antenatal care in Rwanda lessons from implementation research. Global Health Action. 167 2019;12(1):5938 Reference used to illustrate social protection mechanisms in adolescent reproductive health interventions [FREE Full text]
13. Tefera B, Alemayehu M. Impact of health system strengthening initiatives on antenatal care uptake in Ethiopia a population-based study. PLoS One. 2022;e026 2022;17(3):5281 Reference used to illustrate the impact of system-level interventions on ANC uptake in Ethiopia [FREE Full text]
14. Adepoju O, Oluwaseun A. Assessment of antenatal care services in Nigeria a cross-sectional study. BMC Pregnancy Childbirth. 2021 2021;21(1):442 Reference used to support national-level analysis of ANC service delivery in Nigeria [FREE Full text]
15. Nyarko S. Prevalence and correlates of inadequate antenatal care in Ghana. BMC Public Health. 2020 2020;20(1):446 Reference used to support analysis of ANC coverage and equity in Ghanaian health systems [FREE Full text]
16. Kayembe P, Mambu T. Accessibility to maternal health services in the Democratic Republic of Congo a policy review. Afr J Reprod Health 2019;23(4):45 Reference consulted in print; used to support policy analysis of maternal health access in the DRC.
17. Baleke B, Kabanza P. Quality of prenatal consultations in the DRC challengesopportunities. Pan Afr Med J. 2021 2021;38(1):213 Reference used to illustrate operational challenges and opportunities in ANC service delivery in the DRC [FREE Full text]
18. Mpunga D, Muwawa D. Barriers to early antenatal care visits in urban and rural settings of DR Congo findings from a mixed-method study. BMC Health Serv Res. 2020 2020;20(1):345 Reference used to highlight structural and behavioral barriers to ANC initiation in DR Congo [FREE Full text]
19. Lukanu M, Mubiala T. Maternal health system improvement in Sub-Saharan Africa a systematic review of interventions. Int J Health Policy Manag. 2021 2021;10(6):367 Reference consulted in print; used to support synthesis of maternal health system interventions in Sub-Saharan Africa.

Abbreviations

ANC: antenatal care
ANC1: first antenatal consultation
DRC: Democratic Republic of Congo
WHO: World Health Organization

Edited by S Badawy; submitted 03.06.25; peer-reviewed by MP Kasaro, N Mandona; comments to author 21.08.25; revised version received 22.08.25; accepted 10.09.25; published 01.10.25.

Please cite as:
Ilunga Mbayo F, Geri Madragule P, Kanku wa Ilunga P, Bwana Kangulu I, Nkamba Mukadi D
Quality of First Prenatal Consultations in Malemba Nkulu, Democratic Republic of Congo: Challenges and Opportunities in a Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e78511
URL: https://pediatrics.jmir.org/2025/1/e78511
doi:10.2196/78511
PMID:

©Fiston Ilunga Mbayo, Pascal Geri Madragule, Pacifique Kanku wa Ilunga, Ignace Bwana Kangulu, Dalau Nkamba Mukadi. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 01.10.2025. This is an open-access article

XSL•FO
RenderX

distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Augmented Reality Playgrounds to Promote Physical Activity in Young Children: Feasibility Study Using a Repeated Measures Laboratory Design

Sarah M Stearne[1,2], PhD; Amber Beynon[1,2], PhD; Charlotte Lund Rasmussen[1,2], PhD; Juliana Zabatiero[1,2], PhD; Louise Paatsch[2,3], PhD; Daniel Johnson[2,4], PhD; Leon Straker[1,2], PhD; Amity Campbell[1,2], PhD

[1]Curtin School of Allied Health, Curtin University, Building 401 Kent Street, Perth, Australia

[2]Australian Research Council Centre of Excellence for the Digital Child, Brisbane, Australia

[3]School of Education, Deakin University, Geelong, Australia

[4]School of Computer Science, Queensland University of Technology, Brisbane, Australia

Corresponding Author:
Sarah M Stearne, PhD
Curtin School of Allied Health, Curtin University, Building 401 Kent Street, Perth, Australia

Abstract

Background: Only 10% of Australian children meet the recommended daily physical activity guidelines. Augmented reality (AR) is increasingly being used in primary education and clinical rehabilitation, with high enjoyment and motivation to participate frequently reported. AR has increased physical activity participation in adult populations, but whether AR can increase physical activity in young children has yet to be investigated.

Objective: This study aimed to determine if an indoor AR-enhanced playground is enjoyed by young children and prompts physical activity in both low- and high-structured scavenger hunts.

Methods: Seventeen pairs of 5 - to 8-year-olds participated in 2 animal search tasks (ie, AR and non-AR) in 2 activity structure levels (ie, low-structured and high-structured) in a 2×2 repeated measures design in an indoor laboratory playground. Children searched for either AR animals (a custom AR app on a smartphone) or toy animals and followed a set obstacle course route (high-structured) or moved wherever they wished (low-structured). Questionnaires assessed child enjoyment, perceived physical activity, and caregiver perception of enjoyment. Thigh-worn accelerometers (SENS; SENS Innovation ApS) assessed postures and movements, and a video camera recorded engagement time.

Results: Children rated AR conditions (low-structured: mean 4.4, SD 1.0, and high-structured: mean 4.5, SD 0.9) as more enjoyable than high-structured non-AR (mean 4.1, SD 1.0; P=.03). When asked which condition was the most enjoyable, 15 chose the low-structured AR, followed by the high-structured AR (n=11) and low-structured non-AR (n=8). Caregiver perception of children's enjoyment ratings generally aligned. Ratings of perceived physical activity level were the same in all conditions (mean 4.3, SD 0.7; P>.05). Accelerometry showed that a greater percentage of time was spent in low-intensity postures and movements during AR conditions (AR: mean 50%, SD 13% vs non-AR: mean 35%, SD 14%; P<.001), namely in sitting and standing, and in high-intensity movements during non-AR (AR: mean 21%, SD 12% vs non-AR: mean 32%, SD 18%; P<.001). During low-structured conditions, engagement time was significantly longer with the AR animals compared to the toy animals (AR: mean 263.1, SD 65.7 seconds vs non-AR: mean 197.3, SD 76.5 seconds; P=.002).

Conclusions: While the intensity of physical activity was lower during AR, the greater enjoyment and longer engagement time may lead to greater overall accumulation of active play by motivating young children to go to and stay longer at playgrounds. The high-structured AR conditions resulted in higher-intensity physical activity compared to low-structured AR conditions; however, enjoyment ratings from children and caregivers were generally higher in the low-structured AR. Therefore, AR may be suitable to implement in both low- and high-structured play environments. Future research should investigate whether these findings hold true at outdoor playgrounds and examine the impact of novelty over time.

(JMIR Pediatr Parent 2025;8:e75302) doi:10.2196/75302

KEYWORDS

augmented reality; children; play; physical activity; enjoyment; digital technology; smartphone

XSL•FO
RenderX

Introduction

Augmented reality (AR) digital technology is becoming increasingly available and promoted to children in both home and educational settings [1,2]. AR refers to the use of a smart device with an incorporated camera to present the user with an integrated, real-time view of the real world with superimposed digital information. This is commonly a smartphone or tablet, but headset technology is rapidly advancing, making it more affordable and available [3]. AR applications vary enormously, from static overlaid images to animated 3D creatures to semi-immersive 3D worlds. Not only can the appearance and fidelity of AR vary enormously, but so too can the way it is "activated." AR can be activated using a physical marker (eg, a QR code or image) or be markerless (eg, using GPS location or world tracking, where the device camera scans the environment for a flat surface to place the AR object upon). Despite its growing popularity, the implications of AR use by young children remain relatively unstudied. While there is often inherent skepticism and concern about potential risks with children engaging with digital technology [4], the potential benefits of AR should also be investigated.

Primary school education, particularly in science, technology, engineering, and mathematics subject areas, can benefit from AR by allowing teachers to extend learning into a 3D space and for children to visualize concepts that would not normally be accessible in real life [5]. Compared with traditional learning resources, children aged 8 - 10 years have reported a preference for AR games when learning about multiculturalism, solidarity, tolerance, and the water cycle [6,7]. AR has also been shown to increase motivation to learn [5] and knowledge retention [8] in areas such as mathematics [9], literacy, geography, biology [5], and recycling behavior [10]. The increased appeal and motivation that AR provides for children in educational settings could translate into other aspects of their daily lives, for example, motivating children to be physically active in leisure time.

Children's participation in physical activity in many countries is generally low. For example, in Australia, parent-reported data show that in 2020, only 10% of children aged 5 - 18 years participated in the recommended 60 minutes of moderate-to-vigorous physical activity daily [11]. Sufficient physical activity and avoiding excessive sedentary behavior are vital for child health and well-being by reducing obesity risk [12], improving mental health [13], and supporting muscle and bone development [14]. Enjoyment has been identified as a key factor in children's participation in physical activity in theoretical models such as the self-determination theory [15]. Intrinsic motivation and higher enjoyment of physical activity are related to increased physical activity levels [16-18]. Further, a randomized controlled trial of 2087 adolescent girls demonstrated that increasing enjoyment of physical activity resulted in increased voluntary participation in physical activity [19].

AR is effective in increasing physical activity levels in adults and adolescents [20,21]. For example, adolescents in a study of Pokémon Go (2016; Niantic Inc), an AR smartphone game that encourages users to move to different geographical locations to "catch" Pokémon, increased their participation in low, moderate, and vigorous physical activity by ~41 minutes per week [22] over 7 weeks. AR has also been shown to increase the motivation of adolescents to participate in physical education classes [23]. AR applications that encourage children to be physically active are becoming more prevalent [24,25]; however, very little research has been undertaken regarding the feasibility and effectiveness of AR to promote physical activity, motivation, and enjoyment among primary school–aged children. However, evidence shows that AR apps can improve motor function and increase participation in physical rehabilitation among pediatric clinical populations [26]. For example, in children with cerebral palsy, AR has been shown to improve upper limb muscle strength and range of motion [27] and to be an effective tool in improving gait speed [28]. In a review [29], the most frequently reported advantage of AR use in a clinical population was increased motivation leading to increased participation. If AR can effectively increase participation in physical rehabilitation in a clinical pediatric population, it remains possible that it could be an effective way to encourage increased physical activity in typically developing primary school–aged children; however, this has not been investigated.

AR as a tool to encourage physical activity in children is attractive due to its easy access and portability, being predominantly used on a smart device (eg, smartphone or tablet) already owned by many families, and its ability for use in both indoor and outdoor environments. Outdoor play not only provides children with the opportunity to practice and refine gross motor skills [30] but also reduces the risk of myopia [31] and vitamin D deficiency, which has been linked to poor bone development, cardiovascular disease, and diabetes [32]. This flexibility of use across multiple environments contrasts with many other digital devices aimed at eliciting active play in children, such as console-based active video games [33]. The versatility of AR applications, particularly marker-based AR, also allows for easy adaptation to different situations, such as different play styles. Physically active play can be broadly grouped into 2 overarching categories: high-structured and low-structured. High-structured physical play requires children to follow a set of rules or activities (eg, an obstacle course or football drills), while low-structured play is child-led free play. While both play types have overall benefits, highly structured play can emphasize motor skill development, while low-structured or free play can enhance imagination, autonomy, confidence, and self-esteem [34]. Marker-based AR could be adapted to both play styles, as the physical markers can, for example, be placed around an obstacle course by a parent, educator, or coach (high-structure play) or around a playground (low-structure play), prompting children to engage with the AR in diverse ways. However, how AR may encourage physical activity in children engaging in different play types remains unknown. This study aimed to explore whether marker-based AR digital technology could be a useful tool for engaging young children in physical activity during both high-structured and low-structured play, compared to a non-AR task. We hypothesized that children would enjoy AR more than non-AR conditions, and that their physical activity level (perceived and

XSL•FO
RenderX

measured) would be higher in both high-structured and low-structured play.

Methods

Study Design

This was a 2×2 repeated measures study (Animal Format: smartphone AR vs non-AR plastic toys × Activity Structure: low-structure vs high-structure) where children participated in 4 animal scavenger hunts in a laboratory playground setting. Outcome measures included enjoyment, time spent engaging, and level of physical activity. Pilot testing of the study protocol and AR app was conducted with 4 children (2 pairs, aged 5 - 8 years, male and female), and the protocol and app were refined before the commencement of participant data collection.

Laboratory Setup

The indoor laboratory was set up to simulate a playground, with the following equipment: a soft balance beam, wobble cushions, a see-saw plank, a hula-hoop tunnel, wooden boxes to climb, soft cushions to jump on, a mini trampoline, a climbing frame, a soft tunnel to walk through, hanging pillars to navigate, half Bosu balls, and wobble boards (Figure 1). Equipment setup was standardized for all participants and conditions.

Figure 1. Laboratory play equipment setup (all conditions) showing 2 participants in the low-structure non–augmented reality (non-AR) condition.



Participants

Thirty-four children aged 5 - 8 years and their caregivers volunteered to participate in the study. They were recruited from the local community and workplace networks in an Australian city via word of mouth and social media advertisements. Eligible children took part in the study in pairs, either a known friend or sibling (both henceforth termed “peer”). Parents and caregivers (henceforth termed “caregiver”) completed a screening questionnaire to determine if they and their children were eligible before being enrolled in the study. Participants were excluded if they did not speak fluent English (child and caregiver), had a physical injury (eg, sprained ankle) that limited their ability to move normally, a history of seizures or epilepsy, binocular vision abnormalities (eg, strabismus or amblyopia), frequent headaches or earaches, experienced severe motion sickness, had a known skin response to medical tape, or had any known or suspected psychological or physical clinical diagnosis that may influence their ability to understand and follow instructions or perform requested activities. The sample size was deemed appropriate based on previous accelerometer studies with children [35].

Protocol

Children and their caregivers visited the university laboratory for a single data collection session, approximately 60 minutes in duration. A standardized warm-up was completed, which involved a familiarization period with the AR technology, playground equipment, and obstacle course route. Children completed 4 conditions concurrently with their peers. Condition order was randomized (refer to Multimedia Appendix 1). Children were told they could work together with their peers but did not have to; it was their choice.

Animal Format: AR Versus Non-AR

A custom marker-based AR application (Animal Adventures; Curtin University) was developed for this study using Unity Vuforia Engine (Unity Technologies). Ten custom VuMarks (similar to a QR code but colorful images of the animal habitats; Figure 2) were designed, each linked to a different AR animal. VuMarks were 12×7.5 cm each. AR animals were virtual 3D low-poly animated animals (Unity Asset Store, Polyperfect) that appeared to be 30-100 cm in height, including a shark, elephant, panda, penguin, cat, rabbit, wolf, crocodile, seagull, and deer (Figure 2). AR animal size was adjusted to ensure they were visually impressive but not too large to be difficult to view on the smartphone. The distance the AR animal appeared relative to the VuMark was adjusted to ensure the children knew the animal had appeared (ie, close enough to the VuMark) but also far enough away to ensure the entire animal was visible. Once VuMarks were activated by holding them in the phone’s camera view for one second, the AR animal remained visible in that location for the remainder of the condition. The decision to use this setting was to prevent the animal from disappearing while children were viewing and interacting with it, which otherwise resulted in frustration. It also created the illusion of being surrounded by animals at the playground. Children were provided with an Apple iPhone 12 (Apple Inc) each to use

XSL•FO
RenderX

during the AR conditions. Children were given a demonstration and the opportunity to try using the AR app before commencing the first AR condition. For the non-AR conditions, plastic toy animals (Schleich Inc), the same as the AR animals, which ranged in size from 3 - 20 cm, were used (Figure 2).

Figure 2. Top shows children playing with the panda, elephant, and crocodile augmented reality (AR) animals during the AR conditions. The bottom left shows the VuMarks (marker-based AR) used in the AR conditions, including the penguin, deer, and panda. The bottom right shows the plastic toy animals used in the non-AR conditions.



Scavenger Hunt Activity Structure: Low-Structure Versus High-Structure

Conditions involved searching for 6 animals around the indoor play equipment, either AR animals or toy animals (non-AR), depending on the condition. Children were instructed that they could move wherever they wanted to find the animals during the low-structure conditions, or follow a set obstacle course route during the high-structure conditions. During the high-structure obstacle course conditions, children completed 2 laps of the circuit at the same time as their peers but in the opposite direction. They were not given any specific instructions on time, only that they should try to find the 6 animals while completing the 2 laps. During low-structure conditions, children were told there were 6 animals to find, after which they could play until they were told time was up. The low-structure conditions ended after a maximum of 5 minutes or earlier if the children lost interest in playing (total time). The time children stopped engaging with the AR or the non-AR animals during the low-structure conditions was noted and referred to as "engagement time."

Data Collection Tools

Questionnaires

Children completed a series of questionnaires for the outcomes of enjoyment and perceived physical activity. Children and caregivers were blinded to the hypotheses of the research in an attempt to avoid biases such as social desirability bias. Caregivers completed questionnaires regarding the outcomes of perceived enjoyment and their child's previous digital technology experience.

Child enjoyment and caregiver perception of their child's enjoyment were recorded following each condition and after the conclusion of all conditions using items from the Fun Toolkit [36], which have been frequently used with young children [37]. Specifically, children and caregivers were invited to circle the best response on a 5-item Smileyometer [37], a pictorial scale with round yellow faces ranging from awful (=1) to brilliant (=5) (refer to Multimedia Appendix 1) at the end of each condition. In addition, children and caregivers were invited to complete 3 variations of the fun sorter [37] following all 4 conditions. First, they were asked to rank which animal search condition they enjoyed more by placing cut-out images

XSL•FO
RenderX

representing the conditions (eg, AR or non-AR animals) into the appropriate box. Second, they were invited to rate whether they found the low-structure or high-structure conditions more enjoyable. Finally, they were asked to rank all 4 conditions from most enjoyable to least enjoyable. Caregivers were also provided with the option to complete a written open-ended question after each fun sorter task to elaborate on the reason for their answers.

Following each condition, children completed a 5-item pictorial Perceived Physical Activity Rating Scale, selecting how physically active they felt they were during the condition, from completely stationary (=1) to fast running (=5). This scale was adapted from the Children's Physical Activity Rating Scale (CARS) [38], a validated measure of observer-rated physical activity levels in young children. The adapted scale used the same 5 levels as the CARS but included illustrations, and children completed the scale themselves (refer to Multimedia Appendix 1). Caregivers were asked to complete a short questionnaire about their child's previous experience with digital technology.

Video

Total time and engagement time were calculated from accelerometer data and video footage. Video footage was captured from 2 video cameras (model A2403; Apple Inc; 30 Hz super wide lens) affixed to 1-meter-tall tripods and placed at opposite edges of the play area. Low structure condition total time (AR and non-AR conditions) commenced when the children started the condition and ended when either they lost interest in playing or after 5 minutes, whichever was sooner. Low structure condition engagement time (AR and non-AR) commenced when the child started the condition and ended when they lost interest in playing with the AR app or toys. In high-structure conditions, total time and engagement time were the same, commencing when the children started the obstacle course and ending when they completed their 2 circuits.

Accelerometer

The time children spent in different postures and movements was estimated from a thigh-worn accelerometer (SENS Innovation ApS) previously used in research with children of the same age [35]. The SENS motion PLUS (model number A01.6) accelerometer weighs 7 g and is 47×22×4.5 mm in size and was placed on the midline of the child's anterior right thigh halfway between the hip and knee. It was affixed using hypoallergenic double-sided tape underneath the accelerometer and hypoallergenic Fixomull stretch over the top. It was worn for the entire data collection. The accelerometer operated at 12.5 Hz and recorded accelerations in the x, y, and z axes with a range of +4 to −4 G.

Analysis

Accelerometer Analysis

Accelerometer data were cropped using a customized LabVIEW program (National Instruments). The Motus software, based on the Acti4 algorithm as developed and described in Skotte et al [39] and validated for use in school-aged children in a laboratory [35,40], was used to classify postures and movements. The software resamples the accelerometer data to 30 Hz in 2-second windows with a 50% overlap and uses both the inclinations and SDs of the thigh accelerations to classify different postures and movements using a rule-based algorithm [39]. The classified postures and movements are lying, sitting, standing, moving (stationary but with fidgeting legs), walking, running, stair climbing, cycling, or rowing (high-intensity movement that is not classified as running, stairs, or cycling). A customized R program (R Development Core Team) summarized these data into total and percentage of time spent in each movement and posture per condition. Due to the minimal incidences of movement coded as cycling and rowing (average total across all 4 conditions was 4.9, SD 10.1 seconds, and mean 4.6, SD 15.4 seconds, respectively, of a total average of 1200.4, SD 130.2 seconds), they were combined with the stair-climbing time to create a single stairs+ variable. Postures and movements were grouped as low intensity (lying, sitting, standing, and moving), moderate intensity (walking), and high intensity (running and stairs+).

Statistical Analysis

Questionnaire data from children and caregivers, along with pictorial scale numerical values, were transcribed into Microsoft Excel (Microsoft Corporation), and descriptive statistics were calculated. All other statistical analyses were performed in Jamovi (version 2.3.28; Jamovi). A critical alpha probability level was set at $P<.05$ for all analyses. Two-by-two (2×2) repeated-measures ANOVAs with post hoc pairwise comparisons without Bonferroni correction were run for all measures, except binomial fun sorter data, where a chi-square analysis was used. A thematic analysis of caregiver open-ended questionnaire responses was conducted.

Ethical Considerations

The study was approved by the Curtin University Human Research Ethics Committee (HRE2023-0323) before its commencement. An information sheet was provided to caregivers, and time was allowed for questions before the caregiver provided written consent. A simplified version of the information sheet was shown to children with their caregiver present. The study procedures were explained to children using visual illustrations and demonstrations of the study equipment, and time was allowed for questions. Children were invited to provide their verbal and written assent to participate. Three researchers were present for data collection, and all had current Working with Children Clearances. All data were deidentified for analysis when possible.

Results

Participants

All 34 children completed the study. Their average age was 6.2 (SD 1.2) years (range 5 - 8 years), 41% (n=14) were female, and all were currently in primary school education. The majority (n=20, 59%) attended with a friend of the same age and gender, while 41% (n=14) attended with a sibling (4 male-female sibling pairs, 2 brother pairs, and 1 sister pair). Parents reported that 47% (n=16) of children had previous experience with AR, most notably Pokémon Go, 59% (n=20) had active video game experience, and 94% (n=32) had previously played sedentary

XSL•FO
RenderX

games on a computer, tablet, or smartphone. There was no correlation between age and AR experience (r_{32}=0.165; P=.35).

Enjoyment in AR Versus Non-AR

Results from the children's ratings on the 5-item Smileyometer showed that AR was generally rated as more enjoyable than non-AR, and low-structure was sometimes rated as more enjoyable than high-structure. For child ratings of enjoyment, there was no overall main effect of Animal Format (AR: mean 4.5, SD 0.9 vs non-AR: mean 4.3, SD 1.0; $F_{1,33}$=3.79; P=.06) or Activity Structure (low-structure: mean 4.4, SD 0.9 vs high-structure: mean 4.3, SD 0.9; $F_{1,33}$=0.90; P=.35). However, pairwise comparisons revealed children rated low-structure AR and high-structure AR as more enjoyable than high-structure non-AR (t_{33}=2.26; P=.03; d=0.03 and t_{33}=2.26; P=.03; d=0.32, respectively; Table 1 and Figure 3). Caregivers' perception of their child's enjoyment was similar, though with a significant main effect of Animal Format showing AR rated as more enjoyable (AR: mean 4.2, SD 0.7 vs non-AR: mean 3.9, SD 0.6; $F_{1,33}$=6.81; P=.01; d=0.46), but no main effect of Activity Structure (low-structure: mean 4.1, SD 0.7 vs high-structure: mean 4.0, SD 0.7; $F_{1,33}$=0.66; P=.42). Pairwise analysis showed that caregivers rated low-structure AR as more enjoyable than low-structure non-AR and high-structure non-AR (t_{33}=2.54; P=.02; d=0.50 and t_{33}=2.73; P=.01; d=0.54; respectively; Table 1 and Figure 3). Multimedia Appendix 1 displays results based on the number of responses.

XSL•FO
RenderX

Table . Enjoyment, time, and physical activity. Superscript letters indicate statistical groupings. Values within a row that share a letter are not statistically different from each other. Conversely, values with no letters in common are significantly different (P<.05)

	Augmented reality (AR), mean (SD)		Non-AR, mean (SD)	
Outcome	Low-structure	High-structure	Low-structure	High-structure
Child enjoyment (scale 1-5, higher number=greater enjoyment)	4.4 (1.0)[a]	4.5 (0.9)[a]	4.4 (1.0)[a,b]	4.1 (1.0)[b]
Caregiver perception of enjoyment (scale 1-5, higher number=greater enjoyment)	4.2 (0.6)[a]	4.1 (0.8)[a, b]	3.9 (0.6)[b]	3.9 (0.5)[b]
Child fun sorter (1-4 rank, higher number=greater enjoyment)	3.2 (0.9)[a]	2.8 (1.1)[a,b]	2.4 (1.1)[b]	1.6 (0.8)[c]
Caregiver fun sorter (1-4 rank, higher number=greater enjoyment)	3.4 (0.9)[a]	2.7 (0.8)[b]	2.2 (1.1)[b]	1.7 (0.9)[c]
Total time (seconds)	329.6 (22.0)[a]	225.7 (69.4)[b]	312.5 (61.1)[a]	158.1 (61.2)[c]
Engagement time (seconds)	263.1 (65.7)[a]	225.7 (69.4)[b]	197.3 (76.5)[b]	158.1 (61.2)[c]
Child physical activity perception (scale 1-5, higher number=greater percived activity)	4.3 (0.7)	4.3 (0.7)	4.3 (0.8)	4.4 (0.8)
Total percentage low-intensity exercise (combination of lie, sit, stand, and move)	54 (11)[a]	47 (13)[b]	37 (12)[c]	33 (15)[d]
Total percentage moderate-intensity exercise (walk)	28 (9)[a]	30 (11)[a]	34 (12)[b]	30 (13)[a,b]
Total percentage high-intensity exercise (run and stairs+)	18 (11)[a]	24 (12)[b]	29 (15)[c]	37 (20)[d]
Lie (%)	2 (5)[a]	1 (2)[b]	3 (5)[a]	1 (4)[a,b]
Sit (%)	11 (8)[a]	8 (9)[a]	4 (4)[b]	3 (4)[b]
Stand (%)	12 (8)[a]	7 (6)[b]	4 (4)[c]	3 (3)[c]
Move (%)	29 (6)[a,b]	31 (9)[b]	27 (9)[a]	26 (0.1)[a]
Walk (%)	28 (9)[a]	30 (11)[a]	34 (12)[b]	30 (13)[a,b]
Run (%)	12 (10)[a]	13 (12)[a]	23 (14)[b]	28 (19)[c]
Stairs+ (%)	7 (6)[a]	11 (7)[b]	6 (5)[a]	8 (7)[a,b]

[a]Groups with no statistical significance in pairwise comparison (P>.05).

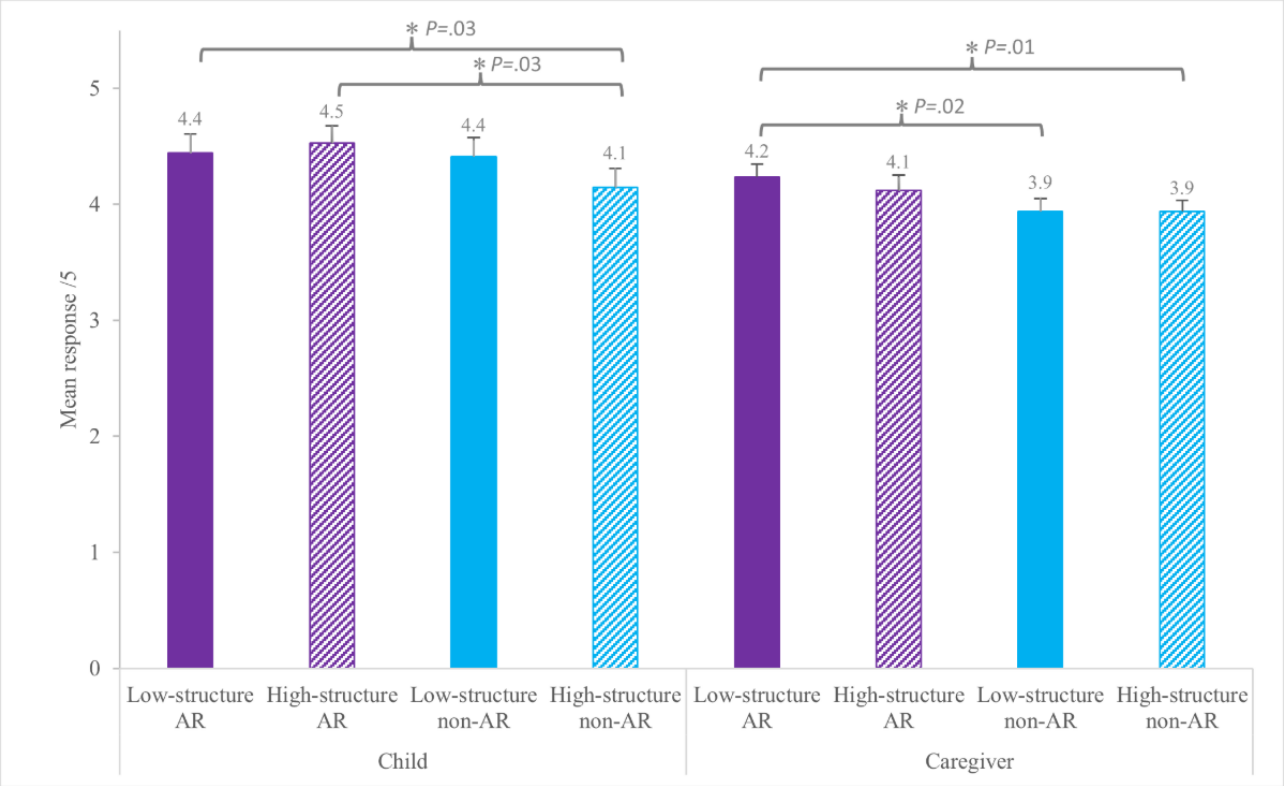
[b]Groups with no statistical significance in pairwise comparison (P>.05).

[c]Groups with no statistical significance in pairwise comparison (P>.05).

[d]Groups with no statistical significance in pairwise comparison (P>.05).

XSL•FO
RenderX

Figure 3. Group mean (SE) for child enjoyment and caregivers' perception of their child's enjoyment on the Smileyometer scale of 1 to 5, where 1 was "awful" and 5 was "brilliant." AR: augmented reality. *Indicates statistically significant differences in pairwise comparison (*P*<.05).

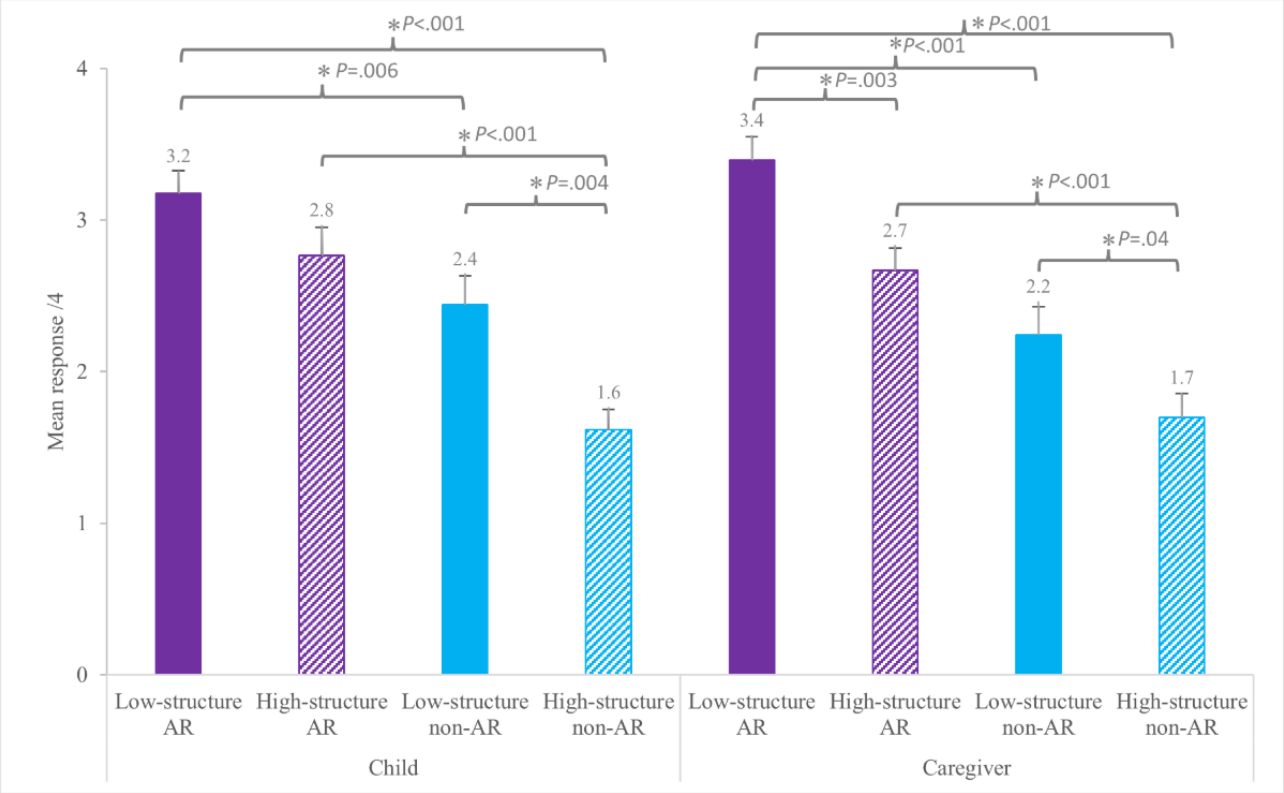


In the fun sorter questionnaire comparing enjoyment in AR and non-AR conditions (or caregivers' perception of their child's enjoyment), both children and caregivers ranked AR higher (children: 82%, n=28, $\chi^2_{1,34}$=15.1; *P*<.001 and caregivers: 91%, n=31, $\chi^2_{1,34}$=21.1; *P*<.001). When comparing enjoyment during low and high-structured conditions, both children and caregivers ranked low-structured conditions higher (children: 69%, $\chi^2_{1,34}$=4.5; *P*=.03 and caregivers: 69%, $\chi^2_{1,34}$=4.5; *P*=.03). There was a significant negative correlation between previous AR experience and AR enjoyment (r_{32}=−0.366; *P*=.03), with those who had not experienced AR previously more likely to rate it as the more enjoyable activity over the non-AR. Younger children (5 or 6 years old) were also more likely to rate the AR experience as more enjoyable (r_{32}=−0.366; *P*=.03) than older children (7 or 8 years old).

When children and caregivers were asked to rank the enjoyment of all 4 conditions individually, there were main effects of Animal Format and Activity Structure for both children ($F_{1,33}$=22.65; *P*<.001 and $F_{1,33}$=7.13; *P*=.01, respectively) and caregivers ($F_{1,33}$=33.21; *P*<.001 and $F_{1,33}$=7.61; *P*=.01, respectively). The majority of children and caregivers ranked low-structure AR as the most enjoyable condition (n=15 and n=21, respectively), followed by high-structure AR (n=11 and n=6, respectively; Table 1, Figure 4, and Multimedia Appendix 1).

XSL•FO
RenderX

Figure 4. Group mean (SE) for child enjoyment and caregivers' perception of their child's enjoyment on the fun sorter ranking scale of all 4 conditions, where 4 was the favorite condition and 1 was the least favorite. AR: augmented reality. *Indicates statistically significant differences in pairwise comparison (*P*<.05).



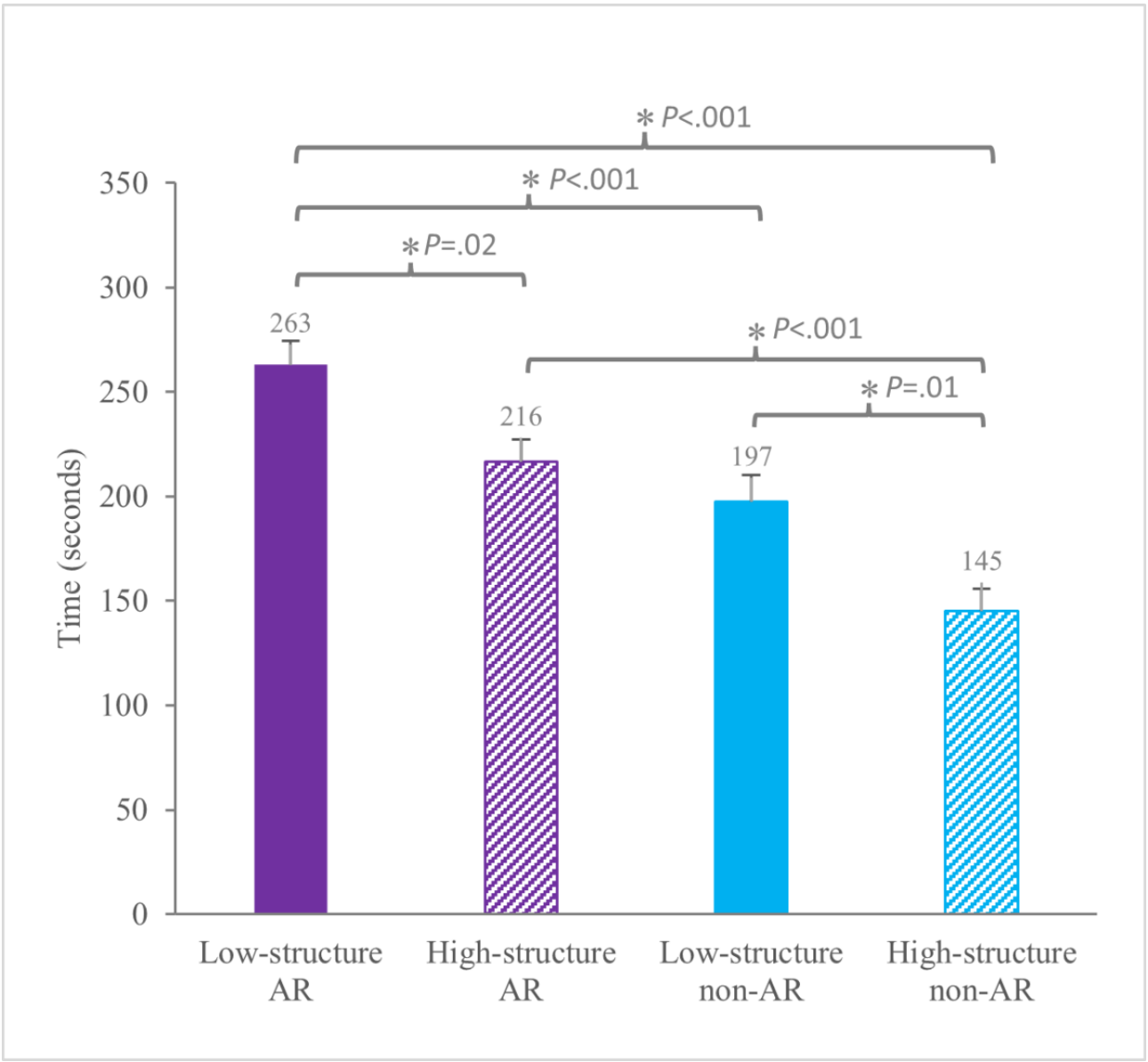
Of the 31 caregivers who rated AR as preferred, 25 chose to provide a written rationale for their rankings. Forty-eight percent (12/25) of caregivers wrote their child demonstrated more signs of excitement during the AR conditions, for example, stating, "More expressive, finding the AR animals 'argh, the shark is scary.'" Forty-eight percent (12/25) of caregivers who rated AR as preferred also referred to the novelty of the AR experience, making it more enjoyable, for example, stating, "[child] has never used AR, I think the novelty of it was a bit more enjoyable for him (new always better than old)." Caregivers also wrote that being able to use technology made the AR more appealing to their children (8/25, 32%), for example, "[child] hasn't used smartphone apps and it's extra exciting to have the technology and AR for the first time." Two caregivers mentioned that AR enhanced the social connection between their children, stating, "I think it added another dynamic to the play and added a social element." Of the 3 caregivers who felt their child preferred the non-AR conditions, all 3 believed this was because they were easier to find, stating, "quicker reward, easier to find." Regarding activity structure, 19 caregivers provided rationales for their responses. Of these, 42% (n=8) believed their child enjoyed the low-structure conditions more because they allowed more freedom and autonomy in play, for example, stating, "a bit more autonomy. They can create their own paths and adventures." Twenty-one percent (n=4) commented on the increased social aspects of low-structure, for example, stating, "We were able to concentrate on finding animals rather than completing the obstacle items and able to interact more with each other rather than being on their separate courses."

Time Spent in Each Condition (Engagement Time)

Time spent engaging with AR or non-AR animals differed significantly with main effects of both Animal Format (AR: mean 239.8, SD 68.3 seconds vs non-AR: mean 171.3, SD 73.9 seconds; $F_{1,33}$=39.17; *P*<.001) and Activity Structure (low-structure: mean 230.2, SD 78.2 seconds vs high-structure: mean 180.9, SD 71.8 seconds; $F_{1,33}$=14.14; *P*<.001). Low-structured AR engaged children for longer than all other conditions (mean 263.1, SD 65.7 seconds), followed by high-structured AR (mean 225.7, SD 69.4 seconds; Table 1 and Figure 5).

XSL•FO
RenderX

Figure 5. Group mean (SE) for engagement time in seconds. AR: augmented reality. *Indicates statistically significant differences in pairwise comparison (*P*<.05).



Physical Activity Intensity Across Conditions

Questionnaire: Perception

Child ratings of physical activity perception showed no main effect of Animal Format (AR: mean 4.3, SD 0.7 vs non-AR: mean 4.3, SD 0.8; $F_{1,33}$=0.03; *P*=.86) or Activity Structure (low-structure: mean 4.3, SD 0.7 vs high-structure: mean 4.3, SD 0.8; $F_{1,33}$=0.30; *P*=.59; Table 1) on perceived physical activity levels. Pairwise comparisons found no significant results. The majority of participants rated their perceived physical activity level as 5 out of 5 in all conditions, indicating they felt they spent the majority of their time running (refer to Multimedia Appendix 1 and Figure 3).

Accelerometer: Percentage of Time Spent in Postures and Movements

Low-Intensity Percentage

There were main effects of Animal Format (AR: mean 50%, SD 13% vs non-AR: mean 35%, SD 14%; $F_{1,33}$=68.13; *P*<.001) and Activity Structure (low-structure: mean 46%, SD 14% vs high-structure: mean 40%, SD 16%; $F_{1,33}$=13.15; *P*<.001) on the percentage of time spent in low-intensity postures and movements. During low-structure AR, the majority of time (54%) was spent in low-intensity postures and movements, a greater percentage than all other conditions (vs high-structure AR, *P*=.004; vs low-structure non-AR, *P*<.001; vs high-structure non-AR, *P*<.001). High-structure AR (47%) also differed from all other conditions (vs low-structure AR, *P*=.004; vs low-structure non-AR, *P*<.001; vs high-structure non-AR, *P*<.001; Figure 6). This was driven primarily by increased time spent standing (12% and 7%, respectively;) and sitting (11% and 8%, respectively; Table 1 and Figure 7). The lowest

XSL•FO
RenderX

percentage of time spent in low-intensity postures and movements was during high-structure non-AR (33%).

Figure 6. Group mean (SE) accelerometer results for the percentage of time spent in low-intensity postures and movements (lie, sit, stand, and move), moderate intensity (walking), and high intensity (run and stairs+) per condition. AR: augmented reality. *Indicates statistically significant differences in pairwise comparison (*P*<.05).

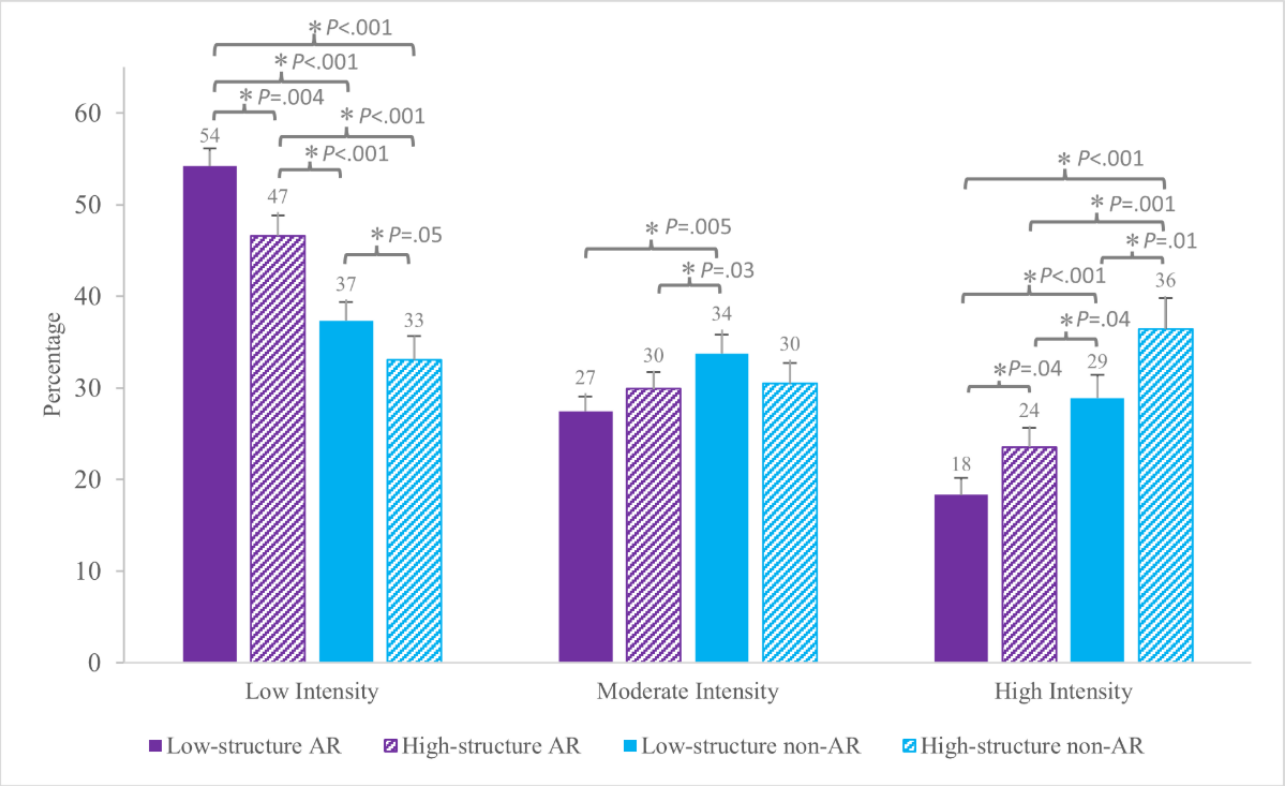
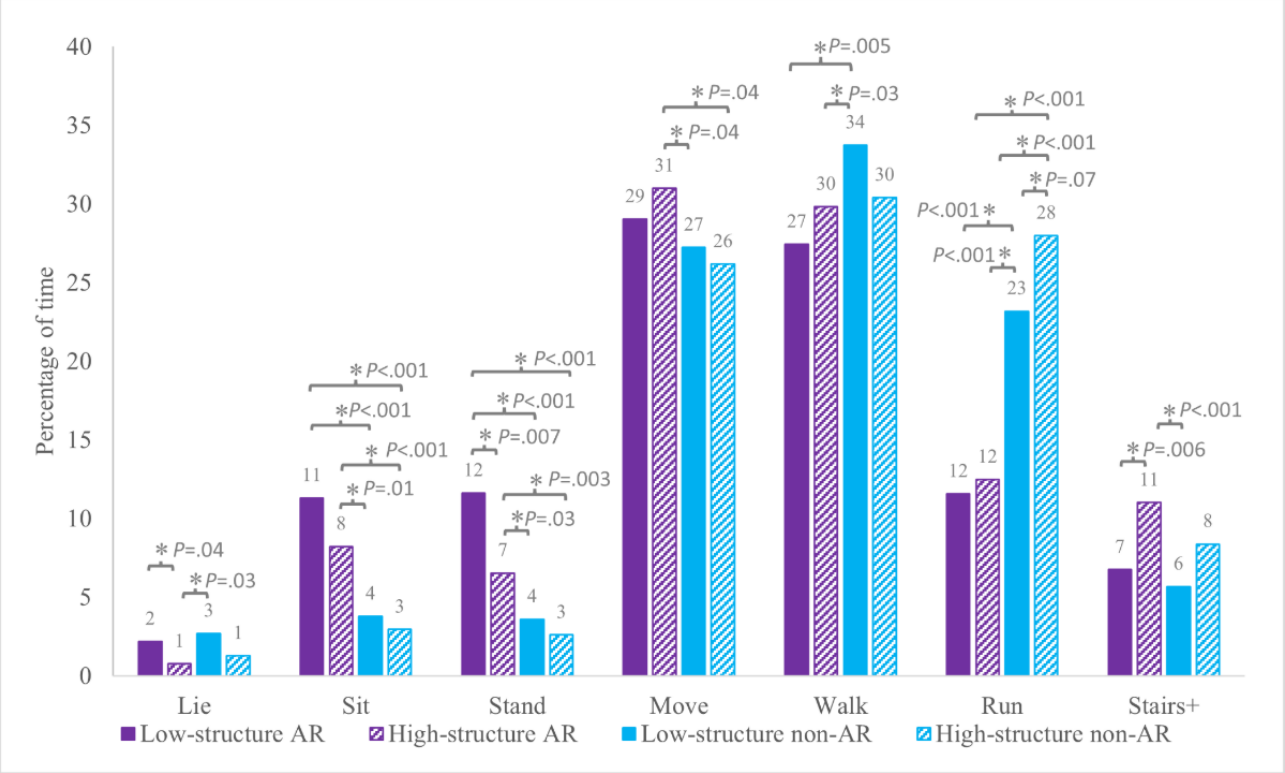


Figure 7. Group mean (SE) accelerometer results for the percentage of total time spent in each posture and movement per condition. AR: augmented reality. *Indicates statistically significant differences in pairwise comparison (*P*<.05).



XSL•FO
RenderX

Moderate-Intensity Percentage

There was a main effect of Animal Format (AR: mean 29%, SD 10% vs non-AR: mean 32%, SD 13%; $F_{1,33}$=6.61; P=.01) on the percentage of time spent in moderate-intensity movements, but no main effect of Activity Structure (low-structure: mean 31%, SD 11% vs high-structure: mean 30%, SD 12%; $F_{1,33}$=0.12; P=.73). A greater proportion of time (34%) was spent walking during low-structure non-AR compared to both AR conditions (low-structure AR: 27%; t_{33}=3.02; P=.005; d=0.60 and high-structure AR: 30%; t_{33}=2.32; P=.03; d=0.36) but did not differ from high-structure non-AR (30%; t_{33}=1.69; P=.10; Table 1; Figures 6 and 7).

High-Intensity Percentage

There were main effects of Animal Format (AR: mean 21%, SD 12% vs non-AR: mean 32%, SD 18%; $F_{1,33}$=37.87; P<.001) and Activity Structure (low-structure: mean 24%, SD 14% vs high-structure: mean 30%, SD 18%; $F_{1,33}$=9.84; P=.004) on the percentage of time spent in high-intensity movements. The greatest proportion of time in high-intensity movements was during non-AR conditions, with 36% of time during high-structure non-AR and 29% in low-structure non-AR (Figure 6). Both were due to an increased percentage of time spent in running (28% and 23%, respectively; Table 1 and Figure 7). The lowest proportion of time spent in high-intensity movements was during low-structure AR (18%; vs high-structure AR: 24%, P=.04; low-structure non-AR: 29%, P<.001; high-structure non-AR: 37%, P<.001). Accelerometer results in seconds are presented in Multimedia Appendix 1.

Discussion

Principal Findings

This study was the first to investigate the effect of a marker-based AR-enhanced versus traditional non-AR laboratory-based playground scavenger hunt on young children's enjoyment and physical activity during both low-structured and high-structured play. Our hypothesis that children would enjoy the AR was supported, with children rating AR in both low- and high-structured scavenger hunts as more enjoyable than non-AR, and they spent longer engaging with the AR. Caregivers' perceptions of their child's enjoyment showed a similar pattern. Physical activity was of a lower intensity during AR conditions; however, given the nature of AR interaction requiring children to be stationary to "activate" it, this is not surprising. Despite the lower intensity of activity, the longer engagement time during AR conditions may lead to greater accumulation of active play and, therefore, health and wellness benefits, although this warrants further investigation.

Enjoyment is reported to be a key factor in children's motivation to participate in physical activity from both theoretical models, such as self-determination theory [15], and research evidence [14,16,18,19,41,42]. In this study, children's enjoyment ratings across all tasks were high (range 4.1 - 4.5 out of 5), but when they were invited to rank conditions, there was a strong preference for AR, with 82% (n=28) of children and 91% (n=31) of caregivers ranking searching for AR animals as more enjoyable than searching for non-AR animals. Condition order was randomized, suggesting the preference for AR was unlikely to be a recency or order effect; however, it is possible there was a novelty effect. Children with no previous AR experience (59%, n=20) were more likely to rate the AR as more enjoyable. In addition, caregivers who ranked AR as more enjoyable commented on the novelty of the AR (48%, n=12) as a possible explanation. This is consistent with research in adults; for example, one study found that most adult participants increased physical activity for only the first 3 to 4 weeks of playing Pokémon Go [43]. How long the potential novelty effect of AR lasts in children is unknown, but could potentially be overcome by the design of the AR application (eg, changing challenges with increased play). Younger children in our study (aged 5-6 years) were more likely to rate the AR as more enjoyable than the non-AR condition in comparison to older children (aged 7-8 years). Given the lack of correlation between age and AR experience, this may be explained by the design of the AR—solo, low-fidelity, slightly animated animals—being too simple to hold the interest of some older children. The AR application used for this study was custom-built for this project by a single programmer and may not be as sophisticated as commercially available products. AR fidelity is an important consideration for future studies, particularly those aimed at an older age group. Caregivers (32%, n=8) also commented on the appeal of technology use as a possible explanation for their child's high enjoyment. The link between technology use, task enjoyment, and motivation to participate has been noted in children in clinical [29] and educational [5] settings and aligns with the self-determination theory and research by Sebire et al [18] that found young children's enjoyment was strongly linked with increased participation in physical activity.

While the enjoyment results suggest that AR may be a useful tool to motivate children to participate in physically active play, the physical activity intensity recorded in this study during AR was low. A greater percentage of time was spent in low-intensity postures and movements during AR, in particular low-structured AR, which saw 11% and 12% of time spent in sitting and standing, respectively, compared to 3% - 4% during non-AR conditions. In contrast, a greater percentage of time was spent in high-intensity movements during non-AR conditions, with 23% and 28% of time spent running in low- and high-structured non-AR conditions, respectively, compared to 12% - 13% during AR conditions. Despite the discrepancies in low- and high-intensity postures and movements, the greatest percentage of time in all conditions was spent moving (any instance when the child was stationary but not still, eg, fidgeting) or walking. Given the nature of the AR task, requiring children to stop and remain stationary to "activate" the AR and subsequently engage with it (eg, lying down to pretend the animal was standing on them), the accelerometer physical activity results are not surprising. It should also be noted that during AR conditions, children did participate in high-intensity movements, with a similar percentage of time spent running as they spent standing. While this particular AR experience may not have prompted as much high-intensity physical activity as non-AR play, it did engage children for 36% longer; if this were extrapolated out to a 1-hour playground visit, this could lead to an additional 22 minutes of play. However, future field-based studies with unrestricted time limits are needed to explore this further.

XSL•FO
RenderX

Interestingly, children perceived their physical activity level to be comparable across all conditions and felt they spent the majority of their time running. This discrepancy in reported versus recorded physical activity levels, possibly explained by social desirability bias, is common in research [44] and highlights the need for objective measures such as accelerometers to be used in children's physical activity research [35,40].

AR may be beneficial to implement in both low- and high-structured play environments. The level of activity structure affected physical activity levels, with a greater percentage of time spent in low-intensity postures and movements in low-structure AR conditions, and a greater percentage of time spent in high-intensity movements during the high-structure AR. This finding, however, may be offset by the generally greater enjoyment reported during the low-structured play, potentially leading to greater motivation to participate for longer. AR is versatile and can be adapted to different environments in comparison to many other digital technologies that encourage active play in children, such as game consoles. While these digital devices have been found to elicit low to moderate physical activity levels during gameplay [45], they are restricted to indoor use and require the purchase of expensive equipment. Marker-based AR, such as that used in this study (as opposed to markerless and GPS-based AR), may be particularly useful as it allows the greatest user control over AR location. For example, this study incorporated marker-based AR into laboratory play equipment, but this could easily be relocated to any other indoor or outdoor playground or obstacle course. AR applications may present a cost-effective way to enhance existing community playground infrastructure. Its simple and versatile application could be implemented by coaches and parents to encourage children to participate in certain movements; for example, AR markers could be placed along a beam to encourage balance, at the top of stairs to encourage climbing, or in a low-structured environment to encourage imagination. However, future research should investigate the potential risk to children colliding with objects and tripping over while moving around play equipment with a smartphone. Smartphone AR use by adults has been associated with poorer road-crossing behaviors [46], but whether the risk of miscoordination exists when children use a smartphone for AR remains unknown and warrants investigation before AR playgrounds can be considered in the community.

Limitations and Future Research

This study had several limitations. The use of subjective ratings in young children may be biased. For example, there were instances where the responses given by some of the children did not match what the researcher or caregiver perceived based on the child's behavior. These instances were not removed from the dataset and were instead considered a limitation of collecting subjective ratings in young children. Another potential limitation of subjective self-report measures completed in the presence of the researcher is the potential for social desirability bias. This may have impacted the perceived physical activity level and enjoyment outcomes; however, children were blinded to the hypotheses of the research in an attempt to reduce this. Future research should consider looking at evidence of children's enjoyment of AR playgrounds beyond self-rating scales and caregiver perspectives and using objective measures of physical activity such as accelerometers. This study was limited to a relatively small population in one geographical region and was conducted under controlled laboratory conditions. Whether these findings remain consistent in a community outdoor playground, where children may behave differently, and in different geographical regions, warrants investigation. It should also be acknowledged that the methods used to classify postures and movements from the accelerometer required the child to be performing the movement (ie, running) for at least one full second. Given the small indoor space and distances between play equipment, high-intensity movements may have been underestimated in all conditions. In an outdoor environment with more space to move, physical activity may be of higher intensity. AR experiences vary enormously, from a static generated image to completely immersive environments where the real-world visibility is minimal. Future research should investigate how children of different ages respond to different levels of AR immersion and whether there are added benefits to increased immersion, such as additional enjoyment or increased physical activity, or if it poses risks such as simulator sickness or falling. Simulator sickness is a common side effect in immersive virtual reality and headset AR [47], but little is known about whether handheld AR poses the same risk to children. An additional risk that should be investigated before smartphone AR games are used in community playgrounds is the distraction and social isolation that the presence of a smartphone may introduce. The potential effect that novelty may have on enjoyment, engagement time, and physical activity results should also be acknowledged. As this study was conducted in a single data collection session with a novel AR app, future longitudinal studies are needed to investigate how the novelty of AR-enhanced playgrounds changes over time. Future field-based studies are also needed to determine if unrestricted play time results in greater accumulated physical activity over time when using AR. Practical considerations for playground and AR designers that arose during this study include fidelity of the AR experience to appeal to a wide age range, the added flexibility and control of marker-based AR, and the potential need to maintain interest after initial novelty has worn off.

Conclusion

This study found that young children enjoyed participating in a search task for AR animals using a smartphone more than searching for traditional toy animals. Given that enjoyment is a key element in children's motivation to participate in tasks [5], including physical activity [41], AR may have the potential to encourage children to be physically active. While physical activity was of a lower intensity during the AR condition, which may be explained by the nature of the AR requiring children to stand to activate it, the engagement time was longer, potentially leading to an overall greater accumulation of active play if time was not restricted. This study cannot rule out the possibility that the novelty of AR may have produced the high enjoyment reported; therefore, future studies should explore the longer-term effects of AR on enjoyment and physical activity and whether these findings translate from the laboratory to a community

XSL•FO
RenderX

outdoor playground. However, these laboratory-based findings suggest that smartphone AR technology could be a novel method to encourage young children to participate in active play.

Acknowledgments

The authors would like to acknowledge Carley Tillett from the Curtin University Hub for Immersive Visualization and eResearch for her contribution to developing the augmented reality application used in this study. This work was supported by the Australian Research Council Centre of Excellence for the Digital Child (project number CE2001000022).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional material with reviewers' comments incorporated without track changes.
[DOCX File, 393 KB - pediatrics_v8i1e75302_app1.docx]

References

1. Das P, Zhu M, McLaughlin L, Bilgrami Z, Milanaik RL. Augmented reality video games: new possibilities and implications for children and adolescents. MTI 2017;1(2):8. [doi: 10.3390/mti1020008]
2. Akçayır M, Akçayır G. Advantages and challenges associated with augmented reality for education: a systematic review of the literature. Educ Res Rev 2017 Feb;20:1-11. [doi: 10.1016/j.edurev.2016.11.002]
3. Minkov R. Best AR glasses and headsets: augmented reality is here to stay!. Phone Arena. 2024. URL: https://www.phonearena.com/ar-vr/picks/best-ar-glasses-headsets_id146955 [accessed 2025-09-10]
4. Straker LM, Coleman J, Skoss R, Maslen BA, Burgess-Limerick R, Pollock CM. A comparison of posture and muscle activity during tablet computer, desktop computer and paper use by young children. Ergonomics 2008 Apr;51(4):540-555. [doi: 10.1080/00140130701711000] [Medline: 18357540]
5. Muhammad K, Khan N, Lee MY, Imran A, Sajjad M. School of the future: a comprehensive study on the effectiveness of augmented reality as a tool for primary school children's education. Appl Sci (Basel) 2021;11(11):5277. [doi: 10.3390/app11115277]
6. Furió D, Juan M‐, Seguí I, Vivó R. Mobile learning vs. traditional classroom lessons: a comparative study. J Comp Assist Learn 2015 Jun;31(3):189-201. [doi: 10.1111/jcal.12071]
7. Furió D, González-Gancedo S, Juan MC, Seguí I, Rando N. Evaluation of learning outcomes using an educational iPhone game vs. traditional game. Comput Educ 2013 May;64:1-23. [doi: 10.1016/j.compedu.2012.12.001]
8. Tekedere H, Göke H. Examining the effectiveness of augmented reality applications in education: a meta-analysis. Int J Envir Sci Educ 2016;11(16):9469-9481 [FREE Full text]
9. Demitriadou E, Stavroulia KE, Lanitis A. Comparative evaluation of virtual and augmented reality for teaching mathematics in primary education. Educ Inf Technol 2020 Jan;25(1):381-401. [doi: 10.1007/s10639-019-09973-5]
10. Juan MC, Furió D, Alem L, Ashworth P, Cano J. Argreenet and basicgreenet: two mobile games for learning how to recycle. Presented at: 19th International Conference in Central Europe on Computer Graphics, Visualization and Computer Vision; Jan 31 to Feb 3, 2011; Plzen, Czech Republic.
11. Reboot! Reimagining physically active lives: 2022 Australian report card on physical activity for children and young people. : Active Healthy Kids Australia; 2022 URL: https://www.activehealthykids.org/wp-content/uploads/2022/03/Australia-report-card-long-form-2022.pdf [accessed 2025-09-10]
12. Hills AP, Andersen LB, Byrne NM. Physical activity and obesity in children. Br J Sports Med 2011 Sep;45(11):866-870. [doi: 10.1136/bjsports-2011-090199] [Medline: 21836171]
13. Ahn S, Fedewa AL. A meta-analysis of the relationship between children's physical activity and mental health. J Pediatr Psychol 2011 May;36(4):385-397. [doi: 10.1093/jpepsy/jsq107] [Medline: 21227908]
14. Fritz J, Rosengren BE, Dencker M, Karlsson C, Karlsson MK. A seven-year physical activity intervention for children increased gains in bone mass and muscle strength. Acta Paediatr 2016 Oct;105(10):1216-1224. [doi: 10.1111/apa.13440] [Medline: 27096878]
15. Deci EL, Ryan RM. The "what" and "why" of goal pursuits: human needs and the self-determination of behavior. Psychol Inq 2000 Oct;11(4):227-268. [doi: 10.1207/S15327965PLI1104_01]
16. Carcamo-Oyarzun J, Herrmann C, Gerlach E, Salvo-Garrido S, Estevan I. Motor competence, motivation and enjoyment in physical education to profile children in relation to physical activity behaviors. Phys Educ Sport Pedagogy ;2023:1-16. [doi: 10.1080/17408989.2023.2265399]

XSL•FO
RenderX

17. Cairney J, Kwan MY, Velduizen S, Hay J, Bray SR, Faught BE. Gender, perceived competence and the enjoyment of physical education in children: a longitudinal examination. Int J Behav Nutr Phys Act 2012 Mar 6;9:1-8. [doi: 10.1186/1479-5868-9-26] [Medline: 22394618]
18. Sebire SJ, Jago R, Fox KR, Edwards MJ, Thompson JL. Testing a self-determination theory model of children's physical activity motivation: a cross-sectional study. Int J Behav Nutr Phys Act 2013 Sep 26;10(1):111. [doi: 10.1186/1479-5868-10-111] [Medline: 24067078]
19. Dishman RK, Motl RW, Saunders R, et al. Enjoyment mediates effects of a school-based physical-activity intervention. Med Sci Sports Exerc 2005 Mar;37(3):478-487. [doi: 10.1249/01.mss.0000155391.62733.a7] [Medline: 15741848]
20. Lee JE, Zeng N, Oh Y, Lee D, Gao Z. Effects of Pokémon GO on physical activity and psychological and social outcomes: a systematic review. J Clin Med 2021 Apr 25;10(9):1-22. [doi: 10.3390/jcm10091860] [Medline: 33922978]
21. Wong FY. Influence of Pokémon Go on physical activity levels of university players: a cross-sectional study. Int J Health Geogr 2017 Feb 22;16(1):8. [doi: 10.1186/s12942-017-0080-1] [Medline: 28228102]
22. Jumareng H, Setiawan E, Németh Z. Augmented Pokemon Go in times of Covid-19: does it have any effect on promoting teenagers' physical activity? Teor metod fiz vihov 2022;22(3):360-365. [doi: 10.17309/tmfv.2022.3.09]
23. Chang KE, Zhang J, Huang YS, Liu TC, Sung YT. Applying augmented reality in physical education on motor skills learning. ILE 2020 Aug 17;28(6):685-697. [doi: 10.1080/10494820.2019.1636073]
24. Daud N, Abdullah MHL. Stimulating children's physical play through augmented reality game. JACTA 2020;2(1):29-34 [FREE Full text]
25. Laine TH, Suk HJ. Designing mobile augmented reality exergames. Games and Culture 2016 Jul;11(5):548-580. [doi: 10.1177/1555412015572006]
26. Han S, Park C, You JSH. Effects of robotic interactive gait training combined with virtual reality and augmented reality on balance, gross motor function, gait kinetic, and kinematic characteristics in Angelman syndrome: a case report. Children (Basel) 2022 Apr 12;9(4):544. [doi: 10.3390/children9040544] [Medline: 35455588]
27. Malick WH, Butt R, Awan WA, Ashfaq M, Mahmood Q. Effects of augmented reality interventions on the function of upper extremity and balance in children with spastic hemiplegic cerebral palsy: a randomized clinical trial. Front Neurol 2022;13:895055. [doi: 10.3389/fneur.2022.895055] [Medline: 35800080]
28. Guinet AL, Bouyer G, Otmane S, Desailly E. Visual feedback in augmented reality to walk at predefined speed cross-sectional study including children with cerebral palsy. IEEE Trans Neural Syst Rehabil Eng 2022;30:2322-2331. [doi: 10.1109/TNSRE.2022.3198243] [Medline: 35951576]
29. Quintero J, Baldiris S, Rubira R, Cerón J, Velez G. Augmented reality in educational inclusion. A systematic review on the last decade. Front Psychol 2019;10:1835. [doi: 10.3389/fpsyg.2019.01835] [Medline: 31456716]
30. Dyment JE, Bell AC. Grounds for movement: green school grounds as sites for promoting physical activity. Health Educ Res 2008 Dec;23(6):952-962. [doi: 10.1093/her/cym059] [Medline: 17956885]
31. Rose KA, Morgan IG, Ip J, et al. Outdoor activity reduces the prevalence of myopia in children. Ophthalmology 2008 Aug;115(8):1279-1285. [doi: 10.1016/j.ophtha.2007.12.019] [Medline: 18294691]
32. Misra M, Pacaud D, Petryk A, Collett-Solberg PF, Kappy M, Drug and Therapeutics Committee of the Lawson Wilkins Pediatric Endocrine Society. Vitamin D deficiency in children and its management: review of current knowledge and recommendations. Pediatrics 2008 Aug;122(2):398-417. [doi: 10.1542/peds.2007-1894] [Medline: 18676559]
33. Straker LM, Abbott RA, Smith AJ. To remove or to replace traditional electronic games? A crossover randomised controlled trial on the impact of removing or replacing home access to electronic games on physical activity and sedentary behaviour in children aged 10-12 years. BMJ Open 2013 Jul 1;3(6):e002629. [doi: 10.1136/bmjopen-2013-002629] [Medline: 23818650]
34. Bento G, Dias G. The importance of outdoor play for young children's healthy development. Porto Biomed J 2017;2(5):157-160. [doi: 10.1016/j.pbj.2017.03.003] [Medline: 32258612]
35. Lund Rasmussen C, Hendry D, Thomas G, et al. Evaluation of the ActiMotus software to accurately classify postures and movements in children aged 3–14. Sensors 2024 Oct 18;24(20):6705. [doi: 10.3390/s24206705] [Medline: 39460185]
36. The third british HCI group one-day meeting "COMPUTERS AND FUN 3". Presented at: Computers and Fun 3 (Third British HCI Group one-day meeting); Dec 13, 2000; York, United Kingdom URL: https://www-users.york.ac.uk/~am1/candf3.html [accessed 2025-09-10]
37. Read JC. Validating the Fun Toolkit: an instrument for measuring children's opinions of technology. Cogn Tech Work 2008 Apr;10(2):119-128. [doi: 10.1007/s10111-007-0069-9]
38. Puhl J, Greaves K, Hoyt M, Baranowski T. Children's Activity Rating Scale (CARS): description and calibration. Res Q Exerc Sport 1990 Mar;61(1):26-36. [doi: 10.1080/02701367.1990.10607475] [Medline: 2091164]
39. Skotte J, Korshøj M, Kristiansen J, Hanisch C, Holtermann A. Detection of physical activity types using triaxial accelerometers. J Phys Act Health 2014 Jan;11(1):76-84. [doi: 10.1123/jpah.2011-0347] [Medline: 23249722]
40. Lendt C, Hettiarachchi P, Johansson PJ, et al. Assessing the accuracy of activity classification using thigh-worn accelerometry: a validation study of ActiPASS in school-aged children. J Phys Act Health 2024 Oct 1;21(10):1092-1099. [doi: 10.1123/jpah.2024-0259] [Medline: 39159934]

XSL•FO
RenderX

41. Brazendale K, Graves B, Penhollow T, Whitehurst M, Pittinger E, Randel A. Children's enjoyment and perceived competence in physical education and physical activity participation outside of school. Emotion Behav Dis Youth 2015:65-69 [FREE Full text]
42. Gao Z, Podlog L, Huang C. Associations among children's situational motivation, physical activity participation, and enjoyment in an active dance video game. J Sport Health Sci 2013 Jun;2(2):122-128. [doi: 10.1016/j.jshs.2012.07.001]
43. Howe KB, Suharlim C, Ueda P, Howe D, Kawachi I, Rimm EB. Gotta catch'em all! Pokémon GO and physical activity among young adults: difference in differences study. BMJ 2016 Dec 13;355:i6270. [doi: 10.1136/bmj.i6270] [Medline: 27965211]
44. Adamo KB, Prince SA, Tricco AC, Connor-Gorber S, Tremblay M. A comparison of indirect versus direct measures for assessing physical activity in the pediatric population: a systematic review. Comput Educ 2009;4(1):2-27. [doi: 10.1080/17477160802315010] [Medline: 18720173]
45. Moller AC, Sousa CV, Lee KJ, Alon D, Lu AS. Active video game interventions targeting physical activity behaviors: systematic review and meta-analysis. J Med Internet Res 2023 May 16;25:e45243. [doi: 10.2196/45243] [Medline: 37191992]
46. Chen PL, Pai CW. Smartphone gaming is associated with pedestrians' head-turning performances: an observational study of street-crossing behaviors at uncontrolled intersection in Taipei. Int J Sustain Transp 2018 Jan 2;12(1):12-18. [doi: 10.1080/15568318.2017.1321706]
47. Rebenitsch L, Owen C. Review on cybersickness in applications and visual displays. Virtual Real 2016 Jun;20(2):101-125. [doi: 10.1007/s10055-016-0285-9]

Abbreviations

AR: augmented reality
CARS: Children's Physical Activity Rating Scale

Edited by A Nguyen; submitted 01.04.25; peer-reviewed by C Aygün, S Wyver; revised version received 01.07.25; accepted 01.08.25; published 09.10.25.

Please cite as:
Stearne SM, Beynon A, Lund Rasmussen C, Zabatiero J, Paatsch L, Johnson D, Straker L, Campbell A
Augmented Reality Playgrounds to Promote Physical Activity in Young Children: Feasibility Study Using a Repeated Measures Laboratory Design
JMIR Pediatr Parent 2025;8:e75302
URL: https://pediatrics.jmir.org/2025/1/e75302
doi:10.2196/75302

© Sarah M Stearne, Amber Beynon, Charlotte Lund Rasmussen, Juliana Zabatiero, Louise Paatsch, Daniel Johnson, Leon Straker, Amity Campbell. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 9.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Development and Implementation of a Birth Forecasting Tool to Optimize Resources in Obstetrical Care During the COVID-19 Pandemic: Mixed-Methods Study

Huibert-Jan Joosse[1], MSc; Karin Jongsma[2], PhD; Marcel Moes[3], BASc; Kitty W Bloemenkamp[4,5], Prof Dr; Wouter M Tiel Groenestege[1], PhD; Wouter W van Solinge[1], Prof Dr; Saskia Haitjema[1], MD, PhD; Maarten B Kok[3,6], PhD

[1]Central Diagnostic Laboratory, University Medical Center Utrecht, University Utrecht, Heidelberglaan 100, Utrecht, The Netherlands

[2]Department of Bioethics & Health Humanities, University Medical Center Utrecht, Utrecht University, Utrecht, The Netherlands

[3]Saltro Diagnostic Center, Unilabs Netherlands, Utrecht, The Netherlands

[4]Department of Obstetrics, Division Woman and Baby, Wilhelmina Children's Hospital, University Medical Center Utrecht, Utrecht, The Netherlands

[5]Network Regional Acute Obstetric Care (Regionaal Acuut Zorg Overleg Midden Nederland), Utrecht, The Netherlands

[6]Digital Innovation Team, Unilabs Group, Geneva, The Netherlands

Corresponding Author:
Saskia Haitjema, MD, PhD
Central Diagnostic Laboratory, University Medical Center Utrecht, University Utrecht, Heidelberglaan 100, Utrecht, The Netherlands

Abstract

Background: Medical resource allocation is important to ensure availability of care, especially in challenging circumstances like a pandemic. In fields of unpredictable care demand such as obstetrics, forecasting may help manage scarce resources.

Objective: The development, validation, and implementation of a regional birth forecasting tool to support obstetrical staff planning in the Utrecht region during the COVID-19 pandemic.

Methods: We combined predicted birth dates retrieved from Saltro, a large regional primary care laboratory, with data from the Dutch national perinatal registry (Perined) and Statistics Netherlands for model development. We created and implemented an HTML tool visualizing these forecasts, which were discussed during the regional acute obstetric health care network meetings. Six months after implementation, we assessed the impact of the tool using an evaluative stakeholder meeting.

Results: We achieved a performance accuracy (*R*) of 0.45, 0.61, and 0.67 (all actual number of births within 95% CI) forecasting the number of births in the region, pooled in 1-, 2-, and 3-weekly bins, respectively. After presenting these findings to stakeholders, we implemented a forecasting tool using the 2-week bin model. The evaluative stakeholder meeting proved that the tool improved communication, awareness of health care need, and collaborations among health care providers in the Utrecht region. Additionally, stakeholders identified additional applications, such as communication with patients and training of obstetric health care providers.

Conclusions: Implementation of a forecasting tool for the number of births based on available data across the health care system added value to obstetrical care by providing insight into care demand, and increasing communication, awareness, and collaboration between health care providers. Further research should aim at improving regional obstetric acute care by fostering data sharing in order to improve health care demand forecasts.

(JMIR Pediatr Parent 2025;8:e68284) doi:10.2196/68284

KEYWORDS

resource allocation; regional health planning; quality of care; routinely collected data; stakeholder participation

Introduction

Clinical care for patients in hospitals, and especially in the acute care chain, depends on the infrastructure and on careful planning of resources such as staff, equipment, and beds. The COVID-19 pandemic magnified this complexity as the combination of patients who were hospitalized with COVID-19 and frequent sick leave of already scarce medical personnel for clinical care posed a burden on hospital capacity. Even more complex is planning in acute care departments, including the emergency departments, the obstetrics ward, and the intensive care where medical personnel are not only scarce, but patients' needs are unpredictable [1,2]. The efficient allocation of resources is an important performance indicator of quality of care (QoC) according to the US Institute of Medicine [3]. The World Health Organization (WHO) identified the impairment of QoC in obstetrics as a major roadblock for ending preventable maternal and neonatal mortality and morbidity and called for skilled care

XSL•FO
RenderX

and evidence-based practices [4]. Managing resources such that high-quality obstetrical care delivery can be maintained is thus essential when hospital capacity is under pressure.

Contrary to acute care needs for emergency departments, the expected date of birth provides an opportunity to predict future average demand in obstetrics. Date of birth itself can be understood as a result of a prediction model, using first day of last menstruation date, and is in the Netherlands confirmed by the crown-rump length (CRL) at ultrasound around 11 weeks of pregnancy [5,6]. In addition, the Dutch health care system offers routine first-line obstetrical care around the eighth week of pregnancy. Around 11 weeks, women are invited to participate in a screening (booking blood) for infectious diseases (HIV, Hepatitis B, and Lues), anemia, and irregular erythrocyte antibodies (eg, Rhesus disease). A total of 99% of women take part in this screening program [7]. On the lab test order form, the calculated date of birth is listed. As such, these laboratories have access to data of expected birth dates. In the midst of regional (larger Utrecht area) capacity problems in acute obstetric care, there was a need within the network regional consultation acute care (ROAZ midden Nederland) to forecast the number of births in the region. Since we were not able to extract the estimated date of delivery from the existing perinatal health care systems, the idea came up to use the data registered during the booking bloods.

The goal of this study was to support obstetrical staff planning during the COVID-19 pandemic by using data from Saltro, a large primary care laboratory in the Utrecht region of the Netherlands and regional obstetrics outcomes to develop, validate, and implement a forecasting tool for the trend in number of births. Additionally, a qualitative stakeholder meeting was held 6 months after implementation in order to discuss the impact of the tool.

Methods

Data Sources

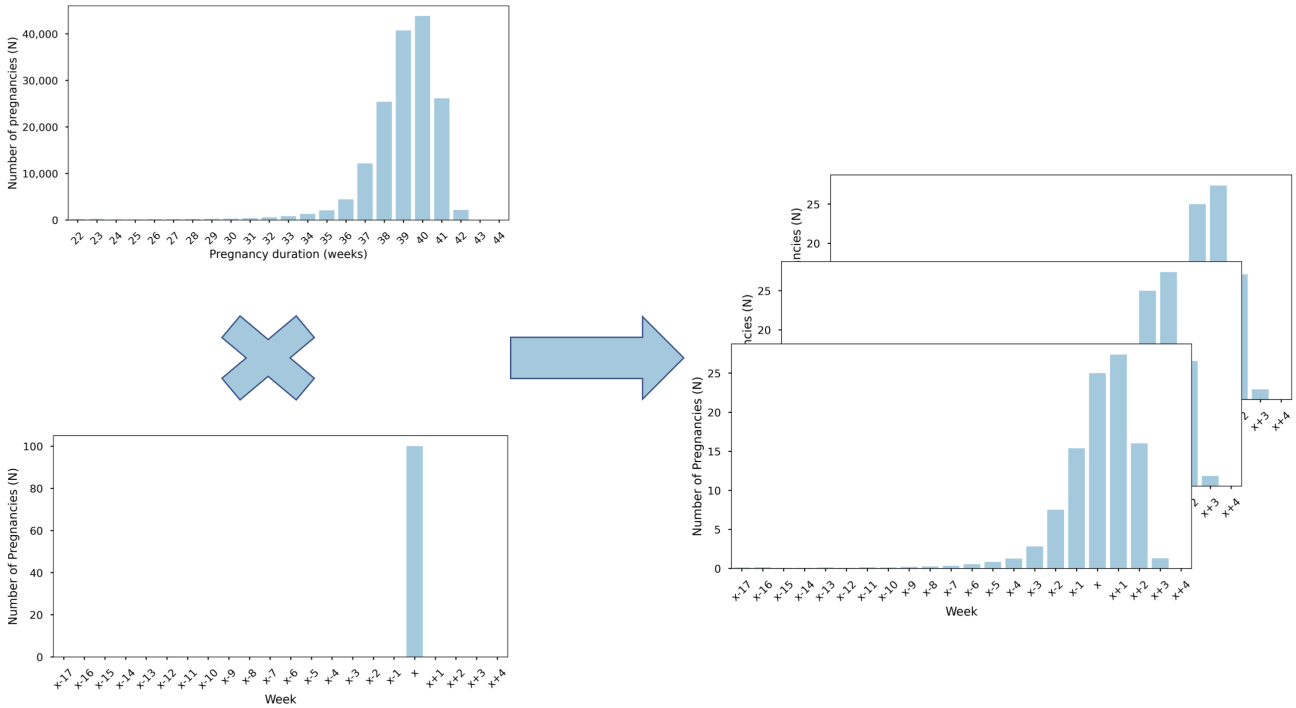
In order to model (trends in) the number of births in the population, we retrieved all historical data of expected birth dates from 2014 to 2019 of Saltro, as registered during the screening around 11th week of pregnancy, and linked them to a dataset of Statistics Netherlands with live births from 2015 - to 2017 as outcomes. To ensure a representative dataset, while also ensuring that data loss was minimized, we included only data from municipalities where Saltro had data on at least 55% of pregnancies. We aggregated the data to the number of births per week. We accounted for the uncertainty of the expected date of birth by using the national pregnancy length distribution (in weeks) of the Dutch national perinatal registry, Perined [8]. According to the Dutch legislation, this research did not fall under the Medical Research Involving Human Subjects Act (WMO). Only anonymized aggregated data were used for analysis. The research was conducted according to the declaration of Helsinki. Health care professionals provided verbal informed consent prior to the interviews.

Forecasting Tool and Model Development

To correctly forecast the number of births per week, we used the expected birth date as the base model. Consequently, we distributed the number of births for each week over the surrounding weeks according to the Perined distribution (Figure 1) and repeated this process 1000 times per week. This resulted in a calculated mean and SD per week. For a certain week, the number of expected date of births would actually be forecasted in the period between 17 weeks before and 5 weeks after the denoted week. When repeating this process for all weeks, the number in every week would become a sum of all these calculations.

XSL•FO
RenderX

Figure 1. Modeling approach. For a specific week (**X**), each expected birth date (left-bottom) was assigned to a specific week using the Perined distribution of pregnancy durations (left-top). By repeating this simulation 1000 times, we were able to calculate a mean estimate and SD assigned to each surrounding week (x-17 to x+4) (right). By repeating this for all weeks in our data, we were able to estimate a cumulative estimate per week.



To validate the modeling output on actual outcome data, we correlated the mean forecasted number of births for each week with the amount as reported by Statistics Netherlands. We combined the number per week to 2- and 3-weekly bins (ie, summing up the numbers for week 1 and 2, week 3 and 4, etc), and assessed whether this improved the correlation and thus predictive accuracy. Considering the potentially high variance of calculated number of births, binning the project number of births to 2- or 3-weekly bins may help smooth out large weekly differences. To compare the mean estimate and a 95% CI of our model to the actual number of births, we normalized the visualization of these two types of data, so that these two were comparable.

This work, and the development of the resulting tool, was performed using the Python programming language (version 3.8, Python Software Foundation) and the *pandas* (Version 1.1), *numpy* (version 1.19), and *scipy* (version 1.5) packages. We used the *plotly* package (version 4.14) for interactive visualization purposes.

Implementation Research Using Stakeholder Meetings

After the model for the tool was validated, we presented our findings to stakeholders in the obstetrics field, including future end-users of the tool, such as managers and obstetric care providers (n=13) during the weekly consultation of the regional obstetric acute care (ROAZ midden Nederland). After an introduction explaining the modeling and the visualization, we sent the forecast to this status meeting on a 2-week basis.

In order to assess the added value of the forecasting tool in the obstetrics care, we invited regional stakeholders (eg, gynecologists, midwives, and managers) from the network regional consultation acute obstetric care (ROAZ Midden Nederland) for an evaluative stakeholder meeting 6 months after implementation of the tool. To this purpose, we created a topic list to investigate the experiences with staff planning and resource management after implementation of the tool as compared to before this implementation, and the experience with use of the forecasting tool (Table S1 in Multimedia Appendix 1). We then analyzed this discussion using Nvivo (version 12.6.1.970; QSR International), and extracted information about the aforementioned topics, as well as remarks on the tool, including possible areas for further research and improvements of the tool.

Ethical Considerations

According to the Dutch legislation [9], this research did not fall under the Medical Research Involving Human Subjects Act (WMO). Only anonymized aggregated data were used for analysis. The research was conducted according to the Declaration of Helsinki. Health care professionals provided verbal informed consent prior to the interviews.

Results

Tool and Model Development

In total, Saltro screening data on 28,361 pregnancies were used from 23,778 patients with births per year ranging from 5052 in 2014 to 6047 in 2017 (mean 5681 per year). The Statistics Netherlands data from the included municipalities encompassed 35,394 births with births per year ranging from 8735 in 2016 to 9051 in 2014 (mean 8849 per year). The municipalities that were included in the development of the forecasting tool are given in Table 1, along with the number of pregnancies as reported by Saltro, and the actual number of births as reported by Statistics Netherlands.

XSL•FO
RenderX

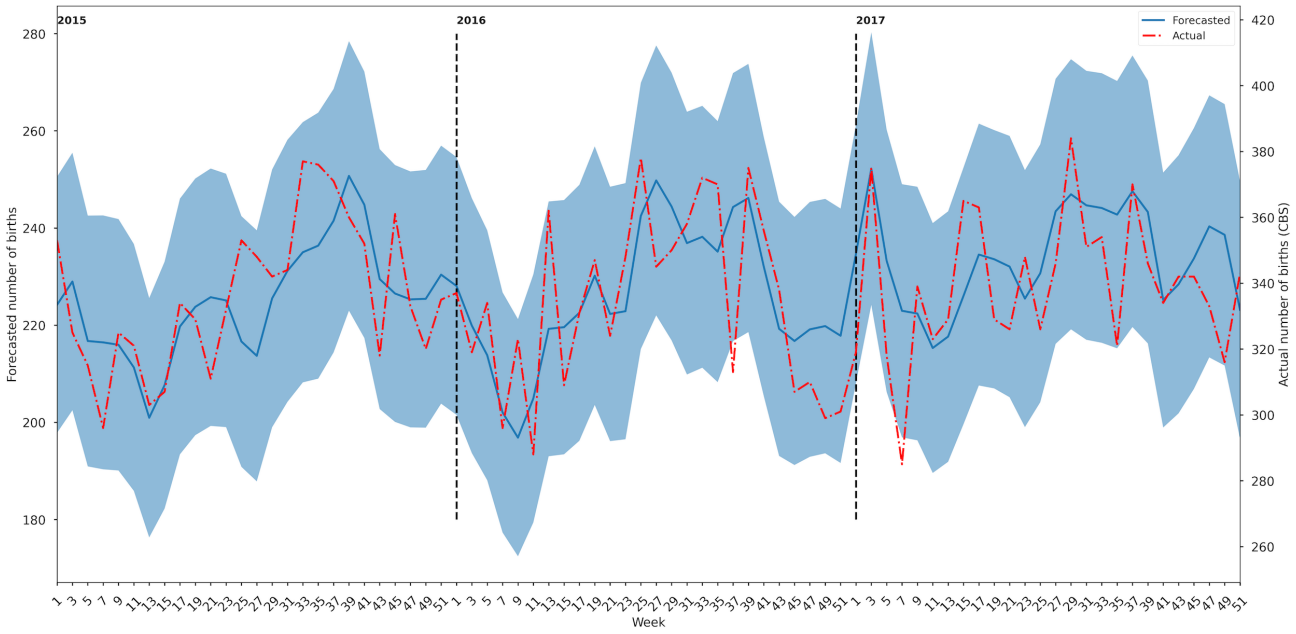
The correlation between the modeling output and number of births as reported by Statistics Netherlands was 0.45 for weekly data. For the 2-weekly bins, we found that the correlation between the model output and the Statistics Netherlands increased to 0.61, and for 3-weekly bins, this was 0.67 (Figure 2; Figures S1 and S2 in Multimedia Appendix 2). All actual number of births were within the forecasted 95% CI, after normalization for differences in scale between modeling output and actual numbers (Figure 2).

Table . Included municipalities and included pregnancies from Saltro and reported births from Statistics Netherlands. Municipalities were included if more than 55% of reported births were found in the Saltro database.

Municipality	Expected date of births (Saltro), n	Date of births (Statistics Netherlands), n	Total births (Saltro data), (%)[a]
Bunnik	367	536	68
Bunschoten	819	1051	78
De Bilt	1148	1369	84
Houten	2011	1993	101
IJsselstein	991	1317	75
Leusden	828	1062	78
Nijkerk	1422	1784	80
Renswoude	231	305	76
Scherpenzeel	505	460	110
Stichtse Vecht	2460	2473	99
Utrecht	13,461	18,420	73
Utrechtse Heuvelrug	1239	1503	82
Woudenberg	566	590	96
Zeist	2313	2531	91

[a]The percentage can be more than 100%, as women can deliver in hospitals, therefore changing the municipality of birth in comparison to the municipality of the mother.

Figure 2. Forecast in 2-weekly bins in 2015, 2016, and 2017. The y-axis of the actual births (right-axis) is normalized on the forecast (left-axis), in order to compare the two data. The forecasted number of births is depicted in blue; the actual number of births is depicted in red.



Presentation to Stakeholders and Implementation

The stakeholders chose a 2-weekly bin for forecast-width as this was considered a good trade-off between actionability with regards to planning (smaller bins mean higher granularity), but also having good predictive power. Additionally, the numbers were presented with an overall average over the preceding years (2015 - 2020). From July 2021 onwards, we provided these forecasts every 4 weeks; in September, this interval was shortened to 2 weeks upon request. We performed forecasts

XSL•FO
RenderX

over 13 weeks in advance, as we observed that forecasts using this time window were most stable in comparison with follow-up forecasts, because of incomplete data in the later weeks.

Evaluative Stakeholder Meeting

In total, 4 stakeholders attended the evaluative stakeholder meeting, including 3 stakeholders that worked in hospitals and 1 stakeholder that worked as community midwife.

Insights Before Introduction of the Tool

The stakeholders noted that before the introduction of the tool, there was a sense of competitiveness between different health care providers, as there was little insight into the upcoming number of births (Textbox 1, quote 1A), and the general need of care in the region. This meant that health care providers tried to provide as much care as possible by themselves, rather than collaborating with other health care providers in the region. Additionally, stakeholders stated that when it came to planning, they only used their own data and experiences, and that sharing of information was not common practice (Textbox 1, quotes 1B and 1C).

Textbox 1. Quotes illustrating insights before the introduction of data from the Saltro and tool. Quotes are translations from original Dutch transcripts.

Quotes

- 1A: We came out of a situation where there was less trust and more competition.
- 1B: We just did something, especially forecasts. We didn't know a lot; we knew what we did ourselves.
- 1C: [We planned based] on our own numbers, not taking forecasts into account, because we didn't predict anything

Insights After Introduction of the Tool

Stakeholders did not use the forecasts for day-to-day staff planning, as the interval of the forecasts was still considered too wide, and the uncertainty around the forecasts was considered too large, as most women give birth in a period of 5 weeks around the predicted date of birth (Textbox 2, quote 2A). Interestingly, the application stressed the increasing sense of urgency of high health care demand and the communication of this urgency to the management and higher-up levels. Additionally, this sense of urgency also resulted in the regional collaborations and a lower sense of competitiveness (Textbox 2, quote 2B).

Textbox 2. Quotes illustrating further use of the tool and room for improvements and research with regards to the tool. Quotes are translations from original Dutch transcripts.

Quotes

- 2A: The problem is that the forecast is done with a period of 5 weeks where women give birth, and then not even all of them give birth [during that time]
- 2B: We dealt with each other in a very different way, because we were each other's competitors and we kept our cards to our chests. That's completely gone.
- 2C: Saying: don't take a holiday] is a difficult one, but we stopped schooling, training, several working groups, social activities, they were all canceled.
- 2D: On the one hand, you have the care demand with the forecasts, on the other hand, you have the care capacity, pretty high level, but it pretty well resembles the weekly reality. It made sure that we felt the urgency to have things together the first two weeks of December. So, canceling schooling, canceling all other stuff, make sure we are ready operationally.
- 2E: [We] have the sense of urgency to talk about this [timeliness], and it [the forecast] is a tool to get things rolling, which were otherwise ignored. Then everyone would have said: "We should look at it sometime." Now it is: "We should look at it now".

This sense of urgency also had implications for planning on the operational level. For example, during the summer and autumn of 2021, the number of births was relatively high, around 10% to 20% above average for that specific period. By using the forecasts, obstetricians were able to increase their number of regional escalation management meetings and subsequently de-escalate when the care demand decreased again in December. Additionally, the sense of urgency also resulted in the cancellation of schooling, working groups, and social activities. The tool helped gain insight into when education and holidays should be planned, moved, or canceled (Textbox 2, quotes 2C and 2D).

Finally, the tool created the insight and urgency to act on other markers for QoC. As the numbers of births increase over a time period, and the availability of resources decreases, the focus of care was not just on patient safety, but also on timeliness and availability of care (Textbox 2, quote 2E).

Other Means of Use

Another way in which the tool could be used and add value was in the communication of the available care toward clients and patients. The stakeholders indicated that, at present, prospective parents are selecting their preferred hospitals for childbirth. However, this preference cannot always be met, due to limited capacity of these hospitals (Textbox 3, quotes 3A and 3B), especially since total capacity of hospitals is based on regional instead of local demand. The stakeholders considered the tool as a helpful tool to discuss expectations of pregnant women and to manage their expectations and preferences. Stakeholders also

XSL•FO
RenderX

identified a current QoC issue in obstetrics, namely when pregnant women receiving extra obstetric care were not always able to deliver in that specific hospital, which was considered undesirable as stakeholders argued that these women should receive care from one single (specialized) hospital (Textbox 3, quote 3C).

Textbox 3. Quotes illustrating further use of the tool and room for improvements and research with regards to the tool. Quotes are translations from original Dutch transcripts.

Quotes

- 3A: The chance that a pregnant woman delivers in the hospital of their choice, let's be positive, is about 60%.
- 3B: We can't make that [choosing the hospital to deliver] happen anymore, we would want to, but we can't make it happen. Using these data, we can tell them why, … and first-line obstetrics care (i.e. community midwives and postpartum caregivers) can profit from this, because they end up telling parents that they can't deliver where they wanted to deliver, so that something that should be beautiful ends up being less beautiful.
- 3C: I think that we get to the point that we are going to talk to each other, that there are patients that we know and that should stay in our hospitals, because there is more at hand with these patients, and that there are patients that have an uncomplicated pregnancy, but develop something in the last weeks, that it doesn't matter where these [patients] end up.
- 3D: We here are 'believers', but there are people who are not used to think in this way, and by showing these numbers over and over again, we show what we can do using these numbers.
- 3E: We don't think together what we have available with regards to capacity, and we don't share [this information] in the first line care what we have filled up with care demand.
- 3F: You know how many pregnancies there are, which is nice, but we don't know where they will deliver, and how this relates to each midwifery practice.
- 3G: I think that postal code is the most important, the area of adherence, because that's where we eventually, if we manage it, can tune the data for the obstetrics and maternity care.
- 3H: Based on historical data you can determine for some group when they will deliver, as long as you have them well monitored.
- 3I: Can you say anything about the percentages of [caesarian sections]? Because then you can also account for length of stay and impact on admission and staffing.
- 3J: We have the opportunity now, because COVID gives us this opportunity. If you look at the [National Coordination Centre for Patient Allocation], data is used differently. We have the opportunity to design something like that, maybe we should start with that regionally.

Another possible application was seen in the education of (health care) professionals in obstetrics, as data on health care demand are not widely shared. Stakeholders argued that, although they themselves were used to these kinds of tools, this was not the case for other health care professionals (Textbox 3, quote 3D). To create more familiarity with these kinds of tools, the stakeholders identified important hurdles. An example of a hurdle was the implementation of data sharing and central data collection. The stakeholders were not used to collaborating and sharing their data, and it was stressed this needed improvement (Textbox 3, quote 3E).

Stakeholders also commented on issues that were not addressed in our study, that is, features that would increase the usability and information density of the tool. Primarily, the stakeholders stated that more information could be gained with regard to specific patient groups: on localization of the patients (Textbox 3, quotes 3F and 3G) or subgroups to be included, e.g., cesarean sections (Textbox 3, quotes 3H and 3I). Stakeholders identified that in order to implement some of these improvements for the tool, more data should be shared among stakeholders in the obstetrics field. For example, stakeholders proposed a centralized data collecting system, similar to the system as implemented in the Netherlands during the COVID-19 (Textbox 3, quote 3J).

Discussion

Main Findings

In this study, we developed, validated, and implemented a tool to forecast and visualize trends of births in the greater Utrecht region, using routinely measured and collected calculated date of births by a primary care laboratory, to support management of the regional acute obstetric care, including staff planning. We developed a forecasting model and found that a 2- and 3-weekly binned forecasting model provided good predictive power when it comes to forecasting trends within birth numbers. Subsequently, we presented our findings to stakeholders in obstetrics and then implemented a tool to visualize our forecasts using a 2-weekly binned forecast. Although 3-weekly binned forecasts showed slightly higher predictive power, the choice for 2-weekly binned forecast was made, as this provided a more granular view of obstetric care demand. After 6 months, using an evaluative stakeholder meeting, we found that, although our tool was not used in day-to-day staff planning but rather on a (global) operational level, we were able to add value to the obstetrics field by adding a sense of urgency, resulting in improved regional collaborations and operational actions and improving QoC in obstetrics.

QoC is multifaceted. According to stakeholders, the use of our tool in daily practice enabled the focus on timeliness. Simultaneously, the tool supported collaborations in obstetric care, leading to more efficient and available obstetric care. A

XSL•FO
RenderX

well-coordinated acute obstetric care chain is important, as impaired communication between health care providers is detrimental to patient safety and continuity of care [10].

We implemented the forecasting tool during the COVID-19 pandemic. This crisis sparked the demand for more insights into obstetric health care demand, especially since during the pandemic, births varied more than before the pandemic. Examples include a birth wave after lockdown and fewer preterm births during the first lockdown [11,12]. Similar to other literature, we found a decrease in birth numbers in 2020 and an increase in birth numbers in 2021. Additionally, the surge of COVID-19 required more flexible resource management, as resource requirements changed or were scarce [13]. Considering that our data are able to capture the true birth rate in the general population opens up additional angles for research. Further study could focus on the decline in birth rate as seen in Nordic countries and Germany after 2021 [14,15], by studying the trend in expected births in our data. The increase in care demand and need for flexible resource management due to the pandemic fueled the development and implementation of the tool, as regional resources had to be more efficiently allocated due to high demands. Stakeholders reported that our tool was helpful in achieving these aims, by offering concrete data that heightened the sense of urgency within the obstetric care.

The academic literature and practice alike highlight the challenges of forecasting acute care demand, as it is often driven by unforeseen events or factors that fall outside the scope of routine data collection [1,2]. Indeed, we observed in our data that it is very hard to forecast the weekly number of births, considering their weekly variance. However, widening the scope of the forecasting interval and retrieving information from these data, such as trends, are of added value to the obstetrics domain according to stakeholders in obstetric care.

Our research should be understood in the light of the following limitations. We have included only limited data, originating from municipalities for which data on at least 55% of pregnancies was available. The extent to which our study therefore suffers from selection bias remains unclear. As the obstetrics care in the Netherlands and the reporting of calculated date of births is standardized, we believe bias is limited. However, future studies could focus on combining data sources for the estimated dates of birth, in order to increase the data coverage, and to mitigate reliance on a single data source. Additionally, our dataset is relatively small. With larger numbers, the use of statistical models such as Autoregressive Integrated Moving Average, or machine learning models may be beneficial [16]. Considering we had data on the actual number of births for 3 years, the use of such models was currently infeasible. To the best of our knowledge, no other forecasting model for the number of births is currently used in the Netherlands.

As stakeholders have stated in the stakeholder meeting, there are several directions for further research. First of all, data should be shared between stakeholders to improve regional (acute) obstetric care. This could help further improve forecasts, as this can help identify subgroups of pregnancies, so that these groups and their health care demand can be further monitored. Additionally, data sharing could lead to further standardization of data collection, making data collection and research to improve obstetric care more feasible and impactful.

Conclusion

Implementation of a forecasting tool for number of births based on available data across the health care system during the COVID-19 pandemic led to increased communication, awareness, and collaboration between obstetric health care providers, showing that combining several sources of data within the routine acute care can add value to the routine acute care process. Providing visualizations of forecasted births created a sense of urgency about the high care demand situation and the impact of this demand on quality of care. Our tool thereby facilitated improved collaborations and cohesion between health care providers in the Utrecht region and aided further initiatives that can increase efficient use of resources in response to high care demand beyond pandemic situations. Further research should aim at improving regional obstetric acute care by fostering data sharing in order to improve health care demand forecasts.

Acknowledgments

The study was supported by Saltro BV and University Medical Center Utrecht.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Topic list evaluative stakeholder meeting.
[DOCX File, 15 KB - pediatrics_v8i1e68284_app1.docx]

Multimedia Appendix 2
Predictions versus actual births in 2016 per week.
[PDF File, 216 KB - pediatrics_v8i1e68284_app2.pdf]

References

XSL•FO
RenderX

1. Saaiman T, Filmalter CJ, Heyns T. Important factors for planning nurse staffing in the emergency department: a consensus study. Int Emerg Nurs 2021 May;56:100979. [doi: 10.1016/j.ienj.2021.100979] [Medline: 33706044]
2. Wargon M, Guidet B, Hoang TD, Hejblum G. A systematic review of models for forecasting the number of emergency department visits. Emerg Med J 2009 Jun 1;26(6):395-399. [doi: 10.1136/emj.2008.062380]
3. Institute of Medicine (US) Committee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century: National Academies Press (US); 2001. [Medline: 25057539]
4. Tunçalp , Were WM, MacLennan C, et al. Quality of care for pregnant women and newborns-the WHO vision. BJOG 2015 Jul;122(8):1045-1049. [doi: 10.1111/1471-0528.13451] [Medline: 25929823]
5. Verburg BO, Steegers EAP, De Ridder M, et al. New charts for ultrasound dating of pregnancy and assessment of fetal growth: longitudinal data from a population-based cohort study. Ultrasound Obstet Gynecol 2008 Apr;31(4):388-396. [doi: 10.1002/uog.5225] [Medline: 18348183]
6. Robinson HP, Fleming JEE. A critical evaluation of sonar "crown‐rump length" measurements. BJOG 1975 Sep;82(9):702-710 [FREE Full text] [doi: 10.1111/j.1471-0528.1975.tb00710.x]
7. Van Der Ploeg CPB, Oomen P, Van Lent M. Prenatale screening infectieziekten en erytrocyten-immunisatie (PSIE) [Dutch]. : RIVM; 2019.
8. Perined. Peristat.nl. URL: https://www.peristat.nl/ [accessed 2011-11-04]
9. Medical research involving human subjects act. Ministry of Health, Welfare and Sport. 2025. URL: https://wetten.overheid.nl/BWBR0009408/ [accessed 2025-07-25]
10. Kripalani S, LeFevre F, Phillips CO, Williams MV, Basaviah P, Baker DW. Deficits in communication and information transfer between hospital-based and primary care physicians: implications for patient safety and continuity of care. JAMA 2007 Feb 28;297(8):831-841. [doi: 10.1001/jama.297.8.831] [Medline: 17327525]
11. Stout MJ, Van De Ven CJM, Parekh VI, et al. Use of electronic medical records to estimate changes in pregnancy and birth rates during the COVID-19 pandemic. JAMA Netw Open 2021 Jun 1;4(6):e2111621. [doi: 10.1001/jamanetworkopen.2021.11621] [Medline: 34081139]
12. Dench D, Joyce T, Minkoff H. United States preterm birth rate and COVID-19. Pediatrics 2022 May 1;149(5):e2021055495. [doi: 10.1542/peds.2021-055495] [Medline: 35383375]
13. Dayal AK, Razavi AS, Jaffer AK, Prasad N, Skupski DW. COVID-19 in obstetrics 2020: the experience at a New York City medical center. J Perinat Med 2020 Nov 26;48(9):892-899. [doi: 10.1515/jpm-2020-0365]
14. Petersen JP, Cueto H, Norman M. Births in the Nordics 2021 to 2022-Pandemic fluctuation or fundamental shift? Acta Paediatr 2024 Jun;113(6):1143-1144. [doi: 10.1111/apa.17209] [Medline: 38477867]
15. Bujard M, Andersson G. Fertility declines near the end of the COVID-19 pandemic: evidence of the 2022 birth declines in Germany and Sweden. Eur J Popul 2024 Jan 22;40(1):4. [doi: 10.1007/s10680-023-09689-w] [Medline: 38252183]
16. Tzitiridou-Chatzopoulou M, Zournatzidou G, Kourakos M. Predicting future birth rates with the use of an adaptive machine learning algorithm: a forecasting experiment for Scotland. Int J Environ Res Public Health 2024 Jun 27;21(7):841. [doi: 10.3390/ijerph21070841] [Medline: 39063418]

Abbreviations:

QoC: quality of care

Edited by S Badawy; submitted 01.11.24; peer-reviewed by P Kumari, R Appiah-Kubi; revised version received 27.04.25; accepted 20.05.25; published 22.08.25.

Please cite as:
Joosse HJ, Jongsma K, Moes M, Bloemenkamp KW, Tiel Groenestege WM, van Solinge WW, Haitjema S, Kok MB
Development and Implementation of a Birth Forecasting Tool to Optimize Resources in Obstetrical Care During the COVID-19 Pandemic: Mixed-Methods Study
JMIR Pediatr Parent 2025;8:e68284
URL: https://pediatrics.jmir.org/2025/1/e68284
doi:10.2196/68284

© Huibert-Jan Joosse, Karin Jongsma, Marcel Moes, Kitty W Bloemenkamp, Wouter M Tiel Groenestege, Wouter W van Solinge, Saskia Haitjema, Maarten B Kok. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 22.8.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic

XSL•FO
RenderX

information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

The Neo-MILK Web App as a Health Technology to Support Mothers of Preterm and Sick Neonates During Lactation: Usability Study

Isabella Schwab[1]; Tim Ohnhaeuser[1]; Roxane Lee Rothe[2]; Till Dresbach[3]; Katharina Schmitz[4]; Natalie Tutzer[5]; Nicola Gabriela Dymek[6]; Juliane Köberlein-Neu[6]; Nadine Scholten[2]; Neo-Milk

[1]Institute of Medical Sociology, Health Services Research, and Rehabilitation Science, Faculty of Medicine and University Hospital Cologne, University of Cologne, Eupener Straße 129, Cologne, Germany

[2]Department for Psychosomatic Medicine and Psychotherapy, Center for Health Communication and Health Services Research, University Hospital Bonn, Bonn, Germany

[3]Department of Neonatology and Pediatric Intensive Care, Children's Hospital, University of Bonn, Bonn, Germany

[4]Department of Neonatology, Center for Pediatric and Adolescent Medicine, University Medical Center of the Johannes Gutenberg-University Mainz, Mainz, Germany

[5]TAKEPART Media + Science GmbH, Cologne, Germany

[6]Centre for Health Economics and Health Services Research, University of Wuppertal, Wuppertal, Germany

Corresponding Author:
Isabella Schwab
Institute of Medical Sociology, Health Services Research, and Rehabilitation Science, Faculty of Medicine and University Hospital Cologne, University of Cologne, Eupener Straße 129, Cologne, Germany

Abstract

Background: Mothers of sick and preterm infants need support to establish and maintain lactation. Although many health technologies on breastfeeding are available, most lack in evidence-based information and are therefore not appropriate for educating mothers. Furthermore, they do not focus on the special challenges of mother-infant separation during lactation in mothers of sick or preterm infants.

Objective: The aim of this study is to examine the usability and perceived usefulness of the evidence-based information about lactation and documentation tools contained in the Neo-MILK web app.

Methods: A cross-sectional online survey was conducted among mothers of sick and preterm infants admitted to a neonatal intensive care unit in Germany. Descriptive statistics were calculated for the System Usability Scale (SUS) and for self-developed items pertaining to overall satisfaction and perceived usefulness of the app. These included items on evidence-based information and the usability of tracking functions.

Results: Of 341 mothers who were contacted, 80 responded (response rate, 23.4%), and data from 63 mothers were analyzed. The mean SUS score was 76.4. The overall satisfaction rate was high, with 84% (n=53) of respondents indicating that they were either satisfied or very satisfied. Further, 82% (n=52) were inclined to recommend the web app to other parents. On average, the evidence-based information was perceived as helpful, more detailed, and not contradictory compared to information provided at the hospital. At the same time, most of the users reported that the Neo-MILK web app did not exert pressure to provide breast milk to their infants. Approximately 71% (n=45) of the mothers used the documentation tool in the web app several times per week to track their milk volumes.

Conclusions: By combining evidence-based information and useful tools to document milk volume, the Neo-MILK web app was high rated in usability and perceived usefulness. Considering the limitations of the study, this web app appears to be a valuable tool for educating and supporting pump-dependent mothers of sick and preterm infants during lactation.

(JMIR Pediatr Parent 2025;8:e69079) doi:10.2196/69079

KEYWORDS

mHealth; lactation; usability; perceived usefulness; lactation web app; preterm and sick infants; pumping; mother's own milk; mobile health

XSL•FO
RenderX

Introduction

For all infants, mother's own milk (MOM) should be the first choice of nutrition and is, therefore, recommended by the World Health Organization [1,2]. Its health-promoting effects are evident and sick and preterm infants, in particular, benefit from the nutrition with MOM due to their high vulnerability [3]. However, achieving a sufficient milk volume has shown to be challenging for mothers of infants admitted to a neonatal intensive care unit (NICU) [4]. As many of these mothers are pump-dependent and cannot directly breastfeed, they require structured lactation support to facilitate MOM feeding in their sick and preterm infants [4,5]. This support enables timely communication about the importance of MOM, early initiation of lactation, and frequent pumping to establish a sufficient milk supply, thus ensuring the infants nutrition with MOM [4,6]. When providing lactation support to mothers, sensitive communication without distressing mothers should be facilitated, as stress may negatively affect lactation [7-9]. Indeed, perceived pressure to provide breast milk has been commonly reported among mothers, which may be associated with other mental health issues [10-12].

Mobile health (mHealth) apps and web app technologies are used in various settings such as disease management, medication reminders, and rehabilitation to promote and support a healthy lifestyle [13]. Several mHealth apps focused on breastfeeding already exist, which have shown to improve breastfeeding knowledge, attitudes, and self-efficacy [14-16]. However, mothers with infants admitted to a NICU require special tools and approaches from an app during lactation due to their unique situation. In general, NICU parents report a high demand for information and a willingness to use electronic devices for information and support [17,18]. This potential is further supported by studies which evaluated evidence-based education and information-sharing apps may promote parental mental health, parent-infant relationship, and family-centred care [19-21]. However, while many apps are already available for this target group, a systematic review showed that only a few of them are of good quality [22]. There is a notable lack of evidence-based and scientifically evaluated mHealth technologies focusing on combining evidence-based information sharing with valuable tools for NICU parents throughout the lactation process. The Neo-MILK web app aims to fill this gap for mothers with infants admitted in the NICU, by including both tools such as milk volume tracking and multimedia evidence-based information on several topics (eg, pumping, breastfeeding, or skin-to-skin contact). It was developed as part of the Neo-MILK project, which supports lactating mothers of infants admitted to a NICU [23]. Therefore, the intention of this web app was to complement rather than replace essential personal and direct lactation support provided within NICUs.

To measure the overall usability of mHealth technologies, the system usability scale (SUS) is a widely used instrument, which showed robust results in previous studies [24]. In addition, usability studies often report on ease of use, user experience, and user engagement, depending on the focus of the study [25]. Therefore, the objective of this study was to examine the usability and perceived usefulness of the evidence-based information about lactation and documentation tools contained in the Neo-MILK web app.

Methods

Research Design

A quantitative, prospective, and cross-sectional questionnaire was developed to evaluate the usability and perceived usefulness of the Neo-MILK web app.

Setting and Relevant Context

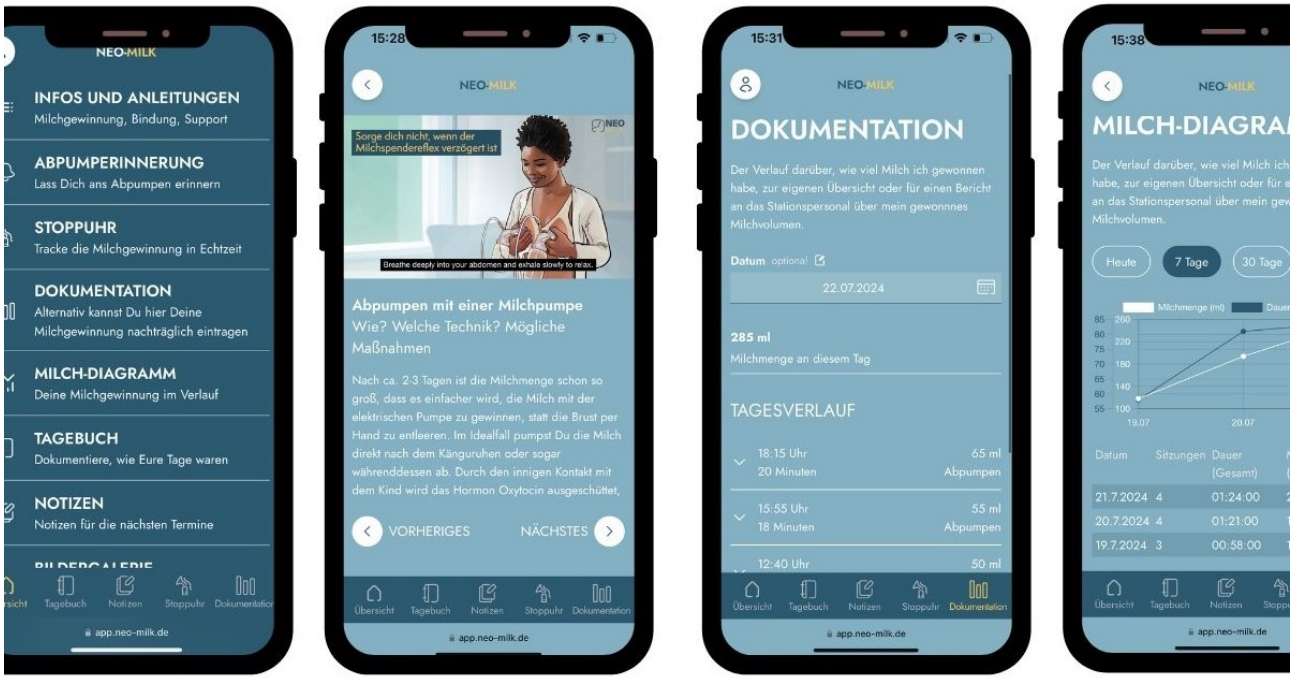
Participants in this study were mothers of preterm and sick infants admitted to a NICU. In Germany, initiation of lactation is often suboptimal [26]. This may be attributed to the often not implemented structured lactation support and lack of consistent information and personal support during lactation [27]. Mobile health technology may serve as a beneficial tool to help provide additional support to pump-dependent mothers.

Web App Development

In a participatory process involving mothers of very low birth weight (VLBW, <1500g) infants, features and content for the Neo-MILK web app were developed by a multidisciplinary team consisting of psychologists, economists, sociologists, neonatologists, neonatal nurses, and a web app developer. To determine the tools and features desired by mothers of VLBW infants, open questions were posted on Instagram. These questions were then ranked in an anonymous online survey completed by 138 mothers. Individual issues, such as the preferred type of communication, were also subject to direct voting via Instagram. Following this participatory process, the final design excluded photographs and instead featured animated parent-infant dyads and drawings. The illustrations were intentionally inclusive to reach a target group which is as diverse as possible. Therefore, the design includes people from different races and ethnicities. The illustrations and texts were developed through a process of various feedback rounds with the multidisciplinary team. As the Neo-MILK web app was part of the Neo-MILK project, the wording and presentation of the web app were aligned to the other materials developed within the project [23]. Finally, tools for recording the time, frequency, and volume of milk during expression, as well as a reminder for milk expression were included. Furthermore, evidence-based information on important topics related to lactation (eg skin-to-skin contact, bonding, milk expression, and hygienic handling of breast milk), along with answers to frequently asked questions regarding breastfeeding and pumping in the form of texts and videos are included in the web app to increase maternal knowledge. To reduce barriers to evidence-based information on pumping and breastfeeding, the videos were featured with subtitles in other languages. These were translated by native speakers working in the Neo-MILK team. Additionally, features such as a diary to document individual milestones of the child and the NICU-related reflections including the mother's mood and feelings were also provided. In cooperation with a media company (TAKEPART Media + Science GmbH), the app was designed as a browser-based web app (Figure 1).

XSL•FO
RenderX

Figure 1. Web app design (left to right: landing page after registration, informational videos, documentation tool, milk diagram).



Measurements

The overall usability was measured using the SUS, which is a widely accepted tool to indicate usability, operability, and suitability for the use of digital health technologies [28]. Four slightly different translations of this scale are available in German. They were reviewed in a recent publication and revealed that the version by Rummel [29] described the developmental process and methodology most clearly. It was shown to be the best balance between methodologically clean development and wording and, therefore, was utilized in this study [29,30].

To measure the perceived usefulness of the information, videos and the documentation tools, self-developed items were assessed. Overall satisfaction was measured using a question: "How satisfied are you with the web app in general?" with a 4-point Likert scale ("very satisfied", "satisfied", "not satisfied", "not at all satisfied"). Moreover, participants were asked if they would recommend the web app to other parents with the following answering options: "yes", "rather yes", "rather no", and "no". Perceived usefulness of the information of videos was measured through a 4-point Likert scale of agreement ("agree", "rather agree", "rather disagree", "disagree") to three statements each for texts and videos which were as follows: (1) "The information I obtained from the texts (videos) were/are helpful for pumping and breastfeeding", (2) "The information I obtained from the texts (videos) were/are contradictory to those in the hospital," and (3) "The information I obtained from the texts (videos) were/are more detailed than those in the hospital."

To assess whether and how frequent mothers used the documentation tool for assessing their pumped milk volume using the following question "How frequently do you use the documentation tool?" which could be rated as: "several times a day", "daily", "several times a week", "several times a month", "less frequent", or "never." Moreover, they were asked whether they found the documentation tools easy to use in a 4-point Likert scale ("difficult", "rather difficult", "rather easy", or "easy"). Furthermore, to analyze whether the Neo-MILK web app caused negative feelings in mothers in terms of pressure to provide breast milk, the following statement was posed: "I felt pressured to provide breast milk by the Neo-MILK web-app" and could be rated on a six-point Likert scale ("totally disagree", "mostly disagree", "rather disagree", "rather agree", "mostly agree", "totally agree"). Data on feeding methods as well as previous experience with pumping or breastfeeding, and sociodemographic variables (eg, education, maternal age, infant's age) were collected. Due to small group sizes, the education level was dichotomized into lower education (lower secondary or secondary school) and higher education (higher education entrance qualification or university degree).

Data Collection

Data collection took place from September 2023 to May 2024 through the anonymous online survey tool Lime Survey (LimeSurvey GmbH). Data were collected and analyzed by researchers at the University of Cologne, who were also the principal investigators of the Neo-MILK project.

Data Analysis

Descriptive statistics including mean (SD), depending on the data distribution were calculated. Group comparisons between educational groups concerning the system usability were performed. Figures were used to visualize the data. Missing values were indicated in the description of the baseline characteristics and, in case of figures, in the figure legends. Data were analyzed using STATA (version 18; StataCorp).

Ethical Considerations

Ethical approval for this study was obtained from the ethics committee of the University of Wuppertal (SK/AE 230329).

XSL•FO
RenderX

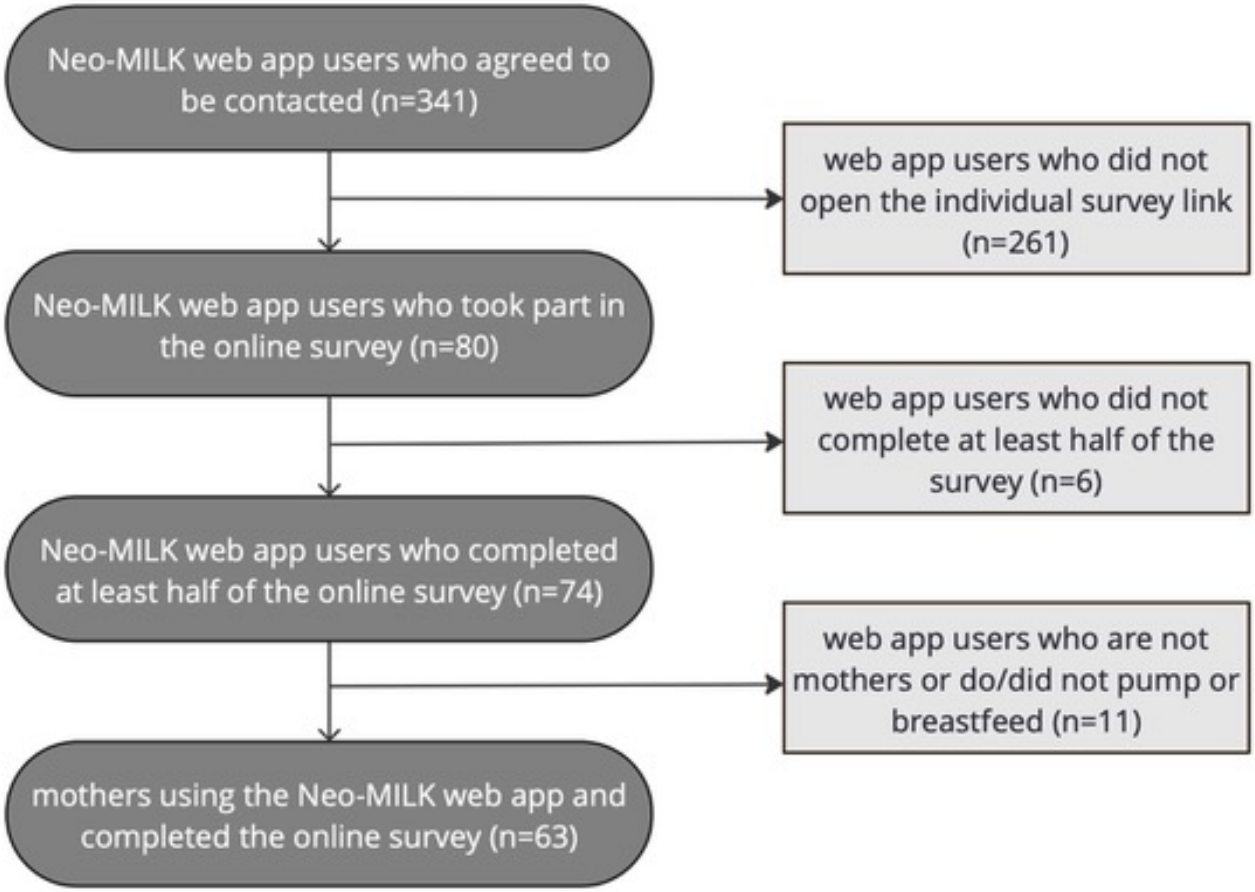
All methods were performed in accordance with this approval. Before being permitted to complete the questionnaire, the participants were required to consent to the data protection regulations to realize informed consent. The resulting data was anonymous, as no personal data was collected. To compensate the time and effort of the participants, they were offered the opportunity to receive a €10b (US $11.60) voucher for a nationally represented drugstore.

Results

Sample

Four to eight weeks after registering in the web app, mothers of sick or VLBW infants were invited to participate in the survey. The requirement for registration was explicit consent to be contacted for scientific studies during the registration process. Therefore, 341 mothers received an email with individual tokens to participate in the survey and were reminded once via email if the questionnaire was not submitted within a two-week period. To further ensure correct sampling, all respondents were asked to indicate whether they were currently engaged in pumping or breastfeeding. Of the 341 mothers who were contacted, 80 responded, representing a response rate of 23.4%. Finally, data from 63 mothers were used for statistical analysis (Figure 2).

Figure 2. Flowchart of recruitment, inclusion, and exclusion of cases.



Sample Characteristics

Maternal sociodemographic characteristics (eg, age, educational level, native language), and whether reasons for expressing milk stem from maternal or child-related factors, as well as information about their infants (ie, past or current hospitalization, age, birth weight) are presented in Table 1.

XSL•FO
RenderX

Table . Characteristics of participating mothers and their infants.

Sociodemographic variables	Participants (n=63)
Age[a] (years), mean (SD)	33.5 (4.6)
Education, n (%)	
Lower secondary/secondary school	14 (22)
Higher education entrance qualification/university degree	48 (76)
Missing data	1 (2)
Native language, n (%)	
Other	4 (6)
German	57 (91)
Missing data	2 (3)
Parity, n (%)	
Singleton	61 (97)
Multiple	2 (3)
Missing data	0 (0)
Infant's hospitalization (past or currently), n (%)	
No	12 (19)
Yes	51 (81)
Missing data	0 (0)
Infant's age[b] (weeks), mean (SD)	8.6 (3.7)
Birth weight (grams), n (%)	
<500	3 (5)
500 - 999	15 (24)
1000g-1499	6 (10)
1500-1999	4 (6)
2000 - 2500	6 (10)
>2500	4 (6)
Missing data	25 (40)
Reasons for pumping, n (%)	
Maternal-related factors	8 (13)
Child-related factors	49 (78)
Preterm birth	32 (65)
Congenital condition	10 (20)
Birth complications	5 (10)
Others	2 (5)
Missing data	6 (10)

[a]There were 59 responses for this questions (ie, 4 did not response).

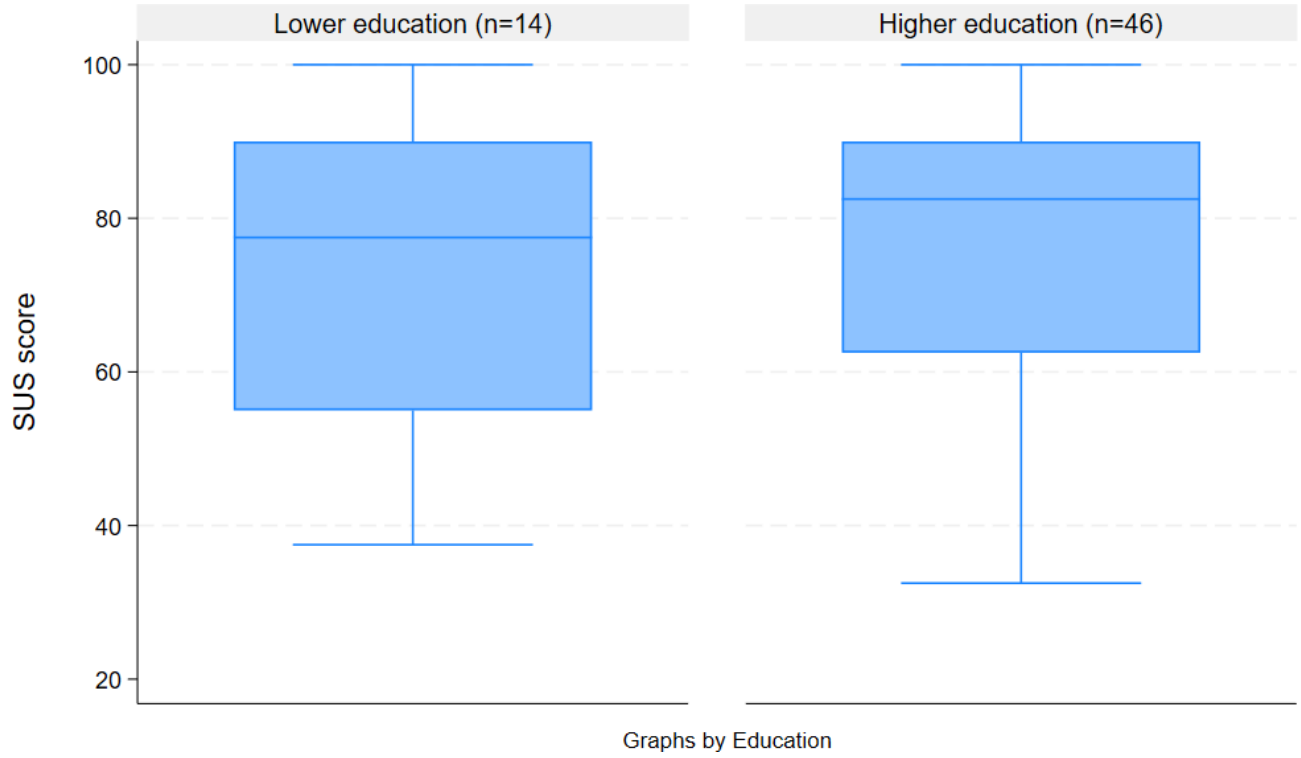
[b]There were 53 responses for this question (ie, 10 did not response).

Usability and Perceived Usefulness

The SUS score showed good usability of the Neo-MILK web app, with a mean score of 76.4 (n=61). The score only slightly differed between the lower and higher educational groups (Figure 3).

XSL•FO
RenderX

Figure 3. Boxplot of SUS score between the two educational groups. SUS: system usability scale.

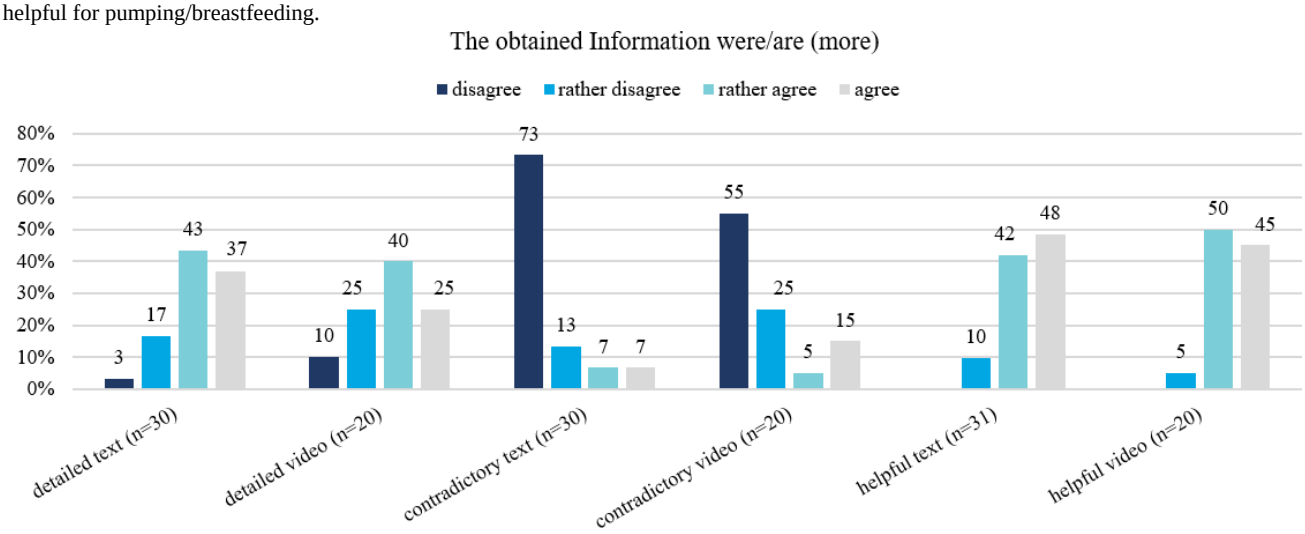


Overall, 62 participants reported high satisfaction with the web app, with 53 (84%) participants being satisfied or very satisfied. Moreover, 52 (82%) would recommend the web app to other parents. The information provided in the web app via texts were accessed by 31 (49%) and videos by 20 (32%) of the participants. Most participants agreed that the information were more detailed than those provided in the hospital and that they were helpful for pumping and breastfeeding. The majority of participants disagreed that the content was contradictory (Figure 4).

Of the 63 participants, 45 (71%) used the pumping documentation tool of the web app (ie pumping timer or manual documentation of pumping) at least several times a week. Of the 54 participants who rated its ease of use, 46 (85%) found it "rather easy" or "easy to use."

Of 62 mothers, 56 (89%) indicated that they did not feel pressured by the Neo-MILK web app to provide breast milk, while only 6 (11%) reported experiencing such pressure.

Figure 4. Distribution of agreement whether information in the web app (texts/videos) were more detailed than or contradictory to those in the hospital, or helpful for pumping/breastfeeding.



Discussion

Principal Findings

This study showed that the Neo-MILK web app provides a suitable tool for mothers of VLBW and sick infants during lactation and pumping. The usability is good, as indicated by SUS scores being clearly over the widely accepted benchmark of 68 [24]. This is further supported by the positively rated overall satisfaction with the web app and the high number of participants who would recommend the app to other parents.

XSL•FO
RenderX

One main feature of the Neo-MILK web app is the provision of evidence-based information about central issues when pumping breast milk for a sick or preterm infant. These include bonding, breast milk expression, and solutions for problems with lactation. Recent studies showed that infant feeding applications are often of poor quality, with incomplete information and lacking in evidence-based content [13,22]. The information provided in the Neo-MILK web app was developed with a multidisciplinary expert team to ensure evidence-based content. Indeed, the results demonstrate that, on average, the information provided was helpful for mothers in their experience of pumping and breastfeeding. Furthermore, the information was more detailed than that provided in the hospital and not contradictory. It can therefore be assumed that the Neo-MILK web app is a suitable tool for informing mothers with an infant admitted to a NICU. However, it remains unknown, whether the mothers in our study received any personal lactation support or if the Neo-MILK web app was the only source of information and support available to them. It is important to emphasize that this web app should provide additional features and information for mothers. Personal and direct lactation support in the NICU, as part of a MOM-friendly hospital policy is crucial for ensuring nutrition with MOM [31,32].

Another central tool is the option to document the expressed milk volume. A recent study showed that tracking features lead to higher ratings of breastfeeding applications in general [33]. This indicates its importance for mothers and may be even more notable for pump-dependent mothers who are not able to feed their infant on demand. In our study, this assumption is strengthened, as most participants used the documentation tools to track their milk volume. In addition, the ranking of the ease of use indicates good usability of these features. This is particularly relevant, as usability has shown to be a crucial factor for the adoption of health technologies [34].

As elaborated before, stress and lactation are assumed to be associated [7,8]. This association is further assumed to be bidirectional, with stress leading to negative breastfeeding outcomes and impaired lactation increasing stress [35]. Due to the high levels of stress NICU mothers perceive, it is of paramount importance to minimize stress rather than triggering further distress [9]. Recent studies showed that mothers feel specific pressure to breastfeed or provide breast milk, which can stem from internal or external factors, for example, from their social environment or health care providers [11,12,36]. However, even though the Neo-MILK web app contains a lot of information about the importance of MOM, as well as tracking options for milk supply, users do not perceive these features as triggering such feelings.

Limitations

This study has some limitations. The SUS is available in four German translations, all of which have different deficiencies, for example, in methodology or wording. Although there is a validated version available, it lacks in terms of translation, leading to unnatural wording. In this analysis, we used the recommended translation, which is regarded as the best compromise between methodologically rigour and comprehensibility [30]. This might have had an impact on the validity of the measurement and therefore influenced the results. The response rate of this study is low. It may be the case that the users were no longer using the web app at the time of the survey. This may particularly apply to mothers who have transitioned from pumping to breastfeeding after a few weeks, and therefore no longer require the tools of the Neo-MILK web app. Another reason for the low response rate could be that registered web app users who were unsatisfied or were not frequent users did not respond due to their dissatisfaction. Furthermore, it can be suggested that the utilization of mHealth technologies is determined by the educational level and age of users, which may indicate a healthy bias among its users [37]. This is reflected by the broad number of participants with a high educational level in this sample. However, the Neo-MILK web app utilization and its ratings might not be biased by educational level, as indicated by only slight differences in the SUS score between these groups. Nevertheless, the information should be accessible for all groups to reduce communication difficulties, including those due to language barriers, which are a common problem in health services [38]. To reduce these barriers, the videos in the Neo-MILK web app are available with subtitles in other languages, including Russian, French, English, and Turkish. In addition, the videos are composed of easily understandable images and keywords. However, the provision of a translated version of the entire web app when necessary would further facilitate the accessibility of the web app to all relevant target groups.

Conclusions

The combination of evidence-based information about lactation and useful tools for tracking was identified as being of particular importance for this special group of mothers, with both elements rated highly in terms of usability and usefulness. Therefore, it can be concluded, that in our study, the Neo-MILK web app serves as a useful tool to complement personal support for pump-dependent mothers during lactation.

Acknowledgments

We want to acknowledge all Neo-MILK Collaborators: Prof. Dr. Nadine Scholten, Prof. Dr. Andreas Müller, Dr. Till Dresbach, (University Hospital Bonn); Prof. Dr. Martin Hellmich, IMSB (University Hospital Cologne); Prof. Dr. Nicole Ernstmann, IfPS (University Hospital Bonn); Dr. Antje Hammer, IfPS (University Hospital Bonn); Prof. Dr. Friederike Eyssel, CITEC (University Bielefeld); PD Dr. Angela Kribs, (University Hospital Cologne); Prof. Dr. Juliane Köberlein-Neu, Bergisches Competence Centre for Health Economics and Health Services Research (University Wuppertal); Prof. Dr. Katharina Lugani, Medical Law (University Düsseldorf); Prof. Dr. Eva Mildenberger (University Hospital Mainz); PD Dr. Jens Ulrich Rüffer, Katja Matthias (TAKEPART Media+Science GmbH); Anne Sunder-Plaßmann, Frauenmilchbank-Initiative; Prof. Dr. Daniel Wiesen, Behavioral Management

XSL•FO
RenderX

Science (University of Cologne); Dr. Dr. Dirk Horenkamp-Sonntag, Dr. Iris Klein, Techniker Krankenkasse; Dr. Melanie Klein, DAK- Gesundheit; Christoph Rupprecht, Laura Schleich, Olaf Beckmann, AOK Rheinland/Hamburg; Anke Kurz, Pronova BKK.

We also convey a special thanks to Julia Jaschke (University of Wuppertal) for her assistance in obtaining ethical approval. The project Neo-MILK is publicly funded by the Innovation Fund of the Joint Federal Committee (funding code: 01NVF19027).

Conflicts of Interest

None declared.

References

1. Infant and young child feeding. Word Health Organization. 2023. URL: https://www.who.int/news-room/fact-sheets/detail/infant-and-young-child-feeding [accessed 2025-01-28]
2. Victora CG, Bahl R, Barros AJD, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. Lancet 2016 Jan 30;387(10017):475-490. [doi: 10.1016/S0140-6736(15)01024-7] [Medline: 26869575]
3. WHO recomendations for care of the preterm or low-birth-weight infant. World Health Organization. 2022. URL: https://iris.who.int/bitstream/handle/10665/363697/9789240058262-eng.pdf?sequence=1 [accessed 2025-01-28]
4. Parker MG, Stellwagen LM, Noble L, et al. Promoting human milk and breastfeeding for the very low birth weight infant. Pediatrics 2021 Nov;148(5):e2021054272. [doi: 10.1542/peds.2021-054272] [Medline: 34635582]
5. Ward LP, Tonnis R, Otuneye AT, Clemens N, Akinbi H, Morrow AL. Impact of institutional breastfeeding support in very low-birth weight infants. Breastfeed Med 2021 Mar;16(3):238-244. [doi: 10.1089/bfm.2020.0137] [Medline: 33211538]
6. Mago-Shah DD, Athavale K, Fisher K, Heyward E, Tanaka D, Cotten CM. Early pumping frequency and coming to volume for mother's own milk feeding in hospitalized infants. J Perinatol 2023 May;43(5):629-634. [doi: 10.1038/s41372-023-01662-z] [Medline: 37037987]
7. Lau C. The effect of stress on lactation--its significance for the preterm infant. Adv Exp Med Biol 2002;503:91-97. [doi: 10.1007/978-1-4615-0559-4_10] [Medline: 12026032]
8. Zanardo V, Gambina I, Begley C, et al. Psychological distress and early lactation performance in mothers of late preterm infants. Early Hum Dev 2011 Apr;87(4):321-323. [doi: 10.1016/j.earlhumdev.2011.01.035] [Medline: 21316877]
9. Roque ATF, Lasiuk GC, Radünz V, Hegadoren K. Scoping review of the mental health of parents of infants in the NICU. J Obstet Gynecol Neonatal Nurs 2017;46(4):576-587. [doi: 10.1016/j.jogn.2017.02.005] [Medline: 28506679]
10. Diez-Sampedro A, Flowers M, Olenick M, Maltseva T, Valdes G. Women's choice regarding breastfeeding and its effect on well-being. Nurs Womens Health 2019 Oct;23(5):383-389. [doi: 10.1016/j.nwh.2019.08.002] [Medline: 31465748]
11. Jackson L, Fallon V, Harrold JA, De Pascalis L. Psychosocial predictors of post-natal anxiety and depression: using structural equation modelling to investigate the relationship between pressure to breastfeed, health care professional support, post-natal guilt and shame, and post-natal anxiety and depression within an infant feeding context. Matern Child Nutr 2024 Jan;20(1):e13558. [doi: 10.1111/mcn.13558] [Medline: 37752680]
12. Schwab I, Dresbach T, Ohnhäuser T, Horenkamp-Sonntag D, Scholten N, Neo-MILK. Pressure to provide milk among mothers of very low birth weight infants: an explorative study. BMC Pregnancy Childbirth 2024 Feb 13;24(1):134. [doi: 10.1186/s12884-024-06315-3] [Medline: 38350865]
13. Cheng H, Tutt A, Llewellyn C, et al. Content and quality of infant feeding smartphone apps: five-year update on a systematic search and evaluation. JMIR Mhealth Uhealth 2020 May 27;8(5):e17300. [doi: 10.2196/17300] [Medline: 32459187]
14. Seyyedi N, Rahmatnezhad L, Mesgarzadeh M, Khalkhali H, Seyyedi N, Rahimi B. Effectiveness of a smartphone-based educational intervention to improve breastfeeding. Int Breastfeed J 2021 Sep 20;16(1):70. [doi: 10.1186/s13006-021-00417-w] [Medline: 34544429]
15. Lau Y, Htun TP, Tam WSW, Klainin-Yobas P. Efficacy of e-technologies in improving breastfeeding outcomes among perinatal women: a meta-analysis. Matern Child Nutr 2016 Jul;12(3):381-401. [doi: 10.1111/mcn.12202] [Medline: 26194599]
16. Griffin LB, López JD, Ranney ML, Macones GA, Cahill AG, Lewkowitz AK. Effect of novel breastfeeding smartphone applications on breastfeeding rates. Breastfeed Med 2021 Aug;16(8):614-623. [doi: 10.1089/bfm.2021.0012] [Medline: 33826418]
17. Williams L, I'Anson J, Malarkey M, Purcell A, de Vries N, McKinlay C. Information sharing in neonatal intensive care: parental perceptions and preferences. J Paediatr Child Health 2020 Jul;56(7):1121-1125. [doi: 10.1111/jpc.14842] [Medline: 32129561]
18. Orr T, Campbell-Yeo M, Benoit B, Hewitt B, Stinson J, McGrath P. Smartphone and internet preferences of parents: information needs and desired involvement in infant care and pain management in the NICU. Adv Neonatal Care 2017 Apr;17(2):131-138. [doi: 10.1097/ANC.0000000000000349] [Medline: 27759567]
19. Ding L, Chen Y, Zhang W, et al. Effect of family integrated care on breastfeeding of preterm infants: a scoping review. Nurs Open 2023 Sep;10(9):5950-5960. [doi: 10.1002/nop2.1888] [Medline: 37306324]

XSL•FO
RenderX

20. Kermani F, Kahouei M, Valinejadi A, Sadeghi M, Momeni M, Pahlevanynejad S. Outcome's classification in mobile applications tailored to parents of premature infants: a systematic review. Iran J Public Health 2023 Aug;52(8):1642-1655. [doi: 10.18502/ijph.v52i8.13402] [Medline: 37744544]
21. Chua JYX, Shorey S. Effectiveness of mobile application-based perinatal interventions in improving parenting outcomes: a systematic review. Midwifery 2022 Nov;114:103457. [doi: 10.1016/j.midw.2022.103457] [Medline: 35985142]
22. Richardson B, Dol J, Rutledge K, et al. Evaluation of mobile apps targeted to parents of infants in the neonatal intensive care unit: systematic app review. JMIR Mhealth Uhealth 2019 Apr 15;7(4):e11620. [doi: 10.2196/11620] [Medline: 30985282]
23. Scholten N, Fitzgerald A, Matthias K, et al. Structured lactation support and human donor MILK for German NICUs-protocol on an intervention design based on a multidimensional status quo and needs assessment (Neo-MILK). PLoS ONE 2023;18(4):e0284621. [doi: 10.1371/journal.pone.0284621] [Medline: 37104486]
24. Hyzy M, Bond R, Mulvenna M, et al. System usability scale benchmarking for digital health apps: meta-analysis. JMIR Mhealth Uhealth 2022 Aug 18;10(8):e37290. [doi: 10.2196/37290] [Medline: 35980732]
25. McKay FH, Cheng C, Wright A, Shill J, Stephens H, Uccellini M. Evaluating mobile phone applications for health behaviour change: a systematic review. J Telemed Telecare 2018 Jan;24(1):22-30. [doi: 10.1177/1357633X16673538] [Medline: 27760883]
26. Scholten N, Mause L, Horenkamp-Sonntag D, Klein M, Dresbach T. Initiation of lactation and the provision of human milk to preterm infants in German neonatal intensive care units from the mothers' perspective. BMC Pregnancy Childbirth 2022 Feb 25;22(1):158. [doi: 10.1186/s12884-022-04468-7] [Medline: 35216574]
27. Schwab I, Wullenkord R, Eyssel F, Dresbach T, Scholten N, Neo-MILK. Lactation support in neonatal intensive care units in Germany from the mothers' perspective - a mixed-method study of the current status and needs. BMC Pregnancy Childbirth 2024 Apr 16;24(1):282. [doi: 10.1186/s12884-024-06339-9] [Medline: 38627697]
28. Schmidt S, Minow A, Böckelmann I. Einsatz und Aussagekraft etablierter quantitativer Usability-Fragebögen in einem User-Test [German]. Zbl Arbeitsmed 2020 Nov;70(6):256-263. [doi: 10.1007/s40664-020-00399-2]
29. Rummel B. System Usability Scale - jetzt auch auf Deutsch. 2016. URL: https://community.sap.com/t5/additional-blogs-by-sap/system-usability-scale-jetzt-auch-auf-deutsch/ba-p/13487686 [accessed 2024-04-15]
30. Brix TJ, Janssen A, Storck M, Varghese J. Comparison of German translations of the system usability scale - Which to take? Stud Health Technol Inform 2023 Sep 12;307:96-101. [doi: 10.3233/SHTI230699] [Medline: 37697842]
31. Bixby C, Baker-Fox C, Deming C, Dhar V, Steele C. A multidisciplinary quality improvement approach increases breastmilk availability at discharge from the neonatal intensive care unit for the very-low-birth-weight infant. Breastfeed Med 2016 Mar;11(2):75-79. [doi: 10.1089/bfm.2015.0141] [Medline: 26901619]
32. Gharib S, Fletcher M, Tucker R, Vohr B, Lechner BE. Effect of dedicated lactation support services on breastfeeding outcomes in extremely-low-birth-weight neonates. J Hum Lact 2018 Nov;34(4):728-736. [doi: 10.1177/0890334417741304] [Medline: 29161535]
33. Dinour LM, Pole A. Evaluation of breastfeeding app features: content analysis study. JMIR Pediatr Parent 2022 Oct 26;5(4):e37581. [doi: 10.2196/37581] [Medline: 36287596]
34. Inal Y, Wake JD, Guribye F, Nordgreen T. Usability evaluations of mobile mental health technologies: systematic review. J Med Internet Res 2020 Jan 6;22(1):e15337. [doi: 10.2196/15337] [Medline: 31904579]
35. Nagel EM, Howland MA, Pando C, et al. Maternal psychological distress and lactation and breastfeeding outcomes: a narrative review. Clin Ther 2022 Feb;44(2):215-227. [doi: 10.1016/j.clinthera.2021.11.007] [Medline: 34937662]
36. Korth CX, Keim SA, Crerand CE, Jackson JL. New mothers' perceptions of pressure to breastfeed. MCN Am J Matern Child Nurs 2022;47(3):160-167. [doi: 10.1097/NMC.0000000000000814] [Medline: 35475926]
37. Krebs P, Duncan DT. Health app use among US mobile phone owners: a national survey. JMIR Mhealth Uhealth 2015 Nov 4;3(4):e101. [doi: 10.2196/mhealth.4924] [Medline: 26537656]
38. O'Toole JK, Alvarado-Little W, Ledford CJW. Communication with diverse patients: addressing culture and language. Pediatr Clin North Am 2019 Aug;66(4):791-804. [doi: 10.1016/j.pcl.2019.03.006] [Medline: 31230623]

Abbreviations

mHealth: mobile health
MOM: mother's own milk
NICU: neonatal intensive care unit
SUS: system usability scale
VLBW: very low birth weight

XSL•FO
RenderX

Edited by S Badawy; submitted 21.11.24; peer-reviewed by A Iellamo, MA Theurich; revised version received 22.01.25; accepted 28.01.25; published 09.07.25.

Please cite as:
Schwab I, Ohnhaeuser T, Rothe RL, Dresbach T, Schmitz K, Tutzer N, Dymek NG, Köberlein-Neu J, Scholten N, Neo-Milk
The Neo-MILK Web App as a Health Technology to Support Mothers of Preterm and Sick Neonates During Lactation: Usability Study
JMIR Pediatr Parent 2025;8:e69079
URL: https://pediatrics.jmir.org/2025/1/e69079
doi:10.2196/69079

© Isabella Schwab, Tim Ohnhaeuser, Roxane Lee Rothe, Till Dresbach, Katharina Schmitz, Natalie Tutzer, Nicola Gabriela Dymek, Juliane Köberlein-Neu, Nadine Scholten, Neo-MILK. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 9.7.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Developing an Evidence- and Theory-Informed Mother-Daughter mHealth Intervention Prototype Targeting Physical Activity in Preteen Girls of Low Socioeconomic Position: Multiphase Co-Design Study

Carol Brennan[1], BA, MSc, PhD; Grainne ODonoghue[1], BSc, MSc, PhD; Alison Keogh[2], BSc, MSc, PhD; Ryan E Rhodes[3], BA, MA, PhD; James Matthews[1], BA, MA, PhD

[1]School of Public Health, Physiotherapy and Sports Science, University College Dublin, Dublin 4, Ireland

[2]School of Medicine, Trinity College Dublin, Dublin, Ireland

[3]Behavioural Medicine Laboratory, University of Victoria, Victoria, BC, Canada

Corresponding Author:
Carol Brennan, BA, MSc, PhD
School of Public Health, Physiotherapy and Sports Science
University College Dublin
Belfield
Dublin 4, DO4C7X2
Ireland
Phone: 353 1 716 3449
Email: carol.brennan1@ucdconnect.ie

Abstract

Background: Preteen girls of lower socioeconomic position are at increased risk of physical inactivity. Parental support, particularly from mothers, is positively correlated with girls' physical activity levels. Consequently, family-based interventions are recognized as a promising approach to improve young people's physical activity. However, the effects of these interventions on girls' physical activity are often inconsistent, with calls for more rigorous, theory-informed, and co-designed family-based interventions to promote physical activity in this cohort.

Objective: This study aimed to use co-design methods to develop an evidence- and theory-informed mother-daughter mobile health intervention prototype targeting physical activity in preteen girls.

Methods: The intervention prototype was developed in accordance with the United Kingdom Medical Research Council framework, the Behaviour Change Wheel, the Theoretical Domains Framework, and the Behaviour Change Techniques Ontology. The Behaviour Change Intervention Ontology was also used to annotate the intervention characteristics. The co-design process incorporated three phases: (1) behavioral analysis, (2) the selection of intervention components, and (3) refinement of the intervention prototype. Throughout these phases, workshops were conducted with preteen girls (n=10), mothers of preteen girls (n=9), and primary school teachers (n=6), with additional input from an academic advisory panel.

Results: This 3-phase co-design process resulted in the development of a theory-informed intervention that targeted two behaviors: (1) mothers' engagement in a range of supportive behaviors for their daughters' physical activity and (2) daughters' physical activity behavior. Formative research identified 11 theoretical domains to be targeted as part of the intervention (eg, knowledge, skills, and beliefs about capabilities). These were to be targeted by 6 intervention functions (eg, education, persuasion, and modeling) and 27 behavior change techniques (eg, goal setting and self-monitoring). The co-design process resulted in a mobile app being chosen as the mode of delivery for the intervention.

Conclusions: This paper offers a comprehensive description and analysis of using co-design methods to develop a mother-daughter mobile health intervention prototype that is ready for feasibility and acceptability testing. The Behaviour Change Wheel, Theoretical Domains Framework, and Behaviour Change Techniques Ontology provided a systematic and transparent theoretical foundation for developing the prototype by enabling the identification of potential pathways for behavior change. Annotating the Behaviour Change Intervention Ontology entities represents the intervention characteristics in a detailed and structured way that supports improved communication, replication, and implementation of interventions.

XSL•FO
RenderX

(JMIR Pediatr Parent 2025;8:e62795) doi:10.2196/62795

KEYWORDS

physical activity; preteen girls; socioeconomic position; maternal support; mHealth; intervention; co-design; pediatric; daughter; design; development; behavior change technique; Behaviour Change Wheel; sedentary; inactivity

Introduction

Background

Globally, 81% of adolescents are not meeting the recommended physical activity (PA) guidelines [1], with PA levels regressing annually throughout adolescence [2,3]. This rate of decline is more pronounced in girls than boys [1,4] and is most apparent during the transition period from primary to secondary school [5,6]. Studies also indicate that children of lower socioeconomic position (SEP) are less likely to be physically active than those of higher SEP [7-9]. Indeed, this is noteworthy in girls of low SEP, as evidence indicates that this cohort experiences a steeper decline in PA than their more advantaged peers at the transition to adolescence [4,9], putting them at a greater risk of obesity, type 2 diabetes, and cardiovascular disease [8,10]. Most interventions targeting children's daily PA levels have taken place during school hours [11]; however, children are reported to be less active during time spent outside of school, such as at weekends or holidays [12]. Thus, there is a need to also promote PA outside of the school context [13].

Families are a central foundation of support and guidance for children and adolescents in shaping healthy PA behaviors particularly outside of school [14]. Parental support is an umbrella term used to represent numerous support behaviors for PA such as encouragement, logistical support, or coactivity [14,15]. This type of parental support is positively correlated with child PA [16,17], with some evidence for stronger effects for girls when they are supported by their mothers rather than by other family members [18,19]. While there has been a growing interest in family-based PA interventions to promote girls' PA, the evidence for such interventions is mixed [20-22]. These inconclusive findings may be due to factors such as poor study design, small sample sizes, the use of self-report measures, the lack of theory to underpin interventions, the absence of the participant voice in the intervention development process [20,23], and differences between modes of delivery (eg, face-to-face vs eHealth or mobile health [mHealth]) [22,23]. Rapid developments in technology in recent decades have seen an increased use of eHealth and mHealth as modes of delivery for promoting PA in preschoolers [24], children and adolescents [25-27], families [22], and individuals of low SEP [28]. Meta-analyses of eHealth and mHealth PA interventions have reported positive effects for PA-related outcomes in children and adolescents, such as steps per day [25,26] and total PA [26,29], with a lack of improvement in moderate to vigorous PA stated as a limitation [25,29]. Considering the prevalence of smartphone phone use across children, adolescents, and adults [30,31] and the cost-effectiveness, reach, and scalability of mHealth interventions [25,26], there is a pressing need for more robust theory-based mHealth interventions to harness the potential of digital platforms for enhancing PA [22,24,25], particularly for individuals of low SEP [28].

Intervention Development

There is increasing recognition of the need for guidance to support the robust design of interventions targeting health behaviors such as PA. Specifically, the United Kingdom Medical Research Council (MRC) has developed a framework for complex interventions that provides a systematic process for developing and evaluating interventions across 4 interacting stages [32]. Within this process the importance of using theory, considering context, developing and refining a program theory and related logic model, and engaging with stakeholders is emphasized [32]. Theory offers a valuable organizing framework for the development of effective interventions and is necessary to test hypothesis, identify constructs that effect behavior, and enable study replication and generalization [33,34]. There have been mixed findings reported regarding the effectiveness of interventions that are underpinned by theory [35,36], predominantly explained by a lack of clarity as to how a particular theory's constructs (ie, mechanisms of action) are targeted and measured within interventions [33,35]. The Behaviour Change Wheel (BCW) builds on MRC guidance and offers a practical guide for how to develop theory- and evidence-based interventions [37]. The BCW is a synthesis of 19 frameworks for classifying behavior change and facilitates the mapping of intervention targets (ie, the behavior, the population, and the context) to specific mechanisms of action (ie, the processes through which behavior change occurs) [38]. At the core of the BCW is the Capability, Opportunity, and Motivation–Behavior (COM-B) model, which proposes that Capability, Opportunity, and Motivation interact to influence behavior. *Capability* refers to the individual's physical and psychological ability to enact the behavior. *Opportunity* denotes the social and physical resources that facilitate or hinder the behavior. Finally, *Motivation* is defined as the reflective or automatic processes that enable the behavior [37]. The BCW contains 9 different intervention functions that can be applied to target the desired behavior and 7 categories of policy that can be used to deliver these intervention functions. The BCW and associated elements have been successfully used in different contexts to develop interventions promoting PA [39-41]. For example, while using the BCW as part of the development process for a PA app, Truelove et al [39] targeted individuals' physical and psychological capabilities, physical and social opportunities, and reflective and automatic motivation to increase PA levels in Canadian adults. To achieve this, the intervention functions of education, persuasion, incentivization, training, environmental restructuring and enablement were chosen from the BCW to be included in the app, alongside 2 policy categories (communication and marketing, and environment and social planning) to support the delivery of the intervention functions [39]. One study has used the BCW to develop a mother-daughter PA intervention for adolescent girls [41] by selecting 6 intervention functions (education, persuasion, incentivization, training, modeling, and enablement).

XSL•FO
RenderX

The COM-B components of the BCW can be further understood by using the Theoretical Domains Framework (TDF) [42]. The TDF is a validated integrative framework of 14 theoretical domains synthesized from 128 theoretical constructs and 33 behavioral change theories [42]. Additionally, the TDF presents a comprehensive grouping of the overlapping constructs within behavioral theories and supports the identification and selection of relevant mechanisms of action (eg, knowledge and beliefs about capabilities) for targeting within interventions [37,43]. The TDF has been applied across a variety of settings to inform the development of PA interventions [44,45]. For example, a study by McQuinn et al [45] identified the TDF domains of social influences, environmental context and resources, behavioral regulation, beliefs about capabilities, goals, and reinforcement as target mechanisms of action for a co-designed school-based intervention promoting PA in adolescent girls. However, to date, no intervention has used the TDF to identify mechanisms of action for an intervention promoting PA in preteen girls and maternal PA support behaviors.

An intervention achieves its functions through the use of behavior change techniques (BCTs), which are "the smallest part of the behaviour change intervention content that are that are observable, replicable and on their own have the potential to bring about behavior change" (eg, self-monitoring of behavior and problem-solving) [46]. The Behaviour Change Techniques Ontology (BCTO) offers a reliable and extensive classification system for behavior change intervention content. Using the BCTO is considered best practice, as it contains considerably more BCTs than the original BCT Taxonomy version 1 (BCTTv1), has more precise and clear groupings, labels and definitions, and links to other characteristics of an intervention, such as mechanisms of action [47]. The influence of intervention content (eg, BCTs) on behavior can differ depending on how it is delivered to participants, and therefore vary its effectiveness [48]. The recently developed Behaviour Change Intervention Ontology (BCIO) assists researchers to fully specify and classify intervention characteristics (eg, delivery) in a way that supports improved communication, replication, and implementation of effective interventions [46]. Within the BCIO, the delivery of an intervention is divided into the following components: (1) mode of delivery (ie, the medium through which an intervention is provided) [49], (2) intervention setting (ie, the setting where an intervention takes place) [50], (3) intervention schedule (ie, the timing of intervention components), and (4) intervention style of delivery (ie, the manner in which the intervention is delivered) [48]. Using the BCIO entities to annotate the delivery of an intervention increases our understanding of how the effect of intervention content differs according to the mode and style within which it is delivered [48]. While using the BCIO may be time consuming for researchers, it is increasingly used for evidence synthesis [51,52] and intervention development [53,54]. The BCIO has not yet been applied in PA interventions as it is a new development and is only recently available. To our knowledge, this is the first study to use the BCIO entities to annotate the characteristics of an intervention targeting PA in children.

Objectives

Alongside this increased emphasis on a systematic theory-informed intervention development, a collaborative approach to intervention design involving the end users of research is essential. Co-design methods ensure meaningful involvement of the end user in the research process [55] by enabling the specific needs and preferences of the target population to be recognized and allowing for the identification of potential implementation challenges early in the intervention development process [56]. Indeed, research that involves end users in the design process leads to interventions that are more contextually relevant and thus more effective [57]. However, while there is a continued call for greater involvement of young people in the research process through participatory methods such as co-design [58,59], only a few studies on family-based interventions targeting girls' PA [41] or on PA in teenage girls from lower SEP have applied such methods [45,60]. Therefore, the purpose of this study was to provide a detailed outline of the systematic process undertaken to using the BCW and TDF to develop an evidence-based and theoretically informed behavior change intervention, using co-design methods, to promote PA in preteen girls incorporating maternal support behaviors, before preliminary testing for feasibility and efficacy.

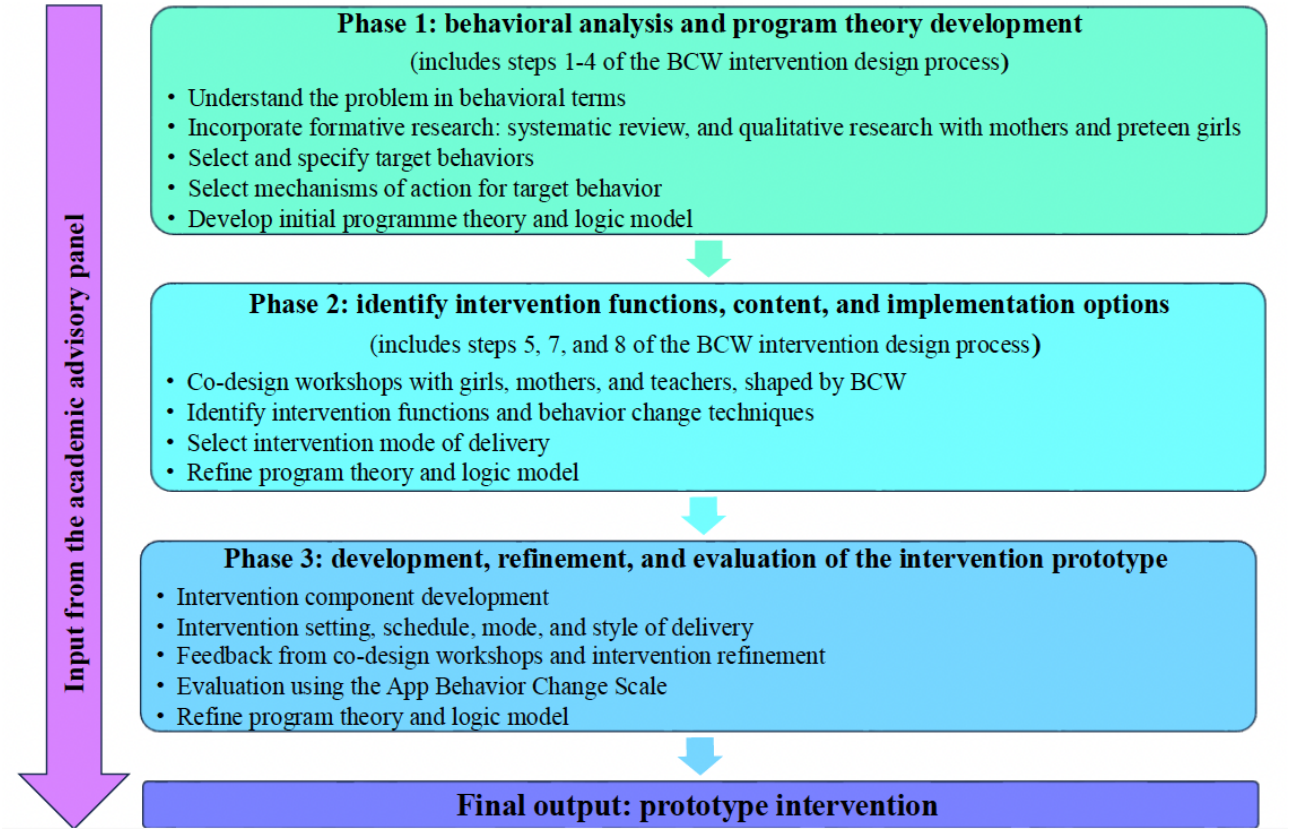
Methods

Overview

This study was informed by the initial development stage of the MRC framework for complex interventions [32]. In line with MRC guidelines, a program theory and logic model were developed and refined throughout the intervention development process. A program theory is a tool that can be used to unpack the relationship between the intervention activities and intended outcomes [61]. Logic models can assist in visually representing the program theory to effectively communicate with research team members and stakeholders [61]. The intervention prototype developed across 3 phases (Figure 1). Phase 1 was guided by the steps in the BCW process [37] and also incorporated the TDF to identify more specific mechanisms of action [42]. Phase 2 involved co-design workshops with stakeholders (ie, mothers, preteen girls, and primary school teachers) to identify potential intervention components and mode of delivery. In phase 3, the prototype was refined through an iterative and dynamic process based on evidence, theory, and input from additional co-design workshops with stakeholders (ie, mothers, preteen girls, and primary school teachers). An academic advisory panel provided guidance throughout the process. The BCIO entities were annotated to report the intervention characteristics; some of the BCIO unique identifiers are provided in the manuscript, with a full list available in Multimedia Appendix 1.

XSL•FO
RenderX

Figure 1. Overview of the intervention development process. BCW: Behaviour Change Wheel.



Ethical Considerations

Ethics approval was obtained by the University College Dublin's Human Research Ethics Committee (LS-22-62) before study commencement. No payments or incentives were offered for participation. Information packs containing information sheets and consent and assent forms were distributed to mothers, children, and teachers alike.

Recruitment

Co-Design Participants

A suburban primary school identified by the Department of Education's Delivering Equality of Opportunity in Schools (DEIS) program was identified as suitable for this study. The Department of Education uses the DEIS classification system to support students attending schools situated in communities at risk of social and economic disadvantage [62]. To classify schools as meeting the DEIS criteria, data from the Department of Education's online database and the HP Deprivation Index for Small Areas (HP Index) are used [62]. The HP Index is a process that measures the relative affluence or disadvantage of small geographical areas using categories such as demographic growth, dependency ratios, education levels, single parent rate, overcrowding, social class, occupation, and unemployment rates [62]. The school in this study is a mixed primary school based in a suburban town located 10 km from Dublin city center, Ireland, with approximately 520 pupils and 33 teachers. After discussions between the lead author (CB) and the school principal, the school principal invited mothers and female guardians of girls aged 10 to 12 years, girls aged 10 to 12 years, and teachers to take part in the study. All girls who were aged between 10 and 12 years and from fourth, fifth, or sixth class were eligible to take part.

Academic Advisory Panel

As part of the research process, an academic advisory panel was established to discuss the findings from the co-design workshops, the use of theory, and support the research team (CB and JM). This panel consisted of 3 academics (GO'D, AK, and RER) with expertise in PA, sedentary behavior, and the development of complex interventions and co-design methodologies. Both GO'D and AK are experienced qualitative researchers and have conducted previous studies exploring PA and sedentary behavior using the TDF, and RER is an experienced researcher with an applied focus on PA during life transitions.

Intervention Prototype Development Process

Phase 1: Behavioral Analysis and Program Theory Development

Phase 1 included steps 1 to 4 of the BCW intervention design process [37]. In line with this approach, the definition of the problem in behavioral terms (step 1) was based on findings from previous literature (ie, preteen girls are not active enough) [1,4]. A systematic review of mother-daughter interventions and formative qualitative research (ie, interviews with 29 mothers of preteen girls and 19 focus groups with 107 low-SEP preteen girls) was then conducted to further understand the problem and the related factors. This was followed by selection and specification of the intervention target behaviors (steps 2 and 3 of the BCW process). After these steps, CB and JM used the TDF to identify the barriers and enablers of the target

XSL•FO
RenderX

behaviors. These were presented to the academic advisory panel (GO'D, AK, and RER) to establish what needs to change to achieve the target behaviors (step 4; Multimedia Appendix 2 [6,14,63-76]). This led to the selection of specific mechanisms of action to be targeted within the proposed intervention. An initial program theory and related logic model for the intervention were then developed.

Phase 2: Identify Intervention Functions, Content, and Implementation Options

This phase includes steps 5, 7, and 8 of the BCW intervention design process [37]. Three co-design workshops took place at the school premises during school hours and were facilitated by CB and JM. Three separate groups took part in a co-design workshop: (1) mothers of preteen daughters (n=9), (2) preteen girls (n=10), and (3) teachers (n=6). The workshops took place in April 2023, with a mean duration of 52 (SD 1.9) minutes. The aim of these workshops was to identify potential intervention functions, BCTs, and modes of delivery to target the proposed mechanisms of action identified in phase 1. A range of age-appropriate and interactive methods were used in these co-design sessions (Multimedia Appendix 3). For example, to encourage participants to think about the practical application of their suggestions to a wide variety of mothers and girls, personas of mothers and girls who were individually, socially, and geographically diverse were provided [77]. Using the information gathered from these co-design sessions, along with findings from phase 1 and further consultation with the academic advisory panel (GO'D, AK, and RER), intervention functions (step 5), BCTs (step 6), and a proposed mode of delivery (step 8) were selected by the research team (CB and JM). The program theory and logic model were also refined.

Phase 3: Development, Refinement, and Evaluation of the Intervention Prototype

This phase involved incorporating the findings from phase 2 into the development of the intervention components. A second series of co-design workshops (n=3) took place in the school premises during school hours and were facilitated by CB and JM. The same participants as phase 1 took part. The three separate workshop groups were (1) mothers of preteen daughters (n=6), (2) preteen girls (n=10), and (3) teachers (n=3). The workshops took place in June 2023, with a mean duration of 44 (SD 5) minutes. The aim of the workshops was to obtain participants' feedback on the acceptability of the proposed intervention components (Multimedia Appendix 4). Following these workshops, the research team (CB and JM) discussed the findings from the workshops, the proposed intervention components, and the use of theory with the academic advisory panel (GO'D, AK, and RER). The 21-item App Behavior Change Scale [78] was also used by the research team to ensure that relevant behavior change components were appropriately included. This scale has been used in several studies targeting PA to assess intervention effectiveness [39,79]. The program theory and logic model were refined for the final time.

Results

Phase 1: Behavioral Analysis and Program Theory Development

As described in the Introduction section, the identified problem behavior was the decline in PA as children transition to adolescence, with this decrease in activity levels particularly prevalent for girls of lower SEP [1,4]. Children whose parents support PA are likely to have higher overall levels of activity than children whose parents do not support their PA, with stronger effects when that support is provided by a parent of the same gender [80,81]. The formative research related to this study is described in previous studies, [82-84] therefore a brief description of it is provided here. A review of behavior change theories and techniques used in mother and daughter PA interventions highlighted a lack of clarity as to why interventions were effective or not and the increased need for a stronger theoretical basis for future interventions as well as enhanced reporting of how these interventions are developed [82]. Qualitative formative work with mothers of preteen girls highlighted barriers and enablers related to engaging in PA-supportive behaviors with their daughters [83]. These ranged from individual-level factors such as their PA-related identity and their confidence to engage in supportive behaviors to social and environmental factors such as the role of other family members and the infrastructure within their communities and their daughters' schools [83]. Finally, qualitative work was conducted with preteen girls who discussed barriers and enablers to their PA, such as the importance of skills and confidence to support their engagement in PA and strengthen their self-identity for PA alongside the important role of family members, friends, teachers, and coaches [84]. On the basis of this formative work, 2 related behaviors were deemed appropriate to target as part of the intervention. The first behavior was to improve mothers' support for their preteen daughters' PA and, in doing so, indirectly increase the likelihood of preteen girls engaging in PA. The second behavior being targeted was to increase preteen girls' PA. These behaviors are presented in Table 1 in terms of who needs to perform the behavior, when, where, and with whom.

The academic advisory panel then reviewed the analysis of the barriers and enablers to the target behaviors. Following discussion with the advisory panel, the research team then chose 11 of the 14 TDF domains as proposed mechanisms of action for enabling these target behaviors (Table 2).

XSL•FO
RenderX

Table 1. Specification of target behaviors of interest.

	Target behavior 1	Target behavior 2
What behavior	Improve mothers' PA[a] support behaviors (eg, encouragement, logistical support, coactivity, and environmental and regulatory support) for their preteen daughters	Increase preteen daughters' PA (includes active travel, sport, family activities [bike rides and walks], and outdoor play)
Who	Mothers of preteen daughters of low SEP[b]	Preteen daughters of low SEP
When	Daily	Daily
Where	In their household residence (BCIO[c]: 026009), sport and exercise facility (BCIO: 026030), and outdoor environment (BCIO: 026044)	In their household residence (BCIO: 026009), sport and exercise facility (BCIO: 026030), and outdoor environment (BCIO: 026044)
With whom	Preteen daughters	Friends, mothers, and other family members

[a]PA: physical activity.

[b]SEP: socioeconomic position.

[c]BCIO: Behaviour Change Intervention Ontology.

XSL•FO
RenderX

Table 2. Mechanisms of action, intervention functions and behaviour change techniques for mother-daughter intervention.

Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA[a] support and promoting PA in preteen girls	BCTs[b] from BCTO[c] for improving maternal PA support and promoting PA in preteen girls
Knowledge Develop mothers' and daughters' understanding of the following: • The rationale and purpose of the program • The types and benefits of PA and PA guidelines • How to be physically active • The types and benefits of maternal PA support behaviors • How to perform maternal PA support • Typical challenges experienced by mothers while engaging in PA support (eg, pushback from daughter) • Typical challenges experienced by preteen girls while engaging in PA support (eg, friends not active) • Available resources to facilitate engagement in PA and PA support	*Education* • About the rationale and purpose of the program • About ways of enacting desired behavior and avoiding undesirable ones • Provide credible, appealing information that can be used to enact target behavior • Provide clear, consistent, and standardized messages about maternal PA support and PA • Provide information to address prevalent misconceptions about maternal PA support and PA behaviors	• Instruct how to perform behavior BCT (BCIOd:007058) • Inform about health consequences BCT (BCIO:007063) • Inform about social consequences BCT (BCIO:007064) • Inform about environmental consequences BCT (BCIO:007176) • Present information from credible influence BCT (BCIO:007075)
Skills Develop skills to do the following: • Select and engage in PA and PA-supportive behaviors • Apply problem-solving and set and review personalized goals for PA and PA support behaviors • Monitor progress of physical activity behaviors • Monitor progress in supporting daughter to be active; overcome the challenges encountered while engaging in selected PA and PA support behaviors	*Training* • Practice and engage in PA support and PA behaviors • Engage in problem-solving and select and review goals related to target behavior • Monitor progress when engaging in PA support and PA behaviors • Engage in behavioral strategies to overcome challenges associated with providing support or being active	• Goal strategizing BCT (BCIO:007008) • Provide feedback on behavior BCT (BCIO:007023) • Self-monitor of behavior BCT (BCIO:007024) • Instruct how to perform behavior BCT (BCIO:007058) • Demonstrate the behavior BCT (BCIO:007055) • Practice behavior BCT (BCIO:007094) • Context-specific repetition of behavior BCT (BCIO:007096) • Set graded tasks BCT (BCIO:007100)
Social role and identity • Develop mothers' identity as a person who provides support for their daughters' PA • Develop mothers' and daughters' identity as a person who is physically active	*Education* • About how to link supportive and PA behaviors to other intrinsic goals • Provide information about positive experiences when supporting their daughter to be active or being active and how to overcome associated challenges • Provide information about extra resources available to help mothers provide support or preteen daughters be active when program ends *Persuasion* • Highlight compatibility with current identity, but expand it to include maternal PA identity or PA behaviors and social identities • Emphasize the role of mother as change agent for daughter and in family	• Social support BCT (BCIO:007028) • Inform about social consequences BCT (BCIO:007064) • Prompt social comparison BCT (BCIO:007073) • Practice behavior BCT (BCIO:007094) • Present information from credible influence BCT (BCIO:007075) • Identify self as role model BCT (BCIO:007158) • Reframe past behavior BCT (BCIO:007056) • Adopt changed self-identity BCT (BCIO:007160)

XSL•FO
RenderX

Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA[a] support and promoting PA in preteen girls	BCTs[b] from BCTO[c] for improving maternal PA support and promoting PA in preteen girls
Beliefs about capabilities Improve perceived competence in ability to do the following: • Perform selected PA and PA support behaviors • Use problem-solving, goal setting, and action planning to engage in PA and PA support • Ability to monitor progress • Overcome challenges encountered while enacting PA and PA support • Engage in long-term PA and PA support behaviors	*Persuasion* • Enhance perceived competence to problem solve, actions plan, select and monitor goals, and self-monitor PA support and PA behaviors • Encourage mothers to believe that providing support is possible or daughters to believe that being active is possible, even given constraints of their circumstances *Enablement* • Assist mothers or daughters in problem-solving and action planning to overcome barriers to providing support or being active *Modeling* • Present real-life examples of mothers or preteen girls in similar circumstances	• Goal strategizing BCT (BCIO:007008) • Social support BCT (BCIO:007028) • Instruct how to perform behavior BCT (BCIO:007058) • Demonstrate the behavior BCT (BCIO:007055) • Practice behavior BCT (BCIO:007055) • Set graded tasks BCT (BCIO:007100) • Advise how to reduce negative emotions BCT (BCIO:050344) • Persuade about personal capability (BCIO:007137) • Prompt focus on past success BCT (BCIO:007139) • Prompt self-talk BCT (BCIO:007140)
Beliefs about consequences • Enhance mothers' expectations related to the positive consequences of engaging in selected PA support • Enhance mothers' and daughters' expectations related to the positive consequences of engaging in selected PA behaviors	*Education* • Explore beliefs and attitudes related to PA and the associated health benefits • Explore beliefs and attitudes between providing PA support and expected outcomes *Persuasion* • Enhance beliefs that being physically active has positive health benefits in the short and long term • Provide expert information about how, where, and why to be active • Enhance beliefs that providing support for daughters' PA would be beneficial • Provide expert information about the short- and long-term benefits of providing PA support *Modeling* • Provide demonstrations of mothers of teen girls or preteen girls to show the benefits they received as a result of providing support or being active	• Inform about health consequences BCT (BCIO:007063) • Inform about social consequences BCT (BCIO:007064) • Inform about environmental consequences BCT (BCIO:007176) • Monitor emotional consequences BCT • (BCIO:007066) • Demonstrate the behavior BCT (BCIO:007055) • Prompt social comparison BCT (BCIO:007073) • Present information from credible influence BCT (BCIO:007075)
Intentions • Increase mothers' and daughters' autonomous motivation to • Engage in and maintain selected PA or PA support behaviors • Engage in problem-solving and setting and reviewing goals to facilitate engagement in selected PA and PA support behavior • Engage with tools to monitor progress	*Education* • Inform about importance of formulating intentions of how and where to provide support or be active *Persuasion* • Encourage mothers and daughters to consider why being active might be important to them and the benefits they will receive • Encourage mothers to consider why providing PA support may be important to them and how it would benefit their daughter and other family members *Modeling* • Provide demonstrations of mothers and preteen girls describing their experiences of setting short- and long-term intentions to be provide support or be active and the associated benefits	• Set behavior goal BCT (BCIO:007003) • Inform about health consequences BCT (BCIO:007063) • Inform about social consequences BCT (BCIO:007064) • Inform about environmental consequences BCT (BCIO:007176) • Instruct how to perform behavior BCT (BCIO:007058) • Demonstrate the behavior BCT (BCIO:007055) • Prompt social comparison BCT (BCIO:007073) • Present information from credible influence BCT (BCIO:007075)

XSL•FO
RenderX

Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA[a] support and promoting PA in preteen girls	BCTs[b] from BCTO[c] for improving maternal PA support and promoting PA in preteen girls
Goals • Support mothers and daughters to • Use action planning, problem-solving, and goal setting to facilitate engagement in selected PA and PA support behaviors • Use tools to monitor progress • Overcome challenges encountered while setting and reviewing goals	*Training* • Select and review personalized goals related to the target behavior *Enablement* • Provide support and guidance for setting realistic goals for mothers to provide support or to preteen girls to be physically active • Affirm small achievable and interim goals and successes • Prompt planning to provide PA support or be active during and after the intervention	• Set behavior goal BCT (BCIO:007003) • Goal strategizing BCT (BCIO:007008) • Action planning BCT • (BCIO:007010) • Provide feedback on behavior BCT (BCIO:007023) • Self-monitor behavior BCT (BCIO:007024) • Instruct how to perform behavior BCT (BCIO:007058) • Demonstrate the behavior BCT (BCIO:007055) • Practice behavior BCT (BCIO:007055) • Set graded tasks BCT (BCIO:007100)
Environmental context and resources • Provide knowledge of and access to a variety of PA opportunities available so that mothers can support daughters' PA and daughters can engage in PA • Provide materials or equipment so that mothers can support their daughters PA or daughters can be active	*Environmental restructuring* • Provide mothers or preteen daughters with practical equipment that can enable them to be active, for example, skipping ropes and balls • Provide mothers and daughters with access to feasible and realistic options that enable them to be active during and after the intervention *Enablement* • Provide practical support for mothers and daughters to action plan and problem solve to engage in PA support and PA behaviors	• Goal strategizing BCT (BCIO:007008) • Action planning BCT (BCIO:007010) • Social support BCT (BCIO:007028) • Present information from credible influence BCT (BCIO:007075) • Add objects to the environment BCT (BCIO:007156)
Social influences • Develop mothers' and daughters' understanding of the type of support available to them regarding supporting their daughters' PA and being active • Develop mothers' and daughters' ability to engage with the social support available to them	*Modeling* • Provide demonstrations of other mothers and girls describing their experiences for seeking and receiving social support and the benefits they received as a result *Enablement* • Prompt mothers and preteen daughters to seek social support and provide examples of types of social support available to them	• Social support BCT (BCIO:007028) • Advise to seek instrumental support BCT (BCIO:007030) • Demonstrate the behavior BCT (BCIO:007055) • Prompt social comparison BCT (BCIO:007073) • Present information from credible influence BCT (BCIO:007075) • Provide positive social consequence for behavior BCT (BCIO:007265) • Persuade about personal capability BCT (BCIO:007137)
Emotion • Promote positive and reduce unpleasant emotions associated with providing PA support (eg, embarrassment while being active with daughter) and being active (eg, enjoyment in activities)	*Persuasion* • Help mothers and daughters recognize the positive feelings associated with providing support or being active *Enablement* • Provide safe and nonjudgmental environment for mothers or daughters to explore emotions around providing support or being active • Provide opportunities for mothers or daughters to evaluate their emotional state after providing support or being active	• Goal strategizing BCT (BCIO:007008) • Social support BCT (BCIO:007028) • Monitor emotional consequences BCT (BCIO:007066) • Present information from credible influence BCT (BCIO:007075) • Advise how to reduce negative emotions BCT (BCIO:050344) • Reframe past behavior BCT (BCIO:007056)
Behavioral regulation Develop mothers' and daughters' ability to do the following: • Select and apply PA or PA support behaviors into their daily life • Implement tools to monitor PA or PA support progress	*Training* • Provide means so that mothers and daughters can assess their progress during the intervention and in the future *Enablement* • Provide opportunity, support, and tools to self-monitor PA support or PA behaviors and related habits	

XSL•FO
RenderX

Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA[a] support and promoting PA in preteen girls	BCTs[b] from BCTO[c] for improving maternal PA support and promoting PA in preteen girls
		• Goal strategizing BCT (BCIO:007008) • Action planning BCT (BCIO:007010) • Self-monitor behavior BCT (BCIO:007024) • Instruct how to perform behavior BCT (BCIO:007058) • Demonstrate the behavior BCT (BCIO:007055) • Practice behavior BCT (BCIO:007055) • Substitute behavior BCT (BCIO:007095) • Context-specific repetition of behavior BCT (BCIO:007096) • Provide positive social consequence for behavior BCT (BCIO:007265) • Advise how to reduce negative emotions BCT (BCIO:050344) • Prompt self-talk BCT (BCIO:007140)

Phase 2: Identify Intervention Functions, Content, and Implementation Options

The co-design workshops led to a number of recommendations from preteen girls, mothers, and teachers. These recommendations are illustrated in Table 3 using exemplar quotes and were categorized under a range of intervention functions as per the BCW intervention design process [37]. The intervention functions included education, training, persuasion, modeling, enablement, incentivization, and environmental restructuring. Potential modes of delivery discussed included face-to-face delivery, remote synchronous delivery (eg, Zoom Communications, Inc), or the use of a mHealth application. The mothers' group recommended the use of a mHealth application as a potential mode of delivery. These recommendations informed the selection of potential intervention functions, BCTs, and a proposed mode of delivery (ie, mHealth application) for each target behavior by the research team and were presented to the academic advisory panel for review. The final listing of intervention functions and BCTs for each mechanism of action are presented in Table 2. The academic advisory panel suggested applying of the principles of self-determination theory (SDT) [85] to the mHealth application content to enhance the communication style within which it is delivered [48].

XSL•FO
RenderX

Table 3. Summary table of the co-design workshops.

	Summary of the recommendations from workshops	Example quotes	Related intervention functions
Improving mothers' knowledge and understanding of PA[a] and PA support	• Provide mothers with information about the different types of PA, the benefits of PA, how to be active, and how much PA is recommended for daughters and themselves • Provide mothers with information and instruction about how to support their daughters, particularly as they transition into teenage years • Provide mothers with more information about what is available to them in their local area for their daughters to be active or for them to be active with their daughters • Information could be provided through videos, social media, websites, an app, parent-teachers association, and word of mouth	• "Maybe something about their mental and physical development, psychosocial development at this age that would help mothers understand what they're going through." [Imelda, daughter in fifth class] • "Making sure mothers know how often children, girls at that age should be exercising each week. Maybe if they're not conscious that they're doing their weekly exercise, how are they supposed to pass it on to their children." [Kate, primary school teacher] • "if you were thinking of an app and giving people ideas, could add the likes of yoga and stuff." [Susan, daughter in sixth class]	• Education • Training
Persuading mothers to support their daughters to be active	• Present mothers with examples of other mothers, coaches, teachers, and local sports partnership representatives explaining how, where, and the benefits of supporting daughters to be active • Provide examples of other mothers supporting their daughters to be active, how they overcame challenges, and being active themselves or with their daughters or family members • Use mainstream media, social media, videos, websites, apps, and word of mouth to promote positive messages	• "Or other mammies probably. I think other mammies would be good to see. Well, if they can balance it, I'm sure there's ways around that we can balance it." [Niamh, daughter in fourth class] • "Someone giving them their personal story" [Sharon, primary school teacher] • "an app would be great because the kids are on it...you can challenge your friends or family members and track what you have done." [Sinead, daughter in sixth class]	• Persuasion • Modeling
Practical help for mothers to engage in support behaviors	• Assistance with cost of activities, thus provide opportunities to try out in school or community for free first • Provide materials for mothers to plan, record, and monitor their PA support behaviors at their own time and pace • Feedback on behavior, in particular, if they engage in activities with daughters, either through technology or in person	• "And the cost of living at the moment is crazy as well. Like you should be really dropping. If the cost of it came down a bit, I think a lot more people would do it, absolutely." [Michelle, daughter in fourth class] • "If you're doing that at your own pace, in your own time. There was ideas on of, you can do this today, tomorrow, next week, or whatever, but also a blank space that you could fill in what you've done. I wasn't able to do this, but I did this, or we done that." [Sinead, daughter in sixth class] • "You can break it into profiles like you can have yours, your partners, your daughters, whatever. It's under the one branch, basically. But you have your own little sections as well, where there's probably things tailor-made for you for that age group. You put in your age, you put in your interest or something...Like Netflix." [Imelda, daughter in fifth class]	• Incentivization • Environmental restructuring

XSL•FO
RenderX

	Summary of the recommendations from workshops	Example quotes	Related intervention functions
Social support for mothers	• Provide opportunities for mothers to get support from other mothers of preteen daughters, for example, Facebook group • Opportunities to get to know other mothers at daughters' activities	• "every club should have a mammies group." [Niamh, daughter in fourth class] • "then you could have like a chat group for them (mothers) on the app." [Susan, daughter in sixth class] • "Yeah, support network through your app, through your group or whatever. Just like, oh, I've done this week, you might like it or I found this video, you might like it whatever." [Anna, primary school teacher] • "Because some of the other parents have groups themselves where they can keep in contact. If one parent doesn't want to do it, the second parent may motivate them to do it. While we're all doing this together." [Joe, primary school teacher]	• Enablement
Improving daughters' knowledge and understanding of PA	• Provide daughters with information and instructions about the different types of PA, the benefits of PA, how to be active in their leisure time, and how much PA is recommended • Provide daughters with information about what is available to them in their local area to be active. Information could be provided through videos, social media, websites, an app, and word of mouth	• "tips on how to play a game or rules of the game." [Emily, fifth class] • "we could have like speakers, people going into the classroom and talking to girls to join sports." [Sophie, sixth class] • "Some people post on YouTube how to do skills. If you're a beginner and you want to learn some skills, you could just look at some YouTube videos and then that would do it." [Robyn, sixth class] • "But the danger is that there are parents who don't know and don't care, and they probably won't look at an app. I would be afraid of that happening...let the child have their own profile." [Jennifer, daughter in sixth class]	• Education • Training
Persuading daughters to be active	• Provide encouragement for daughters with examples of coaches, teachers, and local sports partnership representatives explaining how, where, and the benefits of being active • Provide examples of other preteen girls and older adolescent girls being active and how they overcame challenges • Use mainstream media, social media, videos, websites, apps, and word of mouth to promote positive messages	• "You could tell them how worth it will be when they get stronger and healthier and they can run more. Basically, classes, carrying, and shopping, you'll just get quicker and it'll become easier." [Emily, fifth class] • "They might because they are their own age feel like they are like them." [Aisling, fifth class] • "Probably get girls that do sports, like making ads or something. If girls are watching their phones and you could do that." [Evie, sixth class] • "Like that, if there were videos that they (girls) could click into." [Sharon, primary school teacher]	• Persuasion • Modeling
Practical help for daughters to engage in leisure time PA	• Cost of activities is a barrier, so provide opportunities to try them out in school or community for free first (initial cost) • Provide materials for daughters to plan, record, and monitor their PA behaviors, including opportunity to arrange a reward of their choice for themselves • Feedback on behavior if they engage in activities • Provide equipment and merchandise for daughters to practice with at home, for example, footballs, basketballs, skipping ropes, T-shirts, jerseys, hoodies, water bottles, and merchandise	• "You can write a to-do list, so that way you can be more motivated to keep on schedule."[Emily fifth class] • "They could lend them a ball to practice." [Maisie, fifth class] • "Something like if you have all the jumpers and the jersey's, it makes you feel a part of the team, so you want to go again because you are part of this team." [Evie, sixth class] • "If you could practice it at home to see if you like it." [Sarah fourth class]	• Incentivization • Environmental restructuring
Social support for daughters			• Enablement

XSL•FO
RenderX

	Summary of the recommendations from workshops	Example quotes	Related intervention functions
	• Provide opportunities for daughters to get support from other preteen girls, for example, bringing friends to activities and opportunities to ask girls their own age about certain activities • Opportunities to get to know other girls at activities. Can be organized by coaches, teachers, and other club members	• "They could get a friend to join with them so that they have someone to talk to." [Aisling, fifth class] • "Maybe if one of your friends was not on the team can now join the sport, you could even ask them if they wanted to come down to maybe one of your matches so they could have a look and see what the sport is all about and that might make them want to join." [Sophie sixth class]	

[a]PA: physical activity.

Phase 3: Development, Refinement, and Evaluation of the Intervention Prototype

Intervention Component Development

The research team developed separate mobile apps for each target behavior (ie, mothers' support behaviors and preteen daughters' PA) using the *Pathverse* app design platform for mHealth research [86]. This platform enables researchers to develop mobile apps for testing without the requirement of software developers. It is a "no-code" development platform, which allows researchers to create a mobile app with "drag and drop" features instead of coding [87]. The *Pathverse* platform includes features such as the design of customized multimedia content, implementation of participant surveys, provision of self-monitoring tools, setting of personalized goals, the customization of app notifications, digital badges, and a community group chat option [86]. Intervention components were developed within this platform to ensure that the relevant mechanisms of action were targeted and the related BCTs were enacted. Examples of how the intervention components relate to the targeted mechanisms of action are provided in Tables 4 and 5 for mothers and preteen daughters, respectively. For example, for the mothers' intervention, app module 3 titled "What does supporting your daughter involve?" includes infographics about the benefits of and the different ways for mothers to support their daughter to be active. It also includes videos of mothers describing their experiences of engaging in different supportive behaviors. Similarly, in the daughters' intervention, app module 3 titled "Why should you be active?" includes infographics and a video about the benefits of being active as well as a video of a preteen girl describing her experiences of engaging in PA. The mechanisms of action that these modules target are "knowledge," "beliefs about consequences," and "social influences."

XSL•FO
RenderX

Table 4. Intervention components mapped to the mechanisms of action in the mothers' intervention.

	Intervention components, activities, and resources	Mechanisms of action
Week 1: introduction to the study and group meeting (included after feedback from the co-design workshops, session 2)	• Face-to-face meeting with the mothers who are taking part in the study and introducing them to the research team and providing information about the study and consent forms, equipment and merchandise that are part of study (eg, footballs, skipping rope, yoga mat, T-shirts, and water bottles), demonstration of how to download the app and navigate the modules and features of the app, and inform mothers that they will receive certificate for taking part at the end of the study.	• Knowledge • Beliefs about consequences • Environmental context and resources
App module 1: getting started	• Includes a video with a welcome message and brief description about the study; a video demonstrating how to use the app and answer survey questions; and a survey with questions about demographics, PAa levels, and providing support for daughter's activities	• Knowledge
App module 2: what is PA and why is it important?	• Includes infographics about the module objectives, PA and benefits of being active, how active adults should be, how active children and teenagers should be, the benefits of PA for children and adolescents, and how active our teenage girls currently are • A multiple-choice challenge question about how active children should be and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences
App module 3: what does supporting your daughter to be active involve?	• Includes infographics about the module objectives; why mothers were chosen for the study; the benefits of and ways to support their daughter to be active, for example, providing transportation to their daughter's activities; spectating at daughter's activities; and how and where mothers can be active with their daughters • A video with a mother of preteen girls describing her experience of spectating at her daughter's activities • A multiple-choice challenge question about what a mother can do to help support their daughter to be active and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Social influences
App module 4: who can help you support your daughter?	• Infographics about the module objectives, the benefits of social support, having families as a source of support, how friends can support, how neighbors and people in the local community can support, how a daughter's friends can facilitate providing support, how coaches and teachers can support, and how support groups both web-based and in the local community can help mothers • A video of mothers of preteen girls describing how they avail the social support available to them • A multiple-choice question about who can help mothers with the day-to-day challenges of supporting their daughter to be active and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Intentions • Social influences

XSL•FO
RenderX

	Intervention components, activities, and resources	Mechanisms of action
App module 5: tips to help you support your daughter	• Infographics about the module objectives, the challenges mothers face when supporting their daughter and how to overcome them, to remember why supporting their daughter can help do what is important to them, tips for how to get started when feeling overwhelmed, details about shared decision-making and how it could be helpful, and how to manage a lapse in behavior • A video with tips and advice from a role model, for example, mother of an athlete and how they support their daughter • A multiple-choice questions about the types of support messages mothers would like to receive throughout the study as push notifications (eg, reminders, encouragement, praise, affirmations, or inspirational) and a digital badge of congratulations for reaching the end of the module	• Knowledge • Skills • Identity • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion
App module 6: next steps: planning to support your daughter	• Includes infographics about the module objectives, what is goal setting, why and how to set goals, challenges associated with goal setting and how to overcome them, and showing mothers how they can self-monitor their progress in the app • Provide selection goals related to maternal PA support (eg, spectate at daughter's activity and mother and daughter coactivity) • Mothers select and set a PA support goal of their choice, including when and where and how often the support behavior would be enacted, and a digital badge wishing mothers "good luck" with their chosen goal	• Knowledge • Skills • Beliefs about capabilities • Beliefs about consequences • Intentions • Goals • Behavioral regulation
App module 7: booster module (included after feedback from co-design workshops, session 2)	• Includes infographics about the module objectives; recap on maternal PA support behaviors; how to overcome potential barriers to providing support, for example, using if...then statements; and how lapses in behaviors are normal • A video with messages of encouragement and support from other mothers of teenage girls and a digital badge of congratulations for reaching the end of the module	• Knowledge • Identity • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion • Behavioral regulation
App module 8: final module	• Includes infographics with a summary of the study, recap on maternal PA support behaviors, goal setting, how to overcome challenges, where to look for social support, and what to do next • A survey with questions about PA levels for mothers and daughters and regarding providing support for daughter's activities • A survey providing feedback about acceptability and feasibility of the study and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Intentions • Social influences • Behavioral regulation
App icon: resources	• Links to external websites providing information on local resources, family support services, and community events. Includes podcasts about parenting for PA with a focus on mothers and girls, videos of skills or activities that mothers can practice with daughter (eg, yoga, exercises, and football skills), and videos of other mothers of preteen girls discussing and sharing their experiences	• Knowledge • Skills • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion
App icon: goals	• Summary of goals set for the duration of the study • Mothers can review progress of goals set in the module, for example, spectate at daughter's activity or walk to school with daughter twice a week. Mothers can manually set and record additional goals of their choice	• Intentions • Goals • Behavioral regulation

XSL•FO
RenderX

	Intervention components, activities, and resources	Mechanisms of action
App icon: trackers history	• Option available for mothers to self-monitor their progress of goals set that are paired with a smartwatch that is synced with the app, for example, step count and exercise minutes. Mothers can self-monitor their daily steps and exercise minutes manually. Mothers manually self-monitor an activity (eg, walked to school with daughter), rate their enjoyment factor, and record any notes or points of interest	• Intentions • Goals • Behavioral regulation
App icon: chat	• A feature that enables mothers to join a community forum to send and receive messages to and from the research team; an interactive forum where mothers share their experiences and strategies with other mothers who are partaking in the study; and avail of opportunities to meet other mother and daughter participants for group activities, as per information provided by the research team or as suggested by other participants	• Social influences • Emotion
Intervention feature: motivational messages	• Tailored prompts or cues sent as push notifications to mothers that are relative to their chosen goals and generic messages of encouragement, praise, or inspiration that change each day	• Beliefs about capabilities • Identity • Social influences • Emotion
Week 8: conclusion of study and group meeting (included after feedback from co-design workshops, session 2)	• Face-to-face group meeting with mothers to award mothers with a certificate of completion, receive feedback on the intervention, and answer any questions	• Social influences

[a]PA: physical activity.

XSL•FO
RenderX

Table 5. Intervention components mapped to the mechanisms of action in the preteen girls' intervention.

	Intervention components, activities, and resources	Mechanisms of action
Week 1: introduction to the study and group meeting (included after feedback from the co-design workshops, session 2)	• Face-to-face meeting with the girls who are taking part in the study and introducing them to the research team and providing information about the study and consent forms, equipment and merchandise that are part of study (eg, footballs, skipping rope, yoga mat, T-shirts, and water bottles), demonstration how to download the app and navigate the modules and features of the app, and answers to queries or concerns girls may have • Inform girls that they will receive a certificate for taking part at the end of the study	• Knowledge • Beliefs about consequences • Environmental context and resources
App module 1: welcome to our study	• Includes a video with a welcome message and a brief description about the study; a video demonstrating how to use the app and answer survey questions; a survey with questions about demographics, PAa levels, and being active, and a digital badge of congratulations for reaching the end of the module	• Knowledge
App module 2: what is PA?	• Includes infographics about the module contents, what is PA, how active preteen girls need to be, and different ways to be active • A multiple-choice challenge question about how many minutes per day should preteen girls be active for and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences
App module 3: why should you be active?	• Infographics about the module objectives and the benefits of being active • Videos about the benefits of being active, with a preteen girl describing her experiences of being active and the associated benefits • A multiple-choice challenge question about the benefits of being physically active and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Social influences
App module 4: how can you be active?	• Includes infographics about the module objectives; walking or wheeling to school; outdoor play in the neighborhood with friends; going to local parks, woods, and playgrounds with family members; walking the dog as a way to be active; and yoga as a way to be active • Videos about ways in which preteen girls can be active, of interview with famous female sports stars describing their experiences of playing sport and being active, with mothers and daughters dancing together as a way to be active, and of exercises that can be implemented at home as a way to be active • A question about favorite way to be active and a digital badge of congratulations for reaching the end of the module	• Knowledge • Skills • Beliefs about consequences • Intentions • Social influences
App module 5: who can you be active with?	• Includes infographics about the module objectives, who can support girls to be active and the benefits of social support, having fun with friends at school, playing with children in the neighborhood, and being active with family members • Video of other preteen girls sharing their experiences of who they are active with • A multiple-choice question about who girls can be active with and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Intentions • Social influences

XSL•FO
RenderX

	Intervention components, activities, and resources	Mechanisms of action
App module 6: tips to help you be active	• Includes infographics about the module's objectives; why some girls do not want to be active; about how family members or friends can support you to be active; and remembering why you chose to be active, with a support message about what to do when feeling overwhelmed and with a support message about staying positive in times of self-doubt and how to manage a lapse in behavior • A video of preteen and teenage girls sharing their experiences and how they overcame challenges with being active. A video of a famous female sports star discussing their role models, how they overcame challenges related to staying active, and who supported them along the way. A video demonstrating ways to stay active at home • An infographic with a question about tips to help girls be active • A digital badge of congratulations for reaching the end of the module	• Knowledge • Skills • Identity • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion
App module 7: let us get moving	• Includes infographics about the module's objectives, goal setting what is it, why and how to set goals, the challenges associated with goal setting and how to overcome them, and showing girls how they can monitor their progress in the app • Provide a selection of goals related to leisure time PA for girls to choose from • Girls select a goal of their choice, including when and where the activity would be enacted and with whom, and a digital badge wishing girls "good luck" with their chosen goal	• Knowledge • Skills • Beliefs about capabilities • Beliefs about consequences • Intentions • Goals • Behavioral regulation
App module 8: booster module (included after feedback from the co-design workshops, session 2)	• Includes infographics about the module's objectives; revision of PA behaviors; revision of benefits of being active; how to overcome potential barriers to providing support, for example, using if...then statements; and how lapses in behaviors are normal • A video with support messages from other teenage girls and a digital badge of congratulations for reaching the end of the module	• Knowledge • Identity • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion • Behavioral regulation
App module 9: final module	• Infographics about the module's objective; recap on PA and benefits of PA; recap on goal setting; and recap on how to overcome challenges, where to look for social support, and what to do next • A survey with questions about PA levels and being active. A survey providing feedback about acceptability and feasibility of the study and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Intentions • Behavioral regulation
App icon: resources	• Links to websites of resources available to them in their local area • Podcasts about PA, with a focus on girls • Videos of other preteen girls and their experiences	• Knowledge • Skills • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion
App icon: goals	• Summary of goals set for the duration of the study • Girls can review progress of goals set in the module (eg, walk or wheel to school with mother twice a week and practice skills at home) • Girls can manually set and record additional goals of their choice	• Intentions • Goals • Behavioral regulation

XSL•FO
RenderX

	Intervention components, activities, and resources	Mechanisms of action
App icon: trackers	• Option available for girls to self-monitor their progress of goals set that are paired with a smartwatch that is synced with the app (eg, step count and exercise minutes) • Girls can self-monitor their daily steps and exercise minutes manually • Girls manually self-monitor an activity (eg, practiced skills), rate their enjoyment factor, and record any notes or points of interest	• Intentions • Goals • Behavioral regulation
App feature: motivational messages	• Tailored prompts or cues sent as push notifications to girls that are age appropriate and relative to their chosen goals. Generic messages of encouragement, praise, or inspiration that change each day	• Beliefs about capabilities • Identity • Social influences • Emotion
Week 8: conclusion of study and group meeting (included after feedback from the co-design workshops, session 2)	• Face-to-face group meeting with girls to award girls with a certificate of completion, receive feedback on the intervention, and answer any questions	• Social influences

Intervention Delivery

Intervention delivery was considered from 4 perspectives: mode of delivery, intervention setting, schedule, and delivery style in line with the BCIO [49]. As described in Phase 2: Identify Intervention Functions, Content, and Implementation Options section, the intervention's mode of delivery is primarily through a mobile app with a face-to-face component at the start and end of the intervention. The settings where the intervention takes place for mothers and daughters are at their household residences, local sport and exercise facilities, or in outdoor environments (ie, local parks, greens, forests, or beaches). The time frame chosen for the intervention schedule is based on the findings from formative research, which suggested that mother-daughter interventions lasting <12 weeks were likely to be more effective [82], and from engagement with participants in the co-design sessions and the academic advisory panel. The 8-week intervention schedule starts with face-to-face sessions for both mother and daughter participants. Over the course of the first 2 weeks of the intervention, 5 short modules are released for the participants to complete. Following completion of the modules, both mothers and daughters are then required to select and set a goal of their choice related to the target behavior (module 6). They then self-monitor their progress for 6 weeks. A booster module summarizing the intervention content is released during week 5 of the intervention, and there is a final module to be completed at the end of the intervention. To conclude the intervention and answer any questions, a second face-to-face session is held with the mothers and daughters. Figure 2 provides an overview of the intervention schedule and details of the core learning outcomes of the modules for both apps.

To ensure the communication style in which the intervention content (ie, BCTs) is delivered is collaborative, autonomy supportive, and person centered [48], the principles of SDT [85] were applied. According to SDT, autonomous motivation for a behavior is developed through the satisfaction of the basic psychological needs of autonomy, competence, and relatedness [85]. The need for autonomy refers to a mother's or daughter's desire to have choice and to feel empowered in directing their own behavior [85]. For example, in the app, the goal-setting feature supports the basic need of autonomy by providing mothers and daughters with choices and options, enabling them to make decisions and take responsibility about how they chose to support their daughter or be active. The need for competence relates to a mother's or daughter's need to feel capable of achieving a desired outcome [85]. To illustrate, whenever mothers or daughters log activities on the app, it represents a confirmation that they sustained the behavior and thus enhances their feelings of competence. The need for relatedness denotes an individual's aspirations to feel a sense of belonging and connectedness with others [85]. For instance, the messaging feature enables mothers to connect with others who face the same challenges or achieve the same goals, thus promoting a sense of belonging and providing an opportunity to develop meaningful relations with other participants (Table 6).

XSL•FO
RenderX

Figure 2. Intervention schedule. PA: physical activity.



XSL•FO
RenderX

Table 6. Intervention delivery style, illustrating how app features align with the principles of self-determination theory.

App features	Description	Expected benefit
Autonomy-supportive features		
Goal setting	• This feature provides mothers and daughters with the option to choose from a set of predefined activities or exercises they wish to perform • Mothers and daughters have the option to proactively set a goal they will perform, which is related to either maternal support for PAa or daughters' leisure time activity	• The goal-setting feature supports the basic need of autonomy and promotes autonomous motivation by providing mothers and daughters with choices and options, enabling them to make decisions and take responsibility about how they choose to support their daughter and be active
Reminders	• The app will provide a reminder that is delivered as a push notification around the time the mothers and daughters should perform a specific activity • The reminders are set by the mothers and daughters while they are selecting their goals and are optional	• This feature helps mothers and daughters stay organized and on track with regard to the target behaviors • To reduce the feeling of acting out of pressure or control, this is an optional feature and can only be activated by the mothers and daughters
Motivational messages	• Feature with preset messages delivered as push notifications that provide encouragement, praise, and inspiration to perform target behaviors • Messages are not task inherent and are provided to mothers and daughters at specified time intervals regardless of performance or completion of target behaviors • A feature that allows mothers and daughters to write a brief message about why it is important for them to continue engaging in the target behavior. This self-directed message is available whenever needed and can be delivered as a push notification at chosen time intervals	• Mothers and daughters provided feedback regarding the time and type of messages they would like to receive in an earlier module; the messages are tailored to suit their preferences • The messages provide a meaningful rationale for engaging in the target behaviors • The self-directed messages enable mothers and daughters to reflect on why they want to engage and sustain the behaviors
Competence-supportive features		
Self-monitoring	• Provides mothers and daughters with option to self-record the accomplishment of a goal or the completion of a task related to the target behaviors • Mothers and daughters can record information about what happened on specific days (eg, bad weather, lots of homework, and stress at work) and rate their enjoyment factor while partaking	• Whenever mothers or daughters log an activity, it represents a confirmation that they sustained the behavior and thus enhances their feelings of competence • The information entered helps mothers and daughters know themselves and understand their personal circumstances that influence the target behavior • By entering data into the app, mothers and daughters express their interest in maintaining the behaviors
Activity feedback	• Provides mothers and daughters with information about how the task that was performed and provides them with details of their overall progress toward completing a predefined set of activities or goal. The information might be accompanied by a score (eg, step count) or encouragement message or badge (well done for completing the module) • Timing of feedback is important to avoid unsatisfactory results such as underachievement; therefore, mothers and daughters choose to view their own feedback rather than receiving it unexpectedly • The activity feedback needs to be personal, nonevaluative and specific to the task performed.	• Positive feedback shows growth or improvement trends and enhance mothers' and daughters' sense of competence • Activity feedback in the form of encouragement messages or badges can foster positive emotions toward the target behavior
Relatedness-supportive features		
Community forum	• Enables mothers and daughters to connect with other participants where they have the opportunity to interact and connect with others • The research team will also facilitate opportunities for participants to meet and participate in activities through the group chat feature	• Messaging enables mothers and daughters to connect with other participants who face the same challenges • They can share experiences, provide and receive support, and experience a sense of belonging and relatedness

XSL•FO
RenderX

App features	Description	Expected benefit
Modeling videos or podcasts	• Videos or podcasts of other mothers of preteen daughters and preteen girls sharing their experiences are embedded throughout the app's modules and in the resources icon	• These videos or podcasts provide mothers and girls with information and advice from other mothers and daughters who face similar challenges, which can help satisfy their need for relatedness and support their autonomous motivation to perform the target behavior over time

[a]PA: physical activity.

Feedback From Co-Design Workshops and Intervention Refinement

After the development of the intervention content and delivery (with separate mobile apps for mothers and daughters), a second series of workshops was held to present the mobile apps to mothers, preteen girls, and teachers. All groups acknowledged how the intervention content was informative and persuasive, as shared by Sadie, fifth class:

> *Instead of just getting girls to join sports, giving good reasons as well. Instead of saying like, do you want to try this and try this? It was giving good reasons.*

The girls found the videos of other girls' experiences regarding being active useful and inspiring, particularly those with girls their own age and a little older than them, as described by Sophie, sixth class:

> *Because if they're girls older, like what Evie said, they can be like role models. If they're the same age as you, then they could inspire you to join a team as well.*

This was a similar finding for the mothers and teachers, who recognized how videos demonstrating experiences of "other mothers and girls they can relate to" (Kate, primary school teacher) would encourage maternal PA support and girls to be active. The mothers' and teachers' groups provided positive feedback when exploring the resources feature, which presented what was available to them in their local community for supporting their daughter to be active, as described by Susan, who has a daughter in sixth class:

> *That's brilliant. Little bits like that on it, You just let people know (about the resources feature) and you just click the link then and pick it up.*

Several amendments were suggested at these workshops, which were then included in the final version of the intervention. For example, the mothers and teachers' groups suggested that it would be important to have an initial and final group-based face-to-face session as part of the intervention, as shared by Emer, a primary school teacher:

> *I think at the start, if you get them in like...that first meeting and first introduction thing is crucial. They feel invested in it.*

As a result of this feedback, we introduced both an initial and final group-based face-to-face intervention sessions. Specifically, the initial session will enable mothers and preteen daughters to meet other users of the smartphone app and develop social connections, which can then be reinforced through using some of the social support features on the app. It would also allow mothers and preteen daughters to get instruction from the research team as to how to use the features of the smartphone app. The final face-to-face session will allow mothers and preteen daughters to share their experiences and provide an opportunity to sustain their social network developed as part of the intervention. It was also suggested to avoid providing all the modules on the app at once, instead phasing them in over a few weeks to prevent mothers and daughters from feeling overwhelmed by the information. This recommendation was shared by Michelle, whose daughter was in fourth class:

> *I'd phase it in, different bits of information every couple of weeks...I think if you throw too much at people, they won't bother looking at it. It's just too much information...People don't like too much information at once. It just bugs them.*

Further suggestions were for a booster module to be added to the app to provide a reminder of the key features of the intervention content and for a podcast with parenting tips for teenage daughters to be added to the resources feature as "there's a lot of challenges out there. People are looking for...Looking for help and guidance." (Jennifer, daughter in sixth class).

Evaluation of the Intervention Prototype and Logic Model

The App Behavior Change Scale [78] was used as a checklist by the research team to assess the behavior change elements of the apps. Both proposed mobile apps included 18 items on the scale, indicating a high number of BCTs embedded in the apps and strong behavior change potential (Multimedia Appendix 5 [78]). The academic advisory panel reviewed and agreed on the final intervention prototype as well as the refined program theory. Figure 3 is a logic model that represents the program theory of the mother-daughter intervention. It depicts the flow of the intervention from (1) the identification of the problem (ie, preteen girls are not active enough) to (2) the inputs (ie, target behaviors of maternal PA support and preteen girls' PA), to (3) the mechanisms of action (ie, Table 1), to (4) the intervention components (ie, Tables 4 and 5), to (5) outputs (ie, mothers and daughters develop knowledge and understanding and improve motivation to enact target behaviors), to (6) short-term outcomes (ie, mothers and daughters enact target behaviors), to (7) long-term outcomes (ie, mothers and daughters maintain target behaviors), and finally (8) overall outcomes of the intervention (ie, improved PA levels in preteen girls). The app targeting mothers will be called the Physical Activity Virtual Assistant for Mothers (PAVA-M), whereas the app targeting their preteen daughters will be called Physical Activity Virtual Assistant for Daughters (PAVA-D) (Figures 4 and 5).

XSL•FO
RenderX

Figure 3. Logic model of the intervention prototype. mHealth: mobile health; PA: physical activity; TDF: Theoretical Domains Framework.

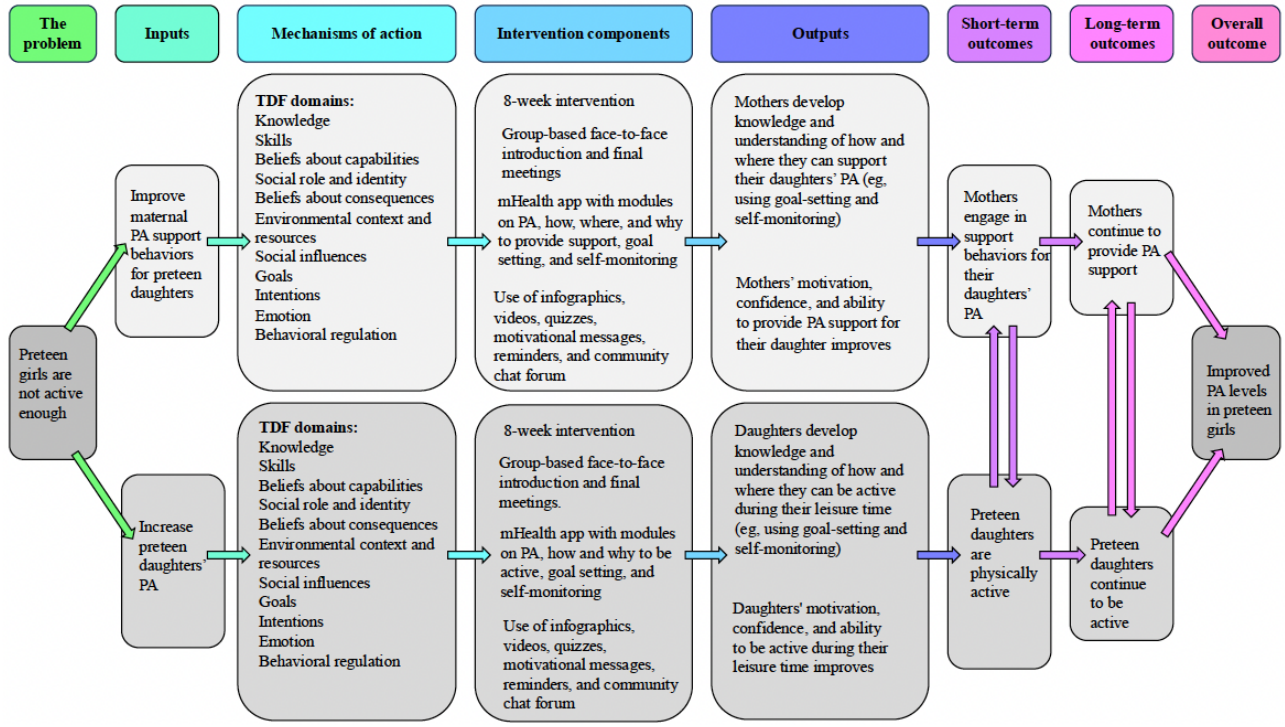
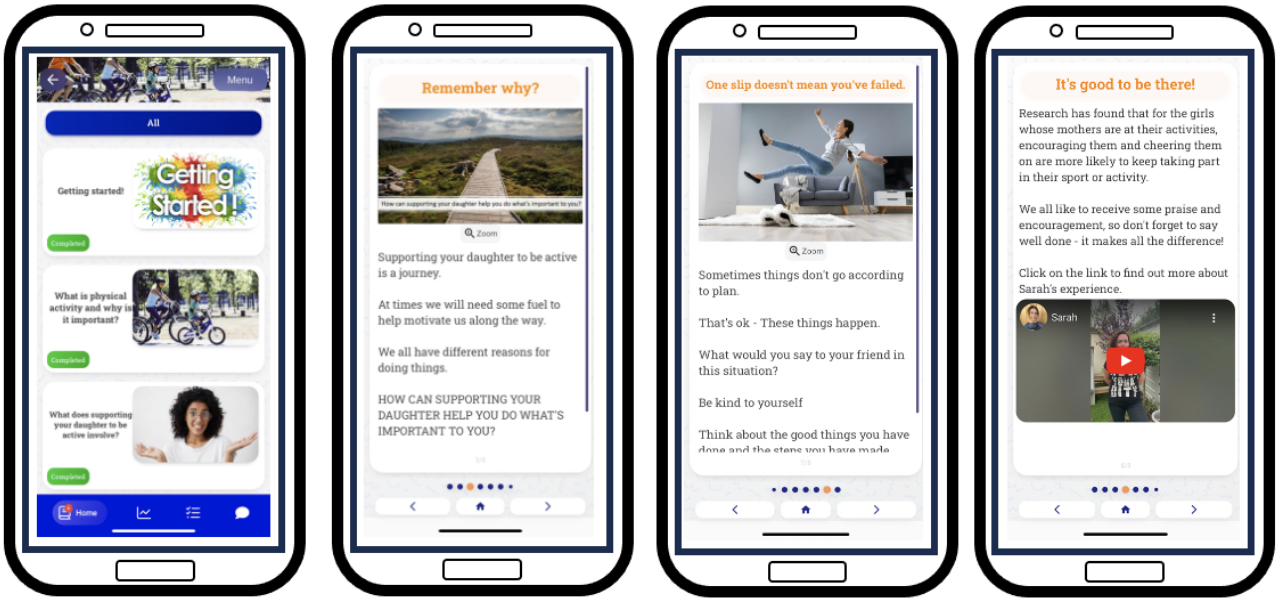
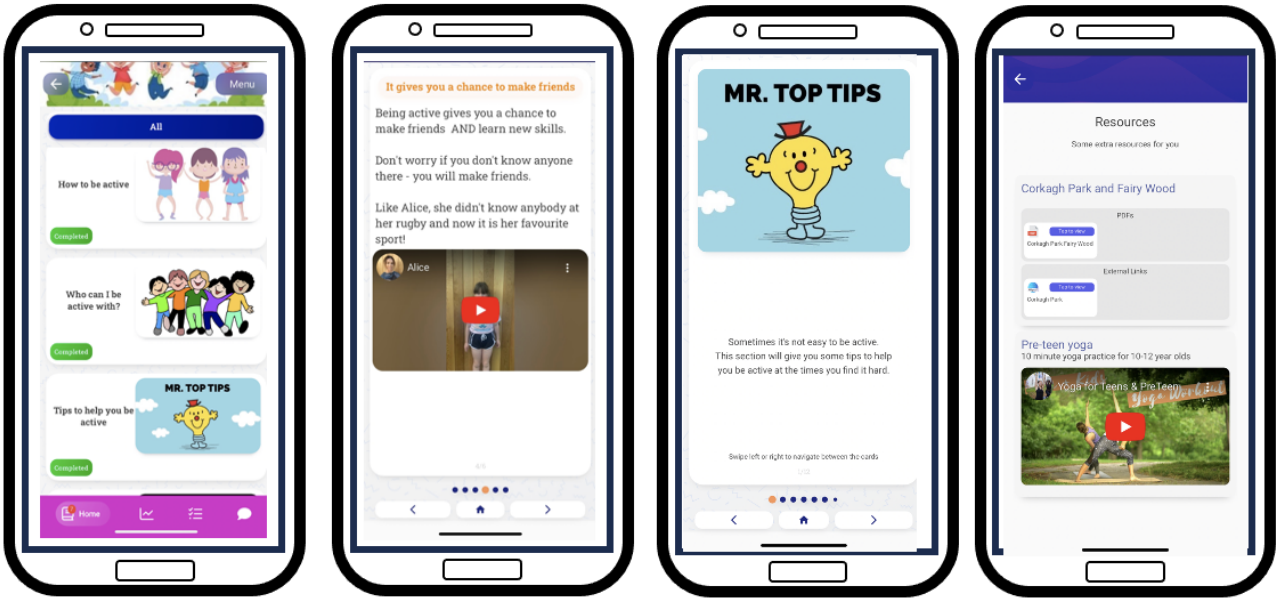


Figure 4. Screenshots from the mothers' mobile app prototype.



XSL•FO
RenderX

Figure 5. Screenshots from the daughters' mobile app prototype.



Discussion

Principal Findings

This paper describes the systematic process to develop an evidence- and theory-informed intervention, using co-design methods, to increase PA in preteen girls of low SEP by incorporating maternal supportive behaviors. This is noteworthy given that levels of PA decline with age in preteen girls of low SEP [4,9], placing them at elevated risk of obesity, type 2 diabetes, and cardiovascular disease [8,10]. In keeping with MRC guidance, the intervention was refined through an iterative and dynamic process based on evidence, theory, feedback from co-design workshops with mothers of preteen daughters, preteen girls, and primary school teachers and input from a multidisciplinary academic advisory panel. This process resulted in the development of an intervention with 2 target behaviors, one targeting mothers' supportive behaviors for their daughters' PA and the other targeting preteen daughters' PA directly, which is ready for feasibility and acceptability testing.

The systematic approach applied in this study was guided by the BCW framework for developing interventions [37]. Using the BCW facilitated a rigorous analysis of the problem and how it could be potentially addressed. It also enabled the consideration and incorporation of evidence from several sources: the extant research literature, formative research [82-84], as well as the judgments of the academic advisory panel. We followed a step-by-step process that involved the following: identifying and specifying the target behaviors; conducting a thorough analysis of the barriers and enablers to these behaviors; using the TDF to identify the proposed mechanisms of action; and selecting feasible intervention functions, BCTs, and delivery methods. One study has used the BCW to develop a mother-daughter PA intervention for adolescent girls [41], but to our knowledge, this is the first study to use the BCW and TDF in conjunction with the BCIO to target children's PA through a theory-informed family-based intervention.

The intervention prototype incorporates 27 BCTs, which is greater than the average of 8 to 10 BCTs per intervention reported in recent systematic reviews of family-based interventions targeting health behaviors such as PA [82,88]. There is some evidence to suggest that more effective interventions include a greater number of BCTs [89]. Furthermore, interventions that include a greater number of BCT clusters, with a threshold of at least 3 clusters, increase the likelihood of intervention effectiveness [90]. There were 13 BCTs clusters within the intervention prototype, and we incorporated particular clusters and specific techniques that have shown promise in theory-based interventions. For example, identity is an important mechanism of action for the promotion and maintenance of PA in adults and young people [63,91] and for providing parental PA support [64]. Our intervention is one of the few to include BCTs, which strengthen maternal identity for PA support and mother and daughter PA identity such as "reframe past behaviour BCT," "identify self as role model BCT," and "adopt changed self-identity BCT" [64]. In addition, this study incorporates BCTs that have proven effective in mother-daughter PA interventions and more broadly in health behavior change research. These include selecting a relevant behavioral goal, self-monitoring progress toward that goal, and developing problem-solving skills to address potential challenges [82,92-94].

This study engaged with end users (eg, mothers and preteen girls) and other relevant stakeholders (eg, primary school teachers) in the intervention development process using co-design methods. Despite continued advocacy for engaging children and adolescents in co-design methods, there is a paucity of studies targeting family-based PA that have applied such methods, in particular when it comes to children aged 10 to 12 years [59]. To the best of our knowledge, this is the first intervention prototype that meaningfully engaged with girls aged 10 to 12 years throughout the entire development process. The girls provided information into the selection of intervention components and towards the acceptability of intervention

XSL•FO
RenderX

materials and resources [95]. Interestingly, the girls in the study suggested that a video of teenage girls slightly older than they were (ie, aged 13-14 years) describing how they overcame challenges to PA would be relatable and helpful for promoting PA in their cohort, an approach that the research team had not considered. Therefore, by including girls aged 10 to 12 years in the co-design process, this study increased the likelihood of acceptability and implementation at the intervention testing stage [56,96]. Furthermore, there is a lack of resources dedicated to detailing and evaluating the process of engaging with participants using co-design methods in the development of interventions [55,97]. As a result, there may be a need to develop guidance as to how to report the use of co-design principles in studies similar to the Template for Intervention Description and Replication (TIDieR) checklist [98] or the BCIO [46].

The mode of delivery of the intervention was another important intervention component. The selection of the mobile app was driven by the end users who wanted flexibility in how they engaged with the intervention. Indeed, mothers in the study highlighted the importance of being able to complete the intervention at their own pace, thus recommending a mobile app as the primary mode of delivery. Mothers often describe barriers to engaging in PA related to household, family, and occupational responsibilities [83]. Thus, the mobile app may allow individuals to complete intervention content at their own pace and facilitate adherence to the intervention. There is increased use of mobile apps as a mode of delivery for PA interventions [22,99,100]. However, research to date in children and adolescent populations is less frequent and is typically poorly designed [100]. Consequently, there is a need for further systematic theoretically informed research on the use of mobile apps with this population, a need which this study attempts to address. One of the challenges in using mobile apps as the mode of delivery for interventions is the cost of development of such apps, which can be prohibitive [101]. This study used the Pathverse platform to address this issue, as it provided our team with a rapid and cost-effective tool for creating and refining the intervention content [86,102]. Alongside the use of the BCW and related elements, we used the App Behavior Change Scale as a checklist during the development of the intervention to maximize the behavior change potential of the applications. However, it is important to note that the App Behavior Change Scale only measures the theoretical behavior change potential of the application, and it does not attempt to investigate the relationship between the actual features of application and behavioral outcomes [39]. Future work should consider the uptake, engagement, and user retention of the app by following frameworks such as the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework [103].

An important component within intervention development is how an intervention is delivered, including the style of delivery of the intervention [48]. Typically, this focuses on human to human interaction; however, there is an increasing realization of the importance of considering a person-centered intervention delivery style, which is reflective and empathetic when designing applications and their related content [104]. Consequently, the principles of SDT [85] were applied to the intervention, ensuring that BCTs and specific features used in the intervention mapped to the basic psychological needs of autonomy, competence, and relatedness proposed by SDT [105-107]. Indeed, there is a growing body of work highlighting how applications underpinned by the SDT principles can strengthen digital therapeutic alliance and increase engagement in behaviors such as PA [107,108].

Future Directions

This study took place within the intervention development phase of the MRC framework [32]. Future research would involve using a no-code development app [102] to assess the feasibility of the intervention and inform decisions about how to progress to the following phases of intervention evaluation and implementation [32]. After engagement with the co-design participants, it was suggested that it was most feasible to promote this intervention via the school environment although it is targeting girls' PA outside of school hours. The school setting can reach children and adolescents of diverse racial and socioeconomic backgrounds and provides a ready-made social network for both mothers and daughters to engage with when undertaking the intervention [109,110]. Furthermore, it would allow for tailoring of the intervention resources within the school and local community that could support increased leisure time PA [109,110]. This is in line with research by Pfledderer et al [111] and van Sluijs et al [23] who recommend that interventions consider both family and community engagement (eg, family based and linked to school) to promote children's and adolescents' PA, particularly for underserved populations such as children and adolescents of low SEP. Although our preference is for mothers and daughters to take part in the intervention, the separate mobile app mode of delivery allows preteen girls to partake in the intervention regardless of their mothers' participation. This is an important feature, given that reaching parents of low SEP is often a challenge for interventions [112].

A limited number of these interventions are scaled-up and applied in real-world settings, identifying a significant research practice gap [113,114]. A recent review by Crane et al [115] found that health interventions (including PA interventions) that followed a research pathway were approximately 3 times more likely to have a positive effect on population health. Therefore, in line with recommendations by McKay et al [113], our future research would involve continuous planning for scaling-up, developing scale-up pathways, and evaluation of the scale-up throughout the duration of the intervention. Schools serving children with low SEP are frequently underresourced and often need more support to reach the same outcomes as their more advantaged counterparts [109,113]. To this end, maintaining relationships with schools and local community partners is essential in the scaling-up process to establish trust and identify potential implementation barriers [113,114]. This would involve hosting meetings with principals, teachers, and administrators to understand the pressing issues in their school environment; engaging with teachers, coaches, and local community partners to overcome implementation barriers; and developing collaborative strategies to encourage mothers and daughters to be physically active and sustain activity levels after the intervention [116]. Finally, based on the findings from this study, potential avenues for future research could be additional studies to evaluate the long-term effectiveness and sustainability

XSL•FO
RenderX

of the intervention, research exploring the factors influencing parental engagement in family-based mHealth interventions, and investigation into the impact of mobile app on PA behavior change in children and adolescents.

Strengths and Limitations

This study used a systematic, evidence- and theory-based approach to integrate a body of evidence from a systematic review, 2 qualitative studies, an academic advisory panel, and end users' knowledge to co-design and develop a novel intervention to promote PA in preteen girls of low SEP. The uniqueness of this study lies in following the first phase of the MRC framework, while using the BCW, the TDF, BCTO, and input from co-design workshops, which offered procedural direction, structure, and transparency. Annotating the BCIO entities enabled us to represent the intervention characteristics in a detailed and structured way, which can be used across contexts and disciplines. In addition, the entities' unique identifiers will facilitate the use of artificial intelligence including machine learning–based methods in data extraction and evidence synthesis [46]. Family-based PA interventions have been the focus of previous research [21,117]. However, no digital intervention to date has specifically focused in promoting PA in preteen girls of low SEP complemented by maternal support behaviors. Thus, this work fills an important gap by seeking to support an at-risk group. Furthermore, the involvement of key stakeholders in the development process is a key strength of this study. It ensures that the content of the intervention was adapted to accommodate the users' needs, making it useful and relevant, thus increasing the likelihood of a more feasible, acceptable, and ultimately effective intervention [56,118].

Our work has some limitations. First, the highly structured and systematic approach used to develop this intervention prototype takes a significant amount of time and resources. For example, using the BCW, the TDF, and the BCTO requires considerable skills and training. Second, the process of converting BCTs into intervention content can be open to interpretation, and the research team had to make subjective and pragmatic decisions regarding intervention content throughout the process [119,120]. Third, we did not collect additional information regarding mothers' backgrounds such as their educational levels and PA experience as part of the co-design workshops. Finally, similar to other research [45], we used DEIS schools to recruit low-SEP preteen girls and their mothers. However, the data might not be fully representative of the target population, as DEIS schools are categorized by district, and it is possible that some girls or mothers in the school might not be of low SEP. Continued efforts should be made to target this cohort, for example, using household income or area level socioeconomic status.

Conclusions

In conclusion, this study uses a systematic evidence- and theory-based approach incorporating findings from a systematic review, formative qualitative research with mothers and preteen girls, input from an academic advisory panel, and knowledge from end users. This process was used to co-design an mHealth intervention prototype aimed at promoting PA in preteen girls, with a focus on maternal support behaviors, and is now ready for feasibility and acceptability testing. The novel contribution of this study lies in the use of theory and the meaningful involvement of key stakeholders throughout the development process. In addition, this study offers a practical example of how to integrate evidence, theory, and stakeholder engagement, which can be adjusted and tailored to fit different contexts and populations. Finally, the comprehensive annotation of the BCIO entities denotes the intervention characteristics in a structured manner that enables improved communication, replication, and implementation of interventions.

Acknowledgments

The authors would like to thank the school principal, teachers, mothers, and girls for taking part in the co-design workshops. The authors would also like to thank Amanda Wilms from Pathverse for her help and guidance with using the no-code app development platform.

Authors' Contributions

CB and JM conceptualized and led on the idea of Physical Activity Virtual Assistant for Mothers (PAVA-M) and Physical Activity Virtual Assistant for Daughters (PAVA-D). GO'D, AK, and RER helped develop the idea of PAVA-M and PAVA-D and provided guidance based on their expertise, including the section of mechanisms of action, behavior change techniques, and intervention components. CB and JM led on the co-design workshops and development and adaptation of the intervention content. CB and JM drafted the original manuscript. GO'D, AK, and RER reviewed the initial content and structure of the manuscript. All authors have read, revised, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Behavior change intervention glossary.
[DOCX File , 26 KB - pediatrics_v8i1e62795_app1.docx]

XSL•FO
RenderX

Multimedia Appendix 2
Barriers and enablers to target behaviors.
[DOCX File , 71 KB - pediatrics_v8i1e62795_app2.docx]

Multimedia Appendix 3
Co-design session 1.
[DOCX File , 9452 KB - pediatrics_v8i1e62795_app3.docx]

Multimedia Appendix 4
Co-design session 2.
[DOCX File , 613 KB - pediatrics_v8i1e62795_app4.docx]

Multimedia Appendix 5
App Behavior Change Scale.
[DOCX File , 19 KB - pediatrics_v8i1e62795_app5.docx]

References

1. Guthold R, Stevens GA, Riley LM, Bull FC. Global trends in insufficient physical activity among adolescents: a pooled analysis of 298 population-based surveys with 1·6 million participants. Lancet Child Adolesc Health 2020 Jan;4(1):23-35 [FREE Full text] [doi: 10.1016/S2352-4642(19)30323-2] [Medline: 31761562]
2. Dumith SC, Gigante DP, Domingues MR, Hallal PC, Menezes AM, Kohl 3rd HW. Predictors of physical activity change during adolescence: a 3.5-year follow-up. Public Health Nutr 2012 Dec 11;15(12):2237-2245 [FREE Full text] [doi: 10.1017/S1368980012000948] [Medline: 22464063]
3. Murphy J, Sweeney MR, McGrane B. Physical activity and sports participation in Irish adolescents and associations with anxiety, depression and mental wellbeing. Phys Act Health 2020;4(1):23 [FREE Full text] [doi: 10.5334/paah.58]
4. Inchley J, Currie D, Budisavljevic S, Torsheim T, Jåstad A, Cosma A, et al. Spotlight on adolescent health and well-being. Findings from the 2017/2018 health behaviour in school-aged children (HBSC) survey in Europe and Canada. World Health Organization. 2020. URL: https://www.who.int/europe/publications/i/item/9789289055000 [accessed 2024-04-29]
5. Woods CB, Ng KW, Britton U, McClelland J, O'Keeffe B, Sheikhi A, et al. Children's sport participation and physical activity study (2022). Physical Activity for Health Research Centre. URL: https://www.sportireland.ie/sites/default/files/media/document/2023-08/CSPPA%202022%20Full%20Report.pdf [accessed 2024-04-29]
6. Knowles AM, Niven A, Fawkner S. A qualitative examination of factors related to the decrease in physical activity behavior in adolescent girls during the transition from primary to secondary school. J Phys Act Health 2011 Nov;8(8):1084-1091. [doi: 10.1123/jpah.8.8.1084] [Medline: 22039126]
7. Alliott O, Ryan M, Fairbrother H, van Sluijs E. Do adolescents' experiences of the barriers to and facilitators of physical activity differ by socioeconomic position? A systematic review of qualitative evidence. Obes Rev 2022 Mar 28;23(3):e13374 [FREE Full text] [doi: 10.1111/obr.13374] [Medline: 34713548]
8. Craike M, Wiesner G, Hilland TA, Bengoechea EG. Interventions to improve physical activity among socioeconomically disadvantaged groups: an umbrella review. Int J Behav Nutr Phys Act 2018 May 15;15(1):43 [FREE Full text] [doi: 10.1186/s12966-018-0676-2] [Medline: 29764488]
9. O'Brien W, Belton S, Fitzpatrick B, Shannon S, Brennan D, Chambers F, et al. Relationship between gender, physical activity, screen time, body mass index and wellbeing in Irish children from social-disadvantage. Child Care in Practice 2021 Mar 12;30(3):220-234 [FREE Full text] [doi: 10.1080/13575279.2021.1887815]
10. Marmot M. Inclusion health: addressing the causes of the causes. Lancet 2018 Jan 20;391(10117):186-188 [FREE Full text] [doi: 10.1016/S0140-6736(17)32848-9] [Medline: 29137870]
11. Mannocci A, D'Egidio V, Backhaus I, Federici A, Sinopoli A, Ramirez Varela A, et al. Are there effective interventions to increase physical activity in children and young people? An umbrella review. Int J Environ Res Public Health 2020 May 18;17(10):3528 [FREE Full text] [doi: 10.3390/ijerph17103528] [Medline: 32443505]
12. Emm-Collison LG, Lewis S, Reid T, Matthews J, Sebire S, Thompson J, et al. Physical activity during the school holidays: parent perceptions and practical considerations. Int J Environ Res Public Health 2019 May 14;16(10):1697 [FREE Full text] [doi: 10.3390/ijerph16101697] [Medline: 31091825]
13. Brazendale K, Beets MW, Armstrong B, Weaver RG, Hunt ET, Pate RR, International Children's Accelerometry Database (ICAD) Collaborators. Children's moderate-to-vigorous physical activity on weekdays versus weekend days: a multi-country analysis. Int J Behav Nutr Phys Act 2021 Feb 10;18(1):28 [FREE Full text] [doi: 10.1186/s12966-021-01095-x] [Medline: 33568183]
14. Rhodes RE, Perdew M, Malli S. Correlates of parental support of child and youth physical activity: a systematic review. Int J Behav Med 2020 Dec 11;27(6):636-646. [doi: 10.1007/s12529-020-09909-1] [Medline: 32529629]

XSL•FO
RenderX

15. Pyper E, Harrington D, Manson H. The impact of different types of parental support behaviours on child physical activity, healthy eating, and screen time: a cross-sectional study. BMC Public Health 2016 Aug 24;16(1):568 [FREE Full text] [doi: 10.1186/s12889-016-3245-0] [Medline: 27554089]
16. Gustafson SL, Rhodes RE. Parental correlates of physical activity in children and early adolescents. Sports Med 2006;36(1):79-97. [doi: 10.2165/00007256-200636010-00006] [Medline: 16445312]
17. Jago R, Fox KR, Page AS, Brockman R, Thompson JL. Parent and child physical activity and sedentary time: do active parents foster active children? BMC Public Health 2010 Apr 15;10(1):194 [FREE Full text] [doi: 10.1186/1471-2458-10-194] [Medline: 20398306]
18. Fuemmeler BF, Anderson CB, Mâsse LC. Parent-child relationship of directly measured physical activity. Int J Behav Nutr Phys Act 2011 Mar 08;8(1):17 [FREE Full text] [doi: 10.1186/1479-5868-8-17] [Medline: 21385455]
19. Sigmundová D, Sigmund E, Badura P, Hollein T. Parent-child physical activity association in families with 4-to 16-year-old children. Int J Environ Res Public Health 2020 Jun 05;17(11):4015 [FREE Full text] [doi: 10.3390/ijerph17114015] [Medline: 32516925]
20. Barnes AT, Young MD, Murtagh EM, Collins CE, Plotnikoff RC, Morgan PJ. Effectiveness of mother and daughter interventions targeting physical activity, fitness, nutrition and adiposity: a systematic review. Prev Med 2018 Jun;111:55-66. [doi: 10.1016/j.ypmed.2017.12.033] [Medline: 29291423]
21. Brown HE, Atkin AJ, Panter J, Wong G, Chinapaw MJ, van Sluijs EM. Family-based interventions to increase physical activity in children: a systematic review, meta-analysis and realist synthesis. Obes Rev 2016 Apr;17(4):345-360 [FREE Full text] [doi: 10.1111/obr.12362] [Medline: 26756281]
22. Rodríguez-González P, Hassan MA, Gao Z. Effects of family-based interventions using mobile apps on youth's physical activity: a systematic review. J Clin Med 2022 Aug 17;11(16):4798 [FREE Full text] [doi: 10.3390/jcm11164798] [Medline: 36013037]
23. van Sluijs EM, Ekelund U, Crochemore-Silva I, Guthold R, Ha A, Lubans D, et al. Physical activity behaviours in adolescence: current evidence and opportunities for intervention. Lancet 2021 Jul 31;398(10298):429-442 [FREE Full text] [doi: 10.1016/S0140-6736(21)01259-9] [Medline: 34302767]
24. Jiang S, Ng JY, Chong KH, Peng B, Ha AS. Effects of eHealth interventions on 24-hour movement behaviors among preschoolers: systematic review and meta-analysis. J Med Internet Res 2024 Feb 21;26:e52905 [FREE Full text] [doi: 10.2196/52905] [Medline: 38381514]
25. Sequí-Domínguez I, Cavero-Redondo I, Álvarez-Bueno C, López-Gil JF, Martínez-Vizcaíno V, Pascual-Morena C. Effectiveness of eHealth interventions promoting physical activity in children and adolescents: systematic review and meta-analysis. J Med Internet Res 2024 Feb 21;26:e41649 [FREE Full text] [doi: 10.2196/41649] [Medline: 38381490]
26. He Z, Wu H, Yu F, Fu J, Sun S, Huang T, et al. Effects of smartphone-based interventions on physical activity in children and adolescents: systematic review and meta-analysis. JMIR Mhealth Uhealth 2021 Feb 01;9(2):e22601 [FREE Full text] [doi: 10.2196/22601] [Medline: 33522980]
27. Baumann H, Fiedler J, Wunsch K, Woll A, Wollesen B. mHealth interventions to reduce physical inactivity and sedentary behavior in children and adolescents: systematic review and meta-analysis of randomized controlled trials. JMIR Mhealth Uhealth 2022 May 11;10(5):e35920 [FREE Full text] [doi: 10.2196/35920] [Medline: 35544294]
28. Western MJ, Armstrong ME, Islam I, Morgan K, Jones UF, Kelson MJ. The effectiveness of digital interventions for increasing physical activity in individuals of low socioeconomic status: a systematic review and meta-analysis. Int J Behav Nutr Phys Act 2021 Nov 09;18(1):148 [FREE Full text] [doi: 10.1186/s12966-021-01218-4] [Medline: 34753490]
29. Wang JW, Zhu Z, Shuling Z, Fan J, Jin Y, Gao Z, et al. Effectiveness of mHealth app-based interventions for increasing physical activity and improving physical fitness in children and adolescents: systematic review and meta-analysis. JMIR Mhealth Uhealth 2024 Apr 30;12:e51478 [FREE Full text] [doi: 10.2196/51478] [Medline: 38687568]
30. Mobile fact sheet. Pew Rearch Centre. URL: https://www.pewresearch.org/internet/fact-sheet/mobile/?tabItem=5b319c90-7363-4881-8e6f-f98925683a2f#who-owns-cellphones-and-smartphone [accessed 2024-09-30]
31. Smartphone ownership penetration in the United Kingdom (UK) in 2012-2024, by age. Stasista. URL: https://www.statista.com/statistics/271851/smartphone-owners-in-the-united-kingdom-uk-by-age/ [accessed 2024-10-01]
32. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ 2021 Sep 30;374:n2061 [FREE Full text] [doi: 10.1136/bmj.n2061] [Medline: 34593508]
33. Gourlan M, Bernard P, Bortolon C, Romain AJ, Lareyre O, Carayol M, et al. Efficacy of theory-based interventions to promote physical activity. A meta-analysis of randomised controlled trials. Health Psychol Rev 2016 Apr 10;10(1):50-66. [doi: 10.1080/17437199.2014.981777] [Medline: 25402606]
34. Rhodes RE, McEwan D, Rebar AL. Theories of physical activity behaviour change: a history and synthesis of approaches. Psychol Sport Exerc 2019 May;42:100-109 [FREE Full text] [doi: 10.1016/j.psychsport.2018.11.010]
35. Hagger MS, Weed M. DEBATE: do interventions based on behavioral theory work in the real world? Int J Behav Nutr Phys Act 2019 Apr 25;16(1):36 [FREE Full text] [doi: 10.1186/s12966-019-0795-4] [Medline: 31023328]
36. Dalgetty R, Miller CB, Dombrowski SU. Examining the theory-effectiveness hypothesis: a systematic review of systematic reviews. Br J Health Psychol 2019 May 21;24(2):334-356 [FREE Full text] [doi: 10.1111/bjhp.12356] [Medline: 30793445]

XSL•FO
RenderX

37. Michie S, Atkins L, West R. The Behaviour Change Wheel: A Guide to Designing. New York, NY: Silverback Publishing; 2014.
38. Connell LE, Carey RN, de Bruin M, Rothman AJ, Johnston M, Kelly MP, et al. Links between behavior change techniques and mechanisms of action: an expert consensus study. Ann Behav Med 2019 Jul 17;53(8):708-720 [FREE Full text] [doi: 10.1093/abm/kay082] [Medline: 30452535]
39. Truelove S, Vanderloo LM, Tucker P, Di Sebastiano KM, Faulkner G. The use of the behaviour change wheel in the development of ParticipACTION's physical activity app. Prev Med Rep 2020 Dec;20:101224 [FREE Full text] [doi: 10.1016/j.pmedr.2020.101224] [Medline: 33134041]
40. Haley JA, Rhind DJ, Maidment DW. Applying the behaviour change wheel to assess the theoretical underpinning of a novel smartphone application to increase physical activity in adults with spinal cord injuries. Mhealth 2023 Apr;9:10 [FREE Full text] [doi: 10.21037/mhealth-22-52] [Medline: 37089265]
41. Murtagh EM, Barnes AT, McMullen J, Morgan PJ. Mothers and teenage daughters walking to health: using the behaviour change wheel to develop an intervention to improve adolescent girls' physical activity. Public Health 2018 May;158:37-46. [doi: 10.1016/j.puhe.2018.01.012] [Medline: 29544174]
42. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci 2012 Apr 24;7:37 [FREE Full text] [doi: 10.1186/1748-5908-7-37] [Medline: 22530986]
43. French SD, Green SE, O'Connor DA, McKenzie JE, Francis JJ, Michie S, et al. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. Implement Sci 2012 Apr 24;7:38 [FREE Full text] [doi: 10.1186/1748-5908-7-38] [Medline: 22531013]
44. Ahern SM, Arnott B, Chatterton T, de Nazelle A, Kellar I, McEachan RR. Understanding parents' school travel choices: a qualitative study using the Theoretical Domains Framework. J Transp Health 2017 Mar;4:278-293. [doi: 10.1016/j.jth.2016.11.001]
45. McQuinn S, Belton S, Staines A, Sweeney MR. Co-design of a school-based physical activity intervention for adolescent females in a disadvantaged community: insights from the Girls Active Project (GAP). BMC Public Health 2022 Mar 29;22(1):615 [FREE Full text] [doi: 10.1186/s12889-022-12635-w] [Medline: 35351045]
46. Michie S, West R, Finnerty AN, Norris E, Wright AJ, Marques MM, et al. Representation of behaviour change interventions and their evaluation: development of the Upper Level of the Behaviour Change Intervention Ontology. Wellcome Open Res 2020 Jun 10;5:123. [doi: 10.12688/wellcomeopenres.15902.1]
47. Marques MM, Wright AJ, Corker E, Johnston M, West R, Hastings J, et al. The behaviour change technique ontology: transforming the behaviour change technique taxonomy v1. Wellcome Open Res 2023 Jul 17;8:308 [FREE Full text] [doi: 10.12688/wellcomeopenres.19363.1] [Medline: 37593567]
48. Wright AJ, Zhang L, Howes E, Veall C, Corker E, Johnston M, et al. Specifying how intervention content is communicated: development of a style of delivery ontology. Wellcome Open Res 2023 Oct 12;8:456 [FREE Full text] [doi: 10.12688/wellcomeopenres.19899.1] [Medline: 39193088]
49. Marques MM, Carey RN, Michie S, Norris E, Evans F, Finnerty AN, et al. Delivering behaviour change interventions: development of a mode of delivery ontology. Wellcome Open Res 2020 Jun 10;5:125. [doi: 10.12688/wellcomeopenres.15906.1]
50. Norris E, Marques MM, Finnerty AN, Wright AJ, West R, Hastings J, et al. Development of an intervention setting ontology for behaviour change: specifying where interventions take place. Wellcome Open Res 2020;5:124 [FREE Full text] [doi: 10.12688/wellcomeopenres.15904.1] [Medline: 32964137]
51. Kenny E, McEvoy JW, McSharry J, Collins LM, Taylor RS, Byrne M. Are behaviour change techniques and intervention features associated with effectiveness of digital cardiac rehabilitation programmes? A systematic review protocol. HRB Open Res 2021 Aug 11;4:88-94 [FREE Full text] [doi: 10.12688/hrbopenres.13355.1] [Medline: 35088032]
52. Froome H, Cheung KL, Martin W, Norris E. Identifying and characterising digital behaviour change interventions to improve fruit and vegetable intake in low-socioeconomic status primary school children: a systematic review. BMC Digit Health 2024 Jun 10;2(1):1-16. [doi: 10.1186/S44247-024-00085-W]
53. Lisowska A, Wilk S, Peleg M. SATO (IDEAS expAnded wiTh BCIO): workflow for designers of patient-centered mobile health behaviour change intervention applications. J Biomed Inform 2023 Feb;138:104276 [FREE Full text] [doi: 10.1016/j.jbi.2022.104276] [Medline: 36586499]
54. McClatchey K, Sheldon A, Steed L, Sheringham J, Holmes S, Preston M, IMP2ART Programme Group. Development of theoretically informed audit and feedback: an exemplar from a complex implementation strategy to improve asthma self-management in UK primary care. J Eval Clin Pract 2024 Feb 12;30(1):86-100. [doi: 10.1111/jep.13895] [Medline: 37438918]
55. Slattery P, Saeri AK, Bragge P. Research co-design in health: a rapid overview of reviews. Health Res Policy Syst 2020 Feb 11;18(1):17 [FREE Full text] [doi: 10.1186/s12961-020-0528-9] [Medline: 32046728]
56. Yardley L, Ainsworth B, Arden-Close E, Muller I. The person-based approach to enhancing the acceptability and feasibility of interventions. Pilot Feasibility Stud 2015 Oct 26;1(1):37 [FREE Full text] [doi: 10.1186/s40814-015-0033-z] [Medline: 27965815]

XSL•FO
RenderX

57. Greenhalgh T, Jackson C, Shaw S, Janamian T. Achieving research impact through co-creation in community-based health services: literature review and case study. Milbank Q 2016 Jun;94(2):392-429 [FREE Full text] [doi: 10.1111/1468-0009.12197] [Medline: 27265562]
58. Larsson I, Staland-Nyman C, Svedberg P, Nygren JM, Carlsson IM. Children and young people's participation in developing interventions in health and well-being: a scoping review. BMC Health Serv Res 2018 Jun 28;18(1):507 [FREE Full text] [doi: 10.1186/s12913-018-3219-2] [Medline: 29954392]
59. Hunleth JM, Spray JS, Meehan C, Lang CW, Njelesani J. What is the state of children's participation in qualitative research on health interventions?: a scoping study. BMC Pediatr 2022 Jun 04;22(1):328 [FREE Full text] [doi: 10.1186/s12887-022-03391-2] [Medline: 35659206]
60. Morgan K, Van Godwin J, Darwent K, Fildes A. Formative research to develop a school-based, community-linked physical activity role model programme for girls: CHoosing Active Role Models to INspire Girls (CHARMING). BMC Public Health 2019 Apr 25;19(1):437 [FREE Full text] [doi: 10.1186/s12889-019-6741-1] [Medline: 31023293]
61. Funnell SC, Rogers PJ. Purposeful Program Theory: Effective Use of Theories of Change and Logic Models. Hoboken, NJ: John Wiley & Sons; 2011.
62. The Refined DEIS Identification model. Social Inclusion Unit, Department of Education. 2022. URL: https://www.google.com/url?sa=i&url=https%3A%2F%2Fassets.gov.ie%2F220043%2Fd6b98002-a904-427f-b48a-0fa0af756ea7.pdf&psig=AOvVaw16uuTwjRSzWcEgkAD8ux=1734106447800&source=images&cd=vfe&opi=89978449&ved=0CAQQjhxqFwoTCKDwyYqKkAxUAAAAAHQAAAAQBA [accessed 2024-04-29]
63. Rhodes RE, Kaushal N, Quinlan A. Is physical activity a part of who I am? A review and meta-analysis of identity, schema and physical activity. Health Psychol Rev 2016 Jun 02;10(2):204-225. [doi: 10.1080/17437199.2016.1143334] [Medline: 26805431]
64. Rhodes RE, Berry T, Faulkner G, Latimer-Cheung AE, O'Reilly N, Tremblay MS, et al. Application of the multi-process action control framework to understand parental support of child and youth physical activity, sleep, and screen time behaviours. Appl Psychol Health Well Being 2019 Jul 11;11(2):223-239. [doi: 10.1111/aphw.12150] [Medline: 30743309]
65. Cowley ES, Watson PM, Foweather L, Belton S, Thompson A, Thijssen D, et al. "Girls aren't meant to exercise": perceived influences on physical activity among adolescent girls-the HERizon project. Children (Basel) 2021 Jan 07;8(1):31 [FREE Full text] [doi: 10.3390/children8010031] [Medline: 33430413]
66. Duffey K, Barbosa A, Whiting S, Mendes R, Yordi Aguirre I, Tcymbal A, et al. Barriers and facilitators of physical activity participation in adolescent girls: a systematic review of systematic reviews. Front Public Health 2021 Oct 15;9:743935 [FREE Full text] [doi: 10.3389/fpubh.2021.743935] [Medline: 34722450]
67. Emm-Collison L, Cross R, Garcia Gonzalez M, Watson D, Foster C, Jago R. Children's voices in physical activity research: a qualitative review and synthesis of UK children's perspectives. Int J Environ Res Public Health 2022 Mar 28;19(7):3993 [FREE Full text] [doi: 10.3390/ijerph19073993] [Medline: 35409676]
68. Ingram G, McCormick A, Gibson K. Parents' experiences of starting and maintaining exercise: a qualitative systematic review. Psychol Sport Exerc 2021 Nov;57:102058. [doi: 10.1016/j.psychsport.2021.102058]
69. McGannon KR, Schinke RJ. "My first choice is to work out at work; then i don't feel bad about my kids": a discursive psychological analysis of motherhood and physical activity participation. Psychol Sport Exerc 2013 Mar;14(2):179-188. [doi: 10.1016/j.psychsport.2012.10.001]
70. Rhodes RE, Cox A, Sayar R. What predicts the physical activity intention-behavior gap? A systematic review. Ann Behav Med 2022 Jan 01;56(1):1-20. [doi: 10.1093/abm/kaab044] [Medline: 34231844]
71. Rhodes RE, Lim C. Promoting parent and child physical activity together: elicitation of potential intervention targets and preferences. Health Educ Behav 2018 Feb 17;45(1):112-123. [doi: 10.1177/1090198117704266] [Medline: 28415853]
72. Rhodes RE, Spence JC, Berry T, Deshpande S, Faulkner G, Latimer-Cheung AE, et al. Understanding action control of parental support behavior for child physical activity. Health Psychol 2016 Feb;35(2):131-140. [doi: 10.1037/hea0000233] [Medline: 26214074]
73. Shannon CS. Facilitating Physically Active Leisure for Children Who Are Overweight. J Leis Res 2017 Dec 13;46(4):395-418. [doi: 10.1080/00222216.2014.11950334]
74. Sohun R, MacPhail A, MacDonncha C. Physical activity parenting practices in Ireland: a qualitative analysis. Sport Educ Soc 2020 Feb 11;26(3):281-294 [FREE Full text] [doi: 10.1080/13573322.2020.1723520]
75. Stirrup J, Duncombe R, Sandford R. 'Intensive mothering' in the early years: the cultivation and consolidation of (physical) capital. Sport Educ Soc 2014 Sep 26;20(1):89-106. [doi: 10.1080/13573322.2014.941797]
76. Sutcliffe JT, Fernandez DK, Kelly PJ, Vella SA. The parental experience in youth sport: a systematic review and qualitative meta-study. Int Rev Sport Exerc Psychol 2021 Nov 11;17(1):236-263. [doi: 10.1080/1750984x.2021.1998576]
77. Law RJ, Langley J, Hall B, Burton C, Hiscock J, Williams L. Promoting physical activity and physical function in people with long-term conditions in primary care: the Function First realist synthesis with co-design. Health Serv Deliv Res 2021;9(16):54 [FREE Full text] [doi: 10.3310/hsdr09160] [Medline: 34582134]
78. McKay FH, Slykerman S, Dunn M. The app behavior change scale: creation of a scale to assess the potential of apps to promote behavior change. JMIR Mhealth Uhealth 2019 Jan 25;7(1):e11130 [FREE Full text] [doi: 10.2196/11130] [Medline: 30681967]

XSL•FO
RenderX

79. Monteiro-Guerra F, Signorelli GR, Tadas S, Dorronzoro Zubiete E, Rivera Romero O, Fernandez-Luque L, et al. A personalized physical activity coaching app for breast cancer survivors: design process and early prototype testing. JMIR Mhealth Uhealth 2020 Jul 15;8(7):e17552 [FREE Full text] [doi: 10.2196/17552] [Medline: 32673271]
80. Lawler M, Heary C, Shorter G, Nixon E. Peer and parental processes predict distinct patterns of physical activity participation among adolescent girls and boys. Int J Sport Exerc Psychol 2021 Mar 01;20(2):497-514 [FREE Full text] [doi: 10.1080/1612197X.2021.1891118]
81. Tanaka C, Okuda M, Tanaka M, Inoue S, Tanaka S. Associations of physical activity and sedentary time in primary school children with their parental behaviors and supports. Int J Environ Res Public Health 2018 Sep 13;15(9):1995 [FREE Full text] [doi: 10.3390/ijerph15091995] [Medline: 30217021]
82. Brennan C, O'Donoghue G, Hall AM, Keogh A, Matthews J. A systematic review of the intervention characteristics, and behavior change theory and techniques used in mother-daughter interventions targeting physical activity. Prev Med 2021 Dec;153:106764 [FREE Full text] [doi: 10.1016/j.ypmed.2021.106764] [Medline: 34411587]
83. Brennan C, O'Donoghue G, Keogh A, Rhodes RE, Matthews J. "It's what mothers do." A qualitative exploration of mothers' experiences of supporting their daughter to be physically active. PLoS One 2024 Apr 1;19(4):e0299260 [FREE Full text] [doi: 10.1371/journal.pone.0299260] [Medline: 38558034]
84. Brennan C, O'Donoghue G, Keogh A, Rhodes RE, Matthews J. "You are either sporty or you are not" a qualitative exploration of pre-teen girls of low-socioeconomic position experiences of being physically active. Psychol Sport Exerc 2024 Sep;74:102692. [doi: 10.1016/j.psychsport.2024.102692] [Medline: 38945186]
85. Ryan RM, Deci EL. Self-Determination Theory: Basic Psychological Needs in Motivation, Development, and Wellness. New York, NY: The Guilford Press; 2017.
86. Liu S, La H, Willms A, Rhodes RE. A "No-Code" app design platform for mobile health research: development and usability study. JMIR Form Res 2022 Aug 18;6(8):e38737 [FREE Full text] [doi: 10.2196/38737] [Medline: 35980740]
87. Willms A, Rhodes RE, Liu S. The development of a hypertension prevention and financial-incentive mHealth program using a "no-code" mobile app builder: development and usability study. JMIR Form Res 2023 Apr 05;7:e43823 [FREE Full text] [doi: 10.2196/43823] [Medline: 37018038]
88. Champion KE, Gardner LA, McCann K, Hunter E, Parmenter B, Aitken T, et al. Parent-based interventions to improve multiple lifestyle risk behaviors among adolescents: a systematic review and meta-analysis. Prev Med 2022 Nov;164:107247 [FREE Full text] [doi: 10.1016/j.ypmed.2022.107247] [Medline: 36075490]
89. Samdal GB, Eide GE, Barth T, Williams G, Meland E. Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults; systematic review and meta-regression analyses. Int J Behav Nutr Phys Act 2017 Mar 28;14(1):42 [FREE Full text] [doi: 10.1186/s12966-017-0494-y] [Medline: 28351367]
90. McEwan D, Beauchamp MR, Kouvousis C, Ray CM, Wyrough A, Rhodes RE. Examining the active ingredients of physical activity interventions underpinned by theory versus no stated theory: a meta-analysis. Health Psychol Rev 2019 Mar 20;13(1):1-17. [doi: 10.1080/17437199.2018.1547120] [Medline: 30412685]
91. Rhodes RE, Liu S, Lithopoulos A, Zhang CQ, Garcia-Barrera MA. Correlates of perceived physical activity transitions during the COVID-19 pandemic among Canadian adults. Appl Psychol Health Well Being 2020 Dec;12(4):1157-1182 [FREE Full text] [doi: 10.1111/aphw.12236] [Medline: 33006279]
92. Hynynen S, van Stralen MM, Sniehotta FF, Araújo-Soares V, Hardeman W, Chinapaw MJ, et al. A systematic review of school-based interventions targeting physical activity and sedentary behaviour among older adolescents. Int Rev Sport Exerc Psychol 2016 Jan 01;9(1):22-44 [FREE Full text] [doi: 10.1080/1750984X.2015.1081706] [Medline: 26807143]
93. Howlett N, Trivedi D, Troop NA, Chater AM. Are physical activity interventions for healthy inactive adults effective in promoting behavior change and maintenance, and which behavior change techniques are effective? A systematic review and meta-analysis. Transl Behav Med 2019 Jan 01;9(1):147-157 [FREE Full text] [doi: 10.1093/tbm/iby010] [Medline: 29506209]
94. Allcott-Watson H, Chater A, Troop N, Howlett N. A systematic review of interventions targeting physical activity and/or healthy eating behaviours in adolescents: practice and training. Health Psychol Rev 2024 Mar 10;18(1):117-140. [doi: 10.1080/17437199.2023.2173631] [Medline: 36722423]
95. Nguyen NT, Collins A, Collins CM. Trends and patterns in the application of co-production, co-creation, and co-design methods in studies of green spaces: a systematic review. Environ Sci Policy 2024 Feb;152:103642 [FREE Full text] [doi: 10.1016/j.envsci.2023.103642]
96. O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, et al. Guidance on how to develop complex interventions to improve health and healthcare. BMJ Open 2019 Aug 15;9(8):e029954 [FREE Full text] [doi: 10.1136/bmjopen-2019-029954] [Medline: 31420394]
97. Bradbury K, Steele M, Corbett T, Geraghty AW, Krusche A, Heber E, et al. Developing a digital intervention for cancer survivors: an evidence-, theory- and person-based approach. NPJ Digit Med 2019 Sep 02;2(1):85 [FREE Full text] [doi: 10.1038/s41746-019-0163-4] [Medline: 31508496]
98. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014 Mar 07;348(mar07 3):g1687 [FREE Full text] [doi: 10.1136/bmj.g1687] [Medline: 24609605]

XSL•FO
RenderX

99. Iribarren SJ, Akande TO, Kamp KJ, Barry D, Kader YG, Suelzer E. Effectiveness of mobile apps to promote health and manage disease: systematic review and meta-analysis of randomized controlled trials. JMIR Mhealth Uhealth 2021 Jan 11;9(1):e21563 [FREE Full text] [doi: 10.2196/21563] [Medline: 33427672]
100. Domin A, Spruijt-Metz D, Theisen D, Ouzzahra Y, Vögele C. Smartphone-based interventions for physical activity promotion: scoping review of the evidence over the last 10 years. JMIR Mhealth Uhealth 2021 Jul 21;9(7):e24308 [FREE Full text] [doi: 10.2196/24308] [Medline: 34287209]
101. Rondina R, Hong M, Sarma S, Mitchell M. Is it worth it? Cost-effectiveness analysis of a commercial physical activity app. BMC Public Health 2021 Oct 27;21(1):1950-1910 [FREE Full text] [doi: 10.1186/s12889-021-11988-y] [Medline: 34706689]
102. Willms A, Rush J, Hofer S, Rhodes RE, Liu S. Advancing physical activity research methods using real-time and adaptive technology: a scoping review of "no-code" mobile health app research tools. Sport Exerc Perform Psychol 2024 Sep 23;7:1. [doi: 10.1037/spy0000360]
103. Glasgow RE, Harden SM, Gaglio B, Rabin B, Smith ML, Porter GC, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. Front Public Health 2019;7:64 [FREE Full text] [doi: 10.3389/fpubh.2019.00064] [Medline: 30984733]
104. Tong F, Lederman R, D'Alfonso S, Berry K, Bucci S. Conceptualizing the digital therapeutic alliance in the context of fully automated mental health apps: a thematic analysis. Clin Psychol Psychother 2023 Apr 11;30(5):998-1012. [doi: 10.1002/cpp.2851] [Medline: 37042076]
105. Gillison FB, Rouse P, Standage M, Sebire SJ, Ryan RM. A meta-analysis of techniques to promote motivation for health behaviour change from a self-determination theory perspective. Health Psychol Rev 2019 Mar 16;13(1):110-130. [doi: 10.1080/17437199.2018.1534071] [Medline: 30295176]
106. Ntoumanis N, Ng JY, Prestwich A, Quested E, Hancox JE, Thøgersen-Ntoumani C, et al. A meta-analysis of self-determination theory-informed intervention studies in the health domain: effects on motivation, health behavior, physical, and psychological health. Health Psychol Rev 2021 Jun 03;15(2):214-244 [FREE Full text] [doi: 10.1080/17437199.2020.1718529] [Medline: 31983293]
107. Villalobos-Zúñiga G, Cherubini M. Apps that motivate: a taxonomy of app features based on self-determination theory. Int J Hum Comput Stud 2020 Aug;140:102449 [FREE Full text] [doi: 10.1016/j.ijhcs.2020.102449]
108. Tong F, Lederman R, D'Alfonso S, Berry K, Bucci S. Digital therapeutic alliance with fully automated mental health smartphone apps: a narrative review. Front Psychiatry 2022 Jun 22;13:819623 [FREE Full text] [doi: 10.3389/fpsyt.2022.819623] [Medline: 35815030]
109. Jourdan D, Gray NJ, Barry MM, Caffe S, Cornu C, Diagne F, et al. Supporting every school to become a foundation for healthy lives. Lancet Child Adolesc Health 2021 Apr;5(4):295-303. [doi: 10.1016/S2352-4642(20)30316-3] [Medline: 33485407]
110. Haapala HL, Hirvensalo MH, Kulmala J, Hakonen H, Kankaanpää A, Laine K, et al. Changes in physical activity and sedentary time in the Finnish Schools on the Move program: a quasi-experimental study. Scand J Med Sci Sports 2017 Nov 26;27(11):1442-1453. [doi: 10.1111/sms.12790] [Medline: 27781314]
111. Pfledderer CD, Burns RD, Byun W, Carson RL, Welk GJ, Brusseau TA. School-based physical activity interventions in rural and urban/suburban communities: a systematic review and meta-analysis. Obes Rev 2021 Sep 03;22(9):e13265. [doi: 10.1111/obr.13265] [Medline: 33938109]
112. Emery LF, Silverman DM, Carey RM. Conducting research with people in lower-socioeconomic-status contexts. Adv Methods Pract Psychol Sci 2023 Oct 31;6(4):25152459231193044 [FREE Full text] [doi: 10.1177/25152459231193044]
113. McKay HA, Kennedy SG, Macdonald HM, Naylor PJ, Lubans DR. The secret sauce? Taking the mystery out of scaling-up school-based physical activity interventions. J Phys Act Health 2024 Aug 01;21(8):731-740 [FREE Full text] [doi: 10.1123/jpah.2024-0274] [Medline: 38936808]
114. McLoughlin GM, Salmon J. How can we equitably scale-up physical activity interventions to ensure everyone has opportunities to thrive? J Phys Act Health 2024 Aug 01;21(8):729-730. [doi: 10.1123/jpah.2024-0342] [Medline: 38936804]
115. Crane M, Lee K, Wolfenden L, Phongsavan P, Bauman A. Real-world public health interventions demonstrate how research evidence informs program scale-up. Health Promot Int 2024 Oct 01;39(5):daae111. [doi: 10.1093/heapro/daae111] [Medline: 39312717]
116. Haggis C, Sims-Gould J, Winters M, Gutteridge K, McKay HA. Sustained impact of community-based physical activity interventions: key elements for success. BMC Public Health 2013 Sep 27;13(1):892 [FREE Full text] [doi: 10.1186/1471-2458-13-892] [Medline: 24069938]
117. Rhodes RE, Hollman H, Sui W. Family-based physical activity interventions and family functioning: a systematic review. Fam Process 2024 Mar;63(1):392-413. [doi: 10.1111/famp.12864] [Medline: 36748347]
118. Thabrew H, Stasiak K, Hetrick SE, Wong S, Huss JH, Merry SN. E-Health interventions for anxiety and depression in children and adolescents with long-term physical conditions. Cochrane Database Syst Rev 2018 Aug 15;8(8):CD012489 [FREE Full text] [doi: 10.1002/14651858.CD012489.pub2] [Medline: 30110718]

XSL•FO
RenderX

119. Wojcik G, Ring N, Willis DS, Williams B, Kydonaki K. Improving antibiotic use in hospitals: development of a digital antibiotic review tracking toolkit (DARTT) using the behaviour change wheel. Psychol Health 2024 Nov 28;39(11):1635-1655. [doi: 10.1080/08870446.2023.2182894] [Medline: 36855847]
120. Hall J, Morton S, Hall J, Clarke DJ, Fitzsimons CF, English C, et al. A co-production approach guided by the behaviour change wheel to develop an intervention for reducing sedentary behaviour after stroke. Pilot Feasibility Stud 2020 Aug 17;6(1):115 [FREE Full text] [doi: 10.1186/s40814-020-00667-1] [Medline: 32821421]

Abbreviations

BCIO: Behaviour Change Intervention Ontology
BCT: behavior change technique
BCTO: Behaviour Change Technique Ontology
BCW: Behaviour Change Wheel
COM-B: Capability, Opportunity, and Motivation–Behavior
mHealth: mobile health
MRC: Medical Research Council
PA: physical activity
PAVA-D: Physical Activity Virtual Assistant for Daughters
PAVA-M: Physical Activity Virtual Assistant for Mothers
SDT: self-determination theory
SEP: socioeconomic position
TDF: Theoretical Domains Framework
TIDieR: Template for Intervention Description and Replication

Edited by S Badawy; submitted 31.05.24; peer-reviewed by MR Sweeney, S Jiang, E Cowley; comments to author 03.09.24; revised version received 21.10.24; accepted 26.10.24; published 06.01.25.

Please cite as:
Brennan C, ODonoghue G, Keogh A, Rhodes RE, Matthews J
Developing an Evidence- and Theory-Informed Mother-Daughter mHealth Intervention Prototype Targeting Physical Activity in Preteen Girls of Low Socioeconomic Position: Multiphase Co-Design Study
JMIR Pediatr Parent 2025;8:e62795
URL: https://pediatrics.jmir.org/2025/1/e62795
doi:10.2196/62795
PMID:

©Carol Brennan, Grainne ODonoghue, Alison Keogh, Ryan E Rhodes, James Matthews. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 06.01.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Augmenting Parenting Programs With the Pause Mobile App: Mixed Methods Evaluation

Nathan Hodson[1], MRCPsych; Peter Ivor Woods[2], MRCP; Stephanie Donohoe[2], MA; Juan Luque Solano[3], BSc; James Gardner[4], MRCPsych; Manuel Giardino[2], MPhil; Michael Sobolev[5], PhD; Domenico Giacco[2], MRCPsych

[1]Warwick Medical School, University of Warwick, Coventry, United Kingdom

[2]University of Warwick, Coventry, United Kingdom

[3]University of Buckingham, Buckingham, United Kingdom

[4]Coventry and Warwickshire Partnership NHS Trust, Coventry, United Kingdom

[5]Cedars-Sinai Medical Center, Los Angeles, CA, United States

Corresponding Author:
Nathan Hodson, MRCPsych
Warwick Medical School
University of Warwick
Gibbett Hill Road
Coventry, CV4 7AL
United Kingdom
Phone: 44 024 7652 3523
Email: nathan.hodson@warwick.ac.uk

Abstract

Background: Parenting programs are the recommended treatment for common mental health problems of childhood such as conduct disorder. In the United Kingdom, local authorities have responsibility for providing or commissioning these programs through face-to-face and video call weekly groups and e-learning style asynchronous offerings. However, there has been a shortage of research into the potential of digital resources to augment and enhance parenting groups.

Objective: This pilot study aimed to explore whether providing digital microinterventions in a mobile app (Pause) to augment parenting programs is a feasible strategy. Pause fits into parenting programs and prompts and supports parents to use each week's new parenting skill at home. Specifically, we want to understand (1) whether parents use Pause, (2) what type of features or tools in Pause are most frequently used for support, and (3) what are the perceived strengths and weaknesses of Pause.

Methods: Pause was provided to parents attending 3 of the most common parenting programs delivered across 3 local authorities in the United Kingdom. During weekly sessions, parents were supported to add "tools" in the app, which mapped onto the training in their session, for example, distracting their child, setting age-appropriate consequences, and using praise. Preprogram surveys were obtained at the first session. After programs were completed, postprogram surveys were administered to measure app use, gather which tools parents used, and explore the strengths and weaknesses of the app. Participants and practitioners were invited for interviews, where the strengths and weaknesses of augmenting parenting programs with Pause were discussed in more detail.

Results: In total, 53 parents were recruited from groups. A total of 25 of 53 (47%) parents completed postsurveys distributed at their final parenting group session, in keeping with typical rates of attrition in parenting programs. In addition, 7 parents and 3 practitioners agreed to interviews after the program. Most of the parents (23/25, 92%) had used Pause. Other than the journal, used by 17 parents, the most popular tools were the relax tool and praise tool, each used by 10 parents. Survey data revealed specific strengths and weaknesses of the tools in Pause, particularly highlighting that parents wanted Pause to provide more ideas for distraction or relaxation activities. Interviews revealed the challenges parents attending programs face, the range of family members using Pause, and the diverse settings where it was used. Interviews also revealed specific opportunities for improving the user interface and for addressing challenges in the journaling function.

Conclusions: This pilot study found good acceptability and engagement with Pause. Interviews revealed promising evidence, suggesting that Pause may improve family life and aid child behavior change. Future research should evaluate whether adding Pause to parenting programs increases their positive effects on children's behavior and mental health.

(JMIR Pediatr Parent 2025;8:e68807) doi:10.2196/68807

XSL•FO
RenderX

KEYWORDS

digital microintervention; parenting app; parenting; children's mental health; local authority

Introduction

Background

Parenting programs are recommended as the first-line treatment for common mental health problems of childhood such as disruptive behavior disorders and attention-deficit/hyperactivity disorder [1-3]. In the United Kingdom, such parenting programs are predominantly commissioned or delivered through local government [4]. Provision tends to include groups (whether face-to-face or via video call) and e-learning style asynchronous offerings [4,5]. However, there has been a shortage of research into the potential of digital resources and mobile technology to augment parenting groups and enhance change in parenting style to better match evidence-based approaches [6,7].

Poor parent engagement is an ongoing challenge in these programs, stopping families from receiving the full benefit of programs, so it is important to evaluate means of augmenting programs to maximize engagement and therefore increase impact. One systematic review found that only around half of parents who start a parenting program finish it [8]. A large study of a web-based parenting intervention found that, in practice, as few as 7% of referred parents complete the program [9]. This problem may arise in part due to the didactic delivery of programs, which is not well-suited to all parents [10]. Moreover, education is not always sufficient for behavior change. Insights from behavioral economics can ensure that interventions to encourage health-promoting behaviors achieve their potential [11,12]. For example, social norm insights can help avoid situations, where interventions aimed at reducing harmful behaviors in fact normalize and increase them [13].

Digital microinterventions provide one potential means of promoting parenting style change due to the focus on optimizing engagement. Digital microinterventions involve a trigger situation prompting a decision rule process, which is mediated by an app but situated within a wider therapeutic process [14].

Pause (Pause Ltd) is a digital platform that was developed to provide parents with a selection of digital microinterventions to augment parenting programs [6]. The digital microinterventions in Pause—called "tools"—each corresponds to one of the skills parents are taught during parenting programs, such as praise, time together, or distract. As the parenting program proceeds and new skills are taught, group leaders support parents to add the corresponding tool to their toolkit on Pause [10]. In between group sessions, they can use those tools to help them increase the frequency and quality of their use of that particular skill. For example, parents can use the "distract tool" to help them think about how to distract their child from emotions or from unwanted behavior. The distract tool includes 4 age-appropriate distraction ideas and includes space for parents to add ideas for ways to distract their particular child. Another tool, the relax zone, guides parents through teaching their child grounding activities, which they can use to manage anxiety or overwhelming emotions. Finally, the consequences tool suggests age- and neurodevelopmentally appropriate consequences and guides parents through the process of setting short feasible consequences and getting back on good terms immediately after. The wide range of tools is designed either to be used in the heat of the moment when parents face a challenge or to structure a planned interaction. Previous papers describe the development of the app [6,7].

Best practice software development is iterative and user-centered. It is therefore important to find out whether the approach taken in Pause is acceptable and engaging to parents, whether any tools are not engaging, and what are the strengths and limitations of this approach.

Aims

This pilot study aimed to explore whether providing digital microinterventions in a mobile app (Pause) to augment parenting programs is a feasible strategy. Specifically, we want to understand (1) whether parents use Pause, (2) what type of features or tools in Pause are most frequently used for support, and (3) what are the strengths and weaknesses of Pause.

Methods

Participants

Participants were recruited through 3 local authorities in the United Kingdom: Wiltshire Council, Leicestershire Council, and Buckinghamshire Council. To accurately draw from Pause's population of interest, inclusion criteria were pragmatic. Included participants were attendees at a parenting program run by a local authority whether or not they had legal parenthood. People younger than 18 years of age were excluded, and people who did not have a mobile phone were unable to participate.

Seven weekly groups were selected for inclusion based on practical considerations at local authorities. All attendees of these groups running between January and June 2024 were invited to participate in the study. Recruitment was conducted directly by parenting practitioners who offered participants QR codes to complete pre- and posttest surveys on Qualtrics (Lake Technology Management, LLC) and to download Pause.

Parenting practitioners' leading groups received 2 personalized training sessions from researchers, where they were shown the relevant tools in Pause. They also had access to ongoing technical and practical support from the research team throughout the study.

Procedures

Practitioners' leading participating groups had 2 training sessions to show them how to add the Pause app to their programs. This training was different for the 3 groups, which were running different programs (Wiltshire Council used a Care for the Family program, Buckinghamshire Council used a Family Links program, and Leicestershire Council used a Triple P program). There was no control group. In the first session, participants were given a chance to download the Pause app, consent to participation, and complete the preintervention surveys. These surveys included demographic information (sex,

XSL•FO
RenderX

decade of age, language spoken, and whether they had a degree), the Parenting Sense of Competence Scale (PSOC), Warwick Edinburgh Well-Being Scale, and the Strengths and Difficulties Questionnaire Conduct Subscale (SDQ-c) [15-17]. At every subsequent session, the practitioner advised participants which "tool" from the Pause app would complement the topic of the session. In every respect aside from the use of the app, practitioners completed the programs as usual. At the end of the study, parents received a second survey, which repeated the consent process and the rest of the preintervention survey as well as including questions about their use of the Pause app and their experience. Specifically, participants were asked which tools on the Pause app had been used. For each tool they had used, they were asked how many times it was used, what was good about it, and what could be improved. All parents who completed these surveys were invited to attend a video call interview with a researcher to explain on how Pause fits into their experience of the parenting program. Finally, parenting practitioners who had led groups using Pause were invited to be interviewed. Interview topic guides are included in Multimedia Appendix 1. Children were not directly involved in this study.

Ethical Considerations

All participants provided informed consent. Participants received a US $13.38 voucher for each survey and a US $26.76 voucher for the interview, up to a maximum of US $53.52. Ethics approval was provided by the Biomedical Sciences Research Ethics Committee at the University of Warwick (BSREC 14/23-24).

Analysis

Demographics

Demographics were described using descriptive statistics, including SDs for continuous measures and percentages for binary measures. The characteristics of those who dropped out were compared with those who completed both surveys using 2-tailed *t* tests and chi-square tests using Stata (version 17; StataCorp LLC).

RQ 1: Did Parents Use Pause?

This research question (RQ) was assessed in 2 ways using data from surveys. First, on the basis that there were no systematic differences between those who completed the postintervention survey and those who were lost to follow-up, we assumed that rates of using the Pause app were the same among those who completed the second survey and those who did not. To measure this, we divided the number who used Pause by the number who completed both surveys.

Second, we calculated the worst-case scenario engagement rate by assuming that none of those who failed to complete the second survey downloaded and used Pause. To measure this, we divided the number who used Pause by the number who completed at least 1 survey.

RQ 2: Which Tools Did Parents Use Pause to Support?

This RQ was assessed using a survey self-report of which tools within Pause were used. Descriptive statistics were used to present how many people used each tool and how many times. These results were presented in a stacked bar chart constructed using Microsoft Excel (version 365). Practitioner interviews were used to evaluate the validity of these findings.

RQ3: What Are the Strengths and Weaknesses of Pause?

This RQ was assessed using thematic analysis based on 3 data sources, free-text data from all postintervention surveys, parent interviews, and practitioner interviews. Surveys were reported using illustrative quotes from each question. Interviews were analyzed using thematic analysis using Taguette qualitative software, conducted following Braun and Clarke's 6 stages, and within a philosophical framework informed by user-centered design [18-20]. Specifically, following familiarization with the data (stage 1), the researchers generated initial codes (stage 2) and searched for themes (stage 3) while remaining attentive to the context of users, their journey through parenting support, the usability of the technology, and opportunities for further refinement—rather than viewing the app as a finished product that either "worked" or "did not." Following these stages, the themes were refined (stage 4), defined and named (stage 5), before being written up (stage 6). Within this framework, the researchers distinguished parents' experience of existing parenting courses from the technology. The technology is added to augment the courses so both are reported because (1) understanding the use of Pause entails a rich understanding of the experience of people in courses and (2) explicitly reporting both reduces the risk of wrongly eliding the course and the app. The resulting coding frame was reported with illustrative quotes.

Results

Participants

In total, 53 parents completed preintervention surveys. Among them, 25 completed the postintervention surveys, 3 of whom had failed to complete preintervention surveys.

The 25 of those who completed the postintervention survey included 22 (88%) female participants, and 3 others were male participants. In total, 3 were in their 20s, 15 were in their 30s, 6 were in their 40s, and 1 was 50 years and older of age. None were in their teenage years. Most of them (n=23, 92%) reported that English was the main language they spoke at home. Only 6 (24%) had a bachelor degree or higher. The mean age of the child they were primarily concerned about was 6.7 (range 3-13) years. A total of 20 were from the Wiltshire site, 3 from Buckinghamshire, and 2 from Leicestershire.

The 22 completers had a mean PSOC score of 55.2 (SD 2.09). In total, 8 (37%) parents scored below the cutoff for low confidence of 58 [21]. The 22 completers had a mean SDQ-c score of 5.5 (SD 2.24), and 18 (82%) scored above the cutoff of 4 for abnormal conduct problems [22]. The 22 completers had a mean adjusted Short Warwick Edinburgh Mental Well-Being Scale (SWEMWBS) score of 18.9 (SD 2.96), and 14 (64%) scored below the cutoff for the lowest 15% of the population (cutoff=19.5) [23].

There were no significant differences between the 22 who completed both surveys and the 29 who only completed the baseline surveys with respect to demographics (sex, age, language spoken at home, educational level, and child age) or

XSL•FO
RenderX

survey responses (PSOC, SDQ-c, and SWEMWBS). Table 1 compares those who completed both surveys with those who only completed one.

Seven participants agreed to interviews. All had completed baseline measures. A total of 4 were from Wiltshire, 1 from Buckinghamshire, and 2 from Leicestershire. They were all female participants, all spoke English at home, and 2 had bachelor degrees. In total, 1 was in her 20s, 5 were in their 30s, and 1 was in her 40s. The mean age of the child they were primarily concerned about was 7.4 (range 4-13) years. Compared with all participants, interviewees had slightly higher confidence (PSOC=58.4; t_{51}=0.943; P=.35), slightly lower conduct problems (SDQ-c=5.0; t_{51}=–1.19; P=.24), and slightly higher well-being (adjusted SWEMWBS=19.8; t_{51}=1.14; P=.26). None of these differences were significant at the .05 level. In addition, we interviewed 3 parenting practitioners who had delivered the Pause program. They were all female, and all from Wiltshire Council.

Table 1. Comparing those who completed only the preintervention survey with those who completed pre- and postintervention surveys.

	Only preintervention survey	Both pre- and postintervention surveys	Statistical tests	
			Statistics	*P* value
PSOC[a], mean (SD)	55.1 (1.87)	55.2 (2.09)	t_{49}=–0.044	.96
SDQ-c[b], mean (SD)	6.14 (1.81)	5.46 (2.24)	t_{49}=1.21	.23
WEMWBS[c] (adjusted), mean (SD)	18.6 (2.36)	18.9 (2.96)	t_{49}=–0.454	.65
Decade of age, mean (SD)	3.1 (0.62)	3.2 (0.81)	t_{49}=–0.62	.54
Child age, mean (SD)	5.9 (2.1)	6.5 (2.5)	t_{49}=–0.93	.36
Female, n (%)	25 (86)	22 (86)	χ^2_1=0.0003	.99
Speaks English at home, n (%)	25 (86)	20 (91)	χ^2_1=0.3	.61
Bachelor degree, n (%)	7 (24)	8 (36)	χ^2_1=0.9	.34

[a]PSOC: Parenting Sense of Competence Scale.

[b]SDQ-c: Strengths and Difficulties Questionnaire Conduct Subscale.

[c]WEMWBS: Warwick Edinburgh Well-Being Scale.

RQ 1: Did Parents Use Pause?

In total, 23 of 25 (92%) parents had downloaded and used the Pause app, and 2 (8%) did not. Both cited concerns about personal data, and 1 reported thinking that using an app to support parenting was inappropriate. They were 1 male and 1 female participant, both in their 30s, both spoke English at home, neither had bachelor degrees, and both from the Wiltshire site.

Given the absence of systematic differences between those who did not complete the postintervention survey and those who completed both surveys, we could assume that the app uptake rate of 92% (23/25) held across the whole sample. However, it is also possible that an unmeasured factor linked both engagement and completion of the second survey. A worst-case scenario estimate is that none of the 29 who dropped out used the app so only 23 of 53 (43%) downloaded and used the Pause app.

RQ 2: Which Skills Did Parents Use Pause to Support?

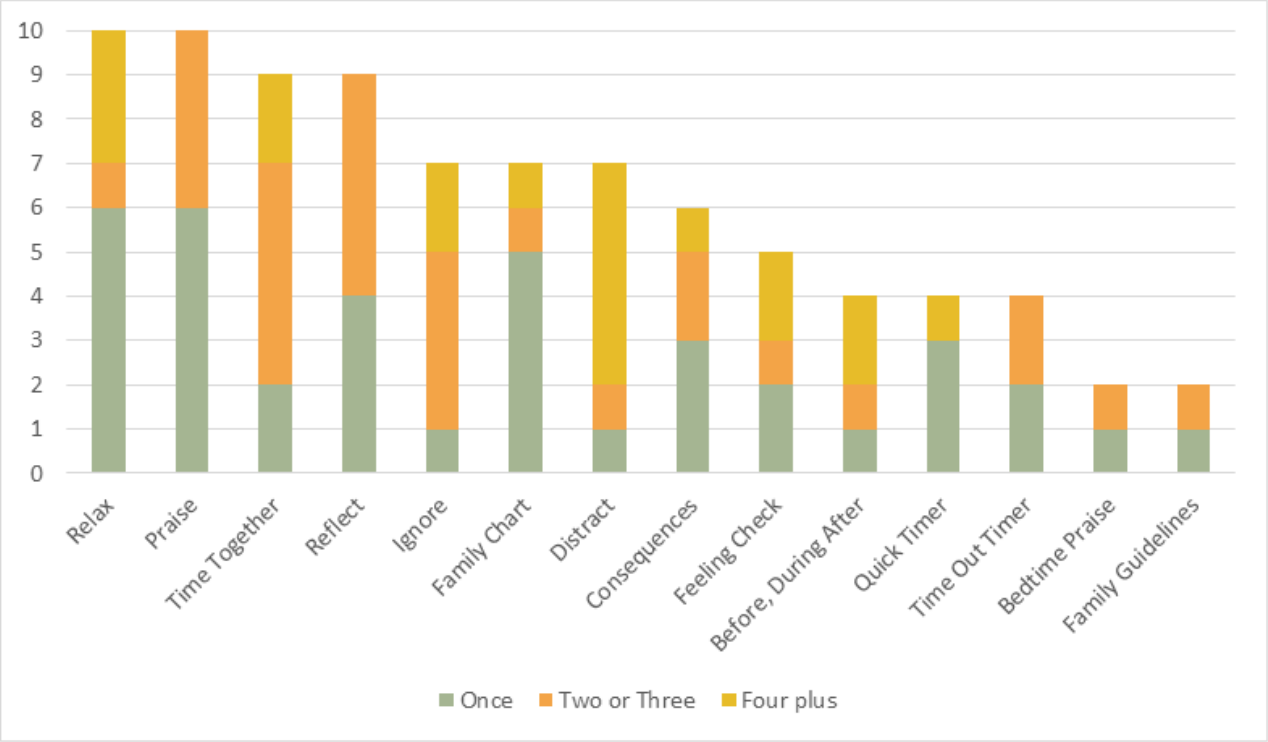
The core components of the Pause app are the child and parent profiles and the journals; in addition to which, there were 15 digital “tools” available to parents. In total, 20 (87%) parents completed the one-off reflective exercise to create a profile for their children, and 15 (65%) completed the one-off reflective activity to create their own parent profile. Only 12 (52%) reported that this was a positive experience, but 2 said that there were too many questions.

In total, 17 (74%) parents had used the journal. Among them, 6 (26%) only used it once, 7 (30%) used it 2 or 3 times, and 4 (17%) used it more than 4 times. A total of 6 (26%) never used it (3 were unaware of the journal, 1 found it confusing, 1 did not think journaling would be helpful, and 1 did not explain why). Among those who used it, for 6 of 17, their favorite feature was writing down thoughts, and for 6 (26%), it was reading it later and noticing their progress. However, when asked about problems with the journal, 7 (30%) reported that they found journaling time-consuming, 3 (313%) reported that they struggled to put thoughts into words, and 2 (9%) reported that they were worried about privacy.

In total, 15 digital “tools” were available for parents through the Pause app. Participating parents were in 3 different parenting programs so they were supported to use different tools. The relax and praise tools were used by 10 (40%) parents each. Both the relax and praise tools were used only once by 6 parents, perhaps because they contain learnable reminders. By contrast, the time together and ignore tools were used more than twice by 7 (28%) and 6 (24%) parents, respectively, only 2 or 1 used the tool only once. Similarly, the distract module was only used by 7 (28%) overall, but 5 of those used it 4 or more times. Figure 1 shows how many parents used each tool and how many times.

XSL•FO
RenderX

Figure 1. How many parents used each tool and how many times?



RQ 3: What Are the Strengths and Limitations of Pause?

Part A: Survey Results

Surveyed parents gave 157 comments about what the "best things" about tools were and also suggested changes. Strengths of the tools included providing a good reminder and a useful distraction, children liking the tools, and creating a helpful structure. Proposed changes included requests for more examples and recommendations, more customization, and simplification. Table 2 describes representative survey results as they relate to each tool.

XSL•FO
RenderX

Table 2. Illustrative quotes of best things and suggested changes to Pause tools.

	Best thing	Suggested changes
Relax	"Daughter found it good when she started struggling she would ask for it as said it helped her" and "It created a distraction when my child's meltdown was about to escalate" [Leicestershire].	"To have more ideas" [Wiltshire].
Praise	"It helps break things down" and "reminder how important it is" [Leicestershire].	"Quite limited, with only a few options" [Wiltshire].
Time together	"It gave us time together and daughter would ask for it" and "The short timers making it easier to show them how long we have" [Leicestershire].	"To add ideas of an activity" [Leicestershire].
Reflect	"Being made aware of how you're feeling as the parent and how it can affect how we parent, it certainly makes you think about what you can do to change your mood in order to be better for your children and in supporting your children through their emotions and difficulties" [Leicestershire].	"Include 'sad' into the emotions" [Leicestershire].
Ignore	"Was a good distraction whilst trying to ignore daughter when she was saying silly/rude words" and "suggestion to distract and timer to help"; "Asks for the reason as to what the need was that caused the behaviour which needed ignoring" [Leicestershire].	"Be able to customise how to ignore not just present one" [Wiltshire].
Family chart	"Being able to set targets for her to follow, and tracking the stars" [Leicestershire].	—[a]
Distract	"Daughter really liked this one, especially if she felt like she was struggling in a situation this would give her something else to focus on and would stop a meltdown" and "Having something to use when out and about" [Leicestershire].	"Add more distract examples" and "be able to customise options" [Wiltshire].
Consequences	"Little games in natural consequences section" [Leicestershire].	"Need to remember to actually look at it. Also didn't look in the moment" [Leicestershire].
Feeling check	"Making them aware of how they're feeling at different times" [Leicestershire].	"Suggestions as to what could be making them feel that way" [Leicestershire].
Before, during, and after	"It was a good way to unpick incidents" and "Breaks it down so you can see what happens during a meltdown and what could have triggered it!" [Leicestershire].	"Option to edit which child as I posted to the wrong child and could not change" and "Be able to voice note it would make it easier to document the event" [Leicestershire].
Quick timer	"Handy and the children can see the timer" [Leicestershire].	—
Time-out	"Handy to have easily accessible" [Buckinghamshire].	"Descriptive example of how to use the option" [Wiltshire].
Bedtime praise	"Prompts" [Buckinghamshire].	—
Family guidelines	—	"Long winded" [Wiltshire].
My body	"It gives you prompts on what to discuss with your child when talking about body" [Wiltshire].	—

[a]Not available.

Part B: Interview Results

Overview

Three themes emerged from these interviews: (1) features of programs without Pause; (2) the interface between parent, child, and Pause app; and (3) the outcomes and effects of the Pause app. The themes are outlined in Table 3.

Table 3. Macro- and microlevel themes.

Macrolevel themes	Microlevel themes
Theme 1: features of programs without Pause	• Theme 1.1: what made programs effective? • Theme 1.2: what made programs difficult?
Theme 2: the interface between parent, child, and app	• Theme 2.1: how Pause was used? • Theme 2.2: interaction with the app
Theme 3: the outcomes and effects of Pause	• Theme 3.1: Pause enhances parenting programs • Theme 3.2: Pause improves behavior and enhances family life

XSL•FO
RenderX

Theme 1: Features of Programs Without Pause (Overview)

Rather than solely discussing Pause, we also explored parents' experience of the program in order to ensure that the strengths and weaknesses of programs in general were not elided with the strengths and weaknesses of Pause. We report these below to illustrate the context in which Pause is being used.

Theme 1.1: What Made Programs Effective?

Participants talked about how their groups were useful because of program content, other parents, and effective practitioners. Nine commented on the content of the program, always positively.

> *I really enjoyed it. I found out a lot of helpful information, so it was really good.* [Participant 2, parent]

The composition of the group, other parents facing similar challenges at home, also added value to the group experience for 4 parents.

> *I'm going through all the things with my child by myself. It kind of makes you feel isolated, so hearing from other parents that they're having the same or similar issues, I think that was the most helpful because it made me feel like it wasn't just me.* [Participant 1, parent]

The careful and inclusive didactic approach of practitioners was also highlighted as a key feature of what made groups useful. Three practitioners specifically mentioned the quality of the explanations.

> *they made sure everyone understood each week what we were doing and made sure by the end of it, everyone was clear of what it was.* [Participant 5, parent]

Theme 1.2: What Made Programs Difficult?

The reasons parents were attending groups also made programs difficult. Specifically, family life was already very difficult due to their children's challenges, and many demands on their time and attention could also lead to attendance problems. Four parents described the problems that had motivated them to seek help for their family, which were primarily due to externalizing behaviors such as meltdowns, anger, violence, and shouting.

> *My son is quite angry and has a lot of angry outbursts. For a long time, I thought he was just being boisterous, but when the same problems started happening at school, I realized there might be something else going on.* [Participant 1, parent]

Six participants commented on the children's neurodevelopmental differences, special educational needs, or subclinical behavior problems, as well as the challenges of long waiting lists and parents' own problems. They did not mention anxiety or low mood among their children.

> *Three out of my four (are) diagnosed autistic and ADHD. My 4 year old is ... he's on waiting lists but he's not quite being diagnosed yet, but he has got traits. I've looked back into my past and things like that and I'm now on waiting lists for an ASD and ADHD diagnosis for myself.* [Participant 6, parent]

All parents were asked about their attendance. Parents and practitioners identified that it is hard for single parents to attend, especially when they have several children with neurodevelopmental disorders, but parents also reported that events come up. Video call sessions were thought to have made it easier to attend.

> *It's rare that you'll get a parent that will attend every single week, because there may be something that's come up, you know, like, obviously, the parents are there and the children have got disabilities.* [Participant 8, practitioner]

All 3 practitioners, but no parents, also gave examples of reasons parents struggle to engage such as circumstances or demographics. For example, unwilling to change parenting style, feeling overwhelmed in groups, or requiring translation.

> *Another barrier is if parents are not willing to make changes but blame everything onto the child.* [Participant 8, practitioner]

Theme 2: The Interface Between Parent, Child, and App (Overview)

Participants reported how Pause was used, noting which people used it, where they used, and which parts of the app they used. They also commented on their experience of interacting with the app, including the user interface and the idea databases.

Theme 2.1: How Pause Was Used

Participants commented on who, where, and when Pause was used and which parts of Pause were used. Nine participants mentioned who used Pause. Pause was used by parents and children. Sometimes it was used by parents and children together, sometimes by parents without their children, and occasionally by children alone. Sometimes it was only used with 1 child, sometimes it was used with all children, and sometimes it was used by the extended family.

> *I've got two children. The oldest is nearly 15, so he wasn't really involved that much. But the youngest is 4, and it was very age-appropriate.* [Participant 1, parent]

Five participants mentioned the settings or scenarios where Pause was used. Parents used the app at relatives' houses, in shops and restaurants, and in their bedrooms alone. They used it during the day, with their children, and also at night alone.

> *It's that big time reassurance that we're going out. We've just been to my nan's and we've had meltdown after meltdown. So I said to her, do you want to do the breathing? And she said yeah, and she sat there with it for a good five minutes, like going through them all. So yeah, it's a great reassurance knowing it's just there and it's a click of a button away.* [Participant 5, parent]

Eight participants commented on specific modules. In total, 11 different modules were mentioned as particularly useful, particularly relax and distract, which were mentioned favorably by 3 parents.

XSL•FO
RenderX

> *We also used the "distract" function a lot. If something was brewing, I'd quickly check for an idea, and now I have a few ideas in my head. It's hard to think on the spot when everything is going on, so it was helpful to have ideas that worked, and it could shift their thought process for a minute.* [Participant 3, parent]

Five participants commented specifically on the function of Pause as a reminder. Parents appreciate Pause providing reminders of when and how to use evidence-based skills.

> *it's been quite helpful as, like, reminders to do things. I've always felt like I'm quite good at praise, but actually having that reminder there, because things can get quite negative quite quickly when you've got behaviors that are quite unwanted. But it's quite good as a reminder.* [Participant 7, parent]

Five participants commented on the good fit between the modules of the Pause app and the content of the parenting programs.

> *I liked, as the course was going on, you could add the modules that you were talking about.*
>
> *Or, you know, so you didn't have everything all in one go. So, as you were going on in the course, they were like, "oh, you can add this module now to your app." I liked that feature because then ... You haven't got everything in one go.* [Participant 6, parent]

Theme 2.2: Interaction With the App

Participants commented freely on the strengths and weaknesses of the user interface, offering ideas for additional features of Pause and particularly requesting additional personalized ideas added to the app.

Nine participants commented on the user interface. Overall, and in general, parents found it easy to use the app. When assigned tasks during the interview, they were almost always able to find things immediately, and all succeeded in the tasks. There were instances of bugs where text entry boxes and buttons did not display properly because the app remains in its infancy.

> *It's really easy to use. So it's fairly self-explanatory. So as you go on to it, you've got your homepage with different sections. Obviously, you can add the sections you want. And it has come in really handy.* [Participant 5, parent]

Parents engaged with the app and had suggestions about potential features that could be added to the app or ideas for improvements to the app. Seven participants offered ideas for additional features. These suggestions related to both interaction with the app and the functions of the app.

> *I wish there was a branch-off for a child version, so he could have it on his iPad. Then he would know when he's starting to feel frustrated. I've implemented a "busy bag" for him, so he might say, "Mum, I think I need 5 minutes quiet time, I'm going to take my busy bag." So maybe there could be a child version of the Pause app, where he could blow out the candles on his iPad or something like that.* [Participant 4, parent]
>
> *Is there a thing in the app where they can request help or ask questions if they're not sure about something?* [Participant 8, practitioner]

Five participants indicated that Pause was particularly useful in providing a database of ideas, which added value for parents.

> *If he's escalating, I can use the app to prompt him, like "How many colors can you name?" I've even sent him to quiet time with a task like, "Can you name as many animals as you can think of?" He's only there for 3 minutes, but it helps.* [Participant 4, parent]

Journaling is a central component of the app so parents were specifically asked about any difficulties with reflection. Several people found reflection hard despite the prompts in Pause, and there is more work to do to ensure everybody gets to reflect on their parenting using Pause.

> *It's just sometimes finding the time to go on your phone to do those things. A lot of the time, things are going on in my head, if you know what I mean, but aren't necessarily on paper or on my phone.* [Participant 7, parent]

Theme 3: The Outcomes and Effects of Pause (Overview)

Parents and practitioners reported that Pause was useful during parenting programs, and parents continued to use it after their programs had finished. Parents reported that Pause had improved their children's behavior and their family life as a whole, linking this to the convenience of using an app. They also reported improved insight into their child's behavior and their own behavior, linking this to the reflection encouraged in Pause.

Theme 3.1: Pause Enhances Parenting Programs

All participants reported that the app helped them. Describing it as "brilliant" (Participant 4, parent) or "really useful" (Participant 2, parent) and explaining that they use it "regularly" (Participant 3, parent).

> *I would say life-changing, really, because before, in a blink of an eye, she could run. And she's fast. Now she will ask for it and it will calm her. So, it has for us made it slightly better going out. Even going to a restaurant now, she will sit with it and she will get the app up and get it up herself. If she's doing the five senses one, she'll walk around the restaurant looking for different stuff and smells. So it has changed a lot for us and it has really helped.* [Participant 5, parent]

Seven participants noted that the app remains useful after the sessions have finished, including all 3 practitioners.

> *I really liked it, and I still use it now. Even though the course has finished, I still use it.* [Participant 2, parent]
>
> *Once they've done the program and they've got the app, they've got it forever. So there'd be no need to come back through the program.* [Participant 10, practitioner]

XSL•FO
RenderX

Theme 3.2: Pause Improves Behavior and Enhances Family Life

Three parents attributed improvements in their child's behavior to Pause.

> *We're out and about and then we feel it's coming, it just, I mean, it works for minutes with her. Once she starts doing it, she's like, I'm calm.* [Participant 5, parent]

> *Now, he's starting to tell me, "I feel a bit fidgety, I need to do something." It would help him take control and gain more independence in regulating himself.* [Participant 4, parent]

Four attributed improvements in their family life to Pause. Parents described how Pause improved life for the whole family, the child who was referred, plus other children and parents.

> *Having the use of the Pause app, where I've been able to take things like consequences and reward systems with me easily, rather than carrying a jar of buttons or a sticker chart—it's enabled me to put other things in place to make life a bit more manageable. Like, when I know there's going to be a meltdown, I can use techniques like "blow out your candles" to stop things before they escalate. So yeah, it's been a really, really good learning curve, and it's been brilliant to be able to apply it to all my children, not just the one who was referred.* [Participant 4, parent]

Five participants commented that the effectiveness of Pause came from it being a mobile app. Specifically, Pause is with parents in their pockets all the time wherever they need it, and parents and children enjoy the interactive nature of sharing the app.

> *They found it useful to be able to refer back to it, because obviously their mobiles are around all the time rather than have, you know, like paperwork.* [Participant 8, practitioner]

Six participants commented on the improvements in insight into children's behavior and what drives them.

> *She said, I'm so glad I've got a Pause app because I used it the whole time through halftime when I felt like I was just losing the plot. And she kept saying that she kept going back to the pause app and it really helped to support her child to know like how he was feeling and to be able to do the before, during and after so she could pick up the patterns and work out why her child was finding, I don't know, doing the particular activity or anything challenging.* [Participant 10, practitioner]

Four participants commented on how parents had also gained insights into their own behavior.

> *It's about taking a step back. We don't need to shout and yell; we can deal with it calmly. It's about making people aware of how to deal with that child and what works.* [Participant 4, parent]

Six participants suggested that reflection had improved due to the Pause app.

> *Especially when I was doing the "before, during, and after," I'd do that on my own and write it down, which I liked because it made me realize, "actually, this happened before," whereas previously, I wouldn't pay attention to that. You'd just think, "what's going on now?" But looking back, I could see it was a trigger.* [Participant 3, parent]

Discussion

Summary of the Results

This pilot study aimed to explore whether providing digital microinterventions to augment parenting programs via the Pause app was feasible. We explored (1) whether parents used Pause, (2) which tools parents used, and (3) what the strengths and weaknesses of the app were. We addressed questions (1) and (2) using a survey of parents who attended groups where Pause was offered. We addressed question (3) by combining survey data with interviews. In total, 25 of 53 (47%) parents completed postsurveys. Only 7 parents and 3 practitioners completed interviews. A total of 23 of 53 (43%) parents who completed presurveys had downloaded and used the Pause app (ie, 92% of those who completed postsurveys used the Pause app). Other than the journal, used by 17 parents, the most popular tools were the relax tool and praise tool, each used by 10 parents. The survey data revealed specific strengths and weaknesses of the tools in the Pause app. Interviews revealed the challenges existing in programs without Pause, the way Pause was used by many family members in diverse settings, and how Pause enhanced parenting programs and improved outcomes for families. Interviews also revealed specific opportunities for improving the user interface and for addressing challenges in the journaling function.

Comparison With the Literature

The main digital alternatives to parenting digital microinterventions are e-learning programs. This study has shown that Pause can offer a different approach. The key limitations of e-learning programs are "providing a 'one size fits all' program with no adaptation or tailoring to the user's state" and "lack of referrals to in-person treatment in relevant cases" [24]. The biggest studies indicate that only around 7% of referred parents complete these interventions [9]. By using Pause to enhance, rather than replace, parenting groups, we ensured that parents received the benefits of tailoring and personalization, which come from group work with a facilitator. This approach is in line with a growing body of research in digital mental health, which highlights the need for human support to ensure long-term engagement and effectiveness of digital tools [25].

In this study, we estimated that 92% of parents used the Pause app sometimes, but acknowledged that it could be as low as 43%, if none of the survey nonresponders downloaded the app. Either way, this figure is difficult to compare with e-learning style programs where sessions are concurrent and so a completion rate can be calculated [26-28]. Patchy engagement

XSL•FO
RenderX

is the norm in digital mental health interventions, and the most important factor is whether parents use evidence-based skills at the appropriate time or whether they do not. Nevertheless, the results of this study indicate that further research to evaluate the effect of the app on parent and child outcomes is appropriate.

Strengths and Limitations

This study tested Pause in a natural setting rather than a laboratory or staged parenting program; this evaluated both the practitioners' engagement with distributing Pause themselves and parents' engagement with the app within the context of the parenting program. Similarly, there were no clinical exclusion criteria so the participants were representative of parenting group attendees in the United Kingdom.

Retention was good within the context of parenting programs. We obtained postprogram surveys from 25 of 53 (47%) parents. Systematic review evidence suggests that 51% of parents disengage before or during long parenting programs such as these, so the proportion of postprogram surveys obtained is likely to represent a large proportion of retained parents [8]. Moreover, 2 parents who did not use Pause completed postprogram surveys, reassuring us that those who did not engage with the intervention were not excluded from data collection. In addition, even after inevitable attrition, the number of included parents was typical for a pilot study of a digital parenting intervention [29-32].

Finally, this paper was strengthened by the use of 4 sources of data: pre- and postprogram surveys, interviews with parents, and interviews with practitioners. These different forms of data collection allowed a rich understanding of how Pause was used within groups.

The main limitation of this study was the self-reported use data. We asked parents to refer to their app to report which "tools" they had added on the app, but it is possible that errors could be made in this process and social desirability bias could have an effect. Although our study design did not include a formal analysis of how frequently tools were used, the self-report data are in keeping with the app feedback, providing some reassurance regarding this potential limitation.

Implications for Research and Practice

Altogether, this pilot study provides preliminary evidence that Pause can be incorporated into parenting programs with positive effects for many parents and no evidence of adverse effects. These findings suggest that it is appropriate to continue honing the Pause app and exploring its short-term and long-term effects on parenting style. Future research should explore whether incorporating Pause into parenting programs leads to greater change in child behavior outcomes such as the Strengths and Difficulties Questionnaire compared with treatment as usual [17]. We used Pause alongside 3 parenting programs in this study, Triple P Primary, Family Links Nurture, and Care for the Family's Time Out for Parents. Future research should explore whether the results are the same with other programs.

In their paper, outlining the basis of digital microinterventions, Baumel et al [14] imagined a "hub" bringing together a suite of digital microinterventions. Pause provides that function for the suite of "tools" in the app. They outlined three areas for research: (1) microrandomized trials, (2) optimizing microintervention suites, and (3) understanding for whom digital microintervention care is suitable for. This paper shines light on (2) and (3) by interrogating the strengths and weaknesses of these microinterventions (allowing optimization) and revealing who uses them (at least 43% of parents who start programs in the included UK local authorities). It also provides proof of concept for augmenting parenting programs with mobile technology, similar to other research in digital mental health [33,34]. We plan to further contribute to research on microinterventions in parenting by exploring options to use microrandomized trials for engagement with Pause [35,36].

Conclusions

The Pause app can be combined with commonly used parenting programs and is well-received by parents. Parents and practitioners identified that Pause enhanced programs and could provide lasting support after programs had finished, with the potential to enhance family life and improve child behavior. Further research is required to evaluate the effect of adding Pause above and beyond treatment as usual, but results indicate that adding digital microinterventions alongside a face-to-face parenting program is a promising, feasible, and acceptable approach at least for some of the parents.

Acknowledgments

The authors would like to thank the local authority teams who supported this project.

Conflicts of Interest

The Pause app is owned by the University of Warwick, and under a division of proceeds agreement, NH and PIW would theoretically be paid from any licensing, but no licensing arrangement is currently underway. PIW is the co-inventor of the Pause Mobile App.

Multimedia Appendix 1
Topic guides.
[DOCX File , 18 KB - pediatrics_v8i1e68807_app1.docx]

References

XSL•FO
RenderX

1. Attention deficit hyperactivity disorder: diagnosis and management: NICE guideline [NG87]. National Institute for Health and Care Excellence. 2019. URL: https://www.nice.org.uk/guidance/ng87 [accessed 2025-03-28]
2. Antisocial behaviour and conduct disorders in children and young people: recognition and management. National Institute for Health and Care Excellence. 2013. URL: https://www.nice.org.uk/guidance/cg158 [accessed 2025-03-28]
3. NA. Conduct disorder. Nat Rev Dis Primers 2019;5(1):44. [doi: 10.1038/s41572-019-0100-5] [Medline: 31249311]
4. Gorringe R, Woods P, Giardino M, Solano JL, Hodson N. Disparities in access to group parenting training programmes: a cross-sectional analysis of local authorities across England. BJPsych open 2024;10(S1):S38-S39. [doi: 10.1192/bjo.2024.153]
5. Baumel A, Pawar A, Kane JM, Correll CU. Digital parent training for children with disruptive behaviors: systematic review and meta-analysis of randomized trials. J Child Adolesc Psychopharmacol 2016;26(8):740-749. [doi: 10.1089/cap.2016.0048] [Medline: 27286325]
6. Hodson N, Woods P, Solano JL, Talbot C, Giacco D. Evaluating a mobile app supporting evidence-based parenting skills: a thematic analysis of parent experience. JMIR Pediatr Parent 2024;7:e53907. [doi: 10.2196/53907]
7. Hodson N, Woods P, Sobolev M, Giacco D. A digital microintervention supporting evidence-based parenting skills: development study using the agile scrum methodology. JMIR Form Res 2024;8:e54892 [FREE Full text] [doi: 10.2196/54892] [Medline: 38941594]
8. Chacko A, Jensen SA, Lowry LS, Cornwell M, Chimklis A, Chan E, et al. Engagement in behavioral parent training: review of the literature and implications for practice. Clin Child Fam Psychol Rev 2016;19(3):204-215. [doi: 10.1007/s10567-016-0205-2] [Medline: 27311693]
9. Dadds MR, Sicouri G, Piotrowska PJ, Collins DAJ, Hawes DJ, Moul C, et al. Keeping parents involved: predicting attrition in a self-directed, online program for childhood conduct problems. J Clin Child Adolesc Psychol 2019;48(6):881-893 [FREE Full text] [doi: 10.1080/15374416.2018.1485109] [Medline: 30067388]
10. Garland AF, Hawley KM, Brookman-Frazee L, Hurlburt MS. Identifying common elements of evidence-based psychosocial treatments for children's disruptive behavior problems. J Am Acad Child Adolesc Psychiatry 2008;47(5):505-514. [doi: 10.1097/CHI.0b013e31816765c2] [Medline: 18356768]
11. Hodson N, Powell BJ, Nilsen P, Beidas RS. How can a behavioral economics lens contribute to implementation science? Implement Sci 2024;19(1):33 [FREE Full text] [doi: 10.1186/s13012-024-01362-y] [Medline: 38671508]
12. Sobolev M. Digital nudging: using technology to nudge for good. In: Mazar N, Soman D, editors. Behavioral Science in the Wild. Toronto: University of Toronto Press; 2022:292-299.
13. Tang MY, Rhodes S, Powell R, McGowan L, Howarth E, Brown B, et al. How effective are social norms interventions in changing the clinical behaviours of healthcare workers? A systematic review and meta-analysis. Implement Sci 2021;16(1):8 [FREE Full text] [doi: 10.1186/s13012-020-01072-1] [Medline: 33413437]
14. Baumel A, Fleming T, Schueller SM. Digital micro interventions for behavioral and mental health gains: core components and conceptualization of digital micro intervention care. J Med Internet Res 2020;22(10):e20631 [FREE Full text] [doi: 10.2196/20631] [Medline: 33118946]
15. Gilmore L, Cuskelly M. Factor structure of the Parenting Sense of Competence scale using a normative sample. Child Care Health Dev 2009;35(1):48-55 [FREE Full text] [doi: 10.1111/j.1365-2214.2008.00867.x] [Medline: 18991983]
16. Tennant R, Hiller L, Fishwick R, Platt S, Joseph S, Weich S, et al. The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS): development and UK validation. Health Qual Life Outcomes 2007;5:63 [FREE Full text] [doi: 10.1186/1477-7525-5-63] [Medline: 18042300]
17. Goodman R. Psychometric properties of the strengths and difficulties questionnaire. J Am Acad Child Adolesc Psychiatry 2001;40(11):1337-1345. [doi: 10.1097/00004583-200111000-00015] [Medline: 11699809]
18. Luna D, Quispe M, Gonzalez Z, Alemrares A, Risk M, Aurelio MG, et al. User-centered design to develop clinical applications. Literature review. Stud Health Technol Inform 2015;216:967. [doi: 10.3233/978-1-61499-564-7-967]
19. Rampin R, Rampin V. Taguette: open-source qualitative data analysis. J Open Source Softw 2021;6(68):3522. [doi: 10.21105/joss.03522]
20. Braun V, Clarke V. Thematic analysis. In: APA Handbook of Research Methods in Psychology Volume 2 Research Designs. Washington, DC: American Psychological Association; 2012:57-71.
21. Johnston C, Mash EJ. A measure of parenting satisfaction and efficacy. J Clin Child Psychol 1989;18(2):167-175. [doi: 10.1207/s15374424jccp1802_8]
22. Bryant A, Guy J, CALM Team, Holmes J. The Strengths and Difficulties Questionnaire predicts concurrent mental health difficulties in a transdiagnostic sample of struggling learners. Front Psychol 2020;11:587821 [FREE Full text] [doi: 10.3389/fpsyg.2020.587821] [Medline: 33329246]
23. Ng Fat L, Scholes S, Boniface S, Mindell J, Stewart-Brown S. Evaluating and establishing national norms for mental wellbeing using the short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS): findings from the health survey for England. Qual Life Res 2017;26(5):1129-1144 [FREE Full text] [doi: 10.1007/s11136-016-1454-8] [Medline: 27853963]
24. Baumel A, Faber K. Evaluating triple P online: a digital parent training program for child behavior problems. Cogn Behav Pract 2018;25(4):538-543. [doi: 10.1016/j.cbpra.2017.10.001]

XSL•FO
RenderX

25. Boucher EM, Raiker JS. Engagement and retention in digital mental health interventions: a narrative review. BMC Digit Health 2024;52(1). [doi: 10.1186/s44247-024-00105-9]
26. Bert SC, Farris JR, Borkowski JG. Parent training: implementation strategies for adventures in parenting. J Prim Prev 2008;29(3):243-261. [doi: 10.1007/s10935-008-0135-y] [Medline: 18446440]
27. Boekhorst MGBM, Hulsbosch LP, Nyklíček I, Spek V, Kastelein A, Bögels S, et al. An online mindful parenting training for mothers raising toddlers: assessment of acceptability, effectiveness, and personal goals. Mindfulness 2020;12(2):519-531. [doi: 10.1007/s12671-020-01542-z]
28. Dittman CK, Farruggia SP, Palmer ML, Sanders MR, Keown LJ. Predicting success in an online parenting intervention: the role of child, parent, and family factors. J Fam Psychol 2014;28(2):236-243. [doi: 10.1037/a0035991] [Medline: 24611694]
29. Murry VM, Berkel C, Liu N. The closing digital divide: delivery modality and family attendance in the Pathways for African American Success (PAAS) program. Prev Sci 2018;19(5):642-651 [FREE Full text] [doi: 10.1007/s11121-018-0863-z] [Medline: 29356928]
30. James Riegler L, Raj SP, Moscato EL, Narad ME, Kincaid A, Wade SL. Pilot trial of a telepsychotherapy parenting skills intervention for veteran families: implications for managing parenting stress during COVID-19. J Psychother Integr 2020;30(2):290-303. [doi: 10.1037/int0000220]
31. Franke N, Keown LJ, Sanders MR. An RCT of an online parenting program for parents of preschool-aged children with ADHD symptoms. J Atten Disord 2020;24(12):1716-1726. [doi: 10.1177/1087054716667598] [Medline: 27609783]
32. Chesnut RP, Czymoniewicz-Klippel M, DiNallo JM, Perkins DF. Grow online: feasibility and proof of concept study. J Child Serv 2019;15(1):25-42. [doi: 10.1108/jcs-10-2018-0026]
33. Moon KC, Sobolev M, Grella M, Alvarado G, Sapra M, Ball T. An mHealth platform for augmenting behavioral health in primary care: longitudinal feasibility study. JMIR Form Res 2022;6(7):e36021 [FREE Full text] [doi: 10.2196/36021] [Medline: 35776491]
34. Bond RR, Mulvenna MD, Potts C, O'Neill S, Ennis E, Torous J. Digital transformation of mental health services. Npj Ment Health Res 2023;2(1):13 [FREE Full text] [doi: 10.1038/s44184-023-00033-y] [Medline: 38609479]
35. Bidargaddi N, Almirall D, Murphy S, Nahum-Shani I, Kovalcik M, Pituch T, et al. To prompt or not to prompt? A microrandomized trial of time-varying push notifications to increase proximal engagement with a mobile health app. JMIR Mhealth Uhealth 2018;6(11):e10123 [FREE Full text] [doi: 10.2196/10123] [Medline: 30497999]
36. Militello L, Sobolev M, Okeke F, Adler DA, Nahum-Shani I. Digital prompts to increase engagement with the Headspace app and for stress regulation among parents: feasibility study. JMIR Form Res 2022;6(3):e30606. [doi: 10.2196/30606] [Medline: 35311675]

Abbreviations

PSOC: Parenting Sense of Competence Scale
RQ: research question
SDQ-c: Strengths and Difficulties Questionnaire Conduct Subscale
SWEMWBS: Short Warwick Edinburgh Mental Well-Being Scale

Edited by S Badawy; submitted 14.11.24; peer-reviewed by TY Wong, M Mansor; comments to author 15.01.25; revised version received 08.02.25; accepted 28.02.25; published 30.04.25.

Please cite as:
Hodson N, Woods PI, Donohoe S, Solano JL, Gardner J, Giardino M, Sobolev M, Giacco D
Augmenting Parenting Programs With the Pause Mobile App: Mixed Methods Evaluation
JMIR Pediatr Parent 2025;8:e68807
URL: https://pediatrics.jmir.org/2025/1/e68807
doi:10.2196/68807
PMID:

©Nathan Hodson, Peter Ivor Woods, Stephanie Donohoe, Juan Luque Solano, James Gardner, Manuel Giardino, Michael Sobolev, Domenico Giacco. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 30.04.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Understanding the Implications of mHealth Technology in Collaborative Care Programs and Its Role in Supporting Postpartum Care: Qualitative Interview Study of the Baby2Home Intervention Using the Parallel Journeys Framework

Chryselle Rego[1], MA; Joshua E Santiago[2], MA; Emily S Miller[3], MD; Craig F Garfield[4], MD; Jacqueline Gollan[4], PhD; Kathleen O'Sullivan[4], MS; Dinah Williams[3], MS; Enid Montague[5], PhD; Young Seok Lee[4], PhD

[1]Jarvis College of Computing and Digital Media, DePaul University, Chicago, United States

[2]The Center for Health and Social Sciences, University of Chicago, Chicago, IL, United States

[3]Division of Maternal Fetal Medicine, The Warren Alpert Medical School, Brown University, Providence, RI, United States

[4]Feinberg School of Medicine, Northwestern Medicine, Chicago, IL, United States

[5]Industrial Engineering, University of Toronto, Toronto, ON, Canada

Corresponding Author:
Chryselle Rego, MA
Jarvis College of Computing and Digital Media
DePaul University
1 E Jackson Blvd
Chicago, 60604
United States
Phone: 1 (312) 362 8000
Email: regochryselle@gmail.com

Abstract

Background: The postpartum period represents a critical period for both birthing and nonbirthing parents due to mental health concerns and new caregiving demands. Collaborative care models aim to address these needs, but postpartum care remains fragmented, lacking continuity and holistic support. Baby2Home (B2H) is a digital intervention rooted in the collaborative care model, specifically designed to support parents through their transition into parenthood by addressing their physical, emotional, and psychosocial needs. This intervention seeks to close the gaps left by traditional care models by providing continuous, organized, and accessible support throughout the postpartum period. In our qualitative study of the B2H intervention, we reference the parallel journeys framework and use it as a part of our analysis to evaluate whether mobile health (mHealth) technology addresses the holistic needs (postpartum and psychosocial) of new parents.

Objective: We aimed to assess how the B2H app supports the holistic needs of new parents and addresses care gaps identified in traditional postpartum services.

Methods: We conducted semistructured interviews with 20 birthing and nonbirthing parents selected through purposive sampling based on their app use. Data were analyzed using the postpartum parallel journeys framework and inductive coding.

Results: Our findings demonstrate the comprehensive impact of the B2H intervention in addressing both the physical and psychosocial needs of new parents. B2H supported postpartum care by helping parents navigate uncertainties, enhancing health care provider–parent communication, promoting self-care, and increasing parental self-efficacy. Psychosocial support included symptom identification, timely care manager assessments, coordinated treatment, and transition resources. The app also addressed care gaps by promoting inclusivity for nonbirthing parents, bridging screening and treatment, supporting real-time treatment navigation, and ensuring continuity of care.

Conclusions: We demonstrate that the use of mHealth technology such as the B2H app can effectively support the multifaceted needs of new parents during their postpartum care period. By applying the parallel journeys framework, the research also identifies gaps in care that are addressed by the B2H app, presenting unique opportunities for future development and research.

(JMIR Pediatr Parent 2025;8:e70936) doi:10.2196/70936

XSL•FO
RenderX

KEYWORDS

mobile health; mHealth; postpartum care; collaborative care programs; mental health; Baby2Home intervention

Introduction

Background

The postpartum period is a critical phase for both birthing and nonbirthing parents as they adjust to the emotional, physical, and lifestyle demands of caring for a newborn [1,2]. Postpartum depression (PPD) is incredibly common among birthing parents, with a prevalence of 10% to 15% [3], and affects about 10% of nonbirthing parents within 3 to 6 months after childbirth [4]. Existing studies on PPD typically focus on birthing parents within the first 2 months post partum. However, a Swedish study [5] extended the time frame to 25 months after childbirth and reported depressive symptoms in 11.3% of birthing parents and 4.9% of nonbirthing parents. Beyond depression, parents face anxiety and psychological distress tied to caregiving responsibilities, which can affect marital quality and parenting behaviors [6,7].

Despite growing recognition of these challenges, postpartum care remains fragmented, often split across multiple care providers, leading to communication gaps and inconsistent support [8]. The COVID-19 pandemic further highlighted the need for scalable, patient-centered care models. In response, collaborative care programs (CCPs) have emerged as a strategic approach to address these gaps in postpartum care, aiming to provide holistic support for new parents [9]. CCPs aim to foster interdisciplinary collaboration by bringing together obstetricians, pediatricians, mental health professionals (care managers [CMs] and psychiatrists) to address the diverse needs of parents and newborns [9]. Health information technologies significantly contribute to the success of these programs by enhancing communication, coordination, and engagement between health care providers and patients. To date, these technologies have primarily included clinician-facing tools [10]. Because collaborative care is a patient-centered approach that seeks to inform and empower patients for improved self-management, incorporating a patient-facing mobile health (mHealth) tool is a logical extension of the collaborative care model (CCM) [11].

Despite the potential of mHealth technology in postpartum care and CCPs, it is crucial to note that the current body of research has primarily focused on designing technologies that support patients in managing their perinatal and postpartum mental health in day-to-day contexts [12]. The key lies in a comprehensive understanding of how mHealth interventions impact the dynamics of CCPs and the extent to which they contribute to the overall success of these programs [13].

Embracing a Holistic Approach: Our Rationale for Developing the Baby2Home Intervention and the Need for Qualitative Inquiry

Previous studies on technology in CCPs have mainly addressed specific aspects of the postpartum experience. Some focused on mobile technologies delivering educational resources to birthing parents [14,15], while others designed interventions targeting their mental health [16-18]. Research also emphasizes that birthing parents' support needs evolve throughout pregnancy and parenthood [19,20]. However, these studies often overlook integrated solutions that address the full postpartum care journey, leaving gaps in how parental mental health, infant care, and overall well-being intersect. In addition, most interventions prioritize birthing parents, often neglecting the significant role of nonbirthing parents in postpartum care [21]. The lack of inclusive, comprehensive programs limits support for families and hinders optimal outcomes for both caregivers and infants [22].

To address this gap, we developed Baby2Home (B2H), an mHealth intervention, based on the CCM, designed to support families holistically by meeting both physical and psychosocial postpartum needs. Unlike existing studies that focus on isolated interventions, B2H is designed to encapsulate the full spectrum of postpartum care for both birthing and nonbirthing parents.

Understanding how such an intervention fits into the broader care experience requires a qualitative approach. A qualitative study enables a deeper exploration of parents' lived experiences, especially around how mHealth technologies influence emotional well-being, engagement with care teams, and adaptation to caregiving roles—dimensions that are not easily captured through quantitative measures.

To guide this inquiry, we applied the parallel journeys framework (PJF). Unlike most frameworks that are primarily designed for health care practitioners, the PJF is distinctive in offering a comprehensive perspective that encompasses the entire postpartum experience from the parent's point of view. This framework uniquely integrates all facets of the postpartum journey, ensuring that the physical and psychosocial needs of parents are thoroughly addressed.

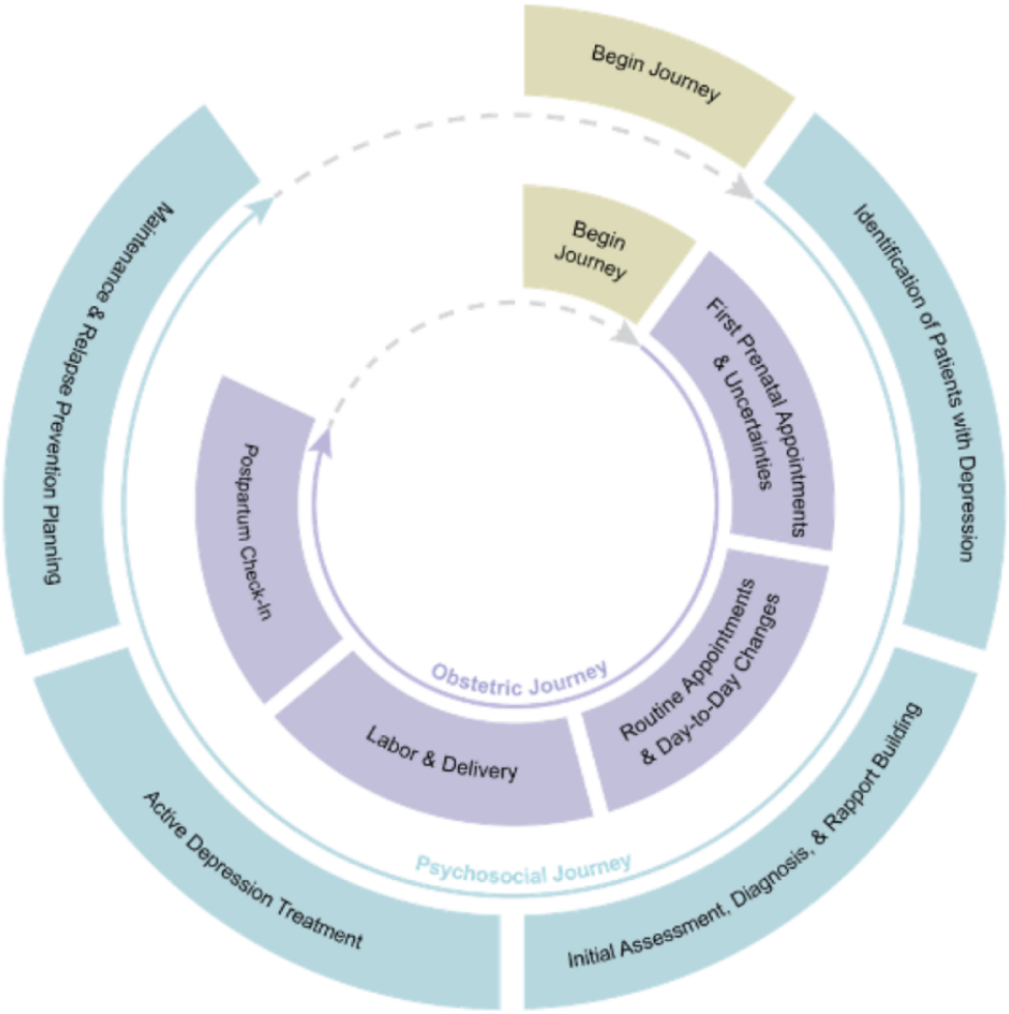
The PJF

Overview

The PJF, conceived by Suh et al [23], offers a lens through which the concurrent and intertwined paths of 2 distinct health care journeys can be examined, especially within collaborative care. Originally developed for collaborative cancer care, this framework sheds light on the intersecting challenges of psychosocial and cancer care journeys. Haldar et al [12] later adapted this framework for perinatal CCPs to delineate the challenges parents face at the intersection of obstetric care and psychosocial care journeys (Figure 1 [12]).

XSL•FO
RenderX

Figure 1. Expansion by Haldar et al [12] of the parallel journeys framework for perinatal care, representing cyclical journeys in obstetric care and psychosocial care.

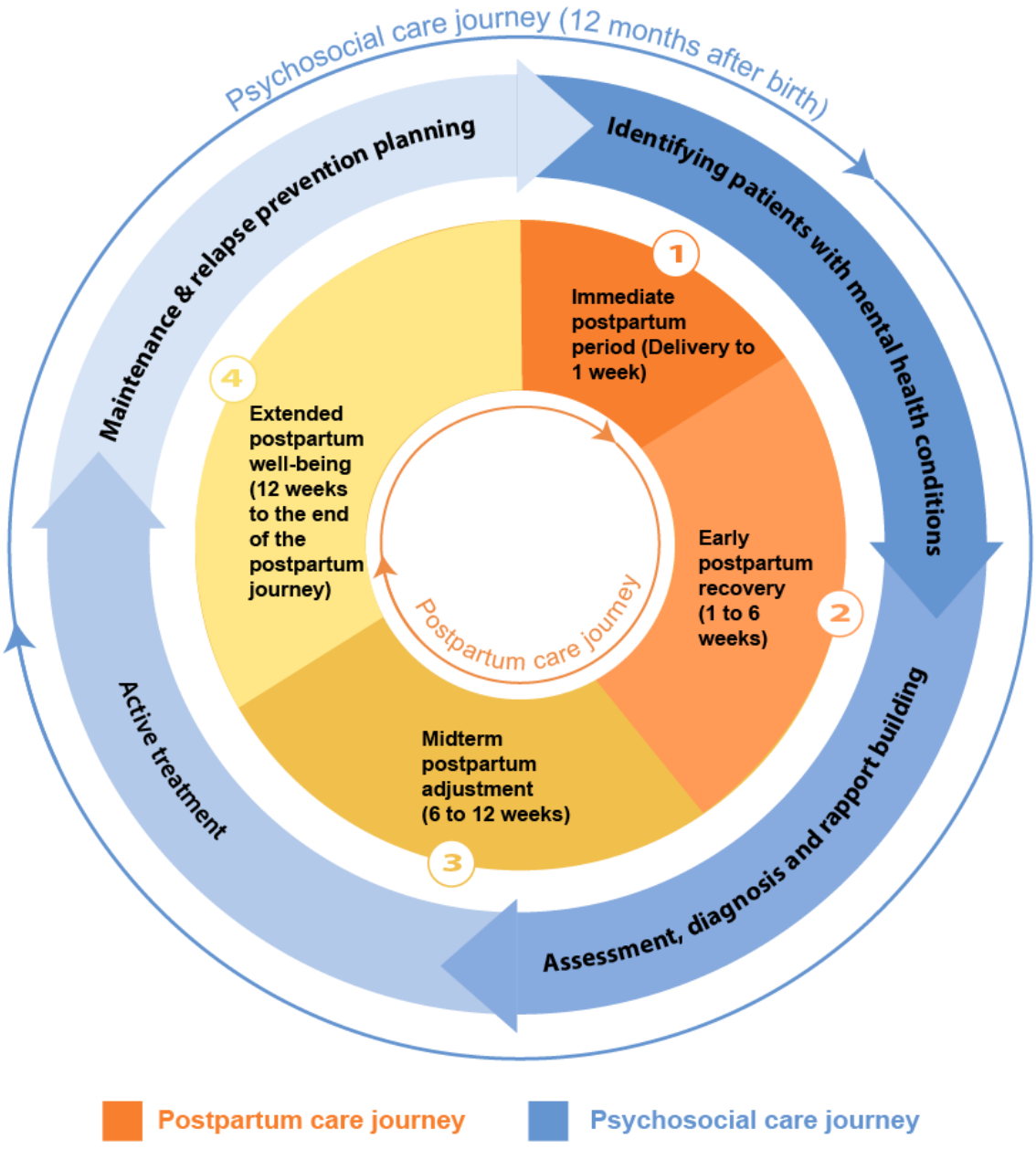


In our study, we have modified the PJF to develop the postpartum PJF (PPJF) (Figure 2) to address the specific needs of postpartum care, which was not emphasized in the framework used by Haldar et al [12]. This adaptation was guided by a theory-driven process, drawing on the structural design by Suh et al [23] and Haldar et al [12] while integrating empirical data from our qualitative interviews. Specifically, each phase of the postpartum and psychosocial care journeys was refined through an iterative coding process informed by participant narratives and validated against existing literature. Feedback from CMs and behavioral health care providers (BHPs; therapists, counselors, and psychiatrists) in perinatal mental health and collaborative care further informed the refinement of stages to ensure clinical and experiential relevance.

The resulting PPJF captures the multifaceted progression of postpartum and psychosocial care by outlining distinct stages of transition, each marked by specific parent needs and challenges. This expanded framework offers a more holistic perspective on postpartum care and serves as the foundation for analyzing how digital interventions, specifically the B2H app, support the evolving needs of both birthing and nonbirthing parents during this critical period.

XSL•FO
RenderX

Figure 2. Our expansion of the parallel journeys framework highlighting the phases of postpartum care and psychosocial care.



Phases in the Postpartum Care Journey

The PPJF delineates the postpartum care journey into 4 phases, each marked by unique challenges, needs, and transitions. These phases are derived from both the interview data and relevant literature, framing the comprehensive journey from immediate postdelivery care to long-term postpartum adjustment.

Immediate Postpartum Care and Transitioning Home (Delivery to 1 Week)

This phase is also known as the initial or acute period, which refers to the time following childbirth and the first few days post partum [24]. The immediate postpartum care phase is characterized by care provided to birthing parents and newborns within 24 hours after delivery. During this time, health care providers closely monitor birthing parents and infants for potential complications and offer support for breastfeeding initiation, bonding, and emotional well-being [25]. The health care team assesses uterine involution, monitors vital signs, addresses any postpartum discomfort or complications, and provides guidance on postpartum care, such as proper hygiene, pain management, and contraception options [26]. Regarding the care provided to the newborn, the postnatal check involves evaluating vital signs, conducting a physical examination, and assessing feeding patterns and weight. Health care providers offer guidance on newborn care, including feeding techniques, diapering, and safe sleep practices [26].

Transitioning home from the hospital marks a significant shift as the family assumes greater responsibility for caring for the newborn. This period involves adapting to the challenges of

XSL•FO
RenderX

parenthood, establishing feeding routines, and managing the physical and emotional changes that accompany childbirth [27]. Overall, the immediate postpartum period and transition home represent a dynamic and emotionally charged time, wherein the integration of medical care, emotional support, and practical guidance sets the foundation for a healthy start to the new family's journey.

Early Postpartum Recovery (2 to 6 Weeks)

The early postpartum recovery phase, also referred to as the subacute postpartum period, spans the first 6 weeks after childbirth and encompasses the initial weeks of physical and emotional adjustment for new birthing parents [24]. Physically, this phase involves the body's gradual recovery from the demands of childbirth. Birthing parents may experience uterine contractions, vaginal healing, and hormonal fluctuations during this time [24]. Emotionally, the postpartum period can bring about a range of feelings, from joy to potential mood fluctuations. In this context, the preparation for the first postpartum visit gains significance.

The first postpartum visit marks an important phase in the continuum of care for both the birthing parent and the newborn. Typically occurring within the first 2 to 4 weeks postpartum, this visit acts as a pivotal touchpoint for health care providers to assess the physical and emotional well-being of the birthing parent [24]. During this phase, the obstetric care provider conducts a physical examination and administers mental health symptom screening to assess health concerns that might have emerged during delivery [10]. The physical examination includes a pelvic examination and checking the birthing parent's blood pressure, weight, and temperature. In case of a vaginal tear or c-section incision, the obstetrician checks to ensure that the stitches are healing [28]. A breast examination is also conducted to assess for engorgement or any changes that can occur with breastfeeding and pumping [29]. As part of the mental assessment, the obstetric care provider uses a paper-based screening tool to assess the risk for PPD. By addressing the physical and emotional aspects of postpartum recovery, the first postnatal visit lays the foundation for ongoing support, promoting the well-being of both birthing parents and the infant.

Midterm Postpartum Adjustment (6 to 12 Weeks)

The midterm postpartum phase, spanning from 6 to 12 weeks after childbirth, is a pivotal period for new parents as they further adapt to the responsibilities of parenthood. This phase is characterized by continued physical recovery from childbirth and deeper emotional adjustments as parents settle into their new roles [30]. During this time, the initial intensity of postpartum recovery begins to wane, and parents may start to feel more physically comfortable [26]. However, this period also brings its own set of challenges and adjustments. Physical recovery may still be underway, with some women experiencing lingering postpartum symptoms, such as pelvic floor issues, hormonal changes, and fatigue [31]. Emotionally, this period can be intense, with new parents grappling with feelings of anxiety, and in some cases, signs of postpartum mood or anxiety disorders [3]. While parents may start to feel more confident in their caregiving abilities, the reality of ongoing sleep deprivation, hormonal adjustments, and the challenges of balancing personal and professional responsibilities can contribute to feelings of fatigue.

As parents approach the end of the midterm postpartum phase, a comprehensive postpartum checkup is recommended [32]. This comprehensive evaluation aims to provide a detailed review of the birthing parent's physical, emotional, and psychosocial health, covering critical areas, such as emotional well-being, care and feeding of the infant, sexual health, contraception, and planning for future pregnancies, as well as management of sleep, fatigue, physical recovery, chronic conditions, and overall health maintenance. For most patients, the comprehensive postpartum appointment is their final touchpoint with their obstetric care provider.

Extended Postpartum Well-Being and Long-Term Adjustment: (3 Months and Beyond)

The extended postpartum well-being phase, also known as the delayed postpartum period, emphasizes a comprehensive and ongoing approach to health for both the birthing parent and infant [24]. As this phase unfolds, the needs of parents evolve while they adapt to more settled routines and face the sustained elements of postpartum care.

Birthing parents experience a multifaceted mix of physical and emotional adjustments during this stage, especially as they transition back to work or adjust to their partners doing so. Physical recovery from childbirth may still be underway, with women navigating changes in skin and hair, hormonal fluctuations that can impact mood and physical well-being, the gradual return of menstruation, and efforts toward weight management [33]. Changes during this phase are extremely gradual. Although change is subtle during this phase, it is important to remember that a birthing parent's body is not fully restored to its prepregnant state until about 6 months after delivery.

Furthermore, the challenges of balancing professional responsibilities with the demands of parenthood and the added stress of securing suitable daycare arrangements can further contribute to elevated stress levels. This period marks a critical juncture where ongoing monitoring of mental health becomes essential as parents navigate through the complexities of returning to work and maintaining the well-being of their expanding family.

Phases in the Psychosocial Care Journey

For new parents, psychosocial well-being encompasses a broad range of factors that contribute to mental, emotional, and social health. Here is a detailed overview of how the psychosocial care journey unfolds within the context of postpartum care.

Identification of Patients With Mental Health Conditions

This phase acknowledges that while it is common for new parents to experience a broad range of emotions, such as periods of sadness, known colloquially as "baby blues," there's a crucial distinction to be made when these feelings persist or intensify, potentially indicating PPD, a more serious condition [32]. Typically occurring at the 2- to 4-week mark, this phase represents a birthing parent's first postpartum encounter with their obstetrician. During this initial postpartum visit, the

XSL•FO
RenderX

obstetric care provider uses standardized paper-based measures, such as the Edinburgh Postnatal Depression Scale [34] or the Patient Health Questionnaire [35], to screen patients for symptoms of PPD. If a parent exhibits symptoms or has a known history of mental health issues, the health care provider introduces CCM as a valuable resource. The health care provider discusses the potential benefits of connecting with CCP and gauges the patient's interest in a referral. However, it is important to note that most perinatal care offices do not have a CCM available on-site and often refer parents to external mental health support.

The significance of this stage lies in its emphasis on timely intervention and the establishment of a supportive care environment that prioritizes mental health. Early identification allows for the timely implementation of support systems and interventions helps promote the overall well-being of both the parent and the newborn [36].

Initial Psychosocial Assessment, Diagnosis, and Rapport Building

Following the detection of symptoms of PPD, birthing parents who screen positive and have a clinical assessment congruent with PPD are referred to a BHP by their obstetric care providers. This process is designed to gather detailed information about the patient's symptom severity. The BHP conducts a thorough psychosocial assessment using standardized tools to establish baseline symptom severity (eg, 9-item Patient Health Questionnaire [PHQ-9] and 7-item Generalized Anxiety Disorder [GAD-7]) [35,37]. In addition to these quantitative measures, the BHP also dives deeper into the patient's personal history, gathering information on a range of factors that could influence their mental health. This includes exploring the patient's family and medical history, which can reveal genetic predispositions or health conditions that may impact mental well-being [38]. Psychiatric and substance use history is also reviewed, as previous or current issues can significantly affect treatment planning and outcomes. In addition, understanding the patient's financial background and social support systems is crucial, as financial stressors and isolation can exacerbate mental health problems [38]. However, it is important to note that despite the critical importance of the referrals provided by the obstetrician, recent data suggest that fewer than 1 in 10 people referred to BHP actually engage with behavioral health services. While an obstetrician may refer a patient to a BHP, this transition often does not occur as intended. Patients frequently face challenges navigating the process, such as identifying the right contact, scheduling an appointment, finding health care providers who accept their insurance, and securing timely appointments close to home. This represents a significant barrier and highlights a substantial gap in the current health care system.

This phase sets the stage for a personalized treatment approach, which is essential for successful outcomes in mental health care. The assessment conducted by the BHP ensures that the subsequent steps in the treatment process are based on a solid understanding of the patient's psychosocial context, facilitating targeted interventions and individualized care plans.

Active Depression Treatment

The active treatment phase for PPD involves a targeted and evidence-based approach [23]. The treatment plan administered during this phase is highly individualized, considering the patient's unique circumstances, preferences, and needs to ensure personalized care [36]. In most clinical settings, when a birthing parent screens positive for depression during their 6-week postpartum visit, the obstetrician prescribes medication. If the patient is receiving mental health care, such as therapy, the clinician will monitor their progress and intervene as necessary. In some instances, insurance providers employ care coordinators who contact postpartum parents at some point after birth to assess for PPD and connect them to appropriate support services.

In the context of PPD, active treatment may involve various therapeutic approaches, including supportive counseling, psychotherapy, and medication management. For parents experiencing mild to moderate depression, psychological interventions, such as cognitive behavioral therapy or interpersonal therapy, are recommended [33]. These therapies aim to enhance coping strategies, address interpersonal issues, and modify negative thought patterns that contribute to depressive symptoms. For those with moderate to severe depression, a combination of psychotherapy and antidepressant medications may be advised [39]. Medications are chosen with care, considering the patient's breastfeeding status and personal preferences to ensure both safety and effectiveness.

The goal of the active depression treatment phase is not only to reduce symptoms of depression but also to empower parents to manage mental health effectively. This process is dynamic and responsive, characterized by a collaborative partnership between the patient and their health care team. Such an approach ensures that treatment aligns with the patient's recovery goals and adapts to their changing needs, ultimately paving the way for a successful recovery from PPD.

Maintenance and Relapse Prevention Planning

The final phase of the psychosocial care journey plays a crucial role in sustaining the well-being of new parents after active treatment has concluded [39]. This phase is designed to equip patients with the resources needed to maintain their mental health and prevent the recurrence of depressive episodes. It acknowledges the reality that the journey through PPD is not solely about overcoming the immediate symptoms but also about building a resilient foundation for long-term mental health [40].

In this phase, BHPs work closely with parents to develop a comprehensive maintenance plan (eg, identifying early warning signs or establishing effective coping strategies) that addresses each individual's unique needs and circumstances [23]. Ideally, postpartum care should extend up to 1 year after birth, as postpartum-related mental health symptoms can often persist throughout this period [12]. However, most clinical settings lack CCMs, with obstetric care typically concluding within 6 to 8 weeks post partum, leaving a gap in ongoing support. Toward the end of obstetric care, BHPs proactively engage with individuals to discuss the end point of their program involvement. In cases where additional support is needed, BHPs

XSL•FO
RenderX

provide external referrals, ensuring that patients can access longer-term therapy or treatment in locations convenient to them [39]. BHPs also encourage parents to engage in self-care practices, such as regular physical activity, healthy eating, and mindfulness exercises, which can contribute to overall well-being and resilience.

In conclusion, the fourth phase helps secure the progress made during the active treatment of PPD and lays the groundwork for sustained mental health. It represents a transition from intensive care to a more self-directed approach, with continued professional support tailored to prevent relapses and promote long-term recovery. Although perinatal care concludes at the 1-year postpartum mark, a patient's mental health treatment may continue beyond this end point outside the postpartum context.

The B2H Intervention

B2H is an mHealth intervention built on the CCM designed to support families during their transition to parenthood. Upon being allocated to the intervention arm, families are introduced to the B2H services through a mandatory download and use of the B2H smartphone app, compatible with both iOS and Android platforms. The app incorporates features designed to support both parent wellness and infant care. These features cover essential postnatal care practices, including, but not limited to, tracking mechanisms for feeding, sleeping patterns, growth milestones, diaper changes, and vaccination schedules. Moreover, the app engages parents with educational content on infant developmental milestones, conducts monthly mental health assessments, and supports adherence to preventive health care schedules for both the parents and their newborns.

The B2H intervention is structured to offer a holistic suite of services aimed at reinforcing the well-being of both parents and infants (Multimedia Appendix 1 [41]). If a parent screens positive for moderate stress (eg, a Perceived Stress Scale [PSS] score of 14-26), the CM reaches out to the parent via chat to assess the parent's stress situation and recommends stress management resources, such as the Stress Management and Resiliency Training module, that teaches self-care practices to manage daily stress and regain a sense of emotional control. If severe stress is identified (eg, PSS≥27), the CM contacts the parent directly to assess the source of stress and provides psychoeducation on stress management techniques.

On the other hand, if a parent screens positive for depression or anxiety (PHQ-9≥10; GAD-7≥10), the CM will contact the patient to facilitate a clinical assessment and initial treatment planning. For individuals who desire psychotherapy, brief behavioral care (8 sessions of behavioral activation) will be initiated, led by the CM via phone. For individuals who desire pharmacotherapy, the CM will refer the participant to a primary care physician or a psychiatrist, with the decision regarding the type of referral informed by the clinical context.

If the assessment scores indicate a level of concern, the CM consults with a clinical psychologist to discuss recommendations for supporting the patient in accessing the appropriate care. This may involve assisting the parents in developing a safety plan and connecting them with the necessary behavioral health services. In more severe cases, this could include contacting the OB or an emergency contact if needed. Once the recommendations are agreed upon, the CM follows up with the parent to ensure that the proposed plan is acceptable and discusses next steps. Through this personalized and supportive approach, B2H aims to enhance the user experience, providing guidance and resources to ensure the parent receives the care they need throughout their postpartum journey.

Methods

Study Design

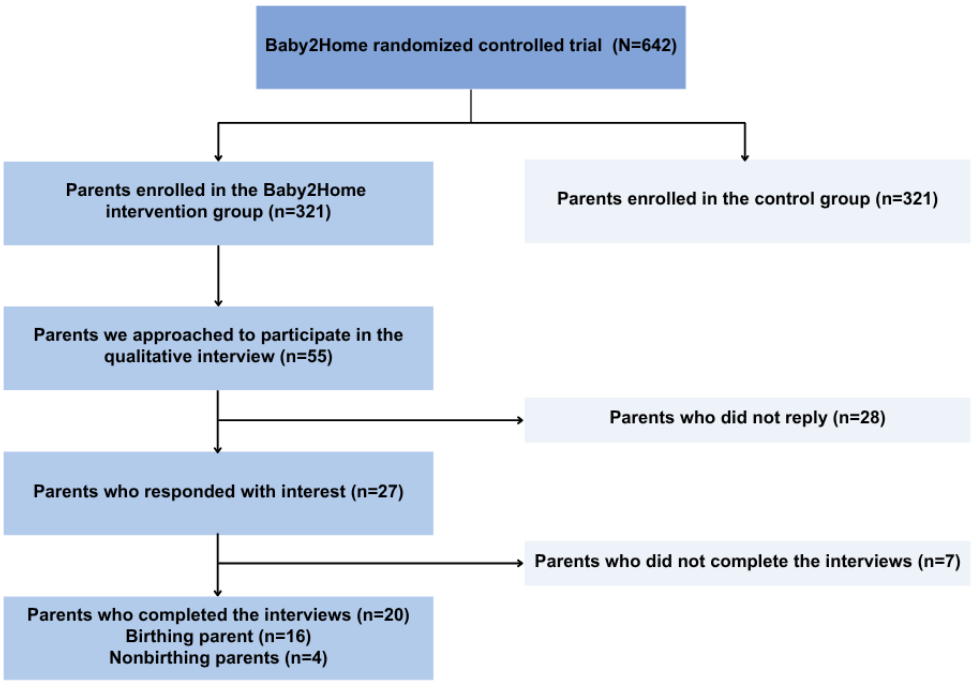
This research is carried out in parallel with a National Institutes of Health–funded (grant #1R01HD105499-01) randomized controlled trial (RCT; NCT05595486) [42] that attempts to investigate the efficacy of mHealth apps (in particular B2H) on preventive health care use for the family unit and patient-reported outcomes trajectories with a focus on mental health. As part of the RCT, 642 diverse families have been randomly assigned to either usual care or the innovative B2H intervention to evaluate the efficacy of B2H health services use and patient-reported outcomes.

This paper, while part of a larger study, specifically focuses on the intervention group. In this group, families (n=321) received the specialized services offered by the B2H app (see Figure 3). In this qualitative study, we aimed to explore the engagement and experiences of both birthing and nonbirthing parents within the intervention group as they interact with the B2H app.

Importantly, this qualitative component offers critical context to the broader findings of the RCT by helping to explain potential mechanisms behind intervention efficacy. While the RCT will evaluate user engagement quantitatively through backend app analytics and assess perceived app efficacy using the User Version of the Mobile Application Rating Scale, this study provides insight into the "why" behind the use patterns, such as the multifaceted needs of new parents during the postpartum period and how these evolving needs influence app engagement. These qualitative findings help contextualize quantitative trends in use, satisfaction, and outcomes, offering actionable design recommendations to enhance intervention effectiveness and inform future iterations of the B2H app.

XSL•FO
RenderX

Figure 3. Flow diagram of the qualitative study participants in the intervention group.



Participant Recruitment and Interviews

A purposive sampling technique was used to select a diverse group of participants from the B2H intervention arm, specifically targeting parents in the 4- to 8-month postpartum period with varying levels of app engagement, categorized based on cumulative time spent on the app. App use was calculated by taking the average of the total number of sessions (number of times the app was opened) and dividing it by the number of participants in the intervention group. Participants were then classified into 2 groups: those with fewer than 175 total sessions were categorized as low use and those with more than 175 sessions as high use (Multimedia Appendix 2). However, it is essential to note that some individuals classified as low app use users demonstrated substantial engagement in specific features of the app, including baby tracking, chat functionality, content consumption, and participation in mental health assessments.

Semistructured interviews facilitated the collection of detailed narratives concerning the participants' use of the B2H app and its impact on their postpartum experience. These interviews, lasting between 45 and 60 minutes, were conducted by the first author via videoconferencing software (Zoom Communications Inc). The semistructured interview schedule was developed by the research team and informed by the objectives of the larger RCT, as well as existing literature on postpartum care, digital health engagement, and CCMs. The interview questions (Multimedia Appendix 3) sought to uncover patterns of app use; impacts on health care accessibility; engagement with the app's specific features (eg, baby tracking, mental health assessments, and educational resources); perceived impacts on postpartum experiences; and areas for improvement. To ensure clarity and relevance, the guide was pilot-tested with 2 participants and refined based on team discussion and feedback from early interviews.

The recruitment process involved systematically disseminating email invitations and providing potential participants with comprehensive details about the study, including its objectives, procedures, and potential benefits. A notable proportion of parents who were initially contacted did not respond, as many of them had recently returned to work and reported difficulty balancing work responsibilities with the demands of caring for a newborn, making it challenging to find time for an interview. In some cases, parents expressed interest but ultimately could not commit due to time constraints. To mitigate this, we followed up with additional emails and initiated phone calls to encourage participation. This iterative recruitment strategy aimed to maximize participant involvement and ensure the diversity of perspectives within the study cohort.

Sample Size and Data Saturation

A subset of 20 parents, exhibiting both low and high app use based on the cumulative time spent on the B2H app in the 4- to 8-month postpartum period, consented to participate in the semistructured qualitative interviews. The participants selected for qualitative interviews exhibited a diverse range of demographic characteristics. The demographic composition included 15% (3/20) of the participants identifying as Hispanic or Latinx, 10% (2/20) as Black or African American, and 75% (15/20) as European or White. Notably, the study cohort reported various postpartum challenges, such as neonatal intensive care unit admissions, PPD, preeclampsia, a fourth-degree tear during childbirth, and previous complications such as miscarriage. A subset of participants (7/20, 35%) had a history of managing one or more pre-existing mental health conditions, including depression, anxiety, bipolar disorder, and attention deficit hyperactivity disorder, before giving birth. These diverse characteristics enrich the qualitative exploration of the B2H app's impact on postpartum care experiences within this unique participant cohort.

XSL•FO
RenderX

Data saturation was reached during the interview process. This was determined when no new themes or patterns emerged from the data, and additional interviews yielded redundancy in responses. The research team monitored for saturation iteratively, and once the analysis of the last few transcripts confirmed that further interviews were unlikely to generate new insights, data collection was concluded.

Data Analysis

We adopted a mixed methodology for our data analysis. The PPJF was used as a guiding lens to organize and interpret our analyses. The phases of the PPJF were first created, after which we adopted an inductive, open-coding methodology for our data analysis. A total of 21 codes were generated, and the identified themes were subsequently organized into different phases of postpartum care and psychosocial care. This process involved multiple team members to ensure a comprehensive and reliable coding framework. The research team applied the coding framework to all transcripts using qualitative data analysis software (ATLAS.ti; Lumivero, LLC). At least 2 team members coded each transcript to ensure reliability and consistency in coding. Any discrepancies or disagreements in coding were resolved through discussion and consensus among team members.

Following the completion of the data analysis, the PPJF was used to organize and interpret the results. Gaps identified in each phase were noted and informed by the qualitative codes generated during the analysis. We also made modifications to the framework proposed by Haldar et al [12] to better align it with the intricacies of the postpartum experience, offering a deeper, more nuanced perspective on the participants' experiences and the role of mHealth technology in navigating the complexities of collaborative care settings.

Rigor and Trustworthiness

To strengthen the trustworthiness of our qualitative findings, we incorporated several strategies throughout the data collection and analysis process by adhering to the guidelines proposed by Lincoln and Guba, as reported in the study by Thomas [43]. Credibility was ensured through triangulation, involving multiple coders who independently analyzed transcripts and resolved discrepancies through discussion and consensus. This meticulous approach ensured that various perspectives were considered, enhancing the reliability and validity of the data analysis. Dependability was enhanced by maintaining a detailed audit trail of coding decisions, analytic memos, and theme development. Confirmability was supported through regular debriefings among the research team to reflect on biases and maintain analytic neutrality. Finally, transferability was addressed by providing rich descriptions of the study's themes and supporting them with direct quotes, all of which helped to support the validity of our analysis and contribute to the study's trustworthiness.

Ethical Considerations

The research protocol adhered to the ethical standards set forth by the institutional review board of DePaul University (research protocol #RB-2024-1203), ensuring compliance with the established guidelines. Informed consent was obtained from all study participants prior to data collection, and participation was voluntary. To safeguard participant privacy, all identifying information was removed, and data were deidentified before analysis. To acknowledge participants' time and effort, compensation was provided in the form of $50 for participation in the interviews, along with additional payments for completion of assessments: $20 for the baseline, 1-month, 2-month, 4-month, and 6-month assessments, and $30 for the 12-month assessment.

Results

To provide a comprehensive analysis of the B2H app's impact, our findings are organized into 2 main areas: postpartum care outcomes (see Figure 4) and psychosocial care outcomes (see Figure 5). This structure not only highlights the multifaceted role of the app in addressing the diverse needs of new parents but also underscores the potential of mHealth technology to bridge gaps in traditional care practices.

XSL•FO
RenderX

Figure 4. Parents reported outcomes indicating app support during the postpartum care journey.

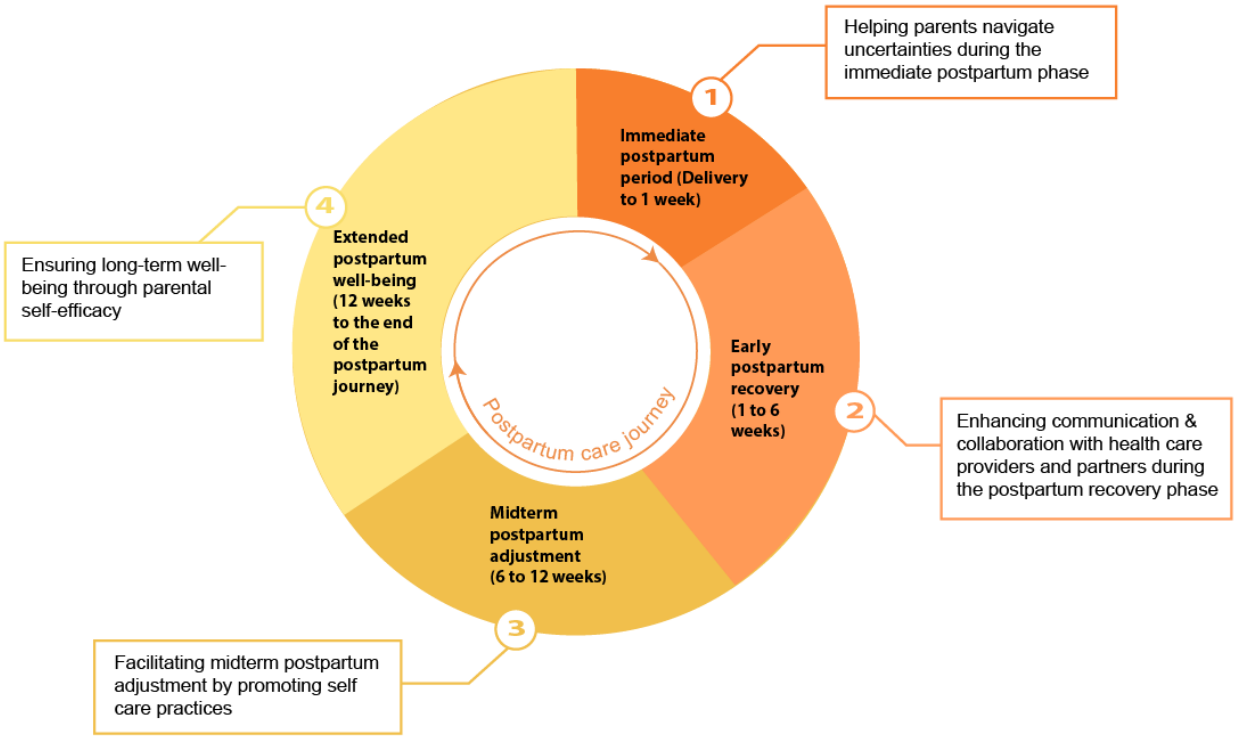
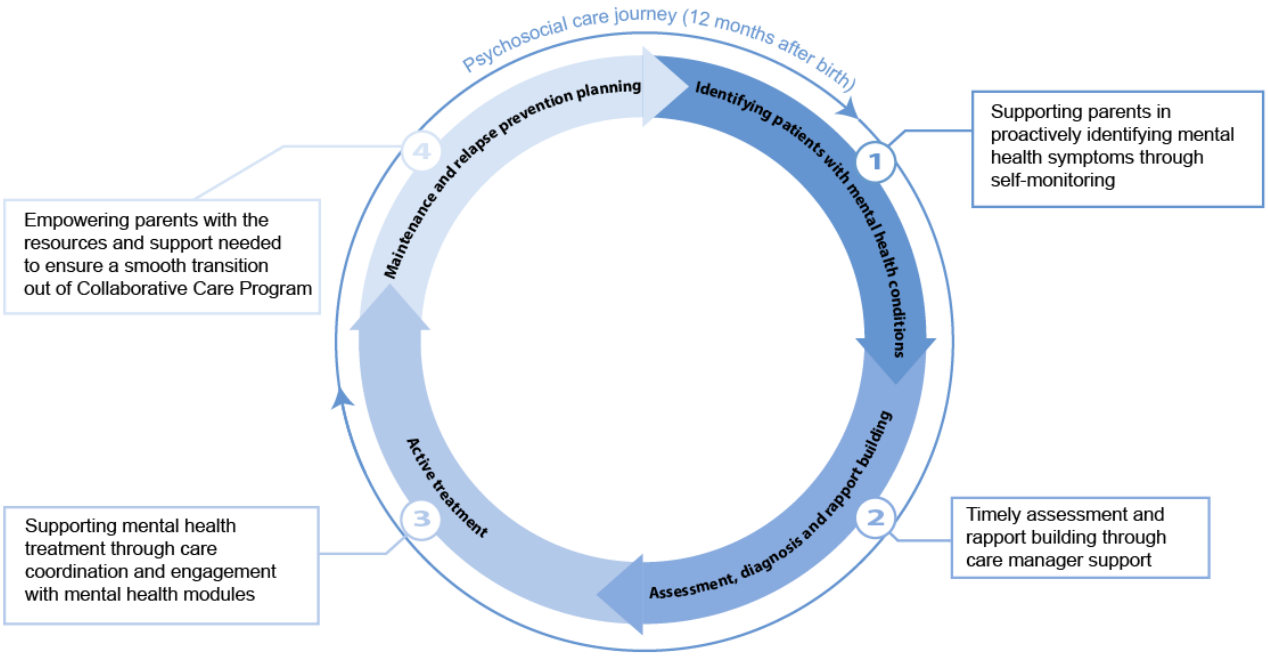


Figure 5. Parents reported outcomes indicating app support during the psychosocial care journey.



XSL•FO
RenderX

Parent-Reported Outcomes Indicating App Support During the Postpartum Care Journey

Theme 1: Helping Parents Navigate Uncertainties During the Immediate Postpartum Phase

Parents in the intervention group reported that the educational articles and the baby tracking features in the B2H app played an essential role in guiding new parents through the multifaceted challenges of this period. Birthing parents, in particular, found solace in the app's extensive library of educational content aimed at easing the transition after childbirth.

One parent explained as follows:

> *5 months into postpartum, I definitely feel better mostly, because I have had a lot of time to just read articles on self-care and de-stressing. As a new parent you tend to prepare a lot for everything surrounding baby care. Everyone tells you that you need this or that but no one really tells you how you're gonna be. I don't think you could really prepare for how you will be doing mentally after giving birth. B2H has been helpful in assisting me navigate those uncharted waters in those earlier weeks.* [P7; birthing parent; low app use]

Other parents reported that the targeted educational content provided within the app on postpartum discomfort and recovery offers essential support for new parents during the critical initial weeks following childbirth. These resources were especially valuable for parents who were uncertain about the postpartum health conditions they could encounter.

One parent reflected as follows:

> *I read the article on B2H about the signs and symptoms of preeclampsia and how you can get it up to six weeks postpartum. And guess what, I had six of the seven symptoms that were listed in that article. This prompted me to call my physician and I went in for an appointment that day, ended up being admitted and was on a magnesium drip for 24 hours. It was pure hell! But that article really helped me solidify that yes, I am definitely not going crazy and this isn't just postpartum psychosis, which I was feeling at that point. I was valid in my reasoning and needed to ask for help.* [P10; birthing parent; low app use]

In the realm of newborn care, parents reported a heightened reliance on the B2H app's baby tracking feature within the app during the initial weeks following childbirth. This heightened engagement with the app can be attributed to the myriad changes and challenges associated with the transition to parenthood.

One participant shared their experience, stating the following:

> *Our daughter was born a little underweight than most babies, and the immediate concern for us was feeding. Just because it was difficult in the hospital, to get her to latch. Being new parents, the scariest thing in the world is the thought that maybe you're doing something that might not be leading to the right type of nourishment. To be able to get some answers on the app on what's normal as far as breast milk production, which is what the article covered, was very useful. The app was helpful to keep track of the feedings and have a timestamp of when you last fed so that you can make sure that you're staying on a feeding schedule.* [P2; nonbirthing parent; high app use]

Another parent reflected on their breastfeeding challenges and the role that B2H played in supporting them:

> *As a new parent, you tend to question every decision made and often underestimate mom guilt. Breastfeeding was not the easiest thing in the world at the start. The article from September 28th, regarding breast milk regulation, which I was able to discuss with my wife, was very useful. To be able to get some answers on what's normal as far as breast milk production which is what the article covered was really helpful. It gave me the confidence to manage breastfeeding on my own terms without going through the hassle of finding and contacting a lactation consultant.* [P20; birthing parent; high app use]

Theme 2: Enhancing Communication and Collaboration With Health Care Providers and Partners During the Postpartum Recovery Phase

The early postpartum recovery phase spans the first 6 weeks after childbirth, encompassing the initial weeks of physical and emotional adjustment for new parents. During this phase, most participants reported an increased engagement and reliance on the baby tracking feature and the library of evidence-based resources on postpartum care and newborn health. According to the feedback provided by the parents, the educational articles and the tracking features served as a key preparatory step for their upcoming postpartum visit and well-child checkup.

In the days leading up to the postpartum visits and the well-child visit, the parents described how the app acted as a valuable preparatory tool, ensuring that they felt confident in discussing their own progress with the obstetricians during the postpartum visit and their newborn's progress during the well-child visit.

One parent reported the following:

> *I do love that there's an option for tracking and added notation. We were able to have a well laid out list or any notes that we had about certain things. This made it easy for me to give detailed responses to the obstetrician's questions about breastfeeding, latching, or ask the pediatrician any specific questions about our baby.* [P1; birthing parent; low app use]

Another parent explained as follows:

> *I struggled for the longest to remember every single thing associated with baby care such as time spent breastfeeding, diapers changed etc. Having to remember all these small details got me stressed out even more. The articles on the app helped shed light on our baby's nutrition. I am now more aware of my baby milestones and what to expect specifically in terms of growth. I see a dip in his weight and the app*

XSL•FO
RenderX

> *helps alert me and allows me to reach out to the pediatrician and get the help needed. This helps reduce any anxieties or uncertainties. Just seeing my baby's weight and height increase on the growth chart within the app gives me this sense of relief because at one point my baby did lose weight which was concerning.* [P6; birthing parent; high app use]

In addition to improving communication with health care providers, birthing parents also mentioned how the app enhanced communication and collaboration with their partners during the early postpartum recovery phase. Birthing parents recovering from the physical demands of childbirth emphasized their reliance on the baby tracking feature as a means of distributing caregiving responsibilities effectively. This feature allowed them to share the workload and ensure that both parents were equally involved in the care of their newborn, fostering a more balanced and supportive environment during this critical period.

One participant recounted as follows:

> *B2H really helps take out all the guesswork in parenting. Before having our baby, my husband and I were actually looking for apps that we could both use simultaneously to input the baby's information. There were other apps that we downloaded but I could only see my entries and my husband couldn't see how many times I had fed the baby or how many times the diapers had been changed or when she last slept. With the B2H app we could see each other's entries which allowed us to be on the same page. We would take turns feeding and used the app as a reference tool to track when the baby was last fed and how much the baby had eaten. I was able to look at the app and say that the baby ate half an hour ago, and my partner would get the bottle prepared when she was ready to eat again within the next 30 minutes.* [P9; birthing parent; high app use]

Theme 3: Facilitating Midterm Postpartum Adjustment by Promoting Self-Care Practices

Parents progressing through the midterm postpartum period reported a noticeable shift in their app use behavior, with a growing reliance on educational content within the B2H app. According to their feedback, this evolution reflects their increasing comfort and confidence in addressing their baby's basic needs, prompting a broader exploration of topics, such as self-care, postpartum well-being, hormonal adjustments, and fatigue management strategies.

One parent reported the following:

> *The baby tracking feature was useful during those initial checkups, allowing me to answer very specific questions about the frequency of feeding and diaper changes. However, in subsequent checkups, I noticed a decrease in the request for such information. Initially, my primary concern centered around my baby's weight, leading to extensive use of the baby tracking feature. However, during subsequent visits, the pediatrician gave me some confidence by saying that as long as my baby stays on her weight curve, there is no reason to be concerned and we can now start feeding on demand. This allowed me to move away from being metric centered and take some time and prioritize my own wellbeing.* [P8; birthing parent; low app use]

As parents become more adept in recognizing their baby's cues and patterns, their transition from heavy use of tracking features to increased focus on educational content signifies a positive evolution in their parenting journey. This shift in app use reflects a natural progression from the intensive tracking required in the immediate postpartum period to a more holistic approach that encompasses a broader understanding of self-care and infant care. Birthing parents, in particular, mentioned how the app addressed this need by providing them with a rich repository of evidence-based information and resources, including articles and educational resources that guide physical recovery, hormonal balance, and improved rest and energy.

One parent shared the following:

> *As new parents, your needs are constantly changing almost every other month. In my case, the need for documentation and tracking was a lot higher during those earlier weeks, gradually transitioning as time passed. I really enjoyed the articles on postpartum recovery. I thought that they were incredibly helpful and gave me some useful tips to manage my fatigue and adjust to the hormonal changes. This made me feel more in control of my recovery and less overwhelmed.* [P12; birthing parent; high app use]

Another parent emphasized how the app supported their self-care routine:

> *The educational content surrounding self care was great. After you have a baby you forget about yourself. Having that content is a nice reminder to check in on yourself. I feel like it gave me a second to breathe and understand what I should be doing. It gave me a different perspective and resources on things to do. I needed to hear that from an outside source, especially when I was having a really bad day. The content made me feel like it was okay to leave my baby in the crib if I needed to. It gave me different avenues to alleviate my stress and know that this stress is just temporary and it will pass.* [P10; birthing parent; low app use]

As parents approach the end of the midterm postpartum phase, a comprehensive postpartum checkup is recommended. This evaluation aims to provide a detailed review of the birthing parent's physical, emotional, and psychosocial health. Birthing parents who attended their comprehensive postpartum checkup reported ways in which the app helped them prepare for this critical consultation:

> *The app allows for the tracking of physical symptoms, emotional states, and key milestones, all of which are useful when talking to my provider. B2H does a good job providing parents with checklists and question prompts which in my case helped me articulate concerns and queries regarding self care and coping*

XSL•FO
RenderX

> *with any lingering postpartum challenges. In a way it helped me have a thorough and productive checkup.* [P16; birthing parent; high app use]

On the other hand, parents who failed to attend their comprehensive postpartum visit mentioned how the educational articles within the app effectively covered any critical areas they might have missed during the comprehensive visit.

One parent remarked as follows:

> *I attended my first postpartum visit and was scheduled for a follow up visit which I ended up skipping as I felt fine for the most part. That being said I don't think I missed out on much as the app's articles pretty much made up for it. They had detailed information on everything from mood and emotional well-being to contraception and planning for future pregnancies. It pretty much covered everything I needed to know about my own recovery.* [P14; birthing parent; high app use]

Theme 4: Ensuring Long-Term Well-Being Through Parental Self-Efficacy

Another significant theme that emerged from the qualitative interviews was the pivotal role that the B2H app played in facilitating long-term adjustment and well-being for new parents as they transitioned from intensive postpartum care to more self-directed management of their physical and mental health. Parents noted that the timely articles and targeted educational content within the app offered them a comprehensive suite of tools designed to enhance their self-efficacy.

In terms of maternal care, birthing parents reported that the weekly articles encouraged them to engage in regular physical activity, healthy eating, and mindfulness exercises, all tailored to fit into their busy schedules. Parents also reported that the app provided them with educational content focused on identifying triggers, managing stressors, enhancing self-efficacy, and empowering parents with the knowledge and skills to navigate future challenges independently.

One parent expressed the following:

> *The articles helped me think and reflect on what I am feeling. They help normalize aspects of my mental health. For instance the article shared with me yesterday by my care manager on grounding and de-stressing techniques reminded me to take some time for self-reflection whenever I feel anxious or stressed. It's helpful to have these resources to refer back to and allows me to practice different ways of coping with stress such as breathing and meditation exercises.* [P6; birthing parent; high app use]

Parents in the extended postpartum phase who were navigating the challenges of returning to work mentioned how the personalized content that was tailored to their baby's age and parenting journey addressed their evolving needs during the postpartum period.

A birthing parent noted as follows:

> *While many online resources cover postpartum care, few actually do a good job preparing you for transitioning back to work and not having the rest you previously did. Because you go from work to having to take care of your child so it's like work and then a different type of work that is full of warmth and fuzzies, but can be exhausting. I remembered coming across some articles on B2H which in a way helped me mentally prepare for this shift and helped me realize that it would be helpful to track my stress levels during this period. Both my wife's and my anxiety levels were slightly elevated compared to our General Anxiety Disorder scores before we resumed work. I checked in with my care manager around this time and she assisted me with daycare options and told me that she can help me find a therapist in my neighborhood to ensure that my new routine did not come in the way of my personal wellbeing.* [P17; birthing parent; high app use]

Another nonbirthing parent mentioned the following:

> *The educational content is laid out where it kind of feels like it's growing with our daughter. The content is targeted towards us during the six to twelve week period which is huge. If this continues with this app, that's gonna make me keep opening the app because there is nothing better than having information that is timed for when you need it or when you start looking for it. It's almost like a reassurance that if I'm going through something at a certain time period, it's probably going to be in that educational center at the time that I need it.* [P2; nonbirthing parent; low app use]

In terms of baby care, parents explained how the targeted content provided within the app helped them navigate the often overwhelming journey of early parenthood, fostering a sense of competence and security as they adapt to their new roles.

One participant reported the following:

> *The app in a way provided me with assurance that my baby is doing okay or that I am doing the right thing as a new parent. Sometimes I just want to know what to expect in terms of my child's developmental milestones. The app works great because it shows you 6-9 months milestones and things to watch out for. I like reading ahead, because I'm a person that likes to plan. For example, after reading an article in the app about visual development and sleep regression, I contacted my pediatrician to discuss these stages in more detail and clarify any questions I had about this.* [P8; birthing parent; low app use]

Another parent commented the following:

> *There are times you go to Google to search for something and are overwhelmed with hundreds of articles where everyone says something different. All the articles on the B2H app are relevant, and I feel safe to follow the information provided by the app because I noticed that all the articles list out the*

XSL•FO
RenderX

source they are coming from at the bottom which makes it trustworthy. [P7; birthing parent; low app use]

Parent-Reported Outcomes Indicating App Support During the Psychosocial Care Journey

Theme 1: Supporting Parents in Proactively Identifying Mental Health Symptoms Through Self-Monitoring

Subtheme 1: Enhancing Health-Promoting Behavior Through the Integration of Multiple Touchpoints and Reminders With Mental Health Screenings

Participants reported an increased engagement and involvement with their mental health care due to the integration of B2H. According to them, this was a direct result of ongoing assessment and the integration of multiple touchpoints with mental health screenings, which played a crucial role in encouraging and sustaining positive health behaviors.

Participants reported that, unlike clinical settings where birthing parents typically have just one touchpoint for mental health screening during the 6-week postpartum visit, the B2H app provided parents with a continuous and proactive method for managing their mental health. The monthly mental health surveys, which are a part of the B2H intervention, encouraged ongoing self-monitoring and reflection, allowing parents to maintain a consistent awareness of their mental well-being.

One parent shared as follows:

> *There are times when I feel deeply connected and engaged with my mental health, but other times I find myself rushing through the monthly surveys, reassuring myself that everything is okay or dismissing any concerns. Yet, there are moments when certain questions prompt me to pause and reflect, often bringing me to tears and making me realize that I may indeed feel a certain way or need to pay closer attention to my mental well-being. These moments underscore the importance and value of consistently taking these surveys.* [P19; nonbirthing parent; high app use]

In addition, parents in the intervention group reported that the app's reminders and prompts for regular check-ins contributed to a more structured and disciplined approach to mental health care.

One parent noted the following:

> *I am a big believer in staying on top of my mental health; however, there were times when I did not remember to open the app on my own. The in-app notifications, text reminders and care manager follow-ups, helped me ensure that I didn't miss any screenings. There were certain times when the reminders were very helpful in reminding me to carve some time for myself and reflect on my mental health. It gave me the space to think rationally about whether I needed to have a conversation with my partner or make an appointment with a therapist.* [P10; birthing parent; low app use]

Subtheme 2: Improving Symptom Awareness as an Outcome of Remote Screening and Comprehensive Mental Health Assessments

Enhanced symptom awareness emerged as another theme in the qualitative interviews. According to the participants, this was a direct outcome of the integration of comprehensive mental health assessments (PHQ-9, GAD-7, and PSS) and remote screening.

Parents reported that the use of comprehensive, evidence-based screening tools enabled them to identify symptoms of anxiety or stress that they might have otherwise overlooked, especially if their initial screenings for PPD during their postpartum visits were negative.

One parent shared the following:

> *There have been stressful moments, certainly, but I haven't felt like I had depression or anything along those lines, so I haven't been actively seeking out help. However, seeing my screening results was truly eye-opening. Although my scores for PhQ9 were moderate, I had no idea that I was experiencing such high levels of stress and anxiety.* [P5; birthing parent; low app use]

In addition, parents who completed paper-based screenings during their postpartum visit reported that they often rush through the assessment, potentially overlooking critical questions about their own mental health as they prioritize asking questions about their infants during their postpartum visit.

One participant noted the following:

> *I felt like I was navigating this complex web of decisions on my own, without consistent guidance or support from my healthcare providers. I attended my 6-week postpartum visit and was scheduled for a 12-week one, but I did not attend it. I feel that the care offered to parents during pregnancy is much better than the postpartum care, which often feels neglected and rushed. In reality, all the support I received during my postpartum visit was mostly centered around caring for the newborns.* [P16; birthing parent; high app use]

On the other hand, parents who engaged with the B2H screenings reported that the transition from paper-based screening to using mHealth tools for mental health assessments provided them with the flexibility needed to manage their mental health more effectively and proactively. A substantial number

of parents reported that the flexibility and privacy of completing these assessments remotely at their convenience enabled them to take more time for self-reflection, which is often not possible in clinical settings.

One parent remarked as follows:

> *The mental health surveys provided by B2H are a nice way for me to reflect upon certain things at my own pace, allowing me to think more deeply about my feelings and recognize symptoms I might have previously missed. The digital surveys are also quick,*

XSL•FO
RenderX

> *like they only take about like five minutes or so. So it's just those five to ten min where I get to focus on my own mental health. Outside of these surveys, I haven't had much time to really worry much about my own well-being at this point.* [P3; nonbirthing parent; high app use]

Subtheme 3: Empowering Birthing Parents to Recognize and Respond to Mental Health Symptoms in Partners Through App Support

The qualitative study findings revealed that by providing a more inclusive approach that screens both birthing and nonbirthing parents, the app not only helped facilitate early detection of mental health issues but also created awareness among birthing parents on the potential mental health challenges their partners might face, which often go unrecognized:

> *For me and my husband, the ability to see our test scores and keep taking those surveys is valuable. Instead of having a pen and paper and having to calculate our scores, the app does a good job tracking our scores for us and is right there at your fingertips. When my husband or I get the survey reminders, we remind each other to take the survey and read the resources provided within the app. We would not compare our scores but discuss them and collectively reflect on the moments that may have resulted in elevated scores. When both you and your partner feel like you are at 25% and need to be there at 100% for the sake of the baby, having these surveys reminds us that we need to talk to each other about this and take time for ourselves or together or as a family if we're both feeling stressed.* [P12; birthing parent; high app use]

Parents reported that the educational content provided on the B2H app equipped them with the knowledge needed to notice symptoms or signs of depression or anxiety in their partners. In addition, the articles helped parents support their partners by sharing useful strategies for managing symptoms and seeking professional help if needed, allowing for equitable mental health care for all parents, regardless of their role in birthing.

One birthing parent reported the following:

> *I specifically enjoyed reading the articles on how to communicate with your partner regarding fatigue and taking some time for yourself. There were times when the article would tell us what to look out for, what to avoid doing, and make suggestions for suitable alternatives, which were pretty helpful. Since my wife and I work in the mental health profession, we often tend to rationalize our mental health. So the articles are a great reminder for us to dedicate time for our self-care and check in on each other's mental health.* [P17; birthing parent; high app use]

Another parent shared as follows:

> *I often felt reassured by my own screening results, but seeing my husband's results was truly eye-opening. I had no idea he was experiencing such high levels of stress and anxiety, as he hides it so well. Without the monthly assessments, I would never have known about his struggles. Seeing his scores made me start checking in on him more frequently to see how he is doing and encourage him to actively seek out mental health support if needed.* [P5; birthing parent; low app use]

Theme 2: Timely Assessment and Rapport Building Through Care Manager Support

The qualitative study revealed that the presence of a CM to monitor scores made a significant difference in the experiences of parents. A significant number of participants reported that having a CM to monitor their scores and provide timely feedback markedly improved their overall experience and outcomes.

One parent reported the following:

> *Although I did not communicate with my care manager frequently. I appreciate that the option was given to me. The care manager reached out to me in those early weeks to let me know that she was available and was there to monitor our mental health scores based on the assessments. It was almost as if there was someone paying close attention to your mental health and even though our communication has not been frequent or consistent, I do know that they're available, which is reassuring.* [P15; birthing parent; low app use]

Feedback from parents underscores the value of having a dedicated CM monitor their scores, compared to an app that lacks human oversight. Parents expressed that knowing there is a person on the other end tracking their progress makes them feel reassured that their mental health is being actively monitored by a professional, thereby strengthening their engagement and confidence in the care process. This human element offered parents a reliable touchpoint for ongoing support, contributing to a more personalized and effective care approach.

One participant reported as follows:

> *To me, having a care manager and monthly mental health surveys within the app goes above and beyond any other baby tracking apps. My care manager did a great job of reaching out to me and checking in with me regularly. She was very responsive and knew when to push and when to pull back. This way I could utilize her in a manner that worked well for me.* [P4; birthing parent; high app use]

Theme 3: Supporting Mental Health Treatment Through Care Coordination and Engagement With Mental Health Modules

When asked how the app supported treatment, many parents highlighted the crucial role of CMs in helping them navigate their treatment plans and the significant impact of the mental health modules in providing effective coping strategies. The combination of these elements fostered a sense of support and empowerment among parents, ensuring that they felt confident and prepared in managing their mental health.

XSL•FO
RenderX

One parent stated the following:

> *A few days after taking my assessment, a care manager reached out to me and offered to do the Behavioral Activation (BA) sessions with me. These sessions were easy to follow, providing tips and methods on how to effectively handle stress. This was incredibly helpful, allowing me to practice different ways of coping with anxiety and stress. The care manager also shared some articles in the chat feature of the app, which gave me something to go back and look into every time I feel anxious.* [P7; birthing parent; low app use]

Another parent emphasized the role of CMs in helping them feel supported with their treatment decision:

> *Having a care manager to discuss the risks and benefits of treatment options made me feel prepared and a bit more confident in my decisions. The conversations we had allowed me to dig deeper into the root causes of what was going on. The care manager would provide resources to support me and schedule check-ins with me. She would follow up kind of in between the survey periods to check and see if the resource she sent worked or if I needed additional support. I think just having that kind of ongoing support made me feel empowered and more likely to engage in my care. Plus the ability to reach out to her at any time gives me this added sense of security and makes me feel less isolated in my treatment journey.* [P14; birthing parent; high app use]

Parents also appreciated the CMs' follow-ups to ensure that they remained connected to care and helped them find therapists covered under their insurance. One parent reported as follows:

> *While the app did not directly influence my treatment decisions, the follow-ups provided by care managers played a crucial role in helping me connect with a therapist. The care manager followed up with me regularly to check on my progress and make sure I was connected to the right care. The care manager even helped me find a therapist covered by my insurance, which was a huge relief.* [P19; birthing parent; high app use]

Theme 4: Empowering Parents With the Resources and Support Needed to Ensure a Smooth Transition Out of the CCP

Parents nearing the end of their postpartum care journey reported that the B2H intervention's approach of integrating continuous support, educational resources, and follow-up care has empowered them to manage their mental health effectively, ensuring a smooth transition out of the CCP. This holistic support system has fostered a sense of confidence and preparedness among parents, allowing them to maintain their well-being independently.

The transition out of the CCP often presents challenges for parents. As parents draw near to the end of their postpartum care journey (12-month postpartum milestone), they usually find themselves needing to connect with external psychosocial care providers to ensure continuity of care. This transition can be fraught with difficulties, such as connecting with new therapists or finding a therapist covered by their insurance. The support provided by the CMs during this transition was particularly appreciated by parents, as it ensured that they remained connected to care resources and felt supported in their mental wellness journey.

One parent shared their experience, stating as follows:

> *I recently moved to a new state and have been struggling to find a therapist that is covered by my healthcare plan. I reached out to the care manager through chat hoping to seek recommendations for a therapist and a new primary care provider. The care manager not only provided me with several options but also followed up to ensure I had all the resources necessary to support the continuity of my care. Having the care manager check in regularly gave me a sense of continuity. I didn't feel like I was being left on my own.* [P17; birthing parent; high app use]

Parents also shared the importance of the guidance and support provided by the educational articles, which helped them maintain the progress they had made during the program.

One parent highlighted how the knowledge gained from the app's educational content prepared them for life after the CCP:

> *The articles and mental health modules on the app taught me so much about recognizing and managing my symptoms. The articles on identifying potential triggers and the ones on stress management techniques gave me the tools needed to confidently handle any future challenges. I now feel equipped with resources needed to help me keep up with my mental health, making it less intimidating to handle things on my own once my postpartum journey ends.* [P9; birthing parent; high app use]

B2H's Role in Addressing Gaps in Usual Care at the Intersection of the 2 Journeys

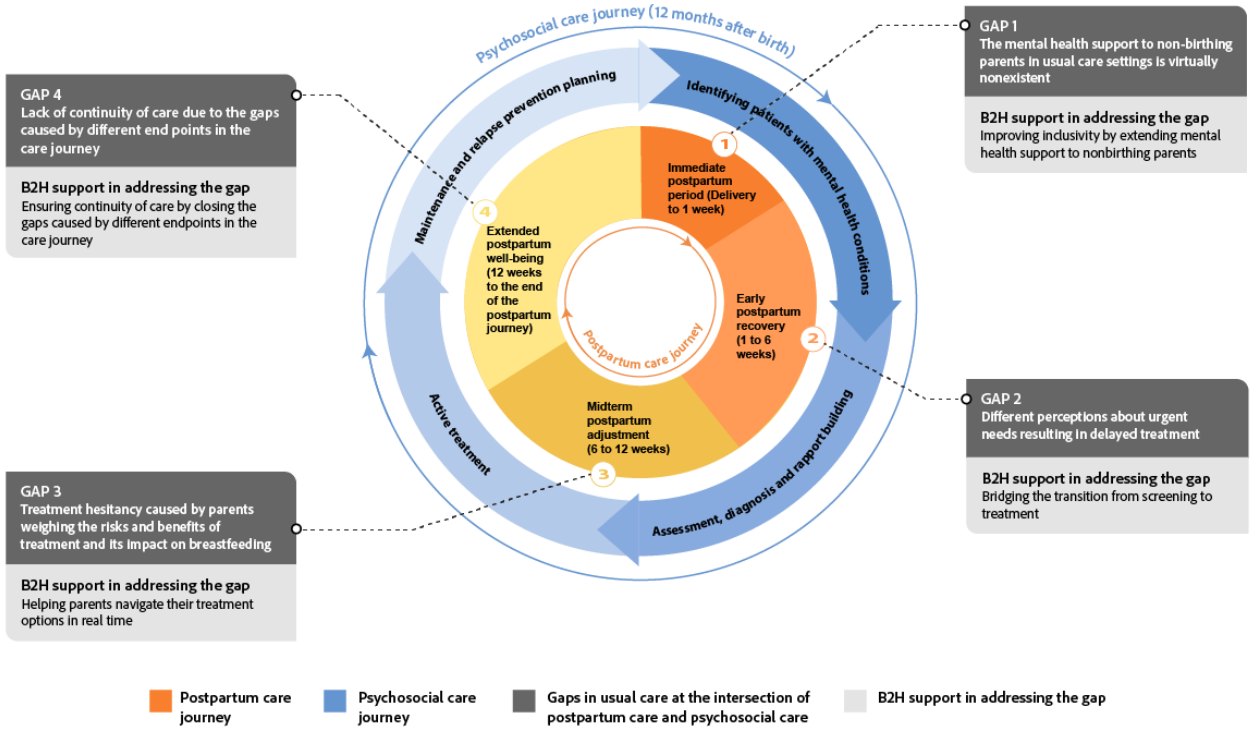
Overview

In addition to demonstrating how the B2H app effectively supports the comprehensive needs of parents in their postpartum care journey, our findings also illuminate several critical gaps in usual care as reported by the parents. By applying the PJF to our analysis, we were able to uncover how these gaps manifest in the real-world experiences of parents and explore the potential of mHealth technology to address these deficiencies.

At the intersection of the 2 journeys, we provide the gaps identified by our data, noting that additional unobserved gaps may exist. Figure 6 demonstrates these gaps and highlights the role of mHealth technology in closing these gaps.

XSL•FO
RenderX

Figure 6. Gaps at the intersections between the psychosocial care journey and the postpartum care journey.



Improving Inclusivity by Extending Mental Health Support to Nonbirthing Parents

The interview findings revealed that the mental health support provided for nonbirthing parents in usual care settings is virtually nonexistent.

One parent reported the following:

> *When I first logged into the app, I just assumed that the app was mainly for baby tracking. That's kind of the only way I was thinking about it. I think as new dads you often get conditioned to thinking that most of the resources and support out there are mainly for the moms or the baby. Sadly dads often get overlooked when it comes to mental health support. Besides the mental health surveys on the apps I don't think I have had any other encounter with mental support in the real world.* [P2; nonbirthing parent; high app use]

This finding supports the existing literature, which indicates that the current system lacks any framework to support screening or treatment for nonbirthing parents, highlighting a significant oversight in the existing approach to care [44]. Unlike routine assessments for depression and anxiety symptoms in new birthing parents during postpartum visits, there is a notable absence of similar checkups for nonbirthing parents. This exclusion often hinders nonbirthing parents from actively participating in postnatal care and fully understanding their role in supporting both the birthing parent and the newborn.

Nonbirthing parents in the intervention group reported positive experiences with the B2H intervention, noting how the tools and resources provided within the app empowered them to take charge of their own mental health and actively participate in the care of their partners. This involvement not only enhanced their own well-being but also contributed to a more supportive and collaborative postpartum care environment.

A nonbirthing parent stated as follows:

> *My wife was dealing with some health stuff before this. So every time she fills out the survey, the care managers in the app check in with her which is nice because there is someone besides me looking out for her. That being said, we are now a little bit aware of our scores due to the assessments and try to track and manage each other's mental health.* [P13; nonbirthing parent; low app use]

In addition, the app also enabled nonbirthing parents to take a proactive role in supporting their partner's mental health journey. It provided them with the tools to regularly check in on their partner's mental well-being, engage in shared decision-making, and offer timely encouragement for seeking professional help when necessary.

One parent recounted the following:

> *Four months into having the baby my husband and I were having a lot of stress mainly because of him working late hours and my health. We did not know how to communicate what we were feeling. Taking the surveys in a way helped us communicate better about our scores and my partner suggested for us to go back to therapy as a way of dealing with our frustrations.* [P10; birthing parent; low app use]

XSL•FO
RenderX

The findings of this study also underscore the role of mHealth technology in facilitating communication and engagement within the family unit. Nonbirthing parents reported that using the B2H app helped them become more informed on critical aspects of postpartum care, including postpartum visits, contraception, and breastfeeding. This increased knowledge significantly enhanced their involvement in their partner's postpartum care journey, enabling them to effectively communicate the importance of attending postpartum visits, encourage continued breastfeeding, and provide both emotional and practical support.

One parent explained as follows:

> *My husband reads more of the articles that I do and informs me on what he reads which in turn helps me stay informed. If my partner comes across an interesting article on the app he shares it with me and after we talk about it for a bit I use Google to dig deeper and get more information surrounding the topic. Like the other day he read something about questions to ask during the postpartum visit and shared the article with me.* [P6; birthing parent; high app use]

However, it is important to note that although nonbirthing parents in the intervention group regularly engaged in the monthly assessments, their app use indicated limited interaction with the mental health modules and low chat use. Further research needs to be conducted to identify ways to enhance the engagement of nonbirthing parents with the CM and the mental health modules.

One parent reported the following:

> *I do not think I reached out to the care manager as much as she reached out to me to check in with me and see how I am doing. She reached out to me based on my scores and shared articles with me. I feel like, just because I read all the articles shared by my care manager I do not really feel like I need to approach her. We would chat like once in a while, especially in the beginning. I do not really need to go to my care manager just because I feel like the app offers a lot of support already.* [P3; nonbirthing parent; high app use]

Another parent reported the following:

> *I personally have not engaged with the mental health content. There've been stressful moments, certainly, but I haven't felt any sort of depression or anything along those lines. I see therapists on the side so I didn't use the app for any mental health content. I actually do teletherapy through zoom but occasionally meet in person. But you know, because I see a therapist monthly I don't normally seek things like this on an app.* [P19; nonbirthing parent; high app use]

Bridging the Transition From Screening to Treatment

Another gap identified by parents in our study was the difference in perceptions between health care providers and parents regarding what constitutes urgent needs, particularly in the context of mental health.

One parent explained as follows:

> *I have a history of depression and anxiety, I was really hoping my postpartum visit would address my mental health more seriously. Instead, I felt like my concerns were kind of brushed off by my provider. The OB told me it was just the typical stress and anxiety that new moms experience. It didn't feel like my needs were prioritized at all, and I left feeling like I wasn't really heard or understood.* [P7; birthing parent; low app use]

This gap often exacerbates challenges, especially during the critical transition from screening to treatment. While national guidelines emphasize the importance of screening for conditions such as PPD and anxiety, the actual follow-through from an elevated screening result to a formal diagnosis and subsequent treatment is often faced with obstacles. These challenges arise because the importance of addressing mental health concerns is not always uniformly recognized by all key informants in usual care settings. Obstetric clinicians, who do not have specialized training in mental health, might underestimate the urgency of the patient's mental health needs. In contrast, parents experiencing significant distress may perceive their needs as urgent but find that the health care system's response does not align with this urgency. This misalignment can lead to delays in care, underdiagnosis, and, ultimately, untreated mental health conditions.

mHealth technology offers a promising solution to bridge this perception gap and facilitate a smoother transition from screening to treatment. Parents reported that the ability of mHealth technologies to track and monitor real-time data allows both parents and CMs to identify any changes in the mental health status and alert them if a situation requires immediate attention. Parents in the study also mentioned that the use of standardized screening tools, such as the PHQ-9, GAD-7, and PSS, empowered them to regularly assess their mental health and communicate their needs and concerns more effectively, making it less likely that their symptoms would be overlooked.

One parent reported the following:

> *Everyone should be screened for depression and anxiety during the postpartum visit. However, what actually occurs can be quite different. While many screen for postpartum depression, only a few are beginning to screen for anxiety, despite the fact that perinatal anxiety is incredibly common. Having these monthly reminders and surveys supported me by highlighting any red flags or providing resources to help me or like point me in the right direction. Although some of the questions in the survey were not necessarily applicable for me, I still think it's important for people who may have a change in their relationship status or might not have the support system that I have. For parents who respond to surveys indicating a change in their relationship or health with the app I would assume that the app would*

XSL•FO
RenderX

> *then allow the care manager to reach out, check in with them and make sure they have additional support.* [P17; birthing parent; high app use]

Moreover, mHealth apps, such as B2H, can streamline the transition from screening to treatment by automatically flagging positive screening results for further evaluation by dedicated CMs. These CMs, trained specifically to identify and respond to symptoms of mental health issues, use a triage model to assess the severity and urgency of the cases. This approach ensures that parents with urgent needs receive immediate attention, reducing their reliance on obstetric clinicians to make diagnostic decisions outside their expertise and ensuring timely and appropriate referrals for those at elevated risk.

Another parent stated as follows:

> *Having a care manager was reassuring during my early days as a parent. It made me feel less alone, knowing there was someone there to check in on me and track my progress. As a new parent, you're always questioning yourself: Am I doing this right? Is this experience normal? Everyone's journey is different, so having a care manager to reassure me that I was on the right track made a huge difference. I think my care manager reached out to me right after my first mental health survey when we were in the NICU, and my stress levels were high as we tried to navigate everything. In a way the care manager made me feel validated, and validated my feelings more than anything.* [P4; birthing parent; high app use]

These findings underscore the benefit of integrating mHealth technology into the postpartum care process, particularly in enhancing the triage system and enabling CMs to track symptom scores in real time. However, the success of this approach relies on the presence of trained collaborative care coordinators within the mHealth framework, who are essential for monitoring changes in parents' mental health status as they occur. By combining real-time data collection with expert analysis, CMs can respond swiftly and accurately to emerging needs. This synergy between technology and specialized care ensures that timely interventions are delivered, effectively bridging the gap between screening and treatment and providing parents with the support they need exactly when they need it most.

Helping Parents Navigate Their Treatment Options in Real Time

Our findings indicated that parents who engaged in mental health treatment often had to consider not only their psychosocial well-being but also their obstetric and infant care journeys. This multifaceted decision-making process involved weighing advice from multiple health care providers and evaluating the potential impacts of treatment—especially medication—on breastfeeding and overall infant health. For some parents, this created a significant source of anxiety, often delaying treatment decisions or causing parents to question the appropriateness of certain interventions.

A major concern expressed by parents was the potential impact of treatment, particularly medication, on breastfeeding.

One parent shared the following:

> *I have a history of ADHD [attention deficit hyperactivity disorder] and was taking medication prior to my pregnancy. But ever since I had the baby, I stopped and haven't been actively seeking out medication since I was still breastfeeding and wasn't sure if it would affect my baby and whether it was safe.* [P7; birthing parent; low app use]

This uncertainty reflects the lack of preparation and support provided to parents once they leave the hospital after delivery. While health care providers typically offer some guidance on postpartum care during the hospital stay, this support is often minimal, leaving parents to navigate the complexities of postpartum care on their own.

One parent noted as follows:

> *There was so much information given to me at the time of delivery, but as soon as I got home, I realized how little I actually knew about managing postpartum care, especially when it came to breastfeeding while considering treatment for my mental health. It felt like I was on my own.* [P9; birthing parent; high app use]

Parents in this study recounted how the abundance of online resources, while well-intentioned, often became overwhelming. The sheer volume of information left many feeling more confused and anxious than reassured.

One parent described as follows:

> *I spent hours researching what is safe during breastfeeding. We have a pile of books in my house that we've tried to make our way through, but have been looking for quick little snippets or tidbits of valuable information that you can quickly read and digest in comparison to reading 300-400 pages. I tried googling this information but every website seemed to have conflicting advice, and I wasn't sure who to trust.* [P5; birthing parent; low app use]

This overwhelming influx of information further highlighted the gap in accessible, timely support during the postpartum period. Without clear, reliable guidance from health care professionals, parents were left navigating complex decisions about their mental and physical health alone, often unsure of the best course of action for their postpartum journey.

The findings from this study underscore the critical role that CMs can play in helping parents make these complex decisions. Care managers, by providing personalized support and guidance, could alleviate much of the confusion and anxiety of parents that stems from the sheer volume of information they encounter. Parents reported how CMs serve as a reliable, accessible resource for answering questions and helping parents navigate their treatment options in real time. This proactive approach to addressing concerns about breastfeeding and mental health treatment can help parents feel more confident in their decision-making.

One parent reflected on how having a CM made a difference in her postpartum care journey:

XSL•FO
RenderX

> *I was unsure about starting medication while breastfeeding. My care manager was the one who really took the time to answer all my questions and made sure I had the latest information from trustworthy sources. It felt reassuring to have like a medical professional guide me through the process, and I didn't feel as anxious about making the decision anymore. Without her, I would have been lost in all the information I found online.* [P9; birthing parent; high app use]

These findings highlight the complex decision-making process parents face when managing their postpartum mental health. The lack of consistent, accessible support after hospital discharge leaves parents vulnerable to confusion and anxiety, often causing treatment hesitancy. The inclusion of a CM within the app provided parents with an additional layer of support, offering personalized, timely support needed to make informed decisions about their mental health and breastfeeding, ultimately promoting more effective treatment engagement. This organized and responsive system of care ensures that parents are not left to troubleshoot issues on their own but are supported in a way that is both comprehensive and accessible. By doing so, mHealth transforms the experience of postpartum care from one associated with feelings of uncertainty and being overwhelmed to one that fosters empowerment and encourages proactive self-care.

Ensuring Continuity of Care by Closing the Gaps Caused by Different End Points in the Care Journey

In most usual care settings, the obstetric care journey comes to an end with the postpartum visit that is usually scheduled during the early postpartum recovery phase (approximately 6 weeks after birth). However, the psychosocial care journey extends 12 months after birth. This disjointed timeline creates challenges for psychosocial care providers and impedes the patient's ability to receive continuous and appropriate care during a critical period when they may still be experiencing or developing mental health issues, such as PPD.

As regular contact with obstetric care providers diminishes after the 6-week postpartum visit, the window for ongoing monitoring and early intervention for issues such as depression and anxiety narrows significantly. This gap creates a vulnerability in the health care system, where the absence of sustained medical oversight may allow psychosocial challenges to go undetected and untreated. The mismatch between the end point of the obstetric care journey and the continued need for psychosocial support highlights the need for more integrated and continuous care pathways that extend beyond the initial postpartum period.

One parent highlighted this gap and reflected on her postpartum journey, stating as follows:

> *It's kind of sad to think about the existing state of postpartum care. I definitely feel like there is so much more that can be done to support new birthing parents with their postpartum journey. There's a striking gap in the time and resources allocated towards pregnancy versus the postpartum period. While a woman might visit her OBGYN multiple times during pregnancy, she'll typically only visit the OB once or twice during the postpartum period. And while it's common for an expectant birthing parent to take a birth education class, it is virtually unheard of for her to receive postpartum education.* [P20; birthing parent; high app use]

mHealth technology offers a promising solution to bridge this care gap by providing continuous, accessible support throughout the extended postpartum period. Through mHealth apps such as B2H, new parents can maintain regular engagement with CMs even after the formal end of their obstetric care. The findings of our study indicate that integrating a CM within mHealth technologies helps facilitate ongoing monitoring of mental health through self-assessments and screening tools that can be administered at intervals well beyond the 6-week mark, ensuring that symptoms of depression or anxiety are not overlooked as time passes.

One parent explained as follows:

> *I really assumed postpartum was only like the first few months after having a baby and I'm learning that that's not the case at all. Now I understand that postpartum doesn't necessarily have a finite time. The surveys kind of prompted me to reconsider what I thought the timeline was for postpartum. What I found most helpful was the care manager check-ins from time to time. I liked bouncing ideas off the care manager. Just having a conversation with the care manager solidified what I was thinking. What I liked about the chat feature was the ability to touch base with someone because you can feel very isolated when you're home with the baby all day.* [P11; birthing parent; low app use]

In addition to facilitating continuous monitoring, integrating various support resources, such as educational content, mental health assessments, and a chat functionality, helps maintain a connection between the patient and their care coordinator, promoting a more seamless transition from obstetric care to comprehensive psychosocial support.

Another parent compared the B2H app to other existing apps, stating the following:

> *There are a lot of apps that once you sign up, they'll send you emails or reminders about upcoming milestones and things like that. However B2H has a lot more daily education that keeps you engaged for the entirety of the postpartum journey. I think with this app there's a lot of information there about things like, mindfulness resources. Just taking those surveys and knowing my scores were a great indicator of my mental health. As a new parent you assume that after six weeks or twelve weeks things are supposed to get better and your scores should be improving but that is always not the case. I did feel that especially after the last survey which prompted me to reflect on the month that I had and what I need to do differently in the next month so that my scores are lower such as looking for a postnatal counseling services.* [P13; birthing parent; low app use]

XSL•FO
RenderX

By leveraging mHealth technology, health care providers can ensure that the psychosocial care journey is not abruptly interrupted by the end of the obstetric journey. Instead, these tools create a continuum of care that supports new parents throughout the first year after birth. This approach not only enhances the ability to monitor and manage mental health concerns but also ensures that the support offered is consistent, responsive, and aligned with the evolving needs of the patient.

Discussion

Principal Findings

Evolving Postpartum Needs and the Role of mHealth

Summary of Key Findings

A summary of key findings about evolving postpartum needs and the role of the mHealth app examined in this study is provided in Table 1.

Table 1. Key findings about the evolving postpartum needs and the role of the mobile health (mHealth) app.

Phases in postpartum care	Emerging needs	App features used	Role of mHealth app (B2H)
Immediate postpartum phase	Navigating uncertainties related to their recovery and newborn care	Heavy reliance on the baby tracking feature (feeding, pumping, diaper, and sleep tracking)	Helped parents monitor newborn activities, support daily caregiving decisions, and reduce anxiety in early care routines
Recovery phase	Establishing routines, enhancing communication with health care providers, and sharing caregiving responsibilities with partners	Continued use of shared baby tracking and educational content (eg, breastfeeding and infant safety)	Facilitated partner collaboration, supported routine formation, and prepared parents for well-child visits and postpartum visits
Midterm postpartum phase	Shifting focus to parental well-being and self-care	Educational content on self-care and monthly mental health assessments	Supported fatigue management, hormonal balance, and mental and emotional health through timely, relevant guidance
Extended postpartum phase	Supporting the baby's developmental milestones	Educational content on baby development	Helped parents track developmental progress and provided age-specific guidance to support caregiving decisions

Implications for mHealth Design

The findings of our study underscore the importance of designing mHealth interventions that can dynamically adapt to the evolving needs of parents across the postpartum journey. In the early and recovery phases, parents exhibited heavy reliance on the baby tracking features (feeding, pumping, and diapering). However, usability issues such as inability to save entries due to app session timeouts, laggy response times when inputting data, and lack of visual clarity in the time tracking interface resulted in decreased app use, prompting parents to switch to alternative apps that provided similar tracking functionalities. Parents also expressed a desire for more personalized visualizations of daily activities and trends across days and weeks to help make sense of their baby's patterns—features available in competing apps. These specific pain points influenced app switching behavior not because users found the app irrelevant, but because they perceived the core tracking functions as unreliable or inefficient. This highlights the importance of seamless design and usability to maintain engagement, particularly when parents need reliable tools the most. In mHealth apps, where user engagement is tied directly to the ability of the app to meet evolving and time-sensitive needs, a frictionless experience is essential. Frustration with core features can lead to disengagement, reduced intervention effectiveness, and fragmented care, limiting opportunities for holistic support such as mental health check-ins and educational content.

As parents progressed into the midterm and extended postpartum phases, their needs shifted toward self-care, mental well-being, and baby developmental milestones. The B2H app's integration of educational content on postpartum recovery and mental health proved particularly valuable during this transition. To better meet these changing needs, future mHealth interventions should consider incorporating modular designs that adjust based on the stage of parenthood. In addition, personalized content recommendations based on the baby's developmental stage and parental mental health screening results could help ensure that mHealth tools remain relevant and engaging throughout the postpartum journey.

Addressing Psychosocial Needs With mHealth Support

Summary of Key Findings

A summary of key findings about addressing psychosocial needs with mHealth support is provided in Table 2.

XSL•FO
RenderX

Table 2. Key findings about addressing psychosocial needs with mobile health (mHealth) support.

Phases in psychosocial care	Emerging needs	App features used	Role of mHealth app (B2H)
Identification of patients with mental health conditions	The need to enhance health-promoting behavior, improve symptom awareness, and empower birthing parents to recognize symptoms in their partner	Monthly mental health assessments using PHQ-9[a], GAD-7[b], and PSS[c]	• Helping parents manage their mental health by offering multiple assessment touchpoints throughout the postpartum journey • Enabling early detection through the use of comprehensive, evidence-based screening tools • Providing remote, self-paced screening, giving parents more time and comfort to reflect on their mental health • Enhancing symptom awareness, including recognition of mental health challenges in their partners
Initial psychosocial assessment, diagnosis, and rapport building	Timely assessment and rapport building through care manager support	In-app chat functionality	• Enabling parents to receive timely support and personalized guidance in managing their mental health by assigning them a dedicated care manager
Active depression treatment	Supporting mental health treatment through care coordination and engagement with mental health modules	Mental health education modules (such as behavioral activation module and stress module); follow-up from care managers	• Helping parents actively manage depression, anxiety, and stress by tracking their mental health score progression and providing them ongoing access to mental health modules and resources • Facilitating informed decision-making by allowing parents to discuss treatment options with a care manager • Offering care manager support to help parents connect with therapists or additional services, improving access to professional care
Maintenance and relapse prevention planning	Empowering parents with resources and support for a smooth transition out of the collaborative care program	Long-term postpartum care resources; care manager–supported transition guidance; reminders and check-ins on relapse indicators	• Helping parents sustain the progress made during the program and prevent relapses through educational resources and articles • Supporting continuity of care by helping parents connect with external psychosocial health care providers as they approached the 12-month postpartum milestone • Providing care manager guidance during the transition period to ensure that parents remained supported and aware of available resources beyond the conclusion of the collaborative care program

[a]PHQ-9: 9-item Patient Health Questionnaire.

[b]GAD-7: 7-item Generalized Anxiety Disorder.

[c]PSS: Perceived Stress Scale.

Implications for mHealth Design

The B2H intervention's success in addressing psychosocial needs demonstrates the ability of mHealth tools to enhance postpartum care. The continuous touchpoints for mental health assessments, combined with CM support, played a crucial role in fostering health-promoting behaviors and ensuring timely mental health interventions. Furthermore, the combination of automated features, such as reminders and surveys, with personalized CM support highlights the importance of integrating both digital and human elements in mHealth solutions. This hybrid approach creates a balanced system where technology facilitates self-monitoring while CMs provide tailored support, ensuring a more holistic and personalized experience.

However, the findings also highlight the need for more targeted efforts to engage nonbirthing parents and address the unique psychosocial challenges they face. This study revealed

XSL•FO
RenderX

disparities in CM engagement between birthing and nonbirthing parents. Nonbirthing parents reported lower interaction levels, which may have limited the intervention's effectiveness for them. Although less involved in physical recovery, nonbirthing parents face significant psychosocial challenges and report elevated stress and anxiety. Their reduced engagement suggests that they may not be receiving adequate support to manage these challenges. This gap highlights a key area for improvement in future iterations of B2H. Increasing outreach and tailored support for nonbirthing parents could enhance the app's impact. Because birthing parents often influence their partners' treatment decisions, educating them to recognize mental health symptoms in their partners and encouraging CM engagement could promote a more collaborative approach, ensuring both parents receive the support they need.

This calls for more equitable support across all users, regardless of their role in caregiving. Future mHealth interventions should consider developing targeted strategies to increase the engagement of nonbirthing parents. This could include personalized check-ins, more targeted reminders, a gamified approach, and additional resources focused on the unique psychosocial stressors nonbirthing parents face. In addition, providing educational content that encourages birthing parents to monitor and support their partners' mental health could foster a more collaborative and inclusive approach to postpartum care.

Contribution of the PPJF in Highlighting the Holistic Needs of New Parents

The application of the PJF in this study provided a comprehensive approach to understanding the distinct yet interconnected experiences of both birthing and nonbirthing parents during the postpartum period. By mapping the postpartum and psychosocial care journeys of each parent and identifying the unique challenges they face, this framework allowed for a more nuanced understanding of how mHealth interventions, such as B2H, can support different roles within the caregiving unit.

CCPs have made significant progress in acknowledging the association between psychological and physiological challenges encountered by birthing parents, highlighting the growing awareness and importance of holistic care. Despite the increased attention to comprehensive patient care, 78% of women who screen positive for PPD do not receive mental health treatment, while nonbirthing parents receive little to no support when it comes to psychosocial care [4]. By applying our modified version of the PPJF to our study, we highlight several missed opportunities or gaps in usual care settings that resulted in parents receiving less-than-ideal care. Through the lens of the parallel journey, our work exposes many of these gaps at the intersection of postpartum and psychosocial care while drawing focus on technological opportunities to ensure that new parents receive adequate support and care.

One of the key contributions of this framework is the ability to draw attention to the often-overlooked psychosocial challenges that affect both birthing and nonbirthing parents. Our findings illuminated the gaps in usual care, particularly in how mental health support is disproportionately provided to birthing parents, while nonbirthing parents are left without adequate resources to manage their own mental health. As revealed in the interviews, nonbirthing parents frequently assumed their role was limited to supporting the birthing parent and the newborn, overlooking their own need for psychosocial support. This study showed how an mHealth intervention, such as B2H, can fill this gap by extending mental health resources to nonbirthing parents, encouraging their active involvement in caregiving and in their own well-being. The inclusion of nonbirthing parents in mental health support systems reflects a more inclusive approach to postpartum care.

In addition, the PPJF exposed several systemic issues that result in less-than-ideal care for parents. First, the findings revealed that health care providers and parents often have differing perceptions of what constitutes urgent mental health needs. This misalignment frequently results in delayed treatment, as mental health concerns raised by parents are sometimes dismissed or minimized by obstetric clinicians who may lack specialized training in mental health. By identifying this gap, the framework highlights the need for better alignment between parent-reported mental health concerns and health care provider responses, an area where mHealth technologies such as B2H can help by flagging urgent needs based on real-time assessments. Second, the framework also illuminated the issue of treatment hesitancy, particularly among birthing parents who face the challenge of weighing the risks and benefits of mental health treatment in the context of breastfeeding. Parents often hesitate to seek treatment, concerned about the potential impact on their infant's health. The PPJF underscores the importance of providing clear, reliable guidance on how to balance mental health needs with infant care. mHealth interventions play a critical role here by offering educational tools and CM support to guide parents through these decisions, thus reducing anxiety and improving treatment engagement. Third, one of the most significant gaps identified through this study is the lack of continuity of care due to the different end points in obstetric and psychosocial care. While postpartum visits typically conclude around 6 weeks after birth, psychosocial care needs often extend much longer, leaving many parents without adequate support during a critical period of their mental health journey. The framework allowed us to highlight how mHealth technologies such as B2H can bridge this gap, providing continuous engagement and monitoring well beyond the obstetric care. This ongoing support ensures that mental health concerns, such as PPD or anxiety, are not overlooked as time passes.

Using the PPJF, we were able to illustrate the experiences of both birthing and nonbirthing parents as part of an interconnected system of care, where psychosocial and physical needs must be addressed simultaneously. It highlights the importance of integrating mental health screening and support into the postpartum journey as a continuous, rather than episodic, process.

Limitations of This Study

While our findings provide valuable insights into postpartum care and have the potential to inform future interventions, several limitations should be acknowledged.

Selection bias is a notable limitation, as the experiences and engagement levels of participants who chose to enroll in the

XSL•FO
RenderX

study might differ from those who declined participation. This could influence the generalizability of our findings, as those who opted in may have had a greater interest in or need for the support provided by the B2H app.

Another limitation is the relatively small number of nonbirthing parents (4/20, 20%) who participated in the study. This smaller sample size may not fully represent the diverse needs and feedback of all nonbirthing parents, which could lead to an incomplete understanding of how the app addresses their specific concerns during the postpartum period. Further research focusing specifically on nonbirthing parents is crucial to better understand their unique challenges and engagement with mHealth tools. By exploring their experiences in greater depth, future studies can identify opportunities to enhance app features and address any unmet needs, ultimately improving support for nonbirthing parents during postpartum care.

Furthermore, our study did not fully address the needs of postpartum parents without smartphones or those who may face barriers to accessing digital health interventions. To ensure greater inclusivity, our next steps include conducting a study in Kenya to explore how B2H can become more equity focused. This study will investigate modifications to the app that make mHealth tools accessible to parents across different socioeconomic and technological divides, ensuring that the benefits of digital health interventions reach a broader and more diverse population of postpartum parents.

Finally, the qualitative nature of this study, while providing in-depth insights, may limit the ability to generalize findings across larger populations. Future research could benefit from a mixed methods approach that combines qualitative insights with quantitative data to validate and expand upon these findings. By acknowledging these limitations, we hope to encourage further exploration and refinement of mHealth technologies, ensuring that they are inclusive, accessible, and capable of addressing the diverse needs of all postpartum parents.

Conclusions

The implications of applying the PPJF to mHealth interventions are significant for both the design and evaluation of postpartum care technologies. This framework provides a structured way to understand how mHealth solutions can support multiple stakeholders within the caregiving unit, ensuring that both birthing and nonbirthing parents are engaged and supported throughout their postpartum journey.

From a design perspective, mHealth technologies should be developed with the recognition that postpartum care is not a singular experience but a set of parallel journeys that intersect and influence one another. This means that features such as mental health screening tools, educational resources, and CM support should be tailored to address the needs of both parents, with attention to how their roles and experiences differ and overlap. For nonbirthing parents, interventions should prioritize increasing their engagement with psychosocial care, helping them to navigate their role in both their own well-being and that of their partner.

In terms of evaluation, the PPJF offers a method for analyzing the success of mHealth technologies by examining their impact on the holistic care experience. It allows researchers and developers to measure not only the physical health outcomes of birthing parents but also the psychosocial outcomes for both parents. This approach can provide a more comprehensive understanding of how mHealth interventions improve care coordination, communication, and mental health outcomes for the entire family unit. By identifying gaps in the usual care settings and showing how mHealth technologies can address these gaps, this framework can be used by other researchers in the future design and evaluation of technologies for postpartum care as a way of ensuring that parents receive the comprehensive, continuous support they need during one of the most critical periods of their lives.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Baby2Home application features.
[DOCX File , 2801 KB - pediatrics_v8i1e70936_app1.docx]

Multimedia Appendix 2
Summary of the participants and their app use.
[DOCX File , 15 KB - pediatrics_v8i1e70936_app2.docx]

Multimedia Appendix 3
Interview guide.
[DOCX File , 14 KB - pediatrics_v8i1e70936_app3.docx]

References

1. Moon K, Sobolev M, Kane JM. Digital and mobile health technology in collaborative behavioral health care: scoping review. JMIR Ment Health 2022 Feb 16;9(2):e30810 [FREE Full text] [doi: 10.2196/30810] [Medline: 35171105]

XSL•FO
RenderX

2. Saharoy R, Potdukhe A, Wanjari M, Taksande AB. Postpartum depression and maternal care: exploring the complex effects on mothers and infants. Cureus 2023 Jul;15(7):e41381 [FREE Full text] [doi: 10.7759/cureus.41381] [Medline: 37546054]
3. Shorey S, Chee CY, Ng ED, Chan YH, Tam WW, Chong YS. Prevalence and incidence of postpartum depression among healthy mothers: a systematic review and meta-analysis. J Psychiatr Res 2018 Sep;104:235-248. [doi: 10.1016/j.jpsychires.2018.08.001] [Medline: 30114665]
4. Paulson JF, Bazemore SD. Prenatal and postpartum depression in fathers and its association with maternal depression: a meta-analysis. JAMA 2010 May 19;303(19):1961-1969. [doi: 10.1001/jama.2010.605] [Medline: 20483973]
5. Johansson M, Svensson I, Stenström U, Massoudi P. Depressive symptoms and parental stress in mothers and fathers 25 months after birth. J Child Health Care 2017 Mar 19;21(1):65-73. [doi: 10.1177/1367493516679015] [Medline: 29156983]
6. Webster-Stratton C, Hammond M. Maternal depression and its relationship to life stress, perceptions of child behavior problems, parenting behaviors, and child conduct problems. J Abnorm Child Psychol 1988 Jun;16(3):299-315. [doi: 10.1007/bf00913802]
7. Kerstis B, Engström G, Sundquist K, Widarsson M, Rosenblad A. The association between perceived relationship discord at childbirth and parental postpartum depressive symptoms: a comparison of mothers and fathers in Sweden. Ups J Med Sci 2012 Nov 10;117(4):430-438 [FREE Full text] [doi: 10.3109/03009734.2012.684805] [Medline: 22574747]
8. Silva de Medeiros MC, de Oliveira MC, Gurgel LV, Ribeiro Rodrigues AG, Micussi MT, Magalhães AG. A health app for evidence-based postpartum information: development and validation study. JMIR Hum Factors 2023 Jul 13;10:e38706 [FREE Full text] [doi: 10.2196/38706] [Medline: 37440288]
9. Truitt FE, Pina BJ, Person-Rennell NH, Angstman KB. Outcomes for collaborative care versus routine care in the management of postpartum depression. Qual Prim Care 2013;21(3):171-177. [Medline: 23968267]
10. Sadural E, Riley KE, Zha P, Pacquiao D, Faust A. Experiences with a postpartum mHealth intervention during the COVID-19 pandemic: key informant interviews among patients, health care providers, and stakeholders. JMIR Form Res 2022 Jun 13;6(6):e37777. [doi: 10.2196/37777] [Medline: 35699998]
11. Falconer E, Kho D, Docherty JP. Use of technology for care coordination initiatives for patients with mental health issues: a systematic literature review. Neuropsychiatr Dis Treat 2018;14:2337-2349 [FREE Full text] [doi: 10.2147/NDT.S172810] [Medline: 30254446]
12. Haldar S, Studd H, Wong N, Mohr DC, Reddy M, Miller ES. Collaboration challenges and technology opportunities at the intersection of perinatal and mental health journeys. Proc ACM Hum Comput Interact 2022 Nov 11;6(CSCW2):1-28 [FREE Full text] [doi: 10.1145/3555614]
13. Doherty K, Marcano-Belisario J, Cohn M, Mastellos N, Morrison C, Car J, et al. Engagement with mental health screening on mobile devices: results from an antenatal feasibility study. In: Proceedings of the 2019 CHI Conference on Human Factors in Computing Systems. 2019 Presented at: CHI '19; May 4-9, 2019; Glasgow, UK URL: https://doi.org/10.1145/3290605.3300416 [doi: 10.1145/3290605.3300416]
14. Kumar N, Anderson RJ. Mobile phones for maternal health in rural India. In: Proceedings of the 33rd Annual ACM Conference on Human Factors in Computing Systems. 2015 Presented at: CHI '15; April 18-23, 2015; Seoul, Republic of Korea URL: https://doi.org/10.1145/2702123.2702258 [doi: 10.1145/2702123.2702258]
15. Gresh A, Cohen M, Anderson J, Glass N. Postpartum care content and delivery throughout the African continent: an integrative review. Midwifery 2021 Jun;97:102976 [FREE Full text] [doi: 10.1016/j.midw.2021.102976] [Medline: 33740519]
16. Sawyer A, Kaim A, Le HN, McDonald D, Mittinty M, Lynch J, et al. The effectiveness of an app-based nurse-moderated program for new mothers with depression and parenting problems (eMums Plus): pragmatic randomized controlled trial. J Med Internet Res 2019 Jun 04;21(6):e13689 [FREE Full text] [doi: 10.2196/13689] [Medline: 31165715]
17. Zingg A, Carter L, Rogith D, Franklin A, Selvaraj S, Refuerzo J, et al. Digital technology needs in maternal mental health: a qualitative inquiry. Stud Health Technol Inform 2021 May 27;281:979-983. [doi: 10.3233/SHTI210324] [Medline: 34042819]
18. McCarter DE, Demidenko E, Sisco TS, Hegel MT. Technology-assisted nursing for postpartum support: a randomized controlled trial. J Adv Nurs 2019 Oct 21;75(10):2223-2235 [FREE Full text] [doi: 10.1111/jan.14114] [Medline: 31222789]
19. Prabhakar AS, Guerra-Reyes L, Effron A, Kleinschmidt VM, Driscoll M, Peters C, et al. "Let me know if you need anything": support realities of new mothers. In: Proceedings of the 11th EAI International Conference on Pervasive Computing Technologies for Healthcare. 2017 Presented at: PervasiveHealth '17; May 23-26, 2017; Barcelona, Spain URL: https://doi.org/10.1145/3154862.3154863 [doi: 10.1145/3154862.3154863]
20. Gui X, Chen Y, Kou Y, Pine K, Chen Y. Investigating support seeking from peers for pregnancy in online health communities. Proc ACM Hum Comput Interact 2017 Dec 06;1(CSCW):1-19 [FREE Full text] [doi: 10.1145/3134685]
21. Johansson M, Benderix Y, Svensson I. Mothers' and fathers' lived experiences of postpartum depression and parental stress after childbirth: a qualitative study. Int J Qual Stud Health Well-being 2020 Dec 28;15(1):1722564 [FREE Full text] [doi: 10.1080/17482631.2020.1722564] [Medline: 31990637]
22. Zingg A, Rogith D, Refuerzo JS, Myneni S. Digilego for peripartum depression: a novel patient-facing digital health instantiation. AMIA Annu Symp Proc 2020;2020:1421-1430 [FREE Full text] [Medline: 33936518]

XSL•FO
RenderX

23. Suh J, Williams S, Fann JR, Fogarty J, Bauer AM, Hsieh G. Parallel journeys of patients with cancer and depression: challenges and opportunities for technology-enabled collaborative care. Proc ACM Hum Comput Interact 2020 May;4(CSCW1):38. [doi: 10.1145/3392843] [Medline: 32656502]
24. Romano M, Cacciatore A, Giordano R, La Rosa B. Postpartum period: three distinct but continuous phases. J Prenat Med 2010 Apr;4(2):22-25 [FREE Full text] [Medline: 22439056]
25. World Health Organization. Counselling for Maternal and Newborn Health Care: A Handbook for Building Skills. Geneva, Switzerland: World Health Organization; 2010.
26. Lopez-Gonzalez DM, Kopparapu AK. Postpartum care of the new mother. In: StatPearls [Internet]. Treasure Island, FL: StatPearls Publishing; 2022.
27. Finlayson K, Crossland N, Bonet M, Downe S. What matters to women in the postnatal period: a meta-synthesis of qualitative studies. PLoS One 2020 Apr 22;15(4):e0231415 [FREE Full text] [doi: 10.1371/journal.pone.0231415] [Medline: 32320424]
28. Lam S. Your first postpartum visit: what to expect. Carnegie Imaging. 2023 Jun 15. URL: https://www.carnegieimaging.com/blog/your-first-postpartum-visit-what-to-expect/ [accessed 2024-03-06]
29. American College of Obstetricians and Gynecologists. Your Pregnancy and Childbirth: Month to Month. Washington, DC: American College of Obstetricians & Gynecologists; 2021.
30. Gjerdingen D, Crow S, McGovern P, Miner M, Center B. Changes in depressive symptoms over 0-9 months postpartum. J Womens Health (Larchmt) 2011 Mar;20(3):381-386 [FREE Full text] [doi: 10.1089/jwh.2010.2355] [Medline: 21351876]
31. Kellie FJ. Postpartum health professional contact for improving maternal and infant health outcomes for healthy women and their infants. Cochrane Database Syst Rev 2017 Jun;2017(6):CD010855 [FREE Full text] [doi: 10.1002/14651858.CD010855.pub2]
32. Optimizing postpartum care. American College of Obstetricians and Gynecologists. 2018 May. URL: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizing-postpartum-care [accessed 2025-08-09]
33. Thirteen weeks postpartum. Ovia Health. URL: https://www.oviahealth.com/guide/263147/thirteen-weeks-postpartum/ [accessed 2024-03-06]
34. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Br J Psychiatry 1987 Jun;150:782-786. [doi: 10.1192/bjp.150.6.782] [Medline: 3651732]
35. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001 Sep;16(9):606-613 [FREE Full text] [doi: 10.1046/j.1525-1497.2001.016009606.x] [Medline: 11556941]
36. Fitelson E, Kim S, Baker AS, Leight K. Treatment of postpartum depression: clinical, psychological and pharmacological options. Int J Womens Health 2010 Dec 30;3:1-14 [FREE Full text] [doi: 10.2147/IJWH.S6938] [Medline: 21339932]
37. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006 May 22;166(10):1092-1097. [doi: 10.1001/archinte.166.10.1092] [Medline: 16717171]
38. American Psychiatric Association, DSM-5 Task Force. Diagnostic and Statistical Manual of Mental Disorders: DSM-5. Washington, DC: American Psychiatric Publishing; 2013.
39. Carlson K, Mughal S, Azhar Y, Siddiqui W. Perinatal depression. In: StatPearls. Treasure Island, FL: StatPearls Publishing; 2025.
40. Dimidjian S, Goodman SH, Felder JN, Gallop R, Brown AP, Beck A. Staying well during pregnancy and the postpartum: a pilot randomized trial of mindfulness-based cognitive therapy for the prevention of depressive relapse/recurrence. J Consult Clin Psychol 2016 Feb;84(2):134-145 [FREE Full text] [doi: 10.1037/ccp0000068] [Medline: 26654212]
41. New families deserve the support they need to thrive. Baby2Home. URL: https://baby2home.com/ [accessed 2025-05-29]
42. Duckworth M, Garfield CF, Santiago JE, Gollan J, O'Sullivan K, Williams D, et al. The design and implementation of a multi-center, pragmatic, individual-level randomized controlled trial to evaluate Baby2Home, an mHealth intervention to support new parents. Contemp Clin Trials 2024 Jul;142:107571. [doi: 10.1016/j.cct.2024.107571] [Medline: 38740296]
43. Thomas DR. A general inductive approach for analyzing qualitative evaluation data. Am J Eval 2006 Jun 01;27(2):237-246. [doi: 10.1177/1098214005283748]
44. Scarff JR. Postpartum depression in men. Innov Clin Neurosci 2019 May 01;16(5-6):11-14 [FREE Full text] [Medline: 31440396]

Abbreviations

B2H: Baby2Home
BHP: behavioral health care provider
CCM: collaborative care model
CCP: collaborative care program
CM: care manager
GAD-7: 7-item General Anxiety Disorder
PHQ-9: 9-item Patient Health Questionnaire
PJF: parallel journeys framework
PPD: postpartum depression

XSL•FO
RenderX

PPJF: postpartum parallel journeys framework
PSS: Perceived Stress Scale
RCT: randomized controlled trial

Edited by S Badawy; submitted 06.01.25; peer-reviewed by E Obikane, S Sharip; comments to author 20.05.25; revised version received 15.07.25; accepted 18.07.25; published 26.08.25.

Please cite as:
Rego C, Santiago JE, Miller ES, Garfield CF, Gollan J, O'Sullivan K, Williams D, Montague E, Lee YS
Understanding the Implications of mHealth Technology in Collaborative Care Programs and Its Role in Supporting Postpartum Care: Qualitative Interview Study of the Baby2Home Intervention Using the Parallel Journeys Framework
JMIR Pediatr Parent 2025;8:e70936
URL: https://pediatrics.jmir.org/2025/1/e70936
doi:10.2196/70936
PMID:

©Chryselle Rego, Joshua E Santiago, Emily S Miller, Craig F Garfield, Jacqueline Gollan, Kathleen O'Sullivan, Dinah Williams, Enid Montague, Young Seok Lee. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 26.08.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Exploring Parental Intentions to Use Digital Tools to Enhance Parent-Child Sexual Communication in Europe: Cross-Sectional Questionnaire Study

Talia Rose Hubble[1], BM BCh, LLM; Luca Carbone[2], MSc, PhD; Laura Vandenbosch[2,3], PhD; Jaan Toelen[3,4], MD, PhD; David De Coninck[3,5], MSc, PhD

[1]EGA Institute for Women's Health, University College London, London, United Kingdom

[2]Media Psychology Lab, Faculty of Social Sciences, KU Leuven, Leuven, Belgium

[3]KU Leuven Child and Youth Institute, Leuven, Belgium

[4]Department of Development and Regeneration, KU Leuven, Leuven, Belgium

[5]Centre for Sociological Research, Faculty of Social Sciences, KU Leuven, Leuven, Belgium

Corresponding Author:
Talia Rose Hubble, BM BCh, LLM
EGA Institute for Women's Health
University College London
Medical School Building, 74 Huntley St
London, WC1E 6DE
United Kingdom
Phone: 44 7826723657
Email: rmjbhub@ucl.ac.uk

Abstract

Background: Parent-child communication about sexuality education is critical for safe adolescent sexual development and well-being. Yet, there is evidence that these conversations are often ineffective. Digital tools have therefore emerged as promising interventions that may assist parents in addressing sensitive or difficult topics. However, our understanding of the factors that may motivate parental adoption of these technologies remains limited.

Objective: This study aimed to explore factors associated with European parents' intentions to use a digital tool designed to support parent-child sexual communication and complement school-based sexuality education. The study was conducted across the United Kingdom, Belgium, and Italy.

Methods: Using the technology acceptance model, we applied structural equation modeling to identify motivators of parents' *intention to use* the hypothetical app. This included *perceived usefulness* and *perceived ease of use*. *Perceived usefulness* was further analyzed by its subcomponents—*relevance to parenting* and *quality of technology*—through an alternative 3-construct model. Additionally, the associations between demographic characteristics (age, gender, country of residence, and education level) and the latent constructs were assessed.

Results: The study sample included 1296 parents. The explanatory power of the model was R^2=0.47. *Perceived usefulness* was significantly associated with *intention to use* (β=0.67, *P*<.001), while *perceived ease of use* showed no significant association with either *intention to use* (β=–0.01, *P*>.05) or *perceived usefulness* (β=0.10, *P*>.05). An alternative 3-construct analysis revealed that *relevance to parenting* and *quality of technology* were both independently significantly associated with *intention to use* (β=0.09, *P*<.001 and β=0.59, *P*<.001, respectively). Demographic characteristics were also significantly related to the technology acceptance model constructs in the model.

Conclusions: These findings highlight the critical role of perceived usefulness, specifically relevance to parenting needs and the perceived quality of technology, in shaping parental intentions to use digital parent-child sexual communication tools. Developers of educational digital technologies should therefore prioritize high-quality design features to inspire usage. Future research should evaluate real-world digital tools to assess actual usage, long-term engagement, and their effectiveness in enhancing parent-child sexual communication.

(JMIR Pediatr Parent 2025;8:e75489) doi:10.2196/75489

XSL•FO
RenderX

KEYWORDS

sex education; parent-child sexual communication; sexual health; adolescent; puberty

Introduction

Background

Sexual health encompasses more than the absence of disease; it includes physical, emotional, psychological, and social well-being [1]. As such, sexuality education must go beyond teaching on anatomy, physiology, and the prevention of sexually transmitted infections and unintended pregnancies. Rather, it should also foster positive self-esteem, the ability to engage in healthy relationships, and the skills needed to navigate adult social and sexual experiences safely and confidently [2]. Effective sexuality education must therefore transcend basic and didactic teaching to engage young people in discussions on diverse attitudes, cultural perspectives, and relationship dynamics [3,4]. This should empower young people to explore their emerging identities and meaningfully engage with the world around them [5].

The role of the sexual health educator may be assumed by different figures in a young person's life: family members, peers, teachers, as well as the wider social and cultural context the child exists within [6-8]. These all act in a network of influence on an adolescent's sexual development [9]. Here, we explore parents' perspectives on a hypothetical intergenerational app designed to support parent-child sexual communication. We proposed an app that would be endorsed by schools and align with regional or national school sexuality education curricula. This app would thus serve as both an educational resource for parents and a prompt to initiating parent-child sexual communication [10]. The app's aim was to enhance young people's sexual development through parental education, as well as ensure close collaboration between the timing and content of parent and teacher sexuality education. Thus, the app would be integrated into the school curriculum and would unlock access to sexuality education content at appropriate times in the child's development, aligned with the timing and topics being covered in school.

Parent-Child Sexuality Communication

Parents are key agents of sexual socialization [8,11]. Recognized as some of the most significant sexual educators, they provide essential information and instill their children with basic values regarding sexual health and well-being [12]. Previous research has examined what constitutes positive and effective parent-child sexual communication. It has been identified that optimal parent-child sexual communication should involve open, supportive, and reciprocal communication [13-15]. Such high-quality parent-child sexual communication appears to support children's safe sexual development [16,17], reduce their sexual risk-taking [18,19], increase their testing for sexually transmitted infections [20], and improve psychological sexual well-being [21]. This provides evidence that parent-child sexual communication can have a significant positive impact on young people.

There are, however, several barriers to effective parent-child sexual communication. First, it appears that parents often initiate discussions after their child's sexual debut [22]. This reduces their ability to influence the young person's behavior. This delay may be because parents perceive their children as too young for sexuality education [23]. Alternatively, it may stem from a desire to protect their child's perceived innocence by avoiding topics deemed too mature or sexual [24]. Parents may also feel unsure how to initiate parent-child sexual communication and therefore not be able to overcome this initial hurdle [25].

Second, parents appear to overestimate the frequency of their parent-child sexual communication. They report more frequent communication episodes than their child counterparts [26]. This is problematic because effective parent-child sexual communication has been shown to involve regular dialogue rather than one-off discussions [26,27]. This implies that parents may need prompting to remember to engage in regular open communication on sexual health topics with their children.

Finally, the quality of parent-child sexual communication may be low. This may be because of parental discomfort, low self-efficacy, or limited sexual health knowledge [23,28-31]. If parents are misinformed, they may engage in conversations that are inaccurate or inappropriate. This includes conducting inappropriately gendered parent-child sexual communication, such as providing insufficient information on sociosexual issues [32] or reinforcing archaic or negative gender stereotypes [33]. The risk of this appears to be amplified when parent-child sexual communication involves sexual or gender minority children [34]. In these circumstances, parents have been observed to conduct inappropriately heteronormative parent-child sexual communication or overly prioritize discussions on the risk of HIV and other sexually transmitted infections over other aspects of sexuality education [35].

For these reasons, there are ongoing attempts to support parents to engage in better parent-child sexual communication. This has included in-person workshops [36], web-based learning [37-39], as well as intergenerational activities for parents and children to engage in together such as joint homework [40] and online games [41]. Yet, despite these efforts, parental engagement with parent-child sexual communication educational resources remained low [42]. It is therefore crucial to identify what motivates parents to adopt tools that may improve parent-child sexual communication.

Technology Acceptance Model

To examine the factors that are associated with parents' intention to use an app to support parent-child sexual communication, we used a modified version of the technology acceptance model (TAM) [43]. Davis developed the TAM as an extension of Ajzen and Fishbein's theory of reasoned action (TRA) [44]. The TRA predicts human behavior as determined by different cognitions including attitudes toward the behavior and subjective norms. Attitudes toward the behavior were defined as an individual's feelings toward performing the behavior, whether negative or positive [44]. The TRA was thus used as a conceptual

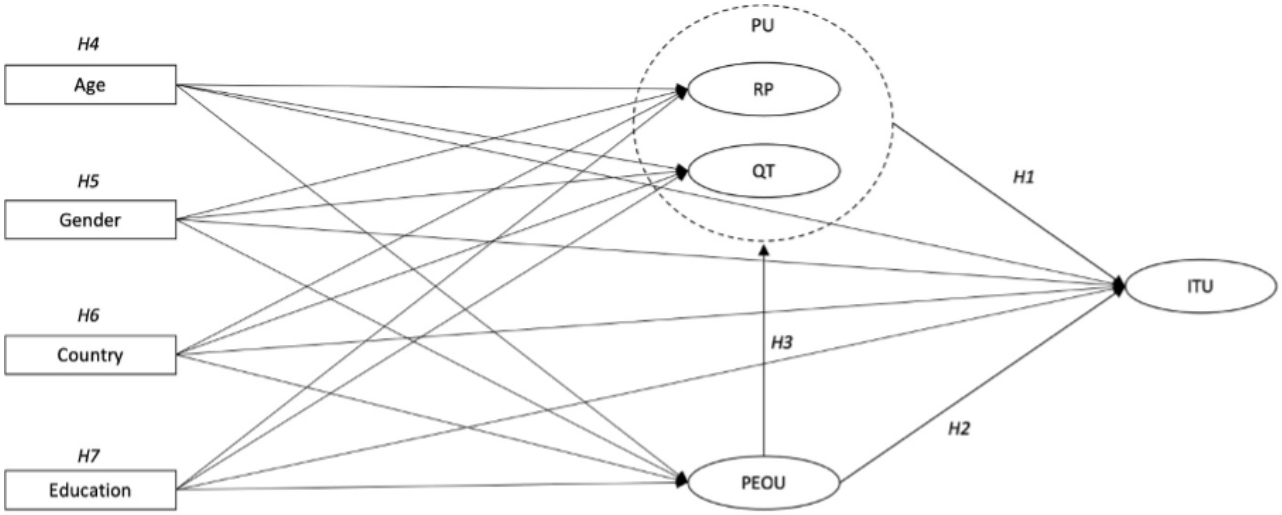
XSL•FO
RenderX

framework for modeling intention to perform voluntary behaviors. The TRA was then adapted in the form of the TAM to apply theories of voluntary behavior to user acceptance and utilization of computer technologies.

The TAM has been previously used as a conceptual framework to assess parental acceptance of educational digital tools [45]. This study is, however, the first to apply the TAM to understand parental intentions to use technology to improve their parent-child sexual communication. According to the TAM, *intention to use* predicts actual system usage. The attitudes that determine *intention to use* are defined as the technology's *perceived usefulness* and *perceived ease of use*.

Perceived usefulness reflects the degree to which a person believes the technology will enhance their job performance. According to the TAM, perceived usefulness has a positive association with intention to use. Thus, individuals should be more likely to adopt technologies that they perceive as beneficial and aligned with their goals. In the context of this study, we hypothesize that parents will be more inclined to use the app if they perceive the digital tool as useful in supporting their parent-child sexual communication (Figure 1).

Figure 1. Technology acceptance model (TAM) framework. Rectangles represent observed (measured) variables, and ellipses indicate latent constructs. The dotted circle denotes a second-order latent construct, where *perceived usefulness* is composed of *relevance to parenting* and *quality of technology*. Arrows indicate hypothesized relationships between variables. ITU: intention to use; PEOU: *perceived ease of use*; PU: *perceived usefulness*; QT: *quality of technology*; RP: *relevance to parenting*.



We adapted the TAM to fit our study's context by inputting elements of the TAM2, in which additional measured factors were added to shape *perceived usefulness* [46]. In our framework, *perceived usefulness* is conceptualized as a second-order latent variable determined by the *quality of technology* and *relevance to parenting*. This decision reflects a theoretical alignment with later iterations of the TAM, in which job relevance (*relevance to parenting*) and output quality (*quality of technology*) are recognized subcomponents of *perceived usefulness* [46]. By embedding *relevance to parenting* and *quality of technology* as dimensions of *perceived usefulness*, our framework acknowledges that parents' perceptions of usefulness are inherently multidimensional. We do, however, adapt the TAM such that *quality of technology* and *relevance to parenting* do not only influence *perceived usefulness* but instead act as its subcomponents.

> Hypothesis: *Perceived usefulness* has a direct and positive association with *intention to use* (H1).

Perceived ease of use may be defined as the extent to which a person believes that using the technology will be free of effort. Perceived ease of use is expected to be positively associated with *intention to use*. If a user finds a technology intuitive and accessible, they are anticipated to be more likely to engage with it [47]. Thus, an app that is easy to navigate should be more appealing to parents and encourage usage (Figure 1).

In our study, we examined parents' *perceived ease of use* of an intergenerational app. We considered that parents might inherently find digital tools difficult to use but may perceive this technology as easier due to its intergenerational design. Specifically, knowing their digitally native children could assist them may positively influence their overall perception of the app's ease of use [48]. Thus, our assessment of *perceived ease of use* incorporated both parents' own perceptions and their views regarding their children's digital fluency.

> Hypothesis: *Perceived ease of use* has a direct and positive association with *intention to use* (H2).

Perceived ease of use is also hypothesized to be positively associated with perceived usefulness, forming an indirect pathway to intention to use [47]. This hypothesis identifies the interplay between the cognitive effort to use a technology and the perception of its functional benefits. Thus, if parents find an app easier to use, they may be more likely to recognize its utility in enhancing parent-child sexual communication. This may then mean that they are more likely to intend to adopt its usage (Figure 1).

> Hypothesis: *Perceived ease of use* has a direct and positive association with *perceived usefulness* (H3).

We hypothesized that parents' sociodemographic factors would be associated with the latent constructs measured in our model (*relevance to parenting*, *quality of technology*, *perceived ease*

XSL•FO
RenderX

of use, and *intention to use*; Figure 1). These factors included age, gender, country of residence, and education level.

We based the relevance of age in our model on previous research identifying the digital divide between adults of different ages [49]. Thus, older generations may feel that they lack the confidence or skills required to effectively engage with an intergenerational app. We anticipated that younger parents may be more accustomed with digital tools and therefore find them easier to use, more useful, and be more willing to engage in technology usage.

We anticipated that parents' gender would also be significantly associated with our first-order latent constructs. Previous research has identified that fathers engage in parent-child sexual communication less frequently than mothers [50]. When fathers educate their daughters on sexual health, they also discuss fewer topics with a more narrowed focus [29]. We therefore predicted that fathers would be less likely to see the app as relevant to their parenting, thus seeing the app as less useful and having reduced intention to use the digital tool.

Parents' *perceived usefulness*, *perceived ease of use*, and their *intention to use* may also be influenced by their perceived social norms. Social norms refer to collective beliefs about typical and appropriate beliefs, behaviors, and actions within a group [51]. These norms are internalized during the socialization process and shaped by cultural and educational contexts [52]. Consequently, our study also examined the influence of the parents' country of residence and education level on the latent constructs. We hypothesized that parents residing in more liberal countries within Europe would be more inclined to engage with parent-child sexual communication digital technologies, whereas parents from more conservative regions would be less willing. Furthermore, consistent with prior research on in-person school-based sexuality education [53], we anticipated that higher parental educational attainment would be associated with greater parental support of sexuality education and thus a higher intention to use a parent-child sexual communication app.

Hypotheses: Age (H4), gender (H5), country of residence (H6), and education level (H7) may be associated with *relevance to parenting*, *quality of technology*, *perceived ease of use*, and *intention to use*.

Methods

Recruitment

This work represents the second phase of a multifaceted survey on parental attitudes toward digital sexuality education [54]. In the first phase, we examined parental views on the age at which adolescents should receive sexuality education topics via a digital app. The present study builds on this by focusing not on the age-appropriateness of content but on parents' intention to use multigenerational digital tools to improve parent-child sexual communication. Data collection occurred between May and June 2022 across 3 regions: Belgium (the Flemish area), the United Kingdom, and Italy. These locations were selected to capture a diverse spectrum of perspectives on sexual and gender diversity within Europe, as reflected by ILGA-Europe rankings. ILGA-Europe assesses the legal and policy landscape for gender and sexual minority people across European countries. It calculates an index score based on the country's laws on equality, gender recognition, family rights, and hate crimes, as well as their tolerance toward freedom of expression. In the 2022 survey, Belgium ranked highly, the United Kingdom received an intermediate ranking, and Italy scored relatively poorly for their lack of inclusive laws and policies [55].

Data were gathered through an anonymous online survey administered by the official polling agency iVOX [56]. iVOX is a Belgian company that holds the largest consumer panel in Belgium. It has been incorporated by the Bilendi research marketing agency, which enables access to panels across European countries. A total of 1500 individuals were recruited from iVOX's closed survey online panels, which comprise between 30,000 and 250,000 members per region. Members voluntarily participated in the surveys and were compensated with gift vouchers upon completion. Members were provided with an informed consent form to complete prior to enrollment. Data were pseudoanonymized at the point of collection.

Eligible participants were adult parents of children aged 9-18 years. The lower age threshold of 9 years was chosen to reflect the age at which many children start to engage with more complex sexuality education in schools [1]. Inclusion criteria required participants to provide essential demographic details such as ethnicity, gender, and sexual identity, as well as complete key sections of the survey (Multimedia Appendix 1). Participants were excluded if they failed to meet these criteria or if their engagement with the survey was deemed insufficient. Insufficient engagement was determined by low or absent variability in response to Likert scale questions, which was presumed to indicate poor attention to the survey content.

Survey Instrument

The survey was administered in English, Dutch, and Italian. The survey was developed in English, and back-translation was performed by native Dutch and Italian speakers (JT and LC, respectively) to ensure linguistic consistency. Before completing the survey, participants were briefed on the hypothetical app. The app was described as a complement to school sexuality education, which would release material in accordance with the school curriculum. It would be available in parent and child versions to download onto their smartphones. To minimize response errors, the questionnaire included working definitions of sexuality education and parent-child sexual communication [57].

Participants reported on individual and family characteristics. Individual characteristics included age, which was nonparametric and presented as median (IQR). Categorical individual characteristics included gender, ethnicity, education level, sexuality, relationship status, and religion. Religiosity was evaluated on a 5-point Likert scale ("I am a religious person"; 1=strongly disagree to 5=strongly agree) and reported as mean (SD). Sociosexual attitude was assessed using items from the Sociosexual Orientation Inventory [58]. Participants rated 3 statements on a 5-point Likert scale (1=strongly disagree to 5=strongly agree): "sex without love is okay," "I can imagine myself being comfortable and enjoying 'casual' sex with different partners," and "I do not want to have sex with a person

XSL•FO
RenderX

unless I am sure that we will have a long-term serious relationship" (reverse coded). Sociosexual attitude was expressed as a composite mean (SD).

Family characteristics included the number of children in the family and the age of the oldest child. These items were nonparametric and expressed as median (IQR). Parents also provided their perceptions of their children's gender and sexual identities. As their children were not surveyed in parallel, we could not confirm the veracity of the perceived identities.

The latent constructs *intention to use*, *perceived ease of use*, *quality of technology*, and *relevance to parenting* were measured using a minimum of two items each (Table 1) [59]. The items for *relevance to parenting* were directly obtained from Pariera [23]. In contrast, the measured items for the other constructs were not previously validated, and their development was informed by prior research instead [23,38,41,60]. To ensure content validity, a panel of 7 European experts in sexuality education and child development reviewed all items. The panel recommended minor adjustments, which were enacted prior to study commencement. All items were rated on a 5-point Likert scale (1=strongly disagree to 5=strongly agree).

Table 1. First-order latent constructs.

Item	Item question
Intention to use (ITU)	
ITU1	I would like my child or children to use the app.
ITU2	I would like to use the app to aid communication with my child about sexual health.
ITU3	I think that the app would improve my child's sexuality education.
Perceived ease of use (PEOU)	
PEOU1	I find apps easy to use.
PEOU2	My child or children find apps easy to use.
Quality of technology (QT)	
QT1	As a parent, I should be able to have my own profile on the app.
QT2	The app should include information sections for me to learn from.
QT3	The app should include example scripts on difficult topics for me to use when talking to my child about sexual health.
QT4	The app should include mock scenarios that I can discuss with my child.
QT5	The app should include educational games for me to play with my child.
QT6	The app should allow my child to flag topics to me that they would like to discuss in person.
QT7	The app should be able to send me alerts to encourage me to broach important or relevant topics with my child.
Relevance to parenting (RP)	
RP1	I think it is important for parents to talk to their children about sex.
RP2	I think parent-child communication about sex has a positive effect on young people.

Statistical Analysis

Demographic data were presented as frequencies for the total sample and stratified by region.

Exploratory factor analysis (EFA) was conducted to identify the dimensionality of the survey instrument. Analysis was performed using maximum likelihood extraction with oblique rotation (oblimin). Confirmatory factor analysis (CFA) was then performed using maximum likelihood with robust standard errors. This was because items were not normally distributed, as determined by the Andersen-Darling tests (P<.001) [61]. Internal consistency was evaluated using composite reliability. Convergent validity was assessed using average variance extracted (AVE), and discriminant validity was evaluated with the Fornell-Larcker criterion [62]. Harman's single-factor test was used to assess for common method bias [63]. Structural equation modeling (SEM) was then applied to test the study hypotheses. Model fits were assessed using multiple commonly used indices—comparative fit index (CFI), Tucker-Lewis Index (TLI), root-mean-square of residuals (RMSR), and root-mean-square error of approximation (RMSEA)—to provide a robust and well-rounded evaluation of fit [64].

Initially, *perceived usefulness* was conceptualized as a latent variable with its own measurement items. However, preliminary analysis revealed that the items developed for *perceived usefulness* did not consistently load onto a factor. To address this, *perceived usefulness* was respecified as a second-order latent variable determined by *quality of technology* and

XSL•FO
RenderX

relevance to parenting. Such higher-order modeling within SEM has been previously performed in other contexts [65]. Thus, in our model, parents' perceived usefulness of a hypothetical parent-child sexual communication app was composed of the quality of the technology and how relevant they deemed the app to their parenting. This adjustment deviates from the TAM but was deemed theoretically plausible and empirically necessary to ensure good alignment between measurement items and their latent constructs. A CFA was performed to assess the loading of *quality of technology* and *relevance to parenting* on the second-order construct *perceived usefulness*. This identified good CFI (0.95) and TLI (0.93), and acceptable RMSEA (0.08). Thus, the adjustment from the original model was empirically justified. Our approach also aligns with prior extensions of TAM in educational contexts, where the original variables of the TAM have been modeled as higher-order constructs to capture multiple elements [45]. Indeed, a recent meta-analysis on the modern use of TAM emphasized the importance of improving the predictive power of technology adoption models by tailoring the TAM to the specific context of the study [47].

The observed constructs—age, gender, country of residence, and education level—were added to the SEM in accordance with our TAM framework. Age was a scale variable. Gender, country of residence, and education level were categorical and therefore inputted with dummy variables. The reference groups for the categorical variables included in the SEM were female, the United Kingdom, and primary education level.

All analyses considered a 2-tailed *P* value of <.05 as statistically significant. This study has been reported in adherence with the Checklist for Reporting Results of Internet e-Surveys (CHERRIES) [66].

Ethical Considerations

Ethics approval was granted on May 25, 2022, by the KU Leuven Social and Societal Ethics Committee (SMEC reference: G-2022-5160). Informed consent was obtained from all participants before survey engagement. Data were anonymized and required and stored securely to ensure confidentiality and compliance with ethical standards. Participants were compensated with gift vouchers through the online platform.

Results

Sample Characteristics

Demographic data are summarized in Table 2. A total of 1296 participants were included in the analysis. The median age of the participants was 46 (IQR 40-51) years. Most participants reached either college-level education (aged 16-18 years) or tertiary education (aged >18 years). The frequencies of gender, ethnic, religious, and sexual minority groups in the sample were low. Only 3.2% (n=42) of study participants identified as noncisgender, 3.9% (n=51) as not heterosexual, and 4.7% (n=61) considered themselves of non-European ethnicity. Similarly, most individuals (n=785, 60.6%) considered themselves Christian. There were, however, a sizeable minority of individuals who identified as not having a religion (n=459, 35.4%). This likely impacted religiosity, where most participants across the 3 regions gave intermediate scores (Table 2). Nearly 89% (n=1150) of participants considered themselves to be in a committed relationship, and the sociosexual attitude scores were intermediate (composite mean 2.89 on a Likert scale from 1 to 5; Table 2). With respect to family characteristics, the median number of children per family was 2 (IQR 1-2). This approximates the total fertility rate across countries in the European Union [67]. The median age of the eldest child of parents surveyed in our sample was 15 (IQR 12-17) years. Across all regions, fewer than 10% of parents perceived their children to identify as a minority gender or sexuality group (n=30 [2.3%] and n=67 [5.2%], respectively).

XSL•FO
RenderX

Table 2. Demographic characteristics.

Demographic characteristics	Total (N=1296)	Region		
		Belgium (n=463)	United Kingdom (n=426)	Italy (n=407)
Parent characteristics , median (IQR)				
Age[a] (years)	46 (40-51)	45 (41-50)	45 (39-50)	45 (40-51)
Gender, n (%)				
Cisgender female	653 (50.4)	232 (50.1)	236 (55.4)	185 (45.5)
Cisgender male	601 (46.4)	231 (49.9)	176 (41.3)	194 (47.7)
Any other gender identity	42 (3.2)	0 (0)	14 (3.3)	28 (6.9)
Ethnicity, n (%)				
European	1235 (95.3)	457 (98.7)	376 (88.3)	402 (98.8)
Any other ethnicity	61 (4.7)	6 (1.3)	50 (11.7)	5 (1.2)
Education level, n (%)				
Primary school (≤12 years)	18 (1.4)	2 (0.4)	2 (0.5)	14 (3.4)
Secondary education (12-16 years)	165 (12.7)	15 (3.2)	73 (17.1)	77 (18.9)
College education (16-18 years)	529 (40.8)	162 (35.0)	144 (33.8)	223 (54.8)
Tertiary education (>18 years) and above	584 (45.1)	284 (61.3)	207 (48.6)	284 (22.9)
Religion, n (%)				
Christianity	785 (60.6)	260 (56.2)	204 (47.9)	321 (78.9)
Any other religion	52 (4.0)	9 (0.7)	27 (6.3)	16 (3.9)
No religion	459 (35.4)	194 (41.9)	195 (45.8)	70 (17.2)
Religiosity[a], mean (SD)	2.6 (1.3)	2.2 (1.1)	2.3 (1.3)	3.2 (1.2)
Sexuality, n (%)				
Heterosexual	1245 (96.1)	438 (94.6)	413 (96.9)	394 (96.8)
Any other sexuality	51 (3.9)	25 (5.4)	13 (3.1)	13 (3.2)
Relationship status, n (%)				
In a committed relationship	1150 (88.7)	411 (88.8)	364 (85.4)	375 (92.1)
In a casual relationship	28 (2.2)	8 (1.7)	11 (2.6)	9 (2.2)
Single	118 (9.1)	44 (9.5)	51 (12.0)	23 (5.7)
Sociosexual attitude[b], mean aggregate value (SD)	2.89 (1.0)	2.9 (1.0)	3.0 (1.0)	2.8 (1.0)
Family characteristics , median (IQR)				
Number of children	2 (1-2)	2 (1-3)	2 (1-3)	2 (1-2)
Age of the oldest child (years)	15 (12-17)	15 (12-17)	15 (12-17)	14 (11-16)
Parental perception of their children's gender, n (%)				
Cisgender female	315 (24.3)	110 (23.8)	106 (24.9)	99 (24.3)
Cisgender male	387 (29.9)	122 (26.3)	114 (26.8)	151 (37.1)
Cisgender female and male	540 (41.7)	213 (46.0)	187 (43.9)	140 (34.4)
One or more transgender, gender fluid, or nonbinary child	30 (2.3)	7 (1.5)	15 (3.5)	8 (2.0)
Their parent does not know	24 (1.0)	11 (2.4)	4 (0.9)	9 (2.2)
Parental perception of their children's sexuality, n (%)				
Heterosexual	1036 (79.9)	336 (72.6)	331 (77.7)	369 (90.7)
One or more homosexual, bisexual, or any other sexuality child	67 (5.2)	30 (6.5)	31 (7.3)	6 (1.5)
Their parent does not know	193 (14.9)	97 (21.0)	64 (15.0)	32 (7.9)

XSL•FO
RenderX

[a]Data were measured on a 5-point Likert scale ("I am a religious person"; 1=strongly disagree to 5=strongly agree).

[b]Data were measured on a 5-point Likert scale reflecting (1=strongly disagree to 5=strongly agree) increasing sexual liberalism.

Measurement Model

The item-level correlation matrix alongside the items' means (SD) is presented in Multimedia Appendix 2. EFA identified 4 factors with eigenvalues >0.5 (Table 3). These factors were assigned based on item loadings ≥0.4, consistent with the recommendations of Stevens [68]. This threshold ensured robust item-factor associations, with all items aligning well with the model's theorized latent constructs. Sample adequacy was confirmed by a Kaiser-Meyer-Olkin statistic of 0.83 [69]. This provided a strong basis for factor analysis. The EFA model demonstrated excellent fit indices: TLI=0.95, RMSEA=0.06, and RMSR=0.02 [70]. The highest interfactor correlation was 0.54, which was below the recommended upper threshold of 0.7 [71]. This supported our assumption of factor independence.

Table 3. Exploratory factor analysis.

	Intention to use (ITU)	Perceived ease of use (PEOU)	Quality of technology (QT)	Relevance to parenting (RP)
ITU1	0.86	—[a]	—	—
ITU2	0.75	—	—	—
ITU3	0.79	—	—	—
PEOU1	—	0.88	—	—
PEOU2	—	0.95	—	—
QT1	—	—	0.57	—
QT2	—	—	0.75	—
QT3	—	—	0.81	—
QT4	—	—	0.73	—
QT5	—	—	0.48	—
QT6	—	—	0.64	—
QT7	—	—	0.63	—
RP1	—	—	—	0.78
RP2	—	—	—	0.90

[a]Not applicable.

To validate the factor structure identified in the EFA, CFA was used (Table 4). The 4-factor CFA model demonstrated similarly excellent fit indices: CFI=0.96, TLI=0.95, and RMSEA=0.06. These values met or exceeded benchmark standards for model fit (CFI>0.9, TLI>0.9, and RMSEA<0.08) [70]. All standardized factor loadings were greater than 0.4, further reinforcing the validity of the associations between items and their respective factors (Multimedia Appendix 3) [68]. Measurement reliability analyses using composite reliability provided additional support as they identified excellent internal consistency (Table 4).

Table 4. Confirmatory factor analysis for first-order latent constructs.

Items	Composite reliability	Average variance extracted
Intention to use	0.86	0.67
Perceived ease of use	0.91	0.84
Quality of technology	0.86	0.48
Relevance to parenting	0.83	0.71

Convergent validity was evaluated using AVE. Three constructs (*intention to use*, *perceived ease of use*, and *relevance to parenting*) achieved AVE values above the recommended threshold of 0.5, reflecting strong convergent validity (Table 4). While the AVE for the *quality of technology* construct was slightly below this threshold at 0.48, it was deemed acceptable given its proximity to the cutoff and the exploratory nature of the study. This was considered appropriate given the overall robustness of the CFA results. Discriminant validity was confirmed using the Fornell-Larcker criterion. Furthermore, Harman's single-factor test revealed that less than 50% of the variance was explained by a single construct model (32%). This alleviated concerns regarding common method bias. Together, these findings confirmed the appropriateness of the model for capturing the intended constructs.

Structural Model

The SEM is presented in Table 5. The SEM demonstrated good fit indices (CFI=0.94, TLI=0.93, and RMSEA=0.05),

XSL•FO
RenderX

demonstrating that the model adequately represented the data. The explanatory power of the model was R^2=0.47.

Perceived usefulness emerged as a dominant determinant of intention to use, demonstrating a strong and statistically significant direct association (β=0.67, *P*<.001). This supports hypothesis H1. However, perceived ease of use did not show a significant relationship with either intention to use (β=–0.01, *P*>.05) or perceived usefulness (β=0.10, *P*>.05). These findings suggested that perceived ease of use, which we had anticipated was a key component of our TAM, did not influence participants' perception of usefulness or their intention to use the parent-child sexual communication app. We therefore rejected hypotheses H2 and H3.

Age was significantly negatively associated with *intention to use* (β=–0.06, *P*=.05). This implied that younger parents were significantly more likely to intend to use the tool to assist with their parent-child sexual communication. Yet surprisingly, this was not explained by any significant relationship between age and the other latent constructs. This included *perceived ease of use*.

Our model identified that male gender had a significant negative association with *relevance to parenting* (β=–0.15, *P*<.001). This indicated that male parents considered the tool less relevant for parent-child sexual communication than their female counterparts. Conversely, male gender was positively associated with *intention to use* (β=0.08, *P*=.01). This suggested that despite its decreased relevance to parenting, men expressed a higher intention to use the digital tool overall. Participants of gender minority groups similarly displayed a significant positive association with *intention to use* (β=0.06, *P*=.05) when compared with their female counterparts. They however had a significant negative association with *perceived ease of use* (β=–0.09, *P*=.05). Thus, compared to female parents, they were less likely to perceive apps as easy to use. However, due to the small sample size of gender minority parents (42/1296, 3.2%), these results should be interpreted cautiously and considered exploratory.

Parents' country of residence also demonstrated significant associations with several constructs. Compared with respondents from the United Kingdom, Belgians demonstrated significant negative associations with *quality of technology* (β=–0.12, *P*=.001), *perceived ease of use* (β=–0.07, *P*=.004), and *intention to use* (β=–0.14, *P*<.001). Thus, the only construct that was not significantly associated with was *relevance to parenting*. This suggests significant cultural differences in technology acceptance between the United Kingdom and Belgium. Conversely, parents from Italy voted similarly to parents from the United Kingdom, except they were significantly less likely to perceive the technology as easy to use (β=–0.79, *P*<.001).

College-educated participants exhibited significant positive associations with *relevance to parenting* (β=0.25, *P*=.05), suggesting increased perceived relevance for parenting among more educated parents. Similarly, those with tertiary or higher education also showed significant positive associations with *relevance to parenting* (β=0.27, *P*=.04). No significant relationships emerged between secondary education level and any of the latent constructs.

Given that *perceived usefulness* was the only observed significant latent construct associated with *intention to use*, we sought to further understand the relative contributions of its subcomponents—*relevance to parenting* and *quality of technology*. A secondary analysis was therefore conducted by constructing an alternative 3-latent-construct model (Figure 2).

This 3-latent-construct model retained good fit indices (CFI=0.91, TLI=0.89, and RMSEA=0.06). The explanatory power of the model was, however, reduced to R^2=0.38. Within this model, both *relevance to parenting* and *quality of technology* had a significant positive association with *intention to use* (β=0.09, *P*=.002 and β=0.59, *P*<.001, respectively). The altered estimates and *P* values for the measured variables are presented in Multimedia Appendix 4 and show equivalent results to the full TAM framework.

XSL•FO
RenderX

Table 5. Structural equation modeling. *P* values are only listed when significant at <.05.

Construct	Unstandardized β	Standardized β	*P* value
H1 : *Perceived usefulness* (PU) has a direct and positive association with *intention to use* (ITU)			
PU → ITU	1.36	0.67	<.001
H2: *Perceived ease of use* (PEOU) has a direct and positive association with *intention to use* (ITU)			
PEOU → ITU	–0.00	–0.01	—
H3: *Perceived ease of use* (PEOU) has a direct and positive association with *perceived usefulness* (PU)			
PEOU → PU	0.04	0.10	—
H4: Age has a direct association with *quality of technology* (QT), *relevance to parenting* (RP), *perceived ease of use* (PEOU), and *intention to use* (ITU)			
Age → QT	0.00	–0.01	—
Age → RP	0.00	0.03	—
Age → PEOU	0.00	0.00	—
Age → ITU	–0.01	–0.06	.05
H5: Gender has a direct association with *quality of technology* (QT), *relevance to parenting* (RP), *perceived ease of use* (PEOU), and *intention to use* (ITU)[a]			
Male gender → QT	–0.01	–0.01	—
Male gender → RP	–0.20	–0.15	<.001
Male gender → PEOU	0.04	0.02	—
Male gender → ITU	0.11	0.08	.01
Other gender identity → QT	0.10	0.05	—
Other gender identity → RP	–0.21	–0.06	—
Other gender identity → PEOU	–0.51	–0.09	<.001
Other gender identity → ITU	0.24	0.06	.05
H6: Country of residence has a direct association with *quality of technology* (QT), *relevance to parenting* (RP), *perceived ease of use* (PEOU), and *intention to use* (ITU)[b]			
Belgium → QT	–0.10	–0.12	.001
Belgium → RP	0.04	0.03	—
Belgium → PEOU	–0.14	–0.07	.004
Belgium → ITU	–0.21	–0.14	<.001
Italy → QT	0.03	0.04	—
Italy → RP	0.08	0.06	—
Italy → PEOU	–1.77	–0.79	<.001
Italy → ITU	0.02	0.02	—
H7: Education level has a direct association with *quality of technology* (QT), *relevance to parenting* (RP), *perceived ease of use* (PEOU), and *intention to use* (ITU)[c]			
Secondary education → QT	0.13	0.12	—
Secondary education → RP	0.20	0.10	—
Secondary education → PEOU	0.18	0.06	—
Secondary education → ITU	0.10	0.05	—
College education → QT	0.16	0.20	—
College education → RP	0.33	0.25	.05
College education → PEOU	0.16	0.08	—
College education → ITU	0.19	0.13	—
Tertiary or higher education → QT	0.12	0.15	—

XSL•FO
RenderX

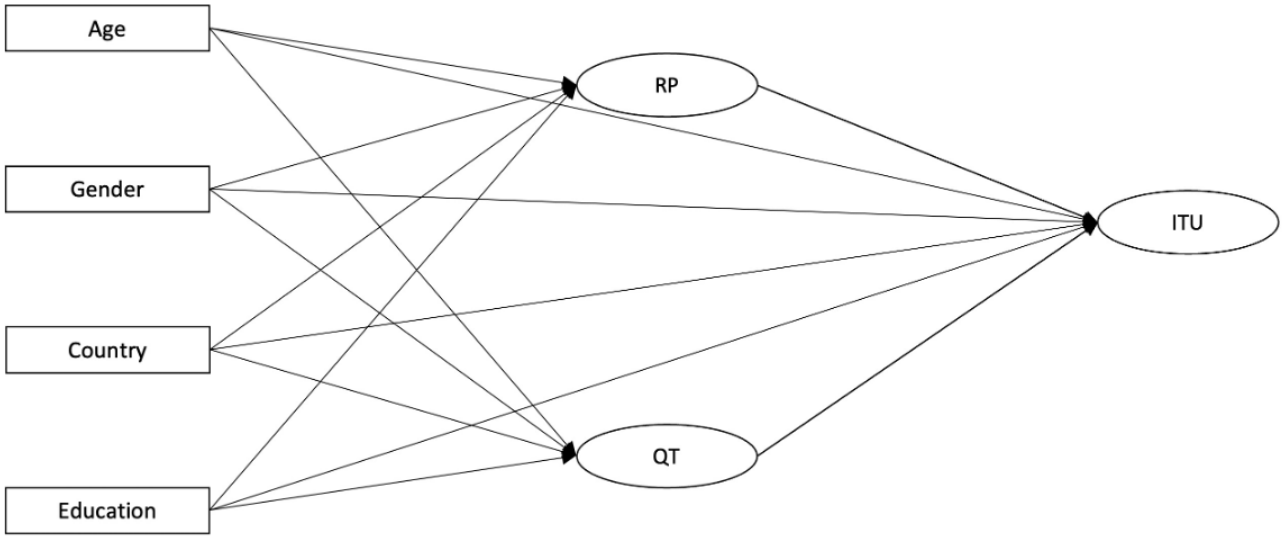
Construct	Unstandardized β	Standardized β	*P* value
Tertiary or higher education → RP	0.35	0.27	.04
Tertiary or higher education → PEOU	0.19	0.09	—
Tertiary or higher education → ITU	0.17	0.12	—

[a]Reference groups are female.

[b]Reference groups are the United Kingdom.

[c]Reference groups are primary education level.

Figure 2. Alternative 3-latent-construct model. Rectangles represent observed (measured) variables, and ellipses indicate latent constructs. Arrows indicate hypothesized relationships between variables. ITU: intention to use; QT: quality of technology; RP: relevance to parenting.



Discussion

Principal Findings and Comparison With Previous Works

This work examined the potential for a hypothetical intergenerational app designed to enhance parent-child sexual communication and align parental efforts with school-based sexuality education. Using a modified TAM [43], we explored factors that may relate to parents' intention to use the proposed digital tool. We sampled across 3 distinct regions in an attempt to obtain perspectives of parents across the spectrum of European opinion. Belgium, the United Kingdom, and Italy were selected because they differ in sociopolitical contexts: Belgium has progressive sexuality education policies, the United Kingdom is in an intermediate position, and Italy lacks a national mandate for sexuality education and holds more conservative social norms [55]. These contextual contrasts were mirrored in our descriptive statistics: Italian parents reported higher religiosity and fewer nonheterosexual identities, while parents from Belgium and the United Kingdom were more open to their children having alternative gender and sexual identities. Together, these findings suggest that both sociopolitical climate and demographic composition shaped parents' responses to the hypothetical technology.

We identified that *perceived usefulness* is significantly associated with participants' *intention to use* the app. This aligns with one of the foundational premises of the TAM, which posits that *perceived usefulness*—the degree to which an individual believes that using the technology will enhance their performance—is a critical driver of technology adoption [43]. The importance of *perceived usefulness* has been observed in previous studies on user adoption of new educational information technologies, including multimedia learning environments [72,73]. The dominance of *perceived usefulness* underscores that, in our context, parents' intentions are primarily related to their perception of the app's utility in addressing their parent-child sexual communication needs.

To further investigate the relative contributions of the first-order constructs, which comprised *perceived usefulness*, *relevance to parenting*, and *quality of technology*, we proposed an alternative 3-latent-construct model. While both models demonstrated good fit indices, the TAM-based model explained a greater proportion of variance in *intention to use* (R^2=0.47) compared to the 3-latent-construct model (R^2=0.38). In the 3-latent-construct model, both *relevance to parenting* and *quality of technology* significantly influenced *intention to use*. These findings align with prior studies on intergenerational sexuality education tools. Parents who ascribe value to sexuality education were more likely to be motivated to engage in new technologies to improve their parent-child sexual communication [42]. Furthermore, we identified the critical role of reliable, engaging, and content-rich technologies in facilitating parental adoption of digital tools [41]. In this work, features deemed attractive by parents included example scripts, interactive games, mock scenarios, and alert features. Similarly, surveys of children and adolescents have emphasized the importance of high-quality

XSL•FO
RenderX

app features in driving user adoption of sexuality education technologies [60,74].

Alongside identifying the significant positive association of *perceived usefulness* with *intention to use*, we also identified that sociodemographic factors were significantly associated with parents' intention to use the digital technology. Younger parents were more likely to intend to use the sexuality education app, which is in keeping with their comfort with digital educational adjuncts [75]. Furthermore, parents who did not identify as female were also more likely to intend to use the app. This may be because mothers feel more self-efficacy and confidence engaging in parent-child sexual communication and therefore do not see the same utility [18]. Notably, the country of residence was also an important determinant of survey responses. Belgian parents reported lower perceived ease of use, technology quality, and intention to use compared with British parents, despite broadly similar demographic profiles. This may reflect differences in cultural expectations around school-parent collaboration, with Belgium's comprehensive sexuality education perhaps reducing the perceived need for supplementary tools [76]. Conversely, in Italy, lower ease of use ratings may be linked to the more limited digital literacy when compared to its European neighbors [77]. These differences suggest parents across Europe will interact differently with virtual sexuality education technologies, and that national policies, sociocultural norms, and digital confidence must be considered when adapting such tools. Finally, we identified that the relative importance ascribed to parent-child sexual communication increased among parents who had higher educational attainment. This has been previously identified in other settings [78,79].

Unlike *perceived usefulness* or sociodemographic factors, *perceived ease of use* was not significantly associated with the other constructs in the model. This diverged from the classical TAM and contrasts with prior research on education technologies, which found that poor usability negatively affected parental engagement in their children's digital education [45]. In those cases, parents were less engaged in their child's online learning when they perceived the technology as difficult to use. However, our findings suggest that parents' intention to use an intergenerational app to support parent-child sexual communication was independent of its usability. Instead, parents were willing to engage with educational technology they found useful, regardless of how easy it was for them or their children to navigate. This discrepancy may be because our study only examined parents' theoretical intention to use, rather than their actual usage behaviors. Alternatively, it may reflect contextual differences, as the referenced study examined parents' technology usage to facilitate children's home-based learning during the global COVID-19 pandemic [45]. Given the heightened parental stress during this period, which negatively impacted children's learning outcomes [80], parents may have had reduced emotional and cognitive capacities to engage effectively with new or challenging educational technologies.

Our work is also not the first study to observe a diminished role for *perceived ease of use* within the TAM. Several studies on online educational platforms have similarly found that *perceived ease of use* does not significantly predict *intention to use* [81,82]. However, unlike our study, these works primarily sampled Generation Z students (born between 1995 and 2012) [83]. As "digital natives" who grew up with internet and mobile phone technologies [84], Generation Z may be less concerned with ease of use due to their familiarity and adaptability with new digital tools. In contrast, our study population consisted of parents with a minimum survey age of 18 years and a median age of 46 (IQR 40-51) years. It may therefore be that parents are willing to overlook usability challenges if they perceive the technology as highly useful or important, such as in the context of parent-child sexual communication. Yet, we also observed that lower parental ages were associated with greater intention to use the technology. This implies that younger parents may have the additional benefit of feeling comfortable tackling new technology challenges, independent of their current perceived ease of use.

Limitations

There are several limitations to the study that warrant discussion. First, the study relied on an online polling agency and a closed survey panel for recruitment, which may have introduced sampling bias. This may have introduced a self-selection bias, where only individuals motivated and interested in the topic with sufficient free time took part in the survey. To reduce the risk of this and increase overall motivation to engage with the project, we ensured that participants were adequately compensated for their involvement. Yet, there remained a predominance of cisgender, heterosexual, Christian, and European ethnicity participants in the sample. This limited diversity constrains the extent to which our findings can be applied to broader and more diverse parent populations. However, this demographic composition aligns with region-specific census data in the United Kingdom, which is the only region studied here with detailed census records available [85]. Nevertheless, it would be important to survey parents and children from backgrounds underrepresented here, who may have different attitudes toward digital parent-child sexual communication tools [13,34]. Future work should therefore use inclusive recruitment strategies to capture the parental attitudes among minority groups, such as community partnerships and targeted oversampling of underrepresented groups. Qualitative approaches such as focus groups or in-depth interviews may also provide richer insights from parents underrepresented in online survey panels.

Second, the hypothetical nature of the app may have constrained participants' engagement with the survey items. Unlike studies evaluating real-world interventions [42], our work relied on participants' imagination to envision the app's features, utility, and their intention to use it. This reliance on the hypothetical may have reduced the real-world applicability of our findings, as stated intention may not translate to actual adoption and engagement in the technology. There is a potential gap between an individual's intent to use and actual usage behaviors, as has been observed among consumers in other settings [86]. Furthermore, causality could not be established due to the cross-sectional nature of the study. While our model provides insights into relationships between constructs, future longitudinal or experimental studies with app prototypes are necessary to determine causal effects and understand how parental

XSL•FO
RenderX

engagement evolves over time in real-world settings. This evaluation may also include objective usage data, for example, in-app analytics.

Third, there are limitations related to our construction of the specific TAM model. Our *perceived ease of use* construct was also measured using only 2 items (capturing parents' ease and their perception of their children's ease). This was to avoid an excessively long and tiring survey, which may have reduced respondent attention and answer quality. Yet while reliability was high, the reduced breadth of our measure may have limited its sensitivity and contributed to the lack of significant associations observed. Future work may therefore expand on our measurement to assess whether these influence parental intent. Furthermore, we modified *perceived usefulness* to a second-order latent construct comprising *quality of technology* and *relevance to parenting*. While this approach was empirically justified, it deviated from the traditional TAM framework [43]. This modification prevented us from evaluating *perceived usefulness* as an original construct. This may limit the comparability of our findings with studies that operationalized *perceived usefulness* as a single first-order construct. However, our decision reflects known extensions of TAM and was therefore both justified. Our decision was in keeping with previous research in educational and e-learning settings, which have adjusted the TAM and its constructs to specific contexts [46]. Furthermore, as the purpose of the TAM is to provide a theoretical springboard for understanding the psychology of technology acceptance, it is necessary to tailor the foundational model to the specific context in which the research is performed. If this is not performed, the predictive capability of the TAM may be limited [47].

Implications of Study Findings

This study provides insights for researchers, educators, and app developers aiming to enhance parent-child sexual communication through digital interventions.

From a theoretical perspective, our findings add to a growing body of evidence that suggests that *perceived ease of use*—a previously core tenet of the TAM—plays a diminishing role in technology adoptions as digital literacy becomes ubiquitous among younger generations [87]. This shift calls for a re-evaluation of traditional TAM constructs when applied to "digital native" groups who feel comfortable with trialing new technologies. Future studies should investigate whether this trend persists across different cultural and technological settings.

From a practical standpoint, the overarching importance of *perceived usefulness* to parents' intention to engage in parent-child sexual communication apps should be central to any future app development. We identified that parents who perceive sexuality education as relevant and important were more likely to be motivated to use an app to assist and guide their parent-child sexual communication. Future work should consider how to encourage and inspire less motivated parents to engage in parent-child sexual communication. Our findings directly inform this, as they highlight which sociodemographic groups may be less likely to adopt the technology and why. Tailored information campaigns may then be developed to build trust and highlight the apps' utility for these groups, as well as explain the benefits of comprehensive sexuality education. For example, our identification of education level as significantly associated with perceived relevance to parenting should be useful to future researchers in this area. Care should be taken to engage parents with lower levels of educational attainment to emphasize the importance of parent-child sexual communication on their children's development. It is, however, noteworthy that this reduction in perceived relevance to parenting did not affect parents' overall intention to use the technology.

Our work also underscores the importance of prioritizing high-quality features in app development to improve parent-child sexual communication. The parents surveyed in this study prioritized the quality of technology as a critical determinant of intention to use. This encompassed app content reliability, functionality, multimedia options, and user engagement features. Educators should therefore focus on developing apps that are functional and high specification. However, balancing these desirable features against the associated development and operational costs of such complex app functionalities is essential [88]. Cost-benefit analyses may therefore be helpful to identify the most impactful features to prioritize in resource-constrained settings [89]. Collaboration between developers, schools, and policymakers could also help distribute costs to ensure high-quality tools are equitably accessible to families. Engaging parents through qualitative work in the design process may yield further insights into their preferences and priorities, ensuring that the most desirable app features are incorporated. Additionally, the recent advent of large language models and artificial intelligence technologies offers promising avenues to enhance content customization to the learning needs of the parent-child dyad with the aim to maximize user interaction [90]. Future work may also explore the role of cost-sharing models, such as government subsidies or collaborations between schools, to make development of high-quality parent-child sexual communication tools feasible and the apps freely accessible to families. When a suitable app prototype has been developed, longitudinal studies will be needed to assess how parental engagement evolves as they interact with a parent-child sexual communication app over time. Understanding these dynamics could inform strategies to sustain long-term adoption and maximize the app's effectiveness. For example, periodic app updates based on user feedback may improve satisfaction and retention [91].

Finally, children's engagement is integral to the success of any intergenerational interventions [26]. It is therefore imperative to include children in future evaluations of parent-child sexual communication apps. The maturity of the educational content they receive on the app and discuss with their parents [1], as well as their preferences for different app features [92], will evolve as they develop. Sampling across diverse age groups will be helpful to ensure apps resonate with children's evolving needs and preferences.

Conclusions

This study contributes novel insights into digital sexuality education technologies aiming to enhance parent-child sexual communication. We identified that *relevance to parenting* and

XSL•FO
RenderX

quality of technology were the critical determinants of parental intention to use hypothetical sexuality education apps. Our findings contribute to the theoretical advancement of the TAM in the context of parent-child sexual communication and provide actionable recommendations for app developers, researchers, and educators. Future research should involve real-world evaluations of intergenerational sexuality education apps to further refine our understanding and improve communication tools available for parents and their children. This is with the overall aim of ensuring parents can engage in high-quality, unprejudicial, and open communication with their children on sexual health topics.

Acknowledgments

We would like to thank the panel of European experts who assisted in modifying and improving the survey instrument.

Data Availability

Anonymized participant data are available upon reasonable request from the corresponding author.

Authors' Contributions

TRH and JT conceived of the project concept. TRH, JT, and LV planned the project. JT and LC performed translation of the survey instrument. TRH and DDC conducted the statistical analysis. TRH wrote the original manuscript, and all authors contributed to the manuscript revision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Inclusion criteria.
[PNG File , 81 KB - pediatrics_v8i1e75489_app1.png]

Multimedia Appendix 2
Item-level correlation matrix presented with item mean (SD). ITU: intention to use; PEOU: perceived ease of use; QT: quality of technology; RP: relevance to parenting.
[DOCX File , 17 KB - pediatrics_v8i1e75489_app2.docx]

Multimedia Appendix 3
Standardized factor loading.
[DOCX File , 14 KB - pediatrics_v8i1e75489_app3.docx]

Multimedia Appendix 4
Structural equation modeling for the alternative three latent construct model.
[DOCX File , 16 KB - pediatrics_v8i1e75489_app4.docx]

References

1. UNESCO Education Sector. International Technical Guidance on Sexuality Education: An Evidence-Informed Approach. Paris, France: United Nations Educational, Scientific and Cultural Organization (UNESCO); 2018.
2. Goldfarb ES, Lieberman LD. Three decades of research: the case for comprehensive sex education. J Adolesc Health 2021;68(1):13-27 [FREE Full text] [doi: 10.1016/j.jadohealth.2020.07.036] [Medline: 33059958]
3. Kim EJ, Park B, Kim SK, Park MJ, Lee JY, Jo AR, et al. A meta-analysis of the effects of comprehensive sexuality education programs on children and adolescents. Healthcare (Basel) 2023;11(18):2511 [FREE Full text] [doi: 10.3390/healthcare11182511] [Medline: 37761708]
4. Thulasi R, Kumar N. Systematic literature review on comprehensive sexuality education intervention. Sex Relatsh Ther 2024;40(1):223-238. [doi: 10.1080/14681994.2024.2331439]
5. Mijatović D. Comprehensive sexuality education protects children and helps build a safer, inclusive society. Commissioner for Human Rights. Strasbourg; 2020 Jul 21. URL: https://www.coe.int/en/web/commissioner/-/comprehensive-sexuality-education-protects-children-and-helps-build-a-safer-inclusive-society [accessed 2025-09-26]
6. Grossman JM, Lynch AD, Richer AM, DeSouza LM, Ceder I. Extended-family talk about sex and teen sexual behavior. Int J Environ Res Public Health 2019;16(3):480 [FREE Full text] [doi: 10.3390/ijerph16030480] [Medline: 30736363]
7. Perrino T, González-Soldevilla A, Pantin H, Szapocznik J. The role of families in adolescent HIV prevention: a review. Clin Child Fam Psychol Rev 2000;3(2):81-96. [doi: 10.1023/a:1009571518900] [Medline: 11227063]

XSL•FO
RenderX

8. Díaz-Rodríguez MV, Perelló VBI, Granero-Molina J, Fernández-Medina IM, Ventura-Miranda MI, Jiménez-Lasserrotte MDM. Insights from a qualitative exploration of adolescents' opinions on sex education. Children (Basel) 2024;11(1):110 [FREE Full text] [doi: 10.3390/children11010110] [Medline: 38255423]
9. Noorman MAJ, den Daas C, de Wit JBF. How parents' ideals are offset by uncertainty and fears: a systematic review of the experiences of European parents regarding the sexual education of their children. J Sex Res 2023;60(7):1034-1044 [FREE Full text] [doi: 10.1080/00224499.2022.2064414] [Medline: 35503865]
10. Ashcraft AM, Murray PJ. Talking to parents about adolescent sexuality. Pediatr Clin North Am 2017;64(2):305-320 [FREE Full text] [doi: 10.1016/j.pcl.2016.11.002] [Medline: 28292447]
11. van de Bongardt D, de Graaf H, Reitz E, Deković M. Parents as moderators of longitudinal associations between sexual peer norms and Dutch adolescents' sexual initiation and intention. J Adolesc Health 2014;55(3):388-393. [doi: 10.1016/j.jadohealth.2014.02.017] [Medline: 24755140]
12. Fletcher KD, Ward LM, Thomas K, Foust M, Levin D, Trinh S. Will it help? Identifying socialization discourses that promote sexual risk and sexual health among African American youth. J Sex Res 2015;52(2):199-212. [doi: 10.1080/00224499.2013.853724] [Medline: 24417331]
13. Matsuda Y, Thalasinos RD, Parra A, Roman Laporte R, Mejia-Botero MA, Adera AL, et al. Parent-child communication about substance use, puberty, sex, and social media use among Hispanic parents and pre-adolescent children. PLoS One 2023;18(11):e0295303 [FREE Full text] [doi: 10.1371/journal.pone.0295303] [Medline: 38033135]
14. Rogers AA, Ha T, Stormshak EA, Dishion TJ. Quality of parent-adolescent conversations about sex and adolescent sexual behavior: an observational study. J Adolesc Health 2015;57(2):174-178 [FREE Full text] [doi: 10.1016/j.jadohealth.2015.04.010] [Medline: 26206438]
15. Astle S, McAllister P, Emanuels S, Rogers J, Toews M, Yazedjian A. Just be open about it or turn up the radio: a qualitative analysis of parent-child sexual communication experiences in adolescence. Sex Res Soc Policy 2021;19(1):133-146. [doi: 10.1007/s13178-020-00530-1]
16. Dittus PJ, Michael S, Becasen J, Gloppen K, McCarthy K, Guilamo-Ramos V. Parental monitoring and its associations with adolescent sexual risk behavior: a meta-analysis. Pediatrics 2015;136(6):e1587-e1599 [FREE Full text] [doi: 10.1542/peds.2015-0305] [Medline: 26620067]
17. Sutton MY, Lasswell SM, Lanier Y, Miller KS. Impact of parent-child communication interventions on sex behaviors and cognitive outcomes for Black/African-American and Hispanic/Latino youth: a systematic review, 1988-2012. J Adolesc Health 2014;54(4):369-384 [FREE Full text] [doi: 10.1016/j.jadohealth.2013.11.004] [Medline: 24388108]
18. Coakley TM, Randolph S, Shears J, Beamon ER, Collins P, Sides T. Parent-youth communication to reduce at-risk sexual behavior: a systematic literature review. J Hum Behav Soc Environ 2017;27(6):609-624 [FREE Full text] [doi: 10.1080/10911359.2017.1313149] [Medline: 31485155]
19. Widman L, Choukas-Bradley S, Noar SM, Nesi J, Garrett K. Parent-adolescent sexual communication and adolescent safer sex behavior: a meta-analysis. JAMA Pediatr 2016;170(1):52-61 [FREE Full text] [doi: 10.1001/jamapediatrics.2015.2731] [Medline: 26524189]
20. Balaji AB, Oraka E, Fasula AM, Jayne PE, Carry MG, Raiford JL. Association between parent-adolescent communication about sex-related topics and HIV testing, United States. 2006-2013. AIDS Care 2017;29(3):344-349. [doi: 10.1080/09540121.2016.1238443] [Medline: 27696905]
21. Astle SM, Anders KM. The relationship between topic-specific quality of parent-child sexual communication and measures of sexual self-concept and sexual subjectivity. J Sex Res 2023;60(7):1055-1067. [doi: 10.1080/00224499.2022.2081312] [Medline: 35699390]
22. Beckett MK, Elliott MN, Martino S, Kanouse DE, Corona R, Klein DJ, et al. Timing of parent and child communication about sexuality relative to children's sexual behaviors. Pediatrics 2010;125(1):34-42 [FREE Full text] [doi: 10.1542/peds.2009-0806] [Medline: 19969618]
23. Pariera KL. Barriers and prompts to parent-child sexual communication. J Fam Commun 2016;16(3):277-283. [doi: 10.1080/15267431.2016.1181068]
24. Robinson KH, Smith E, Davies C. Responsibilities, tensions and ways forward: parents' perspectives on children's sexuality education. Sex Educ 2017;17(3):333-347. [doi: 10.1080/14681811.2017.1301904]
25. Astle SM, Jankovich MO, Vennum A, Rogers AA. Parent-child sexual communication frequency and adolescent disclosure to mothers about sexuality: the moderating role of open communication in a common fate structural equation model. J Sex Res 2023;60(7):1045-1054. [doi: 10.1080/00224499.2022.2045888] [Medline: 35302912]
26. Pariera KL, Brody E. "Talk more about it": emerging adults' attitudes about how and when parents should talk about sex. Sex Res Soc Policy 2018;15(2):219-229. [doi: 10.1007/s13178-017-0314-9]
27. Martino SC, Elliott M, Corona R, Kanouse D, Schuster M. Beyond the "big talk": the roles of breadth and repetition in parent-adolescent communication about sexual topics. Pediatrics 2008;121(3):e612-e618. [doi: 10.1542/peds.2007-2156] [Medline: 18310180]
28. Byers ES, Sears HA, Weaver AD. Parents' reports of sexual communication with children in kindergarten to grade 8. J Marriage Fam 2008;70(1):86-96. [doi: 10.1111/j.1741-3737.2007.00463.x]

XSL•FO
RenderX

29. Jerman P, Constantine NA. Demographic and psychological predictors of parent-adolescent communication about sex: a representative statewide analysis. J Youth Adolesc 2010;39(10):1164-1174 [FREE Full text] [doi: 10.1007/s10964-010-9546-1] [Medline: 20458614]
30. Holman A, Holloway M, Meinecke K, Deatherage S, Kort R, Erie E, et al. “Did I say too much? Did I say enough?”: balancing the competing struggles parents experience in talking to their children about sex-related topics. J Fam Commun 2023;23(3-4):335-346. [doi: 10.1080/15267431.2023.2239230]
31. Rudoe N, Ponsford R. Parental attitudes to school- and home-based relationships, sex and health education: evidence from a cross-sectional study in England and Wales. Sex Educ 2023;24(6):868-885. [doi: 10.1080/14681811.2023.2257602]
32. Nolin MJ, Petersen KK. Gender differences in parent-child communication about sexuality. J Adolesc Res 1992;7(1):59-79. [doi: 10.1177/074355489271005]
33. Paul Halpern H, Perry-Jenkins M. Parents' gender ideology and gendered behavior as predictors of children's gender-role attitudes: a longitudinal exploration. Sex Roles 2016;74(11):527-542 [FREE Full text] [doi: 10.1007/s11199-015-0539-0] [Medline: 27445431]
34. Abboud S, Flores DD. A developmental model of the sexual minority closet: implications for Arab immigrant sexual minorities and parent-LGBTQ child sex communication. Arch Sex Behav 2023;52(5):1897-1902. [doi: 10.1007/s10508-022-02522-1] [Medline: 36596907]
35. McKay EA, Fontenot HB. Parent-adolescent sex communication with sexual and gender minority youth: an integrated review. J Pediatr Health Care 2020;34(5):e37-e48. [doi: 10.1016/j.pedhc.2020.04.004] [Medline: 32861429]
36. Hadley W, Lansing A, Barker DH, Brown LK, Hunter H, Donenberg G, et al. The longitudinal impact of a family-based communication intervention on observational and self-reports of sexual communication. J Child Fam Stud 2018;27(4):1098-1109 [FREE Full text] [doi: 10.1007/s10826-017-0949-4] [Medline: 29910594]
37. Scull TM, Malik CV, Keefe EM, Schoemann A. Evaluating the short-term impact of Media Aware Parent, a web-based program for parents with the goal of adolescent sexual health promotion. J Youth Adolesc 2019;48(9):1686-1706 [FREE Full text] [doi: 10.1007/s10964-019-01077-0] [Medline: 31304562]
38. Bayley JE, Brown KE. Translating group programmes into online formats: establishing the acceptability of a parents' sex and relationships communication serious game. BMC Public Health 2015;15(1):1225 [FREE Full text] [doi: 10.1186/s12889-015-2545-0] [Medline: 26651616]
39. Toombs E, Unruh A, McGrath P. Evaluating the parent-adolescent communication toolkit: usability and preliminary content effectiveness of an online intervention. Nurs Open 2018;5(1):29-36 [FREE Full text] [doi: 10.1002/nop2.107] [Medline: 29344392]
40. De Meyer S, Al-Baghdadi S, Michielsen K. Parental involvement in school-based sexuality education in the WHO European Region: findings from a scoping review and expert consultations. Sex Education 2024 May 27;25(3):406-422. [doi: 10.1080/14681811.2024.2347939]
41. D'Cruz J, Santa Maria D, Dube S, Markham C, McLaughlin J, Wilkerson JM, et al. Promoting parent-child sexual health dialogue with an intergenerational game: parent and youth perspectives. Games Health J 2015;4(2):113-122 [FREE Full text] [doi: 10.1089/g4h.2014.0080] [Medline: 26181805]
42. Aventin A, Gough A, McShane T, Gillespie K, O'Hare L, Young H, et al. Engaging parents in digital sexual and reproductive health education: evidence from the JACK trial. Reprod Health 2020;17(1):132 [FREE Full text] [doi: 10.1186/s12978-020-00975-y] [Medline: 32854734]
43. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS Q 1989;13(3):319-340. [doi: 10.2307/249008]
44. Ajzen I, Fishbein M. Understanding Attitudes and Predicting Social Behaviour. Englewood Cliffs: NJ: Prentice Hall; 1980.
45. Osorio-Saez EM, Eryilmaz N, Sandoval-Hernandez A. Parents' acceptance of educational technology: lessons from around the world. Front Psychol 2021;12:719430 [FREE Full text] [doi: 10.3389/fpsyg.2021.719430] [Medline: 34526938]
46. Venkatesh V, Davis FD. A theoretical extension of the technology acceptance model: four longitudinal field studies. Manag Sci 2000;46(2):186-204. [doi: 10.1287/mnsc.46.2.186.11926]
47. Marikyan D, Papagiannidis S, Stewart G. Technology acceptance research: meta-analysis. J Inf Sci 2023:1-22. [doi: 10.1177/01655515231191177]
48. Vassilakopoulou P, Hustad E. Bridging digital divides: a literature review and research agenda for information systems research. Inf Syst Front 2023;25(3):955-969 [FREE Full text] [doi: 10.1007/s10796-020-10096-3] [Medline: 33424421]
49. Zhou Y, He T, Lin F. The digital divide is aging: an intergenerational investigation of social media engagement in China. Int J Environ Res Public Health 2022;19(19):12965 [FREE Full text] [doi: 10.3390/ijerph191912965] [Medline: 36232259]
50. Schaafsma D. A father’s role in the sexual health education of their children: a scoping review. Sex Educ 2022;23(5):524-539. [doi: 10.1080/14681811.2022.2084061]
51. Heise L, Manji K. Social norms. GSDRC Professional Development Reading Pack No. 31. Birmingham, UK: University of Birmingham; 2016 Jan. URL: https://assets.publishing.service.gov.uk/media/597f335640f0b61e48000023/Social-Norms_RP.pdf [accessed 2025-09-27]
52. Triandis HC. The psychological measurement of cultural syndromes. Am Psychol 1996;51(4):407-415. [doi: 10.1037//0003-066x.51.4.407]

XSL•FO
RenderX

53. Yuodeshko VI. School-based sexuality education curricula: are parents supportive? Popul Econ 2023;7(2):23-39. [doi: 10.3897/popecon.7.e102566]
54. Hubble TR, Carbone L, Vandenbosch L, Toelen J, De Coninck D. Exploring European parents' attitudes towards the age appropriateness of digital sexuality education for adolescents. Am J Sex Educ 2024:1-25. [doi: 10.1080/15546128.2024.2415304]
55. Rainbow Europe Map and Index 2022. ILGA-Europe. 2022 May. URL: https://www.ilga-europe.org/report/rainbow-europe-2022/ [accessed 2023-09-27]
56. iVOX. URL: https://www.ivox.be/ [accessed 2025-09-27]
57. Hufnagel EM, Conca C. User response data: the potential for errors and biases. Inf Syst Res 1994;5(1):48-73. [doi: 10.1287/isre.5.1.48]
58. Penke L, Asendorpf JB. Beyond global sociosexual orientations: a more differentiated look at sociosexuality and its effects on courtship and romantic relationships. J Pers Soc Psychol 2008;95(5):1113-1135. [doi: 10.1037/0022-3514.95.5.1113] [Medline: 18954197]
59. Churchill GA. A paradigm for developing better measures of marketing constructs. J Mark Res 1979;16(1):64-73. [doi: 10.2307/3150876]
60. Kalke KM, Ginossar T, Shah SFA, West AJ. Sex Ed to Go: a content analysis of comprehensive sexual education apps. Health Educ Behav 2018;45(4):581-590. [doi: 10.1177/1090198117749259] [Medline: 29284294]
61. Anderson TW, Darling DA. A test of goodness of fit. J Am Stat Assoc 1954;49(268):765-769. [doi: 10.1080/01621459.1954.10501232]
62. Fornell C, Larcker DF. Evaluating structural equation models with unobservable variables and measurement error. J Mark Res 1981;18(1):39-50. [doi: 10.2307/3151312]
63. Conway JM, Lance CE. What reviewers should expect from authors regarding common method bias in organizational research. J Bus Psychol 2010;25(3):325-334. [doi: 10.1007/s10869-010-9181-6]
64. Hooper D, Coughlan J, Mullen MR. Structural equation modelling: guidelines for determining model fit. Electron J Bus Res Methods 2008;6(1):53-60 [FREE Full text]
65. Koufteros X, Babbar S, Kaighobadi M. A paradigm for examining second-order factor models employing structural equation modeling. Int J Prod Econ 2009;120(2):633-652. [doi: 10.1016/j.ijpe.2009.04.010]
66. Eysenbach G. Improving the quality of web surveys: the Checklist for Reporting Results of Internet e-Surveys (CHERRIES). J Med Internet Res 2004;6(3):e34 [FREE Full text] [doi: 10.2196/jmir.6.3.e34] [Medline: 15471760]
67. Fertility statistics. Eurostat. URL: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Fertility_statistics [accessed 2025-09-27]
68. Stevens JP. Applied Multivariate Statistics for the Social Sciences, 5th ed. New York: Routledge; 2009.
69. Field A. Discovering Statistics Using IBM SPSS Statistics, 5th ed. New Delhi: SAGE; 2017.
70. Clark DA, Bowles RP. Model fit and item factor analysis: overfactoring, underfactoring, and a program to guide interpretation. Multivariate Behav Res 2018;53(4):544-558. [doi: 10.1080/00273171.2018.1461058] [Medline: 29683723]
71. Finch WH. Using fit statistic differences to determine the optimal number of factors to retain in an exploratory factor analysis. Educ Psychol Meas 2020;80(2):217-241 [FREE Full text] [doi: 10.1177/0013164419865769] [Medline: 32158020]
72. Saadé RG, Nebebe F, Tan W. Viability of the "Technology Acceptance Model" in multimedia learning environments: a comparative study. Interdiscip J e-Skills Life Long Learn 2007;3:175-184. [doi: 10.28945/392]
73. Wang X, Lu A, Lin T, Liu S, Song T, Huang X, et al. Perceived usefulness predicts second language learners' continuance intention toward language learning applications: a serial multiple mediation model of integrative motivation and flow. Educ Inf Technol 2022;27(4):5033-5049. [doi: 10.1007/s10639-021-10822-7]
74. Gkatzidou V, Hone K, Sutcliffe L, Gibbs J, Sadiq ST, Szczepura A, et al. User interface design for mobile-based sexual health interventions for young people: design recommendations from a qualitative study on an online Chlamydia clinical care pathway. BMC Med Inform Decis Mak 2015;15:72 [FREE Full text] [doi: 10.1186/s12911-015-0197-8] [Medline: 26307056]
75. Lythreatis S, Singh SK, El-Kassar A. The digital divide: a review and future research agenda. Technol Forecast Soc Change 2022;175:121359. [doi: 10.1016/j.techfore.2021.121359]
76. Ketting E, Brockschmidt L, Ivanova O. Investigating the 'C' in CSE: implementation and effectiveness of comprehensive sexuality education in the WHO European region. Sex Educ 2020;21(2):133-147. [doi: 10.1080/14681811.2020.1766435]
77. Italy: Digital Decade Country Report 2024. European Commission. 2024. URL: https://digital-skills-jobs.europa.eu/en/latest/briefs/italy-snapshot-digital-skills [accessed 2025-08-18]
78. Dake JA, Price JH, Baksovich CM, Wielinski M. Preferences regarding school sexuality education among elementary schoolchildren's parents. Am J Health Educ 2014;45(1):29-36. [doi: 10.1080/19325037.2013.852998]
79. Zhang W, Yuan Y. Knowledge, attitudes, and practices of parents toward sexuality education for primary school children in China. Front Psychol 2023;14:1096516 [FREE Full text] [doi: 10.3389/fpsyg.2023.1096516] [Medline: 36818131]
80. Vogelbacher M, Schneider T. Parental stress and working situation during the COVID-19 shutdown – effects on children's skill development. Adv Life Course Res 2024;60:100609. [doi: 10.1016/j.alcr.2024.100609] [Medline: 38554580]

XSL•FO
RenderX

81. Al-Adwan AS, Li N, Al-Adwan A, Abbasi GA, Albelbisi NA, Habibi A. Extending the technology acceptance model (TAM) to predict university students' intentions to use metaverse-based learning platforms. Educ Inf Technol 2023;28:15381-15413 [FREE Full text] [doi: 10.1007/s10639-023-11816-3] [Medline: 37361794]
82. Han JH, Sa HJ. Acceptance of and satisfaction with online educational classes through the technology acceptance model (TAM): the COVID-19 situation in Korea. Asia Pacific Educ Rev 2021;23(3):403-415. [doi: 10.1007/s12564-021-09716-7]
83. Meet RK, Kala D, Al-Adwan AS. Exploring factors affecting the adoption of MOOC in Generation Z using extended UTAUT2 model. Educ Inf Technol 2022;27(7):10261-10283 [FREE Full text] [doi: 10.1007/s10639-022-11052-1] [Medline: 35431598]
84. Chang CW, Chang SH. The impact of digital disruption: influences of digital media and social networks on forming digital natives' attitude. SAGE Open 2023;13(3):21582440231191741. [doi: 10.1177/21582440231191741]
85. Census 2021. Office for National Statistics. URL: https://www.ons.gov.uk/ [accessed 2025-09-17]
86. Grimmer M, Miles MP. With the best of intentions: a large sample test of the intention - behaviour gap in pro - environmental consumer behaviour. Int J Consumer Studies 2016;41(1):2-10. [doi: 10.1111/ijcs.12290]
87. Mertala P, López-Pernas S, Vartiainen H, Saqr M, Tedre M. Digital natives in the scientific literature: a topic modeling approach. Comput Hum Behav 2024;152:108076. [doi: 10.1016/j.chb.2023.108076]
88. Zhang M, Cheow E, Ho CS, Ng BY, Ho R, Cheok CCS. Application of low-cost methodologies for mobile phone app development. JMIR Mhealth Uhealth 2014;2(4):e55 [FREE Full text] [doi: 10.2196/mhealth.3549] [Medline: 25491323]
89. Jent JF, Golson M, Peskin A, Rothenberg WA, Salem H, Weinstein A, et al. Pocket parent-child interaction therapy (PCIT) online for young children with disruptive behaviors: open trial. J Med Internet Res 2025;27:e69887 [FREE Full text] [doi: 10.2196/69887] [Medline: 40779791]
90. Kasneci E, Sessler K, Küchemann S, Bannert M, Dementieva D, Fischer F, et al. ChatGPT for good? On opportunities and challenges of large language models for education. Learn Individ Differ 2023;103:102274. [doi: 10.1016/j.lindif.2023.102274]
91. Amagai S, Pila S, Kaat AJ, Nowinski CJ, Gershon RC. Challenges in participant engagement and retention using mobile health apps: literature review. J Med Internet Res 2022;24(4):e35120 [FREE Full text] [doi: 10.2196/35120] [Medline: 35471414]
92. Children and parents: media use and attitudes report 2023. Ofcom. 2023 Mar 29. URL: https://www.ofcom.org.uk/media-use-and-attitudes/media-habits-children/children-and-parents-media-use-and-attitudes-report-2023 [accessed 2025-09-27]

Abbreviations

AVE: average variance extracted
CFA: confirmatory factor analysis
CFI: comparative fit index
CHERRIES: Checklist for Reporting Results of Internet e-Surveys
EFA: exploratory factor analysis
RMSEA: root-mean-square error of approximation
RMSR: root-mean-square of residuals
SEM: structural equation modeling
TAM: technology acceptance model
TLI: Tucker-Lewis Index
TRA: theory of reasoned action

Edited by S Badawy; submitted 07.04.25; peer-reviewed by T Ricon, P Wadende; comments to author 18.07.25; revised version received 10.09.25; accepted 20.09.25; published 10.10.25.

Please cite as:
Hubble TR, Carbone L, Vandenbosch L, Toelen J, De Coninck D
Exploring Parental Intentions to Use Digital Tools to Enhance Parent-Child Sexual Communication in Europe: Cross-Sectional Questionnaire Study
JMIR Pediatr Parent 2025;8:e75489
URL: https://pediatrics.jmir.org/2025/1/e75489
doi:10.2196/75489
PMID:

©Talia Rose Hubble, Luca Carbone, Laura Vandenbosch, Jaan Toelen, David De Coninck. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 10.10.2025. This is an open-access article distributed under the terms of the Creative

XSL•FO
RenderX

Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Development of Chatbot-Based Oral Health Care for Young Children and Evaluation of its Effectiveness, Usability, and Acceptability: Mixed Methods Study

Kittiwara Pupong[1], DDS, MS; Jaranya Hunsrisakhun[2,3], DDS, PhD; Samerchit Pithpornchaiyakul[2,3], DDS, MSc; Supawadee Naorungroj[4], DDS, MS, PhD

[1]Dental Public Health Division, Maelan Hospital, Pattani, Thailand

[2]Department of Preventive Dentistry, Faculty of Dentistry, Prince of Songkla University, 15 Kanjanavanich Rd, Hatyai, Songkhla, Thailand

[3]Improvement of Oral Health Care Research Unit, Faculty of Dentistry, Prince of Songkla University, Hatyai, Songkhla, Thailand

[4]Department of Conservative Dentistry, Faculty of Dentistry, Prince of Songkla University, Hatyai, Songkhla, Thailand

Corresponding Author:
Jaranya Hunsrisakhun, DDS, PhD
Department of Preventive Dentistry, Faculty of Dentistry, Prince of Songkla University, 15 Kanjanavanich Rd, Hatyai, Songkhla, Thailand

Abstract

Background: Chatbots are increasingly accepted in public health for their ability to replicate human-like communication and provide scalable, 24/7 services. The high prevalence of dental caries in children underscores the need for early and effective intervention.

Objective: This study aimed to develop the 30-Day FunDee chatbot and evaluate its effectiveness, usability, and acceptability in delivering oral health education to caregivers of children aged 6 to 36 months.

Methods: The chatbot was created using the artificial intelligence (AI) chatbot behavior change model, integrating behavioral change theories into content designed for 3 - 5 minutes of daily use over 30 days. A pre-post experimental study was conducted from December 2021 to February 2022 in Hat Yai District, Songkhla Province, and Maelan District, Pattani Province, Thailand. Fifty-eight caregivers completed a web-based structured questionnaire at baseline and 2 months post baseline to evaluate knowledge, protection motivation theory-based perceptions, and tooth-brushing practices. Usability was assessed via chatbot logfiles and a web-based questionnaire at 2 months post baseline. Acceptability was evaluated through three methods: (1) open-ended chatbot interactions on day 30, (2) a web-based structured questionnaire at 2 months post baseline, and (3) semistructured telephone interviews with 15 participants 2 weeks post intervention. Participants for interviews were stratified by adherence levels and randomly selected from Hatyai and Maelan districts. All self-reported variables were measured on a 5-point Likert scale (1=lowest, 5=highest).

Results: The chatbot was successfully developed based on the 4 components of the AI chatbot behavior change model. Participants had a mean age of 34.5 (SD 8.6) years. The frequency of tooth brushing among caregivers significantly improved, increasing from 72.4% at baseline to 93.1% two months post baseline (P=.006). Protection motivation theory-based perceptions also showed significant improvement, with mean scores rising from 4.0 (SD 0.6) at baseline to 4.5 (SD 0.6) two months post baseline (P<.001). The chatbot received high ratings for satisfaction (4.7/5, SD 0.6) and usability (4.7/5, SD 0.5). Participants engaged with the chatbot for an average of 24.7 (SD 7.2) days out of 30. Caregivers praised the chatbot's content quality, empathetic communication, and multimedia design, but noted the intervention's lengthy duration and messaging system as limitations.

Conclusions: The 30-Day FunDee chatbot effectively enhanced caregivers' perceptions of oral health care and improved tooth-brushing practices for children aged 6 - 36 months. High user satisfaction and engagement demonstrate its potential as an innovative tool for oral health education. These findings warrant further validation through large-scale, randomized controlled trials.

Trial Registration: Thai Clinical Trials Registry Tctr20210927004; https://www.thaiclinicaltrials.org/show/Tctr20210927004

(JMIR Pediatr Parent 2025;8:e62738) doi:10.2196/62738

KEYWORDS

chatbot; conversational agents; tele-dentistry; oral health behavior; in-person toothbrushing; hands-on; children; covid-19; oral health education; development.

XSL•FO
RenderX

Introduction

Chatbots have emerged as a socially responsible technology to bridge socioeconomic disparities and promote equitable access to high-quality health care [1,2]. Chatbots are digital tools that emulate human conversation and have the potential to promote health education, support behavior changes, and deliver health care, especially for clinical or vulnerable populations. Their adaptability also makes them suitable for deployment in a variety of sizeable and diverse samples [3]. Chatbots provide flexible, on-demand support, offering personalized assistance and content with continuous availability, helping to mitigate the limitations of traditional telehealth services [4]. Overall, chatbots offer a humanized interaction that can support health care professionals in managing and preventing conditions on a societal scale [5].

Multiple studies attest to the effectiveness of incorporating chatbots in health care, illustrating their role in facilitating a modification of health-related behaviors [3,6-8]. However, the existing literature on the use of chatbots for dental health purposes is limited [9,10], and few studies have explored the complicated process of constructing chatbots with oral health goals in detail.

Zhang et al [11] suggested some guidelines for the development of an artificial intelligence (AI) chatbot for behavior modification with the formulation of a theoretical framework that consists of four essential components: (1) specifying chatbot characteristics and understanding user backgrounds, (2) establishing relational capacity, (3) establishing persuasive capacity using behavioral-based theory, and (4) implementing an evaluation mechanism to assess outcomes.

Early childhood caries (ECC), identified as a significant chronic disease, emerges from the dynamic interplay of various risk and protective factors over time [12]. In Thailand, the earliest detection of noncavitated caries occurred at 9 months of age, while cavitation was first identified at 10 months of age [13]. In this context, parental tooth brushing, conducted twice daily with a rice-sized amount of fluoridated toothpaste, has been proven to be a pivotal strategy for reducing dental caries in children [12], whereas systematic reviews revealed that the effectiveness of simple health education in preventing ECC is restricted [14]. In line with a review regarding oral health promotion for ECC, home visits, and hands-on techniques for dental health education substantially enhance habit formation and effectiveness [15]. In addition, caregivers should receive practical training and empowerment from oral health professionals [16]. However, these interventions must be tailored to each individual, requiring not only highly skilled dental personnel but also considerable time and financial resources [17]. Chatbots have the potential to serve as a scalable model for skill development, motivation, problem-solving, and continuous follow-up, replicating the advantages of home visits.

Habits emerge as a consequence of acquiring repeated patterns of behavior, originating from consistent contextual stimuli, and they are formed through automated responses to the conditions in which they happen [18]. The research findings revealed that the time required to form habits varied, with values ranging from 18 to 254 days, depending on the level of complexity or challenge associated with a particular behavior [19]. Monitoring and reinforcement are effective ways to develop healthy habits [19,20] toward caries prevention in children [15], however, interaction with health professionals often requires traditional onsite visits, substantial time, and financial cost [21,22].

The protection motivation theory (PMT), a key theory in health psychology, explains how people change their behavior based on their evaluation of threats and their ability to cope with them [23,24]. The threat appraisal component of the PMT comprises 2 key elements: the individual's assessment of the disease's severity (perceived severity) and the probability of developing the disease (perceived vulnerability). The PMT additionally specifies that attitudes and behavior modification are indirectly influenced by the emotional state of fear arousal, which occurs through the evaluation of the danger's severity. The coping appraisal of the model comprises the individual's response efficacy, which is the expectation that implementing the recommendations will eliminate the threat, and self-efficacy, which is the belief in one's own ability to effectively execute the recommended course of action. Behavior performance should be significantly influenced by the intentions that are mediated by the cognitive predictors of threat and coping appraisals [25,26]. Kimhasawad et al [27] used a PMT-based education program to guide caregivers of 9 - to 12-month-old infants in adopting proper tooth brushing techniques, revealing that this approach effectively motivated and increased awareness, leading to a positive change in the oral health behavior of caregivers.

Currently, there is no standard evaluation method for a health care chatbot [28,29]. The concepts of usability and acceptability were identified as important factors for evaluating the use of chatbots [17]. However, there are differing definitions and some overlap between these terms [29,30]. Our study adopted broad interpretations of these concepts: usability as use, engagement, and ease of use; acceptability as satisfaction; continued use intention; and appropriateness. In addition, the frameworks of Zhang et al [11] and Denecke et al [31] were applied for content evaluation integrating usability and acceptability. This comprehensive evaluation provides a holistic assessment of the factors influencing chatbot adoption [32].

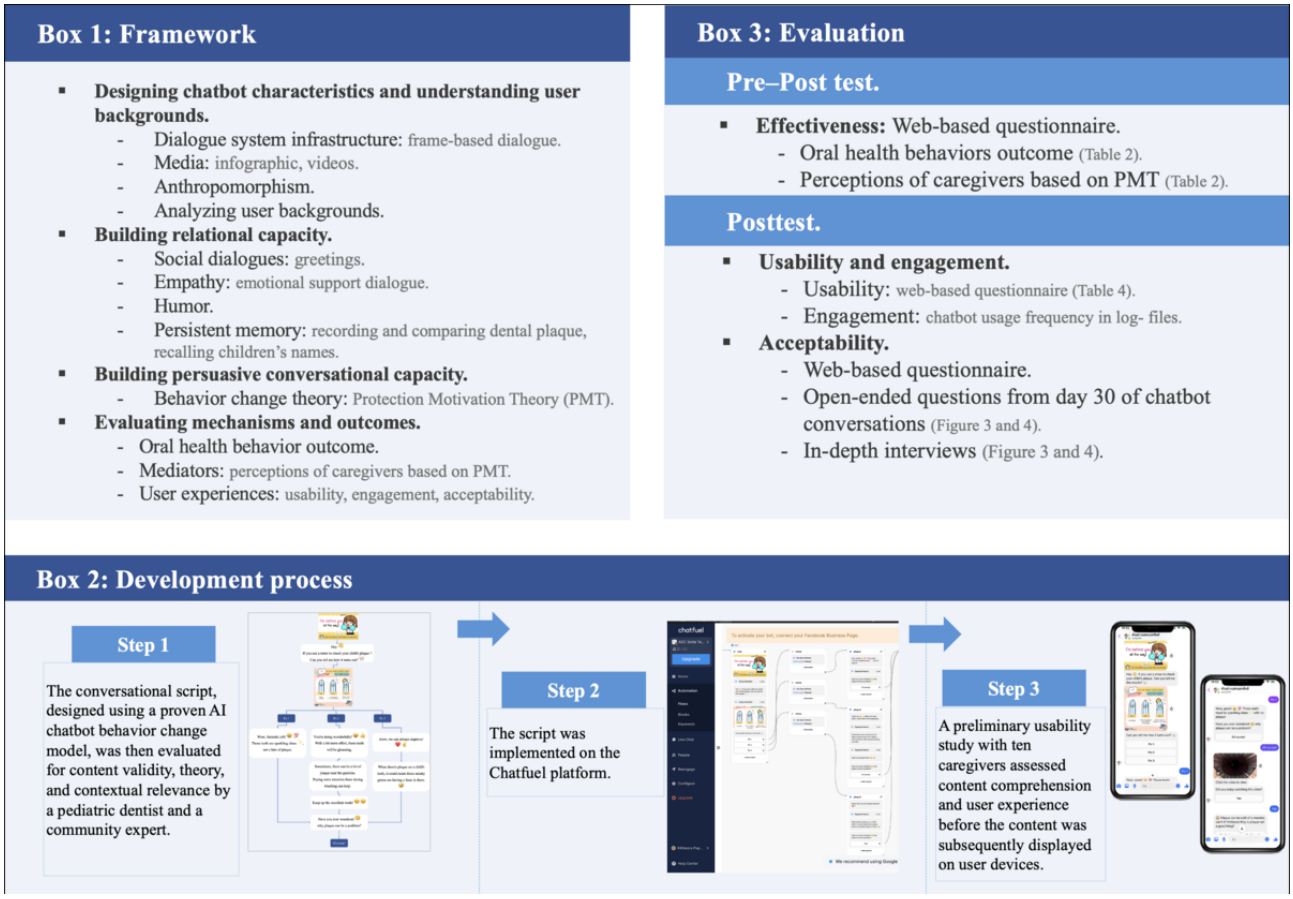
Therefore, the study aimed to elucidate the chatbot development process using PMT and Zhang's model. In addition, the pre-post study sought to assess the effectiveness, usability, and acceptability of a developed chatbot, the "30-Day FunDee," which was intended to educate caregivers of children between 6 and 36 months regarding oral health.

Methods

Figure 1 illustrates the comprehensive process involved in the defining framework, development, and evaluation of the 30-Day FunDee oral health promotion chatbot.

XSL•FO
RenderX

Figure 1. Framework, development, and evaluation of the 30-day FunDee chatbot. AI: artificial intelligence.



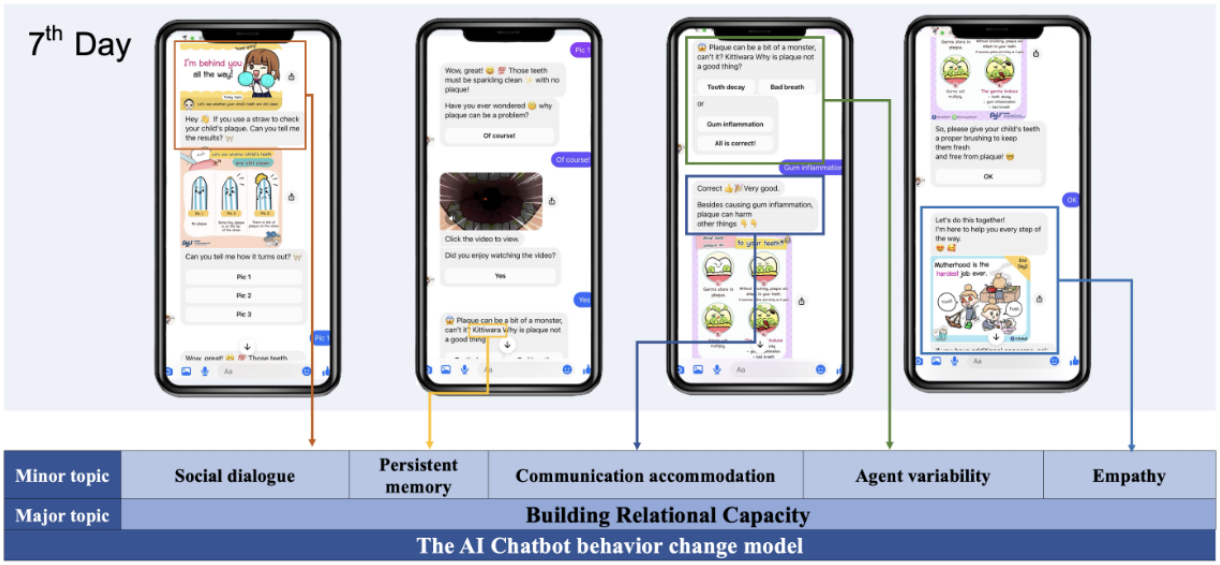
Defining a Framework for the 30-Day FunDee Chatbot

Designing Chatbot Characteristics and Understanding User Background

The objectives and target audience were specified for educating and assisting Thai caregivers with oral hygiene care for children aged 0 to 3 years. Designing chatbot characteristics encompassed dialogue system infrastructure, media, and anthropomorphism [11] as shown in Figure 2. The chatbot's dialogue system infrastructure is frame-based, enabling users to select their responses. The chatbot created a variety of media, including simple and clear language, illustrations, written text, audio components, conversational dialogue, infographics, animations, animated songs, and videos with authentic and animated content. Moreover, within the anthropomorphic realm, "Dr. Pin" the chatbot's dentist avatar, was depicted as a kind, charming, empathetic, and attentive caregiver for children's oral health.

XSL•FO
RenderX

Figure 2. Screen example of the chatbot translated from Thai to English, showing dialogues that incorporate the design characteristics of the AI behavior change model on the seventh day. AI: artificial intelligence.





Understanding the user's background is critical in designing chatbots for behavior change [11,33]. Based on previous studies [34-36], the majority of caregivers were 20- to 40-year-old mothers with low to middle socioeconomic status who were responsible for nurturing their children, especially in relation to their children's tooth brushing. The chatbot's role was to assist users in overcoming obstacles and offering emotional support in childcare. Due to internet availability, both urban and rural caregivers could access the chatbot.

The content of the 30-Day FunDee chatbot was influenced by pediatric and community dentistry experts' recommendations and qualitative research insights on Thai caregivers' experiences with children's tooth-brushing behaviors [35,36], insights from community caregivers, inquiries from dental clinics, and knowledge gained from the earlier 21-Day FunDee chatbot, which is mentioned elsewhere [9]. Therefore, the updated chatbot was extended from 21 to 30 days, including more various media and dialogues, especially focusing on tooth-brushing practices.

Building Relational Capacity

Building relational capacity involves using elements such as social dialogues, empathy, relationship discussion, humor, self-disclosure, persistent memory, and agent variability [11,29]. Daily, the chatbot initiated conversations with charming greetings and concluded with farewell messages (Figure 2) that conveyed understanding and encouraged parents or caregivers in childcare [11]. For goal setting [37], daily welcome cards were designed with topics to be discussed.

The chatbot was designed to consistently display comprehension, empathy, and emotional support during interactions, especially when users encountered obstacles.

XSL•FO
RenderX

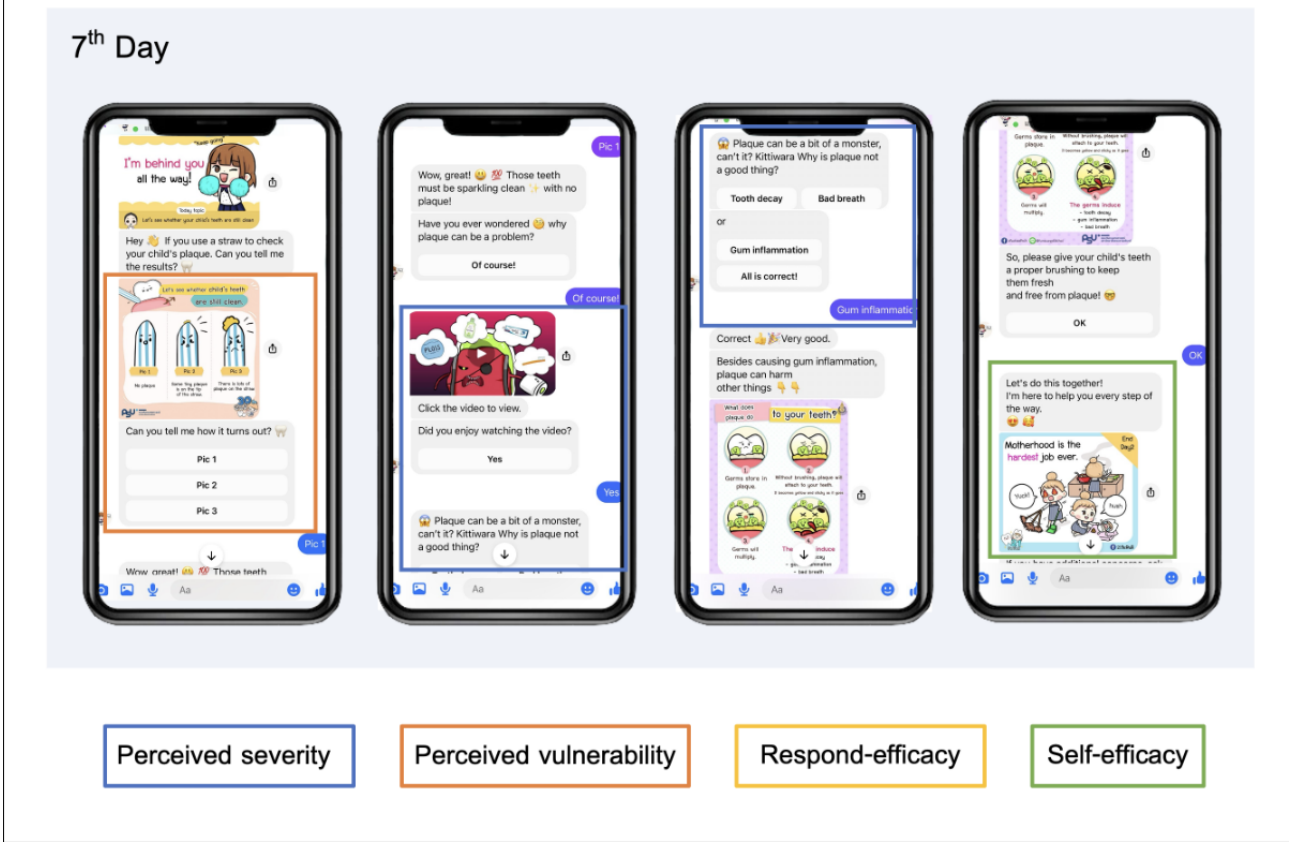
Emojis and animated GIFs conveying positive feedback and emotions were incorporated to increase engagement. Progress tracking enabled self-comparison and confidence-building over time. Periodic child dental plaque assessments prompted reflection on tooth-brushing techniques. Positive reinforcement was provided when plaque decreased, while setbacks received encouragement without punishment. Conversation features like remembering children's names, revisiting prior discussions, and using age-appropriate informal language aimed to simulate natural human-to-human dialogues. These elements enhanced the user experience and facilitated task completion [37,38] (Figure 2).

Building Persuasive Conversational Capacity

Overview

The 30-Day FunDee chatbot, meticulously designed, provided oral health education to caregivers based on PMT (Figure 3) for behavior modification by systematically sequencing threats and coping topics. Examples of chatbot topics are shown in the following sections.

Figure 3. Screen examples of chatbot dialogues translated from Thai to English, incorporating protection motivation theory (PMT) on the seventh day.



Perceived Severity

The importance of primary teeth, the consequences of dental infections, and anticipating problems from poor oral health care were discussed.

Perceived Vulnerability

The chatbot instructed caregivers on the child's dental plaque assessment and provided animation and infographics explaining plaque. Periodic plaque checks were encouraged, and an API enabled tracking of plaque levels over time.

Belief in Response Efficacy

Benefits and instructions, especially for tooth brushing, were incorporated into a variety of videos, infographics, and games. The chatbot also asked caregivers about children's sugar intake and diet to discuss potential health impacts.

Belief in Self-Efficacy

The chatbot was designed to increase caregiver self-efficacy for children's oral health management through motivational techniques and daily emotional support. At the end of each conversation, it expressed empathy for mothers' exhaustion and encouraged overcoming obstacles.

Chatbot Development Process

The development of chatbots followed a systematic, 3-phase process, as illustrated in Figure 1. The first step involved designing the conversational flow, which included scripts, infographics, videos, and other content. This step was crucial to ensure that the chatbot can engage effectively with users. This phase followed an established AI chatbot behavior change model and PMT, which guided the creation of responsive conversations tailored to encourage specific behavioral outcomes. The next step involved implementing the conversational flow using the Chatfuel platform, which enabled the transformation of the predesigned scripts into interactive

XSL•FO
RenderX

conversations accessible on users' devices. The Chatfuel platform facilitated the efficient deployment of the chatbot design, ensuring seamless operation and scalability to accommodate the intended target audience, without advanced programming skills and includes push message functionality [39]. Given that over 80% of Thailand's population uses Facebook [40], Facebook Messenger was chosen as the delivery platform using Chatfuel.

The final step involved presenting the chatbot's content on user devices. After implementation, the chatbot became accessible, with its content displayed across various devices. This stage completed the chatbot's development, enabling it to interact with users as intended and deliver the conversations crafted during the initial phase. The chatbot used persuasive communication, including comprehension, empathy, and suggestions, to address the child's oral health challenges. It used a decision tree with recommended responses along with natural language understanding [37]. A pediatric dentist and a community expert evaluated the content validity, theoretical basis, and contextual appropriateness. A preliminary usability study with 10 caregivers evaluated content understanding and user experience.

Chatbot Evaluation

Chatbot evaluation should assess user patterns, user experience, conversation quality, perceived relational ability, and behavior outcomes [11,31]. This chatbot was evaluated on all aspects with the exception of oral health examinations due to COVID-19 pandemic operation limitations.

Participants and Recruitment

From December 2021 to February 2022, a total of 66 caregivers were recruited using convenience sampling including 29 caregivers from the Early Childhood Development Center at the Faculty of Medicine, Prince of Songkla University, Hat Yai District, Songkhla Province, and 37 caregivers from the Early Childhood Development Center in Maelan District, Pattani Province, Thailand. The inclusion criteria for caregivers were as follows: (1) currently caring for children aged 6 to 36 months with at least 1 tooth; (2) their children had no disabilities or significant underlying medical conditions that could have affected their oral health; and (3) equipped with electronic devices such as computers, tablets, or mobile phones, allowing for daily internet access and a propensity to interact via Facebook Messenger. The exclusion criteria were (1) caregivers who could not speak, read, or write Thai and (2) caregivers who were opposed to the data collection.

The sample size was calculated using G*Power software (version 3.1; Heinrich Heine University Dusseldorf) to determine the mean difference in the frequency of tooth brushing per day between pre- and postintervention time points. An effect size of 0.4283, derived from unpublished data of a previous multicenter study conducted across 6 provinces in southern Thailand that evaluated the effectiveness of a chatbot in promoting tooth-brushing behaviors among 398 children aged 6 months to 2 years [41], was used. Additional parameters included a correlation coefficient of 0.5, an α level of .05, and a power of 0.8. The calculation indicated a minimum of 60 participants was required. To account for a 10% dropout rate, the target sample size was increased to 66 participants to ensure sufficient data for analysis.

Initial contact involved outreach at childcare centers and communication with caregivers via Line or phone calls to assess eligibility and interest in participation. After identifying eligible caregivers, researchers scheduled appointments to provide detailed study information. Invitation letters were distributed by the research team (Multimedia Appendices 1 and 2).

Data Collection

Self-Reported Oral Health Behavior, Usability, and Acceptability

At baseline and 2 months later, a structured self-administered questionnaire (Multimedia Appendices 3 and 4) via Google Forms gathered information regarding participant characteristics and the effectiveness of chatbot use in terms of tooth-brushing behaviors and PMT-based oral health perceptions. At 2 months, usability and overall user satisfaction measures were added.

Oral hygiene behaviors were assessed using categorical questions on tooth cleaning methods, fluoride toothpaste use, and toothpaste amount.

Oral health perceptions were assessed using 14 items based on PMT including perceived severity (5 items), vulnerability (1 item), response efficacy (4 items), and self-efficacy (4 items), measured on a 5-point Likert scale.

A 5-point Likert scale, ranging from 1 (lowest) to 5 (highest), was used for all variables. The mean (SD) for each group was calculated by averaging the total items in each category. Negative items were reverse-scored before calculating the mean. The mean scores were interpreted as follows: 1.0 - 1.79 were the lowest perceptions, 1.8 - 2.59 were low, 2.6 - 3.39 were moderate, 3.4 - 4.19 were high, and 4.2 - 5.0 were highest.

The usability test was designed in relation to models of Denecke et al [31] and Zhang et al [11], consisting of 15 items. This measured user experience (3 items), conversation quality (4 items), perception of relation and capacity (2 items), self-esteem (4 items), and usefulness (2 items) on a 5-point Likert scale with the same calculation and interpretation methods as shown above. In addition, the engagement was quantified by analyzing use days from chatbot logfiles.

The assessment of acceptability was conducted using 3 different methodologies. First, on day 30, participants interacted with the chatbot, responding to open-ended prompts designed to elicit both positive and negative use experiences. Second, a structured questionnaire was administered 2 months post baseline. It consisted of 1 item evaluating overall user satisfaction using a 5-point Likert scale, ranging from 1 (lowest) to 5 (highest).

Two weeks post intervention, semistructured in-depth telephone interviews were conducted. Participants (n=15) were stratified into 4 groups based on adherence levels and were randomly selected from the Hatyai and Maelan districts with equal distribution: 100% adherence (30 d, n=4), 80% - 99% adherence

XSL•FO
RenderX

(24 - 29 d, n=4), 50% - 79% adherence (15 - 23 d, n=4), and <50% adherence (<15 d, n=3).

Participants were contacted to schedule interviews. Nonresponders were replaced through random selection until quotas were met, except in group 4, where participants were unreachable. Interviews, lasting 10 - 15 minutes, covered the study's objectives; interview methods; and explored satisfaction, dissatisfaction, feedback, and suggestions. Field notes were recorded during each interview.

Quality Control of Questionnaire and In-Depth Interview

The content and construct validity of the questionnaires and guiding questions for in-depth interviews were evaluated by 3 experts: a community dentist, a pediatric dentist, and a dentist from a public hospital. The usability test, adapted from Denecke et al [31] and Zhang model frameworks [11], was validated by the same 3 experts. Reliability for PMT-based perceptions was determined using Cronbach α (α=0.85). Face validity of the overall questionnaire was established through pilot telephone interviews with 10 caregivers. The in-depth interview guidelines were validated by 3 experts. To ensure triangulation, 2 additional independent researchers conducted content analysis. Multiple data collection methods were used to assess acceptability.

Statistical Analysis

Descriptive statistics were presented as means (SD) for continuous variables, and frequency (percentage) for categorical variables. Within-group comparisons were used for the nominal/categorical data, and chi-square or Fisher exact tests were used. For continuous data, paired *t* tests were used. Satisfaction scores were reported as the mean (SD) on a 5-point scale. IBM SPSS Statistics for Windows (version 29.0.0.0 (241); IBM Corp) was used.

Analysis of Qualitative Data

The responses of the participants from in-depth interviews were analyzed thematically using an inductive method guided by the procedure outlined by Jang et al [42] and Fitzpatrick et al [37]. Data from in-depth interviews and open-ended queries were analyzed using thematic analysis [43,44] and reported in terms of frequency.

Ethical Considerations

Adhering to social distancing measures recommended during the COVID-19 pandemic, participants attended group Zoom information sessions where researchers explained the study comprehensively. To ensure privacy, attendees could use pseudonyms and disable cameras. The researcher outlined the following: (1) study purpose; (2) data handling procedures; (3) privacy measures; and (4) participant rights, including voluntary participation, and withdrawal options. Questions could be asked during the session or privately via Zoom chat. Verbal consent was obtained during the session, with the completion of the web-based questionnaire (Google Forms) serving as additional confirmation. Participants could withdraw by not completing the questionnaire. Privacy measures included guidelines against sharing others' identities or comments outside the session, and secure data storage with restricted access to research team members only. The protocol was registered to the Thai Clinical Trials Registry (TCTR20210927004) and approved by the Institutional Review Board of the Faculty of Dentistry at Prince of Songkla University (EC6407-053).

Results

Characteristics of Participants at the Baseline

Initially, 66 individuals were enrolled in the study, but following the 30-day postintervention period, 8 enrollees were excluded due to loss of follow-up.

The demographic and socioeconomic status of participants (n=58) were presented below (Table 1). The mean participant age was 34.5 (SD 8.6) years, and 87.9% (n=51) were mothers. The mean child age was 20.9 (SD 7.9) months. Of the participants, 55.2% (n=32) participants obtained oral hygiene advice via the web. Most web-based use was 51.7% (n=30) of the participants for between 3 and 5 hours per day, then >6 hours per day (15/58, 25.9%) and followed by 1 - 2 hours per day (13/58, 22.4%). Daily internet use was 72.4% (n=42) during the week.

XSL•FO
RenderX

Table . Demographic and socioeconomic characteristics of study participants (N=58).

Demographic characteristics	Values, n (%)
Caregiver's education level	
Lower than Bachelor degree	26 (44.8)
Bachelor degree or higher	32 (55.2)
Religion	
Buddhism	26 (44.8)
Islam	32 (55.2)
Caregiver's occupation	
Stay-at-home parent	18 (31)
Civil servant	23 (39.7)
Employee	8 (13.8)
Private sector employee	4 (6.9)
Farmer	2 (3.4)
Business owner	3 (5.2)
Family income	
Not enough	5 (8.6)
Enough	53 (91.4)

Oral Health Behaviors

Results from the posttest showed that tooth brushing by caregivers and the use of fluoride toothpaste and smear-sized toothpaste improved significantly (Table 2).

Table . Oral health behaviors among study participants at baseline and after 2 months from the first day of intervention (N=58). Fisher exact test significance level: $P<.05$.

Behaviors	Preintervention, n (%)	Postintervention, n (%)	*P* value
Teeth cleaning method			.006
Improper or no tooth brushing[a]	16 (27.6)	4 (6.9)	
Tooth brushing by caregiver	42 (72.4)	54 (93.1)	
Frequency of tooth brushing			<.001
<1 time/day	21 (36.2)	8 (13.8)	
≥2 times/day	37 (63.8)	50 (86.2)	
Use of Fluoride toothpaste (Yes)	31 (53.4)	49 (84.5)	.001
Smear-sized toothpaste used	34 (58.6)	48 (82.8)	.008

[a]Improper tooth brushing is defined as insufficient cleaning, rinsing with water only, using a cloth for cleaning, or allowing the child to brush independently.

Perceptions of Caregivers Based on PMT

All perceptions of caregivers based on PMT showed significant improvement from high to highest perceptions, except for perceived vulnerability, which improved but without a statistically significant difference (Table 3).

XSL•FO
RenderX

Table . Perceptions of caregivers based on protection motivation theory (PMT) toward oral health behavior (total score=5). Paired *t* test significance level: *P*<.05.

	Preintervention, mean (SD)	Postintervention, mean (SD)	*P* value
PMT parameters			
Perceived severity	4.0 (0.9)	4.5 (0.7)	<.001
Perceived vulnerability	4.3 (1.1)	4.6 (0.9)	.56
Response-efficacy	3.9 (0.8)	4.4 (0.8)	.04
Self-efficacy	3.9 (0.9)	4.3 (0.7)	.001
Overall	4.0 (0.6)	4.5 (0.6)	<.001

Usability and Engagement

The usability levels were highest in every category (Table 4). Of those who completed the program, 32.8% of the study participants were fully engaged in using the chatbot. The average chatbot user engagement was 24.7 days (SD 7.2), with an additional insight into weekly engagement of 5.8 days (SD 1.7).

Table . Usability on the chatbot (N=58).

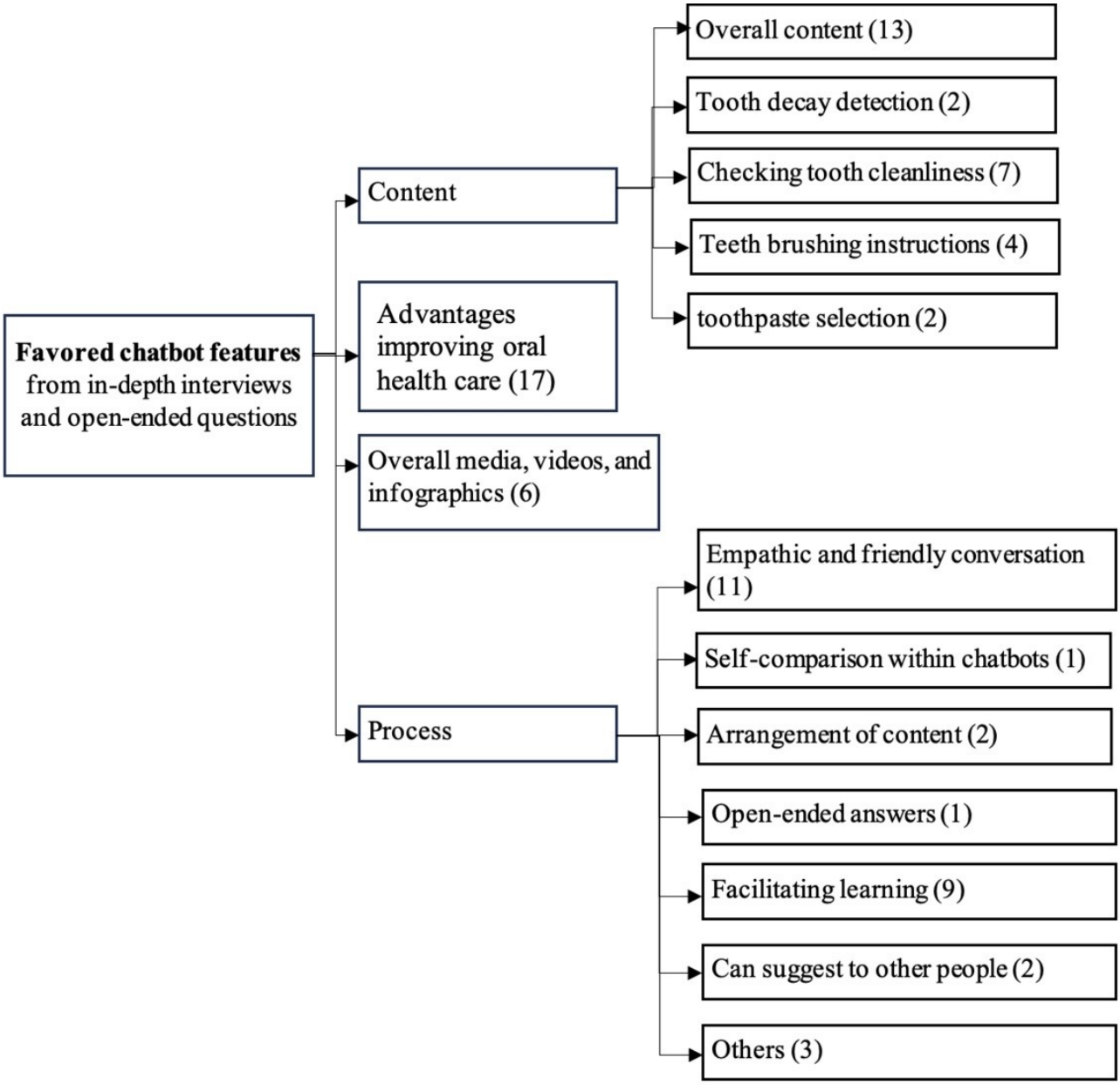
Usability items (total score=5)	Values, mean (SD)
User experiences	4.6 (0.6)
Convenience	4.6 (0.7)
Acceptable performance and acceptance	4.6 (0.7)
Conversational quality	4.7 (0.6)
Understandable media	4.7 (0.6)
Reliable content	4.8 (0.7)
Appropriate content order	4.6 (0.8)
Linguistic features, naturalness, and fluency conversational quality	4.8 (0.6)
Perception of relational and capacity	4.7 (0.6)
Rapport perception of relation and capacity	4.6 (0.8)
Self-efficacy and perceived social support	4.8 (0.6)
Increased self-esteem	4.6 (0.6)
Usefulness of chatbot	4.8 (0.5)
Overall average score	4.7 (0.5)

Acceptability

In the structured questionnaire, overall satisfaction was rated 4.7 out of 5 (SD 0.6). Open-ended questions from day 30 of chatbot conversations (42 users) and in-depth interviews (15 users) revealed 4 major themes through thematic analysis: content, user learning, media, and process (Figure 4). Most users expressed positive feedback on the value of the content and the engagement methods, particularly empathetic communication and media. However, the duration of chatbot interactions and issues with the messaging system were identified as key barriers to sustained engagement (Figure 5).

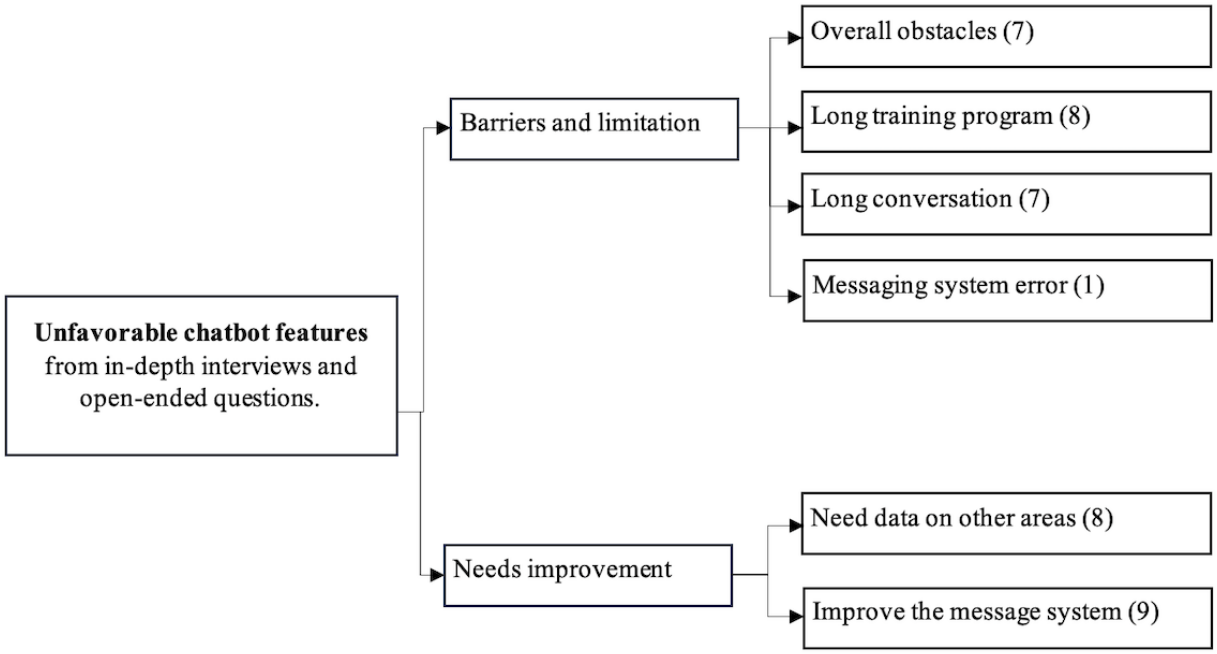
XSL•FO
RenderX

Figure 4. Thematic map of favored chatbot features of chatbot users' experience, drawn from in-depth interviews and open-ended questions. (Number in bracket: number of users).



XSL•FO
RenderX

Figure 5. Thematic map of unfavorable chatbot features of chatbot users' experience, drawn from in-depth interviews and open-ended questions. (Number in bracket: number of users).



Discussion

Principal Findings

The study indicates that using the "30-Day FunDee" chatbot significantly improved PMT-related perceptions and tooth-brushing behavior for young children. High levels of acceptability and usability were reported for the chatbot acceptability and usability were reported.

Several studies supported that knowledge and attitudes regarding tooth brushing can evolve and that alterations in tooth-brushing practices are influenced by or linked to this factor [45,46]. Caregiver-led tooth brushing for children twice daily with a rice-sized amount of fluoridated toothpaste has been proven to be a key strategy for preventing dental caries in children younger than 3 years [12]. In the study, tooth brushing by caregivers increased significantly from 72.4% to 93.1% (a significant increase of approximately 22%). The dedication of caregivers to twice-daily brushing and the use of fluoride toothpaste for children significantly grew, with an increase of approximately 22.4% (from 63.8% to 86.2%) and 31.1% (from 53.4% to 84.5%), respectively. These results go beyond those of other studies involving similar age groups, whether they used traditional oral health education with or without in-person tooth-brushing training [22,47].

Oral health professionals should provide caregivers with practical training and empowerment regarding the prevention of tooth decay in young children [15,16,48]. Within the framework of this chatbot interface, caregivers are expected to autonomously acquire the skill of proper tooth brushing through the use of educational content, encompassing videos, images, and textual information. The resultant feedback on this intervention demonstrated noteworthy effectiveness, reflecting an elevated tooth-brushing behavior and satisfaction level, quantified with a score of 4.7 out of 5. Additionally, media preferences were thoroughly explored through in-depth interviews and open-ended questions within the chatbot interface.

Meta-analyses indicate that 4 key factors within the PMT including perceived severity, perceived vulnerability, response efficacy, and self-efficacy contribute significantly to changes in health behaviors [49]. Perceived severity significantly increased, likely due to integrating PMT principles into the chatbot design and content structure. As in prior research, the perceived severity of the condition (cancer) impacted intentions to prevent disease, suggesting fear appeals influenced the perceived threat of disease [50]. In addition, the systematic review identified self-efficacy within the PMT's coping appraisal construct as the most effective predictor and promoter of physical activity participation [51]. Our findings align with these studies, demonstrating improvements in perceived severity, response efficacy, and self-efficacy.

In this chatbot on perceived vulnerability, we requested caregivers evaluate their children's dental plaque to determine their abilities in tooth brushing. We hypothesized that there would be a significant difference in perceived vulnerability, however this was not supported. Nevertheless, such interactions still improve oral health behaviors in children [27]. Caregivers, with a strong belief in response efficacy, are more likely to change their behavior to take care of their children [27,52]. In this study, we aimed to share tooth-brushing techniques using various media such as conversational text, infographics, both real-life and animated images, and videos. This finding is consistent with the excellent level of user satisfaction observed regarding the understandable media and reliable content

XSL•FO
RenderX

displayed. Self-efficacy is a significant component that plays a critical role in influencing the improvement of health behavior [27,45,46,53].

Consistently maintaining oral health behaviors, crucial for the success of preventing caries, should be upheld over an extended period [54]. As habit formation typically takes place within a range of 18 to 254 days [19], we anticipate that the 30-day exposure to the intervention and the subsequent 60 days from the first day of intervention to the evaluation day will sufficiently ensure a lasting behavioral change.

Behavior change theories were recommended in interventions promoting change, including in-person and digital formats. These approaches emphasized goal-setting, self-monitoring, reviewing goals, addressing obstacles, providing motivation, feedback, social support, and individualized guidance and education [21,55,56]. The 30-Day FunDee chatbot study incorporated these techniques.

Integrating behavior change methods into chatbot interventions likely improved targeted behaviors and overcame limitations of conventional in-person interventions, including restricted health care professional interaction, declining motivation over time, and insufficient access to education. Thus, chatbots may elicit positive behavior changes by addressing the restrictions of traditional approaches [3].

The research involves designing a satisfaction assessment using a web-based questionnaire that was applied to evaluate the design of the AI behavior change model [11]. The evaluation focused on user experiences, conversational quality, perception of relational capacity, self-esteem enhancement, and chatbot usefulness. The results indicate the highest satisfaction across all evaluated criteria and that it was effective enough to increase tooth brushing behavior. Powerful chatbots, such as the 30-Day FunDee chatbot, are not only capable of simple conversation, but also of oral health education and self-training.

The average duration of chatbot engagement, which was 5.8 days per week in this study, is a salient feature. Due to the increased level of satisfaction, this duration is especially noteworthy; it exceeds Todaki's 5.1 days-per-week engagement during a similar 4-week study period [42], but is inferior to Woebot's 6.1 days-per-week engagement in a shorter 2-week study period [37]. Observations from both our own investigations and other research [42] indicate that the chatbot exhibited notable use during the initial week, followed by a decline in use from the second to the fourth week. User feedback revealed 3 key reasons: excessive workload strain, preference for shorter programs, and reliance on chatbot notifications. These findings indicate a misalignment between chatbot functionality and user needs, consistent with previous research highlighting drawbacks such as extended training programs and technical errors [37,42]. Future iterations will prioritize content condensation, enhanced user engagement, and potential platform optimization or replacement to address these challenges and improve overall chatbot efficacy.

According to the challenges of chatbot development in public health, establishing rapport and cultivating relationships with users through compassionate and personalized interactions is critical for a sustained and engaging intervention [3,4,57]. This study aligns with previous research findings, where the term "empathic and friendly conversation" emerged during in-depth interviews and open-ended questions. Similarly, studies on other chatbots corroborated these benefits [37,42,58].

The strengths of this study focus on systematically planning, developing, analyzing, and assessing the chatbot. It was meticulously designed based on behavior modification theory and principles of AI chatbot behavior change. This resulted in profound understanding, facilitating improvement, development, testing, and evaluation of interactive programs to align with the goals. This included the capacity to discuss, summarize outcomes, and conduct extensive comparative analyses with other study findings. The ultimate goal is to formulate guidelines for the next phase of chatbot development.

Our research possesses limitations due to a pre-post design, potentially introducing a maturity bias and consequently, possibly overestimating the chatbot's effectiveness in enhancing oral health behavior. In the research methodology, a self-administered web-based questionnaire was used, raising concerns about compromised validity.

In order to improve the applicability of our results, we recommend that future research use randomized trials involving a wide range of demographic groups and conduct a more extensive evaluation of caries prevention. Furthermore, to enhance the effectiveness, user-friendliness, and acceptance of chatbots, efforts should be made to incorporate adaptive learning and AI-driven conversational methods.

Conclusion

In summary, this research suggests that the 30-Day FunDee chatbot can be an effective, highly usable, and acceptable resource for individuals seeking oral health information and children's caries prevention. Such a tool could be developed in the next phase of chatbots to serve as a scalable complement to conventional treatment approaches.

Acknowledgments

The study was funded by the Faculty of Dentistry, Prince of Songkla University. The researchers express their sincere gratitude to Mrs Thiraporn Auechuchit, Dr Rohannee Yalaeka, and the dedicated staff from the Early Childhood Development Center at the Faculty of Medicine, Prince of Songkla University, Hat Yai District, Songkhla Province, as well as the Maelan hospitals in Pattani Province, for their tremendous support. The researchers would like to extend their heartfelt appreciation to the caregivers who actively participated in this study.

XSL•FO
RenderX

Authors' Contributions

KP, JH, and SP developed the research framework through the design of the study and a comprehensive literature review, the creation of the chatbot, and the collection and analysis of data. SN contributed to the research design and data presentation. KP and JH authored the preliminary version of the manuscript. All authors (KP, JH, SP, and SN) conducted a review and revision of the manuscript to finalize the version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
English invitation letter.
[DOCX File, 28 KB - pediatrics_v8i1e62738_app1.docx]

Multimedia Appendix 2
Thai invitation letter.
[DOCX File, 32 KB - pediatrics_v8i1e62738_app2.docx]

Multimedia Appendix 3
English structured self-administered questionnaire.
[DOCX File, 2139 KB - pediatrics_v8i1e62738_app3.docx]

Multimedia Appendix 4
Thai structured self-administered questionnaire.
[DOCX File, 2438 KB - pediatrics_v8i1e62738_app4.docx]

References

1. Xu L, Sanders L, Li K, Chow JCL. Chatbot for health care and oncology applications using artificial intelligence and machine learning: systematic review. JMIR Cancer 2021 Nov 29;7(4):e27850. [doi: 10.2196/27850] [Medline: 34847056]
2. Hung J. How Southeast Asia can better arrange and deliver internet policies so as to defy the digital divide. In: Radovanović D, editor. Digital Literacy and Inclusion: Stories, Platforms, Communities: Springer International Publishing; 2024:61-77. [doi: 10.1007/978-3-031-30808-6_5]
3. Singh B, Olds T, Brinsley J, et al. Systematic review and meta-analysis of the effectiveness of chatbots on lifestyle behaviours. NPJ Digit Med 2023 Jun 23;6(1):118. [doi: 10.1038/s41746-023-00856-1] [Medline: 37353578]
4. Aggarwal A, Tam CC, Wu D, Li X, Qiao S. Artificial intelligence-based chatbots for promoting health behavioral changes: systematic review. J Med Internet Res 2023 Feb 24;25:e40789. [doi: 10.2196/40789] [Medline: 36826990]
5. Vaidyam AN, Wisniewski H, Halamka JD, Kashavan MS, Torous JB. Chatbots and conversational agents in mental health: a review of the psychiatric landscape. Can J Psychiatry 2019 Jul;64(7):456-464. [doi: 10.1177/0706743719828977] [Medline: 30897957]
6. Schachner T, Keller R, V Wangenheim F. Artificial intelligence-based conversational agents for chronic conditions: systematic literature review. J Med Internet Res 2020 Sep 14;22(9):e20701. [doi: 10.2196/20701] [Medline: 32924957]
7. Bibault JE, Chaix B, Guillemassé A, et al. A chatbot versus physicians to provide information for patients with breast cancer: blind, randomized controlled noninferiority trial. J Med Internet Res 2019 Nov 27;21(11):e15787. [doi: 10.2196/15787] [Medline: 31774408]
8. Chaix B, Bibault JE, Pienkowski A, et al. When chatbots meet patients: one-year prospective study of conversations between patients with breast cancer and a chatbot. JMIR Cancer 2019 May 2;5(1):e12856. [doi: 10.2196/12856] [Medline: 31045505]
9. Pithpornchaiyakul S, Naorungroj S, Pupong K, Hunsrisakhun J. Using a chatbot as an alternative approach for in-person toothbrushing training during the COVID-19 pandemic: comparative study. J Med Internet Res 2022 Oct 21;24(10):e39218. [doi: 10.2196/39218] [Medline: 36179147]
10. Ajay K, Azevedo LB, Haste A, et al. App-based oral health promotion interventions on modifiable risk factors associated with early childhood caries: a systematic review. Front Oral Health 2023;4:1125070. [doi: 10.3389/froh.2023.1125070] [Medline: 36968137]
11. Zhang J, Oh YJ, Lange P, Yu Z, Fukuoka Y. Artificial intelligence chatbot behavior change model for designing artificial intelligence chatbots to promote physical activity and a healthy diet: viewpoint. J Med Internet Res 2020 Sep 30;22(9):e22845. [doi: 10.2196/22845] [Medline: 32996892]
12. Policy on early childhood caries (ECC): classifications, consequences, and preventive strategies. Pediatr Dent 2016 Oct;38(6):52-54. [Medline: 27931420]

XSL•FO
RenderX

13. Vachirarojpisan T, Shinada K, Kawaguchi Y, Laungwechakan P, Somkote T, Detsomboonrat P. Early childhood caries in children aged 6-19 months. Community Dent Oral Epidemiol 2004 Apr;32(2):133-142. [doi: 10.1111/j.0301-5661.2004.00145.x] [Medline: 15061862]
14. Ammari JB, Baqain ZH, Ashley PF. Effects of programs for prevention of early childhood caries. a systematic review. Med Princ Pract 2007;16(6):437-442. [doi: 10.1159/000107748] [Medline: 17917443]
15. Ungchusak C. Oral health promotion and prevention of early childhood caries. Th Dent PH J 2017 Jun;22(Supplement):44-61.
16. Boustedt K, Dahlgren J, Twetman S, Roswall J. Tooth brushing habits and prevalence of early childhood caries: a prospective cohort study. Eur Arch Paediatr Dent 2020 Feb;21(1):155-159. [doi: 10.1007/s40368-019-00463-3] [Medline: 31338770]
17. Tudor Car L, Dhinagaran DA, Kyaw BM, et al. Conversational agents in health care: scoping review and conceptual analysis. J Med Internet Res 2020 Aug 7;22(8):e17158. [doi: 10.2196/17158] [Medline: 32763886]
18. Wood W, Neal DT. A new look at habits and the habit-goal interface. Psychol Rev 2007 Oct;114(4):843-863. [doi: 10.1037/0033-295X.114.4.843] [Medline: 17907866]
19. Lally P, van Jaarsveld CHM, Potts HWW, Wardle J. How are habits formed: modelling habit formation in the real world. Eur J Soc Psych 2010 Oct;40(6):998-1009. [doi: 10.1002/ejsp.674]
20. Verplanken B, Orbell S. Reflections on past behavior: a self-report index of habit strength. J Appl Soc Psychol 2003;33(6):1313-1330. [doi: 10.1111/j.1559-1816.2003.tb01951.x]
21. Colvara BC, Faustino-Silva DD, Meyer E, Hugo FN, Celeste RK, Hilgert JB. Motivational interviewing for preventing early childhood caries: a systematic review and meta-analysis. Community Dent Oral Epidemiol 2021 Feb;49(1):10-16. [doi: 10.1111/cdoe.12578] [Medline: 33000877]
22. Jiang S, McGrath C, Lo EC, Ho SM, Gao X. Motivational interviewing to prevent early childhood caries: a randomized controlled trial. J Dent 2020 Jun;97:103349. [doi: 10.1016/j.jdent.2020.103349] [Medline: 32330548]
23. Rogers RW. A protection motivation theory of fear appeals and attitude change1. J Psychol 1975 Sep;91(1):93-114. [doi: 10.1080/00223980.1975.9915803] [Medline: 28136248]
24. Maddux JE, Rogers RW. Protection motivation and self-efficacy: a revised theory of fear appeals and attitude change. J Exp Soc Psychol 1983 Sep;19(5):469-479. [doi: 10.1016/0022-1031(83)90023-9]
25. Rogers R, Cacioppo J, Petty R. Cognitive and physiological processes in fear appeals and attitude change: a revised theory of protection motivation. In: Social Psychology: A Sourcebook: Guilford; 1983:153-177.
26. Plotnikoff RC, Trinh L. Protection motivation theory: is this a worthwhile theory for physical activity promotion? Exerc Sport Sci Rev 2010 Apr;38(2):91-98. [doi: 10.1097/JES.0b013e3181d49612] [Medline: 20335741]
27. Kimhasawad W, Punyanirun K, Somkotra T, Detsomboonrat P, Trairatvorakul C, Songsiripradubboon S. Comparing protection-motivation theory-based intervention with routine public dental health care. Int J Dent Hyg 2021 Aug;19(3):279-286. [doi: 10.1111/idh.12522] [Medline: 34014618]
28. Ren R, Zapata M, Castro JW, Dieste O, Acuna ST. Experimentation for chatbot usability evaluation: a secondary study. IEEE Access 2022;10:12430-12464. [doi: 10.1109/ACCESS.2022.3145323]
29. Abd-Alrazaq A, Safi Z, Alajlani M, Warren J, Househ M, Denecke K. Technical metrics used to evaluate health care chatbots: scoping review. J Med Internet Res 2020 Jun 5;22(6):e18301. [doi: 10.2196/18301] [Medline: 32442157]
30. Ren R, Castro JW, Acun˜a ST, Lara J. Usability of chatbots: a systematic mapping study. 2019 Jul 10 Presented at: The 31st International Conference on Software Engineering and Knowledge Engineering; Jul 10, 2019; Lisbon, Portugal p. 479-484. [doi: 10.18293/SEKE2019-029]
31. Denecke K, Warren J. How to evaluate health applications with conversational user interface? Stud Health Technol Inform 2020 Jun 16;270:976-980. [doi: 10.3233/SHTI200307] [Medline: 32570527]
32. Zhong S, Yang X, Pan Z, et al. The usability, feasibility, acceptability, and efficacy of digital mental health services in the COVID-19 pandemic: scoping review, systematic review, and meta-analysis. JMIR Public Health Surveill 2023 Feb 13;9:e43730. [doi: 10.2196/43730] [Medline: 36634261]
33. Krebs P, Prochaska JO, Rossi JS. A meta-analysis of computer-tailored interventions for health behavior change. Prev Med 2010;51(3-4):214-221. [doi: 10.1016/j.ypmed.2010.06.004] [Medline: 20558196]
34. Hunsrisakhun J, Pithpornchaiyakul S, Yongstar P. Factors associated with oral hygiene of young children in Southern Province of Thailand. Health Sci J Thai 2022 Jul;4(3):64-73. [doi: 10.55164/hsjt.v4i3.255827]
35. Patcharanuchat P, Hunsrisakhun J, Pothidee T, Watanapa A, Sutanchaiyanonta W, Promsinchai P. Thoughts, beliefs and contexts regarding tooth-brushing and oral care of toddlers: case studies from 3 regions of Thailand. Khon Kaen Dent J 2022;25(2):10.
36. Panaumpan N, Hunsrisakhun J, Watanapa A. Factors influencing the quality tooth brushing behavior for children aged 6-24 months by caregivers based on an ecological model. J Dent Assoc Thai 2022;72(4):619-630.
37. Fitzpatrick KK, Darcy A, Vierhile M. Delivering cognitive behavior therapy to young adults with symptoms of depression and anxiety using a fully automated conversational agent (Woebot): a randomized controlled trial. JMIR Ment Health 2017 Jun 6;4(2):e19. [doi: 10.2196/mental.7785] [Medline: 28588005]
38. Mariamo A, Temcheff CE, Léger PM, Senecal S, Lau MA. Emotional reactions and likelihood of response to questions designed for a mental health chatbot among adolescents: experimental study. JMIR Hum Factors 2021 Mar 18;8(1):e24343. [doi: 10.2196/24343] [Medline: 33734089]

XSL•FO
RenderX

39. Turn facebook messenger contacts into customers on autopilot. Chatfuel. URL: https://chatfuel.com/facebook [accessed 2024-11-24]
40. Thailand internet user behavior report. Electronic Transactions Development Agency (ETDA). 2022. URL: https://www.etda.or.th/getattachment/78750426-4a58-4c36-85d3-d1c11c3db1f3/IUB-65-Final.pdf.aspx [accessed 2024-11-24]
41. Hunsrisakhun J, Pithpornchaiyakul S. Effectiveness of promoting on tooth brushing behavior for children 6 mouths - 2 years old by caregivers under application of protection motivation theory and social media based on adaptation learning 21 for FUN. : Faculty of Dentistry, Prince of Songkla University; 2020.
42. Jang S, Kim JJ, Kim SJ, Hong J, Kim S, Kim E. Mobile app-based chatbot to deliver cognitive behavioral therapy and psychoeducation for adults with attention deficit: a development and feasibility/usability study. Int J Med Inform 2021 Jun;150:104440. [doi: 10.1016/j.ijmedinf.2021.104440] [Medline: 33799055]
43. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
44. Naeem M, Ozuem W, Howell K, Ranfagni S. A step-by-step process of thematic analysis to develop a conceptual model in qualitative research. Int J Qual Methods 2023 Oct;22:16094069231205789. [doi: 10.1177/16094069231205789]
45. Wilson AR, Brega AG, Campagna EJ, et al. Validation and impact of caregivers' oral health knowledge and behavior on children's oral health status. Pediatr Dent 2016;38(1):47-54. [Medline: 26892215]
46. Finlayson TL, Siefert K, Ismail AI, Sohn W. Maternal self-efficacy and 1-5-year-old children's brushing habits. Community Dent Oral Epidemiol 2007 Aug;35(4):272-281. [doi: 10.1111/j.1600-0528.2007.00313.x] [Medline: 17615014]
47. Jiang EM, Lo ECM, Chu CH, Wong MCM. Prevention of early childhood caries (ECC) through parental toothbrushing training and fluoride varnish application: a 24-month randomized controlled trial. J Dent 2014 Dec;42(12):1543-1550. [doi: 10.1016/j.jdent.2014.10.002] [Medline: 25448437]
48. Thanakanjanaphakdee W, Trairatvorakul C. Effectiveness of parental hands-on toothbrushing instruction toward the 1-year incremental dmf rate of 9-18 month old children. J Dent Assoc Thai 2010;60(2):85-94. [Medline: 25070036]
49. Milne S, Sheeran P, Orbell S. Prediction and intervention in health‐related behavior: a meta‐analytic review of protection motivation theory. J Appl Soc Psychol 2000 Jan;30(1):106-143. [doi: 10.1111/j.1559-1816.2000.tb02308.x]
50. Courneya KS, Hellsten LAM. Cancer prevention as a source of exercise motivation: an experimental test using protection motivation theory. Psychol Health Med 2001 Feb;6(1):59-64. [doi: 10.1080/13548500125267]
51. Bui L, Mullan BA, McCaffery KJ. Protection motivation theory and physical activity in the general population: a systematic literature review. Psychol Health Med 2013;18(5):522-542. [doi: 10.1080/13548506.2012.749354] [Medline: 23324044]
52. Beirens TMJ, Brug J, van Beeck EF, Dekker R, den Hertog P, Raat H. Assessing psychosocial correlates of parental safety behaviour using protection motivation theory: stair gate presence and use among parents of toddlers. Health Educ Res 2008 Aug;23(4):723-731. [doi: 10.1093/her/cym058] [Medline: 17947245]
53. Plotnikoff RC, Lippke S, Trinh L, Courneya KS, Birkett N, Sigal RJ. Protection motivation theory and the prediction of physical activity among adults with type 1 or type 2 diabetes in a large population sample. Br J Health Psychol 2010 Sep;15(Pt 3):643-661. [doi: 10.1348/135910709X478826] [Medline: 19917151]
54. Scheerman JFM, van Meijel B, van Empelen P, et al. The effect of using a mobile application ("WhiteTeeth") on improving oral hygiene: a randomized controlled trial. Int J Dent Hyg 2020 Feb;18(1):73-83. [doi: 10.1111/idh.12415] [Medline: 31291683]
55. Fernández CE, Maturana CA, Coloma SI, Carrasco-Labra A, Giacaman RA. Teledentistry and mHealth for promotion and prevention of oral health: a systematic review and meta-analysis. J Dent Res 2021 Aug;100(9):914-927. [doi: 10.1177/00220345211003828] [Medline: 33769123]
56. Aliakbari E, Gray-Burrows KA, Vinall-Collier KA, et al. Home-based toothbrushing interventions for parents of young children to reduce dental caries: a systematic review. Int J Paediatr Dent 2021 Jan;31(1):37-79. [doi: 10.1111/ipd.12658] [Medline: 32333706]
57. Wilson L, Marasoiu M. The development and use of chatbots in public health: scoping review. JMIR Hum Factors 2022 Oct 5;9(4):e35882. [doi: 10.2196/35882] [Medline: 36197708]
58. Hunsrisakhun J, Naorungroj S, Tangkuptanon W, Wattanasit P, Pupong K, Pithpornchaiyakul S. Impact of oral health chatbot with and without toothbrushing training on childhood caries. Int Dent J 2024 Oct 22:S0020-6539(24)01541-7. [doi: 10.1016/j.identj.2024.09.028] [Medline: 39443262]

Abbreviations

AI: artificial intelligence
ECC: early childhood caries
PMT: protection motivation theory

XSL•FO
RenderX

Edited by S Badawy; submitted 30.05.24; peer-reviewed by L Weinert, P Milgrom; revised version received 24.11.24; accepted 26.11.24; published 03.02.25.

Please cite as:
Pupong K, Hunsrisakhun J, Pithpornchaiyakul S, Naorungroj S
Development of Chatbot-Based Oral Health Care for Young Children and Evaluation of its Effectiveness, Usability, and Acceptability: Mixed Methods Study
JMIR Pediatr Parent 2025;8:e62738
URL: https://pediatrics.jmir.org/2025/1/e62738
doi:10.2196/62738

© Kittiwara Pupong, Jaranya Hunsrisakhun, Samerchit Pithpornchaiyakul, Supawadee Naorungroj. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 3.2.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Internet-Based Cognitive Behavioral Therapy for Children and Adolescents With Dental or Injection Phobia: 1-year Follow-Up Assessment

Robert Schibbye[1,2], MSc; Erik Hedman-Lagerlöf[3], PhD; Viktor Kaldo[4,5], PhD; Göran Dahllöf[1,6], PhD; Shervin Shahnavaz[4], PhD

[1]Division of Pediatric Dentistry, Department of Dental Medicine, Karolinska Institutet, Huddinge, Sweden

[2]Center of Pediatric Oral Health, Stockholm, Sweden

[3]Division of Psychology, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

[4]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, & Stockholm Health Care Services, Region Stockholm, Sweden

[5]Department of Psychology, Faculty of Health and Life Sciences, Linnaeus University, Växjö, Sweden

[6]Center for Oral Health Services and Research, Mid-Norway (TkMidt), Trondheim, Norway

Corresponding Author:
Robert Schibbye, MSc
Division of Pediatric Dentistry
Department of Dental Medicine
Karolinska Institutet
Box 4064
Huddinge, 141 04
Sweden
Phone: 46 (0)8 52488044
Email: robert.schibbye@ki.se

Abstract

Background: Dental phobia (DP) and injection phobia (IP) are common in pediatric populations, resulting in inability to receive dental care. Internet-based cognitive behavioral therapy (ICBT) has demonstrated efficacy, but its long-term effects are unexplored.

Objective: This study aimed to evaluate the long-term effects of ICBT on DP and IP in children and adolescents.

Methods: In total, 49 participants (mean age 11.1 years, SD 2.1) with DP, IP, or both underwent a 12-week, parent-guided, exposure-based ICBT, supplemented by visits at local dental clinics and weekly psychologist correspondence. Assessments occurred at baseline, posttreatment, and 1-year follow-up. Primary outcomes included diagnostic status (clinical interview) and ability to receive dental procedures. Secondary outcomes included measures of dental anxiety, injection anxiety, negative cognitions, and self-efficacy. The study was conducted in Sweden.

Results: Of the 49 participants, 42 (86%) completed the 1-year follow-up. At 1-year follow-up, 19 (53%) of 36 (86%) participants who initially met the criteria for DP no longer did (P<.001), and 17 (46%) of 37 (88%) participants who initially met the criteria for IP did not fulfill the IP diagnosis (P<.001). Repeated-measures ANOVA showed significant improvements, with large effect sizes for self-reported ability to undergo dental procedures (d=1.1, P<.001), dental fear (d=1.0, P<.001), negative cognitions (d=0.9, P<.001), injection fear (d=0.7, P<.001), and self-efficacy (d=1.1, P<.001). Predictor analysis showed greater improvements in older participants and males.

Conclusions: This study discussed the clinical implications of and approaches to ICBT implementation. ICBT for children and adolescents with DP and IP maintains its effects over a 1-year follow-up period, facilitating improved self-reported willingness to undergo dental treatment. Given its accessibility and sustained efficacy, ICBT should be considered for managing severe dental fear in pediatric dentistry.

Trial Registration: ClinicalTrials.gov NCT02588079; https://clinicaltrials.gov/study/NCT02588079

(JMIR Pediatr Parent 2025;8:e80376) doi:10.2196/80376

XSL•FO
RenderX

KEYWORDS

adolescents; CBT; cognitive behavioral therapy; ICBT: internet-based cognitive behavioral therapy; dental fear and anxiety; children; dental anxiety; dental fear; dental phobia; injection phobia; internet; specific phobia

Introduction

Dental fear and anxiety (DFA) is widespread, affecting approximately 24% of all children and adolescents [1]. When fear becomes so intense that it significantly disrupts an individual's functioning, it can be classified as a specific phobia according to the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) [2]. A phobic response involves avoiding the feared object; in the context of dental phobia (DP), this often results in patients greatly delaying or being unable to seek dental care [3]. Failing to attend or delaying visits to the dentist is associated with poor oral health [4], making DP a serious health concern for those affected.

Pediatric dentistry has methods for preventing fears and providing children with DFA treatment, including pharmacological treatments and dental behavior support (DBS) [5]. However, the DBS conventionally used has not proven to be as effective in treating children with DP [6]. Similarly, the evidence regarding pharmacological sedation to reduce anxiety is conflicting and inconclusive, with no reports on the long-term effects of reduced anxiety [7].

In contrast, cognitive behavioral therapy (CBT) has been shown to be effective in both children [8] and adults with high DFA or DP [9]. CBT in this context is based on learning theory and uses exposure-based techniques to modify maladaptive responses to negatively valenced stimuli. However, the application of CBT in pediatric dentistry is currently limited in most countries due to constraints in availability, trained personnel, and successful implementation [10].

Internet-based cognitive behavioral therapy (ICBT) was partially developed to address some of the challenges associated with traditional CBT treatments, such as high costs and limited access to trained therapists. Research has previously indicated that ICBT is effective for children with DP [11]. However, the long-term effects of the treatment remain unknown. If ICBT demonstrates positive long-term effects, it has significant potential to enhance availability and cost-effectively assist children and adolescents with dental anxiety in reducing their anxiety and more willingly accepting dental treatment.

The purpose of the study was to assess the long-term efficacy of ICBT on DP, as well as injection phobia (IP), in children and adolescents assessed 1 year after the completion of treatment. The hypothesis was that the effects of ICBT will be maintained at the follow-up assessment.

Methods

Study Design

This study was a long-term follow-up, pooling participants from the research group's pilot study [12] and randomized controlled trial (RCT) [11], which focused on an ICBT for DP and IP. Both studies used the same recruitment strategies, treatment program, and measurements; however, the RCT implemented a randomization process to assign participants to either direct treatment or a waiting list control group after their inclusion and pretreatment measurements. The waiting list control group received the treatment after the 12-week posttreatment measurement. The follow-up assessment was administered 1 year after the completion of treatment.

Study Setting and Participants

The study was conducted in Sweden, and the intervention was delivered as therapist-guided ICBT via an online platform, with concurrent visits to participants' regular dental clinics. In Sweden, both general and specialist pediatric dental services are publicly funded and made available at no cost to all children. Routine dental examinations for children and adolescents are scheduled on an annual or a biennial basis. The intervention was delivered independently without direct collaboration with the children's dental care providers. A central component was parental involvement, wherein parents assumed the role of a coach to support and guide their child or adolescent throughout the treatment. The intervention was therefore designed and targeted for children and adolescents with DP and IP aged 8-15 years. Participants who met the inclusion criteria (Textbox 1) were invited to join the study, and those who met any of the exclusion criteria (Textbox 2) were excluded.

XSL•FO
RenderX

Textbox 1. Inclusion criteria for internet-based cognitive behavioral therapy (ICBT).

Inclusion criteria:

- The child's age is from 8 to 15 years.
- The child and parents sign informed consent forms.
- A psychologist establishes a diagnosis of dental phobia (DP) or injection phobia (IP) according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-4) based on the results of the internet parent version of the Development and Well-Being Assessment (DAWBA) in the initial screening and of the Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children – Present and Lifetime (K-SADS-PL) in the semistructured diagnostic interview.
- The child's and parents' Swedish language skills are sufficient to manage treatment and the questionnaires.
- Access to a computer and the internet is readily available.
- The child and parents have sufficient time and motivation to work with ICBT 3 hours each week for 12 weeks.
- The parents agree to book at least three visits at the dental clinic during the 12 weeks of treatment.
- If a child is diagnosed with IP, the parents agree to exposure training for intraoral injections at the dental clinic, even if the child does not require dental treatment.

Textbox 2. Exclusion criteria for internet-based cognitive behavioral therapy (ICBT).

Exclusion criteria:

- The child and parents obtain full points on the child and parent versions of the Picture-Guided Behavioral Avoidance Test (PG-BAT). The maximum score of 17 means that the child and the parent assess that the child can already manage the most challenging dental situations.
- The child and parents obtain a score of 31 or less on the child and parent versions of the Children's Fear Survey Schedule – Dental Subscale (CFSS-DS), and there is no diagnosis of injection phobia (IP) by the psychologist during screening.
- There is a previously established diagnosis of a neurodevelopmental disorder or a likely diagnosis of a neurodevelopmental disorder according to the results of the Development and Well-Being Assessment (DAWBA) or the psychologist during screening.
- Other psychiatric disorders, such as severe depression, eating disorders, or self-harming behaviors, should be treated before addressing specific dental phobia (DP).
- Psychiatric/psychological examination is ongoing or planned.
- Psychological treatment is ongoing or planned.
- The child has had stressful life experiences over the past 12 months, such as parental divorce or physical illness, that the parent or psychologist views as obstacles to treatment.
- The child has undergone cognitive behavioral treatment for dental fear and anxiety (DFA) or DP/IP in the past 3 years.

Recruitment Process

Participants were recruited through dental clinics and Facebook advertisements, targeting parents of children in the appropriate age range and dental professionals. Information was also shared in Facebook groups directed at dental professionals and psychologists. Dental clinics throughout Sweden were informed about the study and encouraged to promote participation in their waiting areas using posters. The dentists, especially specialists in pediatric dentistry, were asked to recommend patients with severe dental or injection fears that hindered their dental treatment to apply for the study. Interested families were directed to an online platform hosted by the Department of Dental Medicine at Karolinska Institutet. The study's website offered information about the research and its target population. Interested parents or caregivers could apply directly through the website, after which they would receive login credentials for online screening.

The recruitment period for the pilot were from August 2014 to February 2015 [12], while the recruitment for the RCT spanned from October 2015 to December 2019 [11]. The RCT's recruitment timeline had to be extended due to slower-than-expected participant enrollment. Please refer to Schibbye et al [11] and Shahnavaz et al [12] for more specific information about each process.

Screening Procedure

The first stage of the online screening provided detailed information about the study and included a study participation approval form for informed consent for caregivers (hereafter referred to as "parents"). After obtaining informed consent, one parent (designated to complete the questionnaires and participate in the telephone interview) and the child provided basic background information through an online questionnaire. Subsequently, they completed four standardized assessments online: the Picture-Guided Behavioral Avoidance Test (PG-BAT) [12], the Children's Fear Survey Schedule – Dental Subscale (CFSS-DS) [13], the Children's Negative Cognitions in Dentistry (CNCD) scale [12], and the Injection Phobia Scale for Children (IPSC) [14].

After evaluating the initial stage of screening, parents of eligible participants were asked to complete the Development and

XSL•FO
RenderX

Well-Being Assessment (DAWBA) [15] and were provided with new login credentials to access the assessment on a different platform. A clinical psychologist conducted a telephone interview with the parent using a semistructured diagnostic interview based on the specific phobia section of the Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children – Present and Lifetime (K-SADS-PL) [16] to determine whether the child met the criteria for a diagnosis of DP or IP. The psychologist also reviewed the DAWBA results with the parent to identify potential exclusion criteria, which were addressed during the interview.

Allocation Process

The study began by establishing baseline outcome measurements. In the pilot study, all participants could then start their treatment immediately, while in the RCT, they were randomized to either begin treatment directly or be placed on a 12-week waiting list. After 12 weeks on the waiting list, participants completed the outcome measurements again and were then offered an opportunity to start treatment; thus, the follow-up measurement in the RCT served as the baseline measurement for this group in this study.

The Treatment

The ICBT implemented in the study was based on a previously published manual [17]. The primary component of the treatment was exposure therapy, delivered through video and audio recordings, a home-based toolkit, and in vivo exposure sessions at a dental clinic. Additional treatment components included psychoeducation, behavioral analysis, controlled breathing techniques, and parental education (Textbox 3). Parents were encouraged to determine who among them would take on the role of coach, responsible for guiding and supporting the child or adolescent throughout the treatment process. A specific treatment module was designed for the coach (week 2) to provide information about effectively supporting, motivating, and assisting the children or adolescents with their assigned tasks. One of the coach's responsibilities included contacting each participant's local dental care provider to arrange at least three in vivo exposure sessions conducted by the clinic's regular dental staff. Participants downloaded instructions for exposure exercises from the platform and either mailed or submitted digital copies to the clinic. In the second week of treatment, participants also received a toolkit containing dental instruments and a Visual Analogue Scale (VAS) designed to facilitate home-based exposure exercises for the children, adolescents, and their coaches.

Textbox 3. Outline of the 12 internet-based cognitive behavioral therapy (ICBT) modules, with 1 module for each week.

ICBT modules:

- Introduction to cognitive behavioral therapy (CBT) and the online treatment
- For the coach only: psychoeducation, practical arrangements, home assignments, how to guide a child to elicit and reinforce behavioral change, reward strategies, and enhancing the child's self-efficacy
- Behavioral analyses, child psychoeducation and treatment rationale, and goal setting
- Constructing an exposure list and beginning exposure
- Continued exposure (films, training package) and controlled breathing
- Dentistry-related communication training and preparation for the first dental visit
- Evaluation of the dental visit and cognitive restructuring
- Midterm evaluation of ICBT and of exposure at the dentist's, and relaxation techniques
- Pain and pain management education; fear, thoughts, and pain; and focus shift and acceptance training
- Problem solving and mindfulness training
- Repetition, strategies for maintaining change and relapse prevention, and letter to yourself
- Relapse prevention plan, enhancing self-efficacy, and diploma

The intervention consisted of 12 online treatment modules (Textbox 3), provided to participants at a pace of 1 module per week. Each module included written content, with most containing images, animations, and videos or audio recordings of dental procedures to enhance exposure therapy. Each participant was paired with a specific psychologist for support during the treatment process. In total, 3 psychologists were involved to support the online therapy, all of whom held at least a master's level (5-year) degree in clinical psychology. Additionally, all had face-to-face clinical experience in CBT for DP and IP in children and adolescents.

Each week, participants and their coaches completed a new module that ended with an assignment made up of knowledge-based questions and practical exercises. After finishing the assignment, participants submitted their answers and a log of their completed tasks to their assigned psychologist. The psychologist provided feedback and granted access to the next module within 2 business days. Participants could also message their psychologist directly via the platform, with responses typically given within 2 business days. In cases of inactivity, psychologists would send reminders through SMS or email to encourage the continuation of the modules. If a participant remained inactive for more than 10 days, the psychologist would attempt to reach out to them by phone.

XSL•FO
RenderX

The intervention and all related data collection took place on a secure online platform under the supervision of the Internetpsykiatri (the Internet Psychiatry Clinic), Stockholm Health Care Services, Region Stockholm, Sweden. Both the coach and the participants used the same login credentials to access the platform. After 12 weeks, all treatment modules were made accessible to participants on the platform, regardless of whether they had completed them. The accounts for the child or adolescent and their coach, along with their login credentials, remained active for an additional 12 months. However, participants could no longer communicate with their psychologist once the treatment period concluded.

Primary Outcome Measurements

The study used two primary outcome measures. The first was a diagnosis of DP and IP, which was assessed using the specific phobia section of the K-SADS-PL. A clinical psychologist administered this assessment during a semistructured telephone interview with the parent. The K-SADS-PL is a well-established instrument with demonstrated reliability and validity in assessing psychiatric diagnoses [16].

Since it is preferable to use the child as the informant for DFA [18], an additional self-assessed primary outcome was also included, which was the PG-BAT [12]. The PG-BAT was rated independently by both the child and the parent. The PG-BAT assesses the number of dental procedures (n=17; response options: yes=1, no=0) that participants or their parents believe the child can accept and handle voluntarily (Textbox 4). The test features images of 17 dental procedures arranged in a sequence that increases anxiety-provoking potential. Each image includes a written description of the procedure and its context. Scoring ranges from 0 (unable to even enter the dentist's office) to 17 (capable of managing all dental treatment steps). The two outcomes were both considered primary, reflecting their importance in addressing the participants' central clinical issue: the ability to accept dental treatment and the functional impairment resulting from the inability to access dental care. Because of this, the designation of primary outcomes from the pre-registration was revised to include the clinician-rated diagnosis originally listed as a secondary outcome, as this collectively offers a more comprehensive assessment of the same underlying construct. This approach incorporates multiple perspectives and informants—including those of the clinician—and better captures the core dimension of the participants' clinical presentation and functional impairment.

Textbox 4. Dental procedures included in the Picture-Guided Behavioral Avoidance Test (PG-BAT) used in internet-based cognitive behavioral therapy (ICBT).

Dental procedures in the PG-BAT:

- Enter the treatment room.
- Sit in the treatment chair, with a paper bib around the neck.
- Sit in the treatment chair while the chair is lowered.
- Lie in the dental chair, with the lamp turned on and the dental tools close by on a tray.
- Open the mouth and let the dentist look into the mouth.
- Let the dentist use a small saliva ejector in the mouth.
- Let the dentist blow air and water in the mouth.
- Undergo a clinical examination with a dental mirror.
- Undergo a clinical examination with a mirror and a dental probe.
- Let the dentist take an X-ray in the back of the mouth.
- Receive topical anesthesia.
- Receive an injection of a local anesthetic.
- Let the dentist use a large saliva ejector in the mouth.
- Let the dentist attach composite filling to the surface of a tooth.
- Let the dentist drill with a high-speed drill.
- Let the dentist polish a filling with a low-speed drill.
- Let the dentist extract a tooth.

Secondary Outcome Measurements

The CFSS-DS is a widely used tool for assessing DFA. It consists of 15 items rated on a 5-point Likert scale ranging from 1 (no fear) to 5 (high fear). These items evaluate various situations related to dental and medical care, and ratings are provided separately by both the child and the parent. The Swedish version of the CFSS-DS has shown strong psychometric properties [13].

Children also assessed the 5-item CNCD scale using a 10-point VAS. The endpoints of the scale were 0 (no negative thoughts whatsoever) and 10 (some negative thoughts). These endpoints were visually represented by happy and sad figures, respectively. The CNCD measures the presence and intensity of five common

XSL•FO
RenderX

negative thoughts associated with dentistry: feelings of uncontrollability, distrust in dentists, unpredictability, perceived danger, and pain related to dental procedures [12].

The IPSC, completed by the child, consists of 18 items, each assessed on a 5-point Likert scale ranging from 1 (no fear) to 5 (high fear). The items evaluate fear associated with various injection-related situations and procedures. The IPSC has demonstrated strong psychometric properties [14].

Participants also completed the Swedish version of the 14-item Self-Efficacy Questionnaire for Phobic Situations (SEQ-SP), which is evaluated on a 5-point scale ranging from 1 (low self-efficacy) to 5 (high self-efficacy) [19].

Additionally, parents completed the Swedish version of the 12-item Parental Self-Efficacy Questionnaire for Dental Anxiety (P-SEQ-DA) [12], which is assessed on a 10-point scale ranging from 0 (no parental self-efficacy) to 10 (very high parental self-efficacy).

Assessment Schedule

Pretreatment baseline outcome measurements were collected, which included the PG-BAT and the CFSS-DS, rated separately by both the child and the parent. Additionally, the child completed the CNCD scale, the IPSC, and the SEQ-SP. The parent also filled out the P-SEQ-DA.

The posttreatment measurement was conducted 12 weeks after the treatment start and included all baseline outcome measures and a semistructured diagnostic telephone interview by a clinical psychologist using the specific phobia section of the K-SADS-PL. Additional questionnaires gathered qualitative insights into the child's current dental anxiety and experiences with ICBT, using a combination of free text, multiple-choice questions, and the VAS. These included questions about adverse events or unintended treatment effects, which were also addressed during the psychologist's interview.

A follow-up was conducted 1 year after the posttreatment measurement and included all baseline outcome measurements, including the diagnostic telephone interview by a clinical psychologist.

Statistical Analysis

All statistical analyses were conducted using R version 4.3.2 (R Foundation for Statistical Computing) [20]. A type I error rate of 5% was accepted for all analyses. Before conducting the analyses, the data were assessed for normality. The McNemar test was conducted to analyze the differences in diagnosis (yes or no) between paired observations. ANOVA was performed to evaluate potential differences between baseline, posttreatment (12 weeks), and the 1-year follow-up on continuous outcome measurements. A post hoc analysis using a generalized linear model (GLM) with repeated measures and pairwise comparisons was conducted to estimate effect sizes using Cohen d, which represents the standardized mean difference [21]. A GLM with repeated measures, along with Bonferroni correction for multiple comparisons, was used to analyze predictor effects.

The analysis used an intention-to-treat approach, meaning that all participants who started the treatment were included regardless of the degree to which they completed it. Sensitivity analyses were performed by using maximum likelihood estimation to impute missing values into the dataset.

Ethical Considerations

The study received approval from the regional ethics review board in Stockholm (ID 2014/633-31/5) and was pre-registered at ClinicalTrials.gov (NCT02588079). Informed consent was obtained before participant enrollment in the study and screening process completion. Study information and consent forms were provided in Swedish, and consent included authorization for the secondary data analysis without needing additional approval. For participants with two caregivers, consent was required from each caregiver separately. No financial compensation was offered to participants, and the intervention was provided at no cost, consistent with the provision of dental care for children and adolescents in Sweden.

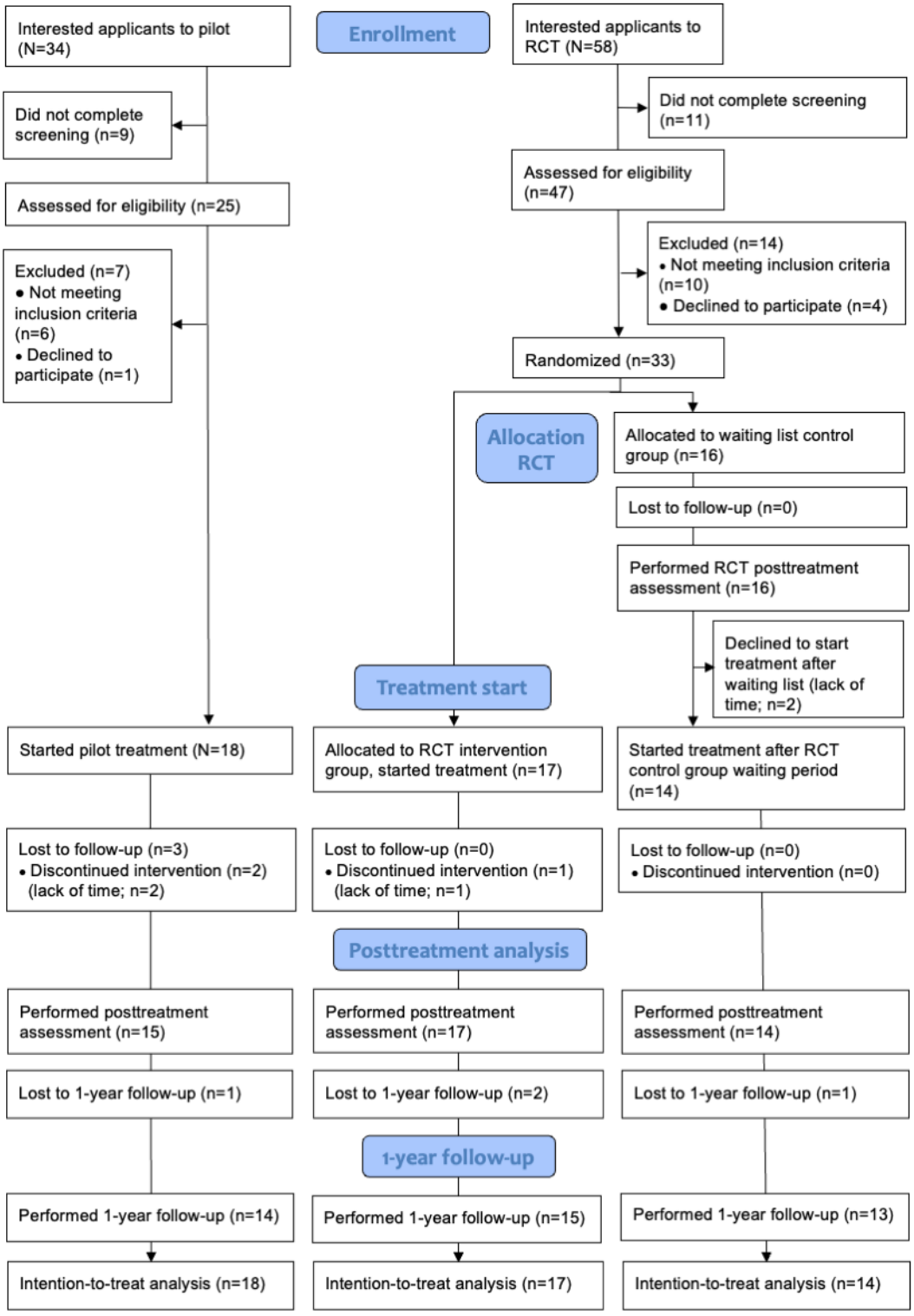
Results

Participant Details

Of the 16 participants in the ICBT control group, 14 (88%) began the treatment after the 12-week waiting period. Those who did not start treatment reported that a lack of time was the reason for their decision. As a result, a total of 31 (94%) participants from the RCT and 18 (100%) participants from the pilot study started ICBT. Consequently, a combined total of 49 participants was included in the long-term analysis of ICBT. For a flowchart of the participants in the ICBT, see Figure 1.

XSL•FO
RenderX

Figure 1. Flowchart of participants in the pilot study and the RCT of ICBT. ICBT: internet-based cognitive behavioral therapy; RCT: randomized controlled trail.



Of the 49 participants who began the treatment, 39 (80%) indicated that their main fear related to dentistry was injections. The majority had experiences with sedation and restraint during previous dental treatments. The most reported specific phobias other than DP and IP among the participants were blood and bee/wasp phobias. For a complete overview of the characteristics of the participants, see Table 1.

XSL•FO
RenderX

Table 1. Characteristics of participants in ICBT[a] from the pilot study and the RCT[b].

Variables	ICBT pilot sample (n=18)	ICBT RCT sample (n=31)	Total ICBT sample (N=49)
Age (years), mean (SD)	10.9 (2.4)	11.1 (1.9)	11.1 (2.1)
Females, n (%)	12 (67)	20 (65)	32 (65)
Both parents born in Sweden, n (%)	14 (78)	27 (87)	41 (84)
Living with both parents, n (%)	12 (67)	26 (84)	38 (78)
Duration (months), mean (SD)			
Fear of the dentist	47.4 (43.3)	44.8 (42.8)	45.8 (42.5)
Fear of injections	73.7 (46.7)	67.9 (49.4)	70 (48)
Diagnosis, n (%)			
DP[c]	16 (89)	26 (84)	42 (86)
IP[d]	17 (94)	27 (87)	44 (90)
DP and IP	15 (83)	22 (71)	37 (88)
Another specific phobia[e]	5 (28)	6 (19)	11 (22)
During previous dental treatment, n (%)			
Sedation was administered	8 (44)	29 (94)	37 (76)
Restraint was used	13 (72)	19 (61)	32 (65)
General anesthesia was administered	4 (22)	6 (19)	10 (20)

[a]ICBT: internet-based cognitive behavioral therapy.

[b]RCT: randomized controlled trial.

[c]DP: dental phobia.

[d]IP: injection phobia.

[e]Diagnosis of a specific phobia besides DP or IP.

Treatment Adherence and Dropout Frequency

After the initial 3 weeks, 3 (6%) of 49 participants did not continue due to time constraints and were classified as dropouts. The remaining 46 (94%) participants completed at least the first 5 modules of the treatment and had started the exposure training, while 40 (82%) progressed to at least module 8 and were identified as treatment completers, having finished the home exposure exercises and conducted in vivo exposure at their local dental clinics by the end of the 12-week period. The average number of modules completed was 9.6 (SD 2.7) of 12.

Of the 49 participants who began the treatment, 47 (96%) completed the posttreatment measurement. At the 1-year follow-up, the parents of 42 (86%) participants and 40 (82%) of the children completed follow-up measurements; the parents who completed the measurements also partook in a clinical phone interview. No participants reported any adverse events of the treatment in the follow-up questionnaires or during the clinical phone interviews.

Main Outcome Measurements

At the 1-year follow-up, 18 (43%) of 42 participants no longer met the diagnostic criteria for either DP or IP, whereas at the posttreatment measurement, 16 (35%) of 46 participants did not fulfill the criteria for either DP or IP. The McNemar test revealed a significant difference compared to before treatment for both groups ($P<.001$); however, the difference was not significant when comparing posttreatment with the 1-year follow-up ($P=.77$). Table 2 presents the intervention results stratified by diagnosis. A statistical difference from before treatment to posttreatment was observed at the 1-year follow-up in all the analyses. However, as seen in Table 2, the proportion of participants meeting the criteria for the respective disorders, any disorder, or both remained stable from posttreatment to the 1-year follow-up. Among the participants who met the diagnostic criteria for DP at baseline, 8 (32%) no longer met the criteria, while 3 (12%) developed a new diagnosis of DP between the posttreatment and 1-year follow-up measurements. Similarly, of those initially diagnosed with IP, 7 (28%) remitted, whereas 5 (20%) developed IP at the 1-year follow-up compared to posttreatment.

XSL•FO
RenderX

Table 2. Participants meeting the criteria for diagnoses of DP[a], IP[b], either DP or IP, or DP and IP before treatment, posttreatment, and at 1-year follow-up in ICBT[c].

Diagnosis	Participants, n/N (%)			*P* value (McNemar test)		
	Before treatment	Posttreatment	1-year Follow-up	Before treatment to posttreatment	Before treatment to 1-year follow-up	Posttreatment to 1-year follow-up
DP	42/42 (100)	25/40 (63)	17/36 (47)	<.001[d]	<.001[d]	.23
IP	44/44 (100)	25/41 (61)	20/37 (54)	<.001[d]	<.001[d]	.77
DP or IP	49/49 (100)	30/46 (65)	25/42 (60)	<.001[d]	<.001[d]	.77
DP and IP	37/37 (100)	19/35 (54)	11/31 (35)	<.001[d]	<.001[d]	.23

[a]DP: dental phobia.

[b]IP: injection phobia.

[c]ICBT: internet-based cognitive behavioral therapy.

[d]Significant *P* values.

A repeated-measures ANOVA was conducted to examine changes in the number of dental procedures managed by the participants (self-assessed through the PG-BAT) before treatment, posttreatment, and at the 1-year follow-up. The analysis revealed a significant main effect of time, as assessed by both the child and the parent (see Table 3). The effect size of the post hoc pairwise comparisons was then calculated, which showed large effects (Cohen d≥1.1) at the 1-year follow-up. There was no significant difference between the children from posttreatment to the 1-year follow-up; however, parents reported more dental procedures managed at the 1-year follow-up than posttreatment (Cohen d=0.3, *P*=.04). The pre- to posttreatment measurements were also significant, showing large effect sizes, as rated both by the child and the parent.

XSL•FO
RenderX

Table 3. Changes rated by children and parents before treatment, after treatment, and at the 1-year follow-up.

Participant	Time points			$F_{2,96}$; *P* value	Within-group effect size, Cohen d (95% CI); *P* value		
	Before treatment, mean (SD; 95% CI); participants (n=49), n (%)	Posttreatment, mean (SD; 95% CI); participants (n=47), n (%)	1-year Follow-up, mean (SD; 95% CI); participants (n=42), n (%)		Before treatment to posttreatment	Before treatment to 1-year follow-up	Posttreatment to 1-year follow-up
Child							
Dental procedures managed[a]	11.7 (3.7; 10.7 to 12.8); 49 (100)	14.9 (2.2; 14.3 to 15.6); 47 (100)	15.0 (1.7; 14.5 to 15.6); 40 (95)	50.1; <.001[b]	1.2 (0.8 to 1.5); <.001[b]	1.1 (0.7 to 1.4); <.001[b]	0.1 (–0.2 to 0.3); .70
DFA[c]	35.1 (11.1; 31.9 to 38.3); 49 (100)	25.5 (8.7; 23.0 to 28.1); 47 (100)	25.9 (8; 23.3 to 28.5); 40 (95)	41.9; <.001[b]	1.3 (0.9 to 1.6); <.001[b]	1.0 (0.6 to 1.3); <.001[b]	–0.2 (–0.4 to 0.1); .26
Negative cognitions[d]	24 (12.8; 20.3 to 27.7); 49 (100)	11.1 (11.4; 7.7 to 14.6); 45 (96)	14.3 (10.5; 10.9 to 17.6); 40 (95)	38.8; <.001[b]	1 (0.7 to 1.4); <.001[b]	0.9 (0.6 to 1.2); <.001[b]	–0.4 (–0.7 to –0.1); .006[b]
Injection fear[e]	42.9 (12.1; 39.4 to 46.4); 49 (100)	33.5 (10.4; 30.4 to 36.6); 46 (98)	34.0 (10.5; 30.6 to 37.3); 40 (95)	27.0; <.001[b]	0.9 (0.6 to 1.3); <.001[b]	0.7 (0.4 to 1.1); <.001[b]	–0.1 (–0.4 to 0.2); .55
Self-efficacy[f]	27.8 (7.5; 26.6 to 29.9); 49 (100)	44.0 (11; 40.8 to 47.3); 46 (98)	42.3 (11.6; 38.6 to 46.0); 40 (95)	65.9; <.001[b]	1.2 (0.8 to 1.5); <.001[b]	1.1 (0.7 to 1.4); <.001[b]	–0.1 (–0.3 to 0.2); .70
Parent							
Dental procedures managed[a]	11.5 (3.9; 10.4 to 12.6); 49 (100)	14.7 (2.4; 14.0 to 15.4); 47 (100)	15.3 (1.9; 14.7 to 15.9); 42 (100)	52.5; <.001[b]	1.1 (0.8 to 1.5); <.001[b]	1.2 (0.8 to 1.5); <.001[b]	0.3 (0.0 to 0.6); .04[b]
DFA[c]	35.9 (10.8; 32.8 to 39.0); 49 (100)	24.9 (7.5; 22.6 to 27.1); 47 (100)	24.0 (12.8; 20.3 to 27.7); 42 (100)	60.1; <.001[b]	1.3 (0.9 to 1.7); <.001[b]	1.1 (0.8 to 1.5); <.001[b]	–0.2 (–0.4 to 0.1); .27
Parental self-efficacy[g]	108.4 (16.3; 103.7 to 113.1); 49 (100)	119.8 (15.8; 115.2 to 124.4); 47 (100)	114.9 (17.3; 109.5 to 120.3); 42 (100)	7.4; <.001[b]	0.8 (0.5 to 1.1); <.001[b]	0.3 (0.0 to 0.6); .04[b]	–0.2 (–0.5 to 0.1); .20

[a]Picture-Guided Behavioral Avoidance Test (PG-BAT; score range: 0-17).

[b]Significant *P* values.

[c]Children's Fear and Survey Schedule – Dental Subscale (CFSS-DS; score range: 15-75).

[d]Children's Negative Cognitions in Dentistry (CNCD) scale (score range: 0-50).

[e]Injection Phobia Scale for Children (IFSC; score range: 18-90).

[f]Self-Efficacy Questionnaire for Phobic Situations (SEQ-SP; score range: 14-70).

[g]Parental Self-Efficacy Questionnaire for Dental Anxiety (P-SEQ-DA; score range: 0-132).

Secondary Outcome Measurements

A repeated-measures ANOVA was conducted, and the effect size of the post hoc pairwise comparisons for the secondary outcome measurements was calculated (see Table 3). The analysis revealed a significant effect of time at the 1-year follow-up on all the secondary outcomes. The effect size was large (Cohen d≥0.8) for most outcomes, except for injection fear (Cohen d=0.7) and parental self-efficacy (Cohen d=0.3). For most outcomes, there was no significant difference between posttreatment and the 1-year follow-up, except for negative cognitions, which increased for the children (indicating that they had more negative cognitions about dentistry) at the 1-year follow-up (Cohen d=–0.4, *P*=.006). A sensitivity analysis was conducted, which showed no change in the statistical significance of any of the main analyses after imputing missing data to the dataset.

Predictor Analysis

Finally, a predictor analysis was conducted to determine whether background variables (participants' age and sex) or the number of modules completed influenced the outcome measures. The results revealed that age influenced the clinical diagnosis outcomes, with older participants being less likely to meet the criteria for a clinical diagnosis at later time points (see Table 4). Additionally, an effect for the participants' sex was found, revealing more favorable results for male participants, particularly at the posttreatment time point, on all measurements. However, only the effects on self-rated injection fear, self-efficacy, and parental-rated DFA were statistically

XSL•FO
RenderX

significant. A separate analysis that included both age and sex was also performed, where all the results from the previous analyses remained significant. Furthermore, more completed treatment modules demonstrated a significant association with more favorable scores of self-rated DFA, negative cognitions, and increased self-efficacy.

Table 4. Predictor effects on the outcome measurements of ICBT[a].

Outcome measurements	Age, F_{df}; P value	Sex, F_{df}; P value	Number of modules completed, F_{df}; P value
Diagnosis			
DP[b]	$F_{1,34}$=9.22; .005[d]	$F_{1,34}$=0.01; .92	$F_{1,34}$=2.03; .16
IP[c]	$F_{1,35}$=6.44;.012[d]	$F_{1,35}$=2.59; .12	$F_{1,35}$=0.52; .48
Child			
Dental procedures managed[e]	$F_{1,38}$=2.65; .11	$F_{1,38}$=1.04; .38	$F_{1,38}$=2.41; .13
DFA[f,g]	$F_{1,38}$=1.30; .26	$F_{1,38}$=2.74; .11	$F_{1,38}$=4.14; .05[d]
Negative cognitions[h]	$F_{1,37}$=0.48;.49	$F_{1,37}$=0.88; .35	$F_{1,37}$=4.52; .04[d]
Injection fear[i]	$F_{1,38}$=0.43; .43	$F_{1,38}$=7.64; .009[d]	$F_{1,38}$=0.16; .69
Self-efficacy[j]	$F_{1,38}$=0.00; .96	$F_{1,38}$=5.30; .03[d]	$F_{1,38}$=14.55; <.001[d]
Parent			
Dental procedures managed[e]	$F_{1,41}$=3.95; .05	$F_{1,41}$=0.34; .56	$F_{1,41}$=1.31; .26
DFA[g]	$F_{1,41}$=0.01; .91	$F_{1,41}$=4.32; .04[d]	$F_{1,41}$=1.05; .31

[a]ICBT: internet-based cognitive behavioral therapy.
[b]DP: dental phobia.
[c]IP: injection phobia.
[d]Significant values.
[e]Picture-Guided Behavioral Avoidance Test (PG-BAT).
[f]DFA: dental fear and anxiety.
[g]Children's Fear and Survey Schedule – Dental Subscale (CFSS-DS).
[h]Children's Negative Cognitions in Dentistry (CNCD) scale.
[i]Injection Phobia Scale for Children (IFSC).
[j]Self-Efficacy Questionnaire for Phobic Situations (SEQ-SP).

Discussion

Principal Findings

At the 1-year follow-up, participants who received ICBT demonstrated significant improvements relative to their pretreatment baseline. Furthermore, the results observed posttreatment were maintained over the follow-up period. After 1 year, 49% of participants no longer met the diagnostic criteria for either DP or IP. Specifically, 53% of participants who initially met the criteria for DP no longer did, and 46% of those who initially met the criteria for IP no longer met the criteria for an IP diagnosis. Additionally, participants self-assessed their ability to manage dental procedure steps at the dentist's significantly higher, showing a large effect size (Cohen d=1.1). They also, compared to baseline, significantly reduced their fear and anxiety, again with a large effect size (Cohen d=1.0), and exhibited improvements across all outcomes, as reported by both the children and their parents. The treatment appeared to be more beneficial for male participants than females and for older individuals, although these findings reflect associations rather than causal relationships. Additionally, a higher number of completed treatment modules was associated with more favorable outcomes of ICBT.

Comparison With Previous Research

The long-term effects of ICBT are comparable to that of face-to-face CBT, further supporting the notion that exposure-based CBT treatments are an effective long-term intervention in pediatric dentistry. An RCT of face-to-face CBT conducted by a clinical psychologist revealed within-group effects comparable to this study on the Behavioral Avoidance Test (BAT) and the CFSS-DS [17]. However, at posttreatment and the 1-year follow-up, 64% and 91%, respectively, of the participants in that study no longer met the diagnostic criteria for DP, while 38% and 53%, respectively, did not meet the diagnostic criteria for DP at the different time points in this study. This discrepancy might be attributed to a higher level of engagement in treatment due to the direct interaction with participants or the advantage of using trained personnel delivering the in vivo exposures. Additionally, it may also indicate that the structures surrounding the CBT, such as

XSL•FO
RenderX

integration with continued dental care, play a crucial role in achieving favorable long-term results from exposure-based CBT in dentistry. The clinic in the face-to-face CBT RCT had trained personnel (clinical psychologists), established routines, and collaborations for referrals back to local clinics that continued the treatment for the participants, whereas the ICBT lacked all these features. In another RCT [22] where specially trained dentists conducted CBT for intraoral IP, the posttreatment effects on their BAT, CFSS-DS, and an injection phobia scale were comparable to the effects observed in this trial. At the 1-year follow-up, 69% of participants were able to receive intraoral injections at the dentist's, indicating that they likely would not meet the diagnostic criteria for intraoral IP. In this study, 46% of participants lost their initial diagnosis of IP at the 1-year follow-up. This difference may once again be attributed to not only the specifically trained personnel delivering the exposure but also the stricter focus on intraoral injection exposure treatment and diagnosis in that study [22], while this study also examined participants' ability to receive injections in health care when establishing the diagnosis of general IP. Finally, a systematic review of the long-term effects of ICBT showed an average long-term symptom improvement of 50% across studies of different conditions [23], consistent with the results of this 1-year follow-up of ICBT for DP and IP, showing that ICBT can provide meaningful long-term effects and should be considered in dentistry. Although research on the stability of diagnosed DP and IP in children and adolescents is limited and needs to be better understood, one study found that stability is lower in younger children under 12 years of age [24]. Notably, the sample in this study had an average duration of 46 months for dentist fear and 70 months for injection fear, and the majority had undergone various prior treatment modalities (76% had received sedation, 20% had received general anesthesia), indicating that ICBT is effective for the group that has stable fears and where conventional methods within pediatric dentistry have been unsuccessful.

Interesting predictor effects of ICBT were observed; however, these results should be interpreted with caution due to the relatively small sample size. Older participants more frequently lost their clinical diagnosis of DP or IP during ICBT. Additionally, although not statistically significant, the trend of the CFSS-DS and the number of dental procedures managed also favored older children. Previous findings on age as a predictor of treatment results for anxiety disorders have been conflicting [25]. However, some suggest that children over 12 years respond better to these treatments [26]. A trend, with some results reaching statistical significance, was observed, indicating that males had a better treatment effect than females, especially at the posttreatment time point. This represents a new finding that has not been reported in previous research on ICBT or psychological anxiety treatments for children and adolescents. Future research is needed to determine whether this is related to the specific conditions of DP and IP or whether these effects are seen in combination with this specific treatment. Nevertheless, DFA and DP have been shown to be more common in females than in males [1], indicating that there could be underlying sex differences affecting both the condition itself and, therefore, possibly its treatment.

Clinical Implications

This study, along with other research on other psychiatric conditions, indicates that ICBT has robust long-term effects for patients who are willing to receive an internet-based intervention and, in many instances, is comparable to in-person CBT. Given the current lack of availability of evidence-based treatment options for children and adolescents with DP and IP, ICBT should be seriously considered for integration into dental practice. However, the methods for effectively incorporating ICBT into standard dental care remain unexplored. This study shows that ICBT can eliminate the need for specialized staff onsite and can be implemented with minimal training of personnel at regular dental clinics. However, further research on the effects of ICBT with better-trained personnel delivering the in vivo exposure is needed since there is a possibility that this could increase its effect. Moreover, the treatment must be presented in such a way that both personnel and patients recognize its benefits; considering the slow recruitment for this study, ICBT needs to be integrated into local practices. Therefore, trained dental personnel aiding in both treatment delivery and its incorporation into ongoing patient care seems imperative. Finally, it is important also to note that efficacy studies on ICBT are based on participants who actively seek this type of treatment or exhibit strong motivation when invited to participate, which may also disproportionately include individuals with higher socioeconomic resources. This distinction must be carefully considered during implementation to ensure the treatment remains both effective and appropriate. ICBT should not be administered to individuals lacking motivation to engage with the treatment or the resources necessary to complete it.

The participants in this ICBT study can be considered selected due to the screening process and inclusion criteria for research participation, as well as the thoroughness of the treatment provided. Those who withdrew or declined to participate indicated that time constraints were the barrier, suggesting that a less intensive treatment could serve patients with limited time and resources, potentially enhancing its use. In addition, in the posttreatment qualitative evaluation, some participants described the intervention as overly extensive and suggested that it could be delivered in a more condensed format. For example, the RCT conducted on children with intraoral IP achieved comparable results using only five sessions. The number of completed modules in the treatment was primarily linked to the cognitive aspects of dental fear, possibly further indicating that a less extensive treatment could still help with the functional aspects of overcoming the challenge of receiving dental care. In the cases of DP and IP, the impaired oral and general health they cause could arguably be the most important aspect to address, aiming to enable the person to receive needed care willingly. Less extensive ICBTs combined with in vivo exposure provided by trained dental personnel, such as dental assistants or hygienists, seem to be a plausible way to implement a treatment that could reach larger patient groups and maintain efficacy. Importantly, they may also be more feasible for implementation in groups with fewer resources, as they place lower demands on the participants and structures around them. The dental staff delivering the treatment would benefit from training in exposure

XSL•FO
RenderX

methods to better assist patients through the ICBT process and serve as a bridge to their ongoing dental care at the clinic. Future research is necessary to establish such treatments' efficacy and effectiveness and determine which patient groups would benefit most from them. A favorable solution would involve establishing an initial assessment that directs the patient to the appropriate level of treatment. This could include a less extensive ICBT that is standardized and focuses more on exposure to a specific stimulus (primarily injections but also aspects such as the drill, gag reflex, or other physiological sensations that might be the main fear) offered at local dental clinics by trained personnel to help patients overcome their hurdles in receiving dental care. When necessary, a more comprehensive ICBT that also emphasizes cognitive aspects, such as the one used in this study, could be provided to those patients who might require it and are interested. Additionally, the option to consult with a clinical psychologist face-to-face is essential for certain groups, such as individuals with comorbid posttraumatic stress disorder (PTSD), other severe psychiatric conditions, or neuropsychological conditions.

The novel findings indicating that age and sex may influence treatment outcomes are intriguing; however, replication in future studies is necessary to substantiate these effects. Given that DFA and DP have been shown to be more prevalent among females, it is possible that sex-specific adaptations to an intervention may be warranted. Future research should establish whether treatment responses for DP, IP, and intraoral IP differ systematically based on sex. If such differences are confirmed, further investigation into potential variations in the etiology of these phobias could inform the development of tailored treatment approaches that address these sex-specific mechanisms.

Moreover, the predicting effect of age on treatment outcomes further underscores the need to explore the efficacy of a more condensed ICBT protocol. A shorter intervention primarily centered on exposures may be a more pragmatic and effective alternative for younger individuals, minimizing the burden of unnecessarily prolonged treatment, while maintaining therapeutic efficacy. This consideration aligns with evidence suggesting that the stability of blood-injection-injury (BII) phobia diagnoses increases significantly after the age of 12 years [24] and that psychological treatments for anxiety disorders might have a better effect on children aged 12 years and above. Consequently, comprehensive CBT interventions for DP and IP should likely be prioritized for older children and adolescents, where the risk of long-term symptom stabilization and treatment efficacy may be greater.

A final consideration concerns how the delivery and organizational responsibility for exposure-based CBT in dentistry should be strategically addressed in policy planning. In most countries, pediatric dentistry and general pediatric health care are administratively and financially separate, often resulting in higher out-of-pocket costs for dental care. Given that DP and IP are psychiatric conditions with a significant impact on overall health, exposure-based CBT should be integrated into the publicly funded health care systems to enhance accessibility and reduce financial barriers. For ICBT, existing national digital health platforms, where available, offer a scalable and cost-effective avenue for dissemination. However, effective implementation into existing dental care structures requires close collaboration with dental services, where the treatment, with its in vivo exposures, is ultimately to be delivered. This underscores the need for coordinated policy efforts across both general health care and dentistry to address the care of patients with a phobia hindering their dental treatment.

Strengths and Limitations

A key strength of this study is the inclusion of a clinically relevant sample, with a substantial proportion of participants experiencing persistent functional impairment due to their severe fear. Notably, the vast majority had previously required sedation and physical restraint during dental procedures, underscoring the long-term efficacy of ICBT in enabling these individuals to undergo dental treatment voluntarily. Furthermore, the study used multiple outcome measures assessed by the children themselves, as well as by independent observers, allowing for a comprehensive evaluation of treatment effects across various dimensions of phobic impairment. The strong concordance among these measures further reinforces the effectiveness of ICBT. Additionally, as the intervention was delivered in routine clinical settings by personnel without extensive formal training in CBT, the findings suggest robust external validity and feasibility for implementation in general dental practice. However, careful considerations regarding implementation and how trained personnel could possibly potentiate the effect of the treatment need to be done.

However, certain methodological limitations must also be acknowledged. The clinical interviews conducted to establish the posttreatment and 1-year follow-up diagnoses were not blinded, which may introduce potential bias. Nevertheless, given the consistency of treatment effects across all outcome measures, this limitation is unlikely to have significantly influenced the overall findings. Another limitation is that rather than assessing intraoral IP specifically, this study classified participants based on the broader diagnosis of a general IP in the posttreatment and 1-year follow-up assessments. However, this only attenuated the results, showing the robustness of the treatment effects.

Additionally, the generalizability of the results to populations excluded from this study remains uncertain, potentially limiting the external validity of the findings for certain clinical subgroups and those with limited socioeconomic resources. Furthermore, unmeasured confounding variables could have influenced the predictor analyses, as the study was not originally designed to systematically investigate these aspects. The relatively small sample size may also have constrained statistical power in these analyses, potentially obscuring significant associations where trends toward significance were observed. Despite these limitations, the findings suggest clinically interesting effects that warrant further investigation in future research.

Conclusion

ICBT for children and adolescents with DP and IP appears to maintain its effects over a 1-year follow-up period. ICBT is associated with long-term reductions in fear and allows the child to willingly accept dental treatment, thus leading to improved dental and general health. This study further supports that ICBT

XSL•FO
RenderX

is a method that enhances accessibility to evidence-based, long-term, effective treatment for fear and anxiety in pediatric dentistry.

Acknowledgments

The authors declare that no funds, grants, or other support was received during the preparation of this manuscript. No artificial intelligence tools, aside from grammar and style suggestions provided by word processing software, were used during the writing of this manuscript.

Data Availability

The datasets used and analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

References

1. Grisolia BM, Dos Santos APP, Dhyppolito IM, Buchanan H, Hill K, Oliveira BH. Prevalence of dental anxiety in children and adolescents globally: a systematic review with meta-analyses. Int J Paediatr Dent 2021 Mar;31(2):168-183 [FREE Full text] [doi: 10.1111/ipd.12712] [Medline: 33245591]
2. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-5®). 5 ed. Washington, DC: American Psychiatric Publishing; 2013.
3. Armfield JM, Stewart JF, Spencer AJ. The vicious cycle of dental fear: exploring the interplay between oral health, service utilization and dental fear. BMC Oral Health 2007 Jan 14;7:1 [FREE Full text] [doi: 10.1186/1472-6831-7-1] [Medline: 17222356]
4. Mohd Khairuddin AN, Bogale B, Kang J, Gallagher JE. Impact of dental visiting patterns on oral health: a systematic review of longitudinal studies. BDJ Open 2024 Mar 06;10(1):18 [FREE Full text] [doi: 10.1038/s41405-024-00195-7] [Medline: 38448428]
5. Mac Giolla Phadraig C, Healy O, Fisal AA, Yarascavitch C, van Harten M, Nunn J, et al. Behaviour support in dentistry: a Delphi study to agree terminology in behaviour management. Community Dent Oral Epidemiol 2024 Aug 22;52(4):550-571 [FREE Full text] [doi: 10.1111/cdoe.12953] [Medline: 38516782]
6. Seligman LD, Hovey JD, Chacon K, Ollendick TH. Dental anxiety: an understudied problem in youth. Clin Psychol Rev 2017 Jul;55:25-40 [FREE Full text] [doi: 10.1016/j.cpr.2017.04.004] [Medline: 28478271]
7. Melini M, Forni A, Cavallin F, Parotto M, Zanette G. Conscious sedation for the management of dental anxiety in third molar extraction surgery: a systematic review. BMC Oral Health 2020 May 28;20(1):155 [FREE Full text] [doi: 10.1186/s12903-020-01136-0] [Medline: 32466796]
8. Gomes HS, Viana KA, Batista AC, Costa LR, Hosey MT, Newton T. Cognitive behaviour therapy for anxious paediatric dental patients: a systematic review. Int J Paediatr Dent 2018 Jul 08 [FREE Full text] [doi: 10.1111/ipd.12405] [Medline: 29984460]
9. Steenen SA, Linke F, van Westrhenen R, de Jongh A. Interventions to reduce adult state anxiety, dental trait anxiety, and dental phobia: a systematic review and meta-analyses of randomized controlled trials. J Anxiety Disord 2024 Jul;105:102891 [FREE Full text] [doi: 10.1016/j.janxdis.2024.102891] [Medline: 38945067]
10. Heyman R, Wojda A, Eddy J, Haydt N, Geiger J, Slep AS. Dentist-perceived barriers and attractors to cognitive-behavioral treatment provided by mental health providers in dental practices. Adv Dent Res 2018 Feb 22;29(1):35-41 [FREE Full text] [doi: 10.1177/0022034517737023] [Medline: 29355419]
11. Schibbye R, Hedman-Lagerlöf E, Kaldo V, Dahllöf G, Shahnavaz S. Internet-based cognitive behavioral therapy for children and adolescents with dental or injection phobia: randomized controlled trial. J Med Internet Res 2024 Feb 21;26:e42322 [FREE Full text] [doi: 10.2196/42322] [Medline: 38381476]
12. Shahnavaz S, Hedman-Lagerlöf E, Hasselblad T, Reuterskiöld L, Kaldo V, Dahllöf G. Internet-based cognitive behavioral therapy for children and adolescents with dental anxiety: open trial. J Med Internet Res 2018 Jan 22;20(1):e12 [FREE Full text] [doi: 10.2196/jmir.7803] [Medline: 29358158]
13. Klingberg G. Reliability and validity of the Swedish version of the Dental Subscale of the Children's Fear Survey Schedule, CFSS-DS. Acta Odontol Scand 1994 Aug;52(4):255-256 [FREE Full text] [doi: 10.3109/00016359409029055] [Medline: 7985512]
14. Wahlund T. Injection Phobia Scale, Swedish. Stockholm: Stockholm University; 2008.
15. Goodman R, Ford T, Richards H, Gatward R, Meltzer H. The development and well-being assessment: description and initial validation of an integrated assessment of child and adolescent psychopathology. J Child Psychol Psychiatry 2000 Jul;41(5):645-655 [FREE Full text] [doi: 10.1111/j.1469-7610.2000.tb02345.x] [Medline: 10946756]

XSL•FO
RenderX

16. Kaufman J, Birmaher B, Brent D, Rao U, Flynn C, Moreci P, et al. Schedule for Affective Disorders and Schizophrenia for School-Age Children-Present and Lifetime Version (K-SADS-PL): initial reliability and validity data. J Am Acad Child Adolesc Psychiatry 1997 Jul;36(7):980-988 [FREE Full text] [doi: 10.1097/00004583-199707000-00021] [Medline: 9204677]
17. Shahnavaz S, Hedman E, Grindefjord M, Reuterskiöld L, Dahllöf G. Cognitive behavioral therapy for children with dental anxiety: a randomized controlled trial. JDR Clin Trans Res 2016 Oct;1(3):234-243 [FREE Full text] [doi: 10.1177/2380084416661473] [Medline: 29417092]
18. Porritt J, Buchanan H, Hall M, Gilchrist F, Marshman Z. Assessing children's dental anxiety: a systematic review of current measures. Community Dent Oral Epidemiol 2013 Apr;41(2):130-142 [FREE Full text] [doi: 10.1111/j.1600-0528.2012.00740.x] [Medline: 22970833]
19. Flatt N, King N. The Self-Efficacy Questionnaire for Phobic Situations (SEQ-SP): development and psychometric evaluation. Behav Change 2012 Feb 22;26(2):141-152 [FREE Full text] [doi: 10.1375/bech.26.2.141]
20. R Core Team. R: A Language and Environment for Statistical Computing. Vienna, Austria: R Foundation for Statistical Computing; 2023.
21. Cohen J. Statistical Power Analysis for the Behavioral Sciences. New York: Routledge; 1988:9780203771587.
22. Berge KG, Agdal ML, Vika M, Skeie MS. Treatment of intra-oral injection phobia: a randomized delayed intervention controlled trial among Norwegian 10- to 16-year-olds. Acta Odontol Scand 2017 May;75(4):294-301 [FREE Full text] [doi: 10.1080/00016357.2017.1297849] [Medline: 28270029]
23. Andersson G, Rozental A, Shafran R, Carlbring P. Long-term effects of internet-supported cognitive behaviour therapy. Expert Rev Neurother 2018 Jan;18(1):21-28 [FREE Full text] [doi: 10.1080/14737175.2018.1400381] [Medline: 29094622]
24. Berg Johnsen I, Wichstrøm L, Dahllöf G. Prevalence and stability of blood-injection-injury phobia in childhood-a prospective community study in Norway. Acta Paediatr 2024 Jan;113(1):105-112 [FREE Full text] [doi: 10.1111/apa.17003] [Medline: 37850719]
25. Pegg S, Hill K, Argiros A, Olatunji BO, Kujawa A. Cognitive behavioral therapy for anxiety disorders in youth: efficacy, moderators, and new advances in predicting outcomes. Curr Psychiatry Rep 2022 Dec 12;24(12):853-859 [FREE Full text] [doi: 10.1007/s11920-022-01384-7] [Medline: 36370264]
26. James AC, Reardon T, Soler A, James G, Creswell C. Cognitive behavioural therapy for anxiety disorders in children and adolescents. Cochrane Database Syst Rev 2020 Nov 16;11(11):CD013162 [FREE Full text] [doi: 10.1002/14651858.CD013162.pub2] [Medline: 33196111]

Abbreviations

BAT: Behavioral Avoidance Test
CBT: cognitive behavioral therapy
CFSS-DS: Children's Fear Survey Schedule – Dental Subscale
CNCD: Children's Negative Cognitions in Dentistry
DAWBA: Development and Well-Being Assessment
DBS: dental behavior support
DFA: dental fear and anxiety
DP: dental phobia
DSM: Diagnostic and Statistical Manual of Mental Disorders
GLM: generalized linear model
ICBT: internet-based cognitive behavioral therapy
IP: injection phobia
IPSC: Injection Phobia Scale for Children
K-SADS-PL: Kiddie Schedule for Affective Disorders and Schizophrenia for School-Age Children – Present and Lifetime
PG-BAT: Picture-Guided Behavioral Avoidance Test
P-SEQ-DA: Parental Self-Efficacy Questionnaire for Dental Anxiety
RCT: randomized controlled trial
SEQ-SP: Self-Efficacy Questionnaire for Phobic Situations
VAS: Visual Analog Scale

XSL•FO
RenderX

Edited by S Badawy; submitted 09.07.25; peer-reviewed by H Buchanan, M Nadia; comments to author 05.08.25; revised version received 23.08.25; accepted 10.09.25; published 17.09.25.

Please cite as:
Schibbye R, Hedman-Lagerlöf E, Kaldo V, Dahllöf G, Shahnavaz S
Internet-Based Cognitive Behavioral Therapy for Children and Adolescents With Dental or Injection Phobia: 1-year Follow-Up Assessment
JMIR Pediatr Parent 2025;8:e80376
URL: https://pediatrics.jmir.org/2025/1/e80376
doi:10.2196/80376
PMID:

©Robert Schibbye, Erik Hedman-Lagerlöf, Viktor Kaldo, Göran Dahllöf, Shervin Shahnavaz. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 17.09.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Promoting Family Engagement With Early Childhood Developmental Screening via the Baby Steps Text Messaging and Web Portal System: Longitudinal Randomized Controlled Trial

Hyewon Suh, PhD; Julie A Kientz, PhD

Human Centered Design and Engineering, University of Washington, Sieg 428, Box 352315, Seattle, WA, United States

Corresponding Author:
Julie A Kientz, PhD
Human Centered Design and Engineering, University of Washington, Sieg 428, Box 352315, Seattle, WA, United States

Abstract

Background: Approximately 1 in 6 US children has a developmental disability. Early detection is crucial but often delayed, especially in families with limited access to resources. Current paper-based screening methods, such as the Ages and Stages Questionnaire, face challenges such as cultural barriers and timing issues. Digital tools can improve parent engagement and screening accuracy. This research explores new technologies to enhance long-term parent involvement in developmental screening.

Objective: The study aims to understand whether features of a digital intervention specifically designed to engage parents in developmental screening are effective over a long-term period.

Methods: Parents of children between 7 and 12 months old were recruited through flyers at clinics and libraries, mailing lists, and social media, and then they self-enrolled after eligibility screening. We conducted a randomized controlled trial with 139 families over 20 months, along with follow-up interviews and surveys. The intervention consisted of an interactive web portal that combined developmental and sentimental record-keeping, family-friendly visualizations, and the ability to answer screening questions via multiple modalities (eg, text messaging and web), without involvement of health care providers. The control condition consisted of a web-based portal with no specific engagement features, modeled after standard web-based developmental screening tools.

Results: Overall, we enrolled 67 parents in the control group and 72 parents in the experimental group, for a total of 139 enrolled participants. Several parent engagement strategies we deployed in the experimental group were effective in increasing milestone questionnaire completion, with text messaging standing out as the most impactful and efficient, offering the highest return relative to the effort required for its development and implementation. Overall, the experimental group demonstrated a 44% higher average response rate compared to controls (t_{125}=−3.32, P<.01). Participants in the experimental group submitted significantly more timely and valid responses, after text messaging was introduced (phase 2: 95% vs phase 1: 71%; t_{107}=−4.44, P<.01), which is a critical factor for effective and timely tracking of child development. The experimental group participants responded to more questions on average (mean 127.60, SD 49.01) than those in the control group (t_{70}=−7.23, P<.01) in phase 2 as well. In addition, study completion rates were significantly higher in the experimental group (83% vs 30%; t_{119}=−8.40, P<.01), indicating greater long-term engagement. Sentimental record-keeping features showed promise but limited use, suggesting the need for integration with tools parents already use.

Conclusions: This study demonstrates that a human-centered design approach for technology-based interventions can significantly enhance parent engagement and completion rates of developmental screening questionnaires. However, further research is needed with a larger sample to determine whether such features effectively prompt parents to seek early intervention services. Future studies should focus on engaging more diverse and underserved populations to validate these findings.

(JMIR Pediatr Parent 2025;8:e73443) doi:10.2196/73443

KEYWORDS

developmental screening; human-centered design; text messaging; mHealth; patient engagement

XSL•FO
RenderX

Introduction

Background

Approximately 1 in 6 children between the ages of 3 and 17 in the United States are diagnosed with a developmental disability, such as autism, attention-deficit hyperactivity disorder, or intellectual disabilities [1]. The earlier developmental delays are detected, the sooner early interventions can start, which can result in better outcomes for these children [2]. Unfortunately, approximately half of the children who eventually receive a diagnosis of developmental delay are not identified until they reach kindergarten in the United States [3], with lower-income populations being missed at a higher rate [4]. Regular screening of child development is one of the primary mechanisms for early detection of many types of developmental disabilities.

The current approach for screening for developmental progress asks parents or primary caregivers a series of questions about a child's abilities in areas such as gross motor, communication, and problem-solving. For example, "does your baby say two-syllable sounds, such as 'da-da' or 'ga-ga'?" or "can your child walk upstairs while holding onto a railing?" A popular screener tool, the Ages and Stages Questionnaire (ASQ), consists of 22 questionnaires with 30 questions each across the child's first 5 years [5]. The screener is administered via paper or through a website, often at Well-Child Visits with the child health care providers, by childcare providers, through community-based services, or by parents self-monitoring their child's development. There are some limitations to using milestone questionnaires for screening, such as questions not being culturally competent, language or literacy barriers, or the potential for parent anxiety when tracking their child's development [6]. However, developmental questionnaires are currently the most effective method for screening according to the American Academy of Pediatrics [7].

A major challenge with paper-based or even web-based screener surveys is that it is often difficult to ensure that parents complete each survey, especially if families are not regularly attending Well-Child Visits or are not yet connected to a Medical Home [7]. Given that Well-Child Visits are months to up to a year apart depending on the child's age, these visits may not be the best timing for conducting timely screens. In addition, when parents answer screener questions in a single sitting in a time- and resource-constrained setting, such as in their child health care provider's waiting room, they may not have the opportunity to try each activity with their child, such as drawing shapes on a piece of paper or interacting with a mirror. Also, busy or overwhelmed parents may just not have the time or available cognitive load to use paper- and web-based systems [8].

Digital interventions that can help prompt parents to answer questions at more regular intervals have the potential to encourage more complete and accurate responses, better patient engagement [9], and parent awareness of their child's activities. Because child development takes place in daily life outside of traditional clinical settings, parents' and caregivers' reports of the early signs of developmental delay are the most reliable way to track them [10]. Therefore, it is important to engage, inform, educate, and empower parents to track and assess their child's development in easier ways to make developmental screening more accessible, accurate, and meaningful. Human-centered design researchers have designed interactive digital tools that can promote this engagement [11-16]. However, there are limitations with standalone software or mobile apps, such as requiring the parent to remember to open the app to answer questions or device compatibility. Even with proactive notifications or email reminders, parents may still not engage as easily and as often as they might otherwise. Because these screening tools are intended to be used over a long period (eg, up to 5 years), they require specifically considered methods to maintain parent engagement over the long term.

Researchers in the computing, health informatics, and medical fields have focused on the usability and feasibility of technology-based interventions designed for use between and outside of clinic visits. Mobile health (mHealth) interventions, in particular, have been introduced to support various health domains for children [15], such as:

1. Providing pregnant mothers with information about pregnancy and newborns [17-19]
2. Promoting healthy infant feeding for obesity prevention [20]
3. Sending infant vaccine reminders [21]
4. Delivering speech developmental education [22]
5. Developmental monitoring and screening [23,24]

However, the long-term impact of mHealth interventions is not well understood due to the limited study periods of deployment studies, and further research is needed to establish long-term effectiveness. For example, Stowell et al [25] highlighted that engaging in extended interactions with participants through formative work can prevent researchers from making premature judgments and conclusions. This approach allows for a deeper understanding of the populations and their contexts. They also emphasized that without prolonged and thorough formative work, researchers might design evaluations based on a superficial understanding of the community's challenges, attitudes, and resources, which can impact health inequities.

In this research, we aimed to (1) develop and evaluate novel techniques for leveraging interactive technology to engage parents in the developmental screening process and (2) assess the immediate and long-term effects of the designed systems in fostering family engagement with early childhood developmental screening.

Design of Baby Steps Web Portal and Text Messaging Intervention

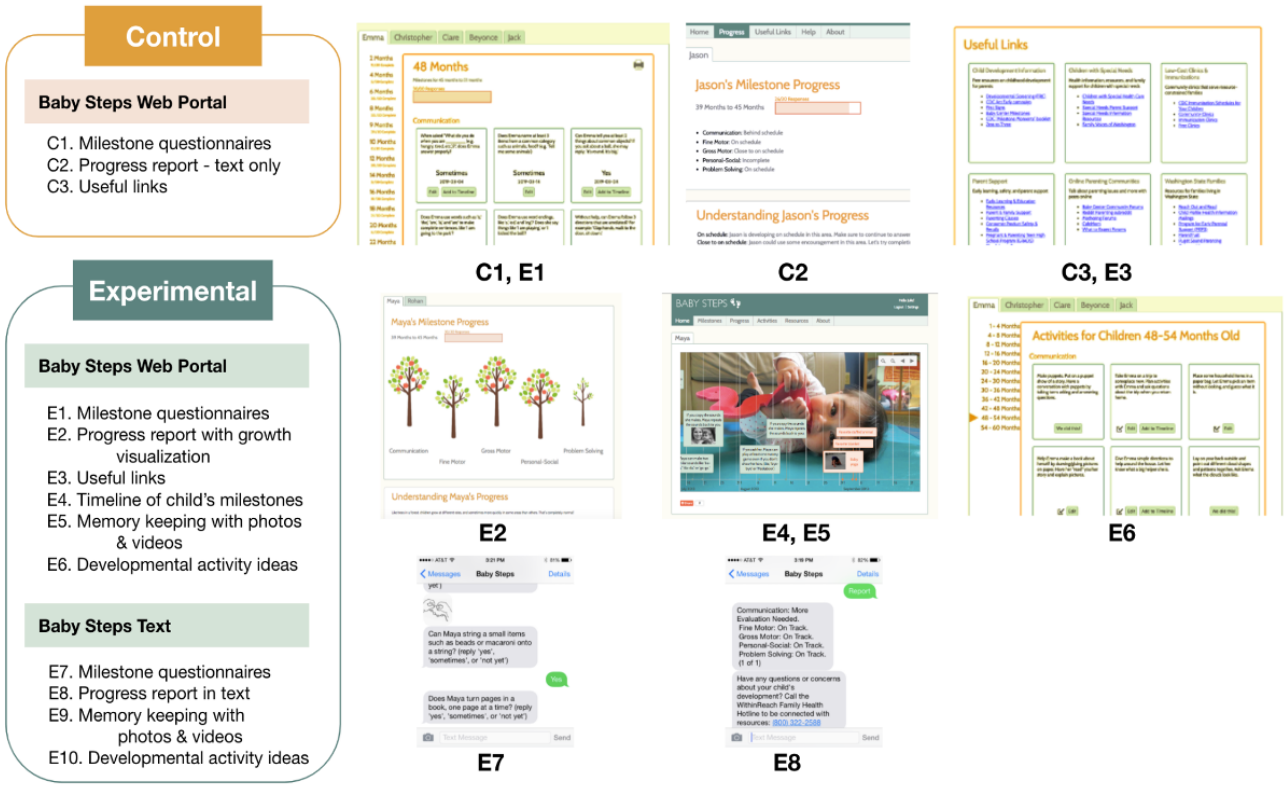
Based on preliminary research with key stakeholders [8,11,23], we identified potential methods for engaging families in the developmental screening process that would be combined in a new digital intervention called Baby Steps. We hypothesized that 3 key design features would help increase parent engagement in the screening process: (1) engaging visualizations to help families interpret results and guide them to appropriate actions, such as completing developmental activities or connecting with early intervention for evaluations; (2) combining developmental screening with sentimental record-keeping, such as keeping track of memories and fun

XSL•FO
RenderX

activities; and (3) multiple, integrated ways to complete screening questionnaires (eg, via web or text messaging). Our goal was to understand whether these engagement features would lead to increased screening completion rates and thus ultimately lead to more connections to early support services if needed.

We designed and implemented 2 versions of Baby Steps that would allow us to test these design features. We designed the control version of Baby Steps to be as close as possible to the current standard of care, which consists of neutral, web-based developmental screening questionnaires with text-based feedback on child progress. The experimental version of Baby Steps included additional features that tested our design hypotheses, such as tracking sentimental information and photos on the baby's timeline, suggestions for activities that parents can do with their child to promote development, family-friendly visualizations of child's progress that promote a growth mindset of development, and integration of text messaging prompts to complete milestone questionnaires that would synchronize with data on the web portal. Figure 1 shows the differences in features between the 2 versions, along with screenshots of those particular features. (The baby photo on the website screenshot was used with parental consent.)

Figure 1. Baby Steps feature differences between control and experimental groups with screenshots. Photo of child included with parents' consent.



Methods

Recruitment and Participants

We recruited parent participants via mailing lists, flyers posted in family-centered locations such as libraries, advertisements on social network services targeting parents of young children in Washington State, postings on local parenting lists, flyers at state-wide Women, Infants, and Children (WIC) clinics, and the University of Washington Communication Studies Participant Pool. We aimed to recruit parents who had a child between 7 and 12 months old, lived in Washington state, and were proficient in English to read and respond to milestone questions on the web portal. To ensure all participants meet the criteria, potential participants completed a screener survey. We recruited on a rolling basis, with the entire recruitment period taking about 7 months. To examine how specific design elements of the intervention affected self-monitoring behavior, we used a between-subjects design. A total of 180 participants completed the screener survey, and 139 were deemed eligible to enroll based on the age of the child and residing within Washington State. The first author used a random number generator to randomly assign participants to each group—if the generated number was odd, participants were assigned to the control group; if it was even, they were assigned to the experimental group. We then invited them to enroll in the study. Overall, we enrolled 67 parents in the control group and 72 parents in the experimental group, for a total of 139 enrolled participants.

Study Procedure

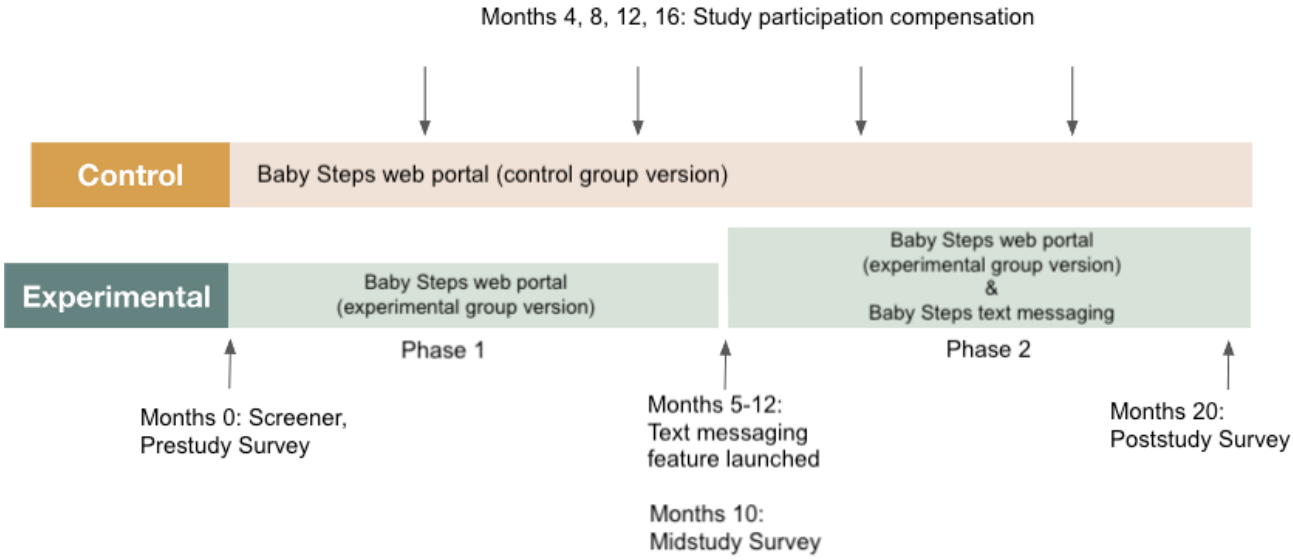
Upon enrollment in the study, participants signed a web consent form and completed a prestudy survey on family demographics, child demographics, current parenting experience, and technology use. We then sent an invitation email to participants to create accounts and register on the Baby Steps web portal. The invitation email contained a brief introduction to the Baby Steps system, information about child development, and details on the study procedure, including the compensation plan. It also included an invitation code to use for portal registration, which

XSL•FO
RenderX

was different for the control group and the experimental group. Depending on which invitation code was entered during registration, participants were exposed to 2 different web portal features as laid out in Figure 1. To study natural and realistic usage, we told our participants they could use Baby Steps as much or as little as they wanted, and we minimized interactions with the research team to allow for naturalistic use. Parents used Baby Steps to answer child developmental questionnaires, without involvement of health care providers. To encourage regular developmental screening, we included a paragraph noting to participants that if they did not interact with the Baby Steps system for more than 60 consecutive days, we might consider them to have withdrawn from the study and would send the exit package with a prorated incentive up to that point. However, we did not drop any participants until they reached the 12-month participation mark.

To track Baby Steps usage, we instrumented the Baby Steps website with timestamped logging that allowed us to see which features were accessed by which participants and when. Due to some technical difficulties initially in the system development, the text messaging option for the experimental group could not be launched at the start of the study. Depending on when a participant started their participation, text messaging was introduced between 5 and 12 months into the study (Figure 2). When text messaging became available, the research team emailed the experimental group to introduce it and provided an instruction sheet. In total, 52 of the 72 experimental group participants registered their mobile phone numbers and began receiving milestone questions via text messages. This enabled us to also collect within-subjects data points from the experimental group and compare specific design characteristics of the web portal and text messaging. We will refer to the experimental group before text messaging as phase 1 and after text messaging as phase 2.

Figure 2. Overview and timeline of Baby Steps study.



During the study, researchers only interacted with participants: (1) to send periodic compensations, (2) to introduce the text messaging option when it became available for the experimental group, and (3) to send a midstudy survey at 10 months. The midstudy survey was designed to receive participant feedback on their experience with Baby Steps, and 118 participants (54 in the control group and 64 in the experimental group) out of 139 enrolled participants completed the survey. At the end of the 20 months, we sent a poststudy survey to all 139 enrolled participants, regardless of how much of the study they had completed and received overall 87 responses (30 from the control group and 57 from the experimental group). Participants received a $20 Amazon.com gift card each at 4-, 8-, 12, 16-, and 20-month completion and a $10 Amazon.com gift card for each survey completion. In addition, participants who completed the entire 20-month study received a $20 Amazon.com gift card completion bonus. Participants who participated in a poststudy interview also received a $20 Amazon.com gift card.

We also partnered with WithinReach Washington [26], a local nonprofit organization and statewide Help Me Grow affiliate [27] that serves many low-income families and maintains a toll-free parent hotline number for parents to answer questions or address concerns about child development. The web portal's progress report page directed parent participants to contact their child's health care provider or the Help Me Grow Washington parent hotline for both the experimental and control conditions, as did the text message progress report in the experimental condition. We worked with WithinReach to cross-reference the names of study participants with parents who had registered with their system to analyze whether parents had reached out as a result of using either version of Baby Steps.

Analysis

Data analysis focused on evaluating the impact of the Baby Steps intervention on parent engagement and the completion of developmental screening questionnaires over a long-term period. We used system usage logs and a survey to assess these. Given the importance of timely tracking of child development, we first separated responses based on whether parents completed milestone questions within the appropriate age range (responses within the valid time window vs those outside it). We then separated sources of response (website vs text messaging). Because the text messaging option was introduced later in the

XSL•FO
RenderX

study, we were able to collect within-subjects data points for the experimental group (phase 1 vs phase 2) as well as between-subjects data (control group vs experimental group; and experimental group who used text messaging in phase 2 vs those who did not use). Descriptive analyses were used to analyze quantitative systems. Where appropriate, quantitative analysis was performed using *t* tests to compare the groups. For qualitative data from 3 surveys (intro, midstudy, and exit) and interviews, we conducted rapid qualitative analysis to identify key themes. These analyses aimed to determine the effectiveness of the design intervention in enhancing engagement and adherence to developmental screening protocols over the long term.

Ethical Considerations

This study was reviewed and approved by the Institutional Review Board of the University of Washington (IRB 49545). All participants gave informed electronic consent before enrolling in the study and were informed about their right to opt out at any time. Participants received a US $20 Amazon.com gift card each at 4-, 8-, 12, 16-, and 20-month completion and a US $10 Amazon.com gift card for each survey completion. In addition, participants who completed the entire 20-month study received a US $20 Amazon.com gift card completion bonus. Participants who participated in a poststudy interview also received a US $20 Amazon.com gift card.

Results

Participant Demographics

Table 1 shows primary parent participant demographics across both groups. Despite our statewide recruitment efforts, the majority of the participants were from the greater Seattle, Washington metropolitan area. Our sample also overrepresents mothers and individuals from higher socioeconomic status compared to the general Washington State population (eg, education and income) [28], though it is closer to the average demographics for Seattle, WA, where the median household income is $118,745 and 38.1% have bachelor's degrees and 31.9% have graduate degrees [29]. The sample does underrepresent the racial and ethnic diversity of the state as well as Seattle, especially that of Black, Hispanic, American Indian or Alaska Native, and Native Hawaiian or Pacific Islander families. This may have been a result of our lack of resources to provide the intervention and study materials in languages other than English. The complete participant flowchart is depicted in Figure 3.

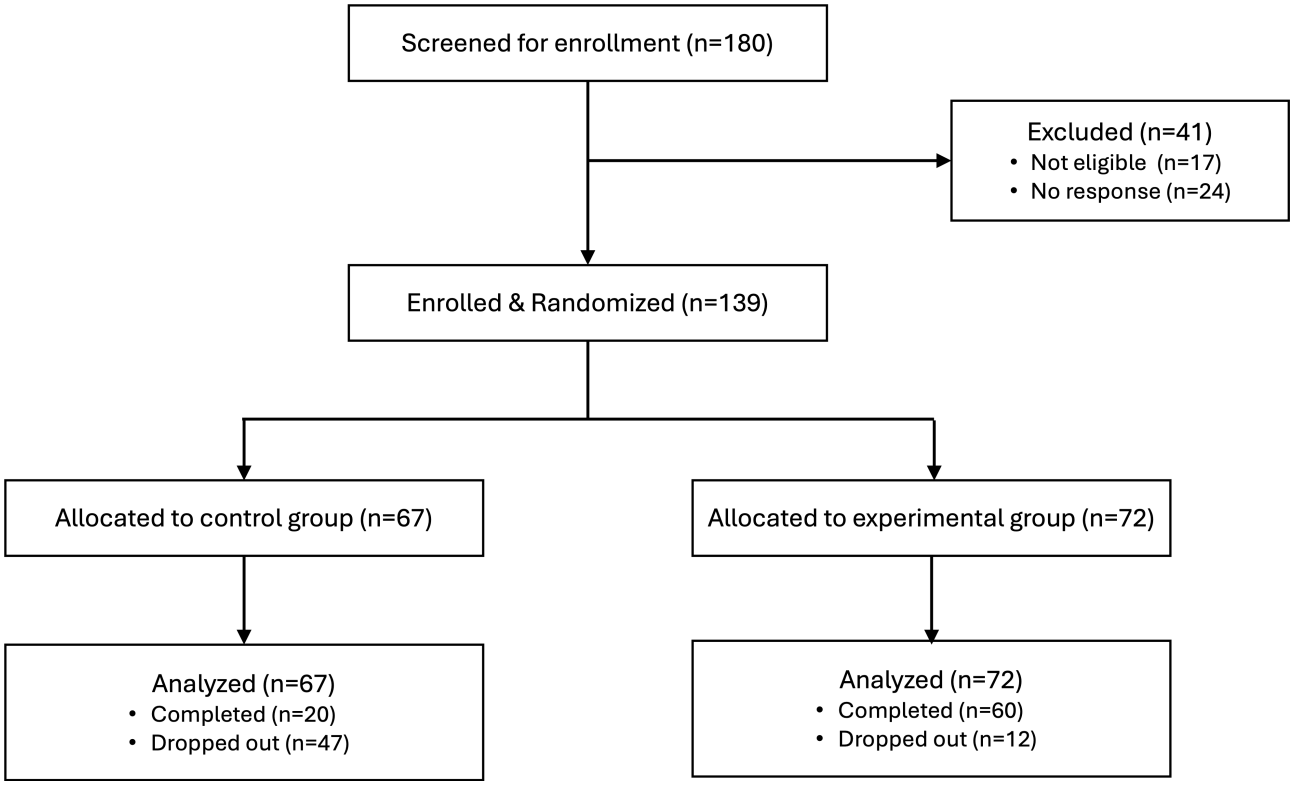
XSL•FO
RenderX

Table . Participant demographics (N=139).

Characteristics	Number of participants, n (%)
Relationship to child	
Mother	134 (96.40)
Father	5 (3.59)
Number of children in family	
1	84 (60.43)
2	43 (30.94)
3	1 (0.72)
4 or more	11 (7.91)
Age of primary parent	
18 - 24	8 (5.76)
25 - 30	35 (25.18)
31 - 40	87 (62.59)
41 - 50	9 (6.47)
Marital status	
Married or partnered	131 (94.24)
Divorced or separated	2 (1.44)
Single, never married	5 (3.60)
Engaged	1 (0.72)
Education level of primary parent	
Less than 12th grade	1 (0.72)
High school or high school equivalency credential	4 (2.88)
Some college	17 (12.23)
College degree	58 (41.73)
Graduate degree	59 (42.45)
Parent Race or Ethnicity	
White	116 (74.84)
Asian	12 (7.74)
Hispanic or Latino	10 (6.45)
Black or African American	3 (1.94)
Other	5 (3.23)
Prefer not to say	9 (5.81)
Household income	
Less than US $15,000	5 (3.60)
US $15,000-$34,999	5 (3.60)
US $35,000-$49,000	10 (7.19)
US $50,000-$74,999	25 (17.99)
US $75,000-$99,999	22 (15.83)
Greater than US $100,000	61 (43.88)
Prefer not to say	11 (7.91)

XSL•FO
RenderX

Figure 3. CONSORT (Consolidated Standards of Reporting Trials) flow diagram for the study.



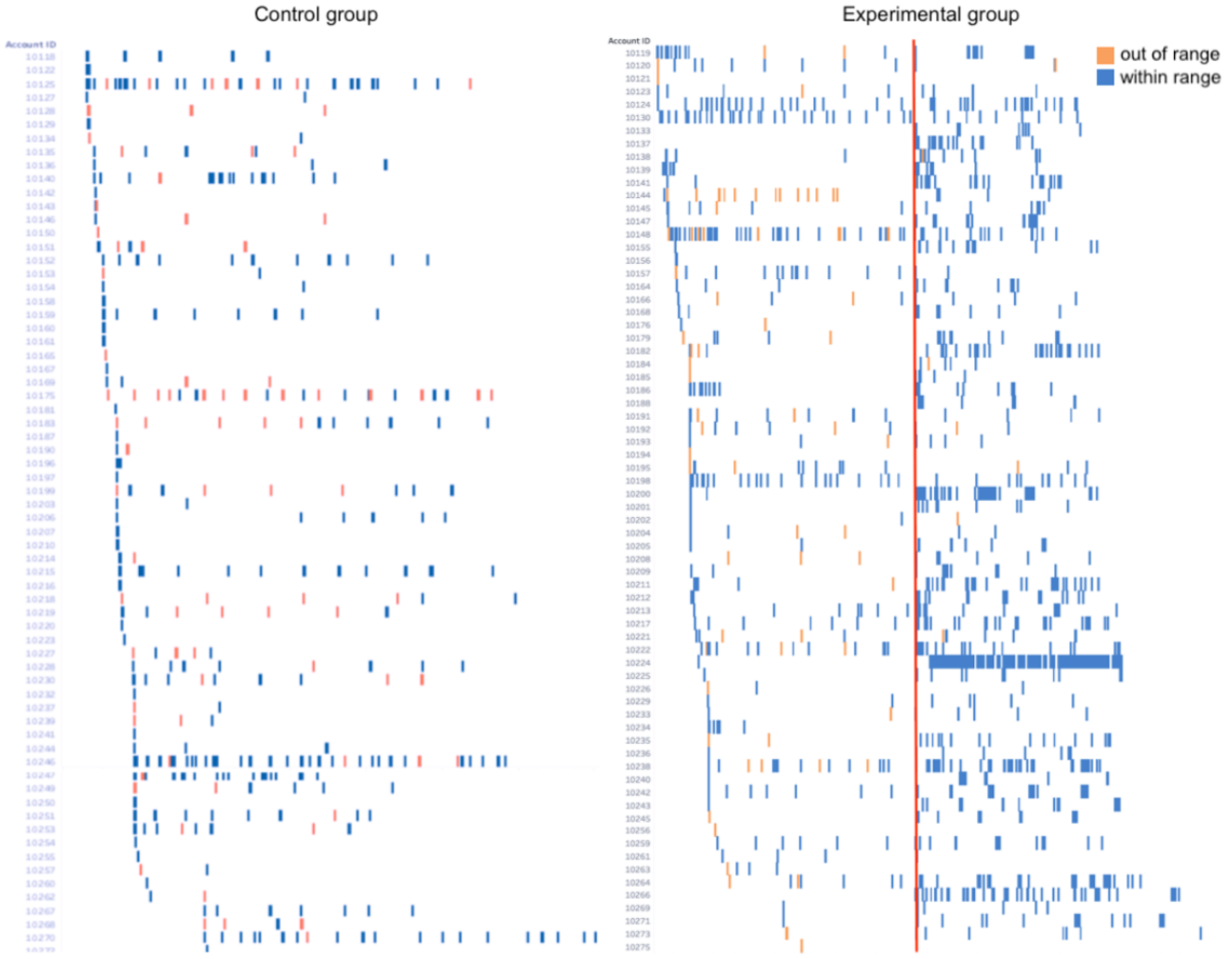
Developmental Screening Questionnaire Responses

There was a statistically significant difference between 2 groups in terms of screening questionnaire response rates (t_{125}=−3.32, P<.01, 2-tailed). The experiment group yielded a total of 15,619 responses (mean 216.93, SD 102.42, median 205, [IQR] 145.75-306) compared to the control group's 10,075 responses (mean 150.37, SD 130.95, median 90, [IQR] = 30-240), resulting in 44% more responses per participant on average. In addition, while there was no control group participant who updated their answers to questions (eg, changing "not yet" to "sometimes" or "yes") when their child became able to meet the milestone, 20/72 (28%) experimental group participants updated their answers to questions, and 95% of those updates were made within the valid time range, indicating the experimental group participants were more engaged in monitoring their child's development beyond answering milestone questions just once.

Figure 4 shows chromograms of responses to developmental questionnaires over the study period. Chromograms are a visualization technique used to detect and present patterns in large datasets [30]. This allows us to show the milestone response patterns of participants in each group over 20 months in one figure. In the figure, the left side represents the control group, and the right side represents the experimental group. Within each side, each participant is a row, and each column represents a day of the study. Because each questionnaire of ASQ is designed for a specific age range, answering outside of the valid age range may not accurately reflect a child's development. We used blue to indicate responses recorded within the valid time range and orange to indicate responses recorded outside the valid time range (eg, the 9-month-old questionnaire was completed after the child was already 12 months old). The date at which text messaging was introduced for the experimental group is highlighted with a red line.

XSL•FO
RenderX

Figure 4. Chromograms of responses to developmental questionnaires over the entire study period. Blue lines indicate questions completed within the correct time range; orange lines indicate questionnaires completed outside of the recommended time range.



Follow-Up With Providers Based on Screening Results

Another goal of this longitudinal study was to determine whether the experimental version of Baby Steps could nudge parents to follow up with child health care providers or early intervention services when the progress report indicated that more evaluation may be needed. The experimental group checked the web-based progress report 1.3 times more often than the control group (8.14 times per participant for the control group vs 10.46 times per participant in the experimental group) but this difference was not statistically significant. In addition, when we cross-referenced the list of study participants with the names of parents who had contacted WithinReach, there were only 6 total study participants that matched names with the WithinReach database (3 from the control group and 3 from the experimental group), and their contact had happened prior to the study, indicating that there was no participant who contacted WithinReach with concerns as a result of using Baby Steps. However, we did learn from our qualitative survey and interview responses that several participants in the experimental group contacted their child's health care providers after reviewing the progress reports in Baby Steps.

> *"Used this data to discuss delays with pediatrician, got referrals to early intervention services for therapy and other developmental delays and child will be starting developmental preschool next month with an IEP."* [(E20)]

> *"On one occasion, he was delayed in his development (based on the progressreport) and at his doctor's well check appointment I brought it up and after some tests, it was discovered that my child had iron deficiency. He was prescribed a supplement and right after, my son's condition improved, and he eventually caught up to his development milestone. I would not have discovered or noticed the iron deficiency if not for the app"* [(E34)]

Engagement With Sentimental Memory Tracking and Timeline

We hypothesized that adding sentimental memory keeping to developmental tracking would help engage parents in a strength-based approach [31] to development rather than a deficit-focused one by allowing them to celebrate meaningful events in their child's development (eg, first steps, first zoo visit, etc), which could help reduce emotional burden and promote positivity and resilience. However, memory keeping was not frequently used by the participants. Only 44/72 (61%) experimental group parents logged memories at least once, and of those, 23 (32%) used this feature 3 times or fewer. In the poststudy survey and interview, participants expressed

XSL•FO
RenderX

uncertainty about keeping their memory logging data in the long term as a barrier to the usage of the feature.

> *"I was not clear on how the information was going to be retained. At first, I was using the site every few days to track new developments, but then I realized that I probably wasn't going to be able to keep the data. There was no option for printing it or saving it, so I ended up transitioning to a paper baby book instead."* [(E27)]

However, several participants in the control group suggested adding a memory-keeping feature to the Baby Steps system, implying a desire for combining developmental tracking with sentimental memory keeping.

> *"(I want a) place to save photos of them [a child] attempting the tasks"* [(C26)]

> *"It would be nice to have a record of when my child was able to do some of the tasks at each milestone"* [(C3)]

Engagement With Web Portal Versus Text Messaging for Questionnaire Completion

Between-Subject Comparisons: Control Group Versus Experimental Group

While there was no statistically significant difference in the milestone question response rate between the control group and experimental group rate in phase 1, there was a statistically significant difference between the groups in phase 2, when 88% of the experimental group responses were from text messaging (t_{136}=−7.71, P<.01). Five experimental group participants who answered fewer than 5 milestone questions via the website over 10 months of participation answered over 100 milestone questions respectively after text messaging was added in (in less than 10 months). This indicates that the introduction of text messaging significantly increased long-term participant engagement in the experimental group.

Also, before the text messaging option was introduced, the experimental group answered more questions within the valid time window than the control group (86% of the experimental group's responses vs 72% of the control group's responses) but the difference between the groups was not statistically significant. However, since the introduction of the text messaging option, the experimental group responses were statistically significantly more within a valid range (t_{135}=−7.90, P<.01). Thus, the addition of text messaging improved the timeliness and validity of responses in the experimental group.

Between-Subjects Comparison: Experimental Group With Text Messaging Versus Without

The positive effect of using text messaging was evident again when we compared the experimental group who used text messaging in phase 2 (n=52) versus the experimental group who did not use text messaging in phase 2 (n=20). There was a statistically significant difference between the 2 groups (t_{70}=−7.23, P<.01). The group that used text messaging answered 127.60 questions on average (SD 49.01, median 120 (IQR) 90.75-150), while the group that did not use text messaging answered 36.85 questions on average (SD 44.07, median 15.5 (IQR) 0-67.25), resulting in 246.27% more responses per participant on average. These findings underscore the substantial impact of text messaging on increasing participant response rates over time.

Within-Subjects Comparison (Phase 1 vs Phase 2)

In addition to between-subjects differences, when we compared within-subjects data of experimental group participants in phase 1 versus phase 2, the experimental group participants answered more milestone questions within the valid range in phase 2 (95%, 7279/7639) compared to phase 1 (71%, 5691/7980); t_{107}=−4.44, P<.01. This within-subjects comparison further confirms the effectiveness of text messaging in enhancing response validity over time.

Overall, these findings demonstrate that the introduction of the text messaging option significantly enhanced long-term adherence among participants. This method not only increased the number of milestone questions answered but also improved the timeliness and validity of responses. Consequently, text messaging proved to be an effective tool for more accurate and timely tracking of child development, as reconfirmed by the positive feedback in the survey responses.

> *"LOVED the text portion. It's so easy to get side tracked with kids and constantly forget. I needed to text prompts and it made it easy to participate."* [(E23)]

> *"Text was much much better, so easy to use and good for on the go. Gave me fun ideas to try in the moment as well."* [(E45)]

Overall Engagement and Completion of the Study

Finally, we ran descriptive statistics and compared general usage patterns between the 2 groups, and there was a significant difference in study completion rates. While only 30% (20/67) of the control group finished the entire 20-month study, 83% (60/72) of the experimental group remained enrolled in the study through the end (t_{119}=−8.40, P<.01, 2-tailed), suggesting the experimental group study design was successful in engaging parents over a long period of time.

Discussion

Principal Findings

In this research, we aimed to (1) design and evaluate new approaches that use interactive technology to involve parents in the developmental screening process and (2) examine long-term impacts of these systems on promoting family engagement with early childhood developmental screening. Overall, design features to explicitly engage parents over time implemented in Baby Steps increased engagement and screening questionnaire completion rates. As early child developmental screening requires continuous monitoring over the first 5 years of a child's life, it is promising that a large number of the experimental group participants were able to complete the 20-month study. However, the study was inconclusive regarding whether greater engagement led to connections to early intervention resources, and thus more research may be needed

XSL•FO
RenderX

to understand what design features, if any, might prompt parents to follow up on making those connections. Because there were a very small number of cases, it is premature to conclude whether the differences in progress reports (text vs visualization) made a difference in follow-ups, but it is promising to know the progress reports were successful in triggering follow-up actions with their child's health care providers for several parents.

The introduction of text messaging seemed to be a clearer success. We acknowledge that the proactive notifications that drew people to engage with the system were a big part of this, which prior research has also identified as important [32,33], and we also believe this success is due to the integration into a communication mechanism that is frequently used by parents already, which has been advocated for as a way to lower barriers to access [34] and can increase accessibility for lower-income populations without access to higher-end digital devices and data plans [35,36]. We believe that being able to answer milestone questions directly via text message, as opposed to just text-based reminders to log into the website, was a useful implementation of this feature that would benefit from further exploration.

More research is also needed to better understand the role that combining developmental screening with sentimental memory keeping can play in parent engagement. Although we saw low use of this feature overall, numerous parents reported finding the idea to be promising. However, because Baby Steps was separate from other ways that they tracked their baby's sentimental milestones in baby books or using social media, the feature could be improved to better integrate with families' needs. Adding the option to print information as physical books or integrate with Facebook or Instagram, which parents already frequently use to share information about their child with others [37] and benefit from [38,39], could be a promising next step.

Limitations

Our study shows promising results for improving parent engagement with developmental screening, but this study is not without its limitations. Despite our best efforts for a broad recruitment approach, most of our study's participants were of a higher socioeconomic status and less racially or ethnically diverse than the general population of Washington State [28]. It is known that many resource-constrained populations, such as low-income or immigrant families, lack the insurance to cover Well-Child Visits, frequently move, or face language barriers that make it difficult to access information about normal child development, and they often struggle because they may not be aware of what to monitor [40,41]. Therefore, further research is needed to examine the efficacy of interventions and monitor outcomes in larger, more diverse populations. As a follow-up to this work, the research team has started work via a community-based participatory research approach [42] to ensure that both technology designs and study designs better fit the needs of people from marginalized communities and to better understand how systems such as Baby Steps can fit into a broader macrosystem of care [43], including pediatric practices, community organizations, childcare providers, and public health organizations. Another limitation is that the ASQ currently has a cost per screen associated with it that we paid as part of our study's grant. Future work could use an open-source screening tool, such as the Survey of Wellbeing in Young Children [44].

Conclusions

This paper describes the findings from a long-term, randomized controlled trial of a novel technology-based intervention aimed to engage parents of children aged 0 - 5 in the process of developmental screening. We enrolled 139 parent participants over a 20-month period and randomly assigned parents to use one of 2 versions of the system: one being a neutral, web-based screening questionnaire tool that mimics current standards for web-based developmental screening, and one that followed a human-centered design process to develop features aimed to engage parents in developmental screening over the long term. Our study determined that the version of the system designed via a human-centered process resulted in twice as many people completing the full study and engaged parents significantly more in completing timely developmental screening questionnaires. However, it was inconclusive whether the designed features would prompt parents to take actions such as engaging in activities to promote development or engaging with early intervention services if needed, as the overall number of children in the study who fell below the cutoff for developmental concerns was small. This study provides evidence that human-centered design methods for designing technology-based interventions can lead to systems that are engaging and improve the completion of developmental screening questionnaires. More community-based design research is needed to understand how to better engage families from more underserved communities.

Acknowledgments

This work was primarily funded by the National Science Foundation (Award no. 0952623) with supplemental funding from the University of Washington Innovation Fund and Provost's Bridge Funding. The authors have no competing interests to declare. We acknowledge Alexis Hiniker, John Porter, Robert Racadio, and Yi-Chen Sung for their contributions to the design and development of the Baby Steps web portal and text messaging system. We also acknowledge Within Reach for assisting us with data collection from participants who reached out to their Help Me Grow hotline. This work was reviewed and approved by the University of Washington Human Subjects Division.

Conflicts of Interest

None declared.

XSL•FO
RenderX

Checklist 1
CONSORT-EHEALTH (V 1.6.1) checklist.
[PDF File, 1032 KB - pediatrics_v8i1e73443_app1.pdf]

References

1. Zablotsky B, Black LI, Maenner MJ, et al. Prevalence and trends of developmental disabilities among children in the United States: 2009-2017. Pediatrics 2019 Oct;144(4):e20190811. [doi: 10.1542/peds.2019-0811] [Medline: 31558576]
2. Landa RJ. Efficacy of early interventions for infants and young children with, and at risk for, autism spectrum disorders. Int Rev Psychiatry 2018 Feb;30(1):25-39. [doi: 10.1080/09540261.2018.1432574] [Medline: 29537331]
3. Maenner MJ, Shaw KA, Baio J, et al. Prevalence of autism spectrum disorder among children aged 8 years - Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2016. MMWR Surveill Summ 2020 Mar 27;69(4):1-12. [doi: 10.15585/mmwr.ss6904a1] [Medline: 32214087]
4. Baskin ML, Ayoob KT, Jain A, Rao G, Woolford SJ. Improving access to care for African-American and Latino children and adolescents: barriers and opportunities. Child Obes 2010 Aug;6(4):177-183. [doi: 10.1089/chi.2010.0415]
5. Barba P, Rizzo I, Serrano AM. Ages and Stages Questionnaires, a facilitator system of parental involvement and knowledge of child development. RPTF 2015 Dec 1;04:21-27 [FREE Full text] [doi: 10.21281/rptf.2015.04.04]
6. Garg P, Ha MT, Eastwood J, et al. Health professional perceptions regarding screening tools for developmental surveillance for children in a multicultural part of Sydney, Australia. BMC Fam Pract 2018 Apr 2;19(1):42. [doi: 10.1186/s12875-018-0728-3] [Medline: 29609547]
7. Council on Children With Disabilities, Section on Developmental Behavioral Pediatrics, Bright Futures Steering Committee, Medical Home Initiatives for Children With Special Needs Project Advisory Committee. Identifying infants and young children with developmental disorders in the medical home: an algorithm for developmental surveillance and screening. Pediatrics 2006 Jul 1;118(1):405-420. [doi: 10.1542/peds.2006-1231]
8. Kientz JA, Arriaga RI, Chetty M, et al. Grow and know: understanding record-keeping needs for tracking the development of young children. Presented at: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems; Apr 28 to May 3, 2007; San Jose California US. [doi: 10.1145/1240624.1240830]
9. Nahum-Shani I, Shaw SD, Carpenter SM, Murphy SA, Yoon C. Engagement in digital interventions. Am Psychol 2022 Oct;77(7):836-852. [doi: 10.1037/amp0000983] [Medline: 35298199]
10. Marshall J, Coulter ML, Gorski PA, Ewing A. Parent recognition and responses to developmental concerns in young children. Infants Young Child 2016;29(2):102-115. [doi: 10.1097/IYC.0000000000000056]
11. Suh H, Porter JR, Racadio R, Sung YC, Kientz JA. Baby Steps text: feasibility study of an SMS-based tool for tracking children's developmental progress. AMIA Annu Symp Proc 2016;2016:1997-2006. [Medline: 28269959]
12. Kientz JA, Arriaga RI, Abowd GD. Baby Steps: evaluation of a system to support record-keeping for parents of young children. Presented at: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems; Apr 4-9, 2009; Boston MA USA. [doi: 10.1145/1518701.1518965]
13. Song S, Kim J, Kang B, Park W, Kim J. BebeCODE: collaborative child development tracking system. Presented at: Proceedings of the 2018 CHI Conference on Human Factors in Computing Systems; Apr 21-26, 2018; Montreal QC Canada. [doi: 10.1145/3173574.3174114]
14. Ben-Sasson A, Ben-Sasson E, Jacobs K, et al. Baby CROINC: an online, crowd-based, expert-curated system for monitoring child development. : Association for Computing Machinery Presented at: Proceedings of the 11th EAI International Conference on Pervasive Computing Technologies for Healthcare; May 23-26, 2017; Barcelona Spain p. 110-119. [doi: 10.1145/3154862.3154887]
15. DeWitt A, Kientz J, Coker TR, Liljenquist K. mHealth technology design and evaluation for early childhood health promotion: systematic literature review. JMIR Pediatr Parent 2022 Oct 6;5(4):e37718. [doi: 10.2196/37718] [Medline: 36201391]
16. DeWitt A, Kientz J, Liljenquist K. Quality of mobile apps for child development support: search in app stores and content analysis. JMIR Pediatr Parent 2022 Nov 8;5(4):e38793. [doi: 10.2196/38793] [Medline: 36346656]
17. Evans WD, Wallace JL, Snider J. Pilot evaluation of the text4baby mobile health program. BMC Public Health 2012 Nov 26;12:1031. [doi: 10.1186/1471-2458-12-1031] [Medline: 23181985]
18. Evans W, Nielsen PE, Szekely DR, et al. Dose-response effects of the text4baby mobile health program: randomized controlled trial. JMIR Mhealth Uhealth 2015 Jan 28;3(1):e12. [doi: 10.2196/mhealth.3909] [Medline: 25630361]
19. Gazmararian JA, Elon L, Yang B, Graham M, Parker R. Text4baby program: an opportunity to reach underserved pregnant and postpartum women? Matern Child Health J 2014 Jan;18(1):223-232. [doi: 10.1007/s10995-013-1258-1] [Medline: 23494485]
20. Jiang H, Li M, Wen LM, et al. A community-based short message service intervention to improve mothers' feeding practices for obesity prevention: quasi-experimental study. JMIR Mhealth Uhealth 2019 Jun 3;7(6):e13828. [doi: 10.2196/13828] [Medline: 31162133]

XSL•FO
RenderX

21. Domek GJ, Contreras-Roldan IL, O'Leary ST, et al. SMS text message reminders to improve infant vaccination coverage in Guatemala: a pilot randomized controlled trial. Vaccine (Auckl) 2016 May 5;34(21):2437-2443. [doi: 10.1016/j.vaccine.2016.03.065] [Medline: 27026145]
22. Olson KB, Wilkinson CL, Wilkinson MJ, Harris J, Whittle A. Texts for talking: evaluation of a mobile health program addressing speech and language delay. Clin Pediatr (Phila) 2016 Oct;55(11):1044-1049. [doi: 10.1177/0009922816664721] [Medline: 27554765]
23. Suh H, Porter JR, Hiniker A, Kientz JA. @BabySteps. Presented at: Proceedings of the SIGCHI Conference on Human Factors in Computing Systems; Apr 26 to May 1, 2014; Toronto Ontario Canada. [doi: 10.1145/2556288.2557386]
24. Johnson PR, Bushar J, Dunkle M, Leyden S, Jordan ET. Usability and acceptability of a text message-based developmental screening tool for young children: pilot study. JMIR Pediatr Parent 2019 Jan 30;2(1):e10814. [doi: 10.2196/10814] [Medline: 31518329]
25. Stowell E, Lyson MC, Saksono H, et al. Designing and evaluating mhealth interventions for vulnerable populations. Presented at: Proceedings of the 2018 CHI Conference on Human Factors in Computing Systems; Apr 21-26, 2018; Montreal QC Canada p. 1-17. [doi: 10.1145/3173574.3173589]
26. Every family deserves food, health care, and stability. WithinReach. URL: https://withinreachwa.org [accessed 2025-08-12]
27. A better future starts with Help Me Grow. Help Me Grow National Center. URL: https://helpmegrownational.org [accessed 2025-08-12]
28. U.S. Census Bureau. Washington state profile.: data.census.gov URL: https://data.census.gov/profile/Washington?g=040XX00US53 [accessed 2025-04-02]
29. U.S. Census Bureau. Seattle city, Washington.: data.census.gov URL: https://data.census.gov/profile/Seattle_city,_Washington?g=160XX00US5363000 [accessed 2025-04-02]
30. Wattenberg M, Viégas FB, Hollenbach K. Visualizing activity on wikipedia with chromograms. In: Human-Computer Interaction – INTERACT 2007 Lecture Notes in Computer Science: Springer; 2007, Vol. 4663. [doi: 10.1007/978-3-540-74800-7_23]
31. Swartz MK. A strength-based approach to care. J Pediatr Health Care 2017;31(1):1. [doi: 10.1016/j.pedhc.2016.10.008] [Medline: 27939585]
32. Fry JP, Neff RA. Periodic prompts and reminders in health promotion and health behavior interventions: systematic review. J Med Internet Res 2009 May 14;11(2):e16. [doi: 10.2196/jmir.1138] [Medline: 19632970]
33. Klasnja P, Pratt W. Healthcare in the pocket: mapping the space of mobile-phone health interventions. J Biomed Inform 2012 Feb;45(1):184-198. [doi: 10.1016/j.jbi.2011.08.017] [Medline: 21925288]
34. Kientz JA. Embedded capture and access: encouraging recording and reviewing of data in the caregiving domain. Pers Ubiquit Comput 2012 Feb;16(2):209-221. [doi: 10.1007/s00779-011-0380-6]
35. Kitsao-Wekulo P, Kipkoech Langat N, Nampijja M, Mwaniki E, Okelo K, Kimani-Murage E. Development and feasibility testing of a mobile phone application to track children's developmental progression. PLoS One 2021;16(7):e0254621. [doi: 10.1371/journal.pone.0254621] [Medline: 34265009]
36. Anderson-Lewis C, Darville G, Mercado RE, Howell S, Di Maggio S. mHealth technology use and implications in historically underserved and minority populations in the United States: systematic literature review. JMIR Mhealth Uhealth 2018 Jun 18;6(6):e128. [doi: 10.2196/mhealth.8383] [Medline: 29914860]
37. Moser C, Chen T, Schoenebeck SY. Parents' and children's preferences about parents sharing about children on social media. : Association for Computing Machinery; 2017 May 2 Presented at: CHI '17; May 6-11, 2017; Denver Colorado USA p. 5221-5225 URL: https://dl.acm.org/doi/proceedings/10.1145/3025453 [doi: 10.1145/3025453.3025587]
38. Ammari T, Kumar P, Lampe C, et al. Managing children's online identities: how parents decide what to disclose about their children online. : Association for Computing Machinery Presented at: Proceedings of the 33rd Annual ACM Conference on Human Factors in Computing Systems; Apr 18-23, 2015; Seoul Republic of Korea p. 1895-1904. [doi: 10.1145/2702123.2702325]
39. Kumar P, Schoenebeck S, Association for Computing Machinery. The modern day baby book: enacting good mothering and stewarding privacy on facebook. 2015 Presented at: Proceedings of the 18th ACM Conference on Computer Supported Cooperative Work & Social Computing; Mar 14-18, 2015; Vancouver, BC, Canada p. 1302-1312.
40. Baker J, Kohlhoff J, Onobrakpor SI, et al. The acceptability and effectiveness of web-based developmental surveillance programs: rapid review. JMIR Mhealth Uhealth 2020 Apr 23;8(4):e16085. [doi: 10.2196/16085] [Medline: 32324149]
41. Escobedo L, Arriaga RI. Understanding the challenges of deploying a milestone-tracking application in a cross-cultural context. Int J Hum Comput Stud 2022 Jun;162:102801. [doi: 10.1016/j.ijhcs.2022.102801]
42. Minkler M, Wallerstein N. Community-Based Participatory Research for Health: From Process to Outcomes: John Wiley & Sons; 2011. [doi: 10.1525/9780520958494-020]
43. Mikles SP, Suh H, Kientz JA, Turner AM. The use of model constructs to design collaborative health information technologies: a case study to support child development. J Biomed Inform 2018 Oct;86:167-174. [doi: 10.1016/j.jbi.2018.09.003] [Medline: 30195086]

XSL•FO
RenderX

44. Perrin EC, Sheldrick C, Visco Z, Mattern K. The Survey of Well-Being of Young Children (SWYC) User's Manual: Floating Hospital for Children at Tufts Medical Center; 2016. URL: https://www.floatinghospital.org/The-Survey-of-Wellbeing-of-Young-Children/Manual-Training-Resources [accessed 2025-09-12]

Abbreviations

ASQ: ages and stages questionnaires
CONSORT : Consolidated Standards of Reporting Trials
JMIR: Journal of Medical Internet Research
mHealth: mobile health
WIC: women, infants, and children

Edited by S Badawy; submitted 02.04.25; peer-reviewed by R Marshall; revised version received 26.06.25; accepted 01.07.25; published 26.09.25.

Please cite as:
Suh H, Kientz JA
Promoting Family Engagement With Early Childhood Developmental Screening via the Baby Steps Text Messaging and Web Portal System: Longitudinal Randomized Controlled Trial
JMIR Pediatr Parent 2025;8:e73443
URL: https://pediatrics.jmir.org/2025/1/e73443
doi:10.2196/73443

© Hyewon Suh, Julie A Kientz. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 26.9.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Usability Testing of an Internet-Based Responsive Parenting Program for Caregivers of Young Survivors of Childhood Cancer Living in Rural and Appalachian Communities: Mixed Methods Study

Emily L Moscato[1,2], PhD; Eva Darow[1], BS; Jessica Quach[1], BS; Adrien M Winning[1], PhD; Matthew Schmidt[3,4], PhD; Shari L Wade[5,6], PhD; Cynthia A Gerhardt[1,2], PhD; Emre Sezgin[1,2], PhD

[1]The Center for Biobehavioral Health, The Research Institute, Nationwide Children's Hospital, 431 S 18th St, Columbus, OH, United States

[2]Department of Pediatrics, College of Medicine, The Ohio State University, Columbus, OH, United States

[3]Department of Workforce Education and Instructional Technology, Mary Frances Early College of Education, University of Georgia, Athens, GA, United States

[4]Department of Clinical and Administrative Pharmacy, College of Pharmacy, University of Georgia, Athens, GA, United States

[5]Division of Rehabilitation Medicine, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, United States

[6]Department of Pediatrics, College of Medicine, University of Cincinnati, Cincinnati, OH, United States

Corresponding Author:
Emily L Moscato, PhD
The Center for Biobehavioral Health, The Research Institute, Nationwide Children's Hospital, 431 S 18th St, Columbus, OH, United States

Abstract

Background: Young survivors of childhood cancer diagnosed and treated before the age of 7 years are at heightened risk of developmental difficulties. As a result, their caregivers may experience stress as they navigate various educational and health care systems while advocating for their child's needs. To our knowledge, there are no tailored early interventions or support programs to address the unique and multifaceted needs of young survivors of childhood cancer and their caregivers. Digital platforms can provide anticipatory guidance and developmental resources, which may be especially impactful for families at increased risk for health and educational disparities, particularly in underserved rural and Appalachian areas.

Objective: This mixed methods study describes the usability testing of an internet-based responsive parenting program for caregivers of young survivors of childhood cancer, called the Preparing for Life and Academics for Young Survivors (PLAY) program.

Methods: Twelve caregivers of young survivors of childhood cancer (9 biological parents, 2 grandfathers, and 1 legal guardian; 33% rural, 33% Appalachian, and 83% White) participated in an online usability session with a task-based, think-aloud method. This session was followed by completion of the System Usability Scale (SUS), responses to reaction cards to describe their experiences with the platform, and a semistructured interview. Two trained coders used rapid analysis and consensus methods to identify themes.

Results: Overall, caregivers found the platform easy to use (92% SUS >68; mean 82.2, SD 14.45). Most caregivers provided positive feedback in response to reaction cards (eg, useful, appealing, and valuable) to describe the platform. Qualitative findings highlighted that most caregivers perceived the platform as "easy to use," and several participants described it as a helpful educational tool. Participants noted that potential platform improvements should include accessibility features (eg, closed captioning for videos), more tailored content, and usability on mobile devices.

Conclusions: With further improvements, digital platforms such as PLAY may be a promising avenue to bridge access to care for high-need groups and ultimately improve child neurodevelopmental outcomes.

(JMIR Pediatr Parent 2025;8:e70055) doi:10.2196/70055

KEYWORDS

pediatrics; oncology; parenting; rural; Appalachian

XSL•FO
RenderX

Introduction

Survival rates for most types of childhood cancers have fortunately risen to over 80%, resulting in a growing cohort of nearly half a million childhood cancer survivors in the United States [1]. However, life-saving cancer treatments, such as chemotherapy and radiation, can be detrimental to a child's development and lead to a host of chronic health needs for up to two-thirds of survivors, termed late effects [1]. Late effects from cancer treatment can vary and include impacts on physical, cognitive, social, and emotional development that may impair long-term academic functioning and quality of life [1-4]. Cancer treatment is particularly disruptive to early development, with young survivors of childhood cancer who are diagnosed and treated before the age of 7 years at heightened risk for chronic late effects [5-7].

The emotional toll of cancer extends to caregivers, who are faced with the daily realities of caring for a young child with cancer [8]. Even after cancer, caregivers may need to manage chronic medical needs and heightened anxiety about recurrence, with up to 40% of caregivers having clinically significant levels of post-traumatic stress symptoms [9]. Caregivers have reported a high need for information about their child's medical condition and future late effects [10]. Parenting stress has also been linked with poorer developmental outcomes for young survivors of childhood cancer [11], further exacerbating the detrimental impact of cancer treatment. In other neurologically vulnerable populations, such as those with traumatic brain injury (TBI) and preterm birth, responsive parenting programs that teach parents how to increase warmth and cognitive stimulation and take care of themselves may lead to improvements in child developmental outcomes [12,13], suggesting potential intervention opportunities for young survivors of childhood cancer.

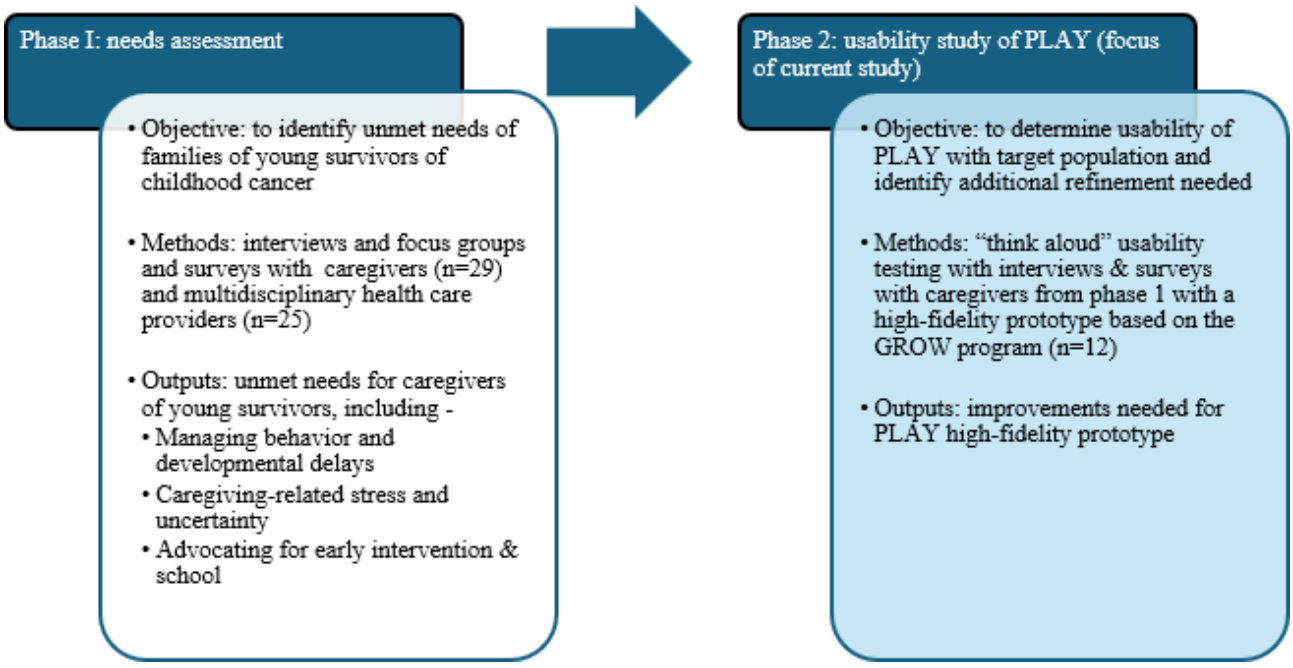
Still, young survivors of childhood cancer and their families living in underserved rural or Appalachian areas have barriers to survivorship care. Appalachia is a 250,000-square-mile region extending from New York to Mississippi and includes over 25.7 million residents [14]. This region has been plagued by economic distress, often resulting in residents with limited access to specialty health care due to financial barriers and distance [15]. Access to mental health care is further limited by stigma and misperceptions of the potential benefits of these services [16,17]. Although research is scarce in young survivors of childhood cancer, older CCS in rural regions have demonstrated deficits in social competence as compared to their nonrural counterparts [18,19]. Thus, to improve health equity, it is essential to identify accessible, evidence-based early interventions and psychosocial supports for young survivors of childhood cancer and their caregivers to mitigate disparities in outcomes.

Digital health interventions may be a potential solution to increase access to specialized care for underserved populations [20], such as rural and Appalachian young survivors of childhood cancer and their caregivers. Recent systematic reviews have identified over 30 studies (N=32) focused on digital health interventions for families of children with special health care needs [21]. A few of these studies identified additional barriers to care for rural pediatric populations, including poor internet connectivity, leading to poor video quality and interruptions to care [21,22]. Thus, to facilitate future implementation and uptake, and to promote health equity, user-centered design methods that begin at the earliest stages of intervention development are needed [23]. The Consolidated Framework for Implementation Research (CFIR) has identified innovation design, or the extent to which an intervention is accessible and easy to use, as a key component of uptake and implementation [24]. Furthermore, interventions that have included user-centered design have also demonstrated greater effectiveness [25,26].

To our knowledge, there are no tailored early intervention or support programs to address the unique and multifaceted needs of young survivors of childhood cancer and their caregivers, especially for those living in underserved rural or Appalachian areas. Therefore, we sought to develop a responsive parenting program for this population. Figure 1 provides an overview of this work. The findings from the needs assessment (phase 1; Darow et al, report in preparation; Kaufman et al, report under review; and Moscato et al; report in preparation) suggested several unmet psychosocial needs for young survivors of childhood cancer (eg, behavioral dysregulation, developmental delays, and impaired quality of life), as well as their caregivers (eg, caregiving-related stress, managing uncertainty, and advocacy related to early intervention services and school). Given that the unmet needs endorsed by caregivers of young survivors of childhood cancer were similar to those identified by caregivers of other neurologically vulnerable populations, such as individuals with TBI, we opted to tailor a previously developed internet-based intervention called the Gaining Real Life Skills Over the Web (GROW) program. The GROW program was designed for caregivers of young children after TBI (ages 0 - 4 years) [27] and targeted responsive parenting and caregiver distress through psychoeducation and individualized coaching [28].

XSL•FO
RenderX

Figure 1. Overview of the development of the Preparing for Life and Academics for Young Survivors program, including the previous phase of research (phase 1 [Darow et al, report in preparation; Kaufman et al, report under review; and Moscato et al; report in preparation] and phase 2 [focus of this paper]). GROW: Gaining Real Life Skills Over the Web program; PLAY: Preparing for Life and Academics for Young Survivors.



Following the needs assessment, our team tailored the wording of the content in GROW to fit the population-specific needs of young survivors of childhood cancer (eg, changing "brain injury" to "cancer experience") in the adapted intervention, now called the Preparing for Life and Academics for Young Survivors (PLAY) program. We also opted to focus on young survivors of childhood cancer aged 3 - 6 years for the PLAY program, given that state-based early intervention programs focus on 0 - 3 years, and caregivers in phase 1 identified an unmet need related to the transition to preschool and kindergarten. The focus of this study (Figure 1, phase 2) is a preimplementation, mixed methods usability testing study [24] involving interviews and standardized measures with 12 caregivers of young survivors of childhood cancer using a high-fidelity prototype of the PLAY program. The purpose of this phase of the study is to inform the refinement of PLAY based on usability metrics, including both standardized measures (ie, the System Usability Scale [SUS] and acceptable usability indicated by scores >68) [29,30] and qualitative feedback from caregivers. The ultimate goal of this program of research is to develop an accessible program that will improve parenting stress and child outcomes for this vulnerable group of young survivors of childhood cancer, especially those in underserved rural and Appalachian areas.

Methods

Overview

We used a mixed methods research design with a sample of caregivers (n=12) to examine the usability of the PLAY high-fidelity prototype. A high-fidelity prototype is a simplified version representing the skeletal framework of a website or application's interface [31]. Specifically, we used an expedited iterative design process to advance the study timeline. Rapid usability analysis has been used to speed the interpretation of user feedback and maximize identified codes and themes via reviewing conversations (ie, audio and video recording) instead of transcriptions [32-34]. This approach is known for its efficiency in distilling user feedback, accelerating the identification of codes and themes by analyzing audio and video recordings directly, thereby bypassing the labor-intensive transcription process. This method ensures swift progression from user feedback to design iteration, aligning with user-centered design principles [23]. By engaging a diverse cross-section of caregivers, including a significant representation from underserved rural or Appalachian regions (over 30%), we aimed to rapidly pinpoint and implement essential modifications to tailor the platform to the needs of these communities.

PLAY High-Fidelity Prototype

A high-fidelity prototype of the PLAY website, based on GROW (Figure 1), was developed and shared with caregivers in this study to (1) determine usability among caregivers of young survivors of childhood cancer and (2) identify recommendations for tailoring the program to their unique needs. The PLAY website was based on the GROW website, a fully developed digital health intervention program originally designed for caregivers of young children ages 0 - 4 years following TBI, to improve responsive parenting skills and cognitive stimulation [27,28]. Participants were instructed to review the content, as generally about having a child with a chronic medical condition. The GROW intervention involves internet-based learning modules (ie, GROW platform), as well as live one-on-one coaching via videoconferencing and weekly homework. GROW was based on a previously developed and tested responsive parenting program called PLAY and Learning Strategies (PALS) [35] and informed by caregivers and experts in special education and TBI. All 3 programs (ie, PALS, GROW, and PLAY) are rooted in attachment theory [36] and sociocultural models of child development [37]. The core treatment target is responsive

XSL•FO
RenderX

parenting, which involves increasing caregiver warmth and contingent reactions to their child's cues, while also providing verbal stimulation that enriches development.

The PLAY website, such as GROW, has six learning modules: (1) interactions, (2) language development, (3) attention/play, (4) parent self-care, (5) relationships, and (6) working with schools. Each module includes brief text content on the topic area, videos highlighting examples of caregivers interacting with their children and practicing the skills, and exercises to apply learned information, such as matching and quizzes (refer to previous publications) [27]. The interface was built using the popular content management platform WordPress (Automattic, Inc), augmented with the LearnDash plugin to provide learning management system functionality. This system is compatible with PC, mobile (Android and iOS), and tablet browsing due to an inbuilt responsive design.

Procedure

Purposive sampling was used to identify potentially eligible caregivers of young survivors of childhood cancer from the cancer registry of a Midwest pediatric academic medical center. Inclusion criteria for eligible participants included caregivers of a child who (1) was diagnosed with cancer before the age of 7 years, (2) was between the ages of 3 - 12 years at the time of study participation, (3) did not have a history of a neurodevelopmental disorder prior to their cancer diagnosis (eg, neurofibromatosis, tuberous sclerosis, Down syndrome, and autism), (4) had completed treatment for cancer at least 6 months prior or was on maintenance oral chemotherapy only, without evidence of recurrent disease or current hospitalization. Caregivers also were required to be (1) the child's legal guardians, (2) living with the identified child at least 50% of the time, (3) fluent in English, and (4) residing in the state of the institution or surrounding states (ie, Ohio, Kentucky, Pennsylvania, or West Virginia). Note that families at different time points post treatment were recruited to provide a range of perspectives, and that caregivers of children currently aged 7 - 12 years were asked to retrospectively consider unmet needs and the use of the PLAY program during the planned target age range of 3 - 6 years.

Stratified purposive sampling was conducted by using random sampling within subgroups to ensure representation by diagnosis type (ie, brain tumor, leukemia/lymphoma, and solid tumor), geographic location (ie, rural, nonrural, Appalachian, and non-Appalachian as defined by the Rural Urban Commuting Codes [38] and Appalachian Regional Commission [14]), and age of the young survivors of childhood cancer (ie, either 3 - 6 or 7 - 12 years; to include those at various time points postcancer diagnosis/treatment). We also intentionally oversampled individuals from racial and ethnic minority groups to increase representation in our sample and reflect the institutional cancer registry (ie, 9% Black and 6% Latinx).

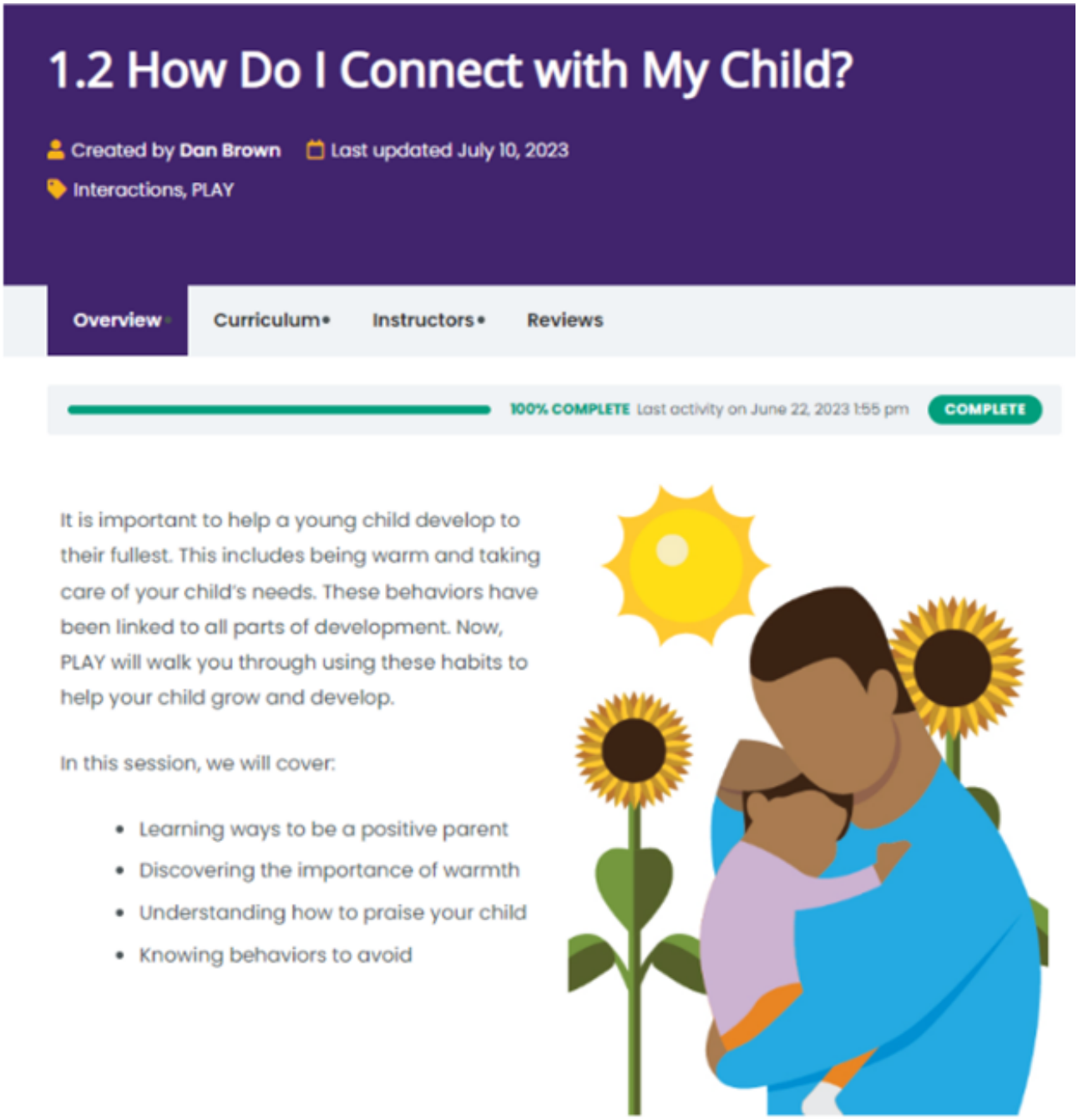
Caregivers were invited to participate with a mailed letter from their oncologist or neurosurgeon, which was followed by attempts to contact the caregiver by phone. Caregivers could opt out of future contact with the research team. In phase 1 of this study, caregivers were initially invited to participate in a mixed methods assessment of their unmet psychosocial and educational needs involving internet-based REDCap (Research Electronic Data Capture; Vanderbilt University) surveys and an interview conducted by phone or secure videoconferencing. Caregivers could also elect to participate in a monthly Community Advisory Board (CAB) and future research. Research staff discussed the CAB and usability testing with potentially interested members during their scheduled phone/videoconference interview until the desired sample size for planned usability testing was acquired (n of at least 10) [39] and saturation in rapid data analysis was attained.

Usability testing visits were scheduled at the convenience of caregivers on a secure videoconferencing platform with screen sharing and recording capabilities. All visits were recorded and transcribed automatically by the secure videoconferencing platform for cross-referencing during the coding process. During the usability testing visit, a trained research staff member who conducted phase 1 with the caregiver provided brief context on the platform (ie, currently designed for families of young children following TBI). Next, caregivers were provided with the link to the platform and were instructed to engage in unstructured navigation of the platform on their own for 5 minutes while sharing their screen (ie, hereafter "unguided use"). Caregivers were encouraged to "think aloud" about any of their feedback. Pages accessed and verbal comments were noted for analysis.

Following this, caregivers were instructed to perform a series of structured, task-based scenarios involving one specific module of the platform (refer to Figure 2; minimodule: "How Do I Connect with My Child?" and File S1 in Multimedia Appendix 1) for standardization across caregivers. This minimodule introduced the key concept of warmth, including how to use specific, labeled praises and the skill of diaphragmatic breathing for caregiver stress management. On each page of this module, research staff members provided standardized prompts (eg, "start the module," "go to the next page," "watch the video," and "complete the exercise") and encouraged caregivers to continue to "think aloud." Total time to complete the scenario, navigation challenges, and verbal comments were noted for analysis. Following the completion of the scenario, caregivers completed brief online surveys (refer to the "Measures" section below) to indicate the device used (ie, mobile, tablet, or PC) and to provide feedback about the platform. Caregivers also engaged in a semistructured interview based on the technology acceptance model [40] about their overall impressions of the platform, other potential components of the intervention (ie, coaching by videoconferencing and text messaging), and suggestions for improvement. A copy of the semistructured interview guide is included in File S2 in Multimedia Appendix 1.

XSL•FO
RenderX

Figure 2. Sample module web page from the high-fidelity prototype of the responsive parenting platform for usability testing.



Measures

Background Characteristics

In phase 1 of the study, caregivers completed a brief demographic survey including their relationship status, family income, employment status, race, ethnicity, and self-identification as Appalachian/non-Appalachian. The institutional cancer registry was also used to obtain information about the cancer diagnosis of young survivors of childhood cancer and to code for geographic region based on the family's current address.

Device Usage

Caregivers completed a brief survey on the type of device used to access the platform (ie, smartphone, laptop/desktop computer, iPad/tablet, and other), the type of device they believed would be most useful for the platform (repeated options), and the selection of all devices available in their household.

System Usability Scale

Caregivers completed the 10-item SUS [30] to quantitatively assess usability. The SUS is a widely used, validated, and reliable measure of the acceptability and comprehensibility of the online program, ranging from 1 to 100, with higher scores indicating higher usability. A score more than 68 is considered acceptable/above average usability [29,41].

Reaction Cards

Caregivers selected words from an abbreviated list of 55 adjectives based on the Microsoft reaction cards [42] to describe

XSL•FO
RenderX

their feelings and reactions toward the platform, providing qualitative insights into desirability and aesthetic design.

Data Analysis Plan

Descriptive statistics (means and SDs) and frequency counts were calculated for demographic and medical variables, device usage, SUS scores, reaction cards, and documented data from the sessions (ie, pages accessed and length of time for scenario). For the qualitative data, a rapid analysis approach [32-34] was implemented with 2 trained research staff members, who served as interviewers and coders (EM, a postdoctoral fellow and licensed clinical psychologist, and ED, a clinical research coordinator). They attended usability testing sessions live and took detailed field notes. Recordings and field notes were reviewed a second time, with general codes extracted into summary templates organized by interview question in Microsoft Excel spreadsheets. Double coding was conducted for 25% of the interviews, with consensus reached prior to independent coding for the remainder of the data. A second consensus meeting was held to identify themes endorsed by a majority of participants across interviews using a matrix. Member checking was conducted with Caregiver Advisory Board members, who confirmed the findings and coding themes.

Ethical Considerations

This study was reviewed and approved by the Nationwide Children's Hospital's institutional review board (00002939). As a minimal risk study, participants verbally agreed to participate after reviewing a written information sheet detailing risks and potential benefits. Participants also had an opportunity to ask questions of the study staff.

Results

Participants

Of 524 families in the cancer registry, 137 families were randomly selected as part of the stratification process in the "Procedure" section and were attempted to be contacted. Of those, 84 caregivers were reached by phone, and 32 caregivers agreed to participate in phase 1. A total of 25 agreed to be recontacted to participate in the CAB and other future studies, and the first 12 caregivers were sequentially invited for usability testing. There were no significant differences in demographic characteristics of the caregiver or child with cancer (ie, geographic region, sex, income, race, ethnicity, and diagnostic type) between the subsample of 12 participants who completed usability testing and the 32 participants from phase 1 (Fisher exact tests; $P>.05$), except that caregivers who completed usability testing were slightly older (mean 42.67 and SD 6.5 years) than those who did not participate in the usability phase (mean 36.8 and SD 6.8 years; $t_{30}=-2.41$, $P=.02$).

A total of 12 usability sessions were conducted by videoconference. However, there was 1 technical difficulty in saving the video for 1 father, and thus, only audio was available for that visit. Detailed field notes were also documented for each visit by 2 staff members in attendance. The sample of caregivers who participated was mostly White (n=10, 83%) and married (n=8, 67%). They were equally dispersed amongst metropolitan, rural, and Appalachian areas (n=4 each, 33% each). Although most caregivers were biological parents (n=9, 75%), there were 2 grandfathers and 1 legal guardian/adoptive parent. At the time of the interview, young survivors of childhood cancer were between the ages of 3 and 9 years. Demographic characteristics are presented in Tables 1 and 2.

XSL•FO
RenderX

Table . Demographic characteristics of caregivers who participated in usability testing.

Characteristics of caregivers	Women caregivers (N=7)	Men caregivers (N=5)
Caregiver age (years), mean (SD)	39.00 (4.04)	47.80 (5.93)
Number of children in the home, n (%)		
One child	2 (29)	2 (40)
Two or more children	5 (71)	3 (60)
Race, n (%)		
White	6 (86)	4 (80)
Black or African American	1 (14)	—
Prefer not to respond	—	1 (20)
Ethnicity, n (%)		
Hispanic or Latinx	1 (14)	—
Not Hispanic or Latinx	5 (72)	3 (60)
Prefer not to respond	1 (14)	2 (40)
Geographic area, n (%)		
Metropolitan	3 (42)	1 (20)
Rural	2 (29)	2 (40)
Appalachian	2 (29)	2 (40)
Educational attainment, n (%)		
High school	1 (14)	—
Some college	1 (14)	2 (40)
College	4 (57)	2 (40)
Graduate or professional	1 (14)	1 (20)
Annual family income, n (%)		
US $25,001-$50,000 per year	3 (42)	1 (20)
US $50,001-$75,000 per year	1 (14)	1 (20)
US $75,001-$100,000 per year	1 (14)	—
US $100,000 or more per year	2 (29)	2 (40)
Prefer not to respond	—	1 (20)
Relationship status, n (%)		
Single	—	1 (20)
Married	5 (71)	3 (60)
Divorced	1 (14)	—
Living with someone	1 (14)	1 (20)
Relationship to young survivor, n (%)		
Biological parent	6 (86)	3 (60)
Grandparent	—	2 (40)
Legal guardian	1 (14)	—

XSL•FO
RenderX

Table . Demographic characteristics of children from families (N=10) who participated in usability testing.

Characteristic	Value
Age at time of participation (years), mean (SD)	5.80 (1.69)
Age at diagnosis (years), mean (SD)	2.30 (1.55)
Cancer diagnosis, n (%)	
Brain tumor	2 (20)
Leukemia or lymphoma	3 (30)
Non-CNS[a] solid tumor	5 (50)
Cancer treatment history, n (%)	
Chemotherapy	7 (70)
Radiation	1 (10)
Neurosurgery	2 (20)
Documented in the electronic medical record problem list, n (%)	
Speech difficulties	4 (40)
Gross motor difficulties	3 (30)
Fine motor difficulties	2 (20)
Neuropathy	4 (40)
Learning or attention-related difficulties	3 (30)
Emotional or behavioral challenges	7 (70)

[a]CNS: central nervous system.

Preliminary Impressions

Passive Use Feedback

During the 5 minutes of unguided use of the platform, the top viewed pages included: “What changes to expect” (module 1 landing page, n=9), “telling my child” (n=6), “growth of my child” (n=5), and “effects of health condition” (n=5; refer to File S3 in Multimedia Appendix 1 for heatmap of engagement). Given that these were several of the first pages of the first module, it seemed that most caregivers preferred to review the content in chronological order. Notably, some caregivers explored the module overview page and selected topics based on title (n=4), while fewer reviewed the resources page (n=3), and only 1 caregiver watched the tutorial video. Caregivers noted positive initial impressions of the platform, including that it was user-friendly and liked the overall design. For example, one mother of a 7-year-old described: “Anyone with young children would probably want to go through it and play around.” Similarly, a grandfather of a 7-year-old reported: “I think this is a wonderful program, and would be very beneficial for families going through this with their child.” Caregivers also made suggestions for improvement, including greater accessibility (eg, captioning on video and audio versions of content) and tailoring of content for this population. For example, related to the integration of audio content, one mother of a 7-year-old described: “Some parents are just so tired, they don’t wanna sit there, and their eyes just look at a screen. They just want to sort of listen.”

Scenario-Based Feedback

Caregivers spent an average of 17.83 (SD 6.28; range 8 - 31) minutes completing the scenario (module 1.2: How do I connect with my child?). They made several positive comments about the videos, design, and relatability of the content. For example, one mother described: “It’s easy to read, not too many words, which is nice, because I feel like when you wanna learn information…you wanna get to what’s important.” Caregivers also made suggestions for improvements, including the mobile navigation and ease of starting the modules.

Summative Feedback

SUS Results

All but one mother, who used PLAY on a smartphone, found the platform easy to navigate and usable (92% SUS score>68, indicating acceptable usability; total mean 82.2). Both men and women caregivers reported similar levels of overall usability (men: mean 82.50, SD 6.85; 100% SUS score>68 and women: mean 83.21, SD 18.75; 86% SUS score>68).

Device Usage

Half of the caregivers used a laptop or desktop PC to access the platform (n=6, 50%), while 5 (42%) used a smartphone, and 1 used an iPad. Caregiver responses for their preferred device to access the platform mirrored their usage for the usability testing. However, all caregivers reported that they had access to a smartphone, while 11 (92%) reported having a laptop or desktop PC, and 9 reported having an iPad/tablet (75%). Usability scores were lower and more variable for caregivers who used a smartphone as compared to those who used a PC (smartphone user: mean 79.50, SD 20.95; PC user: mean 84.16, SD 8.76).

XSL•FO
RenderX

However, these group differences were not statistically significant (t_9=−0.50; P=.63), nor were the scores below the SUS threshold (<68) for acceptable usability.

Reaction Cards

Caregivers used primarily positively valenced adjectives to describe their impressions of the platform, including useful, valuable, easy to use, accessible, and appealing. A heatmap displaying the frequency of adjectives selected is presented in Figure 3.

Figure 3. Heatmap of reaction cards following usability testing regarding the website. The numbers in parentheses indicate the number of participants who selected the adjective, with the most highly endorsed adjectives in the top right corner.

Useful (10)	Easy to use (10)	Organized (9)	Inviting (7)	Empowering (6)	Desirable (4)	Stimulating (4)	Trustworthy (2)
Valuable (10)	Accessible (9)	Consistent (7)	Straight forward (6)	Simplistic (4)	Exciting (3)	Reliable (2)	Sophisticated (0)
Appealing (9)	Usable (7)	Attractive (5)	Connected (4)	Fast (3)	Timesaving (2)	Intimidating (0)	Too technical (0)
Motivating (7)	Comprehensive (5)	Personal (4)	Collaborative (3)	Complex (1)	Inconsistent (0)	Patronizing (0)	Overbearing (0)
High quality (5)	Efficient (5)	Flexible (3)	Fresh (1)	Rigid (0)	Confusing (0)	Time-consuming (0)	
Fun (3)	Relevant (3)	Hard to use (1)	Gets in the way (0)	Frustrating (0)	Familiar (0)		
Busy (1)	Customizable (1)	Unpredictable (0)	Predictable (0)	Stressful (0)			
Slow (1)	Unconventional (0)	Uncontrollable (0)	Not valuable (0)				

Rapid Analysis

The summative interview data yielded several themes, which are displayed in Table 3 and throughout the “Results” section.

XSL•FO
RenderX

Table . Rapid analysis themes on the innovation design based on Preparing for Life and Academics for Young Survivors program prototype.

Themes	Enablers	Overarching suggestions for improvement
Overall impressions	• Easy-to-use interface • Positive toward the platform • Simple/straightforward design (M)[a]	• Reduce/reformat text • Changes to videos • Message boards with caregivers • Chat feature with professionals • Other websites/resources to learn about specific tumor types and treatments • Links to local support groups • Directory for resources • Discounts for parents to destress (eg, spa/massages) • Link to electronic medical record
Perceived usefulness	• Found to be useful for supporting and teaching responsive parenting skills	• Add more realistic scenarios dealing with stress • Use "coach" vs "therapist" • Add more real-life examples of dealing with stress as a parent • List of questions to ask at follow-up appointments • Ways to destress before scans/follow-up appointments • More information about feeling misunderstood by friends • Improvements to videos, including a greater variety of ages, closed captioning, and video testimonials about the program
Design and layout	• Favorable design	• Reduce text: more images and graphic representation of concepts • Visual progress bar • Bold key points • More accessible "take-away points" • More concise instructions on exercises • More layman's terms • Option to have text read aloud
Navigation	• Easy-to-use interface	• Improved mobile menu and mobile accessibility • Linkages between modules
Preferred format and timing	• Internet-based and easily accessible format	• Offer a platform to women caregivers shortly after diagnosis (W)[b] • Offer a platform to men caregivers on the transition off treatment (M)

[a]M indicates theme for men caregivers only.

[b]W indicates theme for women caregivers only.

Overall Impressions

Overall, most caregivers noted that they found the platform "easy to use," including comments that the platform was "simple," "straightforward," and "user-friendly." A few caregivers made suggestions about "reducing and reformatting text" to make it easier to digest, such as including more comics and images to "break up the text," bolding key points, and including key takeaways that are easily accessible for future reference in bullet point format. Specific enablers and suggestions for improvement are presented in Table 3. Caregivers also recommended "improvements to the videos," such as closed captioning and showing a greater variety of age groups and developmental periods. One mother of a 7-year-old survivor noted that she would prefer if the videos were "more fun" and "less forced." Caregivers "denied concerns about privacy" while using the platform, with a few noting that it seemed "trustworthy" with the ability for an individual log in.

Perceived Usefulness

Most caregivers described that the platform "could be useful." One father of a 3-year-old survivor described that he liked that the platform showed: "the various challenges that you're about to embark upon and puts them into nice boxes...modules that are easily digestible." Several caregivers noted that some of the content was familiar to them. On the other hand, caregivers described that they may benefit from learning how to "be more specific with praise" in interacting with their children. One

XSL•FO
RenderX

grandfather of an 8-year-old survivor noted that presenting this information in this online format reduces defensiveness, as compared to having someone else tell you what to do. Specifically, he described:

> *I think it's (platform) better than hearing their parents tell them how to do it or having another person tell them how to do it directly...because then they…kind of have some more time to process what they're seeing and viewing...I think that it's good because it gives them an opportunity to process versus having just people saying it to their face and then being defensive. With a module like this, they can…be defensive to the module, but nothing is going to talk back to them.* [Grandfather of an 8-year-old survivor]

One suggestion for improvement included more "real life examples" of caregivers managing stress in the moment, such as taking a break or a walk. One mother of an 8-year-old survivor suggested that it would be important to incorporate relatable examples:

> *Real-life scenarios, real-life practice, and examples that we (caregivers) can do with our child that are just kind of practical, like even if it's not traditional. Just a reminder that when you go out to a park with your child today, why not ask them about the colors they see or count how many swings are at the swing set? Just a reminder of simple things we (caregivers) can do.* [Mother of an 8-year-old survivor]

Caregivers also described that the platform may be useful for "enhancing teachers' understanding" of cancer, as well as caregivers' understanding of late effects of cancer treatment and the impact of cancer on siblings. They also noted that the platform would, in the words of a mother of a 6-year-old survivor, help caregivers be "more empowered to be advocates for their child."

Design and Layout

In relation to the design and navigation, most caregivers commented "positively," describing the platform as "pleasant," "relatable," and saying that the "preschool" designs are fitting for the age group.

Navigation

Consistent with the reduced SUS scores for the mobile version, a few caregivers suggested improvements for mobile usability, including expanding the mobile menu and navigating to start the modules.

Preferred Format

Most caregivers (9/12) described that individual coaching in a future intervention program "could be helpful" and should be offered as "an option" for families to provide "another level of support." Still, one grandfather of a 5-year-old survivor noted that it is important that caregivers do not feel "graded" or "judged." Caregivers also emphasized the need for ease of scheduling these appointments, such as evenings, weekends, and flexibility with appointments (eg, last-minute cancellations).

With respect to offering text messaging as a supplement to the internet-based modules, caregivers described that they could be helpful as reminders of skills learned on the platform. Caregivers noted that it would be important to ask about preferences for frequency (eg, weekly and monthly) to prevent these reminders from becoming overwhelming.

Preferred Timing

Regarding the timing of a responsive parenting program, caregivers expressed a variety of opinions, which differed by the gender of the caregiver. Most women caregivers described desiring this type of support within a few months of diagnosis. One mother of an 8-year-old survivor described:

> *Definitely not the first month…we were in the hospital for two weeks. It was a whirlwind. Parents were taking time off work. The family's coming to town. No one knows what's going on...and then you're sort of in denial for the first month, and you're in fight or flight mode. So, I would say probably month two or three would be a good time, because now you're sort of learning, learning how your kid responds to some of the treatment.* [Mother of an 8-year-old survivor]

Another mother of a 6-year-old survivor commented about feeling somewhat helpless at the beginning and that there is "not much action you can take right away, except for learning how to help your child." In contrast, most men caregivers reported that they would prefer to receive this support after the conclusion of treatment. For instance, one grandfather of a 5-year-old survivor described the intensity of the acute treatment period as: "It's like you're hit with a sledgehammer."

Discussion

Principal Findings

This mixed methods study involved initial usability testing of a high-fidelity prototype of an internet-based responsive parenting intervention program called PLAY, designed to support caregivers of young survivors of childhood cancer. Overall, all but one caregiver found PLAY usable (92% reported SUS scores ≥68). Acknowledging the limitations of the SUS as a summative measure, we supplemented this analysis with qualitative feedback and the use of reaction cards [42,43]. Caregivers primarily selected positively balanced adjectives (eg, useful, valuable, easy to use, accessible, and appealing) to describe the program. These results are promising and comparable to other internet-based support and educational resources for caregivers of children with various chronic and developmental conditions and for those from rural and remote areas (eg, autism and asthma) [44-48]. Similarly, in the previous pilot of the 6-session intervention with caregivers of young children with TBI, all 11 families who completed the full 6-session intervention reported high satisfaction with the program [27].

This study, strengthened by a mixed methods approach to usability testing, yielded valuable and detailed information related to the innovation design (ie, CFIR) [24] of PLAY. Caregivers identified key aspects to tailor the program for the unique needs of the young survivors of childhood cancer, such

XSL•FO
RenderX

as resources specific to cancer and late effects, examples and resources related to advocacy for their child in health care and school settings, and the importance of the caregiver managing their own stress and uncertainty (eg, "scanxiety") in their capacity to implement responsive parenting skills. Other general suggestions included increasing usability, offering coaching and texting as optional supports, and considering intervention timing, which differed by gender of the caregiver. With respect to usability, caregivers repeatedly underscored the necessity of PLAY being highly mobile-friendly, practical, and brief, given multiple competing demands on caregivers' time and attention. Most caregivers agreed that the length of the module was appropriate (approximately 15 - 20 minutes), and all caregivers reported having access to a smartphone and a preference for mobile usability. This is comparable to other studies with caregivers of young children with autism, in which mobile usability was a top priority [45]. The Pew Center also highlights that most adults living in both metropolitan (89%) and rural (80%) areas own a smartphone [49]. Still, both quantitative (ie, SUS) and qualitative data indicated that improvements were needed in the mobile usability and design of the platform, such as easier navigation to the main menu on the mobile version. Other suggestions to improve accessibility included closed captioning on videos and options for the text to be read aloud on each module page. These suggestions are in line with similar studies of digital health interventions (DHI) for caregivers [50,51]. Furthermore, these adaptations would assist in bridging the "disability digital divide" [52].

Most caregivers described receptiveness to coaching from a trained professional and occasional text message reminder, in addition to the self-guided platform resource. Caregivers emphasized that these supports should be optional and individually tailored in terms of frequency. They also recommended that coaching should be flexibly scheduled to increase accessibility for busy families with young children (ie, evenings and weekends). In studies of telehealth interventions for caregivers of children with autism [46], caregiver retention and positive outcomes were superior following weekly contact with a therapist, as compared to self-guided. Multimodal interventions may be especially needed, given the documented decline in caregiver participation over the course of internet-based positive parenting programs [53]. One consideration for future intervention development is that videoconference coaching may require high-speed broadband coverage, which may reduce accessibility for this benefit for rural families, as approximately 73% of rural households have home subscriptions [49].

Unexpectedly, there were some gender differences in the preferred modality and timing of this type of responsive parenting resource. Specifically, women caregivers preferred resources in the immediate period after diagnosis, while men caregivers preferred resources after cancer treatment had concluded. Although not universal even amongst our participants, this may be attributed to the common division of responsibility and typical gender roles after a child is diagnosed with cancer. Mothers often directly support the child in the hospital, while fathers and grandfathers often maintain their work schedule and household responsibilities [54,55]. Fathers may prefer to wait until after treatment is concluded when they feel more involved and included in care. Furthermore, there may be gender differences in how caregivers cope and adjust to the diagnosis and treatment [56], which may affect readiness for intervention. Still, this difference in preferred timing of resources may also be attributed to the difference in mean age and caregiver type, such that there were two grandfathers but no grandmothers in our small sample. At least one grandfather reported that he preferred to receive information about responsive parenting through the self-guided platform as opposed to coaching due to feeling defensive or "judged." This aligns with previous work suggesting that fathers and other caregivers who are men may face unique barriers in help-seeking [57] and are often excluded from parenting intervention research [58]. Given that preferences in timing and modality may differ across family members, DHI such as PLAY might be offered to families earlier and more periodically throughout the illness trajectory, with careful framing of the parenting intervention to encourage father engagement.

Limitations

Although this usability testing study offers several insights for the refinement of digital health platforms for caregivers of young children with chronic health conditions, several limitations should be considered. First, although we attempted to conduct stratified sampling, our post hoc testing indicated possible ascertainment bias with our subsample, including slightly older caregivers, who may have differing usability and information preferences than younger caregivers. Similarly, our recruitment rate of approximately 40% was relatively low, yet higher than a similar study with caregivers of young children following TBI (25%) [27]. This highlights the inherent challenges of engaging with caregivers of young children with complex medical needs, requiring future work to identify additional ways to engage and provide accessible psychosocial care to this underserved and sometimes hard-to-reach group. Second, although our sample size was sufficient to assess usability experience [39], we were not powered to examine subgroup differences based on type of caregiver or diagnostic group. Third, we used a rapid analysis approach [34], in which we were unable to calculate interrater reliability between coders. The interviewers and coders were part of the study team and, thus, their probing during interviews and observations in rapid analysis may have been biased. Still, the usability was assessed with multiple methods (ie, standardized measures, reaction cards, and "think aloud" procedures), in line with current research recommendations [43]. Finally, the single-session usability testing limited the review of only one module in detail (ie, responsive parenting). Future work will need to obtain perspectives of the PLAY intervention comprehensively (ie, other modules listed in File S3 in Multimedia Appendix 1).

Future Study Plans

Overall, internet-based responsive parenting interventions to support caregivers of young children may have promising transdiagnostic applications. However, creative problem-solving may be needed to improve future engagement, uptake, and implementation. Guided by the CFIR framework and designing with implementation in mind, our next step (ie, phase 3) will

XSL•FO
RenderX

involve an iterative co-design process [59] with a CAB (n=13) and a multidisciplinary Healthcare Provider Advisory Board (HPAB; n=11). Co-design involves close collaboration between researchers, designers, and users, who serve as the experts due to their experiences [59]. For our proposed study, the research study team will partner with both the CAB and HPAB during monthly meetings held via videoconference to review and discuss feedback on each module of the PLAY program to allow for in-depth feedback and tailoring of each page of the intervention. For example, the self-care and relationships (refer to File S3 in Multimedia Appendix 1) modules focus on how the caregiver and their relationships have been affected, as well as strategies that may help (eg, relaxation strategies, and "I statements"). Both advisory boards will collaborate with the study team to develop and iteratively refine the graphics, videos, exercises, and text-based content to reflect their lived experiences and clinical expertise. Additional single-session user-experience testing with another group of caregivers will be conducted to ensure adequate usability (SUS ≥68) with the refined and tailored PLAY program. A pilot of the PLAY intervention will test feasibility and acceptability with caregivers of young survivors of childhood cancer, with a small randomized controlled trial to follow. A future larger randomized controlled trial will determine whether the program improves responsive parenting behaviors over several months and leads to downstream effects on neurodevelopmental outcomes for young survivors of childhood cancer. Future work will also identify barriers and facilitators in the inner and outer settings from the CFIR framework to support the adoption of the PLAY intervention in clinical practice.

Conclusion

Designing equitable digital health interventions demands the active and ongoing engagement of individuals with lived experience across all stages of design, particularly ensuring the inclusion of underrepresented groups to optimize success.

Acknowledgments

The authors would like to acknowledge and thank the funding and support of The Ohio State University Presidential Postdoctoral Scholars program and the American Psychological Association Division 54 Drotar-Crawford Postdoctoral Fellowship Research Grant in Pediatric Psychology, which were each awarded to Emily Moscato, PhD, and her mentor, Cynthia A. Gerhardt, PhD. This publication was also supported, in part, by The Ohio State University Clinical and Translational Science Institute (CTSI) and the National Center for Advancing Translational Sciences of the National Institutes of Health (grant UM1TR004548). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. We would also like to acknowledge the families of young survivors who participated in this project and served on the Preparing for Life and Academics for Young Survivors Caregiver Advisory Board, and on our Healthcare Provider Advisory Board during the co-design process. Finally, we would like to acknowledge the original development of the Gaining Real Life Skills over the web team from Cincinnati Children's Hospital Medical Center and the graphic design support in developing the heatmap from Will Ray, PhD, from Nationwide Children's Hospital.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Conflicts of Interest

ES is an editorial board member of JMIR.

Multimedia Appendix 1
High-fidelity prototype of the Preparing for Life and Academics for Young Survivors (PLAY) program module 1.2 used during usability testing, semistructured interviewing guide, and heatmap of pages accessed during passive usability.
[DOCX File, 2007 KB - pediatrics_v8i1e70055_app1.docx]

References

1. Erdmann F, Frederiksen LE, Bonaventure A, et al. Childhood cancer: survival, treatment modalities, late effects and improvements over time. Cancer Epidemiol 2021 Apr;71(Pt B):101733. [doi: 10.1016/j.canep.2020.101733] [Medline: 32461035]
2. Pierson C, Waite E, Pyykkonen B. A meta‐analysis of the neuropsychological effects of chemotherapy in the treatment of childhood cancer. Pediatr Blood Cancer 2016 Nov;63(11):1998-2003. [doi: 10.1002/pbc.26117]
3. Bhakta N, Liu Q, Ness KK, et al. The cumulative burden of surviving childhood cancer: an initial report from the St Jude Lifetime Cohort Study (SJLIFE). Lancet 2017 Dec;390(10112):2569-2582. [doi: 10.1016/S0140-6736(17)31610-0]
4. Nightingale CL, Quinn GP, Shenkman EA, et al. Health-related quality of life of young adult survivors of childhood cancer: a review of qualitative studies. J Adolesc Young Adult Oncol 2011 Sep;1(3):124-132. [doi: 10.1089/jayao.2011.0033] [Medline: 23610733]

XSL•FO
RenderX

5. Godoy PBG, Simionato NM, de Mello CB, et al. Assessment of executive functions after treatment of childhood acute lymphoid leukemia: a systematic review. Neuropsychol Rev 2020 Sep;30(3):386-406. [doi: 10.1007/s11065-020-09446-4] [Medline: 32720195]
6. Neu MA, Schlecht J, Schmidt MF, et al. Mental health and health‐related quality of life in preschool‐aged childhood cancer survivors. Results of the prospective cohort study ikidS‐OEVA. Pediatr Blood Cancer 2021 Aug;68(8):e29039. [doi: 10.1002/pbc.29039]
7. Willard VW, Cox LE, Russell KM, et al. Cognitive and psychosocial functioning of preschool-aged children with cancer. J Dev Behav Pediatr 2017;38(8):638-645. [doi: 10.1097/DBP.0000000000000512]
8. Ljungman L, Cernvall M, Grönqvist H, et al. Long-term positive and negative psychological late effects for parents of childhood cancer survivors: a systematic review. PLoS ONE 2014;9(7):e103340. [doi: 10.1371/journal.pone.0103340] [Medline: 25058607]
9. Dunn MJ, Rodriguez EM, Barnwell AS, et al. Posttraumatic stress symptoms in parents of children with cancer within six months of diagnosis. Health Psychol 2012 Mar;31(2):176-185. [doi: 10.1037/a0025545] [Medline: 21942750]
10. Ilic A, Sievers Y, Roser K, et al. The information needs of relatives of childhood cancer patients and survivors: a systematic review of qualitative evidence. Patient Educ Couns 2023 Sep;114:107840. [doi: 10.1016/j.pec.2023.107840] [Medline: 37321115]
11. Willard VW, Qaddoumi I, Zhang H, et al. A longitudinal investigation of parenting stress in caregivers of children with retinoblastoma. Pediatr Blood Cancer 2017 Apr;64(4):e26279. [doi: 10.1002/pbc.26279] [Medline: 27808461]
12. Antonini TN, Raj SP, Oberjohn KS, et al. A pilot randomized trial of an online parenting skills program for pediatric traumatic brain injury: improvements in parenting and child behavior. Behav Ther 2014 Jul;45(4):455-468. [doi: 10.1016/j.beth.2014.02.003] [Medline: 24912459]
13. Landry SH, Smith KE, Swank PR, Guttentag C. A responsive parenting intervention: the optimal timing across early childhood for impacting maternal behaviors and child outcomes. Dev Psychol 2008 Sep;44(5):1335-1353. [doi: 10.1037/a0013030] [Medline: 18793067]
14. Appalachian counties served by ARC. Appalachian Regional Commission. 2022. URL: arc.gov/appalachian-counties-served-by-arc/ [accessed 2025-07-08]
15. Yao N, Alcalá HE, Anderson R, Balkrishnan R. Cancer disparities in rural Appalachia: incidence, early detection, and survivorship. J Rural Health 2017 Sep;33(4):375-381. [doi: 10.1111/jrh.12213] [Medline: 27602545]
16. Fisher AP, Patronick J, Moscato EL, et al. Barriers to care and perceived need for mental health services among adolescent and emerging adult survivors of pediatric brain tumors. J Adolesc Young Adult Oncol 2024 Jun;13(3):469-480. [doi: 10.1089/jayao.2023.0119] [Medline: 38100322]
17. Warner EL, Montenegro RE, Stroup A, et al. Health care concerns of rural childhood cancer survivors. J Health Care Poor Underserved 2014 May;25(2):901-912. [doi: 10.1353/hpu.2014.0095] [Medline: 24858893]
18. Olson AL, Boyle WE, Evans MW, Zug LA. Overall function in rural childhood cancer survivors. The role of social competence and emotional health. Clin Pediatr (Phila) 1993 Jun;32(6):334-342. [doi: 10.1177/000992289303200603] [Medline: 8344043]
19. Moscato EL, Fisher AP, Patronick J, et al. Quality of life for rural and Appalachian pediatric brain tumor survivors in Ohio and Kentucky. Clin Pract Pediatr Psychol 2025;13(1):11-16. [doi: 10.1037/cpp0000524]
20. Bird M, Li L, Ouellette C, et al. Use of synchronous digital health technologies for the care of children with special health care needs and their families: scoping review. JMIR Pediatr Parent 2019 Nov 21;2(2):e15106. [doi: 10.2196/15106] [Medline: 31750840]
21. Chi NC, Demiris G. A systematic review of telehealth tools and interventions to support family caregivers. J Telemed Telecare 2015 Jan;21(1):37-44. [doi: 10.1177/1357633X14562734] [Medline: 25475220]
22. Mobile broadband maps. United States Federal Communications Commission. 2021. URL: https://www.fcc.gov/BroadbandData/MobileMaps [accessed 2025-07-08]
23. Schmidt MM, Earnshaw Y, Tawfik A, Jahnke I. Methods of user centered design and evaluation for learning designers. In: Learner and User Experience Research: An Introduction for the Field of Learning Design &Amp; Technology: EdTechBooks; 2020:1-129 URL: https://www.researchgate.net/publication/344752507_Methods_of_User_Centered_Design_and_Evaluation_for_Learning_Designers [accessed 2025-07-16]
24. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci 2009 Aug 7;4(1):50. [doi: 10.1186/1748-5908-4-50] [Medline: 19664226]
25. Dopp AR, Parisi KE, Munson SA, Lyon AR. A glossary of user-centered design strategies for implementation experts. Transl Behav Med 2019 Nov 25;9(6):1057-1064. [doi: 10.1093/tbm/iby119] [Medline: 30535343]
26. Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q 2004;82(4):581-629. [doi: 10.1111/j.0887-378X.2004.00325.x] [Medline: 15595944]
27. Maggard BL, Gies LM, Sidol CA, et al. Online intervention for caregivers of children with early traumatic brain injury: pilot trial. J Pediatr Psychol 2023 Mar 20;48(3):205-215. [doi: 10.1093/jpepsy/jsac080] [Medline: 36240452]

XSL•FO
RenderX

28. Gies LM, Narad M, Moscato EL, et al. An open pilot of GROW, a responsive parenting intervention for young children with brain injuries: preliminary efficacy. Disabil Rehabil 2024 Oct 14:1-8. [doi: 10.1080/09638288.2024.2413177] [Medline: 39397520]
29. Hyzy M, Bond R, Mulvenna M, et al. System Usability Scale benchmarking for digital health apps: meta-analysis. JMIR Mhealth Uhealth 2022 Aug 18;10(8):e37290. [doi: 10.2196/37290] [Medline: 35980732]
30. Brooke J. SUS-a quick and dirty usability scale. In: Usability Evaluation in Industry: Taylor & Francis Group; 1996:189-194 URL: https://www.taylorfrancis.com/chapters/edit/10.1201/9781498710411-35/sus-quick-dirty-usability-scale-john-brooke [accessed 2025-07-16]
31. Schmidt MM, Earnshaw Y, Tawfik A, et al. Methods of user centered design and evaluation for learning designers. In: Learner and User Experience Research: An Introduction for the Field of Learning Design & Technology: EdTechBooks; 2020. URL: https://www.researchgate.net/publication/344752507_Methods_of_User_Centered_Design_and_Evaluation_for_Learning_Designers [accessed 2025-07-16]
32. Taylor B, Henshall C, Kenyon S, et al. Can rapid approaches to qualitative analysis deliver timely, valid findings to clinical leaders? A mixed methods study comparing rapid and thematic analysis. BMJ Open 2018 Oct 8;8(10):e019993. [doi: 10.1136/bmjopen-2017-019993] [Medline: 30297341]
33. Nevedal AL, Reardon CM, Opra Widerquist MA, et al. Rapid versus traditional qualitative analysis using the Consolidated Framework for Implementation Research (CFIR). Implement Sci 2021 Jul 2;16(1):67. [doi: 10.1186/s13012-021-01111-5] [Medline: 34215286]
34. Beebe J. Rapid Assessment Process: An Introduction: AltaMira Press; 2001. URL: https://search.worldcat.org/title/rapid-assessment-process-an-introduction/oclc/45871052 [accessed 2025-07-16]
35. Landry SH, Smith KE, Swank PR. Responsive parenting: establishing early foundations for social, communication, and independent problem-solving skills. Dev Psychol 2006 Jul;42(4):627-642. [doi: 10.1037/0012-1649.42.4.627] [Medline: 16802896]
36. Ainsworth MDS, Blehar MC, Waters E, Wall S. Patterns of Attachment: A Psychological Study of the Strange Situation: Psychology Press; 2015. URL: https://psycnet.apa.org/record/1980-50809-000 [accessed 2025-07-16]
37. Bornstein MH, Tamis-LeMonda CS. Maternal responsiveness and cognitive development in children. New Dir Child Adolesc Dev 1989;1989(43):49-61. [doi: 10.1002/cd.23219894306]
38. Rural-urban commuting area codes. USDA Economic Research Service. 2025. URL: ers.usda.gov/data-products/rural-urban-commuting-area-codes/ [accessed 2025-06-14]
39. Nielsen J, Phillips VL. Estimating the relative usability of two interfaces: heuristic, formal, and empirical methods compared. Presented at: Proceedings of the INTERACT '93 and CHI '93 Conference on Human Factors in Computing Systems; Apr 24-29, 1993; Amsterdam, NL URL: https://dl.acm.org/doi/10.1145/169059.169173 [accessed 2025-07-16]
40. Holden RJ, Karsh BT. The technology acceptance model: its past and its future in health care. J Biomed Inform 2010 Feb;43(1):159-172. [doi: 10.1016/j.jbi.2009.07.002] [Medline: 19615467]
41. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the System Usability Scale. Int J Hum Comput Interact 2008 Jul 29;24(6):574-594. [doi: 10.1080/10447310802205776]
42. Benedek J, Miner T. Measuring desirability: new methods for evaluating desirability in a usability lab setting. Presented at: Proceedings of Usability Professionals Association, 2002; Jul 8-12, 2002; Orlando, FL URL: https://tinyurl.com/mv9fupur [accessed 2025-07-16]
43. Lu J, Schmidt M, Lee M, Huang R. Usability research in educational technology: a state-of-the-art systematic review. Education Tech Research Dev 2022 Dec;70(6):1951-1992. [doi: 10.1007/s11423-022-10152-6]
44. O'Connor A, Tai A, Brinn M, et al. Co-design of an augmented reality asthma inhaler educational intervention for children: development and usability study. JMIR Pediatr Parent 2023 Jul 25;6:e40219. [doi: 10.2196/40219] [Medline: 37490325]
45. Pickard KE, Kilgore AN, Ingersoll BR. Using community partnerships to better understand the barriers to using an evidence-based, parent-mediated intervention for autism spectrum disorder in a medicaid system. Am J Community Psychol 2016 Jun;57(3-4):391-403. [doi: 10.1002/ajcp.12050] [Medline: 27216766]
46. Parsons D, Cordier R, Vaz S, Lee HC. Parent-mediated intervention training delivered remotely for children with autism spectrum disorder living outside of urban areas: systematic review. J Med Internet Res 2017 Aug 14;19(8):e198. [doi: 10.2196/jmir.6651] [Medline: 28807892]
47. Kobak KA, Stone WL, Wallace E, et al. A web-based tutorial for parents of young children with autism: results from a pilot study. Telemed J E Health 2011 Dec;17(10):804-808. [doi: 10.1089/tmj.2011.0060] [Medline: 22011005]
48. Fidika A, Herle M, Lehmann C, et al. A web-based psychological support program for caregivers of children with cystic fibrosis: a pilot study. Health Qual Life Outcomes 2015 Feb 4;13:11. [doi: 10.1186/s12955-015-0211-y] [Medline: 25652684]
49. Internet, broadband fact sheet. Pew Research Center. 2024. URL: https://www.pewresearch.org/internet/fact-sheet/internet-broadband/ [accessed 2025-07-08]
50. Păsărelu CR, Kertesz R, Dobrean A. The development and usability of a mobile app for parents of children with ADHD. Children (Basel) 2023 Jan 14;10(1):164. [doi: 10.3390/children10010164] [Medline: 36670714]
51. Stinson J, Gupta A, Dupuis F, et al. Usability testing of an online self-management program for adolescents with cancer. J Pediatr Oncol Nurs 2015;32(2):70-82. [doi: 10.1177/1043454214543021] [Medline: 25037173]

XSL•FO
RenderX

52. Pettersson L, Johansson S, Demmelmaier I, Gustavsson C. Disability digital divide: survey of accessibility of eHealth services as perceived by people with and without impairment. BMC Public Health 2023 Jan 27;23(1):181. [doi: 10.1186/s12889-023-15094-z] [Medline: 36707791]
53. Dadds MR, Sicouri G, Piotrowska PJ, et al. Keeping parents involved: predicting attrition in a self-directed, online program for childhood conduct problems. J Clin Child Adolesc Psychol 2019;48(6):881-893. [doi: 10.1080/15374416.2018.1485109] [Medline: 30067388]
54. Hjelmstedt SK, Forinder UM, Lindahl Norberg AM, Hovén EIM. A balancing act: working and caring for a child with cancer. J Child Fam Stud 2021 Aug;30(8):1881-1894. [doi: 10.1007/s10826-021-01997-1]
55. Clarke NE, McCarthy MC, Downie P, et al. Gender differences in the psychosocial experience of parents of children with cancer: a review of the literature. Psychooncology 2009 Sep;18(9):907-915. [doi: 10.1002/pon.1515] [Medline: 19319828]
56. Compas BE, Bemis H, Gerhardt CA, et al. Mothers and fathers coping with their children's cancer: Individual and interpersonal processes. Health Psychol 2015 Aug;34(8):783-793. [doi: 10.1037/hea0000202] [Medline: 25622077]
57. Tully LA, Piotrowska PJ, Collins DAJ, et al. Optimising child outcomes from parenting interventions: fathers' experiences, preferences and barriers to participation. BMC Public Health 2017 Jun 7;17(1):550. [doi: 10.1186/s12889-017-4426-1] [Medline: 28592244]
58. Panter-Brick C, Burgess A, Eggerman M, et al. Practitioner review: engaging fathers--recommendations for a game change in parenting interventions based on a systematic review of the global evidence. J Child Psychol Psychiatry 2014 Nov;55(11):1187-1212. [doi: 10.1111/jcpp.12280] [Medline: 24980187]
59. Sanders EBN, Stappers PJ. Co-creation and the new landscapes of design. CoDesign 2008 Mar;4(1):5-18. [doi: 10.1080/15710880701875068]

Abbreviations:

CAB: Caregiver Advisory Board
CFIR: Consolidated Framework for Implementation Research
DHI: digital health interventions
GROW: Gaining Real Life Skills Over the Web
HPAB: Healthcare Provider Advisory Board
PALS: Play and Learning Strategies
PLAY: Preparing for Life and Academics for Young Survivors
REDCap: Research Electronic Data Capture
SUS: System Usability Scale
TBI: traumatic brain injury

Edited by S Badawy; submitted 13.12.24; peer-reviewed by N Yamaji, NH Mohamad Zainal; revised version received 21.05.25; accepted 22.05.25; published 05.08.25.

Please cite as:
Moscato EL, Darow E, Quach J, M Winning A, Schmidt M, Wade SL, Gerhardt CA, Sezgin E
Usability Testing of an Internet-Based Responsive Parenting Program for Caregivers of Young Survivors of Childhood Cancer Living in Rural and Appalachian Communities: Mixed Methods Study
JMIR Pediatr Parent 2025;8:e70055
URL: https://pediatrics.jmir.org/2025/1/e70055
doi:10.2196/70055

© Emily L Moscato, Eva Darow, Jessica Quach, Adrien Winning, Matthew Schmidt, Shari L Wade, Cynthia A Gerhardt, Emre Sezgin. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 5.8.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Evaluating a Digital Intervention to Reduce Aggression and Pro-Firearm Violence Attitudes Among Young Black Males: Pretest-Posttest Feasibility Study

Chuka Emezue[1], PhD, MPH, MPA, CHES; Jessica Bishop-Royse[1], MPH, PhD; Andrew Froilan[1], RN, MSN; Tara Wilkes[1], RN, BSN, CCRN; Niranjan S Karnik[2], MD, PhD; Wrenetha A Julion[1], RN, CNL, MPH, PhD

[1]Department of Women, Children and Family Nursing, College of Nursing, Rush University, 600 S Paulina St, Suite 1080, Armour Academic Center, Chicago, IL, United States

[2]Department of Psychiatry, University of Illinois Chicago, College of Medicine, Institute for Juvenile Research, Chicago, IL, United States

Corresponding Author:
Chuka Emezue, PhD, MPH, MPA, CHES
Department of Women, Children and Family Nursing, College of Nursing, Rush University, 600 S Paulina St, Suite 1080, Armour Academic Center, Chicago, IL, United States

Abstract

Background: Pediatric and adolescent firearm injuries and fatalities in the United States have surged to levels not seen since the mid-1990s, marking a critical public health inflection point. Young Black males (ages 15 - 24) experience firearm-related fatality rates 24 times higher than their White peers. Despite this disproportionate risk, they are less likely to participate in traditional firearm violence prevention programs. This disparity highlights the urgent need for innovative, culturally responsive approaches that address the emotional, behavioral, and social determinants of violence.

Objective: This pilot study aims to evaluate the preliminary effects of BrotherlyACT, a culturally responsive, trauma-informed, multicomponent mobile and web-based intervention designed to support young Black males (ages 15 - 24) in navigating and preventing community violence, substance use, and mental health challenges. The intervention aims to increase access to precrisis support and mental health resources for youth living in low-resource, high-violence settings.

Methods: Seventy young Black males with Serious Fighting, Friend Weapon Carrying, Community Environment, and Firearm Threats (SaFETy) scores between 1 and 5 (indicating low-to-moderate firearm violence risk) were enrolled in this prospective pretest-posttest study. Participants completed a psychoeducational component of the BrotherlyACT intervention, consisting of 7 video-based modules. Surveys were administered at baseline and again 4 weeks later to assess changes in attitudes toward guns and violence (Attitudes Toward Guns and Violence Questionnaire), reactive and proactive aggression (Reactive-Proactive Aggression Questionnaire), psychological distress (Kessler Psychological Distress Scale), and depressive symptoms (8-item Patient Health Questionnaire). Paired *t* tests were conducted to analyze pre-post differences.

Results: A total of 70 young Black males (mean age 20.97 years, SD 2.44 years) participated in the study. Nearly half reported recent physical fights (48/70, 69%), gun threats (39/70, 56%), or hearing gunshots in their neighborhood (63/70, 90%). More than 50% (39/70, 56%) reported illicit drug use, and 32 out of 70 (46%) reported substance-related violence. SaFETy scores revealed heterogeneous but elevated exposure to firearm risk factors, particularly in community violence and firearm threats. Postintervention, participants demonstrated a statistically significant reduction in attitudes toward guns and violence (Attitudes Toward Guns and Violence Questionnaire; mean 29.8-26.1, $P<.001$, $d=0.53$), with the largest shift observed in "Aggressive Response to Shame" (28% reduction). Reactive aggression significantly declined (mean 10.48-8.67, $P=.008$, $d=0.37$), whereas proactive aggression remained stable. Psychological distress and depressive symptoms remained stable. Nearly all participants (68/70, 97%) completed all modules in a single session, with 47 out of 70 (67%) finishing within an hour, suggesting high feasibility and user engagement.

Conclusions: Preliminary findings indicate that BrotherlyACT may reduce proviolence attitudes and reactive aggression among young Black males. These results underscore the feasibility and potential impact of culturally responsive digital interventions as a strategy to prevent firearm violence among underserved youth populations.

Trial Registration: ClinicalTrials.gov NCT06359990; https://clinicaltrials.gov/study/NCT06359990

International Registered Report Identifier (IRRID): RR2-10.2196/43842

(JMIR Pediatr Parent 2025;8:e70048) doi:10.2196/70048

XSL•FO
RenderX

KEYWORDS

mental health; youth violence; substance use; digital intervention; prevention

Introduction

Firearm injuries and homicides constitute a national public health crisis in the United States, representing the leading cause of death among children and youth aged 0‐24 years [1,2]. This epidemic, including firearm homicides, suicides, incidental shootings, and nonfatal incidents, disproportionately affects children and adolescents in low-income urban and rural communities. Young Black males aged 15–24 experience the highest firearm homicide burden in the United States, with rates reaching 52.9 per 100,000 [2-4], more than 18 to 24 times higher than those of their White male peers, particularly in the aftermath of the COVID-19 pandemic [3,5-9].

Black youth remain historically underserved in mental health and early violence prevention systems (ie, primary prevention). Barriers to accessing trauma-informed care include stigma, institutional mistrust, racialized criminalization, and systemic underinvestment in their communities [10]. Even after injury, long wait times, limited follow-up, cold referrals, and provider mistrust deter intervention and engagement with follow-up services [11-16]. Critically, a major limitation of existing pediatric firearm injury prevention programs is their focus on postviolence contexts, typically after youth present in emergency departments (EDs) [17-19] or at advanced stages of violence involvement, such as during adjudication or institutionalization [16,17,20]. While ED-based programs show promising effects in reducing aggression and trauma [17,18,21-23], they face challenges such as staffing shortages, reimbursement issues, and difficulties with postdischarge follow-up [18]. These systemic and structural barriers continue to discourage young male engagement in interventions and contribute to service avoidance or early dropouts from programs.

Before an injury or ED contact, psychosocial and behavioral risk factors, such as aggression, emerge as modifiable determinants of firearm violence that can be addressed early in life [3,7,24-28]. Within this context, 2 subtypes of aggression are noteworthy: reactive and proactive aggression. Reactive aggression is characterized by impulsive responses to perceived threats and emotional dysregulation [29-32], whereas proactive aggression is calculated, planned, and self-serving, often associated with status and protection [33,34]. These aggression subtypes predict firearm risk more reliably than household firearm access alone [35], yet they are rarely targeted in primary prevention efforts aimed at reducing pediatric firearm injuries and homicides.

Recent evidence indicates that digital mental health interventions can effectively improve mental and behavioral health outcomes among children and adolescents, including those from high-risk or marginalized backgrounds with limited access to existing and traditional resources. In a systematic review focused on low- and middle-income settings, Lehtimaki et al [36] found that digital interventions produced promising reductions in adolescent depression and anxiety. Similarly, self-guided digital interventions have been shown to reduce suicidal ideation among youth [37]. In high-income contexts, Lattie et al [38] emphasized the importance of user-centered design in mobile and web-based tools targeting depression and anxiety among young adults. Additionally, Ranney et al [39,40] demonstrated that app-based tools used in ED settings can reduce aggressive behaviors in urban adolescents. These findings highlight the potential of digital health interventions as scalable and accessible tools for youth mental health and violence prevention.

Building on this evidence, we developed *BrotherlyACT*, a culturally responsive, trauma-informed, multicomponent mobile and online intervention designed to support young Black males (aged 15‐24 years) in navigating and preventing community violence, substance use, and mental health challenges. The app aims to improve access to precrisis support and mental health resources for youth living in low-resource, high-violence environments. We conducted a single-group, prospective pre-post pilot study to evaluate the preliminary effects of BrotherlyACT's video-based psychoeducational modules. Primary outcomes were changes in reactive and proactive aggression, firearm-related attitudes, and mental health indicators.

Methods

Study Design

This prospective pretest/posttest pilot study was conducted from June to July 2024. It adheres to the guidelines for nonrandomized pilot and feasibility studies, as well as the CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) guidelines. A comprehensive description of the study protocol is provided elsewhere [41].

In addition, prior usability testing and heuristic evaluation of the BrotherlyACT intervention involving young Black males and mobile health (mHealth) specialists have been documented elsewhere [42]. The app received an average System Usability Scale score of 79, equivalent to an A-minus grade and placing it in the 85th percentile, indicating near-excellent usability [42]. Similarly, heuristic evaluation by mHealth experts identified only minor and cosmetic usability issues, with a median severity score of 1 across various heuristics (on a scale of 0‐3), indicating minimal impact on user experience. Overall, minor adjustments were recommended to improve navigation, customization, and user guidance, while the app's visual and functional design was generally well received [42].

Ethical Considerations

This study was reviewed and approved by the Rush University Institutional Review Board (approval number 21122902), and the protocol was registered on ClinicalTrials.gov (NCT06359990). Informed e-consent was obtained from all participants. For those under 18 years of age, parental or guardian consent and participant assent were obtained before enrollment. Participants were informed of the voluntary nature of their involvement, their right to withdraw at any time without

XSL•FO
RenderX

penalty, and measures to protect their confidentiality and data privacy. All data were deidentified, coded using unique participant IDs, and stored in encrypted, password-protected databases accessible only to authorized study staff. No identifiable information was linked to survey responses or intervention data. Given the vulnerability of this population, additional safeguards were implemented, including private consent procedures, information on local support services, and on-call support for participants reporting distress or imminent risk. To compensate participants for their time and contribution, US $50 was provided after completing the pretest survey and intervention, and an additional US $50 (Target or Amazon e-gift card) was distributed 4 weeks later following completion of the posttest questionnaires.

Study Procedures

Participants: Inclusion and Eligibility Criteria

Eligible participants met the following criteria: (1) male-identifying; (2) Black/African American; (3) aged 15 - 24 years; (4) a score >1 on the 4-item Serious Fighting, Friend Weapon Carrying, Community Environment, and Firearm Threats (SaFETy) clinical screening tool, indicating elevated risk for future firearm violence based on 4 domains: Serious Fighting, Friends' Weapon Carrying, Community Environment, and Firearm Threats [43,44]; (5) English literate; and (6) able to assent/consent (with parental consent if under 18).

Exclusion criteria were (1) being detained or incarcerated; (2) inability to complete assent/consent and assessment forms due to language barriers, cognitive dysfunction, or injury; (3) presenting with an acute psychotic disorder, a suicide attempt as the mechanism of firearm injury, or a recent sexual assault requiring intensive psychosocial support; and (4) a score ≥6 on the SaFETy tool, as such individuals were referred to more intensive programs, as recommended by Goyal et al [45]. Recruitment was successfully conducted in collaboration with community partners, including local organizations, school-based health centers, and social media, with minimal loss to follow-up due to the intervention's brief and single-session format.

Upon expressing interest in the study, participants completed a sociodemographic enrollment form on Research Electronic Data Capture (REDCap; Vanderbilt University), adapted from the biennial cross-sectional Youth Risk Behavior Surveillance System (YRBS) survey. All study procedures were reviewed and approved by the Rush University Institutional Review Board. Informed e-consent was obtained in accordance with federal and institutional guidelines for research involving minors using REDCap. Consent and assent forms were written in age-appropriate and culturally sensitive language, and all participants were informed of their right to decline or withdraw at any time without penalty.

Participants then completed a pretest survey battery comprising 63 questions assessing psychological distress (Kessler Psychological Distress Scale [K10]), depression (8-item Patient Health Questionnaire [PHQ-8]), attitudes toward guns and violence (Attitudes Toward Guns and Violence Questionnaire [AGVQ]), and aggression (Reactive-Proactive Aggression Questionnaire [RPQ]). All survey questions remained unchanged, as these instruments have been previously validated for use with children and adolescents. To ensure greater control over participant access, engagement tracking, and data capture during the pilot phase, the intervention was delivered via REDCap, with embedded YouTube-hosted videos simulating the app's video modules. This approach enabled secure and streamlined testing of the core acceptance and commitment therapy (ACT)–based video modules before full app deployment, allowing us to evaluate the acceptability and preliminary effects of the behavioral modules while testing fidelity to content delivery and use styles, and engagement tracking.

Immediately following baseline survey completion, participants were given access to the BrotherlyACT modules and instructed to complete all video-based modules and in-app content either in 1 sitting or at their own pace within a 48-hour window. The posttest survey was administered electronically exactly 4 weeks (28 days) after the pretest, regardless of when participants completed the intervention content.

Additionally, we tracked the amount of time participants spent on the REDCap page and their engagement with the videos (ie, in-app quiz completion, likes and comments). Participants who completed the video content prematurely, either by not viewing all the materials or by skipping through them rapidly, were encouraged to reengage through various means, including indicating approval, providing comments, or submitting a summary of the knowledge acquired from the video content via email. Incentives for participating in the study were distributed after completion of the pretest and video modules (US $50) and again 4 weeks later, following completion of the posttest questionnaires (US $50 in the form of Target and Amazon e-gift cards).

Intervention: BrotherlyACT's Video-Based Psychoeducational Modules

Drawing from evidence-based behavior change models and community insights, the app incorporated elements that address the personal, social, and environmental factors contributing to youth firearm-related violence. Its development involved collaborative design with young Black males from the target age group, ensuring that the app's content, imagery, language, and delivery methods were culturally attuned to their real-life experiences.

As at testing, the app comprised a set of 8 concise, video-based psychoeducational modules that depict realistic situations. These modules address topics such as refusing guns, resisting gang involvement, practicing gun safety, saying no to alcohol and drugs, resolving conflicts, avoiding retaliation, recognizing healthy and unhealthy relationships, practicing mindfulness, cultivating a positive outlook on the future, and using adaptive coping strategies. They incorporate behavioral skills training, emotional regulation techniques, and decision-making strategies to help reduce youth violence and risky firearm behavior. The app's video modules are primarily based on ACT [46-49], a third-wave cognitive behavioral therapy that emphasizes accepting and navigating difficult thoughts and emotions rather than attempting to persistently change or avoid them [50-54]. ACT has demonstrated efficacy in improving emotional

XSL•FO
RenderX

regulation and reducing aggression among trauma-exposed youth, who often cannot control their environments but can control how they respond to and navigate these chronic and intersecting issues [55]. Utilizing a micro-learning approach, complex topics were broken down into smaller, ready-to-use and life skill-based components to enhance comprehension, application, and retention, particularly for youth with various attention spans [56,57].

A Black male narrator presents the modules with multimedia and interactive heuristics, offering skills for navigating and preventing firearm-related scenarios such as peer pressure to carry weapons, retaliatory violence, and rejecting gang involvement. The modules use culturally familiar language and visuals, with a tone that emphasizes respect, empowerment, motivational enhancement, and nonpunitive language to avoid pathologizing young people's behavior. Table 1 summarizes the behavioral skill objectives and theoretical frameworks underpinning each BrotherlyACT module.

Table . BrotherlyACT module overview: focus areas, behavioral skills, and theoretical underpinnings.

Module title	Module target	Behavioral skills taught	Theoretical underpinning
Gun Safety 101	Firearm safety and harm reduction	Safe storage awareness and noncarry decision-making	Harm reduction theory and social cognitive theory
Gun Refusal Skills 101	Peer pressure and firearm refusal	Assertive communication and verbal refusal strategies	Social norms theory and motivational interviewing
Healthy Relationship Skills	Intimate partner and peer conflict	Emotional literacy, boundary-setting, and consent communication	Attachment theory and acceptance and commitment therapy
Gang Resistance Skills	Gang avoidance and safety navigation	Risk recognition, exit planning, and identity affirmation	Strength-based approach and narrative therapy
Coping Skills	Managing stress, trauma, and emotion	Emotion regulation, distress tolerance, and adaptive self-talk	Acceptance and commitment therapy and cognitive behavioral theory
Mindfulness for Black Boys	Emotional regulation and trauma recovery	Grounding, breathwork, and body scanning	Acceptance and commitment therapy and mindfulness-based stress reduction
Alcohol and Drug Refusal Skills	Substance use prevention	Refusal techniques and decision-making	Social learning theory and motivational interviewing
Conflict Resolution Skills	De-escalation and self-regulation	"Cool down" tools, perspective-taking, and problem-solving	Acceptance and commitment therapy and problem-solving therapy

The broader BrotherlyACT app also includes additional features such as (1) a safety planning toolkit with interactive tools for mood tracking, risk assessment, mindfulness exercises, goal setting, and a zip code–enabled directory of local mental health services, community support resources, and violence prevention programs within a 50-mile (80.47 km) radius; and (2) service engagement and talk therapy via an artificial intelligence–powered chatbot named DEVON, a confidential and programmed resource for discussing stressors, emotional triggers, and challenges related to violence and substance use. DEVON was designed as a trauma-informed conversational agent to simulate peer dialogue and support help-seeking behaviors. Embedded within the app interface, the chatbot provides confidential, just-in-time emotional support accessible outside structured intervention sessions. Conversations with DEVON are anonymous, with user input logged only as anonymized session data. Participants are advised not to enter personal identifiers. App access was password-protected and intended for use on personal or study devices in private settings. These additional features were not evaluated in this study.

Sociodemographic Measures

Overview

We adapted items from the Centers for Disease Control and Prevention's biennial YRBS, which assesses health-related behaviors among a nationally representative sample of US students in grades 9‐12. Our analysis included sociodemographic variables such as age, gender, race/ethnicity, socioeconomic status (ie, household income), school and employment status, zip code or address, dating relationship status, and smartphone ownership. The questionnaire also assessed violence (physical and psychological violence toward a partner, 30-day weapon carriage, and community violence) and substance use experiences (ie, 30-day adolescent binge drinking, nonmedical drug use, and substance-related violence perpetration). Substance use behaviors were assessed due to their known association with youth aggression, trauma exposure, and risky weapon-related behaviors [8,27,58]. These variables were included to examine participants' broader behavioral profiles and identify overlapping intervention targets. Table 2 summarizes the sociodemographic characteristics of participants who completed the pretest and posttest questionnaires and received the intervention (ie, the analytic sample).

XSL•FO
RenderX

Table . Sociodemographic characteristics of study participants.

Sociodemographic variables and descriptors	Sample, n (%)
Age (years)[a]	
15 - 18	11 (16)
19 - 24	58 (84)
Ethnicity	
Hispanic/Latinx	7 (10)
Non-Hispanic	63 (90)
Education level	
Some high school (eg, general educational development)	13 (19)
High school diploma	20 (29)
Some trade/technical school	11 (16)
Some college or university	24 (34)
Master's degree	1 (1)
Other	1 (1)
Relationship status	
Dating (serious, casual, or hooking up)	30 (43)
Single	39 (56)
Common law: living with partner/significant other	1 (1)
Employment status[b]	
Full-time (working at least 35 hours/week)	9 (13)
Part-time (working less than 35 hours/week)	34 (49)
Laid off or unemployed	14 (20)
Student	12 (17)
Other	1 (1)
Total annual household income	
Less than US $20,000	17 (24)
US $20,000-US $39,999	17 (24)
US $40,000-US $59,999	15 (21)
US $60,000-US $79,999	11 (16)
US $80,000-US $99,999	7 (10)
US $100,000 or more	3 (4)
Binge drinking in the past 30 days: During the past 30 days, what is the highest number of alcoholic drinks you had in a row, that is, within a couple of hours?	
0 - 0 drinks	17 (24)
1 - 1 or 2 drinks	5 (7)
2 - 3 drinks	15 (21)
3 - 4 drinks	16 (23)
4 - 5 drinks	11 (16)
5 - 6 or 7 drinks	2 (3)
6 - 8 or 9 drinks	3 (4)
7 - 10 or more drinks	1 (1)
Illicit drug use: Used any medications or drugs other than those required for medical reasons	
No	31 (44)

XSL•FO
RenderX

Sociodemographic variables and descriptors	Sample, n (%)
Yes	39 (56)
Violence after substance use: Have you been involved in, perpetrated, or committed any sort of violence or aggression after taking any drugs or alcohol?	
No	38 (54)
Yes	32 (46)
Serious physical fight (past 6 months)	
0 (never)	22 (31)
1 (once)	11 (16)
2 (twice)	17 (24)
3 (3 - 5 times)	19 (27)
4 (6 or more times)	1 (1)
Friend who carried weapons in the past 6 months: How many of your friends have carried a knife, razor, or gun[c]?	
1 (none)	31 (45)
2 (some)	31 (45)
3+ (many, most, or all)	7 (10)
Threatened with a gun in the past 6 months: How often, in the past 6 months, including today, has someone pulled a gun on you?	
0 (never)	31 (44)
1 (once)	22 (31)
2+ (twice or more)	17 (24)
Heard gunshots in the past 6 months: In the past 6 months, how often have you heard guns being shot?[d]	
0 (never)	5 (7)
1 (once or twice)	8 (12)
2 (a few times)	30 (44)
3 (many times)	25 (37)
Community violence in the past year: Have you been impacted by any sort of violence or aggression in the last 12 months (eg, physical fighting, dating or relationship violence, school violence, bullying, threats with weapons, and gang-related violence)?	
Yes	53 (76)
No	17 (24)
Have you ever seen someone get physically attacked, beaten, stabbed, or shot in your community or neighborhood?	
No	13 (19)
Yes	57 (81)
Psychological violence toward partner in the past year: In the past year, have you been psychologically aggressive toward a romantic or dating partner (eg, threatened to hurt them, insulted them, spoke to them in a hostile or mean tone of voice, threatened them with a weapon or threatened to hit them or throw something at them)?	
No	29 (41)
Yes	41 (59)
Physical violence toward partner in the past year: In the past year, have you been physically aggressive toward a romantic or dating partner (eg, slapped them, kicked, hit, punched them, or threatened them with a weapon)?	
No	39 (56)
Yes	31 (44)
Carried a weapon in the past 30 days: During the past 30 days, how many days did you carry a weapon such as a gun, knife, or club?	
0 days	33 (47)
1 day	9 (13)
2 or 3 days	17 (24)
4 or 5 days	9 (13)

XSL•FO
RenderX

Sociodemographic variables and descriptors	Sample, n (%)
4 - 6 or more days	2 (3)

[a]Age missing for 1 participant; percentages calculated among respondents to this item (n=69).

[b]Employment status categories are not mutually exclusive; respondents could select more than 1 type (eg, part-time worker and student). Counts therefore exceed N. Percentages are calculated using the total sample size (N=70).

[c]Item nonresponse for 1 participant; percentages calculated among respondents to this item (n=69).

[d]Item nonresponse for 2 participants; percentages calculated among respondents to this item (n=68).

The SaFETy Score

The SaFETy score, a 4-item firearm risk assessment questionnaire included in our enrollment survey, was used to categorize participants into low-risk (0), medium-risk (1-5), and high-risk (≥6) groups for firearm violence based on weighted item responses. The questionnaire inquired about the frequency of serious physical fights, friends carrying weapons, hearing gunshots, and having guns pulled on them in the past 6 months. This clinically feasible tool has been shown to correlate with firearm violence, although further validation is needed [43]. The SaFETy score demonstrates potential in predicting future firearm violence risk, with each point increase associated with a 1.5-fold higher likelihood of firearm violence within 2 years (odds ratio 1.5), underscoring its value as a clinical screening instrument [44,59]. Administration of the tool takes less than 1 minute, and Goldstick et al [44] suggested referring patients with scores ≥6 to more intensive programs.

Attitudes Toward Guns and Violence

The 23-item AGVQ assesses individual attitudes toward using guns and violence for conflict resolution, power assertion, or safety across 4 scales: Aggressive Response to Shame (disrespect sensitivity; items 1, 2, 5, 10, 15, 16, 18, and 20), Comfort With Aggression (violence acceptance; items 8, 12, 13, 17, 21, and 22), Excitement (gun-related excitement; items 6, 7, 9, 11, and 14), and Power/Safety (power and safety from guns; items 3, 4, 19, and 23). Cronbach α coefficients were 0.83, 0.81, 0.79, and 0.72, respectively. Respondents rated their agreement on a scale from 0 (disagree) to 2 (agree). The summed scores for the AGVQ subscales ranged from 0 to 46, with higher scores indicating more favorable attitudes toward guns and violence. Juvenile firearm possession is linked to violence lethality and may reflect risky exposure to firearms or a proviolence viewpoint. Although the correlation between attitude and behavior change varies, modifying attitudes is crucial for changing behavior [60]. Youth typically complete the AGVQ in 5 - 10 minutes. The AGVQ correlates with handgun ownership [31] and with various psychological and behavioral assessment instruments, supporting its construct validity and helping to understand how attitudes toward guns and violence relate to broader patterns of violent behavior, cognitions, and emotions. Although the AGVQ remains an insufficiently addressed aspect of pediatric firearm violence prevention, interventions such as the "Cradle to Grave" program have shown potential in reducing AGVQ scores, particularly among students with higher baseline tendencies toward violence [61].

The Reactive-Proactive Aggression Questionnaire

The RPQ is a 23-item validated self-report instrument designed to differentiate between reactive aggression (11 items; eg, "Reacted angrily when provoked by others") and proactive aggression (12 items; eg, "Had fights to show who was on top"). Respondents reflect on these behaviors over the past 30 days, rating each item on a 3-point Likert scale (0=never, 1=sometimes, and 2=often). Subscale scores were summed to generate separate reactive and proactive aggression scores, as well as a combined total aggression score. Higher scores indicate a greater frequency of aggressive behaviors [29,62]. The RPQ has demonstrated good reliability and construct validity in adolescent populations and has been extensively used in research on aggression, violence, and trauma exposure. Reactive aggression is more strongly linked to internalizing symptoms, such as anxiety and depression, whereas proactive aggression is associated with externalizing and antisocial traits [29,62].

Kessler Psychological Distress Scale

The K10 [63] is a widely used self-report diagnostic tool for identifying individuals who may require further evaluation for anxiety and depression. It is applicable in both the general population and clinical settings. The K10 comprises 10 questions rated on a 5-point scale (5=all the time to 1=none of the time), reflecting experiences over the past 4 weeks. Scores range from 10 (no distress) to 50 (severe distress), with lower scores indicating less distress. The scale includes 2 subscales: depression (items 1, 4, 7, 8, 9, and 10) and anxiety (items 2, 3, 5, and 6). Items 3 and 6 are omitted if the previous response is "none of the time" [64].

Patient Health Questionnaire-8

The PHQ-8 is extensively used to evaluate depression severity in clinical and research settings [65,66]. It comprises 8 items aligned with the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria for major depressive disorder and serves as a reliable tool for screening and monitoring depressive symptoms. The PHQ-8 is a shortened version of the PHQ-9, omitting the item on suicidal ideation. It assesses mood and feelings over the past 2 weeks on a 4-point scale from 0 (not at all) to 3 (nearly every day), with total scores ranging from 0 to 24. Scores above 10 indicate moderate depression, while scores above 20 indicate severe major depression.

Data Analysis

All analyses were conducted using the JASP software system (version 0.18.3 for Windows) and Microsoft Excel, with results subsequently verified using STATA (version 18; StataCorp LLC). Participant characteristics are presented as means with SDs for continuous variables, and as frequencies and percentages (%) for categorical variables.

All surveys were scored to calculate total and subscale raw scores. Higher scores indicated a proclivity toward violence or

XSL•FO
RenderX

aggression (AGVQ and RPQ) or poorer mental health status (K10 and PHQ-8). Paired-sample *t* tests and Wilcoxon signed rank test (a nonparametric measure) were used to detect differences in scores across all validated instruments, with *P* values <.05 (2-tailed hypothesis) considered statistically significant.

Initial data analysis focused on ensuring data quality by checking for allowable ranges, errors, and patterns of missing data, as well as examining outliers and variable distributions to confirm alignment with the assumptions underlying the planned analyses. Missing data were observed in 6 out of 70 (9%) cases and ≤3-4 out of 70 (<5%) variables. This missingness was addressed using listwise deletion, which may have introduced bias if the data were not missing completely at random. While this approach preserved the internal consistency of the paired analyses, it may limit the generalizability of the findings and reduce statistical power.

Owing to limited prior effect size estimates, we conducted an a priori power analysis using G*Power 3.1.9.7 to determine the minimum sample size required to detect a medium effect (*dz*=0.5) in a paired-sample *t* test comparing pre- and postintervention scores on the AGVQ. Assuming α=.05 and 95% power, the minimum required sample size was 54 participants. To account for potential attrition and up to 20% missing posttest data, we oversampled and enrolled 70 young Black males (aged 15 - 24 years) from a larger multiphase study (N=312). Pre- and postintervention data were analyzed to evaluate statistically significant changes and effect sizes across key outcomes.

Results

Participant Characteristics

Our sample consisted of 70 young Black men aged 15 - 24 years (mean age 20.97, SD 2.44 years). All participants identified as African American, and 7 (10%) also identified as Hispanic or Latinx. Educational attainment varied, with 18 (26%) having less than or equal to a high school diploma, and 22 (31%) reporting a college or university education. Nearly half of the participants (34/70, 49%) worked part-time (<35 hours per week). Over half were single (39/70, 56%) or dating (30/70, 43%). Smartphone ownership was nearly universal (68/70, 97%), highlighting access to digital intervention. Regarding annual household income, 46 (66%) reported between US $40,000 and US $59,999. Most participants were recruited from Illinois (47/70, 67%), followed by Florida (6/70, 9%), New York (4/70, 5%), Texas (3/70, 4%), and Pennsylvania (3/70, 4%). Other participants were recruited from Alabama, Georgia, Michigan, New Jersey, Louisiana, and Wisconsin.

Firearm Violence Profile

To characterize the participants' violence exposure and firearm risk, we collated both descriptive data (ie, YBRS survey questions) and domain-specific scores (ie, SaFETy screening tool).

Descriptive Profile of Violence Exposure

Community Violence and Interpersonal Aggression: Participant Experiences

Nearly half of the participants (32/70, 46%) reported engaging in a serious physical fight within the past 6 months. During the same period, 31 (44%) indicated that a friend had carried a weapon (knife, razor, or gun), and 31 (44%) reported having been directly threatened with a gun at least once. Additionally, 41 (59%) had heard gunshots in their neighborhood in the previous 6 months. Exposure to community violence was highly prevalent, with 49 (70%) participants endorsing direct or indirect involvement in violence (eg, fighting, threats, or gang activity) in the past year. Furthermore, 53 (76%) respondents reported witnessing someone being attacked, beaten, stabbed, or shot in their neighborhood. Regarding relationship aggression, 41 (59%) reported psychological aggression toward a romantic or dating partner, and 31 (44%) disclosed having engaged in physical aggression in the past year. Notably, 31 (44%) reported carrying a weapon at least once in the past 30 days.

SaFETy Score Breakdown

Table 3 presents item-level responses and scoring contributions for each domain of the SaFETy score: Serious Fighting, Friend Carrying Weapons, Community Environment, and Firearm Threats. The most commonly endorsed level for Serious Fighting was "3 - 5 times in the past 6 months," reported by 19 of 70 (27%) participants, contributing 2 points to the SaFETy score. In the Friend Carrying Weapons domain, 38 (54%) participants reported that at least some of their friends had carried a weapon in the past 6 months, with 7 (10%) participants reporting that many, most, or all of their friends had done so, contributing 1 point.

XSL•FO
RenderX

Table . Breakdown of SaFETy[a] score distribution.

Category and question/scale levels	Values, n (%)	SaFETy contribution
Serious Fighting		
In the past 6 months, including today, how often did you get into a serious physical fight?		
0 (never)	22 (31)	0
1 (once)	11 (16)	1
2 (twice)	17 (24)	1
3 (3 - 5 times)	19 (27)	1
4+ (6 or more times)	1 (1)	4
Friend Carrying Weapons		
In the past 6 months, including today, how many of your friends have carried a knife, razor, or gun?		
1 (none)	31 (44)	0
2 (some)	31 (44)	0
3+ (many, most, or all)	7 (10)	1
Community Environment		
In the past 6 months, how often have you heard guns being shot?		
0 (never)	5 (7)	0
1 (once or twice)	8 (11)	0
2 (a few times)	30 (43)	0
3 (many times)	25 (36)	1
Firearm Threats		
How often, in the past 6 months, including today, has someone pulled a gun on you?		
0 (never)	31 (44)	0
1 (once)	22 (31)	3
2+ (twice or more)	17 (24)	4

[a]SaFETy: Serious Fighting, Friend Weapon Carrying, Community Environment, and Firearm Threats.

Community environment exposure was notably high: 57 (81%) participants reported hearing gunshots at least “a few times” in the past 6 months, with 26 (37%) hearing them “many times,” contributing 3 points. The highest-weighted item was Firearm Threats: 17 (24%) participants reported being threatened with a gun 2 or more times, contributing 4 points. Notably, 22 (31%) respondents scored 0 across all categories of firearm threat. These distributions reflect a high prevalence of direct and indirect exposure to firearm violence in this sample, contributing to higher cumulative SaFETy scores and elevated future firearm violence risk.

The distribution of total SaFETy scores among participants reveals a wide range of firearm risk exposure. While a notable portion of the sample scored 0, indicating minimal or no reported exposure to serious fighting, weapon-carrying peers, gunfire in the community, or direct firearm threats, the majority reported at least one source of exposure. A significant subset scored between 4 and 7, reflecting high cumulative exposure, particularly in the domains of community gun violence and direct firearm threats. This right-skewed distribution suggests heterogeneity in risk profiles, with a sizable group facing elevated vulnerability to firearm-related harm, an important consideration for intervention targeting and future risk stratification.

Substance Use Profile

We measured 30-day adolescent binge drinking, nonmedical drug use, and substance-related violence perpetration. Nearly one-fourth of the participants (17/70, 24%) had engaged in binge alcohol consumption, defined as more than 5 drinks in a single sitting within the past 30 days. Over half reported illicit use of pharmaceuticals or narcotics for nonmedical purposes, impacting 39 (56%) participants. Finally, 32 (46%) participants reported perpetrating substance-related violence.

Intervention Preliminary Effects

Overview

We assessed multiple outcomes (summarized in Table 4), such as attitudes toward guns and violence, reactive and proactive aggression, and mental health outcomes (eg, psychological distress).

XSL•FO
RenderX

Table . Pretest and posttest changes in the study outcomes.[a]

Outcome	Test used	Pretest, mean (SD)	Posttest mean (SD)	*t* test (*df*) or *z* value	*P* value	Effect size (Cohen *d*)
Attitudes toward guns and violence	Paired *t* test	29.8 (8.7)	26.1 (9.0)	3.52 (44)	<.001	0.53
Reactive aggression	Paired *t* test	10.48 (5.39)	8.67 (4.92)	2.74 (53)	.008	0.37
Proactive aggression	Paired *t* test	6.89 (4.95)	6.70 (5.01)	0.82 (53)	.42	0.11
Psychological distress (Kessler Psychological Distress Scale)	Paired *t* test	18.2 (6.3)	18.1 (6.2)	0.20 (58)	.84	0.03
Depressive symptoms (8-item Patient Health Questionnaire)	Wilcoxon signed rank test	9.82 (6.41)	9.33 (6.26)	0.90[b]	.37	N/A

[a]*P*<.05 considered statistically significant. Paired *t* tests were used for normally distributed outcomes, and the Wilcoxon signed rank test was used for nonnormally distributed data (8-item Patient and Health Questionnaire).

[b]*z* value.

Attitudes Toward Guns and Violence

A significant reduction in AGVQ scores was observed among participants (n=43) from pretest (mean 29.8, SD 8.7) to posttest (mean 26.1, SD 9.0), with a mean difference of 3.69 (SE 1.05, t_{42}=3.522, *P*<.001), and a moderate effect size (Cohen *d*=0.53). Subscale analysis revealed the most considerable improvement in the "Aggressive Response to Shame" subscale (28% reduction), followed by the "Excitement Toward Guns and Violence" subscale (14.8%), the "Feelings of Power/Safety" subscale (8%), and the "Comfort with Aggression" subscale (2.3%). These crucial findings indicate that participants experienced reduced emotional reactivity to perceived threats and decreased excitement and reliance on firearms for power and safety. For example, Goldberg et al [61] found that small but statistically significant decreases in AGVQ scores were predictive of lower intentions to carry firearms and decreased willingness to use violence in future peer conflict situations.

Reactive and Proactive Aggression

Mean scores indicated that reactive aggression significantly decreased from 10.48 (SD 5.39) preintervention to 8.67 (SD 4.92) postintervention (mean difference 1.82, SE 0.66, t_{53}=2.74, *P*=.008), with a small-to-moderate effect size (Cohen *d*=0.37), suggesting a notable improvement in managing impulsive, emotionally driven responses to perceived threats following exposure to the intervention. By contrast, no significant change was detected in proactive aggression scores between the pre- and posttest (t_{53}=0.82, *P*=.42), with a small effect size (Cohen *d*=0.11), indicating the need for longer-term or more intensive and targeted interventions to address the underlying cognitive patterns and motivations associated with planned aggression.

Psychological Distress

A paired-samples *t* test was used to evaluate changes in psychological distress, focusing on subscales (depression and anxiety) and overall psychological distress (ie, total scores) from pre- to posttest. No significant changes were found in depression symptoms from pretest (mean 15.85, SD 6.28) to posttest (mean 15.97, SD 5.85, t_{58}=–0.20, *P*=.84, Cohen *d*=0.03). Likewise, anxiety scores did not significantly differ between pretest (mean 10.32, SD 3.93) and posttest (mean 10.02, SD 3.88, t_{58}=0.76, *P*=.45, *d*=0.10). In addition, overall psychological distress scores remained stable from pretest (mean 26.17, SD 10.02) to posttest (mean 25.98, SD 9.54, t_{58}=0.20, *P*=.84), with a negligible effect size (*d*=0.03). At baseline, 21 of 70 (30%) respondents reported potentially moderate to severe psychological distress (K10 scores>16), highlighting a substantial mental health burden within this sample.

A change of 5 points or more on the K10 is considered clinically meaningful for psychological distress [67,68]. Based on our sample mean difference (mean difference 0.186), the absence of both statistically and clinically significant changes suggests that the intervention may have had a limited short-term impact on psychological distress, underscoring the need for enhanced or sustained mental health support in the long term.

Depression (PHQ-8)

The Shapiro-Wilk test revealed a significant deviation from normality in the pretest scores (*W*=0.939, *P*=.008), indicating a need for a nonparametric approach. A Wilcoxon signed-rank test was conducted to compare pretest (mean 9.82, SD 6.41) and posttest (mean 9.33, SD 6.26) scores. The results showed no statistically significant difference (*W*=597.50, *z*=0.903, *P*=.37) in depression, corroborating earlier findings. Although descriptive statistics suggested a slight reduction in the mean PHQ-8 scores, this change was not significant. For the PHQ-8, a reduction of 5 points or more is widely accepted as the minimal clinically important difference in both primary care and research settings [66].

XSL•FO
RenderX

Intervention Engagement Outcomes

Backend analytics from REDCap were used to monitor time stamps and session durations. Almost all participants (68/70, 97%) completed the video modules in a single session, with 47 (67%) finishing within an hour, suggesting high feasibility of BrotherlyACT as a digital intervention. Participants were advised to complete 1-2 modules daily, with no upper limit per session. This flexible approach accommodated varying schedules and comfort levels while ensuring consistent content delivery. Future iterations will aim to explore sustained engagement and assess feasibility in school and clinical settings.

Discussion

Principal Findings

This study evaluated the preliminary effects of BrotherlyACT, a culturally responsive, trauma-informed, multicomponent mobile and online intervention designed to support young Black males (aged 15 - 24) in navigating and preventing community violence, substance use, and mental health challenges. The app aims to improve access to precrisis support and mental health resources for youth living in low-resource, high-violence environments. BrotherlyACT builds on promising ED-based models, such as that by Carter et al [17], by expanding intervention reach beyond clinical settings. Its mobile delivery, cultural relevance, and trauma-informed framework address key barriers to care—namely, limited access to early interventions, lack of continuity, and low trust in traditional systems.

Our findings demonstrated a significant reduction in overall attitudes toward guns and violence, with the most considerable reduction occurring in the "Aggressive Response to Shame" subscale (a 28% decrease). This result aligns with research linking shame and emotional dysregulation to aggression, particularly in populations exposed to high levels of systemic inequities and chronic community violence [55,69,70]. Shame proneness during adolescence is a significant psychological construct linked to aggressive behavior, often mediated by hostility and externalization of blame [71].

Additionally, notable reductions in "Excitement Toward Guns and Violence" (14.8%) and "Feelings of Power/Safety" (8%) suggest meaningful shifts in attitudes associated with the perceived role of firearms in self-protection, empowerment, and identity formation among adolescents. These changes reflect progress in addressing key psychosocial drivers of risky firearm behavior. The medium effect size for the overall AGVQ outcome (d=0.53) also suggests that the observed difference was not only statistically significant but also practically notable. We posit that the intervention effectively shifted attitudes toward firearms and violence by challenging norms that reinforce gun carrying and retaliation, and by altering cognitive frameworks around violence, likely through the promotion of nonviolent problem-solving and prosocial coping strategies. These attitudinal changes may reflect the malleability of belief systems when disrupted by relatable, peer-aligned narratives. The app's nondidactic tone and culturally resonant scenarios may have reduced defensiveness and increased engagement, particularly among youth resistant to adult-led violence messaging.

In terms of aggressive behavior, the intervention's differential impact on the *reactive aggression* subtype underscores its potential to mitigate impulsive, emotionally driven aggression, a key contributor to firearm injuries and homicides in urban settings [72]. Several mechanisms may explain these shifts. First, the app's video content was designed to engage users through culturally salient and emotionally resonant messaging, aligning with principles of social learning theory and narrative persuasion frameworks. Youth may have identified with the characters and scenarios presented, leading to emotional mirroring and internalization of the modeled prosocial behaviors. Notably, reactive aggression, typically driven by perceived threat and emotional dysregulation, may have been mitigated through the vicarious modeling of alternative conflict resolution strategies presented in the modules.

Conversely, we observed a nonsignificant decline in proactive aggression, which prior studies suggest may be more responsive to interventions that explicitly target cognitive processes such as empathy and moral reasoning [73,74]. Addressing proactive aggression may also require longer-term interventions, such as dialectic behavioral therapy, in combination with content that affirms identity, fosters critical consciousness, challenges harmful masculinity norms, and promotes consequential thinking and value realignment. Importantly, interventions targeting proactive aggression must also address the broader social determinants of health that shape youth behavior.

Similarly, no significant changes were observed in psychological distress (depression or anxiety), aligning with prior research in the neuroscience of aggression that underscores the importance of trauma-informed or mental health–focused components—approaches shown to be effective in analogous nondigital contexts [75]. This finding was anticipated, as key mental health features of BrotherlyACT, including the safety planning toolkit and artificial intelligence–powered talk therapy chatbot, were not fully implemented or tested at this stage. Additionally, it remains unclear whether the minimal changes observed in depression were cognitive, affective, or somatic in nature, an area that will be explored in the larger planned study.

The absence of change in psychological distress supports the notion that distress may not be the primary mechanism through which video-based interventions reduce aggression. However, we are investigating a hypothesized pathway of effects in supplemental analysis. Nonetheless, these findings provide a robust foundation for refining intervention strategies aimed at improving both aggression-related outcomes and mental health outcomes.

Lastly, the significant rate of substance misuse in this group emphasizes the critical need to cotarget drug and alcohol use as a concurrent risk factor within this population. Over half of the participants (39/70, 56%) reported illicit drug use, and substance-related violence perpetration (32/70, 46%). These findings are consistent with other studies linking substance use to elevated risks of both perpetrating and experiencing firearm violence [58,76]. Future interventions may benefit from expanding current modules that directly address substance misuse, given its interplay with firearm violence.

XSL•FO
RenderX

Implications for Practice and Prevention

Traditional firearm safety interventions for youth often emphasize parent-focused messaging and home-based storage practices. However, these strategies may not align with how at-risk older adolescents, particularly young Black males, access and engage with firearms. Such approaches frequently overlook structural realities, such as neighborhood-level firearm acquisition, systemic mistrust of support systems, and limited access to secure and inexpensive storage options. BrotherlyACT addresses these gaps by directly engaging high-risk youth through developmentally appropriate, culturally grounded modules focused on gun safety, nonretaliation, and coping within violence-impacted environments.

Critically, the intervention is grounded in trauma-informed design and rooted in evidence-based behavioral frameworks, including ACT and motivational interviewing. These frameworks promote emotional regulation, values-driven decision-making, and self-reflection, offering a nonstigmatizing, empowering alternative to punitive behavior change models. Given that 97% of US adolescents own smartphones [77], BrotherlyACT offers a scalable and discreet solution for reaching youth who may avoid traditional services. The high levels of engagement observed in this study underscore its feasibility; however, variability in module completion points to the need for additional engagement strategies, such as personalized incentives or enhanced interactive features to improve module completion and reuse.

Reducing firearm-related injuries and deaths among young Black males requires a multilevel public health strategy. This includes individual behavioral interventions, community-level engagement, and systemic policy changes, all underpinned by trauma-informed, culturally sensitive approaches, including direct-to-youth interventions that address care barriers and societal drivers of firearm violence [3,78]. Ultimately, BrotherlyACT contributes a novel, culturally responsive tool to this effort. Future research should explore how digital tools such as BrotherlyACT can integrate with broader structural and environmental interventions to produce sustainable, equity-centered outcomes.

Because of its modular design and digital delivery, BrotherlyACT is particularly well-suited for integration into school-based health centers, community mental health clinics, after-school programs, and youth-serving community-based organizations. Importantly, the intervention is consistent with both citywide and national priorities that emphasize trauma-informed, equity-centered approaches to the prevention of youth gun violence. For instance, in Chicago, we are investigating opportunities to align BrotherlyACT with the city's *Office of Gun Violence Prevention* and its trauma recovery ecosystem, as well as with initiatives funded under the Chicago Youth Service Corps.

At the policy level, this study provides preliminary evidence to inform future digital health innovation grants, Medicaid reimbursable pilots for technology-based behavioral health tools, and public health department efforts aimed at expanding digital care access for underserved youth. Our proposed scale-up model includes collaboration with public school systems, local Federally Qualified Health Centers, and youth justice diversion programs, guided by implementation science frameworks and equity-based partnership principles. Future research will focus on formalizing these implementation pathways, evaluating institutional readiness, and identifying sustainable policy mechanisms for long-term adoption.

Limitations and Strengths

A central strength of this study is its focus on an urban, high-risk sample of young Black males most impacted by firearm violence. The utilization of validated self-report instruments, namely, the AGVQ and RPQ, facilitated a direct assessment of attitudes and behaviors related to aggression, specifically in the context of gun violence. Previous research corroborates the reliability of these measures within similar populations [79]. Furthermore, the confidential and computerized format of our survey likely mitigated response bias concerning sensitive topics such as gun use and substance involvement, particularly in a population that exhibits a high level of mistrust regarding the disclosure of personal information and details.

However, some limitations are worth noting. Self-report data remain vulnerable to social desirability bias, which may have influenced participants' disclosures. While this could inflate observed changes, it is a common limitation in violence prevention research. Additionally, the RPQ and AGVQ may oversimplify the complex and context-dependent nature of youth attitudes toward firearms and aggression. Although we reported subscale results where appropriate, aggregating scores can obscure important variability. In addition, the pilot design was not powered to detect subgroup differences or interaction effects. While missing data were minimal, our use of listwise deletion may have reduced power and introduced bias. Future studies will need to incorporate more robust missing data techniques, such as multiple imputation.

Critically, participants only engaged with the video-based module component of BrotherlyACT via REDCap, rather than the full app interface. This limited exposure may have underestimated the intervention's true engagement potential. Moreover, we did not capture objective metrics of video engagement (eg, watch time or skipping behavior), limiting interpretation of intervention dose effects. We also did not collect data on firearm use motivations, such as distinctions between recreational, protective, or aggressive carrying, which bear implications for study interpretation. Despite these limitations, module completion rates remained high and nearly all participants completed the content in a single sitting, supporting the feasibility and acceptability of brief digital violence prevention tools. These early findings reinforce the promise of BrotherlyACT as a scalable, youth-centered intervention.

Conclusions

This study demonstrates the promise of BrotherlyACT as a culturally responsive, trauma-informed tool for addressing both attitudinal and behavioral risk factors linked to firearm violence among young Black males. By targeting reactive aggression and shifting norms around violence, BrotherlyACT offers a novel, scalable approach to primary prevention in medium- to

XSL•FO
RenderX

high-risk groups. These findings lay important groundwork for future strategies aimed at reducing dynamic and context-dependent risks, such as seasonal or escalating violence, through brief, targeted interventions. However, given the multifaceted nature of aggression and the systemic barriers faced by this population, further refinement of intervention components and deeper engagement with structural determinants will be critical. Sustained progress in firearm violence prevention will require integrative solutions that blend individual-level change with community and policy-level action to promote long-term safety and well-being.

Acknowledgments

We express our gratitude to the Urban Male Network, from which most of our study participants were recruited, for their assistance in youth consultations and coordination of recruitment efforts. We also thank Hekademeia Research Solutions (Blake Anderson and Shana Permenter) for their contributions to the design and programming of BrotherlyACT. We are deeply grateful to the young Black male participants who participated in this pilot study, and the Rush-BMO Institute for Health Equity Scholars Program at Rush University.

Our research was made possible through funding from various sources: the Chicago Chronic Condition Equity Network via the National Institute on Minority Health and Health Disparities (grant 5P50MD017349-02), the Institute for Translational Medicine through the National Institutes of Health/National Center for Advancing Translational Sciences (grants UL1TR002389, KL2TR002387, and TL1TR00238), and the Rush-BMO Institute for Health Equity Scholars Program at Rush University.

Data Availability

Study data can be obtained by contacting the corresponding author with a valid request. Access to the data is limited to safeguard participant anonymity, given the small number of subjects and identifiable institutional connections. Any data access inquiries will be evaluated in accordance with organizational and funder protocols regarding data distribution and subject privacy.

Authors' Contributions

CE, the principal investigator, conceptualized the study and played a pivotal role in its design, supervision, and manuscript editing. Statistical analyses were conducted collaboratively by CE and JBR. The entire research team, comprising CE, JBR, AF, TW, WAJ, and NSK, contributed to the study's conceptualization, design, oversight, and manuscript revision. CE and JBR were responsible for data preparation, validation, and analysis. The initial manuscript draft was authored by CE, with subsequent versions incorporating feedback from all the coauthors. The final manuscript was reviewed and approved by the entire research team.

Conflicts of Interest

None declared.

Checklist 1
CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth) checklist.
[PDF File, 1112 KB - pediatrics_v8i1e70048_app1.pdf]

References

1. Lee LK, Fleegler EW, Goyal MK, et al. Firearm-related injuries and deaths in children and youth: injury prevention and harm reduction. Pediatrics 2022 Dec 1;150(6):e2022060070. [doi: 10.1542/peds.2022-060070]
2. Rees CA, Monuteaux MC, Steidley I, et al. Trends and disparities in firearm fatalities in the United States, 1990-2021. JAMA Netw Open 2022 Nov 1;5(11):e2244221. [doi: 10.1001/jamanetworkopen.2022.44221] [Medline: 36445703]
3. Bottiani JH, Camacho DA, Lindstrom Johnson S, Bradshaw CP. Annual research review: youth firearm violence disparities in the United States and implications for prevention. J Child Psychol Psychiatry 2021 May;62(5):563-579. [doi: 10.1111/jcpp.13392] [Medline: 33797082]
4. Grinshteyn E, Hemenway D. Violent death rates: the US compared with other high-income OECD countries, 2010. Am J Med 2016 Mar;129(3):266-273. [doi: 10.1016/j.amjmed.2015.10.025] [Medline: 26551975]
5. AbiNader MA, Salas-Wright CP, Vaughn MG, Oh S, Jackson DB. Trends and correlates of youth violence-prevention program participation, 2002-2016. Am J Prev Med 2019 May;56(5):680-688. [doi: 10.1016/j.amepre.2018.12.016] [Medline: 30905485]
6. Andrews AL, Killings X, Oddo ER, Gastineau KAB, Hink AB. Pediatric firearm injury mortality epidemiology. Pediatrics 2022 Mar 1;149(3):e2021052739. [doi: 10.1542/peds.2021-052739] [Medline: 35224633]

XSL•FO
RenderX

7. Beardslee J, Docherty M, Mulvey E, Schubert C, Pardini D. Childhood risk factors associated with adolescent gun carrying among Black and White males: an examination of self-protection, social influence, and antisocial propensity explanations. Law Hum Behav 2018 Apr;42(2):110-118. [doi: 10.1037/lhb0000270] [Medline: 29172558]
8. Carter PM, Mouch CA, Goldstick JE, et al. Rates and correlates of risky firearm behaviors among adolescents and young adults treated in an urban emergency department. Prev Med 2020 Jan;130:105891. [doi: 10.1016/j.ypmed.2019.105891]
9. Chadha S, McLone S, Mason M, Sheehan K. Adolescent firearm homicides in Chicago, 2013-2017. J Adolesc Health 2020 Sep;67(3):438-443. [doi: 10.1016/j.jadohealth.2020.02.025] [Medline: 32295721]
10. Lindsey MA, Joe S, Nebbitt V. Family matters: the role of mental health stigma and social support on depressive symptoms and subsequent help seeking among African American boys. J Black Psychol 2010 Nov 1;36(4):458-482. [doi: 10.1177/0095798409355796] [Medline: 20953336]
11. Cunningham R, Rosenberg M, Corbin T, et al. Using science to reduce firearm injuries and deaths. NAM Perspect 2023;2023(8). [doi: 10.31478/202310a] [Medline: 38784640]
12. Ghafoori B, Barragan B, Palinkas L. Mental health service use among trauma-exposed adults: a mixed-methods study. J Nerv Ment Dis 2014 Mar;202(3):239-246. [doi: 10.1097/NMD.0000000000000108] [Medline: 24566510]
13. Kondo MC, Andreyeva E, South EC, MacDonald JM, Branas CC. Neighborhood interventions to reduce violence. Annu Rev Public Health 2018 Apr 1;39(1):253-271. [doi: 10.1146/annurev-publhealth-040617-014600] [Medline: 29328874]
14. Motley R, Banks A. Black males, trauma, and mental health service use: a systematic review. Perspect Soc Work (Houst) 2018;14(1):4-19. [Medline: 30556064]
15. Richardson JB, Wical W, Kottage N, Galloway N, Bullock C. Staying out of the way: perceptions of digital non-emergency medical transportation services, barriers, and access to care among young black male survivors of firearm violence. J Prim Prev 2021 Feb;42(1):43-58. [doi: 10.1007/s10935-020-00611-2] [Medline: 33025246]
16. Voith LA, Lee H, Salas Atwell M, et al. A phenomenological study identifying facilitators and barriers to Black and Latinx youth's engagement in hospital‐based violence intervention programs. Health Social Care Comm 2022 Nov;30(6):e4873-e4884. [doi: 10.1111/hsc.13900]
17. Carter PM, Cunningham RM, Eisman AB, et al. Translating violence prevention programs from research to practice: SafERteens implementation in an urban emergency department. J Emerg Med 2022 Jan;62(1):109-124. [doi: 10.1016/j.jemermed.2021.09.003]
18. Roche JS, Philyaw-Kotov ML, Sigel E, et al. Implementation of a youth violence prevention programme in primary care. Inj Prev 2022 Jun;28(3):231-237. [doi: 10.1136/injuryprev-2021-044293] [Medline: 34716179]
19. Walton MA, Chermack ST, Shope JT, et al. Effects of a brief intervention for reducing violence and alcohol misuse among adolescents. JAMA 2010 Aug 4;304(5):527. [doi: 10.1001/jama.2010.1066]
20. Heard-Garris N, Johnson TJ, Hardeman R. The harmful effects of policing-from the neighborhood to the hospital. JAMA Pediatr 2022 Jan 1;176(1):23-25. [doi: 10.1001/jamapediatrics.2021.2936] [Medline: 34491269]
21. Watkins J, Scoggins N, Cheaton BM, et al. Assessing improvements in emergency department referrals to a hospital-based violence intervention program. Inj Epidemiol 2021 Sep;8(S1):44. [doi: 10.1186/s40621-021-00333-x]
22. Cunningham RM, Chermack ST, Zimmerman MA, et al. Brief motivational interviewing intervention for peer violence and alcohol use in teens: one-year follow-up. Pediatrics 2012 Jun 1;129(6):1083-1090. [doi: 10.1542/peds.2011-3419]
23. Lyons VH, Floyd AS, Griffin E, et al. Helping individuals with firearm injuries: a cluster randomized trial. J Trauma Acute Care Surg 2021;90(4):722-730. [doi: 10.1097/TA.0000000000003056]
24. Basile KC, Clayton HB, DeGue S, et al. Interpersonal violence victimization among high school students - Youth Risk Behavior Survey, United States, 2019. MMWR Suppl 2020 Aug 21;69(1):28-37. [doi: 10.15585/mmwr.su6901a4] [Medline: 32817605]
25. Bauer AG, Christensen K, Bowe-Thompson C, Lister S, Aduloju-Ajijola N, Berkley-Patton J. "We Are Our Own Counselor": resilience, risk behaviors, and mental health service utilization among young African American men. Behav Med 2020;46(3-4):278-289. [doi: 10.1080/08964289.2020.1729087] [Medline: 32787722]
26. Berny LM, Tanner-Smith EE. Interpersonal violence and suicide risk: examining buffering effects of school and community connectedness. Child Youth Serv Rev 2024 Feb;157:107405. [doi: 10.1016/j.childyouth.2023.107405] [Medline: 38371909]
27. Botvin GJ, Griffin KW, Nichols TD. Preventing youth violence and delinquency through a universal school-based prevention approach. Prev Sci 2006 Dec;7(4):403-408. [doi: 10.1007/s11121-006-0057-y] [Medline: 17136462]
28. Cunningham MC, Cobbina JE, Melde C, et al. Attitudes towards police and weapon carriage among adolescents. Am J Crim Just 2022 Apr;47(2):246-265. [doi: 10.1007/s12103-021-09643-8]
29. Fite PJ, Stoppelbein L, Greening L. Proactive and reactive aggression in a child psychiatric inpatient population. Journal of Clinical Child & Adolescent Psychology 2009 Mar 17;38(2):199-205. [doi: 10.1080/15374410802698461]
30. Raine A, Dodge K, Loeber R, et al. The Reactive-Proactive Aggression Questionnaire: differential correlates of reactive and proactive aggression in adolescent boys. Aggress Behav 2006 Apr 1;32(2):159-171. [doi: 10.1002/ab.20115] [Medline: 20798781]
31. Shapiro JP, Dorman RL, Burkey WM, Welker CJ, Clough JB. Development and factor analysis of a measure of youth attitudes toward guns and violence. J Clin Child Psychol 1997 Sep;26(3):311-320. [doi: 10.1207/s15374424jccp2603_10] [Medline: 9292389]

XSL•FO
RenderX

32. Shapiro JP, Dorman RL, Welker CJ, Clough JB. Youth attitudes toward guns and violence: relations with sex, age, ethnic group, and firearm exposure. J Clin Child Psychol 1998 Mar;27(1):98-108. [doi: 10.1207/s15374424jccp2701_11] [Medline: 9561942]
33. Lohbeck A. Reactive and proactive aggression among children and adolescents: a latent profile analysis and latent transition analysis. Children (Basel) 2022 Nov 11;9(11):1733. [doi: 10.3390/children9111733] [Medline: 36421182]
34. Papachristos AV, Wildeman C. Network exposure and homicide victimization in an African American community. Am J Public Health 2014 Jan;104(1):143-150. [doi: 10.2105/AJPH.2013.301441] [Medline: 24228655]
35. Shapira H, Liang C, Lin KH. How attitudes about guns develop over time. Sociol Perspect 2022 Feb;65(1):12-34. [doi: 10.1177/07311214211021123]
36. Lehtimaki S, Martic J, Wahl B, Foster KT, Schwalbe N. Evidence on digital mental health interventions for adolescents and young people: systematic overview. JMIR Ment Health 2021 Apr 29;8(4):e25847. [doi: 10.2196/25847] [Medline: 33913817]
37. Torok M, Han J, Baker S, et al. Suicide prevention using self-guided digital interventions: a systematic review and meta-analysis of randomised controlled trials. Lancet Digit Health 2020 Jan;2(1):e25-e36. [doi: 10.1016/S2589-7500(19)30199-2] [Medline: 33328037]
38. Lattie EG, Adkins EC, Winquist N, Stiles-Shields C, Wafford QE, Graham AK. Digital mental health interventions for depression, anxiety, and enhancement of psychological well-being among college students: systematic review. J Med Internet Res 2019 Jul 22;21(7):e12869. [doi: 10.2196/12869] [Medline: 31333198]
39. Ranney ML, Goldstick J, Eisman A, Carter PM, Walton M, Cunningham RM. Effects of a brief ED-based alcohol and violence intervention on depressive symptoms. Gen Hosp Psychiatry 2017 May;46:44-48. [doi: 10.1016/j.genhosppsych.2017.01.008] [Medline: 28622815]
40. Ranney ML, Stettenbauer EG, Delgado MK, Yao KA, Orchowski LM. Uses of mHealth in injury prevention and control: a critical review. Curr Epidemiol Rep 2022;9(4):273-281. [doi: 10.1007/s40471-022-00312-w] [Medline: 36404873]
41. Emezue C, Karnik NS, Reeder B, et al. A technology-enhanced intervention for violence and substance use prevention among young black men: protocol for adaptation and pilot testing. JMIR Res Protoc 2023 May 1;12(1):e43842 [FREE Full text] [doi: 10.2196/43842] [Medline: 37126388]
42. Emezue C, Dan-Irabor D, Froilan A, et al. Evaluating an app-based intervention for preventing firearm violence and substance use in young black boys and men: usability evaluation study. JMIR Form Res 2024 Nov 26;8(1):e60918. [doi: 10.2196/60918] [Medline: 39589765]
43. Goldstick JE, Carter PM, Walton MA, et al. Development of the SaFETy score: a clinical screening tool for predicting future firearm violence risk. Ann Intern Med 2017 May 16;166(10):707-714. [doi: 10.7326/M16-1927]
44. Goldstick JE, Carter PM, Whiteside L, Delgado MK, Cunningham RM. Association between the SaFETy score and self-reported firearm violence among young adults presenting to emergency departments in three cities: a cross-sectional study. Ann Intern Med 2024 Jun;177(6):831-833. [doi: 10.7326/M24-0026] [Medline: 38648646]
45. Goyal A, Labellarte PZ, Hayes AA, et al. Screening for youth firearm violence exposure in primary care. AJPM Focus 2024 Feb;3(1):100146. [doi: 10.1016/j.focus.2023.100146] [Medline: 38089425]
46. Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and commitment therapy: model, processes and outcomes. Behav Res Ther 2006 Jan;44(1):1-25. [doi: 10.1016/j.brat.2005.06.006] [Medline: 16300724]
47. Gloster AT, Walder N, Levin ME, Twohig MP, Karekla M. The empirical status of acceptance and commitment therapy: a review of meta-analyses. J Contextual Behav Sci 2020 Oct;18:181-192. [doi: 10.1016/j.jcbs.2020.09.009]
48. Atkins PWB, Ciarrochi J, Gaudiano BA, et al. Departing from the essential features of a high quality systematic review of psychotherapy: a response to Öst (2014) and recommendations for improvement. Behav Res Ther 2017 Oct;97:259-272. [doi: 10.1016/j.brat.2017.05.016]
49. Lawrence E, Mazurek C, Reardon KW. Comparing recidivism rates among domestically violent men enrolled in ACTV versus Duluth/CBT. J Consult Clin Psychol 2021 May;89(5):469-475. [doi: 10.1037/ccp0000649] [Medline: 34124928]
50. Hayes SC. Acceptance and commitment therapy, relational frame theory, and the third wave of behavioral and cognitive therapies. Behav Ther 2004 ;35(4):639-665. [doi: 10.1016/S0005-7894(04)80013-3]
51. Hayes SC, Pistorello J, Levin ME. Acceptance and commitment therapy as a unified model of behavior change. Couns Psychol 2012 Oct;40(7):976-1002. [doi: 10.1177/0011000012460836]
52. Zarling A, Lawrence E, Marchman J. A randomized controlled trial of acceptance and commitment therapy for aggressive behavior. J Consult Clin Psychol 2015 Feb;83(1):199-212 [FREE Full text] [doi: 10.1037/a0037946] [Medline: 25265545]
53. Byrne G, Cullen C. Acceptance and commitment therapy (ACT) for anger and aggression in children, adolescents, and young adults: a systematic review. Trauma Violence Abuse 2024 Apr;25(2):935-946 [FREE Full text] [doi: 10.1177/15248380231167393]
54. Zarling A, Lawrence E, Marchman J. A randomized controlled trial of acceptance and commitment therapy for aggressive behavior. J Consult Clin Psychol 2015;83(1):199-212 [FREE Full text] [doi: 10.1037/a0037946]
55. Garofalo C, Velotti P, Zavattini GC. Emotion regulation and aggression: the incremental contribution of alexithymia, impulsivity, and emotion dysregulation facets. Psychol Violence 2018;8(4):470-483. [doi: 10.1037/vio0000141]

XSL•FO
RenderX

56. Shail MS. Using micro-learning on mobile applications to increase knowledge retention and work performance: a review of literature. Cureus 2019 Aug 2;11(8):e5307. [doi: 10.7759/cureus.5307] [Medline: 31511813]
57. Gabrielli S, Kimani S, Catarci T. The design of microlearning experiences: a research agenda. Semantic Scholar. 2017. URL: https://www.semanticscholar.org/paper/The-Design-of-MicroLearning-Experiences%3A-A-Research-Gabrielli-Kimani/af327ca4c6e48a9caf013d1b3957bd4727588ece [accessed 2023-05-02]
58. Chen D, Wu LT. Association between substance use and gun-related behaviors. Epidemiol Rev 2016;38(1):46-61. [doi: 10.1093/epirev/mxv013] [Medline: 26769722]
59. Cunningham RM, Carter PM, Zimmerman M. The Firearm Safety Among Children and Teens (FACTS) Consortium: defining the current state of the science on pediatric firearm injury prevention. J Behav Med 2019 Aug;42(4):702-705. [doi: 10.1007/s10865-019-00077-6] [Medline: 31367935]
60. Loveland-Jones C, Ferrer L, Charles S, et al. A prospective randomized study of the efficacy of "Turning Point," an inpatient violence intervention program. J Trauma Acute Care Surg 2016;81(5):834-842. [doi: 10.1097/TA.0000000000001226]
61. Goldberg AJ, Toto JM, Kulp HR, et al. An analysis of inner-city students' attitudes towards violence before and after participation in the "Cradle to Grave" programme. Injury 2010 Jan;41(1):110-115. [doi: 10.1016/j.injury.2009.09.024]
62. Fite PJ, Raine A, Stouthamer-Loeber M, Loeber R, Pardini DA. Reactive and proactive aggression in adolescent males. Crim Justice Behav 2010 Feb;37(2):141-157. [doi: 10.1177/0093854809353051]
63. Kessle RC, Andrews G, Colpe L, et al. Short screening scales to monitor population prevalences and trends in nonspecific psychological distress. Psychol Med 2002;32(6):959-976. [doi: 10.1037/t08324-000]
64. Andrews G, Slade T. Interpreting scores on the Kessler Psychological Distress Scale (K10). Aust N Z J Public Health 2001 Dec;25(6):494-497. [doi: 10.1111/j.1467-842x.2001.tb00310.x] [Medline: 11824981]
65. Flores JP, Kahn G, Penfold RB, et al. Adolescents who do not endorse risk via the Patient Health Questionnaire before self-harm or suicide. JAMA Psychiatry 2024 Jul 1;81(7):717. [doi: 10.1001/jamapsychiatry.2024.0603]
66. Kroenke K, Strine TW, Spitzer RL, Williams JBW, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. J Affect Disord 2009 Apr;114(1-3):163-173. [doi: 10.1016/j.jad.2008.06.026] [Medline: 18752852]
67. Furukawa TA, Kessler RC, Slade T, Andrews G. The performance of the K6 and K10 screening scales for psychological distress in the Australian National Survey of Mental Health and Well-Being. Psychol Med 2003 Feb;33(2):357-362. [doi: 10.1017/s0033291702006700] [Medline: 12622315]
68. Staples LG, Dear BF, Gandy M, et al. Psychometric properties and clinical utility of brief measures of depression, anxiety, and general distress: The PHQ-2, GAD-2, and K-6. Gen Hosp Psychiatry 2019 Jan;56:13-18. [doi: 10.1016/j.genhosppsych.2018.11.003]
69. Cooley JL, Ritschel LA, Frazer AL, Blossom JB. The influence of internalizing symptoms and emotion dysregulation on the association between witnessed community violence and aggression among urban adolescents. Child Psychiatry Hum Dev 2019 Dec;50(6):883-893. [doi: 10.1007/s10578-019-00890-9] [Medline: 30989477]
70. Garofalo C, Neumann CS, Velotti P. Psychopathy and aggression: the role of emotion dysregulation. J Interpers Violence 2021 Dec;36(23-24):NP12640-NP12664. [doi: 10.1177/0886260519900946] [Medline: 31984830]
71. Liang J, Wang Y, Wang H, Chen YH, Wu YW, Yan WJ. Understanding shame-driven aggression: the roles of externalization of blame and hostility in Chinese adolescents. Psychol Res Behav Manag 2024;17:2795-2805. [doi: 10.2147/PRBM.S463475] [Medline: 39082005]
72. Wilkowski BM, Robinson MD. The anatomy of anger: an integrative cognitive model of trait anger and reactive aggression. J Pers 2010 Feb;78(1):9-38. [doi: 10.1111/j.1467-6494.2009.00607.x] [Medline: 20433611]
73. Karnik NS, Steiner H. Evidence for interventions for young offenders. Child Adolesc Ment Health 2007 Nov;12(4):154-159. [doi: 10.1111/j.1475-3588.2007.00460.x] [Medline: 32811014]
74. Karnik NS, Thompson HM, Afshar M. Response to Fitzgerald & Barenholtz: There is still much work to be done for digital classifiers. Addiction 2022 May;117(5):1496. [doi: 10.1111/add.15788] [Medline: 34964190]
75. Felitti VJ MD, FACP, Anda RF MD, MS, Nordenberg D MD, et al. Relationship of childhood abuse and household dysfunction to many of the leading causes of death in adults. Am J Prev Med 1998 May;14(4):245-258. [doi: 10.1016/S0749-3797(98)00017-8]
76. Harper CR, Li J, Sheats K, et al. Witnessing community violence, gun carrying, and associations with substance use and suicide risk among high school students - Youth Risk Behavior Survey, United States, 2021. MMWR Suppl 2023 Apr 28;72(1):22-28. [doi: 10.15585/mmwr.su7201a3] [Medline: 37104385]
77. Gelles-Watnick R, Massarat N. Teens, Social media and technology 2022. Pew Research Center. URL: https://www.pewresearch.org/internet/2022/08/10/teens-social-media-and-technology-2022/ [accessed 2022-09-22]
78. Castater C, Jaeger BW, Hampton-Anderson J, Smith RN. Addressing health disparities in violence. Curr Trauma Rep 2024 Jun;10(2):24-29. [doi: 10.1007/s40719-024-00267-x]
79. Brener ND, Billy JOG, Grady WR. Assessment of factors affecting the validity of self-reported health-risk behavior among adolescents: evidence from the scientific literature. J Adolesc Health 2003 Dec;33(6):436-457. [doi: 10.1016/s1054-139x(03)00052-1] [Medline: 14642706]

XSL•FO
RenderX

Abbreviations

ACT: acceptance and commitment therapy
AGVQ: Attitudes Toward Guns and Violence Questionnaire
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
ED: emergency department
K10: Kessler Psychological Distress Scale
mHealth : mobile health
PHQ-8: 8-item Patient and Health Questionnaire
RPQ: Reactive-Proactive Aggression Questionnaire
SaFETy: Serious Fighting, Friend Weapon Carrying, Community Environment, and Firearm Threats
YRBS: Youth Risk Behavior Surveillance System

Edited by S Badawy; submitted 23.12.24; peer-reviewed by MH Rahman, MC Osborne; revised version received 17.06.25; accepted 01.07.25; published 25.08.25.

Please cite as:
Emezue C, Bishop-Royse J, Froilan A, Wilkes T, Karnik NS, Julion WA
Evaluating a Digital Intervention to Reduce Aggression and Pro-Firearm Violence Attitudes Among Young Black Males: Pretest-Posttest Feasibility Study
JMIR Pediatr Parent 2025;8:e70048
URL: https://pediatrics.jmir.org/2025/1/e70048
doi:10.2196/70048

© Chuka Emezue, Jessica Bishop-Royse, Andrew Froilan, Tara Wilkes, Niranjan S Karnik, Wrenetha A Julion. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 25.8.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Effects of Cold and Vibration on Venipuncture Pain Management in Children Aged 2-7 Years Old: Randomized Controlled Trial

Zi-yun Zhou[1,2*], MM; Long-yi Hu[2,3*], MM; Ming-li Wang[2], MM; Si-qi Li[2], MM; Le-shan Zhou[2], PhD

[1]Hunan Provincial Comprehensive Childcare Service Center, Changsha, China

[2]Department of Clinical Nursing, Xiangya School of Nursing, Central South University, 172 Tong Zi Po Road, Yuelu District, Hunan, Changsha, China

[3]Teaching and Research Section of Clinical Nursing, Xiangya Hospital Central South University, Changsha, China

[*]these authors contributed equally

Corresponding Author:
Le-shan Zhou, PhD
Department of Clinical Nursing, Xiangya School of Nursing, Central South University, 172 Tong Zi Po Road, Yuelu District, Hunan, Changsha, China

Abstract

Background: The pain resulting from venipuncture is one of the primary sources of stress during childhood and can have adverse effects on children. The Buzzy device can play an important role in alleviating the pain of venipuncture in children.

Objective: The aim of this study is to investigate the independent and combined effects of cold and vibration in reducing venipuncture pain and resistance behavior in children aged 2-7 years.

Methods: A total of 130 children who underwent venipuncture were randomly assigned to 4 groups: 32 in the control group, 30 in the external cold group, 37 in the vibration group, and 31 in the cold combined with vibration group. The cold, vibration, and cold combined with vibration interventions used the Buzzy device. Nurses used the Face, Legs, Activity, Cry, Consolability Pain Behavior Scale and the Children's Behavior Scale to assess pain and resistance behaviors before and during the venipuncture.

Results: Compared with the control group, the cold group, vibration group, and cold combined with vibration group experienced milder pain and demonstrated weaker resistance behavior (P<.05). Pairwise comparison results showed that the combination group was superior to the vibration group (P<.05).

Conclusions: External cold and vibration are effective in reducing procedural pain and improving compliance in children aged 2-7 years undergoing venipuncture. The cold combined with vibration has a synergistic effect, and the effect is better than vibration only.

Trial Registration: Chinese Clinical Trial Registry ChiCTR2400079536; https://www.chictr.org.cn/showprojEN.html?proj=192511

(JMIR Pediatr Parent 2025;8:e67918) doi:10.2196/67918

KEYWORDS

external cold; pediatric nursing; children; childhood; venipuncture; phlebotomy; stress; procedural pain; pediatrics; toddler; cold; vibration; nonpharmacological; Buzzy device; Buzzy; Face, Legs, Activity, Cry, Consolability; Pain Behavior Scale; randomized; controlled trial; randomized controlled trial; RCT

Introduction

Background

Venipuncture is a common medical procedure, with moderate to severe pain stimulation [1]. Needle pricks are a significant part of early pain experiences [2]. Needle-related procedural pain is one of the primary sources of stress in childhood, causing fear in children [3]. Early pain experiences can affect physiological indicators and hormonal changes in children, potentially leading to reduced immunity and disrupted pain thresholds in the long term, which is detrimental to the development of the nervous system [4]. Furthermore, Cuenca-Martínez et al [5] suggest that children are more likely to develop a bias in pain memory toward acute pain. Therefore, improper pain management can lead to negative pain memories and needle phobia in children, which may not only increase pain but also trigger it [6]. However, many children do not receive adequate pain prevention and management during venipuncture [7].

The Buzzy device is a widely used nonpharmacological method for alleviating venipuncture pain in children. It is a bee-shaped tool that combines ice pack cooling and vibration. The device includes a vibration-generating engine powered by batteries, with a detachable ice pack as its wings. Compared to other nonpharmacological methods like virtual reality [8] and distraction interventions [9], it is simple to operate: you only

XSL•FO
RenderX

need to place it approximately 5 centimeters above the puncture site and activate the device a few minutes before venipuncture. The Buzzy device's soothing effect combines cold and vibration, two common and effective methods for reducing pain in children [10]. The individual use of cold or vibration has been well-validated in pediatric pain management [11]. Among nonpharmacologic strategies, the use of cold and vibration is a common and effective method for pain reduction in children [12]. Cold packs work by applying cold to a specific body area, which slows or inhibits pain transmission via peripheral nerves and induces vasoconstriction, thus raising the pain threshold [13]. Vibration stimulates tactile receptors in the skin, which localizes the sensation of pain and, when applied repetitively, reduces its intensity. This vibratory stimulation activates pain-blocking mechanisms and increases the release of β-endorphins, which raise the pain threshold and diminish the perception of pain [14,15]. The Buzzy device has been widely used to reduce pain during venipuncture in children [16].

However, researchers found that the combined use of cold and vibration with the Buzzy device did not seem as effective as imagined. Semerci et al [17] discovered that in school-aged children, using cold spray alone was more effective in relieving pain compared to the combined use of cold and vibration with the Buzzy device. Similarly, Ueki et al [18] found that for children under 6 years old, there was no difference in pain relief whether or not the vibration feature of the Buzzy device was activated when using an ice pack. Moreover, the pain relief effect of the Buzzy device might be due to the distraction caused by its bee-like appearance, which diminishes in older children [19]. Therefore, it seems there is a debate on whether the pain relief effect of the Buzzy device in children is due to the cold, the vibration, or the combination of both; current studies compare the Buzzy device with other pain management methods (such as cold spray) while neglecting the effects of the device itself. Compared to other nonpharmacological approaches, the Buzzy device is more cost-effective and easier to operate. If we can demonstrate that either cold application or vibration alone is effective, the Buzzy device could still be a viable option for pain relief—even if cold spray proves more effective.

According to a paper titled "A practical guide to acute pain management in children" [20], most pain assessment tools define age 7 as the threshold at which children can accurately self-report. Furthermore, Hedén et al [21] believe that children over the age of 7 are better able to distinguish between fear and pain. Younger children may develop a psychological and behavioral resistance to injections due to fear, increasing the risk of unsafe venipuncture [22]. For children under 2 years old, incomplete skin barrier function and thermoregulatory capabilities make them susceptible to skin damage, so cold is not recommended [23]. Therefore, this study selected children aged 2-7 as subjects to explore the independent effects and interactions of cold and vibration during the venipuncture process using the Buzzy device. The aim is to reduce pain and resistance behavior during venipuncture, enhance children's adherence to treatments, and ultimately improve pain management in children.

Objective

This study aims to investigate the independent and combined effects of cold and vibration in reducing venipuncture pain in children aged 2-7 years. The research hypothesis is that there are independent and interactive effects between vibration and external cold in solving procedural pain in children.

Methods

Participants

A randomized controlled trial was conducted to select children aged 2-7 years requiring venipuncture between May 2023 and November 2023 in the Department of Pediatrics of a tertiary hospital in Changsha City, Hunan Province, including the pediatric emergency department and pediatric ward, and the main reason for venipuncture was blood sampling, requiring peripheral intravenous access. This trial was reported using CONSORT (Consolidated Standards of Reporting Trials) guidelines. Informed consent was obtained from parents, and verbal assent was acquired from the children prior to their participation.

The inclusion criteria were (1) no history of cognitive or neurodevelopmental delay and (2) informed consent/assent obtained from both the children and their parents. The exclusion criteria were as follows: (1) difficulty in cooperation (ie, the child's strong resistance to venipuncture, continuous struggle throughout the entire venipuncture process, and inability to cooperate with the use of the Buzzy device); (2) use of sedative drugs or treatments prior to venipuncture; (3) broken skin at the needle puncture site; (4) extreme sensitivity to cold (Raynaud's syndrome or sickle cell disease); (5) experience with external cold or vibration within the past week; and (6) withdrawal of consent during venipuncture process.

While the child was waiting for the venipuncture, the researchers explained the purpose and methods of the study to the parents and obtained written consent from them. In addition, the researchers would explain the study to the child in simple and understandable language. If the child refused to participate, we would exclude the child from the study even if the parents agreed.

Sample Size Calculation

The efficacy analysis of a 2-factor, 2-level ANOVA was performed using G*Power with settings of 1-β=.80, effect size=0.40, α=.05 according to the preexperimental results, a degree of freedom of 3, and 4 groups. Considering a 15% sample attrition rate, it was determined that each group should include at least 21 participants, requiring a total of 84 participants across the 4 groups.

A total of 145 children, aged 2-7 years and meeting the inclusion and exclusion criteria, were enrolled in the study. Participants were randomized into 4 treatment groups using IBM SPSS software (version 24.0; IBM Corp) based on the random number table method. Of the original cohort, 15 participants withdrew their consent by refusing to use the Buzzy tool during the venipuncture phase, leaving 130 participants for the final analysis.

XSL•FO
RenderX

Ethical Considerations

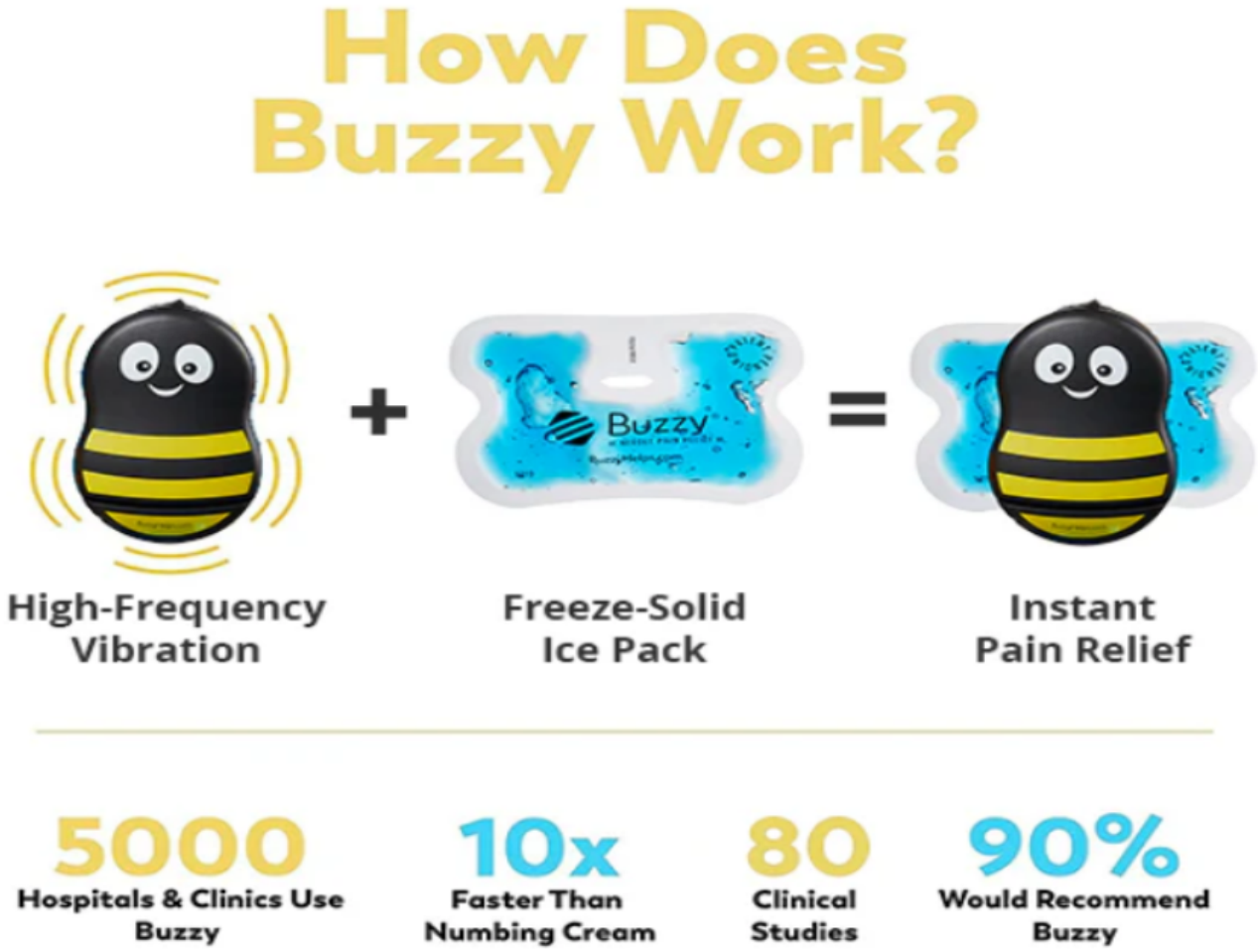
The study was approved by the Ethics Review Committee of Xiangya School of Nursing, Central South University (E2023149) on June 23, 2023, and registered with the Clinical Trials Register (ChiCTR2400079536) on January 5, 2024. All participants were informed of the study's purpose and the venipuncture process. Informed consent was obtained from parents, and verbal assent was acquired from the children prior to their participation. Participants did not receive any compensation. To protect the privacy of participants, we numbered them and did not retain any identifying information.

Setting

Before starting the venipuncture, the researcher introduced the study to the children and their families. Due to the characteristics of the Buzzy device and the principle of informed consent, it was not possible to blind the children and their families. The nurses performing the venipuncture had all been working in pediatrics for over 5 years, held the title of "nurse-in-charge," and had all undergone standardized pediatric venipuncture training, obtaining the necessary qualifications for conducting venipuncture.

The Buzzy device (MMJ Labs) is a bee-shaped tool, measuring 8 × 5 × 2.5 cm, that integrates both vibration (the body of the bee) and cold (a removable ice pack). The ice pack is stored in the freezer and inserted into the device before the venipuncture. After use, it is returned to the freezer to maintain its cooling effect (Figure 1).

Figure 1. Buzzy device (image by MMJ Labs).



Preparation for Venipuncture

The pediatric outpatient emergency injection room is designed to accommodate the needs of children, featuring decorations such as cartoon characters and warm colors. The room maintains appropriate levels of natural light, temperature, and humidity. Nurses ensure they are properly prepared, organize the necessary injection supplies and emergency equipment, and perform double-checks on medications to ensure accuracy.

Venipuncture

For the control group, routine nursing care was implemented. The children's and their families' basic information was verified, and the purpose of the venipuncture was explained. According to the recommended usage of the Buzzy device [24], 1 minute before the injection, the Buzzy device was placed 5 centimeters above the puncture site before tightening the tourniquet. The cold pack and the vibration switch were not activated. An appropriate injection site and vessel were chosen, the area was disinfected twice, and the needle was positioned at a 15 - 30° angle with the skin, bevel up, and advanced slightly after seeing

XSL•FO
RenderX

blood return. Blood return was checked before advancing the needle slightly for fixation. The needle was secured and the Buzzy device was removed after securing the pillow. During the injection, the child was encouraged, engaged in conversation, and provided with timely feedback and praise. Postinjection, instructions on precautions were given, and the child was monitored for any discomfort or adverse reactions.

For the observation group, the other conditions were the same as the control group, but for one group, the vibration switch was activated, for another, an ice pack was applied for cold therapy, and the final group received both vibration and cold therapy.

Data Collection

Before puncture (denoted as T_0, no venipuncture or movement within the injection room) and during the puncture process (denoted as T_1, from the application of the tourniquet to confirmation of successful puncture and fixation), two time periods were observed. Based on the scale, one research team member assessed the patient's resistance behaviors while another evaluated the level of pain and recorded it.

General Information

The child-specific information collected included gender, age, height, weight, punctured vein, whether it is the first intravenous injection, the time of the most recent injection, how many puncture attempts were needed for success, any hospitalization experience, presence of needle phobia, type of disease, and typical sensitivity to pain. This information was provided by the parents.

Children's Pain (Primary Outcome Measure)

The Face, Legs, Activity, Cry, Consolability (FLACC) Pain Behavior Scale is used to assess pain in children aged 2 months to 7 years or in individuals unable to communicate their pain. Each category is scored from 0 to 2, with a total score of 0 to 10. A score of 0 indicates no pain; 1 - 3 indicates mild pain; 4 - 6 indicates moderate pain; and 7 - 10 indicates severe pain. Liu et al [25] translated it into Chinese, and it has demonstrated reliability and validity, with a Cronbach α of 0.88.

Behavioral State

A compliance and resistance behavior assessment was conducted for each child. This involved evaluating the child's behavior during the injection, including crying, screaming, agitation, struggling, and avoidance. A scoring system of 0-3 was used, with 5 items in total and a maximum score of 15. The higher the score, the poorer the compliance and the stronger the resistance behavior [22].

Statistical Analysis

Statistical analysis was conducted using SPSS software (version 24.0; IBM Corp). Measurement data were described as mean (SD), and ANOVA was used for comparisons between groups. Categorical data were described using frequency and composition ratios, and comparisons were made using the chi-square test and Fisher exact test. The significance level was set at 0.05. For measurement data that did not follow a normal distribution or exhibited heterogeneity of variance, the median (percentile) was used for description, and intergroup differences were analyzed using nonparametric rank-sum tests (Kruskal-Wallis rank-sum test). In cases of homogeneity of variance, post hoc multiple comparisons were performed using the Bonferroni test.

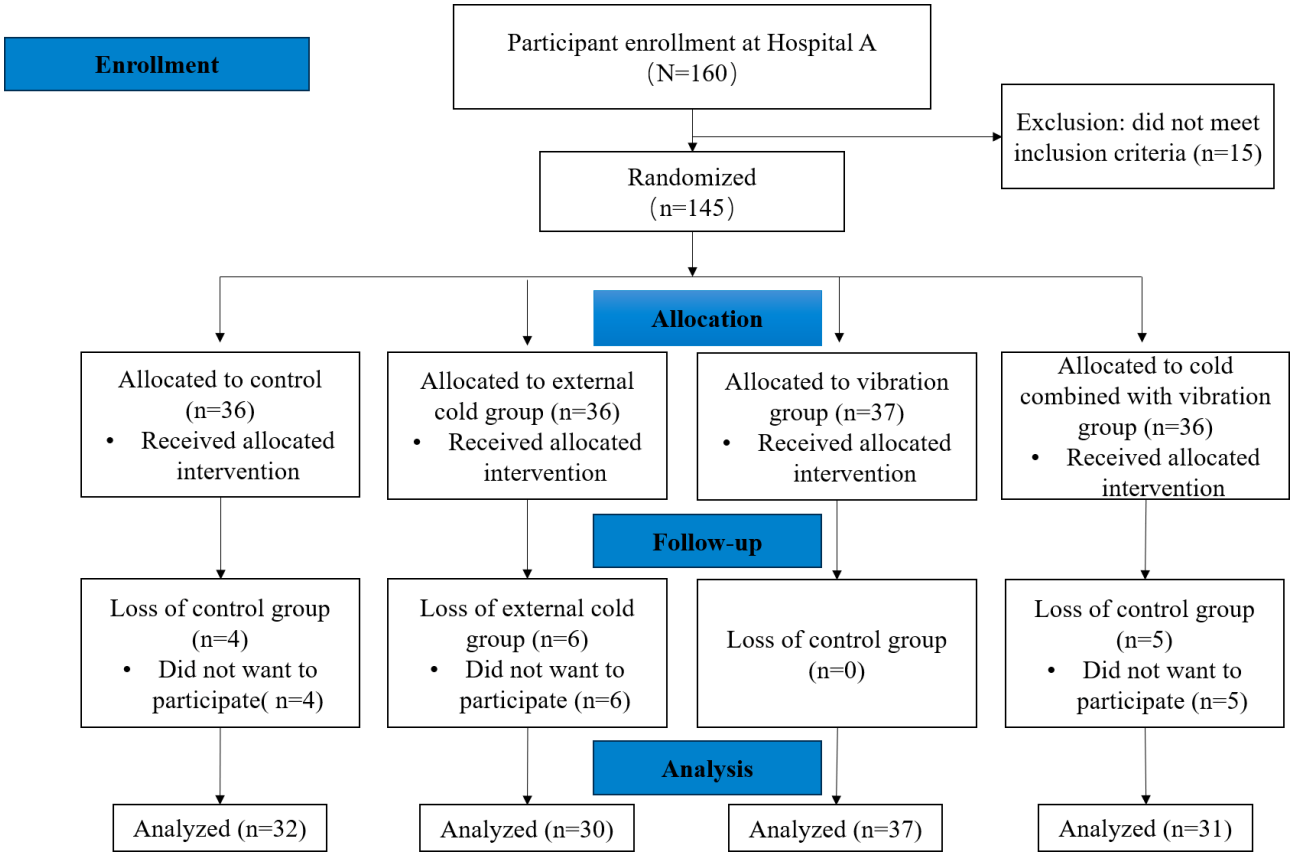
Results

Demographic Information

A total of 145 children were enrolled in the study and randomized into 4 treatment groups. Of these, 15 participants withdrew their consent, leaving 130 participants for the final analysis. The flowchart of participant allocation is shown in Figure 2.

XSL•FO
RenderX

Figure 2. Flow diagram.



A total of 130 sets of data on children aged 2-7 years were collected, including 32 in the control group, 30 in the external cold group, 37 in the vibration group, and 31 in the combined cold and vibration group. The results showed that the average age of patients in the control group, external cold group, vibration group, and combined cold and vibration group was 3.97, 4.03, 4.00, and 3.77 years, respectively. There were no statistically significant differences in demographic variables between control, vibration, cold, and combined treatment groups (P>.05), indicating a general comparability, as shown in Table 1.

XSL•FO
RenderX

Table . Demographic information (N=130).

Items	Control (n=32)	External cold (n=30)	Vibration (n=37)	Cold combined with vibration (n=31)	*F* test (*df*=3) or chi-square (*df*=3)	*P* value
Gender, n (%)					0.978[a]	.81
Male	16 (50)	16 (53.3)	19 (51.4)	19 (61.3)		
Female	16 (50)	14 (46.7)	18 (48.6)	12 (38.7)		
Age (years), mean (SD)	3.97 (1.69)	4.03 (1.71)	4.00 (1.76)	3.77 (1.63)	0.146[b]	.93
Height (cm), mean (SD)	105.25 (11.46)	107.27 (12.04)	104.49 (11.50)	104.63 (11.97)	0.373[b]	.77
Weight (kg), mean (SD)	16.68 (4.27)	17.38 (3.62)	17.49 (4.81)	16.52 (3.91)	0.438[b]	.73
BMI, mean (SD)	14.94 (1.69)	15.20 (1.79)	15.95 (2.24)	15.02 (1.35)	2.281[b]	.08
Last injection time, n (%)					0.659[a]	.88
≤7 days	26 (81.2)	22 (73.3)	28 (75.7)	23 (74.2)		
>7 days	6 (18.8)	8 (26.7)	9 (24.3)	8 (25.8)		
Puncture success, n (%)					1.734[a]	.84
Once	31 (96.9)	29 (96.7)	35 (94.6)	31 (100)		
Twice	1 (3.1)	1 (3.3)	2 (5.4)	0 (0)		
Vessel site, n (%)					6.568[a]	.09
Back of the hand	21 (65.6)	25 (83.3)	27 (73)	28 (90.3)		
Other	11 (34.4)	5 (16.7)	10 (27)	3 (9.7)		
Disease, n (%)					7.706[a]	.26
Respiratory system	19 (59.4)	22 (73.3)	20 (54.1)	23 (74.2)		
Blood system	8 (25)	3 (10)	6 (16.2)	5 (16.1)		
Other	5 (15.6)	5 (16.7)	11 (29.7)	3 (9.7)		
Experience of hospitalization, n (%)					1.454[a]	.69
No	13 (40.6)	14 (46.7)	19 (51.4)	17 (54.8)		
Yes	19 (59.4)	16 (53.3)	18 (48.6)	14 (45.2)		
Needle phobia, n (%)					1.436[a]	.70
No	14 (43.8)	14 (46.7)	18 (48.6)	18 (58.1)		
Yes	18 (56.2)	16 (53.3)	19 (51.4)	13 (41.9)		
Sensitivity to pain, n (%)					3.019[a]	.82
Not	2 (6.3)	2 (6.7)	5 (13.5)	3 (9.7)		
General	21 (65.6)	19 (63.3)	23 (62.2)	16 (51.6)		
Very	9 (28.1)	9 (30)	9 (24.3)	12 (38.7)		

[a]Chi-square.

[b]*F* test.

Impact of External Cold and Vibration on Pain and Resistance Behavior

After comparing pain (*P*=.26) and compliance resistance behavior scores (*P*=.31) among the groups of children at the T_0 stage, the differences were not statistically significant. The differences at the T_1 stage were statistically significant (*P*<.001). Pairwise comparison results showed that at T_1, the pain scores of the control group were higher than those of the external cold, vibration, and combination group (*P*<.001), and the vibration group had higher pain scores than the combination group (*P*=.03). Furthermore, the mean pain scores from highest to

XSL•FO
RenderX

lowest were as follows: control group (4.38, SD 2.25), vibration group (1.81, SD 1.4), external cold group (1.10, SD 1.77), and combination group (0.65, SD 1.20). At T_1, the resistance behavior of the control group was higher than that of the external cold, vibration, and combination group (P<.001), and the vibration group exhibited higher resistance behavior than the combination group (P=.01), with the differences before and after decreasing in the following order: control group (mean 2.97, SD 2.39), vibration group (mean 1.08, SD 1.23), external cold group (mean 0.57, SD 1.89), and combination group (mean 0.26, SD 0.93) (Table 2).

Table . Comparison of pain and resistance behavior scores.

Items	Control (n=32)	External cold (n=30)	Vibration (n=37)	Cold combined with vibration (n=31)	*F* test (*df*=3) or *H* test	*P* value
FLACC[a]						
T_0, mean (SD)	1.97 (2.25)	3.00 (2.36)	2.16 (2.48)	2.68 (1.88)	1.366[b]	.26
T_1, mean (SD)	6.34 (2.96)[c,d,e]	4.10 (2.62)[f]	3.97 (2.98)[f]	3.32 (1.92)[f]	7.759[b]	<.001
△, mean (SD)	4.38 (2.25)[c,d,e]	1.10 (1.77)[f]	1.81 (1.41)[e,f]	0.65 (1.20)[d,f]	16.293[b]	<.001
Resistance behavior						
T_0, median (IQR)	5 (5-6)	6 (5-7)	5 (5-7)	6 (5-6)	3.580[g]	.31
T_1, mean (SD)	8.72 (3.22)[c,d,e]	6.67 (1.88)[f]	7.16 (2.18)[f]	6.19 (1.35)[f]	7.364[b]	<.001
△, mean (SD)	2.97 (2.39)[c,d,e]	0.57 (1.89)[f]	1.08 (1.23)[e,f]	0.26 (0.93)[d,f]	16.293[b]	<.001

[a]FLACC: Face, Legs, Activity, Cry, Consolability.

[b]*F* test.

[c]Different from the external cold group.

[d]Different from the vibration group.

[e]Different from the cold combined with vibration group.

[f]Different from the control group.

[g]Kruskal-Wallis test.

The Independent and Combined Effects of External Cold and Vibration Intervention

Both external cold and vibration had statistically significant main effects on reducing pain and compliance-resistance behaviors in children (P<.001), and there was a statistically significant interaction between external cold and vibration (FLACC scores: F=12.469, P=.001; resistance behavior: F=7.025, P=.009), as shown in Table 3 and Figures 3 and 4.

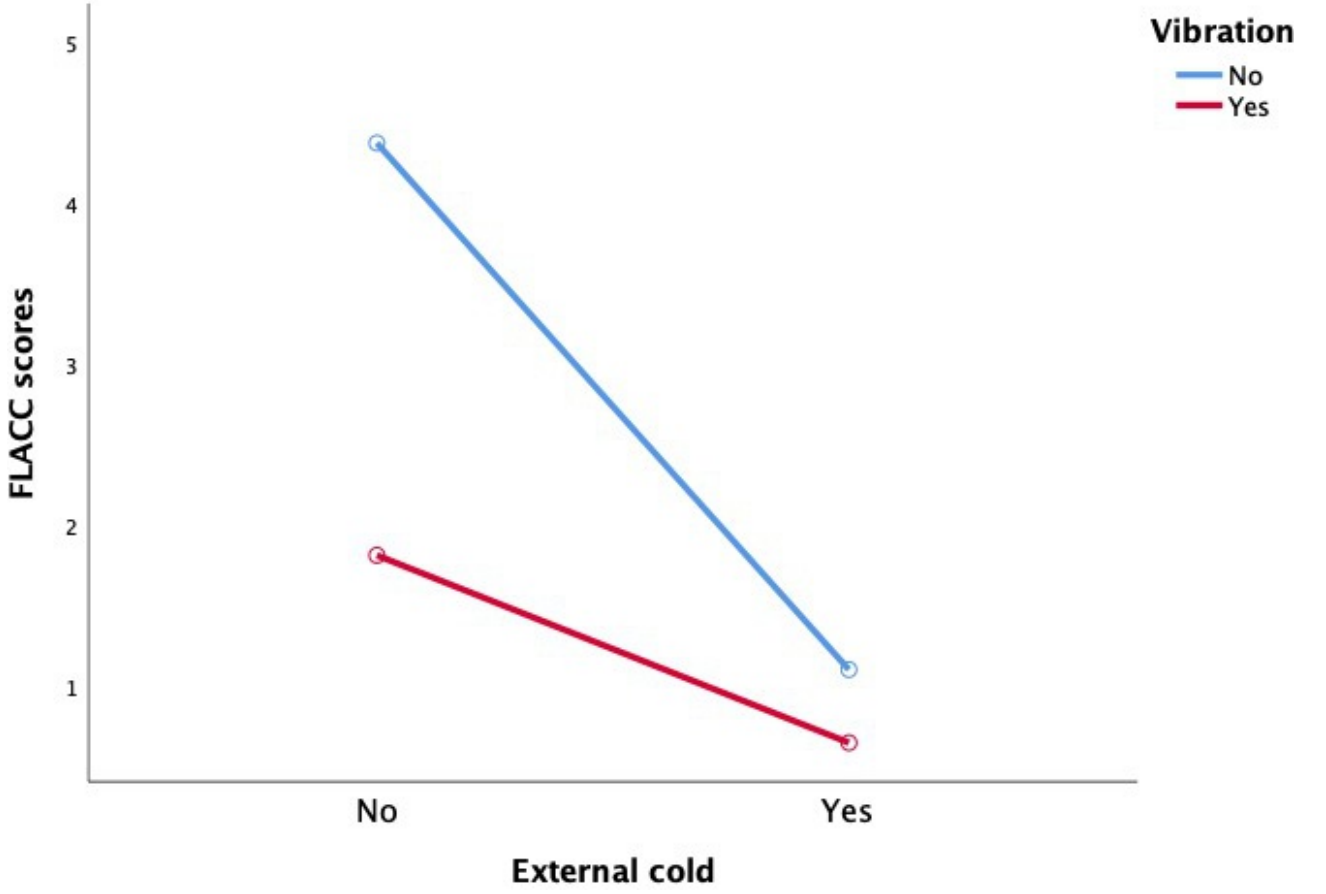
Table . Analysis of group differences and interaction effects in pain and compliance-resistance behavior scores.

Intervention factor	Type III sum of squares	Mean square	*F* test (*df*=1)	*P* value
FLACC[a]				
External cold	159.196	159.196	55.262	<.001
Vibration	73.582	73.582	25.543	<.001
Interaction (cold × vibration)	35.920	35.920	12.469	.001
Resistance behavior				
External cold	83.970	83.970	29.306	<.001
Vibration	38.941	38.941	13.591	<.001
Interaction (cold × vibration)	20.130	20.130	7.025	.009

[a]FLACC: Face, Legs, Activity, Cry, Consolability.

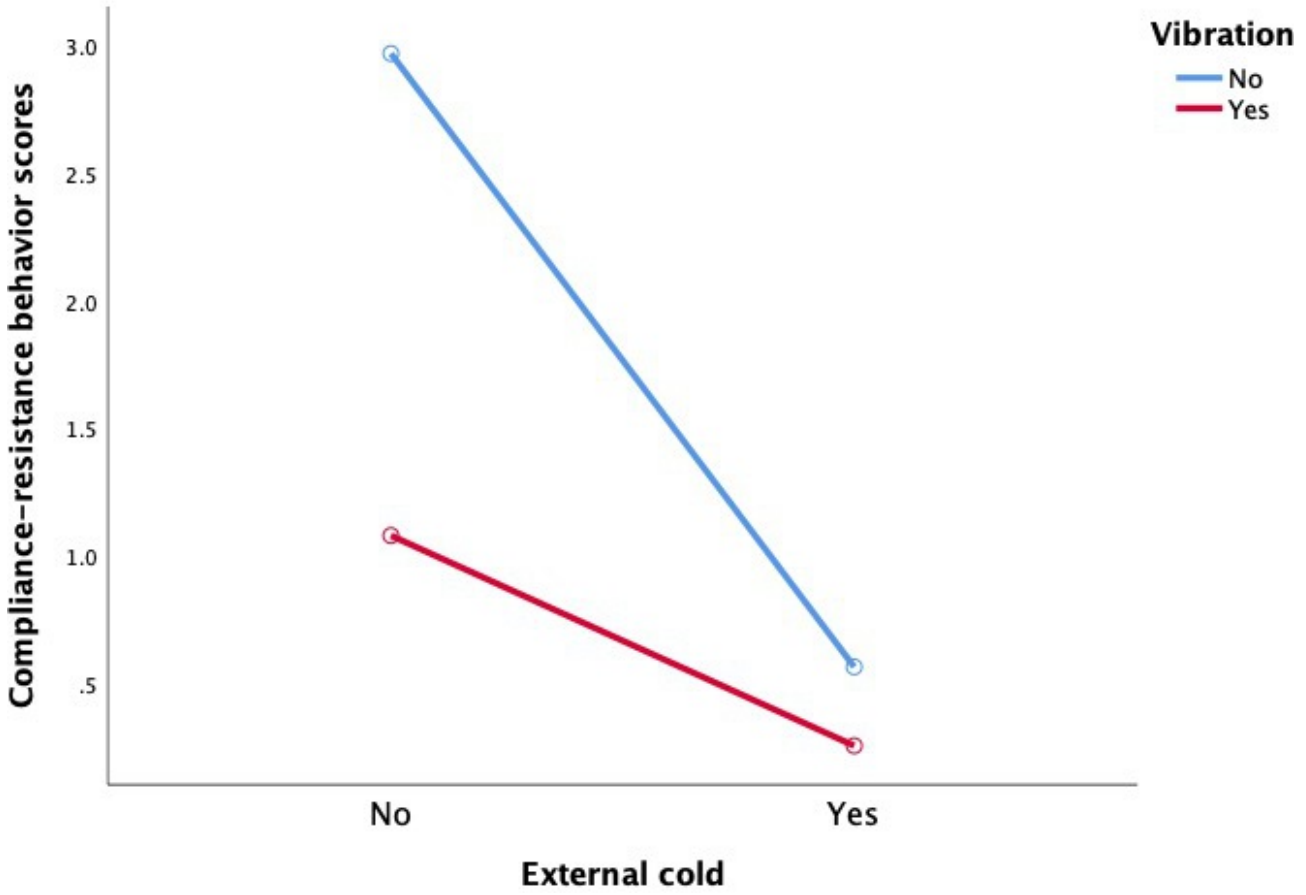
XSL•FO
RenderX

Figure 3. Comparison of mean FLACC score values resulting from cold and/or vibration intervention in children aged 2-7 years old. FLACC: Face, Legs, Activity, Cry, Consolability.



XSL•FO
RenderX

Figure 4. Comparison of the effect of cold and/or vibration intervention on compliance-resistance behaviors in children aged 2-7 years old.



Discussion

Main Finding

The main finding of this study is that cold and vibration methods can effectively reduce resistance behavior and increase compliance, while decreasing pain in children aged 2-7 years during venipuncture. The cold combined with vibration is superior to external cold or vibration alone.

Impact of External Cold and Vibration on Pain and Resistance Behavior

The findings of this study are consistent with previous research [26-28]. Ballard et al [24] suggested the Buzzy device works through gate control theory. According to this theory, nonpainful stimuli (like touch, pressure, and temperature) carried by large nerve fibers can inhibit pain signals transmitted by smaller A-δ and C fibers. Applying external cold and vibration before venipuncture generates nonpainful sensory signals that activate inhibitory functions in neural transmission, causing the gate that regulates pain signals entering the brain to close, blocking pain signal transmission and thereby reducing pain [29]. The cold and vibration also trigger β-endorphin release, raising pain thresholds. Additionally, external cold causes vasoconstriction, increasing the pain threshold and reducing pain perception [12], while vibration stimulates skin tactile receptors, such as Pacinian and Meissner's corpuscles, confining pain to a local area [30]. Furthermore, these stimuli distract children from pain, increasing their comfort [31].

Current research mostly focuses on the effect of reducing pain in children during venipuncture, neglecting the assessment of behavioral state effects [12,32]. Our research explores this. On the one hand, by effectively reducing venipuncture pain, the child's resistance to the venipuncture is diminished; on the other hand, it serves as an effective distraction, lowering the child's anticipatory anxiety about the venipuncture, thereby reducing irritability and restlessness [33]. Cold and vibration can decrease discomfort and uneasiness in children during venipuncture, helping them to overcome negative perceptions and responses, increasing compliance, and improving the success rate of venipuncture [34].

The Independent and Combined Effects of External Cold and Vibration Intervention

The study results indicate that during venipuncture in children aged 2-7 years, cold and vibration interventions have both independent effects and interaction effects on reducing resistance behavior and pain. That is, the effects of cold or vibration can change with the level of either intervention, with a synergistic interaction between them, enhancing the effects when combined. The group receiving both external cold and vibration showed a better effect in reducing resistance behavior and alleviating venipuncture pain than the groups receiving only external cold or only vibration. This suggests that the cold combined with vibration is more beneficial, as demonstrated by Faghihian et al's results [35], which indicated that combining external cold with vibration was more effective in alleviating anesthesia injection pain in children aged 6-12 compared to using only an

XSL•FO
RenderX

ice bag to apply external cold. External cold and vibration can each play a role by blocking pain signal transmission and affecting neurotransmitter secretion mechanisms, respectively, reducing pain perception and increasing pain thresholds [36], thereby minimizing the children's resistance behavior due to pain.

There was no difference in reduced pain results when using vibration with cold. Ueki et al [18] also found that when children's pain was assessed by researchers, there was no significant difference in pain relief from vaccination when using only cold or a combination of both cold and vibration. However, they did not further explore the difference between using the Buzzy device and not. This "1+1<2" result may be related to the limited interception of pain signals by nonpain sensory signals provided by cold application and vibration. The specific reasons require further investigation. The individual use of cold and vibration is more convenient, and future studies could conduct a cost-effectiveness analysis of using the Buzzy device to apply cold, vibration, and cold combined with vibration.

Clinical Implication

This study demonstrated the effectiveness of the Buzzy device for pain management in children aged 2 - 7 years, providing a theoretical basis for clinical practice in pediatric pain management.

Limitations

The participants in this study all came from the same hospital and only included children aged 2 - 7 years, which limits its representativeness. Future studies could implement multicenter research and include all age groups. The effect of external cold in this experiment may vary with different seasons and temperatures, and this study did not compare the minimal clinically important difference, which could be further explored in future research.

Conclusion

The application of cold and vibration methods has been shown to significantly mitigate resistance and enhance compliance, concurrently diminishing pain in children aged 2-7 years undergoing venipuncture. The combined effect of cold and vibration was superior to vibration alone, but no different from cold compress alone. Future research could focus on the cost-effectiveness analysis of using the Buzzy device for cold, vibration, and both interventions.

Conflicts of Interest

None declared.

Checklist 1
CONSORT (Consolidated Standards of Reporting Trials) checklist.
[PDF File, 87 KB - pediatrics_v8i1e67918_app1.pdf]

References

1. Pancekauskaitė G, Jankauskaitė L. Paediatric pain medicine: pain differences, recognition and coping acute procedural pain in paediatric emergency room. Medicina (Kaunas) 2018 Nov 27;54(6):94. [doi: 10.3390/medicina54060094] [Medline: 30486427]
2. Göthesson J, Håkansson L, Olinder AL, et al. Children's and adolescent's narratives about pain and negative experiences in diabetes treatment. J Spec Pediatr Nurs 2023 Jan;28(1):e12396. [doi: 10.1111/jspn.12396] [Medline: 36316154]
3. Healy P, Lu C, Silk JS, et al. An exposure-based video game (Dr. Zoo) to reduce needle phobia in children aged 3 to 6 years: development and mixed methods pilot study. JMIR Serious Games 2023 Oct 16;11:e42025. [doi: 10.2196/42025] [Medline: 37843885]
4. McLenon J, Rogers MAM. The fear of needles: a systematic review and meta-analysis. J Adv Nurs 2019 Jan;75(1):30-42. [doi: 10.1111/jan.13818] [Medline: 30109720]
5. Cuenca-Martínez F, Herranz-Gómez A, Varangot-Reille C, et al. Pain memory in children: a systematic review and meta-analysis with a meta-regression. Pain 2024 Jul 1;165(7):1450-1463. [doi: 10.1097/j.pain.0000000000003170] [Medline: 38314811]
6. Taddio A, McMurtry CM, Logeman C, et al. Prevalence of pain and fear as barriers to vaccination in children - systematic review and meta-analysis. Vaccine (Auckl) 2022 Dec 12;40(52):7526-7537. [doi: 10.1016/j.vaccine.2022.10.026] [Medline: 36283899]
7. Birnie KA, Noel M, Chambers CT, Uman LS, Parker JA. Psychological interventions for needle-related procedural pain and distress in children and adolescents. Cochrane Database Syst Rev 2018 Oct 4;10(10):CD005179. [doi: 10.1002/14651858.CD005179.pub4] [Medline: 30284240]
8. Czech O, Wrzeciono A, Rutkowska A, Guzik A, Kiper P, Rutkowski S. Virtual reality interventions for needle-related procedural pain, fear and anxiety-a systematic review and meta-analysis. J Clin Med 2021 Jul 23;10(15):3248. [doi: 10.3390/jcm10153248] [Medline: 34362032]
9. Shen T, Wang X, Xue Q, Chen D. Active versus passive distraction for reducing procedural pain and anxiety in children: a meta-analysis and systematic review. Ital J Pediatr 2023 Aug 31;49(1):109. [doi: 10.1186/s13052-023-01518-4] [Medline: 37653423]

XSL•FO
RenderX

10. McNair C, Campbell-Yeo M, Johnston C, Taddio A. Nonpharmacologic management of pain during common needle puncture procedures in infants: current research evidence and practical considerations: an update. Clin Perinatol 2019 Dec;46(4):709-730. [doi: 10.1016/j.clp.2019.08.006] [Medline: 31653304]
11. Oschman A, Rao K. Challenges in management of refractory pain and sedation in infants. Front Pharmacol 2023;14:1259064. [doi: 10.3389/fphar.2023.1259064] [Medline: 38235119]
12. Sapçi E, Bilsin Kocamaz E, Gungormus Z. Effects of applying external cold and vibration to children during vaccination on pain, fear and anxiety. Complement Ther Med 2021 May;58:102688. [doi: 10.1016/j.ctim.2021.102688] [Medline: 33640458]
13. Chen CT, Tung HH, Chen YC, et al. Cold application for pain and anxiety reduction following chest tube removal: a systematic review and meta-analysis. J Clin Nurs 2023 Feb;32(3-4):574-583. [doi: 10.1111/jocn.16315] [Medline: 35388557]
14. Ahmad KA, Shoaib RM, Ahsan MZ, et al. Microglial IL-10 and β-endorphin expression mediates gabapentinoids antineuropathic pain. Brain Behav Immun 2021 Jul;95:344-361. [doi: 10.1016/j.bbi.2021.04.007] [Medline: 33862171]
15. Avan Antepli N, Bilsin Kocamaz E, Güngörmüş Z. The effect of vibration on pain during heel lance procedures in newborns: a randomized controlled trial. Adv Neonatal Care 2022 Apr 1;22(2):E43-E47. [doi: 10.1097/ANC.0000000000000918] [Medline: 34334677]
16. Gahlawat M, Kodi M, Deol R. Effect of external cold and thermomechanical stimulation on anxiety and pain during intravenous cannulation among children. Sudan J Paediatr 2021;21(2):162-172. [doi: 10.24911/SJP.106-1590387019] [Medline: 35221428]
17. Semerci R, Akarsu Ö, Kılıç D. The effect of buzzy and cold spray on pain, anxiety, and fear of children during venipuncture in pediatric emergency department in Turkey; a randomized controlled study. J Pediatr Nurs 2023;68:e1-e7. [doi: 10.1016/j.pedn.2022.08.019] [Medline: 36089558]
18. Ueki S, Matsunaka E, Takao K, Kitao M, Fukui M, Fujita Y. The effectiveness of vibratory stimulation in reducing pain in children receiving vaccine injection: a randomized controlled trial. Vaccine (Auckl) 2021 Apr 8;39(15):2080-2087. [doi: 10.1016/j.vaccine.2021.03.013] [Medline: 33744043]
19. Cho MK, Choi MY. Effect of distraction intervention for needle-related pain and distress in children: a systematic review and meta-analysis. Int J Environ Res Public Health 2021 Aug 31;18(17):9159. [doi: 10.3390/ijerph18179159] [Medline: 34501749]
20. Gai N, Naser B, Hanley J, Peliowski A, Hayes J, Aoyama K. A practical guide to acute pain management in children. J Anesth 2020 Jun;34(3):421-433. [doi: 10.1007/s00540-020-02767-x] [Medline: 32236681]
21. Hedén L, von Essen L, Ljungman G. Children's self-reports of fear and pain levels during needle procedures. Nurs Open 2020 Jan;7(1):376-382. [doi: 10.1002/nop2.399] [Medline: 31871722]
22. Wang X, Feng T, Yu X, Xu QH. Observation of the clinical intervention of psychological care in the treatment of pediatric orthodontic patients. World Latest Med Inf 2019;19(32):286-287. [doi: 10.19613/j.cnki.1671-3141.2019.32.206]
23. Ye L, Lai Q, Wang X, et al. Trend of changes in epidermal biophysical properties in the Chinese aged 1 month to 17-year old. Skin Res Technol 2023 Mar;29(3):e13297. [doi: 10.1111/srt.13297] [Medline: 36973975]
24. Ballard A, Khadra C, Adler S, Trottier ED, Le May S. Efficacy of the Buzzy device for pain management during needle-related procedures: a systematic review and meta-analysis. Clin J Pain 2019 Jun;35(6):532-543. [doi: 10.1097/AJP.0000000000000690] [Medline: 30829735]
25. Liu M, Chen LQ, Zheng JL. The appraisal of reliability and validity of the FLACC observation tool for scoring painfulness of children with cleft lip and palate. Nurs J Chin People's Liberation Army 2012;29(13):20-22 [FREE Full text]
26. Tirupathi SP, Rajasekhar S. Effect of precooling on pain during local anesthesia administration in children: a systematic review. J Dent Anesth Pain Med 2020 Jun;20(3):119-127. [doi: 10.17245/jdapm.2020.20.3.119] [Medline: 32617406]
27. Suohu T, Sharma S, Marwah N, Mishra P. A comparative evaluation of pain perception and comfort of a patient using conventional syringe and Buzzy system. Int J Clin Pediatr Dent 2020;13(1):27-30. [doi: 10.5005/jp-journals-10005-1731] [Medline: 32581474]
28. Albouni MA, Kouchaji C, Al-Akkad M, Voborna I, Mounajjed R. Evaluation of the injection pain with the use of Vibraject during local anesthesia injection for children: a randomized clinical trial. J Contemp Dent Pract 2022 Jul 1;23(7):749-754. [Medline: 36440524]
29. Shetty A, Naik SS, Patil RB, Valke PS, Mali S, Patil D. Effectiveness of an extraoral cold and vibrating device in reducing pain perception during deposition of local anesthesia in pediatric patients aged 3-12 years: a split-mouth crossover study. J Dent Anesth Pain Med 2023 Dec;23(6):317-325. [doi: 10.17245/jdapm.2023.23.6.317] [Medline: 38076506]
30. Zafar T, Zaki S, Alam MF, et al. Effect of whole-body vibration exercise on pain, disability, balance, proprioception, functional performance and quality of life in people with non-specific chronic low back pain: a systematic review and meta-analysis. J Clin Med 2024 Mar 13;13(6):1639. [doi: 10.3390/jcm13061639] [Medline: 38541865]
31. Yaz Ş, Başdemir S, Geçtan E. The effect of vibrating cold application and puppet use on pain and fear during phlebotomy in children: a randomized controlled study. J Pediatr Nurs 2024;74:77-84. [doi: 10.1016/j.pedn.2023.11.018] [Medline: 38029689]

XSL•FO
RenderX

32. Cho YH, Chiang YC, Chu TL, Chang CW, Chang CC, Tsai HM. The effectiveness of the Buzzy device for pain relief in children during intravenous injection: quasirandomized study. JMIR Pediatr Parent 2022 Apr 29;5(2):e15757. [doi: 10.2196/15757] [Medline: 35486419]
33. Jain N, Juneja P, Masih U, Bhushan AKB, Bhaduaria US, Badjatya K. Efficacy of external cold and a vibrating device in reducing pain and anxiety during local anaesthesia. J Family Med Prim Care 2021 Nov;10(11):4017-4022. [doi: 10.4103/jfmpc.jfmpc_305_21] [Medline: 35136761]
34. Alanazi KJ, Pani S, AlGhanim N. Efficacy of external cold and a vibrating device in reducing discomfort of dental injections in children: a split mouth randomised crossover study. Eur Arch Paediatr Dent 2019 Apr;20(2):79-84. [doi: 10.1007/s40368-018-0399-8] [Medline: 30519955]
35. Faghihian R, Esmaeili M, Asadi H, Nikbakht MH, Shadmanfar F, Jafarzadeh M. The effect of external cold and vibration on infiltration-induced pain in children: a randomized clinical trial. Int J Dent 2022;2022:7292595. [doi: 10.1155/2022/7292595] [Medline: 36105381]
36. Yilmaz Menek M, Dansuk E, Tayboga UI. Effect of local vibration therapy on pain, joint position sense, kinesiophobia, and disability in cervical disc herniation: a randomized controlled trial. J Clin Med 2024 Aug 5;13(15):4566. [doi: 10.3390/jcm13154566] [Medline: 39124832]

Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
FLACC: Face, Legs, Activity, Cry, Consolability

Edited by S Badawy; submitted 24.10.24; peer-reviewed by C Brimeyer, X Zhou; revised version received 19.04.25; accepted 23.04.25; published 25.08.25.

Please cite as:
Zhou ZY, Hu LY, Wang ML, Li SQ, Zhou LS
Effects of Cold and Vibration on Venipuncture Pain Management in Children Aged 2-7 Years Old: Randomized Controlled Trial
JMIR Pediatr Parent 2025;8:e67918
URL: https://pediatrics.jmir.org/2025/1/e67918
doi:10.2196/67918

© Zi-yun Zhou, Long-yi Hu, Ming-li Wang, Si-qi Li, Le-shan Zhou. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 25.8.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Review

Extended Reality (XR) in Pediatric Acute and Chronic Pain: Systematic Review and Evidence Gap Map

Courtney W Hess[1], PhD; Brittany N Rosenbloom[2,3], PhD, CPsych; Giulia Mesaroli[4,5,6], MScPT; Cristal Lopez[7,8], PhD; Nhat Ngo[7,8], BA, BS; Estreya Cohen[9], BA; Carley Ouellette[10], RN, MSc; Jeffrey I Gold[7,8,11], PhD; Deirdre Logan[12,13], PhD; Laura E Simons[1], PhD; Jennifer N Stinson[6,14], RN-EC, PhD, CPNP

[1]Department of Anesthesiology, Perioperative, & Pain Medicine, Stanford University School of Medicine, Palo Alto, CA, United States

[2]Toronto Academic Pain Medicine Institute, Women's College Hospital, Toronto, ON, Canada

[3]Department of Anesthesia and Pain Medicine, University of Toronto, Toronto, ON, Canada

[4]Department of Rehabilitation Services, Hospital for Sick Children, Toronto, ON, Canada

[5]Department of Physical Therapy, University of Toronto, Toronto, ON, Canada

[6]Research Institute, Hospital for Sick Children, Toronto, ON, Canada

[7]The Saban Research Institute, Children's Hospital Los Angeles, Los Angeles, CA, United States

[8]Department of Anesthesiology Critical Care Medicine, Children's Hospital Los Angeles, Los Angeles, CA, United States

[9]Department of Psychology, York University, Toronto, ON, Canada

[10]School of Nursing, McMaster University, Hamilton, ON, Canada

[11]Department of Anesthesiology, Pediatrics, and Psychiatry and the Behavioral Sciences, Keck School of Medicine, University of Southern California, Los Angeles, CA, United States

[12]Department of Anesthesiology, Critical Care and Pain Medicine, Boston Children's Hospital, Boston, MA, United States

[13]Department of Anesthesiology, Critical Care and Pain Medicine, Harvard Medical School, Cambridge, MA, United States

[14]Lawrence S. Bloomberg Faculty of Nursing, University of Toronto, Toronto, ON, Canada

Corresponding Author:
Courtney W Hess, PhD
Department of Anesthesiology, Perioperative, & Pain Medicine
Stanford University School of Medicine
3145 Porter Drive
Palo Alto, CA, 94304
United States
Phone: 1 650 497 6896
Email: cwhess@stanford.edu

Abstract

Background: The use of extended reality (XR), including virtual reality (VR) and augmented reality (AR), for treating pain has accelerated in the last 10 years. XR is an attractive biobehavioral intervention that may support management of pain or pain-related disability. Reviews of the literature pertaining to adults report promising results, particularly for acute procedural pain.

Objective: This study aimed to (1) summarize the available evidence with respect to feasibility, safety, and effectiveness (pain intensity) of XR for pediatric acute and chronic pain; (2) summarize assessment tools used to measure study outcomes; and (3) identify gaps in evidence to guide future research efforts.

Methods: This study is a systematic review of the literature. Multiple databases (CINAHL, Cochrane Central, Embase, MEDLINE, PsycINFO) were searched from inception until March 2023. Titles, abstracts, and full-text articles were reviewed by 2 team members to determine eligibility. Articles were included if the (1) participants were aged 0 to 18 years; (2) study intervention was VR or AR; (3) study outcomes included safety, feasibility, acceptability, or effectiveness on the outcome of pain; and (4) study design was observational or interventional. Data were collected on bibliographic information; study characteristics; XR characteristics; outcome domains; outcome measures; and study findings pertaining to safety, feasibility, and effectiveness.

Results: We included 90 articles in the review. All included studies used VR, and 93% (84/90) studied VR in the context of acute pain. Of the 90 studies, 74 studies were randomized trials, and 15 studies were observational. Safety was assessed in 23 studies of acute pain, with 13 studies reporting no adverse events and 10 studies reporting events of low concern. Feasibility was

XSL•FO
RenderX

assessed in 27 studies. Of the 84 studies of acute pain, 62% (52/84) reported a positive effect on pain intensity, 21% (18/84) reported no effect, and 13% (11/84) reported mixed effects. All 6 studies of chronic pain reported a positive effect on pain intensity. An evidence gap map was used to illuminate gaps in specific research areas stratified by subtypes of pain. Risk of bias assessment revealed 67 studies had a moderate risk of bias, 17 studies had a high risk, and 5 studies were deemed to be low risk.

Conclusions: The current body of literature around XR for pediatric pain is focused on acute pain with promising results of safety and effectiveness on pain intensity. The literature pertaining to chronic pain lags behind, limiting our ability to draw conclusions. The risk of bias in studies is problematic in this field, with the inherent challenge of blinding participants and researchers to the intervention. Future research should aim to measure effectiveness beyond pain intensity with a consistent approach to measuring key outcome domains and measures. Current efforts are underway to establish expert consensus on best research practices in this field.

Trial Registration: Prospero CRD42022307153; https://www.crd.york.ac.uk/PROSPERO/view/CRD42022307153

(JMIR Pediatr Parent 2025;8:e63854) doi:10.2196/63854

KEYWORDS

virtual reality; augmented reality; extended reality; acute pain; chronic pain; pediatrics; adolescents; safety; feasibility; effectiveness; evidence gap map; child; children; VR; XR; biobehavioral; intervention; systematic review

Introduction

Acute and chronic pain are common among children [1-3] and can result in negative short and long-term health and mental health consequences. Within pediatric populations, acute pain can negatively impact treatment adherence such as vaccination schedules [4] and routine port access [5] and can worsen outcomes in the context of surgery and rehabilitation [6,7]. Additionally, acute pain can transition into chronic pain if not adequately assessed, managed, and treated [8]. If not addressed in childhood, these pain and other health-related problems often continue into adulthood and therein increase risk for functional disability and mental health challenges including depression, suicidality, and substance use, with particular concern for opioid use or misuse [9-12].

Technologies have been emerging to support the management of pain for both acute and chronic pain, including the integration of extended reality (XR) into clinical care. XR is most often inclusive of virtual reality (VR) and augmented reality (AR), which aim to immerse a person or patient in a simulated environment that they perceive to be real [13]. In the context of VR, youth are transported to a new or alternative environment, while AR alters or enhances the environment in which the youth is already existing [14].

The integration of XR into health care has been a rapidly growing area of clinical research and treatment, with promise surrounding the management of pain across a variety of acute and chronic conditions for youth and adults [15-17]. Much research has been conducted in the acute pain management context and specifically surrounding wound care, venipuncture ("needle pokes"), and minor procedures (eg, dental fluoride therapy, orthopedic pin removal). Among adults, XR has also been used commonly to manage chronic pain such as low back pain or fibromyalgia [18,19]. Together, results to date indicate that XR holds great promise for supporting biopsychosocial treatment for pain management for youth and adults; however, consistency in measurement as well as defined outcomes for assessing the effectiveness of XR research are missing, thereby limiting the ability to coordinate research efforts and examine effectiveness on a large scale.

One reason for the variability and the lack of consensus in technology and outcomes in XR research is related to the rapid adoption and evolution of technology (ie, hardware and software). Since the initial studies of XR for pain began in the 1980s, the rate at which XR is being evaluated and integrated into clinical care for pain management has sharply increased, with over 250 PubMed-indexed studies published since 2020 alone compared with the total 78 studies published in the 20 years preceding. Identifying a core outcome set for XR trials in pain is needed given the rapid adoption and evolution of this technology into clinical research and the potential for XR to provide breakthroughs in the treatment and management of acute and chronic pain. We undertook this task and, as a part of this effort, conducted a systematic review to summarize the current state of the literature with a specific aim toward understanding how researchers are currently assessing XR effectiveness.

Therefore, the purpose of this systematic review was to describe the feasibility, safety, and effectiveness of XR for pediatric acute and chronic pain. Moreover, this review collated current research to establish an evidence and gap map for guiding future research efforts. Finally, given the variability in XR study treatment outcomes, this review also assessed the measurement tools that have been used to measure outcomes in XR research. Together, these findings provide an updated description of the state of the field and highlight a path forward for improving the application, feasibility, and effectiveness of XR research in the context of pediatric acute and chronic pain.

Methods

Search Strategy

The systematic review protocol was registered on PROSPERO (#CRD42022307153). The literature search strategy was developed in consultation with a medical librarian who executed the searches. Examples of search terms (including MeSH terms) included "virtual reality," "pain," "treatment outcome," "safety," and "feasibility studies." A randomized controlled trial (RCT)

XSL•FO
RenderX

hedge or study-type filter was not applied as it was considered too limiting for the overall search. Major electronic databases (CINAHL, Cochrane Central, Embase, MEDLINE, PsycINFO) were searched from database inception to March 2023. The full search strategy is included in Multimedia Appendix 1.

Selection Criteria

The inclusion criteria for the current review included (1) participants aged 0 to 18 years; (2) study intervention of XR (VR or AR); (3) study outcomes of safety, feasibility, acceptability, or effectiveness on the outcome of pain; and (4) observational or interventional study design. For this review, XR was defined as "technology that blurs the lines between the physical and virtual worlds, creating a sense of immersion and enhancing the realism of virtual experiences" [20-22]. Additionally, the age criterion was not applied until screening to allow for a comprehensive search of the literature.

Studies were excluded from the review if they were reviews, opinion papers, case studies with ≤4 participants, or conference proceedings. Studies in which the participant sample was exclusively adults (>18 years old) were excluded as well as studies in which the intervention was not deemed to align with the definition of XR (eg, intervention delivered on a computer screen or flat board display panel) or where there was insufficient description of the hardware to determine whether the intervention met the definition of XR. Although no uniform definition nor criterion exists for defining XR as immersive or not immersive, through group discussion and guided by existing definitions [23], we excluded technology where the user only existed in the real world (eg, looking at a 2D image on a computer). If a reviewer was uncertain about whether the XR trial was immersive, additional review of the study and group discussion were used to determine whether the paper was included in the review. Papers that were not available in the English language were also excluded from the review.

Study Selection

Following completion of each of the systematic literature searches, 2 reviewers independently screened titles and abstracts for inclusion following established PICO (Population, Intervention, Comparison, Outcome) strategies. Disagreements between raters were resolved by a third reviewer. Following initial review of title and abstracts, a subsequent review of retained studies was completed, reviewing complete texts to evaluate for inclusion. Disagreements between raters were resolved by the same third reviewer. All screening was completed through Covidence [24], a web-based collaboration software platform that streamlines systematic review management and allows for blinded, independent review of included studies.

Assessment of Study Quality

Assessment Tools

For studies that assessed the effectiveness of the XR intervention, a study risk of bias assessment was conducted. For RCTs, the Cochrane Risk of Bias Tool (RoB-2) was used, and for nonrandomized studies, the Methodological Index for Non-Randomized Studies (MINORS) was used. The risk of bias assessment was completed by 2 separate groups with one group conducting risk of bias for the RCTs and the other group conducting risk of bias for the nonrandomized trials. Given the distinct tools used for each group, it was deemed appropriate to allow for 2 separate coding groups.

Risk of Bias in RCTs

To assess the RCTs, the 2 reviewers used and adhered to the RoB-2 protocol [25]. RoB-2 serves as an algorithmic framework for considering the risk of bias in the outcomes of RCTs [26]. The tool asks reviewers to rate the bias in RCT protocols among 5 domains: (1) randomization process, (2) deviations from intended interventions, (3) missing outcome data, (4) measurement of the outcome, and (5) selection. Reviewers evaluated the studies independently then met to discuss agreement on rating. If the raters disagreed on a rating, a third rater resolved the disagreement. Each domain was assigned an algorithm result and an assessor's judgement of Low, Some Concerns, or High. The overall bias followed the same 3 outcomes.

Risk of Bias in Nonrandomized Studies

To assess the nonrandomized studies (eg, observational, interventional without control), the reviewers used MINORS [27]. MINORS consists of 12 method-oriented items (eg, "A clearly stated aim") to assess quality and risk of bias in nonrandomized studies. Each item is rated on a scale from 0 to 2, with 0 indicating that the item was not reported, 1 indicating that the item was reported but inadequate, and 2 indicating the item was reported and adequate. MINORS can be used for studies with or without a comparator group, with the first 8 items applying to all studies and the final 4 items specific to comparative studies. Total scores for noncomparative studies range from 0 to 16, and total scores for comparative studies range from 0 to 24, with higher scores indicating more methodological integrity. For this review, 2 raters independently rated each of the nonrandomized studies then met to compare. Each of the 12 items as well as the total scores were compared between raters. Any disagreements were resolved through discussion and, if needed, through consultation with a third rater.

Data Extraction

A data extraction form was created and pilot tested to ensure relevant data were pulled based on the form directions. A team of research assistants was trained on the data extraction form, and each research assistant independently extracted data for their assigned studies. Data extracted included study characteristics (participants, design, setting, control group), intervention characteristics (hardware, software, intervention protocols), outcome domains (safety, feasibility, effectiveness), outcome measures used, and a summary of study findings.

Data Coding (Evidence Gap Map)

All included studies were uploaded to EPPI Reviewer, software designed for systematic reviews and in support of developing evidence and gap maps. Using existing literature, authors CWH and GM developed operational definitions for each of the pain populations and target outcomes, which were reviewed by the larger author group and iterated until a final draft was created

XSL•FO
RenderX

then used to guide coding of the studies. To code studies for the evidence and gap map, reviewers were assigned a series of studies in EPPI Reviewer and were asked to review the manuscript and code each article for the patient population (adult or pediatrics), pain population, and outcomes targeted by VR. Two training meetings were held with all reviewers to provide operational definitions, and they were asked to code a single article. A subsequent meeting was held to provide feedback and answer questions to increase consistency across coding. Once all articles were coded, any articles identified as unclear were reviewed again by a single author. Operational definitions are provided in Multimedia Appendix 2.

Data Synthesis

Included studies were summarized, and fulsome details of all included studies are provided in Multimedia Appendix 3. Additionally, descriptive statistics were used to synthesize study characteristics and aims as well as intervention characteristics. To synthesize data pertaining to outcome domains, an evidence and gap map was created. To create the evidence and gap map, 7 reviewers independently coded each study according to the study population including age (pediatric, adult) and pain type (acute pain-venipuncture, acute pain-wound care, acute pain-procedural, acute pain-other, chronic pain-cancer related, chronic pain-postsurgical/trauma, chronic pain-headache/migraine, chronic pain-musculoskeletal, chronic pain-neuropathic, chronic pain-other), as well as the pain-related outcomes targeted by the XR intervention (user experiences, participation/engagement, cognitive, behavioral, physical functioning, pain intensity, quality of life, health care utilization, safety, feasibility). Each study was also coded according to its established risk of bias (low, moderate, high). Coding was conducted through EPPI Reviewer [28], a collaborative web-based research synthesis software that supports study classification, and EPPI Mapper, a web-based program that generates evidence and gap maps based on coding conducted in EPPI Reviewer. Finally, for each of the identified pain treatment targets, the measures used to assess those targets were extracted by 2 authors and summarized to indicate the number of unique measures reported for each treatment target, and the number of studies that used the measure.

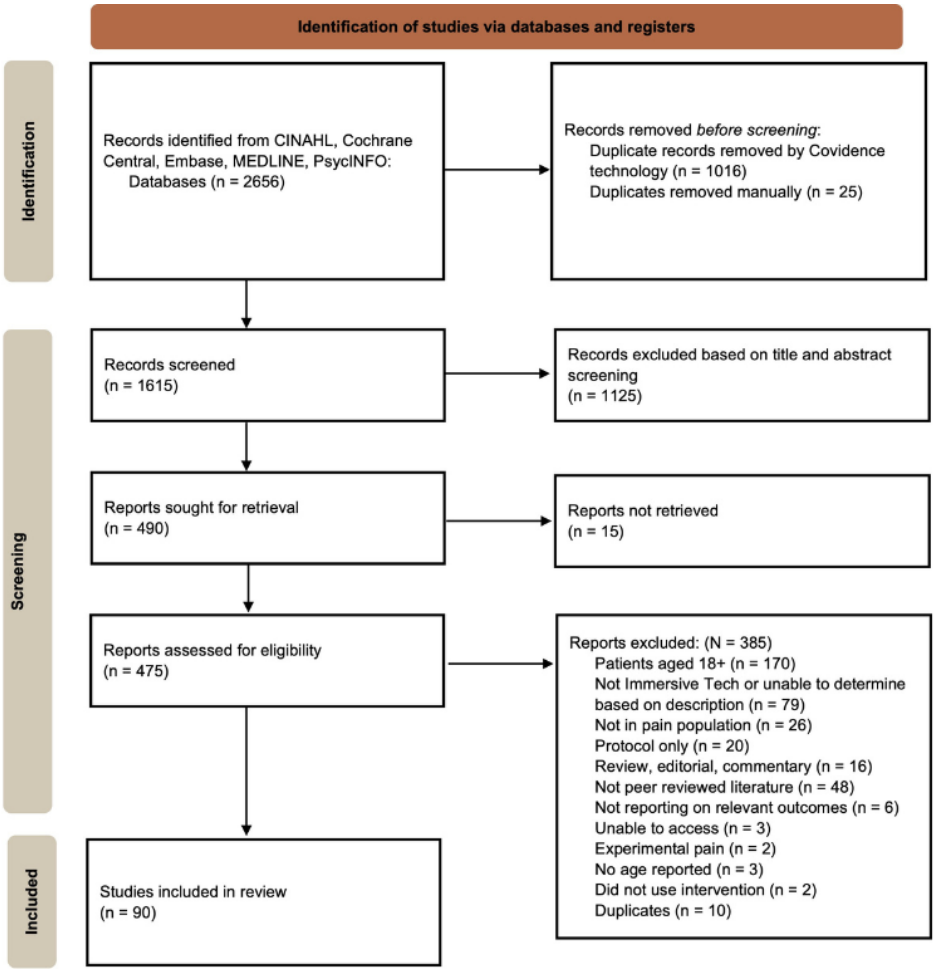
Results

Article Identification

The search identified 2656 articles across the 5 identified databases. Of the articles identified, 1041 duplicates were identified and removed prior to abstract and title screening. We screened 1615 articles for inclusion based on abstract and title, and 1125 were removed based on relevancy to the review. Of the remaining 490 studies, 15 could not be located, so 475 full-text articles were screened for inclusion. Of those, 90 studies were included in the review. The most common reason for exclusion was that the study sample was exclusively adult (170 studies) followed by determination that the XR technology was not immersive (79 studies). See Figure 1 for additional information related to the screening process.

XSL•FO
RenderX

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.

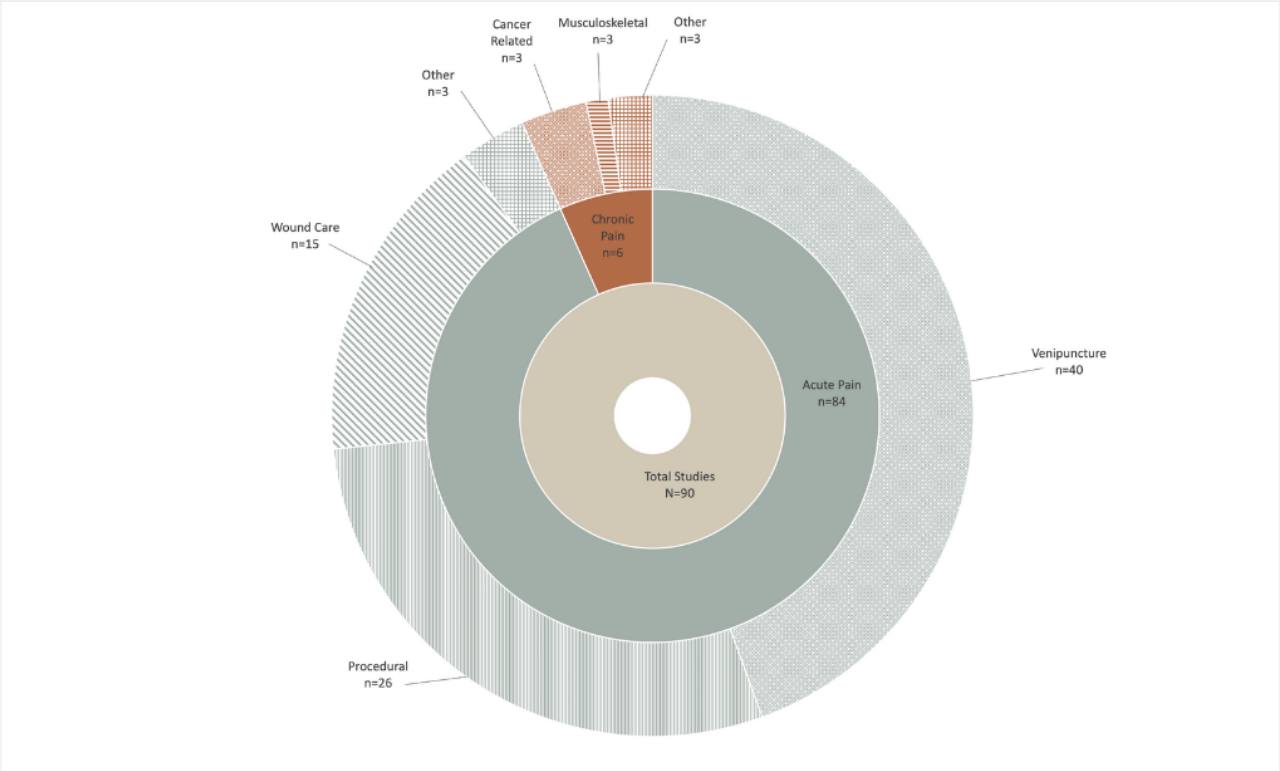


Study Characteristics

Of the included articles, all 90 studies used VR technology, and no studies reported the use of AR technology. As such, when discussing XR for pediatric pain management, currently this is exclusively VR technology. Additionally, the majority of studies focused on assessment of VR in pediatric acute pain (84/90, 93%), specifically venipuncture (40/90, 48%) [29-68], burn dressing and wound care (15/90, 18%) [69-83], and minor procedures (26/90, 31%) [31,84-108], as well as other acute pain (3/90, 3%; ie, acute pain in emergency department, acute upper limb rehabilitation, vaso-occlusive crisis) [109-111]. A much smaller number of studies (n=6) examined the utility of VR in chronic pain populations including intensive pain rehabilitation (n=1) [112], chronic burn dressing (n=1) [113], chronic musculoskeletal pain (n=1) [114], chronic cancer-related pain (n=2) [115,116], and chronic abdominal pain (n=1) [117]. See Figure 2 for the summary of pain populations included across the studies. Within the 90 included studies, there were a total of 6596 participants enrolled, including 3615 enrolled in intervention arms and 2981 enrolled in control arms. Study sample sizes ranged from 5 to 254. Across studies, 3631 participants were male, while 2929 were female. The age of the participants ranged from 3 years to 18 years. Among participants enrolled in the intervention group, the mean age was 11.07 (SD 2.64) years, and in the control groups, the mean age was 10.38 (SD 2.37) years. Most studies (84/90, 93%) evaluated the use of XR in the context of pediatric acute pain management, while 7% (6/90) of the studies focused on XR in the context of pediatric chronic pain. Most studies took place in a hospital setting (63/90, 70%), and interventions were most often delivered by a researcher (36/90, 40%) or nurse (19/90, 21%). Regarding intervention design, an RCT was used 82% (74/90) of the time. See Table 1 for a full description of the study characteristics.

XSL•FO
RenderX

Figure 2. Pain types across all included studies.



XSL•FO
RenderX

Table 1. Study characteristics (n=90).

Characteristic	Studies, n (%)
Acute pain (n=84)	
Venipuncture	40 (45)
Procedural	26 (32)
Wound care	15 (18)
Other	3 (5)
Chronic pain (n=6)	
Cancer related	2 (33)
Musculoskeletal pain	1 (17)
Other	3 (50)
Study design	
Interventional RCT[a]	74 (82)
Interventional no control	13 (14)
Case series	1 (1)
Prospective observational	2 (2)
Study setting	
Hospital/burn center	69 (77)
Research	2 (2)
Dental	9 (10)
Home	1 (1)
Clinical	9 (10)
Sample size (n= 6596)	
VR[b] intervention	3615 (55)
Control	2981 (43)
Intervention delivered by	
Registered nurse	19 (21)
Physical therapist	2 (2)
Dentist	1 (1)
Other clinician	2 (2)
Researcher	36 (40)
Caregiver	1 (1)
Unknown	29 (32)

[a]RCT: randomized controlled trial.

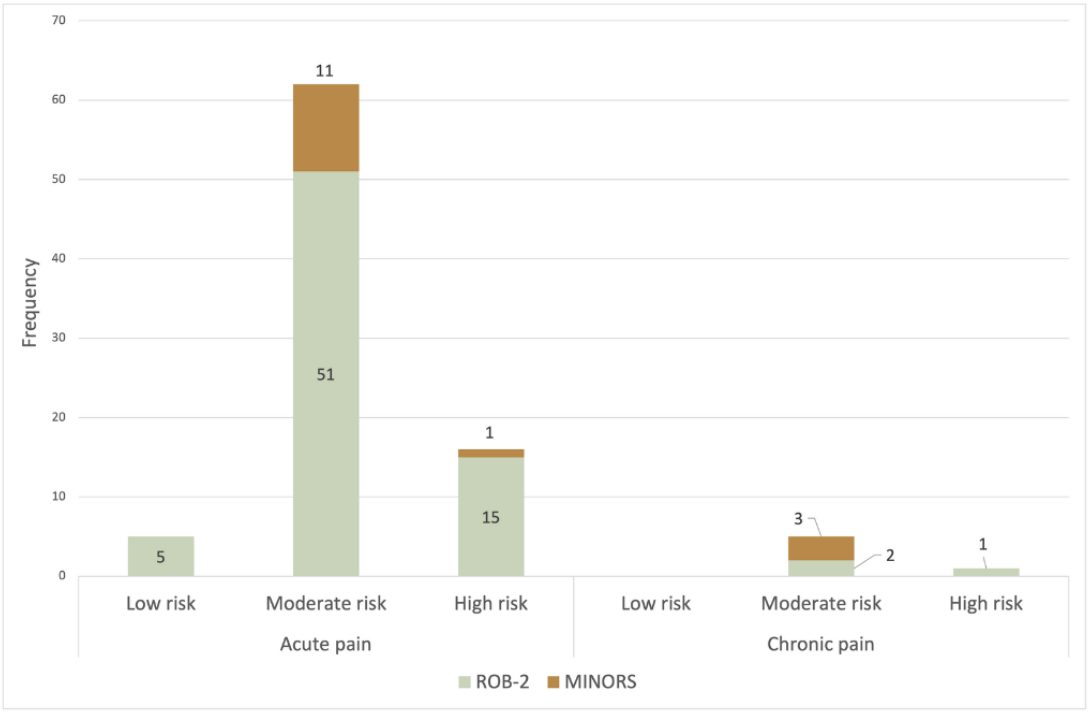
[b]VR: virtual reality.

Study Quality Assessment

Where possible, studies were examined for risk of bias based on study design. Of the 90 studies, 74 studies were evaluated using the RoB-2 assessment for randomized trials and 15 studies were evaluated using the MINORS assessment for nonrandomized interventional and observational studies. We could not assess 1 study due to the study design (ie, case series: Birnie et al [34]). Results of the risk of bias assessment revealed that most included studies (67/90, 74%) had a moderate risk of bias, while 17 studies (17/90, 19%) had a high risk of bias, and 5 studies (5/90, 6%) were deemed to have a low risk of bias. To see the summary of risk of bias ratings for each study, please see Figure 3. Although sources indicating risk of bias were variable across studies, most included studies were identified as moderate or high risk of bias due to their failure to blind study participants to the intervention and researchers to who was in the intervention arm (69 studies). Increased risk of bias was also commonly identified in the randomization procedures, although to a much lesser degree (19 studies).

XSL•FO
RenderX

Figure 3. Risk of bias for included studies (N=89). MINORS: Methodological Index for Non-Randomized Studies; RoB-2: Cochrane Risk of Bias Tool.



XR Feasibility

Across all included studies, feasibility was evaluated 43% (39/90) of the time. Within chronic pain studies, 50% (3/6) of the studies assessed the feasibility of VR. Although limited in scope, of the 3 studies that examined feasibility, results did indicate VR to be a positive experience that supported their management of pain. Within the acute pain studies (n=84), feasibility was assessed in 35 studies. When evaluated, feasibility of VR appears to be high according to patients, caregivers, and health care staff. Feasibility was assessed in several different ways including but not limited to recruitment and withdrawal rates, satisfaction surveys, patient-reported "fun," and provider-reported disruption in clinical flow. Recruitment rates varied but indicated moderate (40/65, 62%) to high (66/71, 93%) levels of interest in VR use, and dropout rates were reported to be low. Health care professionals also indicated good feasibility. VR was perceived to not interfere with procedure time, decrease the perceived difficulty of procedures, and be easily implementable in the clinic setting, and health care staff expressed interest in repeated use. Patients and caregivers reported ease of use, high levels of satisfaction with VR, preference for VR over alternate distraction methods, and interest in repeated use in future procedures. As such, although more consistent assessment of VR feasibility is needed, the available data from the pediatric acute pain management setting suggest that VR is acceptable and feasible across stakeholders.

XR Safety

Across included studies, safety, often measured through the presence of adverse events, was measured or reported 49% (44/90) of the time. Within the chronic pain studies, only 2 studies examined the safety of the VR intervention, so conclusions regarding the safety of VR for chronic pain populations cannot be made. Among the pediatric acute pain studies, 44 studies examined safety, limiting our ability to draw robust conclusions for safety. However, when safety or adverse events were reported, most studies (31/44, 70%) reported no adverse events or no differences between their control and VR intervention groups. When adverse events were reported, they were most often mild in nature and occurred in a minority of the participants. Rates of adverse events varied, occurring in <1% to 17% of participants, with intensity and severity of the concern low (eg, nausea rating of 4/100). Two studies reported that at least 1 participant withdrew from the intervention due to reported adverse events.

XR Effectiveness

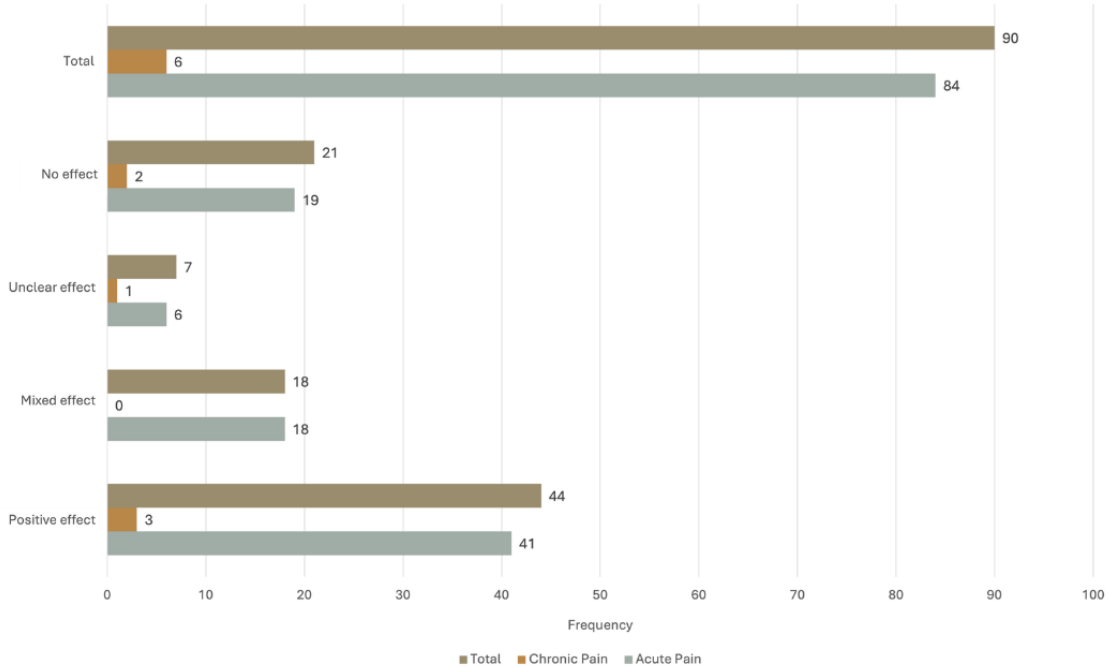
Several treatment targets emerged through the review as relevant to the effectiveness of VR for pain management. That is, targets of VR interventions for acute and chronic pain often went beyond pain intensity itself, as measures of effectiveness spanned several domains (eg, pain intensity, physical functioning, fear, anxiety). Given the wide variety of targeted outcomes, we summarized the findings across the identified target domains for acute and chronic pain. The variability in targets highlights several areas where additional research is needed to adequately examine the effectiveness of VR for pediatric pain.

Pain intensity was examined across all included studies (n=90), and overall, VR interventions demonstrated good effectiveness for reducing pain intensity (see Figure 4). Among the acute pain studies, 63% (53/84) demonstrated a positive effect (statistically significant reduction in pain) of VR on pain intensity, 21% (18/84) demonstrated no effect (nonsignificant reduction in pain or no change in pain), and 12% (10/84) demonstrated a mixed effect (different results across pain measures, pain reporter, or

XSL•FO
RenderX

at different time points in the intervention) on pain intensity. Mixed effect findings were often due to a variable impact of VR on pain across a procedure (eg, positive impact on postprocedural pain but no effect on pain during the procedure) or variable impact of VR on pain across informants (eg, child reported improved pain, no improvement in pain reported by health care provider). No studies reported worse pain than the control or following the VR intervention. Among the chronic pain studies, 100% (6/6) of the studies demonstrated improved pain intensity in the context of the VR intervention.

Figure 4. Effects of virtual reality on pain across pediatric acute and chronic pain.

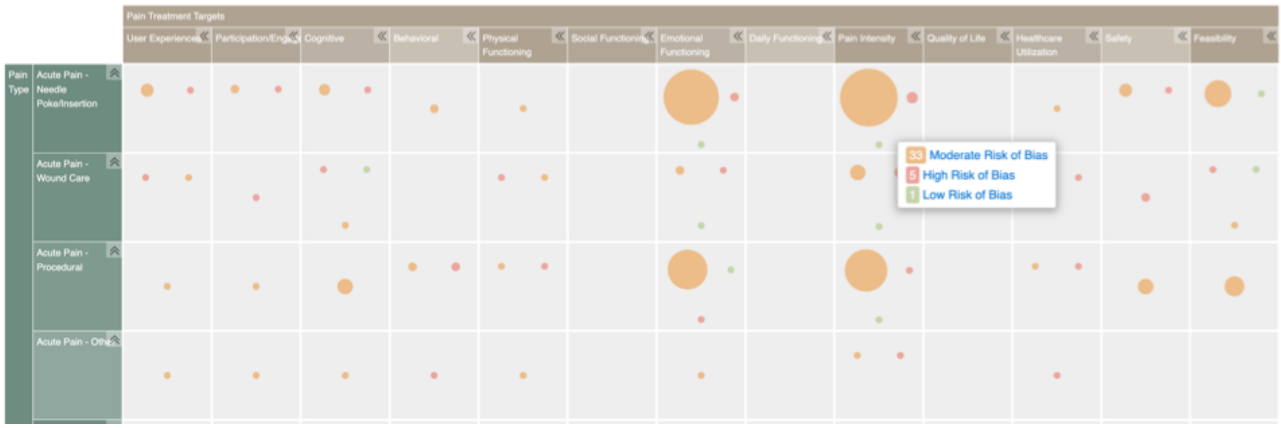


Evidence and Gap Map

There was a wide range of outcome targets across studies. We created an evidence and gap map to collate current targets of VR in pain management as well as illuminate gaps (Figure 5). Guided by the conceptual model described by Trost et al [118], we categorized studies according to their target population as well as measured outcome targets. Additionally, the risk of bias results were integrated into the evidence and gap map. Therefore, the map illustrates, across the 90 included studies, the populations and pain targets with greater amounts of research evidence and those with missing or scant research evidence as well as the quality of evidence at various intersections (eg, pediatric venipuncture research targeting anxiety and pain intensity). Specifically, for XR research, the gap map illuminated significant gaps in research using XR to support pain management in pediatric chronic pain populations. Within the chronic pain populations, no research exists related to postsurgical or trauma-related pain, headaches, or neuropathic pain. Additionally, the risk of bias across all studies was moderate to high, prompting the need for more sophisticated research designs to reduce the risk of bias, particularly as it relates to blinding the research team and study participants. Within the acute pain setting, the most studied patient populations were children undergoing venipunctures and minor procedures. Primary targets of XR intervention for acute pain include pain intensity and emotional functioning. Across acute and chronic pain, measuring the effectiveness of XR on other important outcomes such as user experience, social functioning, and quality of life are important gaps that emerged from this review.

XSL•FO
RenderX

Figure 5. Snapshot of the evidence and gap map for virtual reality trials in pediatric acute and chronic pain [118]. The interactive evidence and gap map can be found in [119].



Measures in XR Research

Across all study outcomes (feasibility, safety, effectiveness targets), there was tremendous variability in the outcome measures used. As such, we identified the number of distinct measures and the frequency of measures used across each outcome, which are summarized in Table 2. Full details of the measures used within each outcome domain can be found in Multimedia Appendix 4. Measures in XR research include validated, study-specific, researcher-developed and researcher-adapted tools. Additionally, similar measures are often used in distinct ways to measure different outcomes. For example, some researchers used heart rate as a measure of physical functioning, while others used heart rate as a measure of anxiety. The outcome target with the highest number of measures was psychological constructs, which contained 31 distinct measures across 67 studies. This is unsurprising as psychological construct is a broad outcome inclusive of multiple psychological and emotional states including but not limited to anxiety, mood, fear of pain, and pain catastrophizing. The outcome target with the second highest number of measures was feasibility, which contained 14 distinct measures across 28 studies, followed by user experience, which contained 13 distinct measures across 18 studies. The number of measures used across studies for each outcome domain is summarized in Table 2. This review highlighted that there is little agreement regarding how best to measure outcomes in XR research, an important area for future study, particularly given the high number of researcher-developed or researcher-adapted measures currently being used.

Table 2. The number of measures used within each outcome domain across pediatric acute and chronic pain studies.

Outcome domain	Measures, n
Pain intensity	21
Adverse events	8
User experience	13
Psychological constructs	31
Pain interference	8
Feasibility	14
Health care utilization	9
Quality of life	2
Physiological markers	10

Discussion

Principal Findings

Overall, in the context of pediatric acute pain, specifically venipuncture and minor procedural pain, good evidence exists to support continued use of XR, as it is effective for the management of pain and emotional functioning and demonstrates good feasibility and safety. Limited evidence exists, however, to guide the use of XR research in chronic pain populations. Although initial evidence does appear promising for the utility of XR to support pain management in several chronic pain populations (eg, cancer-related pain, abdominal pain, diffuse musculoskeletal pain), more robust examination is needed as is research that assesses the safety and feasibility of implementing XR into the flow of clinical care. Another area requiring more research in pediatric populations is the subacute period (ie, up to 3 months after injury, trauma, or surgery). Research has demonstrated this period to be a vulnerable time for the development of fear avoidance related to pain and movement, which increases the risk for the transition of acute pain to chronic pain [8]. XR interventions would likely be useful during this period as both a form of distraction and to support confrontation of feared movements.

XSL•FO
RenderX

This review indicates that most studies to date have been implemented within the context of a children's hospital, which is unsurprising given the preponderance of research focused on acute pain management. However, there is limited research to guide the implementation of XR research outside the context of a hospital setting, which may be particularly important for chronic pain patients who may be receiving care across a variety of treatment settings (eg, home, outpatient clinic, physical therapy clinic). In the adult literature, XR has been successfully implemented into community care for chronic pain management [120,121]; however, this is unstudied in pediatric populations. The use of implementation science frameworks (eg, Consolidated Framework for Implementation Research) [122] to evaluate contextual and personnel differences as they relate to technology integration in settings outside of a hospital can support these efforts.

This review also demonstrated that research to date has been exclusively on the use of VR in pediatric pain management, and, as such, little is known about the potential for AR to support acute and chronic pain. Exploration of the utility of AR is particularly relevant in the context of chronic pain where exposure to painful movements may benefit from gradation such that a young person is first fully distracted by immersion into a VR world then gradually progressed toward exposure of their environment using an AR system to continue to support distraction while increasing exposure to their lived environment [123-125].

Another finding of this review is the significant variability in the way outcomes are being measured across XR studies. That is, measurement remains an area for needed consensus to support a better ability to compare effectiveness of XR across studies. Moreover, efforts are needed and indeed underway to better define both process (eg, immersion) [23] and outcome (eg, pain intensity) variables in XR trials, which will facilitate better reporting and thus improved ability to effectively compare XR across studies. Moreover, definitions of emotional functioning were also quite varied across studies, even when similar constructs were being targeted (ie, anxiety, fear, mood). Different definitions of anxiety and fear emerged across studies as well as how they were operationalized and assessed. For example, some studies assessed anxiety vis-à-vis heart rate variability and oxygen saturation, while other studies completed self-report assessments, proxy reports, and behavioral observations. Although all approaches to assessing anxiety may be valid, it limits the comparability of anxiety as an outcome across studies. Additionally, mood was examined to a much lesser degree in the reviewed studies and warrants increased attention, particularly in the context of chronic pain or acute-to-chronic pain transition. Another challenge with comparing XR effectiveness across studies is inconsistent reporting of study protocols. In this review, several studies were excluded because of an insufficient description of the XR technology. Creation of standards for reporting for XR studies, including how to describe the technology used (eg, hardware and software) and intervention protocol (eg, number of sessions, duration of intervention), is needed to increase the ability to replicate studies and compare outcomes across studies, thereby improving our ability to understand which XR approaches are most effective, when they are most effective, and for whom they are most effective.

There are also potential outcomes or targets of XR research that warrant attention, namely social and academic functioning alongside quality of life. Given the growing feasibility of real-time social interactions in the context of XR alongside established challenges for youth with pain to engage socially with peers [126], examination of the potential for XR research to improve or support social functioning is an important area for future work. Building from existing literature that has demonstrated the effectiveness of virtual peer-to-peer pain groups [127-130], development of virtual pain groups that can target multiple domains of functioning (eg, physical functioning, social functioning) is an untapped and potentially high-yield target for XR research. Similarly, academic functioning is commonly cited as a challenge for youth with chronic pain [131,132], and although research is emerging in this domain [133], more is needed to evaluate the potential for XR research to support academic engagement and facilitate a return to school learning for youth with pain. Finally, quality of life was minimally examined in the included studies (n=2). This is likely due to the overwhelming number of studies focused on acute pain where quality of life measures may be less relevant; however, development of quality of care measures or consideration for implementation of quality of care measures that are relevant to the acute pain context may be important to truly capture the impact of XR on patients. Moreover, as additional research is conducted in the chronic pain population, where pain and anxiety may become less of an emphasis, quality of life measures will be important markers of improvement.

Finally, decreasing the risk of bias in XR studies also emerged as an important priority for future research. That is, most studies had a moderate to high risk of bias according to the RoB-2 assessment, prompting the need for more sophisticated research designs. Specific areas where innovation is needed are addressing participant blinding to the intervention and the development of prespecified analysis plans. Given the nature of XR interventions, innovation for blinding participants to their assigned group, such as the development and use of sham XR software, is needed to decrease the risk of bias. Prepublished analysis plans and transparency surrounding blinding of the analyses are also needed.

Limitations

This systematic review has some limitations that are important to note. First, the search for this systematic review was completed in March 2023 and likely omits several manuscripts published since then. Given the rapidity of XR research in pediatrics, it was not feasible for this research group to keep pace with the rate of publication. Moreover, this review was conducted with the aim of supporting the consensus conference surrounding outcomes for pediatric XR research. Future updates to this review are needed to support ongoing identification of gaps in research and inform clinical practice. Additionally, although a strength of this review is the breadth of studies included, future research could be conducted to allow for more focused assessment of efficacy, particularly as it relates to specific patient populations and XR configurations. To this end,

XSL•FO
RenderX

future research should consider the interaction of XR interventions and child development to assess whether developmental stage or chronological age impact XR feasibility, safety, or effectiveness and guide precision medicine to match the XR intervention or configuration to best meet the needs of youth across diverse developmental stages. This review assessed the risk of bias for all included studies; however, this is not synonymous with quality and should be interpreted with caution. That is, studies may have been of high quality yet received high risk of bias scores due to their lack of blinding, a common challenge faced by XR researchers. Finally, studies were limited to the English language and excluded gray literature and conference papers, which may limit the inclusion of important research published in languages other than English and could reinforce publication bias such that studies in which XR was unhelpful or not feasible are not well represented.

Conclusion

This systematic review provides an important update regarding the state of XR research for pediatric acute and chronic pain. Review of XR feasibility, safety, and effectiveness solidified the significant potential of XR for pain management across a variety of pain presentations and for a range of diverse outcomes. Moreover, the developed evidence and gap map illuminated important gaps in the current research base that warrant attention. Finally, limitations identified in the research studies reviewed also highlight the need for innovative research designs, establishment of measurement consensus, and improved reporting standards for XR studies to more effectively establish best practices in XR intervention research and improve clinical translation of the evidence base.

Acknowledgments

The authors thank medical librarian Jessie Cunningham at The Hospital for Sick Children for their assistance with development and execution of the literature search strategy. The authors would also like to thank all the research coordinators and research assistants in the Biobehavioral Pediatric Pain Lab (principal investigator [PI]: LES), Nicole Jehl, Ellison Choate, Amanda VanOrden, Hannah Nguyen, and Yerin Yang for your support in extracting data and formatting Table 1. Thank you also to the research coordinator and summer students in the Improving Outcomes in Child Health (iOUCH) lab (PI: JNS), Prabdeep Panesar, Ariane Isaac-Bertrand, and Sandy Luu, for your support in extracting data.

The authors recognize the funding from Canadian Institutes of Health Research (CIHR) for the planning and dissemination grant (Co-PIs: JNS and Fahad Alam) and MayDay fund (PI: DL). Additionally, BNR conducted this work during her postdoctoral fellowship at The Hospital for Sick Children and was funded by a CIHR Banting Fellowship. Across the duration of this study, authors CWH and LES were funded by the National Institutes of Health under NIAMS R21 grant AR079140. Author GM is funded by a CIHR Canada Graduate Scholarship (Doctoral) and SickKids Clinician Scientist Training Program (CSTP) scholarship.

Authors declare that there was no use of GenAI in the production of the described research, analysis or interpretation of data, or in the writing of the submitted manuscript.

Data Availability

All data from the systematic review are available upon request from primary or senior authors.

Authors' Contributions

JNS, LES, DL, and JIG were involved in the conceptualization of the study, funding acquisition, and supervision as well as data analysis and review and editing of the drafted manuscript. CWH, BNR, and GM were involved in the conceptualization of the study, data curation, formal analysis, data visualization, and writing of the manuscript. CO was involved in the data curation and offered her expertise as a person with lived experience. EC was responsible for project administration and data visualization. All authors made substantial contributions to the study and provided approval of the submitted manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Librarian search strategy.
[DOCX File , 28 KB - pediatrics_v8i1e63854_app1.docx]

Multimedia Appendix 2
Operational definitions of pain populations and outcome targets to guide evidence and gap map coding.
[DOCX File , 21 KB - pediatrics_v8i1e63854_app2.docx]

Multimedia Appendix 3

XSL•FO
RenderX

Fulsome details of 90 included VR intervention studies for pediatric acute and chronic pain.
[XLSX File (Microsoft Excel File), 46 KB - pediatrics_v8i1e63854_app3.xlsx]

Multimedia Appendix 4
Measures used across outcome domains in VR trials for pediatric acute and chronic pain.
[XLSX File (Microsoft Excel File), 14 KB - pediatrics_v8i1e63854_app4.xlsx]

Multimedia Appendix 5
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOCX File , 32 KB - pediatrics_v8i1e63854_app5.docx]

References

1. Crombie IK, Croft PR, Linton SJ, LeResche L, Van Korff M. Epidemiology of Pain: A Report of the Task Force on Epidemiology of the International Association for the Study of Pain. Washington, D.C: IASP Press; 1999.
2. Holley AL, Wilson AC, Palermo TM. Predictors of the transition from acute to persistent musculoskeletal pain in children and adolescents: a prospective study. Pain 2017 May 22;158(5):794-801 [FREE Full text] [doi: 10.1097/j.pain.0000000000000817] [Medline: 28151835]
3. King S, Chambers CT, Huguet A, MacNevin RC, McGrath PJ, Parker L, et al. The epidemiology of chronic pain in children and adolescents revisited: a systematic review. Pain 2011 Dec;152(12):2729-2738. [doi: 10.1016/j.pain.2011.07.016] [Medline: 22078064]
4. Taddio A, McMurtry CM, Logeman C, Gudzak V, de Boer A, Constantin K, et al. Prevalence of pain and fear as barriers to vaccination in children - Systematic review and meta-analysis. Vaccine 2022 Dec 12;40(52):7526-7537 [FREE Full text] [doi: 10.1016/j.vaccine.2022.10.026] [Medline: 36283899]
5. Hedström M, Haglund K, Skolin I, von Essen L. Distressing events for children and adolescents with cancer: child, parent, and nurse perceptions. J Pediatr Oncol Nurs 2003;20(3):120-132 [FREE Full text] [doi: 10.1053/jpon.2003.76] [Medline: 12776260]
6. Rosenbloom BN, Katz J. Modeling the transition from acute to chronic postsurgical pain in youth: a narrative review of epidemiologic, perioperative, and psychosocial factors. Can J Pain 2022 Jun 09;6(2):166-174 [FREE Full text] [doi: 10.1080/24740527.2022.2059754] [Medline: 35711297]
7. Rosenbloom BN, Pagé MG, Isaac L, Campbell F, Stinson JN, Wright JG, et al. Pediatric chronic postsurgical pain and functional disability: a prospective study of risk factors up to one year after major surgery. JPR 2019 Nov;Volume 12:3079-3098. [doi: 10.2147/jpr.s210594]
8. Rabbitts JA, Fisher E, Rosenbloom BN, Palermo TM. Prevalence and predictors of chronic postsurgical pain in children: a systematic review and meta-analysis. J Pain 2017 Jun;18(6):605-614 [FREE Full text] [doi: 10.1016/j.jpain.2017.03.007] [Medline: 28363861]
9. Groenewald CB, Law EF, Fisher E, Beals-Erickson SE, Palermo TM. Associations between adolescent chronic pain and prescription opioid misuse in adulthood. J Pain 2019 Jan;20(1):28-37 [FREE Full text] [doi: 10.1016/j.jpain.2018.07.007] [Medline: 30098405]
10. Murray CB, Groenewald CB, de la Vega R, Palermo TM. Long-term impact of adolescent chronic pain on young adult educational, vocational, and social outcomes. Pain 2020 Feb 21;161(2):439-445 [FREE Full text] [doi: 10.1097/j.pain.0000000000001732] [Medline: 31651579]
11. Walker LS, Dengler-Crish CM, Rippel S, Bruehl S. Functional abdominal pain in childhood and adolescence increases risk for chronic pain in adulthood. Pain 2010 Sep;150(3):568-572 [FREE Full text] [doi: 10.1016/j.pain.2010.06.018] [Medline: 20615615]
12. Zernikow B, Ruhe AK, Stahlschmidt L, Schmidt P, Staratzke T, Frosch M, et al. Clinical and economic long-term treatment outcome of children and adolescents with disabling chronic pain. Pain Med 2018 Jan 01;19(1):16-28. [doi: 10.1093/pm/pnx067] [Medline: 28486647]
13. Kardong-Edgren S, Farra S, Alinier G, Young H. A call to unify definitions of virtual reality. Clinical Simulation in Nursing 2019 Jun;31:28-34 [FREE Full text] [doi: 10.1016/j.ecns.2019.02.006]
14. Milman NB. Defining and conceptualizing mixed reality, augmented reality, and virtual reality. Distance Learning; Charlotte 2018;15(2):55-58 [FREE Full text] [doi: 10.4324/9781315099866-8]
15. Mallari B, Spaeth EK, Goh H, Boyd BS. Virtual reality as an analgesic for acute and chronic pain in adults: a systematic review and meta-analysis. J Pain Res 2019;12:2053-2085 [FREE Full text] [doi: 10.2147/JPR.S200498] [Medline: 31308733]
16. Shahrbanian S, Ma X, Aghaei N, Korner-Bitensky K, Simmonds J. Use of virtual reality (immersive vs. non immersive) for pain management in children and adults: a systematic review of evidence from randomized controlled trials. European Journal of Experimental Biology 2012;2(5):1408-1422 [FREE Full text]

XSL•FO
RenderX

17. Smith V, Warty RR, Sursas JA, Payne O, Nair A, Krishnan S, et al. The effectiveness of virtual reality in managing acute pain and anxiety for medical inpatients: systematic review. J Med Internet Res 2020 Nov 02;22(11):e17980 [FREE Full text] [doi: 10.2196/17980] [Medline: 33136055]
18. Brea-Gómez B, Torres-Sánchez I, Ortiz-Rubio A, Calvache-Mateo A, Cabrera-Martos I, López-López L, et al. Virtual reality in the treatment of adults with chronic low back pain: a systematic review and meta-analysis of randomized clinical trials. Int J Environ Res Public Health 2021 Nov 11;18(22):1 [FREE Full text] [doi: 10.3390/ijerph182211806] [Medline: 34831562]
19. Cortés-Pérez I, Zagalaz-Anula N, Ibancos-Losada MDR, Nieto-Escámez FA, Obrero-Gaitán E, Osuna-Pérez MC. Virtual reality-based therapy reduces the disabling impact of fibromyalgia syndrome in women: systematic review with meta-analysis of randomized controlled trials. J Pers Med 2021 Nov 09;11(11):1167 [FREE Full text] [doi: 10.3390/jpm11111167] [Medline: 34834518]
20. Lee H, Chung S, Lee W. Presence in virtual golf simulators: the effects of presence on perceived enjoyment, perceived value, and behavioral intention. New Media & Society 2012 Nov 26;15(6):930-946. [doi: 10.1177/1461444812464033]
21. Soliman M, Peetz J, Davydenko M. The impact of immersive technology on nature relatedness and pro-environmental behavior. Journal of Media Psychology 2017 Jan;29(1):8-17. [doi: 10.1027/1864-1105/A000213]
22. Suh A, Prophet J. The state of immersive technology research: a literature analysis. Computers in Human Behavior 2018 Sep;86:77-90 [FREE Full text] [doi: 10.1016/j.chb.2018.04.019]
23. Slater M. A note on presence terminology. Presence Connect 2003:1-5 [FREE Full text]
24. Covidence. URL: https://www.covidence.org [accessed 2025-03-12]
25. Higgins JPT, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, Cochrane Bias Methods Group, Cochrane Statistical Methods Group. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ 2011 Oct 18;343(oct18 2):d5928-d5928 [FREE Full text] [doi: 10.1136/bmj.d5928] [Medline: 22008217]
26. Higgins JPT, Savović J, Page MJ, Elbers RG, Sterne JAC. Assessing risk of bias in a randomized trial. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al, editors. Cochrane Handbook for Systematic Reviews of Interventions, Second Edition. London, England: Cochrane; 2019.
27. Slim K, Nini E, Forestier D, Kwiatkowski F, Panis Y, Chipponi J. Methodological index for non-randomized studies (minors): development and validation of a new instrument. ANZ J Surg 2003 Sep;73(9):712-716 [FREE Full text] [doi: 10.1046/j.1445-2197.2003.02748.x] [Medline: 12956787]
28. EPPI-Reviewer 4: software for research synthesis. EPPI Reviewer. URL: https://eppi.ioe.ac.uk/cms/er4/Features/tabid/3396/Default.aspx [accessed 2025-03-12]
29. Alonzi S, Caruso TJ, Sindher SB, Cao S, Varadharajulu S, Collins WJ, et al. Virtual reality reduces pediatric anxiety during food allergy clinical trials: a pilot randomized, pragmatic study. Front Allergy 2021 Jan 13;2:779804 [FREE Full text] [doi: 10.3389/falgy.2021.779804] [Medline: 35387040]
30. Althumairi A, Sahwan M, Alsaleh S, Alabduljobar Z, Aljabri D. Virtual reality: Is it helping children cope with fear and pain during vaccination? JMDH 2021 Sep;Volume 14:2625-2632. [doi: 10.2147/jmdh.s327349]
31. Atzori B, Lauro Grotto R, Giugni A, Calabrò M, Alhalabi W, Hoffman HG. Virtual reality analgesia for pediatric dental patients. Front Psychol 2018 Nov 23;9:2265 [FREE Full text] [doi: 10.3389/fpsyg.2018.02265] [Medline: 30532720]
32. Atzori B, Vagnoli L, Graziani D, Hoffman HG, Sampaio M, Alhalabi W, et al. An exploratory study on the effectiveness of virtual reality analgesia for children and adolescents with kidney diseases undergoing venipuncture. Int J Environ Res Public Health 2022 Feb 17;19(4):2291 [FREE Full text] [doi: 10.3390/ijerph19042291] [Medline: 35206481]
33. Aydın A, Özyazıcıoğlu N. Using a virtual reality headset to decrease pain felt during a venipuncture procedure in children. J Perianesth Nurs 2019 Dec;34(6):1215-1221. [doi: 10.1016/j.jopan.2019.05.134] [Medline: 31495558]
34. Birnie KA, Kulandaivelu Y, Jibb L, Hroch P, Positano K, Robertson S, et al. Usability testing of an interactive virtual reality distraction intervention to reduce procedural pain in children and adolescents with cancer. J Pediatr Oncol Nurs 2018;35(6):406-416. [doi: 10.1177/1043454218782138] [Medline: 29950139]
35. Canares T, Parrish C, Santos C, Badawi A, Stewart A, Kleinman K, et al. Pediatric coping during venipuncture with virtual reality: pilot randomized controlled trial. JMIR Pediatr Parent 2021 Jul 28;4(3):e26040 [FREE Full text] [doi: 10.2196/26040] [Medline: 34319249]
36. Caruso TJ, George A, Menendez M, De Souza E, Khoury M, Kist MN, et al. Virtual reality during pediatric vascular access: a pragmatic, prospective randomized, controlled trial. Paediatr Anaesth 2020 Feb 19;30(2):116-123. [doi: 10.1111/pan.13778] [Medline: 31785015]
37. Chad R, Emaan S, Jillian O. Effect of virtual reality headset for pediatric fear and pain distraction during immunization. Pain Manag 2018 May;8(3):175-179. [doi: 10.2217/pmt-2017-0040] [Medline: 29722606]
38. Chan E, Hovenden M, Ramage E, Ling N, Pham JH, Rahim A, et al. Virtual reality for pediatric needle procedural pain: two randomized clinical trials. J Pediatr 2019 Jun;209:160-167.e4. [doi: 10.1016/j.jpeds.2019.02.034] [Medline: 31047650]
39. Chang ZY, Kang GC, Koh EYL, Fong RJK, Tang J, Goh CK, et al. Immersive virtual reality in alleviating pain and anxiety in children during immunization in primary care: a pilot randomized controlled trial. Front Pediatr 2022 Mar 25;10:847257 [FREE Full text] [doi: 10.3389/fped.2022.847257] [Medline: 35402359]

XSL•FO
RenderX

40. Chau B, Chi B, Wilson T. Decreasing pediatric pain and agitation during botulinum toxin injections for spasticity with virtual reality: lessons learned from clinical use. PRM 2018 Sep 26;11(3):199-204. [doi: 10.3233/prm-180534]
41. Chen Y, Cheng S, Lee P, Lai C, Hou I, Chen C. Distraction using virtual reality for children during intravenous injections in an emergency department: a randomised trial. J Clin Nurs 2020 Feb 04;29(3-4):503-510. [doi: 10.1111/jocn.15088] [Medline: 31715039]
42. Dumoulin S, Bouchard S, Ellis J, Lavoie KL, Vézina MP, Charbonneau P, et al. A randomized controlled trial on the use of virtual reality for needle-related procedures in children and adolescents in the emergency department. Games Health J 2019 Aug;8(4):285-293. [doi: 10.1089/g4h.2018.0111] [Medline: 31135178]
43. Erdogan B, Aytekin Ozdemir A. The effect of three different methods on venipuncture pain and anxiety in children: distraction cards, virtual reality, and Buzzy® (randomized controlled trial). J Pediatr Nurs 2021 May;58:e54-e62. [doi: 10.1016/j.pedn.2021.01.001] [Medline: 33485746]
44. Gerçeker GÖ, Bektaş M, Aydınok Y, Ören H, Ellidokuz H, Olgun N. The effect of virtual reality on pain, fear, and anxiety during access of a port with huber needle in pediatric hematology-oncology patients: Randomized controlled trial. Eur J Oncol Nurs 2021 Feb;50:101886. [doi: 10.1016/j.ejon.2020.101886] [Medline: 33321461]
45. Gerçeker GÖ, Binay ?, Bilsin E, Kahraman A, Yılmaz HB. Effects of virtual reality and external cold and vibration on pain in 7- to 12-year-old children during phlebotomy: a randomized controlled trial. J Perianesth Nurs 2018 Dec;33(6):981-989. [doi: 10.1016/j.jopan.2017.12.010] [Medline: 29559294]
46. Sanna G, Camporesi A, Diotto V, Abbiati G, Torri A, Gemma M. Virtual sedation as a substitute to pharmacological sedation during PICC placement in pediatric patients: a feasibility study. J Vasc Access 2024 Jan 30;25(1):313-317. [doi: 10.1177/11297298221085424] [Medline: 35773952]
47. Gold JI, Mahrer NE. Is virtual reality ready for prime time in the medical space? A randomized control trial of pediatric virtual reality for acute procedural pain management. J Pediatr Psychol 2018 Apr 01;43(3):266-275. [doi: 10.1093/jpepsy/jsx129] [Medline: 29053848]
48. Gold JI, SooHoo M, Laikin AM, Lane AS, Klein MJ. Effect of an immersive virtual reality intervention on pain and anxiety associated with peripheral intravenous catheter placement in the pediatric setting: a randomized clinical trial. JAMA Netw Open 2021 Aug 02;4(8):e2122569 [FREE Full text] [doi: 10.1001/jamanetworkopen.2021.22569] [Medline: 34432011]
49. Goldman RD, Behboudi A. Virtual reality for intravenous placement in the emergency department-a randomized controlled trial. Eur J Pediatr 2021 Mar 10;180(3):725-731. [doi: 10.1007/s00431-020-03771-9] [Medline: 32779029]
50. Hoag JA, Karst J, Bingen K, Palou-Torres A, Yan K. Distracting through procedural pain and distress using virtual reality and guided imagery in pediatric, adolescent, and young adult patients: randomized controlled trial. J Med Internet Res 2022 Apr 18;24(4):e30260 [FREE Full text] [doi: 10.2196/30260] [Medline: 35436209]
51. Hsu M, Whu Y, Lin I, Liu C, Lai F, Liu P, et al. Effectiveness of virtual reality interactive play for children during intravenous placement: a randomized controlled trial. Asian Nurs Res (Korean Soc Nurs Sci) 2022 May;16(2):87-93 [FREE Full text] [doi: 10.1016/j.anr.2022.03.002] [Medline: 35306189]
52. Hundert AS, Birnie KA, Abla O, Positano K, Cassiani C, Lloyd S, et al. A pilot randomized controlled trial of virtual reality distraction to reduce procedural pain during subcutaneous port access in children and adolescents with cancer. Clin J Pain 2021 Dec 30;38(3):189-196 [FREE Full text] [doi: 10.1097/AJP.0000000000001017] [Medline: 34974512]
53. İnangil D, Şendir M, Büyükyılmaz F. Efficacy of cartoon viewing devices during phlebotomy in children: a randomized controlled trial. J Perianesth Nurs 2020 Aug;35(4):407-412. [doi: 10.1016/j.jopan.2020.01.008] [Medline: 32360128]
54. Litwin SP, Nguyen C, Hundert A, Stuart S, Liu D, Maguire B, et al. Virtual reality to reduce procedural pain during IV insertion in the pediatric emergency department: a pilot randomized controlled trial. Clin J Pain 2021 Feb 01;37(2):94-101. [doi: 10.1097/AJP.0000000000000894] [Medline: 33177370]
55. Mohanasundari SK, Raghu VA, Joseph J, Mohan R, Sharma S. Effectiveness of flippits and virtual reality therapy on pain and anxiety among children undergoing painful procedures. Cureus 2021 Aug;13(8):e17134 [FREE Full text] [doi: 10.7759/cureus.17134] [Medline: 34548966]
56. Osmanlliu E, Trottier ED, Bailey B, Lagacé M, Certain M, Khadra C, et al. Distraction in the emergency department using virtual reality for intravenous procedures in children to improve comfort (DEVINCI): a pilot pragmatic randomized controlled trial. CJEM 2021 Jan 23;23(1):94-102. [doi: 10.1007/s43678-020-00006-6] [Medline: 33683617]
57. Özalp Gerçeker G, Ayar D, Özdemir EZ, Bektaş M. Effects of virtual reality on pain, fear and anxiety during blood draw in children aged 5-12 years old: a randomised controlled study. J Clin Nurs 2020 Apr 22;29(7-8):1151-1161. [doi: 10.1111/jocn.15173] [Medline: 31889358]
58. Piskorz J, Czub M. Effectiveness of a virtual reality intervention to minimize pediatric stress and pain intensity during venipuncture. J Spec Pediatr Nurs 2018 Jan 20;23(1):e12201. [doi: 10.1111/jspn.12201] [Medline: 29155488]
59. Ryu J, Han S, Hwang SM, Lee J, Do S, Kim J, et al. Effects of virtual reality education on procedural pain and anxiety during venipuncture in children: a randomized clinical trial. Front Med (Lausanne) 2022 Apr 7;9:849541 [FREE Full text] [doi: 10.3389/fmed.2022.849541] [Medline: 35463010]
60. Semerci R, Akgün Kostak M, Eren T, Avci G. Effects of virtual reality on pain during venous port access in pediatric oncology patients: a randomized controlled study. J Pediatr Oncol Nurs 2021;38(2):142-151. [doi: 10.1177/1043454220975702] [Medline: 33300448]

XSL•FO
RenderX

61. Thybo KH, Friis SM, Aagaard G, Jensen CS, Dyekjaer CD, Jørgensen CH, et al. A randomized controlled trial on virtual reality distraction during venous cannulation in young children. Acta Anaesthesiol Scand 2022 Oct 11;66(9):1077-1082 [FREE Full text] [doi: 10.1111/aas.14120] [Medline: 35898121]
62. Ustuner Top F, Kuzlu Ayyıldız T. Pain management in children during invasive procedures: a randomized clinical trial. Nurs Forum 2021 Oct 30;56(4):816-822. [doi: 10.1111/nuf.12616] [Medline: 34053097]
63. Walther-Larsen S, Petersen T, Friis SM, Aagaard G, Drivenes B, Opstrup P. Immersive virtual reality for pediatric procedural pain: a randomized clinical trial. Hosp Pediatr 2019 Jul;9(7):501-507. [doi: 10.1542/hpeds.2018-0249] [Medline: 31160472]
64. Sander Wint S, Eshelman D, Steele J, Guzzetta CE. Effects of distraction using virtual reality glasses during lumbar punctures in adolescents with cancer. Oncol Nurs Forum 2002;29(1):E8-E15. [doi: 10.1188/02.ONF.E8-E15] [Medline: 11845217]
65. Wong CL, Choi KC. Effects of an immersive virtual reality intervention on pain and anxiety among pediatric patients undergoing venipuncture: a randomized clinical trial. JAMA Netw Open 2023 Feb 01;6(2):e230001 [FREE Full text] [doi: 10.1001/jamanetworkopen.2023.0001] [Medline: 36795410]
66. Wong CL, Li CK, Chan CWH, Choi KC, Chen J, Yeung MT, et al. Virtual reality intervention targeting pain and anxiety among pediatric cancer patients undergoing peripheral intravenous cannulation. Cancer Nurs 2020 Jun 4;44(6):435-442. [doi: 10.1097/ncc.0000000000000844]
67. Yilmaz Yelvar GD, Çırak Y, Dalkılınç M, Parlak Demir Y, Guner Z, Boydak A. Is physiotherapy integrated virtual walking effective on pain, function, and kinesiophobia in patients with non-specific low-back pain? Randomised controlled trial. Eur Spine J 2017 Feb 15;26(2):538-545. [doi: 10.1007/s00586-016-4892-7] [Medline: 27981455]
68. Yıldırım BG, Gerçeker GÖ. The effect of virtual reality and Buzzy on first insertion success, procedure-related fear, anxiety, and pain in Children during Intravenous Insertion in the pediatric emergency unit: a randomized controlled trial. J Emerg Nurs 2023 Jan;49(1):62-74. [doi: 10.1016/j.jen.2022.09.018] [Medline: 36376127]
69. Ali RR, Selim AO, Abdel Ghafar MA, Abdelraouf OR, Ali OI. Virtual reality as a pain distractor during physical rehabilitation in pediatric burns. Burns 2022 Mar;48(2):303-308. [doi: 10.1016/j.burns.2021.04.031] [Medline: 34154898]
70. Armstrong M, Lun J, Groner JI, Thakkar RK, Fabia R, Noffsinger D, et al. Mobile phone virtual reality game for pediatric home burn dressing pain management: a randomized feasibility clinical trial. Pilot Feasibility Stud 2022 Aug 18;8(1):186 [FREE Full text] [doi: 10.1186/s40814-022-01150-9] [Medline: 35982492]
71. Das DA, Grimmer KA, Sparnon AL, McRae SE, Thomas BH. The efficacy of playing a virtual reality game in modulating pain for children with acute burn injuries: a randomized controlled trial [ISRCTN87413556]. BMC Pediatr 2005 Mar 03;5(1):1 [FREE Full text] [doi: 10.1186/1471-2431-5-1] [Medline: 15745448]
72. Faber AW, Patterson DR, Bremer M. Repeated use of immersive virtual reality therapy to control pain during wound dressing changes in pediatric and adult burn patients. J Burn Care Res 2013;34(5):563-568 [FREE Full text] [doi: 10.1097/BCR.0b013e3182777904] [Medline: 23970314]
73. Hoffman HG, Patterson DR, Rodriguez RA, Peña R, Beck W, Meyer WJ. Virtual reality analgesia for children with large severe burn wounds during burn wound debridement. Front Virtual Real 2020 Dec 10;1:1 [FREE Full text] [doi: 10.3389/frvir.2020.602299] [Medline: 33585833]
74. Jeffs D, Dorman D, Brown S, Files A, Graves T, Kirk E, et al. Effect of virtual reality on adolescent pain during burn wound care. Journal of Burn Care & Research 2014;35(5):395-408. [doi: 10.1097/bcr.0000000000000019]
75. Kaya M, Karaman Özlü Z. The effect of virtual reality on pain, anxiety, and fear during burn dressing in children: a randomized controlled study. Burns 2023 Jun;49(4):788-796. [doi: 10.1016/j.burns.2022.06.001] [Medline: 35753857]
76. Kipping B, Rodger S, Miller K, Kimble RM. Virtual reality for acute pain reduction in adolescents undergoing burn wound care: a prospective randomized controlled trial. Burns 2012 Aug;38(5):650-657 [FREE Full text] [doi: 10.1016/j.burns.2011.11.010] [Medline: 22348801]
77. Le May S, Hupin M, Khadra C, Ballard A, Paquin D, Beaudin M, et al. Decreasing pain and fear in medical procedures with a pediatric population (DREAM): a pilot randomized within-subject trial. Pain Manag Nurs 2021 Apr;22(2):191-197. [doi: 10.1016/j.pmn.2020.10.002] [Medline: 33495093]
78. Bannink Mbazzi F, Nimusiima C, Akellot D, Kawesa E, Abaasa A, Hodges S, et al. Use of virtual reality distraction to reduce child pain and fear during painful medical procedures in children with physical disabilities in Uganda: a feasibility study. Pain Med 2022 Apr 08;23(4):642-654. [doi: 10.1093/pm/pnab206] [Medline: 34185091]
79. Özsoy F, Ulus B. Comparison of two different methods in reducing pain and fear due to dressing change in 7-10 years old children. JPR 2022 Mar 8;9(1):66-75. [doi: 10.4274/jpr.galenos.2021.68335]
80. Schmitt YS, Hoffman HG, Blough DK, Patterson DR, Jensen MP, Soltani M, et al. A randomized, controlled trial of immersive virtual reality analgesia, during physical therapy for pediatric burns. Burns 2011 Feb;37(1):61-68 [FREE Full text] [doi: 10.1016/j.burns.2010.07.007] [Medline: 20692769]
81. van Twillert B, Bremer M, Faber AW. Computer-generated virtual reality to control pain and anxiety in pediatric and adult burn patients during wound dressing changes. Journal of Burn Care & Research 2007;28(5):694-702. [doi: 10.1097/bcr.0b013e318148c96f]
82. Wang Q, Xu S, Guo B, Xu Y, Lu W. Virtual reality as an adjunctive non-pharmacological therapy to reduce pain in school-aged children with burn wounds. J Burn Care Res 2023 Jul 05;44(4):832-836. [doi: 10.1093/jbcr/irac149] [Medline: 36181672]

XSL•FO
RenderX

83. Xiang H, Shen J, Wheeler KK, Patterson J, Lever K, Armstrong M, et al. Efficacy of smartphone active and passive virtual reality distraction vs standard care on burn pain among pediatric patients: a randomized clinical trial. JAMA Netw Open 2021 Jun 01;4(6):e2112082 [FREE Full text] [doi: 10.1001/jamanetworkopen.2021.12082] [Medline: 34152420]
84. Addab S, Hamdy R, Le May S, Thorstad K, Tsimicalis A. The use of virtual reality during medical procedures in a pediatric orthopedic setting: a mixed-methods pilot feasibility study. Paediatr Neonatal Pain 2024 Sep 14;6(3):45-59. [doi: 10.1002/pne2.12078] [Medline: 39473832]
85. Alshatrat SM, Sabarini JM, Hammouri HM, Al-Bakri IA, Al-Omari WM. Effect of immersive virtual reality on pain in different dental procedures in children: a pilot study. Int J Paediatr Dent 2022 Mar 05;32(2):264-272. [doi: 10.1111/ipd.12851] [Medline: 34133809]
86. Poureslami H, Asl Aminabadi N, Sighari Deljavan A, Erfanparast L, Sohrabi A, Jamali Z, et al. Does timing of eruption in first primary tooth correlate with that of first permanent tooth? A 9-years cohort study. J Dent Res Dent Clin Dent Prospects 2015 Jun 10;9(2):79-85 [FREE Full text] [doi: 10.15171/joddd.2015.0016] [Medline: 26236432]
87. Bernaerts S, Bonroy B, Daems J, Sels R, Struyf D, Gies I, et al. Virtual reality for distraction and relaxation in a pediatric hospital setting: an interventional study with a mixed-methods design. Front Digit Health 2022 May 31;4:866119 [FREE Full text] [doi: 10.3389/fdgth.2022.866119] [Medline: 35712230]
88. Buyuk ET, Odabasoglu E, Uzsen H, Koyun M. The effect of virtual reality on children's anxiety, fear, and pain levels before circumcision. J Pediatr Urol 2021 Aug;17(4):567.e1-567.e8. [doi: 10.1016/j.jpurol.2021.04.008] [Medline: 34006462]
89. Clerc PGB, Arneja JS, Zwimpfer CM, Behboudi A, Goldman RD. A randomized controlled trial of virtual reality in awake minor pediatric plastic surgery procedures. Plast Reconstr Surg 2021 Aug 01;148(2):400-408. [doi: 10.1097/PRS.0000000000008196] [Medline: 34398091]
90. Du Q, Ma X, Wang S, Zhou S, Luo C, Tian K, et al. A digital intervention using virtual reality helmets to reduce dental anxiety of children under local anesthesia and primary teeth extraction: a randomized clinical trial. Brain Behav 2022 Jun;12(6):e2600 [FREE Full text] [doi: 10.1002/brb3.2600] [Medline: 35485000]
91. Eijlers R, Dierckx B, Staals LM, Berghmans JM, van der Schroeff MP, Strabbing EM, et al. Virtual reality exposure before elective day care surgery to reduce anxiety and pain in children: a randomised controlled trial. Eur J Anaesthesiol 2019 Oct;36(10):728-737 [FREE Full text] [doi: 10.1097/EJA.0000000000001059] [Medline: 31356373]
92. Goldman RD, Behboudi A. Pilot randomized controlled trial of virtual reality vs. standard-of-care during pediatric laceration repair. J Child Adolesc Trauma 2021 Jun 26;14(2):295-298 [FREE Full text] [doi: 10.1007/s40653-021-00350-4] [Medline: 33986914]
93. Goudman L, Jansen J, De Smedt A, Billot M, Roulaud M, Rigoard P, et al. Virtual reality during intrathecal pump refills in children: a case series. J Clin Med 2022 Oct 05;11(19):5877 [FREE Full text] [doi: 10.3390/jcm11195877] [Medline: 36233743]
94. Kucher N, Larson JM, Fischer G, Mertaugh M, Peterson L, Gershan LA. 3-dimensional nature-based therapeutics in pediatric patients with total pancreatectomy and islet auto-transplant. Complement Ther Med 2020 Jan;48:102249. [doi: 10.1016/j.ctim.2019.102249] [Medline: 31987236]
95. Kumari S, Bahuguna R, Garg N, Yeluri R. Immersive and non-immersive virtual reality distraction on pain perception to intraoral injections. J Clin Pediatr Dent 2021 Dec 01;45(6):389-394 [FREE Full text] [doi: 10.17796/1053-4625-45.6.5] [Medline: 34996111]
96. Liu KY, Ninan SJ, Laitman BM, Goldrich DY, Iloreta AM, Londino AV. Virtual reality as distraction analgesia and anxiolysis for pediatric otolaryngology procedures. Laryngoscope 2021 May 05;131(5):E1714-E1721. [doi: 10.1002/lary.29148] [Medline: 33017065]
97. Luo W, Chen C, Zhou W, Cao A, Zhu W, Zhou Y, et al. Biophilic virtual reality on children's anxiety and pain during circumcision: a randomized controlled study. J Pediatr Urol 2023 Apr;19(2):201-210. [doi: 10.1016/j.jpurol.2022.10.023] [Medline: 36336624]
98. Niharika P, Reddy NV, Srujana P, Srikanth K, Daneswari V, Geetha KS. Effects of distraction using virtual reality technology on pain perception and anxiety levels in children during pulp therapy of primary molars. J Indian Soc Pedod Prev Dent 2018;36(4):364-369. [doi: 10.4103/JISPPD.JISPPD_1158_17] [Medline: 30324926]
99. Olbrecht VA, O'Conor KT, Williams SE, Boehmer CO, Marchant GW, Glynn SM, et al. Guided relaxation-based virtual reality for acute postoperative pain and anxiety in a pediatric population: pilot observational study. J Med Internet Res 2021 Jul 12;23(7):e26328 [FREE Full text] [doi: 10.2196/26328] [Medline: 34048358]
100. Olbrecht VA, O'Conor KT, Williams SE, Boehmer CO, Marchant GW, Glynn SM, et al. Transient reductions in postoperative pain and anxiety with the use of virtual reality in children. Pain Med 2021 Nov 26;22(11):2426-2435. [doi: 10.1093/pm/pnab209] [Medline: 34175959]
101. Ran L, Zhao N, Fan L, Zhou P, Zhang C, Yu C. Application of virtual reality on non-drug behavioral management of short-term dental procedure in children. Trials 2021 Aug 23;22(1):562 [FREE Full text] [doi: 10.1186/s13063-021-05540-x] [Medline: 34425901]
102. Rao DG, Havale R, Nagaraj M, Karobari NM, Latha AM, Tharay N, et al. Assessment of efficacy of virtual reality distraction in reducing pain perception and anxiety in children aged 6-10 years: a behavioral interventional study. Int J Clin Pediatr Dent 2019;12(6):510-513 [FREE Full text] [doi: 10.5005/jp-journals-10005-1694] [Medline: 32440065]

XSL•FO
RenderX

103. Richey AE, Hastings KG, Karius A, Segovia NA, Caruso TJ, Frick S, et al. Virtual reality reduces fear and anxiety during pediatric orthopaedic cast room procedures: a randomized controlled trial. J Pediatr Orthop 2022;42(10):600-607. [doi: 10.1097/BPO.0000000000002250] [Medline: 36040069]
104. Sharma Y, Bhatia HP, Sood S, Sharma N, Singh A. Effectiveness of virtual reality glasses digital screens and verbal command as a method to distract young patients during administration of local anesthesia. Int J Clin Pediatr Dent 2021;14(Suppl 2):S143-S147 [FREE Full text] [doi: 10.5005/jp-journals-10005-2094] [Medline: 35645477]
105. Shetty V, Suresh LR, Hegde AM. Effect of virtual reality distraction on pain and anxiety during dental treatment in 5 to 8 year old children. J Clin Pediatr Dent 2019;43(2):97-102 [FREE Full text] [doi: 10.17796/1053-4625-43.2.5] [Medline: 30730798]
106. Specht BJ, Buse CR, Phelps JR, Phillips MR, Chiavacci SD, Harrell LE, et al. Virtual reality after surgery-a method to decrease pain after surgery in pediatric patients. Am Surg 2023 Apr;89(4):596-602 [FREE Full text] [doi: 10.1177/00031348211032204] [Medline: 34275343]
107. Taylor JS, Chandler JM, Menendez M, Diyaolu M, Austin JR, Gibson ML, et al. Small surgeries, big smiles: using virtual reality to reduce the need for sedation or general anesthesia during minor surgical procedures. Pediatr Surg Int 2021 Oct 16;37(10):1437-1445. [doi: 10.1007/s00383-021-04955-6] [Medline: 34269867]
108. Zaidman L, Lusky G, Shmueli A, Halperson E, Moskovitz M, Ram D, et al. Distraction with virtual reality goggles in paediatric dental treatment: a randomised controlled trial. Int Dent J 2023 Feb;73(1):108-113 [FREE Full text] [doi: 10.1016/j.identj.2022.06.003] [Medline: 35940954]
109. Butt M, Kabariti S, Likourezos A, Drapkin J, Hossain R, Brazg J, et al. Take-Pause: efficacy of mindfulness-based virtual reality as an intervention in the pediatric emergency department. Acad Emerg Med 2022 Mar 09;29(3):270-277 [FREE Full text] [doi: 10.1111/acem.14412] [Medline: 34741370]
110. Diaz-Hennessey S, O'Shea ER, King K. Virtual reality: augmenting the acute pain experience in children. Pediatric Nursing 2019;45(3):122-127 [FREE Full text]
111. Phelan I, Furness PJ, Dunn HD, Carrion-Plaza A, Matsangidou M, Dimitri P, et al. Immersive virtual reality in children with upper limb injuries: findings from a feasibility study. PRM 2021 Sep 28;14(3):401-414. [doi: 10.3233/prm-190635]
112. Griffin A, Wilson L, Feinstein AB, Bortz A, Heirich MS, Gilkerson R, et al. Virtual reality in pain rehabilitation for youth with chronic pain: pilot feasibility study. JMIR Rehabil Assist Technol 2020 Nov 23;7(2):e22620 [FREE Full text] [doi: 10.2196/22620] [Medline: 33226346]
113. Hua Y, Qiu R, Yao W, Zhang Q, Chen X. The effect of virtual reality distraction on pain relief during dressing changes in children with chronic wounds on lower limbs. Pain Manag Nurs 2015 Oct;16(5):685-691. [doi: 10.1016/j.pmn.2015.03.001] [Medline: 25972074]
114. Riera L, Verger S, Montoya PJ, Perales FJ. Advances in the cognitive management of chronic pain in children through the use of virtual reality combined with binaural beats: a pilot study. Advances in Human-Computer Interaction 2022 Dec 31;2022:1-10. [doi: 10.1155/2022/2495182]
115. Sharifpour S, Manshaee GR, Sajjadian I. Effects of virtual reality therapy on perceived pain intensity, anxiety, catastrophising and self‐efficacy among adolescents with cancer. Couns and Psychother Res 2020 Mar 28;21(1):218-226. [doi: 10.1002/capr.12311]
116. Tennant M, Youssef GJ, McGillivray J, Clark T, McMillan L, McCarthy MC. Exploring the use of immersive virtual reality to enhance psychological well-being in pediatric oncology: a pilot randomized controlled trial. Eur J Oncol Nurs 2020 Oct;48:101804. [doi: 10.1016/j.ejon.2020.101804] [Medline: 32949941]
117. Wren AA, Neiman N, Caruso TJ, Rodriguez S, Taylor K, Madill M, et al. Mindfulness-based virtual reality intervention for children and young adults with inflammatory bowel disease: a pilot feasibility and acceptability study. Children (Basel) 2021 May 05;8(5):368 [FREE Full text] [doi: 10.3390/children8050368] [Medline: 34063034]
118. Trost Z, France C, Anam M, Shum C. Virtual reality approaches to pain: toward a state of the science. Pain 2021 Feb 01;162(2):325-331 [FREE Full text] [doi: 10.1097/j.pain.0000000000002060] [Medline: 32868750]
119. Virtual Reality Interventions in Pediatric Acute and Chronic Pain. SickKids. URL: https://lab.research.sickkids.ca/iouch/eppimapper-demo/ [accessed 2025-04-04]
120. Darnall BD, Krishnamurthy P, Tsuei J, Minor JD. Self-administered skills-based virtual reality intervention for chronic pain: randomized controlled pilot study. JMIR Form Res 2020 Jul 07;4(7):e17293 [FREE Full text] [doi: 10.2196/17293] [Medline: 32374272]
121. Eccleston C, Fisher E, Liikkanen S, Sarapohja T, Stenfors C, Jääskeläinen SK, et al. A prospective, double-blind, pilot, randomized, controlled trial of an "embodied" virtual reality intervention for adults with low back pain. Pain 2022 Sep 01;163(9):1700-1715 [FREE Full text] [doi: 10.1097/j.pain.0000000000002617] [Medline: 35324507]
122. Kirk MA, Kelley C, Yankey N, Birken SA, Abadie B, Damschroder L. A systematic review of the use of the Consolidated Framework for Implementation Research. Implement Sci 2016 May 17;11(1):72 [FREE Full text] [doi: 10.1186/s13012-016-0437-z] [Medline: 27189233]
123. Dekker C, van Haastregt JCM, Verbunt JAMCF, de Jong JR, van Meulenbroek T, Pernot HFM, et al. Pain-related fear in adolescents with chronic musculoskeletal pain: process evaluation of an interdisciplinary graded exposure program. BMC Health Serv Res 2020 Mar 14;20(1):213 [FREE Full text] [doi: 10.1186/s12913-020-5053-6] [Medline: 32171308]

XSL•FO
RenderX

124. Simons LE, Harrison LE, Boothroyd DB, Parvathinathan G, Van Orden AR, O'Brien SF, et al. A randomized controlled trial of graded exposure treatment (GET living) for adolescents with chronic pain. Pain 2024 Jan 01;165(1):177-191. [doi: 10.1097/j.pain.0000000000003010] [Medline: 37624900]
125. Simons LE, Harrison LE, O'Brien SF, Heirich MS, Loecher N, Boothroyd DB, et al. Graded exposure treatment for adolescents with chronic pain (GET Living): protocol for a randomized controlled trial enhanced with single case experimental design. Contemp Clin Trials Commun 2019 Dec;16:100448 [FREE Full text] [doi: 10.1016/j.conctc.2019.100448] [Medline: 31650069]
126. Forgeron PA, King S, Stinson JN, McGrath PJ, MacDonald AJ, Chambers CT. Social functioning and peer relationships in children and adolescents with chronic pain: a systematic review. Pain Res Manag 2010 Jan;15(1):27-41 [FREE Full text] [doi: 10.1155/2010/820407] [Medline: 20195556]
127. Berkanish P, Pan S, Viola A, Rademaker Q, Devine KA. Technology-based peer support interventions for adolescents with chronic illness: a systematic review. J Clin Psychol Med Settings 2022 Dec 11;29(4):911-942 [FREE Full text] [doi: 10.1007/s10880-022-09853-0] [Medline: 35147830]
128. Kavanagh E, Chur-Hansen A, Ferencz N. A critical analysis of online social support for young people experiencing chronic pain. Australian Journal of Psychology 2023 May 25;75(1):1. [doi: 10.1080/00049530.2023.2216303]
129. Linkiewich D, Dib KC, Forgeron PA, Dick BD, McMurtry CM. Roadmap to the 'Chronic Pain GPS for Adolescents' intervention: content and design considerations for a group peer support intervention. Clin J Pain 2024 May 01;40(5):288-298 [FREE Full text] [doi: 10.1097/AJP.0000000000001201] [Medline: 38303597]
130. Tolley JA, Michel MA, Williams AE, Renschler JS. Peer support in the treatment of chronic pain in adolescents: a review of the literature and available resources. Children (Basel) 2020 Sep 07;7(9):129 [FREE Full text] [doi: 10.3390/children7090129] [Medline: 32906581]
131. Groenewald CB, Tham SW, Palermo TM. Impaired school functioning in children with chronic pain: a national perspective. Clin J Pain 2020 Sep;36(9):693-699 [FREE Full text] [doi: 10.1097/AJP.0000000000000850] [Medline: 32487871]
132. Logan DE, Simons LE, Stein MJ, Chastain L. School impairment in adolescents with chronic pain. J Pain 2008 May;9(5):407-416 [FREE Full text] [doi: 10.1016/j.jpain.2007.12.003] [Medline: 18255341]
133. Logan DE, Khanna K, Randall E, O'Donnell S, Reks T, McLennan L. Centering patient and clinician voices in developing tools to address pain related school impairment: a phase I study of a virtual reality school simulation for children and adolescents with chronic pain. Children (Basel) 2023 Oct 01;10(10):1644 [FREE Full text] [doi: 10.3390/children10101644] [Medline: 37892307]

Abbreviations

AR: augmented reality
MINORS: Methodological Index for Non-Randomized Studies
PICO: Population, Intervention, Comparison, Outcome
RCT: randomized controlled trial
RoB-2: Cochrane Risk of Bias Tool
VR: virtual reality
XR: extended reality

Edited by S Badawy; submitted 01.07.24; peer-reviewed by BC Reynolds, I Kathner; comments to author 05.12.24; revised version received 16.01.25; accepted 28.02.25; published 07.04.25.

Please cite as:
Hess CW, Rosenbloom BN, Mesaroli G, Lopez C, Ngo N, Cohen E, Ouellette C, Gold JI, Logan D, Simons LE, Stinson JN
Extended Reality (XR) in Pediatric Acute and Chronic Pain: Systematic Review and Evidence Gap Map
JMIR Pediatr Parent 2025;8:e63854
URL: https://pediatrics.jmir.org/2025/1/e63854
doi:10.2196/63854
PMID:

©Courtney W Hess, Brittany N Rosenbloom, Giulia Mesaroli, Cristal Lopez, Nhat Ngo, Estreya Cohen, Carley Ouellette, Jeffrey I Gold, Deirdre Logan, Laura E Simons, Jennifer N Stinson. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 07.04.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete

XSL•FO
RenderX

bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Supervised and Unsupervised Screen Time and Its Association With Physical, Mental, and Social Health of School-Going Children in Dhaka, Bangladesh: Cross-Sectional Study

Shahria Hafiz Kakon[1], MBBS, MPH; Tanjir Rashid Soron[2], MBBS, MD; Mohammad Sharif Hossain[1], MS; Rashidul Haque[1], MBBS, PhD; Fahmida Tofail[3], MBBS, PhD

[1]Infectious Diseases Division, International Centre for Diarrheal Disease Research, Bangladesh, 68, Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka, Bangladesh

[2]Telepsychiatry Research and Innovation Network Ltd, Dhaka, Bangladesh

[3]Maternal and Child Nutrition, Nutrition Research Division, International Centre for Diarrheal Disease Research, Bangladesh, Dhaka, Bangladesh

Corresponding Author:
Shahria Hafiz Kakon, MBBS, MPH
Infectious Diseases Division, International Centre for Diarrheal Disease Research, Bangladesh, 68, Shaheed Tajuddin Ahmed Sarani, Mohakhali, Dhaka, Bangladesh

Abstract

Background: Children's screen time has substantially increased worldwide, including in Bangladesh, especially since the pandemic, which is raising concern about its potential adverse effects on their physical, mental, and social health. Parental supervision may play a crucial role in mitigating these negative impacts. However, there is a lack of empirical evidence assessing the relationship between parental screen time supervision and health outcomes among school children in Dhaka, Bangladesh.

Objective: We aimed to explore the association between supervised and unsupervised screen time on the physical, mental, and social health of school-going children in Dhaka, Bangladesh.

Methods: We conducted a cross-sectional descriptive study between July 2022 and June 2024. A total of 420 children, aged 6 - 14 years, were enrolled via the stratified random sampling method across three English medium and three Bangla medium schools in Dhaka. Data were collected through a semistructured questionnaire; anthropometry measurements; and the Bangla-validated Strength and Difficulties Questionnaire (SDQ), Pittsburgh Sleep Quality Index (PSQI) Scale, and Spencer Children Anxiety Scale (SCAS).

Results: A total of 234 out of 420 students (56%) used digital screen devices without parental supervision. We did not find a substantial difference in the duration of the daily mean use of digital devices among the supervised students (4.5 hours, SD 2.2 hours) and the unsupervised students (4.6 hours, SD 2.4 hours). According to the type of school, English medium school children had a mean higher screen time (5.46 hours, SD 2.32 hours) compared to Bangla medium school children (3.67 hours, SD 2.00 hours). Headache was significantly higher among the unsupervised digital screen users compared to those who used digital screens with parental supervision (175/336 students, 52.1% versus 161/336 students, 47.9%; P<.003). Moreover, students who used digital screens without parental supervision had poor quality of sleep. Behavioral problems such as conduct issues (119/420 students, 28.3%) and peer difficulties (121/420 students, 28.8%) were observed among the participants. However, when comparing supervised and unsupervised students, we found no statistically significant differences in the prevalence of these issues.

Conclusions: The findings of the study showed that the lack of screen time supervision is associated with negative health effects in children. The roles of various stakeholders, including schools, parents, policy makers, and students themselves, are crucial in developing effective guidelines for managing screen use among students. Further research is needed to demonstrate causal mechanisms; identify the best interventions; and determine the role of mediators and moderators in households, surroundings, and schools.

(JMIR Pediatr Parent 2025;8:e62943) doi:10.2196/62943

KEYWORDS

screen time; parental supervision; Strength and Difficulties Questionnaire; Spencer Children Anxiety Scale; Pittsburgh Sleep Quality Scale; children; sleep quality; headache; behavioral problems

XSL•FO
RenderX

Introduction

To what extent can parental supervision mitigate the effects of excessive digital screens in school-going adolescents? This is becoming an increasingly common concern of parents and researchers, as digital screens fill our living spaces and take up our quality time. A recent study showed that daily screen time for users aged 16 - 64 years has increased to 6 hours 37 minutes worldwide [1]. Across age groups, 44% of all waking hours are spent on screens [1]. In 2020, the World Health Organization released a milestone report with detailed guidelines on sedentary behavior including screen time for children under the age of 5 years, defining screen time as time spent passively watching screen-based entertainment (TV, computer, or mobile devices) [2]. The American Academy of Child and Adolescent Psychiatry agreed with the findings, recommending less than 2 hours of daily screen time for children aged under 5 years, but for children aged 6 years and older, recommending "healthy habits" and to "limit activities that include screens" [3]. At present, no concrete guidelines have been presented for adolescents, although health concerns are just as pressing for them [4].

Higher sedentary behavior such as screen time is associated with a range of physical and mental health issues, including headaches, myopia, obesity, sleep disorders, behavioral disorders, and anxiety [4-8]. A study of 5844 children around the world found that children averaged 8.6 hours of daily sedentary time, associated with poor weight status and physical inactivity [9]. Lauricella and Cingel [10] found one of the most reliable predictors of higher screen time among adolescents to be parental media use, along with weaker associations with parental attitudes to technology and screen time rules.

In Asia, higher incomes and a rising middle class have led to longer exposure to screen time (>2 h a day) for children and adolescents [11,12]. Without parental intervention, excessive screen time exposure has been associated with less sleep duration among Asian preschoolers, but Lin et al [13] found parental education and awareness, among best practices, to be an effective intervention against these effects.

Bangladesh's rising socioeconomic status has contributed to an explosion in digital device access and usage across demographics [14]. Khan and Burton [15] found that almost 80% of Bangladeshi adolescents have high recreational screen time, reported at 4.0 (SD 2.2) hours per day on average, with the mean values of 4.3 (SD 2.4) hours for boys and 3.6 (SD 2.3) hours for girls. High screen time was associated with sleep disturbance and higher family income, among other factors [15]. Anjum et al [16] found a higher incidence of depressive symptoms in adolescents with higher screen time exposure (>2 h per day), alongside other physical and mental health concerns including sleep disturbance and mood disorders prior to the COVID-19 pandemic.

During the COVID-19 lockdown, Bangladeshi children began to spend much more time on the internet, for entertainment, communication, and education [17-19]. Koly and colleagues [20] noted worsening psycho-social health of school-going students in this period, associated with quarantine adaptations and difficulties with online learning. Simultaneously, Rashid and colleagues [21] found physical and mental health deterioration among secondary school students, with symptoms including headaches, backaches, visual and sleep disturbance, and depression. During the pandemic, online learning became a necessity, leading to a significant increase in children's digital screen use. While it ensured educational continuity, this shift also contributed to extended screen time, potentially indicating the physical, mental, and emotional health risks associated with excessive screen exposure [4,22].

Following the pandemic, increased digital screen time did not lessen, leading to significant adverse consequences on adolescent health [23,24]. For instance, Shuvo and Biswas [25] note that when electronic device exposure overlaps with eating times and habits, there is an increased likelihood of obesity. Meanwhile, heavier reliance on technology for education, entertainment, and socialization after COVID is associated with increased anxiety, difficulty sleeping, addiction, and various sociobehavioral difficulties [23,24,26].

In Bangladesh, there is a dearth of comprehensive academic research on the effects of screen time on adolescents, despite the fact that there is a substantial amount of empirical evidence around the world [4,22,27-34]. Furthermore, as the results are utilized to create thorough screen-use guidelines, these studies have significant policy ramifications. Furthermore, while parental supervision is crucial in preventing excessive screen time, researchers found that inappropriate methods to discipline children and adolescents may increase long-term screen use and exaggerate other adverse psychosocial effects [24,35]. Therefore, this study aimed to distinguish between the effects of supervised and unsupervised screen time on the physical, mental, and social health of Bangladeshi schoolchildren.

Methods

Study Setting, Participants, and Sampling

This was a cross-sectional descriptive study and adopted a quantitative approach. The survey was conducted between July 2022 to June 2024. We purposively selected 6 schools from the list of all schools in Dhaka North and South city corporations to ensure the equal distribution of the Bangla and English medium schools. Moreover, we considered the socioeconomic, geographic, and feasibility of data collection. During the school selection, with the approval of the school authorities, we considered children aged between 6 to 14 years who were in class 2 to class 8 and who had more than 2 hours of screen time each day as the qualifying criteria for sample inclusion. Smartphones, tablets, laptops, personal computers, gaming consoles, televisions, and portable gaming devices were among the acceptable gadgets. Children with preexisting conditions, such as physical or psychological impairment, were excluded from the study, as this might have influenced the results. We used a stratified random sampling method to recruit a total of 420 students, by including 70 students from each school (ie, 10 students from each grade from grades 2 to 8).

Data Collection Procedure

We collected data through face-to-face interviews with parents and students on school grounds. The day prior to the interview,

XSL•FO
RenderX

study staff scheduled the appointment time with parents, and the class teacher brought the students during the lunch break. A half-hour interview period was allotted for students and an hour for parents. To check for differences in accuracy between staff and trainers (ie, psychologists who trained all the staff on each of the psychometric tools used in this study), 30 pilot tests were performed prior to the start of data collection. Interrater reliability was measured using the Cohen kappa coefficient to quantify the level of agreement between each of the three staff and trainers (n=30 nonstudy participants/staff) for all the Bangla-validated scales. On average, the calculated Cohen kappa values ranged between 0.84 and 0.89 (scores for 30 nonstudy participants/staff-trainer pairs), indicating strong agreement among the staff.

All data collection forms were checked at the field site for completeness, accuracy, and consistency. The quality control team was responsible for regular observations at school, and identical forms and tools were used across the duration of the study. Investigators personally traveled to the sites weekly to ensure proper field implementation.

Study Instruments

Screen Time

A semistructured questionnaire was developed to collect information about screen time from both parents and students. The parents' questionnaires included socioeconomic factors, pattern and quantity of child screen time usage, gadget-using behavior of the children, and parents' mediating role in screen time exposure (supervised vs unsupervised). The student's questionnaire included the type of device use, time and pattern of use, and purpose of device use. Screen time was considered to be any time spent engaging with content in front of a digital device with an electronic screen, including but not limited to iPads, gaming consoles, laptops, smartphones, tablets, and desktop devices. Students were categorized into supervised versus unsupervised based on the self-reporting information regarding the supervision. In this study, supervised screen time is defined as when parents are aware of their child's digital device usage, including what they are doing, how much time they spend, and the type of content they consume. In contrast, unsupervised screen time occurs when parents lack awareness of their child's activities, duration of use, and the content they engage with on digital devices. Similar definitions have been used in other studies [36,37].

Physical Health

Anthropometric measurements (weight and height) were collected from students on school premises during data collection. Measurements were calibrated daily before data collection to ensure standardization. The BMI (kg/m^2) was calculated and converted to z-scores, then categorized according to cut-off points given by the World Health Organization BMI-for-age growth chart for ages 5 to 19 years: underweight (<15 kg/m^2, −1 SD), normal weight (15 - 25 kg/m^2), overweight (25 - 30 kg/m^2, +1 SD), obese (30 - 40 kg/m^2, +2 SD), and morbidly obese (>40 kg/m^2, +4 SD) [38]. Additional physical health issues, such as blurred vision, headaches, indigestion, backache, and neck pain, were also asked of the students via a questionnaire. The students' physical health responses were initially categorized into four groups: "No," "Sometimes," "Often," and "Most of the time." These categories were then consolidated into two broader groups: "No" and "Yes," with "Yes" encompassing the responses "Sometimes," "Often," and "Most of the time."

Mental and Social Health

Age-appropriate Bangla-validated versions of the following scales were used to find well-being indicators for children's mental and social health.

Strength and Difficulties Questionnaire

This is a behavioral questionnaire (25 questions) designed to identify a combination of positive and negative attributes across 5 dimensions–emotional symptoms, conduct problems, hyperactivity or attention deficit, peer relationship problems, and prosocial behavior. The sum of the scores of the four negative behavior subscales represents the children's general difficult behavior with a maximum score of 40, whereas the maximum score for prosocial behavior is 10. Gustin and colleagues have verified the Strength and Difficulties Questionnaire (SDQ) against independent clinical diagnoses of Bangladeshi children [39,40].

Spencer Children Anxiety Scale

This scale is used to evaluate symptoms relating to separation anxiety, social phobia, obsessive-compulsive disorder, panic, agoraphobia, generalized anxiety, and fear of injury. Goodman et al have validated the Spencer Children Anxiety Scale (SCAS) as a reliable instrument for Bangla-speaking communities [41].

Pittsburgh Sleep Quality Index

This questionnaire has components spanning several subcategories such as subjective sleep quality, latency, duration, habitual efficiency, disturbances, sleeping medication, and daytime dysfunction. Mamun et al [42] have successfully used the Pittsburgh Sleep Quality Index (PSQI) to identify sleep-related concerns among Bangladeshi students.

Statistical Analysis

Data were entered via IBM SPSS version 20.0 (IBM Corp) and analyzed on Stata version 15.1 (StataCorp LLC). Categorical data were represented as frequency numbers and percentages, while continuous data with reasonably normal distributions were summarized as means and SDs. Nonnormal continuous data were instead summarized as medians and IQRs. Participants were categorized into two main subgroups, supervised and unsupervised. Subsequently, a comparative analysis was performed across various factors, including demographic characteristics, amount of screen time, and health metrics. To assess differences across groups, the chi-squared test for independence was employed for categorical data, and the 2-tailed unpaired *t* test for differences between proportions was used for continuous data with nearly normal distributions. A significance threshold of $P<.05$ was used to assess statistical significance.

XSL•FO
RenderX

Ethical Considerations

This study was approved by the Institutional Review Board of icddr,b (protocol number: PR-22002). Written informed consent was obtained from all parents, and confidentiality and anonymity were maintained throughout the study. Children aged above 11 years provided assent in addition to their parents' consent. All the respondents were informed in Bengali about their rights related to their voluntary participation in the study as well as their right to withdraw from the interview at any time during the interview.

Results

A total of 420 students were enrolled based on the screening criteria. Of them, 186 (44%) children were supervised and 234 (56%) children were unsupervised. Table 1 represents the demographic summary statistics of the population. The students were between 6 and 14 years, with a mean age of 10.9 (SD 1.9) years; 207 out of the 420 children (49.3%) were girls. Of the 420 children, 292 (69.5%) belonged to single-family households. In families with 1 - 2 children, 161 out of 288 children (55.9%) were unsupervised, while for families with more than 3 children, 73 out of 132 children (55.3%) were unsupervised.

Table . Demographic and socioeconomic information of study participants.

Characteristics	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)
Child's age (years)			
Mean (SD)	10.9 (1.9)	11.0 (1.9)	10.8 (1.9)
Child's sex, n (%)			
Male	213 (50.7)	101 (47.4)	112 (52.6)
Female	207 (49.3)	85 (41.1)	122 (58.9)
Family type, n (%)			
Single	292 (69.5)	132 (45.2)	160 (54.8)
Joint	128 (30.5)	54 (42.2)	74 (57.8)
Number of children in the family, n (%)			
1 - 2	288 (68.6)	127 (44.1)	161 (55.9)
≥3	132 (31.4)	59 (44.7)	73 (55.3)
Average monthly income, n (%)			
<BDT[a] 50,000 (<US$ 420)	137 (32.6)	57 (41.6)	80 (58.4)
BDT 50,000 - 100,000 (>US$ 420 to <US$ 840)	144 (34.3)	63 (43.8)	81 (56.2)
>BDT 100,000 (>US$ 840)	139 (33.1)	66 (47.5)	73 (52.5)

[a]BDT: Bangladeshi taka.

The mean total daily screen time for the entire population was 4.6 (SD 2.3) hours. The large SD relative to the mean indicates widely varying screen habits among the study population. The range of screen time for the unsupervised group was 0.3 - 15 hours and that for the supervised group was 0 - 12 hours. The mean total daily screen time for the unsupervised group was 4.6 (SD 2.4) hours, slightly higher than the supervised group's mean of 4.5 (SD 2.2) hours. These large deviations imply factors other than supervision contribute more to total screen time.

Multimedia Appendix 1 shows the mean daily screen time spent by children categorized by age, sex, and type of school. No significant difference was observed in the mean daily screen time between different age groups (6 - 10 years vs 11 - 14 years) or between male and female participants. However, children attending English medium schools had a significantly higher average daily screen time (5.4 hours) compared to those attending Bangla medium schools (3.6 hours).

Table 2 shows the prevalence of physical symptoms among students with supervised and unsupervised use of digital devices. Overall, out of 420 students, 391 (93.1%) students experienced blurred vision, 341 (81.2%) reported abdominal pain, 336 (80%) had headaches, and 327 (77.9%) experienced dry eyes or soreness. Considering all the health issues, a higher proportion of unsupervised students experienced these problems compared to supervised students. Headaches were significantly more prevalent among the unsupervised group (175/336 children, 52.1%) than the supervised group (161/336 children, 47.9%; P<.003). All the data are shown in Table 2.

XSL•FO
RenderX

Table . Prevalence of physical symptoms among study participants with supervised and unsupervised use of digital screens and devices.

Physical symptoms	Frequency (N=420), n (%)	Supervised (n=186), n (%)	Unsupervised (n=234), n (%)	*P* value
Eye problems	150 (35.7)	64 (42.7)	86 (57.3)	.62
Dry eye or soreness	327 (77.9)	150 (45.9)	177 (54.1)	.22
Blurred vision	391 (93.1)	177 (45.3)	214 (54.7)	.14
Hearing difficulty	14 (3.3)	6 (42.9)	8 (57.1)	.91
Indigestion or gas	276 (65.7)	118 (42.8)	158 (57.2)	.38
Headache	336 (80.0)	161 (47.9)	175 (52.1)	.003
Neck pain	192 (45.7)	86 (44.8)	106 (55.2)	.85
Abdominal pain	341 (81.2)	150 (44.0)	191 (56.0)	.80
Back or any other musculoskeletal problem	134 (31.9)	63 (47.0)	71 (53.0)	.44
Diabetes	4 (1.0)	0 (0.0)	4 (100.0)	.07
Change in appetite	204 (48.6)	86 (42.2)	118 (57.8)	.39
Sleep issues	82 (19.5)	32 (39.0)	50 (61.0)	.29

Table 3 shows a mean BMI of 19.3 (SD 4.7) kg/m^2 for the study population. There was a slight difference in the mean BMI between the supervised (mean 19.6 kg/m^2, SD 4.9 kg/m^2) and unsupervised (mean 19.1 kg/m^2, SD 4.4 kg/m^2) groups (*P*=.26 indicates statistical insignificance). Overall, out of 420 children, 335 (80.1%) children were healthy, 21 (5%) were underweight, and 42 (10.1%) were overweight/obese. No statistically significant differences were observed in the distribution of BMI between the supervised and unsupervised categories.

Table . Association of BMI with supervised and unsupervised digital screen use.

Characteristics	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)	*P* value
BMI, kg/m^2				.26
Mean (SD)	19.3 (4.7)	19.6 (4.9)	19.1 (4.4)	
BMI category, n (%)				.50
Underweight	21 (5.0)	9 (42.9)	12 (57.1)	
Healthy weight	335 (80.1)	143 (42.7)	192 (57.3)	
Overweight	42 (10.1)	21 (50.0)	21 (50.0)	
Obesity	16 (3.8)	9 (56.2)	7 (43.8)	
Severe obesity	4 (1.0)	3 (75.0)	1 (25.0)	

Table 4 shows the association of anxiety with supervised and unsupervised digital screen use. Out of 420 children, 414 (98.6%) children were identified within the normal range. Just 1 of the 6 children fell into the high anxiety range; only 1 was left unsupervised and the other 5 were in the supervised group. Despite the fact that there was a significant difference (*P*<.05), the small number of individuals in this group could provide an inaccurate correlation. It is recommended to conduct additional research before drawing any conclusions. There were no discernible variations between the supervised and unsupervised proportions for any specific anxiety subcategory on the SCAS.

Multimedia Appendix 2 shows the results of the SDQ scale in the 420 students; of the 420 students, 119 students (28.3%) had conduct problems, 121 students (28.8%) had peer problems, 66 students (15.7%) reported emotional problems, 73 students (17.4%) experienced hyperactivity, and 28 students (6.7%) reported prosocial behaviors. Based on the borderline/abnormal results shown in Multimedia Appendix 2, Table 5 was prepared, and it shows the distribution of supervised and unsupervised children categorized as having borderline/abnormal results for digital screen use based on the SDQ subcategories (emotional symptoms, conduct problems, hyperactivity or attention deficit, peer relationship problems, and prosocial behavior).

The percentage of unsupervised children was greater than that of supervised children among those classified as having borderline or abnormal results. The most common abnormality was peer relationship problems among the children. Of the 420 students, 121 (28.8%) had peer relationship problems: 55 students (45.38%) were supervised and 66 students (55.6%) were unsupervised. Less borderline/abnormal results were found considering prosocial behavior. Of the 420 students, 28 (6.7%) were identified with abnormal/borderline results: 11 (39.29%) were supervised and 17 (60.71%) were unsupervised.

XSL•FO
RenderX

Table . Association of anxiety with supervised and unsupervised digital screen use by using the Spencer Children Anxiety Scale (SCAS).

SCAS	Overall (N=420), n (%)	Supervised (n=186), n (%)	Unsupervised (n=234), n (%)	*P* value
Overall				.05
Normal range	414 (98.6)	181 (43.7)	233 (56.3)	
Elevated range	6 (1.4)	5 (83.3)	1 (16.7)	

Table . Distribution of supervised and unsupervised children categorized as borderline/abnormal for digital screen use based on the Strength and Difficulties Questionnaire subcategories (emotional symptoms, conduct problems, hyperactivity, peer relationship problems, and prosocial behavior).

Category	Supervised (%)	Unsupervised (%)
Emotional symptoms	43.94	56.66
Conduct problems	45.38	54.62
Hyperactivity	47.95	52.05
Peer relationship problems	45.45	54.55
Prosocial behavior	39.29	60.71

Table 6 shows that a majority of children reported good quality of sleep on the PSQI (358/420, 85.2%). Of those who reported bad sleep, the proportions were similar between supervised and unsupervised children (14% of supervised children vs 15.4% of unsupervised children). Nonetheless, a potentially significant result was found on comparing the mean total sleeping durations: supervised children sleep on average for 7.7 (SD 1.5) hours, compared to 7.4 (SD 1.6) hours for unsupervised children (against an overall mean of 7.6, SD 1.6). However, the *P* value showed borderline significance; furthermore, if the children were subcategorized by the average hours of sleep (>7, 6 - 7, 5 - 6, and <5 hours), no significant difference was found across any subgroup between supervised and unsupervised children.

XSL•FO
RenderX

Table . Association of quality of sleep using the Pittsburgh Sleep Quality Index (PSQI) scale with supervised and unsupervised digital screen use.

PSQI scale	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)	*P* value
Sleep status, n (%)				.69
Good sleep (global PSQI score ≤5)	358 (85.2)	160 (44.6)	198 (55.3)	
Bad sleep (global PSQI score >5)	62 (14.8)	26 (14.0)	36 (15.4)	
Sleep time				.05
Mean bedtime, PM	11:17	11:11	11:21	
Mean wake time, AM	7:19	7:24	7:16	
Total sleeping duration (h), mean (SD)	7.6 (1.6)	7.7 (1.5)	7.4 (1.6)	
Sleep quality, n (%)				.18
Very good	202 (48.1)	82 (44.1)	120 (51.3)	
Fairly good	199 (47.4)	94 (50.5)	105 (44.9)	
Fairly bad	17 (4.0)	10 (5.4)	7 (3.0)	
Very bad	2 (0.5)	0 (0.0)	2 (0.9)	
Sleep latency, n (%)				.85
0	100 (23.8)	41 (22.0)	59 (25.2)	
1 - 2	207 (49.3)	94 (50.5)	113 (48.3)	
3 - 4	105 (25.0)	48 (25.8)	57 (24.4)	
5 - 6	8 (1.9)	3 (1.6)	5 (2.1)	
Sleep duration, n (%)				.06
>7 hours	237 (56.4)	112 (60.2)	125 (53.4)	
6 - 7 hours	123 (29.3)	53 (28.5)	70 (29.9)	
5 - 6 hours	44 (10.5)	19 (10.2)	25 (10.7)	
<5 hours	16 (3.8)	2 (1.1)	14 (6.0)	
Habitual sleep efficiency, n (%)				.40
>85%	393 (93.6)	176 (94.6)	217 (92.7)	
75 - 84%	25 (6.0)	10 (5.4)	15 (6.4)	
65 - 74%	2 (0.5)	0 (0.0)	2 (0.9)	
<65%	0 (0.0)	0 (0.0)	0 (0.0)	
Sleep disturbances, n (%)				.80
0	38 (9.0)	18 (9.7)	20 (8.6)	
1 - 9	364 (86.7)	161 (86.6)	203 (86.8)	
10 - 18	17 (4.0)	7 (3.8)	10 (4.3)	
19 - 27	1 (0.2)	0 (0.0)	1 (0.4)	
Use of sleeping medication, n (%)				.30
Not during the past month	417 (99.3)	186 (100.0)	231 (98.7	
Less than once a week	2 (0.5)	0 (0.0)	2 (0.9)	
Once or twice a week	1 (0.2)	0 (0.0)	1 (0.4)	
Three or more times a week	0 (0.0)	0 (0.0)	0 (0.0)	
Daytime dysfunction, n (%)				.88

XSL•FO
RenderX

PSQI scale	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)	*P* value
0	283 (67.4)	124 (66.7)	159 (68.0)	
1 - 2	121 (28.8)	54 (29.0)	67 (28.6)	
3 - 4	13 (3.1)	7 (3.8)	6 (2.6)	
5 - 6	3 (0.7)	1 (0.5)	2 (0.9)	

Discussion

Principal Results and Comparison With Prior Works

This study enrolled a total of 420 children, with 186 (44%) supervised and 234 (56%) unsupervised children. Unsupervised children had a slightly higher mean screen time of 4.6 (SD 2.4) hours compared to supervised children who had a mean screen time of 4.5 (SD 2.2) hours. Additionally, the study found a higher prevalence of physical symptoms and slightly different BMI distributions among unsupervised children. No significant differences in sleep quality were observed between supervised and unsupervised children, although supervised children slept slightly longer. A greater percentage of unsupervised children were categorized as having borderline or abnormal findings based on the SDQ subcategories (emotional symptoms, conduct problems, hyperactivity or attention deficit, peer relationship problems, and prosocial behavior).

Significant variations depending on the type of education were found in this study, which examined key facets of the role of parental supervision in digital screen use among students in Dhaka city. Although teenagers attending school spent a mean of 4.6 (SD 2.3) hours a day on screens, there was no discernible difference in the amount of time spent on screens between students who were under supervision and those who were not. Nevertheless, when stratified by the type of education, students in Bengali medium schools had screen time of 3.67 hours, while students in English medium schools showed considerably higher screen time (5.46 hours). This discrepancy could have several causes. In Bangladesh, English medium students often come from higher-income households that can afford the higher costs of English medium education, making them more likely to have access to personal digital devices. A similar indication was provided in an article published by The Daily Star [43]. Additionally, English medium students are typically Ordinary level (O level) or Advanced Level (A level) candidates, an internationally recognized qualification that is considered to be the equivalent of Cambridge IGCSE and UK General Certificate of Secondary Education; the preparation for these international-standard examinations necessitates greater screen exposure as part of their learning process [44]. Despite the differences in total screen time, the study did not find any correlations between parental education or income level and screen time supervision. Another study also showed the same findings that no significant association was observed between parental education or income level and screen time supervision [45].

Such trends are concerning given the established negative effects of excessive screen time on adolescent health, including obesity, diabetes, poor sleep, and increased risks of depression and anxiety [5-9]. Effective parental supervision is known to reduce screen time and mitigate these adverse effects. Parent-child interaction improved prosocial behavior and reduced psychosocial difficulties while contributing to healthier body mass indices and better sleep [11]. Furthermore, the findings of this study align with the results from previous studies [7, 9]. The empirical evidence found that parental mediation and active participation are associated with improved physical health outcomes, including BMI and sleep duration [7,9]. School-going participants in this study also reported a range of health concerns, with blurred vision, abdominal pain, headaches, dry or sore eyes, and indigestion being the most commonly noted. Such impacts are also reported by several previous studies [46-48]. A notable difference was observed between supervised and unsupervised groups specifically for headaches, with a higher proportion of unsupervised students reporting this issue. A previous study also reported that unsupervised children are more vulnerable to associated health issues [49]. Although supervision did not significantly impact other physical indicators, the findings suggested a potential association with blurred vision and diabetes. However, the small number of patients with diabetes limits the interpretability of these findings. Therefore, further research is needed to explore the effects of different supervision methods on these health concerns and to identify any potential correlations.

In contrast, the statistical significance indicates that factors other than supervision, such as lifestyle, might have a greater impact on other physical issues. For instance, a sizable percentage (28.3%) of kids showed conduct and peer relationship problems when they had results in the borderline or abnormal range on the SDQ. Despite these findings, no significant differences were observed between supervised and unsupervised groups across the SDQ subcategories, suggesting that these behavioral issues may be influenced by factors beyond supervision, including lifestyle and home or school conditions.

Furthermore, we identified a concern that supervision might exacerbate anxiety. This is because, among the 6 children who reported overall anxiety, only 1 was unsupervised. Although the result is statistically significant, this finding should be interpreted with caution due to the small sample size. Collectively, these observations highlight a significant deficiency in effective parental guidance and supervision methods among contemporary urban families in Dhaka. Therefore, further research is needed to explore the specific supervision strategies employed by parents and their impact, with the aim of developing guidelines for healthy technology use.

Finally, we explored a potential correlation between parental supervision of digital screen use and the mean total bedtime based on PSQI data, with the supervised group having slightly more sleep on average compared to their counterpart. However,

XSL•FO
RenderX

when analyzing total sleep duration and examining differences related to supervision across various subgroups, the significance diminished, indicating that the observed differences were not conclusive. Specifically, the proportions of children who slept more than 7 hours were similar between the supervised and unsupervised groups, and these proportions did not differ meaningfully from the overall study sample. Given these borderline findings, further investigation is warranted to explore the potential associations between supervision and sleep patterns.

Limitations

This study has several limitations. First, inconsistencies emerged between the parents' and children's reports, as many parents used a broad definition of "supervised," such as occasional checks or limited awareness of the child's activities on the device. As the children's reports were found to be more reliable predictors, final supervision categorization was based on the children's statements. A similar approach has been followed previously [44]. Second, the study's scope was limited to 6 schools (3 Bangla and 3 English medium schools), which may not be representative of the broader variation between urban and rural settings or differing school resources. Third, data on technological interactions and parental mediation were collected via face-to-face interviews, which may have introduced recall bias. Finally, discrepancies between parent and child reports could not be independently verified. Future research should include diverse populations and settings to provide a more comprehensive understanding of screen time impacts.

Strengths

Despite these limitations, the strength of this study lies in its pioneering exploration of the association of parental supervision with the physical, mental, and social well-being of students in Bangladesh. Additionally, by including students from both Bangla and English medium schools, the study provides valuable comparative insights. The findings are expected to motivate and inform parents, policy makers, and educational authorities, highlighting the need for enhanced supervision and education to promote healthier and more balanced lifestyles for students. Further research is required that may explore causal relationships through experimental or longitudinal designs.

Conclusions

The results of this study enhance our understanding of how to mitigate the negative impacts of unsupervised screen time on students' well-being. Effective guidelines for managing screen use require the involvement of multiple stakeholders: schools, parents, policy makers, and the students themselves. Schools can play a crucial role in educating students about safe screen use and enforcing balanced screen time through workshops and seminars. Parents need to be informed about the risks of excessive screen time and the benefits of active supervision, adopting strategies to enhance their children's well-being. Additionally, accessible mental health services, including counseling and support groups, can help students manage stress and anxiety related to screen time. Conducting further research to develop comprehensive screen time guidelines is essential for promoting the health and well-being of future generations.

Acknowledgments

The authors would like to acknowledge their affiliation, with the icddr,b and its core donors who provide unrestricted support to icddr,b for its operations and research, including the governments of Bangladesh and Canada. We gratefully acknowledge our core donors for their support and commitment to the research efforts at icddr,b. The authors are also grateful to the school authorities for their unconditional support. The current study was financially supported by the Bangladesh government's Mujib100 Research Grant for Women award, in collaboration with icddr,b, grant no. 1945. All authors declared that they had insufficient funding to support open access publication of this manuscript, including from affiliated organizations or institutions, funding agencies, or other organizations. JMIR Publications provided article processing fee (APF) support for the publication of this article.

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author upon reasonable request.

Authors' Contributions

SHK contributed to conceptualizing, analyzing, writing, revising, and finalizing the manuscript with the support of TRS, MSH, RH, and FT. All the authors have read, revised, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Mean daily screen time (hours) by sociodemographic characteristics.
[DOCX File, 15 KB - pediatrics_v8i1e62943_app1.docx]

Multimedia Appendix 2

XSL•FO
RenderX

Distribution of normal and borderline/abnormal responses for the student behavior on the Strength and Difficulties Questionnaire (SDQ) scale.
[DOCX File, 14 KB - pediatrics_v8i1e62943_app2.docx]

References

1. Kemp S. Digital 2023: GLOBAL overview report. Meltwater. 2023. URL: https://wearesocial.com/wp-content/uploads/2023/03/Digital-2023-Global-Overview-Report.pdf [accessed 2024-12-06]
2. Bull FC, Al-Ansari SS, Biddle S, et al. World Health Organization 2020 guidelines on physical activity and sedentary behaviour. Br J Sports Med 2020 Dec;54(24):1451-1462. [doi: 10.1136/bjsports-2020-102955] [Medline: 33239350]
3. Screen time and children. The American Academy of Child and Adolescent Psychiatry. 2024. URL: https://www.aacap.org/AACAP/Families_and_Youth/Facts_for_Families/FFF-Guide/Children-And-Watching-TV-054.aspx [accessed 2024-12-06]
4. Singh S, Balhara YPS. "Screen-time" for children and adolescents in COVID-19 times: need to have the contextually informed perspective. Ind J Psychiatry 2021;63(2):192-195. [doi: 10.4103/psychiatry.IndianJPsychiatry_646_20] [Medline: 34194066]
5. Przybylski AK, Weinstein N. Digital screen time limits and young children's psychological well‐being: evidence from a population‐based study. Ch Dev 2019 Jan;90(1):e56-e65. [doi: 10.1111/cdev.13007]
6. Robidoux H, Ellington E, Lauerer J. Screen time: the impact of digital technology on children and strategies in care. J Psychosoc Nurs Ment Health Serv 2019 Nov 1;57(11):15-20. [doi: 10.3928/02793695-20191016-04] [Medline: 31670830]
7. Jalil J, Bashir F. Screen time, effects on cognitive, psychological and physical development of children. Pak Armed Forces Med J 2021;71(2):375-376 [FREE Full text]
8. Tong L, Ye Y, Yan Q. The moderating roles of bedtime activities and anxiety/depression in the relationship between attention-deficit/hyperactivity disorder symptoms and sleep problems in children. BMC Psychiatry 2018 Sep 17;18(1):298. [doi: 10.1186/s12888-018-1879-4] [Medline: 30236084]
9. LeBlanc AG, Katzmarzyk PT, Barreira TV, et al. Correlates of total sedentary time and screen time in 9-11 year-old children around the world: the international study of childhood obesity, lifestyle and the environment. PLoS One 2015;10(6):e0129622. [doi: 10.1371/journal.pone.0129622] [Medline: 26068231]
10. Lauricella AR, Cingel DP. Parental influence on youth media use. J Child Fam Stud 2020 Jul;29(7):1927-1937 [FREE Full text] [doi: 10.1007/s10826-020-01724-2]
11. Zhao J, Zhang Y, Jiang F, et al. Excessive screen time and psychosocial well-being: the mediating role of body mass index, sleep duration, and parent-child interaction. J Pediatr 2018 Nov;202:157-162. [doi: 10.1016/j.jpeds.2018.06.029] [Medline: 30100232]
12. Bernard JY, Padmapriya N, Chen B, et al. Predictors of screen viewing time in young Singaporean children: the GUSTO cohort. Int J Behav Nutr Phys Act 2017 Sep 5;14(1):112. [doi: 10.1186/s12966-017-0562-3] [Medline: 28870219]
13. Lin YM, Kuo SY, Chang YK, et al. Effects of parental education on screen time, sleep disturbances, and psychosocial adaptation among Asian preschoolers: a randomized controlled study. J Pediatr Nurs 2021;56:e27-e34. [doi: 10.1016/j.pedn.2020.07.003] [Medline: 32703680]
14. Chowdhury MD. Socio-economic impacts of mobile penetration in SAARC countries with special emphasis on Bangladesh. Asian bus rev 2015;5(2):66-71. [doi: 10.18034/abr.v5i2.56]
15. Khan A, Burton NW. Screen-based behaviors of adolescents in Bangladesh. J Phys Act Health 2016 Nov;13(11):1156-1163. [doi: 10.1123/jpah.2015-0514] [Medline: 27334303]
16. Anjum A, Hossain S, Hasan MT, Alin SI, Uddin ME, Sikder MT. Depressive symptom and associated factors among school adolescents of urban, semi-urban and rural areas in Bangladesh: A scenario prior to COVID-19. Front Psychiatry 2021;12:708909. [doi: 10.3389/fpsyt.2021.708909] [Medline: 34650452]
17. Sultana A, Tasnim S, Hossain MM, Bhattacharya S, Purohit N. Digital screen time during the COVID-19 pandemic: a public health concern. F1000Res 2021;10(May):81 [FREE Full text] [doi: 10.12688/f1000research.50880.1]
18. Marfua A. Exploring the influences of prolonged screen time on the behavior of children aging 3 to 6 years during covid-19 crisis. Brac University Institutional Repository. 2021. URL: https://dspace.bracu.ac.bd/xmlui/handle/10361/16330?show=full [accessed 2024-12-23]
19. Islam MS, Sujan MSH, Tasnim R, et al. Problematic internet use among young and adult population in Bangladesh: correlates with lifestyle and online activities during the COVID-19 pandemic. Addict Behav Rep 2020 Dec;12:100311. [doi: 10.1016/j.abrep.2020.100311] [Medline: 33364319]
20. Koly KN, Islam MS, Potenza MN, et al. Psychosocial health of school-going adolescents during the COVID-19 pandemic: findings from a nationwide survey in Bangladesh. PLoS One 2023;18(3):e0283374. [doi: 10.1371/journal.pone.0283374] [Medline: 36972260]
21. Rashid SMM, Mawah J, Banik E, et al. Prevalence and impact of the use of electronic gadgets on the health of children in secondary schools in Bangladesh: a cross-sectional study. Health Sci Rep 2021 Dec;4(4):e388. [doi: 10.1002/hsr2.388] [Medline: 34622022]

XSL•FO
RenderX

22. Susilowati IH, Nugraha S, Alimoeso S, Hasiholan BP. Screen time for preschool children: learning from home during the COVID-19 pandemic. Glob Pediatr Health 2021;8:2333794X211017836. [doi: 10.1177/2333794X211017836] [Medline: 34031645]
23. Robin K, Shamsi T. Screen addiction and behavioral change among school going students in Dhaka city. SSRN Electron J 2024 [FREE Full text] [doi: 10.2139/ssrn.4763077]
24. Rizwan AA, Manir M, Ahsan M, Makbul S, Islam K. Psychological impact of electronic devices among adolescents in Bangladesh. World J Pharm Res 2023 Jun;12(9):136-148 [FREE Full text] [doi: 10.20959/wjpr20239-28202]
25. Shuvo SD, Biswas BK. The degree of association between overweight and obesity with the use of electronic media among Bangladeshi adolescents. PLoS One 2023;18(1):e0280544. [doi: 10.1371/journal.pone.0280544] [Medline: 36662815]
26. Anjum A, Hossain S, Hasan MT, Uddin ME, Sikder MT. Anxiety among urban, semi-urban and rural school adolescents in Dhaka, Bangladesh: Investigating prevalence and associated factors. PLoS One 2022;17(1):e0262716. [doi: 10.1371/journal.pone.0262716] [Medline: 35061810]
27. González SA, Sarmiento OL, Florez-Pregonero A, Katzmarzyk PT, Chaput JP, Tremblay MS. Prevalence and associated factors of excessive recreational screen time among Colombian children and adolescents. Int J Public Health 2022;67:1604217. [doi: 10.3389/ijph.2022.1604217] [Medline: 35283721]
28. Sanders T, Parker PD, Del Pozo-Cruz B, Noetel M, Lonsdale C. Type of screen time moderates effects on outcomes in 4013 children: evidence from the longitudinal study of Australian children. Int J Behav Nutr Phys Act 2019 Nov 29;16(1):117. [doi: 10.1186/s12966-019-0881-7] [Medline: 31783878]
29. Muppalla SK, Vuppalapati S, Reddy Pulliahgaru A, Sreenivasulu H. Effects of excessive screen time on child development: an updated review and strategies for management. Cureus 2023 Jun;15(6):e40608. [doi: 10.7759/cureus.40608] [Medline: 37476119]
30. Pardhan S, Parkin J, Trott M, Driscoll R. Risks of digital screen time and recommendations for mitigating adverse outcomes in children and adolescents. J Sch Health 2022 Aug;92(8):765-773. [doi: 10.1111/josh.13170] [Medline: 35253225]
31. Toombs E, Mushquash CJ, Mah L, et al. Increased screen time for children and youth during the COVID-19 pandemic. Sci Briefs Ont COVID-19 Sci Advis Table 2022;3(59):1-19 [FREE Full text] [doi: 10.47326/ocsat.2022.03.59.1.0]
32. Al-Shoaibi AAA, Zamora G, Chu J, et al. Family conflict and less parental monitoring were associated with greater screen time in early adolescence. Acta Paediatr 2024 Nov;113(11):2452-2458. [doi: 10.1111/apa.17349] [Medline: 39031509]
33. Varadarajan S, Govindarajan Venguidesvarane A, Ramaswamy KN, Rajamohan M, Krupa M, Winfred Christadoss SB. Prevalence of excessive screen time and its association with developmental delay in children aged <5 years: A population-based cross-sectional study in India. PLoS One 2021;16(7):e0254102. [doi: 10.1371/journal.pone.0254102] [Medline: 34228768]
34. de Souza S, Marques KC, Reuter CP. Screen time above recommendations in children and adolescents: analysis of the associated nutritional, behavioral and parental factors. Rev Bras Cresc Desenvolv Hum 2020;30(3):363-370 [FREE Full text] [doi: 10.7322/jhgd.v30.11067]
35. Hawi NS, Rupert MS. Impact of e-discipline on children's screen time. Cyberpsychol Behav Soc Netw 2015 Jun;18(6):337-342. [doi: 10.1089/cyber.2014.0608] [Medline: 26075921]
36. Council on Communications and Media. Media and young minds. Pediatrics 2016 Nov;138(5):e20162591. [doi: 10.1542/peds.2016-2591] [Medline: 27940793]
37. John JJ, Joseph R, David A, Bejoy A, George KV, George L. Association of screen time with parent-reported cognitive delay in preschool children of Kerala, India. BMC Pediatr 2021 Feb 11;21(1):73. [doi: 10.1186/s12887-021-02545-y] [Medline: 33573623]
38. de Onis M, Onyango AW, Borghi E, Siyam A, Nishida C, Siekmann J. Development of a WHO growth reference for school-aged children and adolescents. Bull World Health Organ 2007 Sep;85(9):660-667. [doi: 10.2471/blt.07.043497] [Medline: 18026621]
39. Kippler M, Tofail F, Hamadani JD, et al. Early-life cadmium exposure and child development in 5-year-old girls and boys: a cohort study in rural Bangladesh. Environ Health Perspect 2012 Oct;120(10):1462-1468. [doi: 10.1289/ehp.1104431] [Medline: 22759600]
40. Gustin K, Tofail F, Vahter M, Kippler M. Cadmium exposure and cognitive abilities and behavior at 10 years of age: a prospective cohort study. Environ Int 2018 Apr;113:259-268. [doi: 10.1016/j.envint.2018.02.020] [Medline: 29459184]
41. Goodman R, Renfrew D, Mullick M. Predicting type of psychiatric disorder from Strengths and Difficulties Questionnaire (SDQ) scores in child mental health clinics in London and Dhaka. Eur Child Adolesc Psychiatry 2000 Jun;9(2):129-134. [doi: 10.1007/s007870050008] [Medline: 10926063]
42. Mamun MA, Hossain M, Kamruzzaman M, et al. Prevalence of poor sleep quality and its determinants among Bangladeshi students: a pilot study. Sleep Vigil 2020 Dec;4(2):185-193 [FREE Full text] [doi: 10.1007/s41782-020-00109-1]
43. Chandan MSK. English medium schools: when money matters most. The Daily Star. 2022. URL: https://www.thedailystar.net/weekend-read/news/when-money-matters-most-3083141 [accessed 2024-12-06]
44. Gentile DA, Nathanson AI, Rasmussen EE, Reimer RA, Walsh DA. Do you see what I see? Parent and child reports of parental monitoring of media. Fam Relat 2012 Jul;61(3):470-487. [doi: 10.1111/j.1741-3729.2012.00709.x]

XSL•FO
RenderX

45. Dinkha J, Mitchell C, Zogheib B. Parental control: the relationship amongst parental supervision, education, income and children's viewing habits. Am J Hum Soc Sci 2014;2(3):157-170 [FREE Full text] [doi: 10.11634/232907811402563]
46. Gammoh Y. Digital eye strain and its risk factors among a university student population in Jordan: a cross-sectional study. Cureus 2021 Feb 26;13(2):e13575. [doi: 10.7759/cureus.13575] [Medline: 33815983]
47. Gadain Hassan HA. Computer vision syndrome among medical students at the University of Khartoum, Sudan: prevalence and associated factors. Cureus 2023 May;15(5):e38762. [doi: 10.7759/cureus.38762] [Medline: 37303411]
48. Chu GCH, Chan LYL, Do CW, et al. Association between time spent on smartphones and digital eye strain: a 1-year prospective observational study among Hong Kong children and adolescents. Environ Sci Pollut Res Int 2023 Apr;30(20):58428-58435. [doi: 10.1007/s11356-023-26258-0] [Medline: 36991204]
49. Hadley W, Barker D, Thamotharan S, Houck CD. Relationship Between unsupervised time and participation in an emotion regulation intervention and risk outcomes. J Dev Behav Pediatr 2017;38(9):714-722. [doi: 10.1097/DBP.0000000000000498] [Medline: 28902065]

Abbreviations

PSQI: Pittsburgh Sleep Quality Index
SCAS: Spencer Children Anxiety Scale
SDQ: Strength and Difficulties Questionnaire

Edited by S Badawy; submitted 05.06.24; peer-reviewed by EP Silva, SC Chong; revised version received 05.10.24; accepted 10.10.24; published 14.01.25.

Please cite as:
Kakon SH, Soron TR, Hossain MS, Haque R, Tofail F
Supervised and Unsupervised Screen Time and Its Association With Physical, Mental, and Social Health of School-Going Children in Dhaka, Bangladesh: Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e62943
URL: https://pediatrics.jmir.org/2025/1/e62943
doi:10.2196/62943

© Shahria Hafiz Kakon, Tanjir Rashid Soron, Mohammad Sharif Hossain, Rashidul Haque, Fahmida Tofail. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 14.1.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Effectiveness of Virtual Reality–Based Cognitive Control Training Game for Children With Attention-Deficit/Hyperactivity Disorder Symptoms: Preliminary Effectiveness Study

Hyunjoo Song[1], Prof Dr; Yunhye Oh[2], Prof Dr Med; JongIn Choi[3], Prof Dr; Seong-Yong Ohm[4], Prof Dr

[1]Division of Psychology and Cognitive Science, Seoul Women's University, Hwarang Ro 621, Nowon Goo, Seoul, Republic of Korea

[2]Department of Psychiatry, Hallym University Sacred Heart Hospital, Republic of Korea

[3]Department of Digital Media Design and Application, Seoul Women's University, Seoul, Republic of Korea

[4]Department of Software Convergence, Seoul Women's University, Seoul, Republic of Korea

Corresponding Author:
Hyunjoo Song, Prof Dr
Division of Psychology and Cognitive Science, Seoul Women's University, Hwarang Ro 621, Nowon Goo, Seoul, Republic of Korea

Abstract

Background: Recent advancements in digital technologies hold promise for psychological interventions. Virtual reality (VR) has emerged as a particularly innovative tool, and its application expanded during the COVID-19 pandemic period. A recent study combining material and psychological rewards within a VR platform showed that this approach effectively improves attention-deficit behaviors in children with attention-deficit/hyperactivity disorder (ADHD), enhancing their inhibitory control abilities.

Objective: This study aimed to evaluate the effectiveness of a newly developed VR-based cognitive control training game for children with ADHD symptoms. Specifically, it examined the sustainability of the training effects through a 3-month follow-up assessment. In addition, the study analyzed training response patterns and influential factors using a clustering method.

Method: A total of 29 children and adolescents (21 males and 8 females) aged 10-14 years participated in the study, with a mean IQ of 94 (SD 16.53). For 20 consecutive days, participants self-administered the training on a daily basis using the VR app. The following assessments were administered face-to-face: the Korean Wechsler Intelligence Scale for Children, Fourth Edition; the Stroop test; the Color Trails test; and the Flanker test from the National Institutes of Health toolbox. In addition, the parent-completed Korean Child Behavior Checklist was used to identify behavioral problems in the children. Participants engaged in at least 20 minutes of daily training for 20 consecutive days, with assessments conducted at baseline, posttraining, and follow-up.

Results: Repeated measures ANOVA revealed significant main effects in the Stroop Color-Word test ($F_{2,56}$=4.97; P=.001; ηp^2=0.151), Child Behavior Checklist (CBCL) Total Problems ($F_{2,56}$=21.0; P<.001; ηp^2=0.429), CBCL Attention Problems ($F_{2,56}$=11.7; P<.001; ηp^2=0.294), and CBCL ADHD ($F_{2,56}$=3.46; P=.004; ηp^2=0.110). K-means clustering identified 2 distinct clusters that did not differ significantly in IQ variables but showed significant differences in game-related behavioral variables, including mean correct response time (t_{27}=−2.56; P=.02) and the correct response ratio (t_{27}=2.60; P=.02).

Conclusions: The findings indicate that the VR-based training effectively improved cognitive control on the Stroop test and ADHD-related symptoms as measured by the CBCL. However, no significant training effects were observed on other attentional measures, namely the Color Trails test and the Flanker test from the National Institutes of Health toolbox. This VR-based approach shows promise as a potential therapeutic intervention for children with ADHD symptoms.

Trial Registration: Clinical Research Information Service KCT0009447; https://cris.nih.go.kr/cris/search/detailSearch.do?seq=27234

(JMIR Pediatr Parent 2025;8:e66617) doi:10.2196/66617

KEYWORDS

cognitive control; virtual reality; serious game; attention-deficit/hyperactivity disorder; ADHD; training effectiveness

XSL•FO
RenderX

Introduction

Technological advancements have significantly transformed psychological interventions, particularly through digital therapeutics and personalized treatment strategies. The concept of "enhanced psychotherapy" has been introduced, which builds on traditional psychotherapy by integrating innovative treatment modules, approaches, or techniques [1]. A distinctive feature of this enhanced psychotherapy is the use of personalized treatment strategies, incorporating digital technologies, wearable devices, and computerized cognitive behavioral therapy. Recent advancements in digital technologies hold significant promise for psychological interventions. For instance, the integration of formally recognized treatment options, such as EndeavorRX (Akili Interactive; AKL-T01), which has received approval from the Food and Drug Administration, has enhanced both the feasibility and applicability of digital therapeutics in clinical practice [2]. It has been argued that current technologies could transform cognitive interventions, allowing for better targeting of individuals in need of specific treatments [3]. In addition, it has been emphasized that the ability to dynamically tailor treatments in real-time through data processing technologies marks the dawn of a new era in psychiatry [4].

Virtual reality (VR) has emerged as a particularly innovative tool [5]. It has revolutionized psychotherapy and psychological assessment [6,7], and its application significantly expanded during the COVID-19 pandemic, including in sensitive contexts [8-10]. VR interventions have been explored in the treatment of anxiety disorders, pain management, eating disorders, psychosis, autism, and addiction. Research suggests that VR-based interventions can be as effective as, or even more beneficial than, traditional treatment methods [11]. Several recent studies have highlighted the potential of VR in cognitive intervention. For instance, attention training using VR has been reported to be effective in patients with acquired brain injuries [12]. Research has demonstrated that VR technology provides significant benefits in mental health management for adolescents experiencing various challenges, including emotional, cognitive, and social difficulties [13,14].

Although treatments for attention-deficit/hyperactivity disorder (ADHD) have been rigorously documented [15], therapies focusing on enhancing cognitive control lack systematic validation regarding both efficacy and long-term treatment effects [16]. In addition, there is a notable shortfall in ecologically valid treatment outcomes. Basically, treatment benefits should translate into improvements in real-world functioning. Spooner and Pachana [17] stressed that neuropsychological assessment should correlate closely with daily functioning outcomes. However, a recent meta-analysis reflecting on 2 decades of research identified only 7 studies that included parental reporting on ADHD symptoms and behaviors in daily life [18].

Cognitive control is a foundational concept in modern cognitive neuroscience, encompassing decision-making, goal-directed behavior, response inhibition, and attention allocation [19]. Deficits in cognitive control have been closely linked to childhood and adolescent behavioral problems, including ADHD [20-22], autism spectrum disorder [23], conduct disorder, and various impulsive behaviors [24]. ADHD is notably associated with deficits in cognitive control, which can be identified through behavioral assessments and neuroimaging measures [25]. The prefrontal cortex, with its extensive interconnectivity with sensory, motor, and subcortical structures, serves as a hub for cognitive control [19,20,26].

One study illustrated VR's potential in treating ADHD, showing results comparable to those achieved with methylphenidate treatment [14]. In addition, a recent study combining material and psychological rewards within a VR platform showed that this approach effectively improves attention-deficit behaviors in children with ADHD, enhancing their inhibitory control abilities [26]. Furthermore, research has demonstrated that older adults experiencing cognitive and functional decline benefit from VR game interventions, with particularly pronounced effects observed in self-adaptive VR interventions [27]. This highlights the importance of participant-centered approaches in optimizing both cognitive and motor outcomes while prioritizing the enhancement of user experiences. The recent review exploring VR and exercise simulator intervention in patients with ADHD emphasized the need for a comprehensive approach to interventions and advocated improving technological interventions to address the varied needs of individuals with ADHD [28,29].

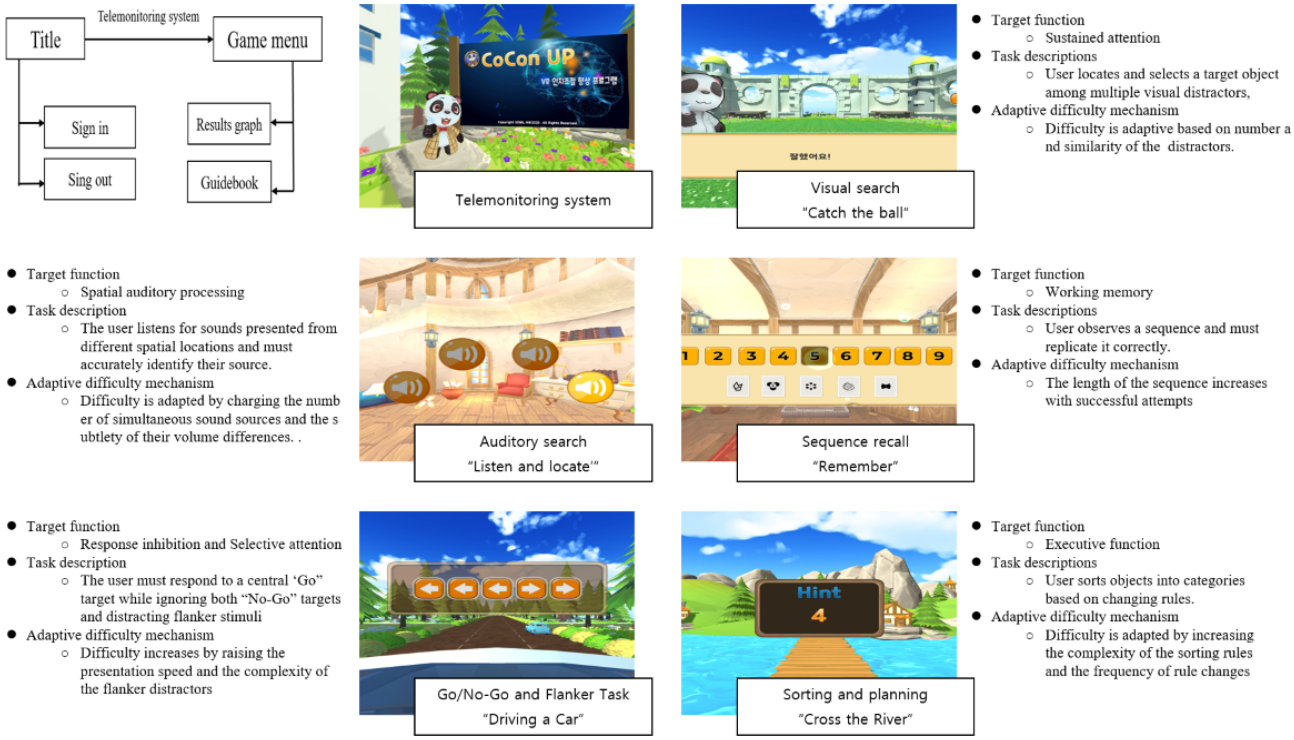
We hypothesized that the immersive experience of VR could offer an optimal training environment for children with ADHD symptoms, particularly those who struggle to maintain focus due to difficulties in filtering irrelevant stimuli. In addition to the immersive experience, the newly developed VR game encompasses 3 core aspects. First, the intervention is built on rigorous cognitive neuroscience principles. This VR game was designed based on carefully selected games from the cognitive control training app, CoCon (Huno [30]). CoCon, a previously validated 2D mobile app, has shown promising results in improving cognitive control in children, thus providing a strong foundation for this VR-based extension. Each game was designed based on a cognitive experimental paradigm relevant to cognitive control functions, such as visual and auditory search, working memory, response inhibition, and executive function [30]. Second, this VR game uses an adaptive difficulty algorithm, ensuring that participants benefit from the training regardless of their baseline attention capabilities. The game difficulty progressively increases as users advance, pausing when users reach their cognitive capacity limits. Task difficulty is regulated using algorithms derived from an adaptive staircase approach. The adaptive staircase algorithm, originally developed based on established psychophysical methods and now patented (10-2019-0125031), enables real-time adjustment of task difficulty to individual cognitive thresholds. Third, this VR game incorporates a remote monitoring system, encouraging consistent engagement in the training program. Research assistants track participants' progress through server data and provide feedback via phone, engaging primary caregivers when necessary. This integrated approach of at-home training, combined with direct support, has been designed to optimize treatment outcomes. The overall structure and primary cognitive functions of each VR game are depicted in Figure 1. This figure

XSL•FO
RenderX

shows the main modules of the game system, including the user interface, the core gameplay loop, the data management module, and their interconnections.

This study aims to examine the efficacy of the VR-based cognitive training through a structured 20-day intervention program, followed by a 3-month follow-up assessment to evaluate the durability of training effects. We hypothesize that the intervention will yield significant and sustained improvements in key domains of cognitive control, including attention regulation, inhibitory control, and executive functioning.

Figure 1. Key components of the game's architecture.



Methods

Participants

A total of 32 children aged 10-14 years participated in this study. This age range was selected to ensure participants had the developmental capacity to understand instructions, operate the VR equipment, and adhere to the training protocol. A total of 22 participants were recruited from the Department of Psychiatry at a general hospital in Seoul, where they were diagnosed with ADHD by a child psychiatrist. None had comorbidities. Notably, 18 participants were medicated with varying types and dosages, while 4 were medication-naive. An additional 10 participants were recruited from the community via social networks and community boards. Inclusion criteria for community participants were based on the mobile-based cognitive control assessment app, CoCon. To be included, candidates had to score below a T-score of 40 on at least one of 4 indices: sustained attention, working memory, cognitive control, and cognitive execution. A T-score of 40 on the CoCon app represents a mean score 50 (1 SD) below the mean. There were no significant differences between the clinical and community participants in the basic variables (Table S1 in Multimedia Appendix 1).

Sample size calculation was performed using G*Power version 3.1 software (Heinrich-Heine-Universität Düsseldorf [31]). Initially, the study was designed as a between-subjects repeated measures ANOVA, and a sample size of 86 was recommended, assuming a medium effect size (Cohen *f*=0.25), an α level of .05, and a statistical power of 0.80. However, due to uncontrollable circumstances, such as the COVID-19 pandemic, it was not feasible to recruit enough participants for the between-subjects design. Therefore, the study design was changed to a within-subjects repeated measures ANOVA. Based on this revised design, a sample size of 28 was recommended under the same parameters (Cohen *f*=0.25; α=.05; power=0.80), assuming a medium effect size for a within-subjects context. To account for an estimated dropout rate of 20%, the final target sample size was increased to 32 participants. Overall, 3 participants dropped out during training, resulting in a final count of 29 participants. In addition, 1 participant who reported red-green color blindness after the pretraining test had their Stroop test data replaced with mean values from corresponding variables for analysis. For the 29 participants who completed all study assessments, all of them also completed the full 20-day training protocol, demonstrating 100% adherence among this group.

Study Design

This VR game was developed using the Unity (Unity Technologies) game engine and is compatible with the Oculus Quest 2 (Meta) VR device. The VR game app was designed for home-based cognitive control training, with each participant expected to engage in at least 20 minutes of training daily for 20 days. Research assistants monitored training data and proactively addressed difficulties over the phone each day, conducting in-home visits as needed for technical challenges.

XSL•FO
RenderX

This study included 3 assessment phases comprising a pretest for initial assessment, a posttest after 20 days of training, and a follow-up test conducted 3 months later. To evaluate the retest effect specifically, 14 participants underwent an additional test (retest) without training. Participants, including those in the no training retest group, were alternately allocated based on enrollment order with randomization. After evaluations, this group participated in training sessions, followed by subsequent posttests and follow-up assessments.

The pretest included the Korean Wechsler Intelligence Scale for Children-Fourth Edition (K-WISC-IV) [32], the Korean Color Trails test (CTT) 1 and 2 [33], the Korean Stroop test [34], the NIH toolbox [35], and the Korean Child Behavioral Checklist (K-CBCL) [36], lasting approximately 90 minutes excluding the parent-completed K-CBCL. The posttest and follow-up tests included CTT 1 and 2 [33], Stroop test, Flanker test from the NIH toolbox [35], and the K-CBCL [36], each taking about 30 minutes, excluding the parent-completed K-CBCL [36]. Training monitoring and assessments were conducted by research assistants who had graduated from master's programs specializing in clinical psychology.

Measurements

K-WISC-IV Assessment

The K-WISC-IV [32] uses 10 core subtests to measure intelligence. The subtests yield scaled scores (mean 10, SD 3) and 4 composite indices, such as verbal comprehension index (VCI), perceptual reasoning index (PRI), working memory index (WMI), and processing speed index (PSI), presented as standard scores (mean 100, SD 15).

Korean Version of the Color Trails Test 1 and 2

The Color Trails test [33] comprises 2 parts. The first (CTT1) part assesses attention sustainability, and the second (CTT2) part assesses the ability to shift attention. Converted T-scores based on the completion time for both assessment parts were used for analysis.

Korean Version of the Stroop Color-Word Test for Children

The Stroop Color-Word test [34] evaluates the ability to inhibit irrelevant information and select relevant responses. The Korean version, which demonstrated reliability (Cronbach α=0.72 for the normative population and 0.73 for the clinical population), was administered. Normative data are available for children aged 5-14 years. In this study, the number of correctly reported color words within 45 seconds served as the measurement.

NIH Toolbox Flanker Test

The Flanker Inhibitory Control test from the National Institutes of Health (NIH) toolbox [35] was used to evaluate executive function. This task assesses a participant's ability to inhibit irrelevant visual information while maintaining attention on a target. The age-corrected standard scores (range 59 - 140) were used for analysis.

K-CBCL Assessment

The K-CBCL [36] was used to identify behavioral problems in children, adapted from the Achenbach [37] Child Behavioral Checklist (CBCL). Raw scores were converted to T-scores (mean 50, SD 10). The analysis focused on the total problem score, attention problem score, and ADHD score.

Mobile-Based Cognitive Control Assessment App (CoCon)

CoCon [30] served to screen high-risk groups in the community. Its concurrent validity was established through comparisons with traditional neuropsychological tests, including the Stroop test and the CTT. Four composite indices were produced, converted into T-scores (mean 50, SD 10): sustained attention, working memory, cognitive control, and cognitive execution. A T-score of 40 was used as the cutoff for high-risk group selection (higher scores indicating better function).

Statistical Analysis

Data analysis was performed using Jamovi software [38]. Demographic data were summarized by calculating means, SDs, and frequencies. Game-related behaviors were analyzed, including login frequency, instances of exiting games midway, total game time, total trial numbers, correct-incorrect counts, and reaction times. Paired 2-tailed *t* tests evaluated retest effects. The main analysis used repeated-measures ANOVAs to assess training effects at 3 time points, such as pretraining, posttraining, and 3 months posttraining. Scatter plots depicting pretest, posttest, and follow-up test results were generated using the *ggplot* function [39,40] in Jamovi software [38]. In addition, the Pearson correlation analysis was conducted between game-related behaviors and difference scores between pretests and follow-up tests in the Stroop test and CBCL total score, attentional problem score, and ADHD score. Training response patterns were analyzed using the *k*-means clustering method, applying Lloyd algorithm to identify distinct clusters based on standardized *z* scores (mean 0, SD 1) from difference scores between pretests and follow-up tests in the Stroop test and CBCL total score, attentional problem score, and ADHD score. Group comparisons were conducted using independent 2-tailed *t* tests across various parameters, including IQ subscales (verbal comprehension, perceptual reasoning, working memory, and processing speed) and game behaviors (correct/incorrect ratios, total response times, total trial numbers, number of exits during games, and login frequencies).

Ethical Considerations

This study received approval from the institutional review board (SWU IRB-2020A-56; Multimedia Appendix 2). Written informed consent was obtained from participants and their parents, with each participant receiving 90,000 KRW (US $70) upon completing all evaluations. Data were anonymized.

Results

Participant Characteristics and Retest Effects

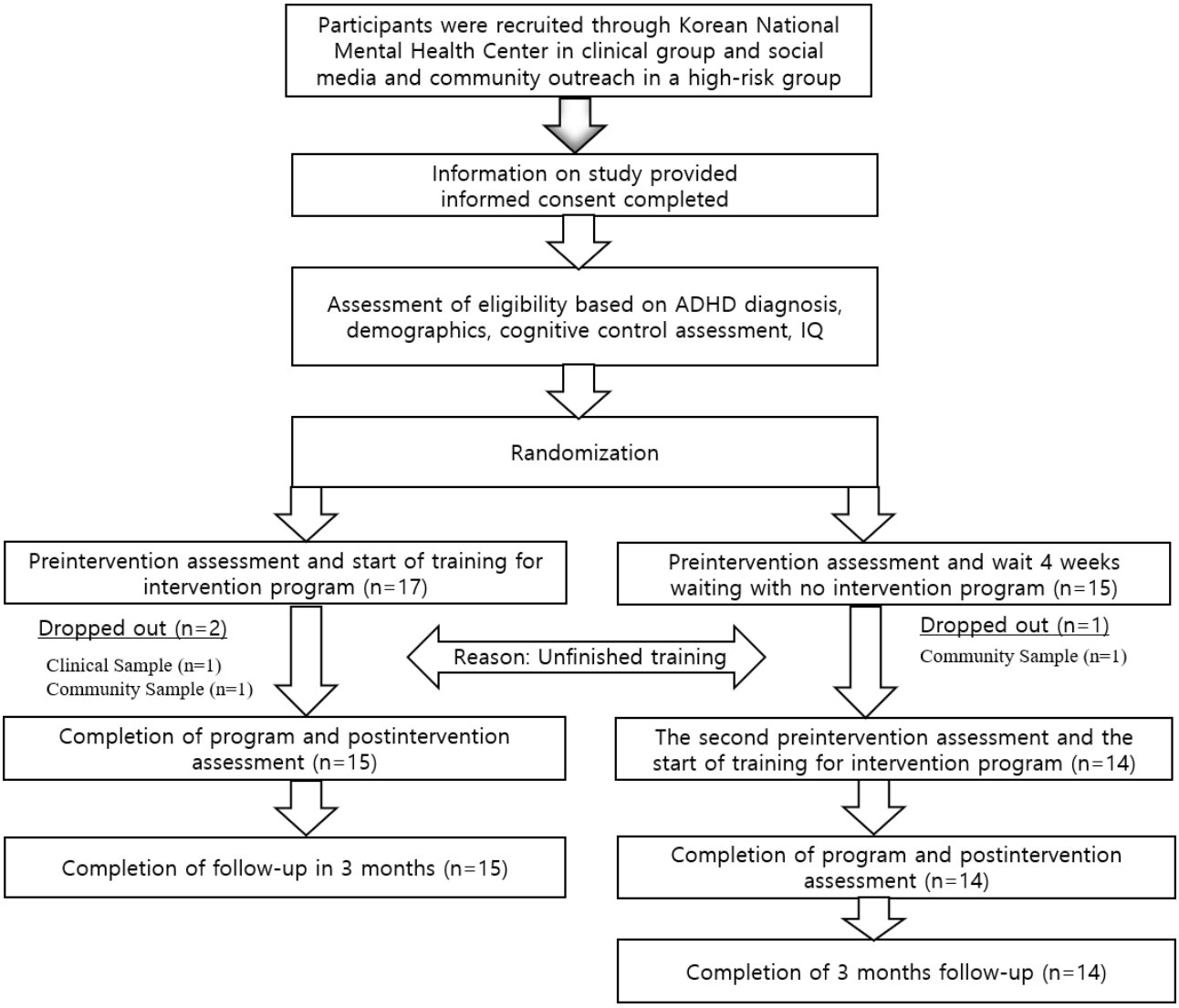
Basic data analysis indicated that the mean age of the participants was 11.3 (SD 1.13) years, with ages ranging from 10 to 14 years (no retest group: 11.1, SD 1.28 years; no training retest group: mean 11.5, SD 0.94 years). A visual representation of the entire process depicting subsequent posttests and follow-up assessments can be found in Figure 2. The mean total

XSL•FO
RenderX

IQ (K-WISC-IV) was 94.2 (SD 16.5; no retest group: mean 95.4, SD 15.97; no training retest group: 93, SD 17.62). The gender distribution among the 29 particpants comprised 21 (72%) boys and 8 (28%) girls. There was no significant group difference regarding gender ratio, with a chi-square (χ^2) test resulting in P=.07.

The retest effects, assessed using paired t tests, revealed no significant changes between initial assessments and reevaluations without intervention across various measures (t_{13}=−1.979, P=.07 for CTT 1; t_{13}=−0.711, P=.49 for CTT 2; t_{13}=−0.899, P=.39 for Flanker test from NIH toolbox; t_{13}=−1.773, P=.10 for Stroop test; t_{13}=1.224, P=.30 for CBCL Total score; t_{13}=1.694, P=.11 for CBCL Attention Problems score; and t_{13}=1.224, P=.24 for CBCL ADHD score).

Figure 2. Flow diagram of the study. ADHD: attention-deficit/hyperactivity disorder.



Effects of VR Training on Cognitive and Behavioral Measures

Table 1 details the observed training effects across pretest, posttest, and follow-up assessments. Repeated measures ANOVA revealed significant effects in the Stroop test ($F_{2,56}$=4.97; P=.01; ηp^2=0.151; pretest<posttest P=.006), CBCL Total Problems Score ($F_{2,56}$=21.0; P<.001; ηp^2=0.429; pretest<posttest P<.001; pretest<follow-up test P<.001), CBCL Attention Problems Score ($F_{2,56}$=11.7; P<.001; ηp^2=0.294; pretest<posttest P<.001; pretest<follow-up test P=.002), and CBCL ADHD score ($F_{2,56}$=3.46; P=.04; ηp^2=0.110; pretest<posttest P=.03). Figure 3 presents plots comparing the within-group results from the pretest, posttest, and follow-up tests, created using *ggplot2*. CTT1 and CTT2 and the Flanker test from the NIH toolbox did not demonstrate any significant effects among the pretest, posttest, and follow-up test.

XSL•FO
RenderX

Table . Repeated measures ANOVA results comparing pretest, posttest, and follow-up.

Measure and group	Pretest, mean (SD)	Posttest, mean (SD)	Follow-up, mean (SD)	*F* (*df*)	*P* value	ηp2
CTT[a]1				0.345 (2, 56)	.71	0.012
Total	54.6 (8.93)	55.9 (8.82)	55.9 (10.1)			
Group 1	57.3 (9.00)	58.8 (6.70)	58.8 (7.43)			
Group 2	51.7 (8.20)	56.3 (7.27)	52.9 (11.9)			
CTT2				1.29 (2, 56)	.28	0.044
Total	50.8 (7.29)	51.5 (8.82)	53.4 (8.86)			
Group 1	52.4 (7.02)	48.7 (11.7)	52.5 (7.86)			
Group 2	49.1 (7.43)	50.6 (10.5)	54.4 (10.0)			
Stroop Color-Word				4.97 (2, 56)	.01[b]	0.151
Total	49.8 (14.0)	56.7 (17.4)	55.6 (16.5)			
Group 1	52.6 (10.6)	56.9 (13.1)	54.6 (15.9)			
Group 2	46.9 (14.0)	56.4 (21.6)	56.7 (17.7)			
NIH[c] Flanker test				1.76 (2, 56)	.18	0.059
Total	104 (17.5)	109 (19.0)	107 (18.2)			
Group 1	101 (16.3)	106 (15.4)	103 (16.5)			
Group 2	107 (18.9)	110 (19.6)	112 (19.5)			
CBCL[d] Total Problems				21.0 (2, 56)	<.001[e]	0.429
Total	64.9 (9.26)	60.5 (9.23)	58.4 (7.94)			
Group 1	63.7 (9.43)	59.7 (11.2)	57.1 (8.76)			
Group 2	66.3 (9.22)	65.0 (9.47)	59.8 (7.01)			
CBCL Attentional Problems				11.7 (2, 56)	<.001[e]	0.294
Total	65.8 (7.61)	61.9 (7.10)	61.1 (7.99)			
Group 1	64.0 (5.59)	60.7 (7.45)	60.6 (7.70)			
Group 2	67.6 (9.15)	65.1 (8.48)	61.6 (7.70)			
CBCL ADHD[f]				3.46 (2, 56)	.03[b]	0.110
Total	66.0 (7.71)	63.0 (7.93)	62.6 (10.2)			
Group 1	64.3 (5.78)	61.5 (8.37)	61.8 (8.71)			
Group 2	67.9 (9.22)	66.6 (8.85)	63.5 (11.9)			

[a]CTT: Color Trails test.

[b]Statistically significant at $P<.05$.

[c]NIH: National Institutes of Health.

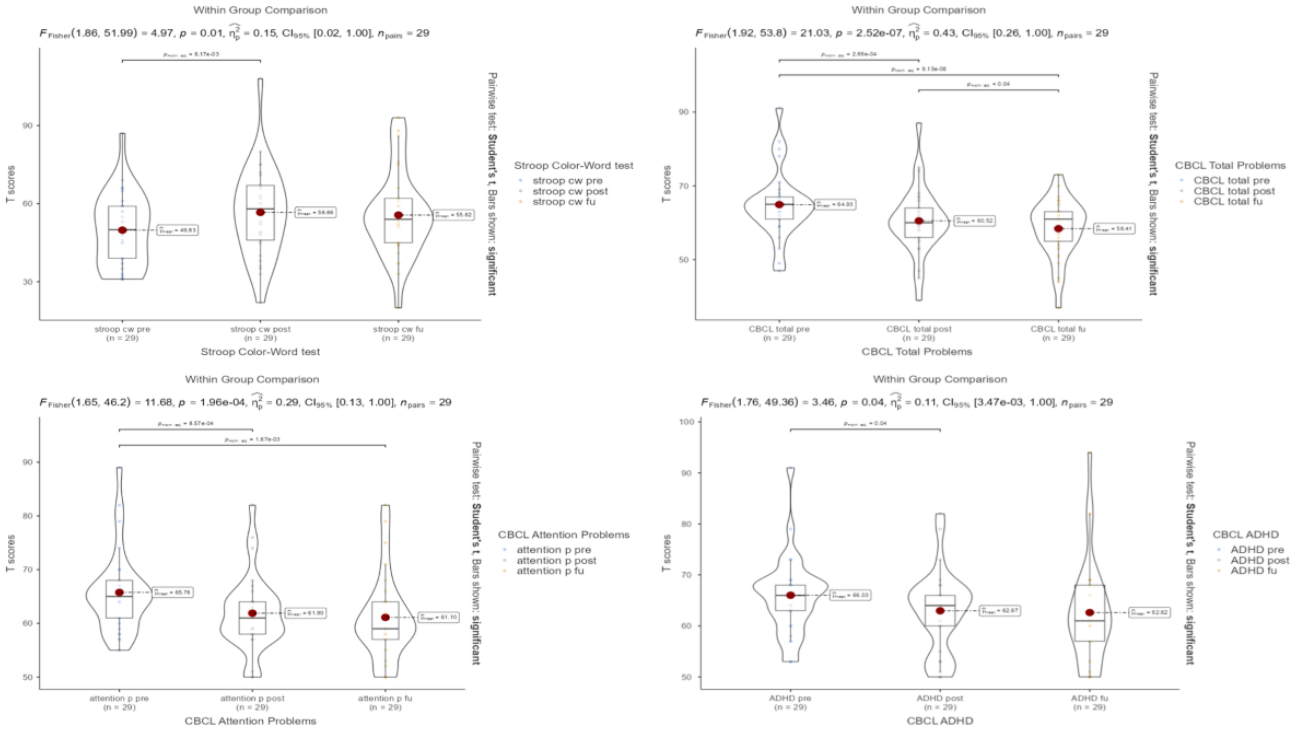
[d]CBCL: Child Behavior Checklist.

[e]Statistically significant at $P<.001$.

[f]ADHD: attention-deficit/hyperactivity disorder.

XSL•FO
RenderX

Figure 3. Scatterplots of Stroop test and CBCL subscale scores at pretest, posttest, and follow-up. ADHD: attention-deficit/hyperactivity disorder; CBCL: Child Behavior Checklist.



Analysis of Training Response Patterns

A Pearson correlation analysis revealed significant positive correlations between the correct response ratio and the difference scores on the CBCL Total Problems, Attention Problems, and ADHD scales. Furthermore, significant correlations were found between the mean correct response time and the difference scores on the Stroop Color-Word test, as well as the CBCL Attention Problems and ADHD scales. The total login frequency was also significantly correlated with the difference scores on all 3 CBCL scales (see Table S1 in Multimedia Appendix 3 for details). The k-means cluster analysis, which used *z* scores of the difference between pretest and follow-up on the Stroop test and CBCL scales, produced 2 distinct clusters. Cluster 1 (n=10) did not show significant improvement, while cluster 2 (n=19) exhibited overall improvements from pretest to follow-up. A comparative analysis did not reveal any significant differences between the 2 clusters in age or on the IQ-related indices. However, there was a borderline significant difference in gender distribution between the clusters (χ^2_1=3.84; *P*=.05). Furthermore, a significant association was found between sample type (clinical vs community) and cluster membership (χ^2_1=8.03; *P*=.005) (see Tables S1 and S2 in Multimedia Appendix 4 for details). In addition, there were significant differences in game-related behavioral variables, including mean correct response time (t_{27}=−2.56; *P*=.02) and the correct response ratio (t_{27}=2.60; *P*=.02). These results suggest that a longer correct response time and a lower correct response ratio were associated with better training outcomes. The detailed results are presented in Table 2 and Figure 4.

XSL•FO
RenderX

Table . Cluster comparisons of IQ and game-related variables.

Variable (cluster)	Mean (SD)	*t* test (*df*)	*P* value
Age		1.89 (27)	.07
1	11.8 (1.32)		
2	11.0 (0.94)		
K-WISC-IV[a]			
Verbal comprehension		–0.636 (27)	.53
1	97.2 (24.93)		
2	102.2 (17.62)		
Perceptual reasoning		0.84 (27)	.41
1	104.4 (14.27)		
2	99.1 (16.61)		
Working memory		–1.18 (27)	.25
1	86.2 (21.56)		
2	94.1 (14.35)		
Processing speed		1.66 (27)	.11
1	92.4 (14.29)		
2	84.4 (11.06)		
Total IQ		–0.03 (27)	.97
1	94.1 (21.97)		
2	94.3 (13.55)		
Total trials		–1.10 (27)	.32
1	2617.3 (2576.5)		
2	3055.2 (2793.0)		
Game-related variables			
Game performance			
Total RT[b]		–1.14 (27)	.17
1	3319.4 (2914.1)		
2	5036.2 (3531.6)		
Correct RT (mean)		–2.56 (27)	.02[c]
1	1.2 (1.16)		
2	1.4 (1.33)		
Correct response ratio		2.60 (27)	.02[c]
1	77.3 (78.2)		
2	67.7 (70.8)		
Game behavior			
Login frequency		–1.98 (27)	.06
1	71.6 (61.5)		
2	117.7 (95.0)		
Frequency of midgame exit		0.32 (27)	.74
1	118.4 (108.0)		
2	112.8 (114.0)		
The RT of the first response		0.84 (27)	.41

XSL•FO
RenderX

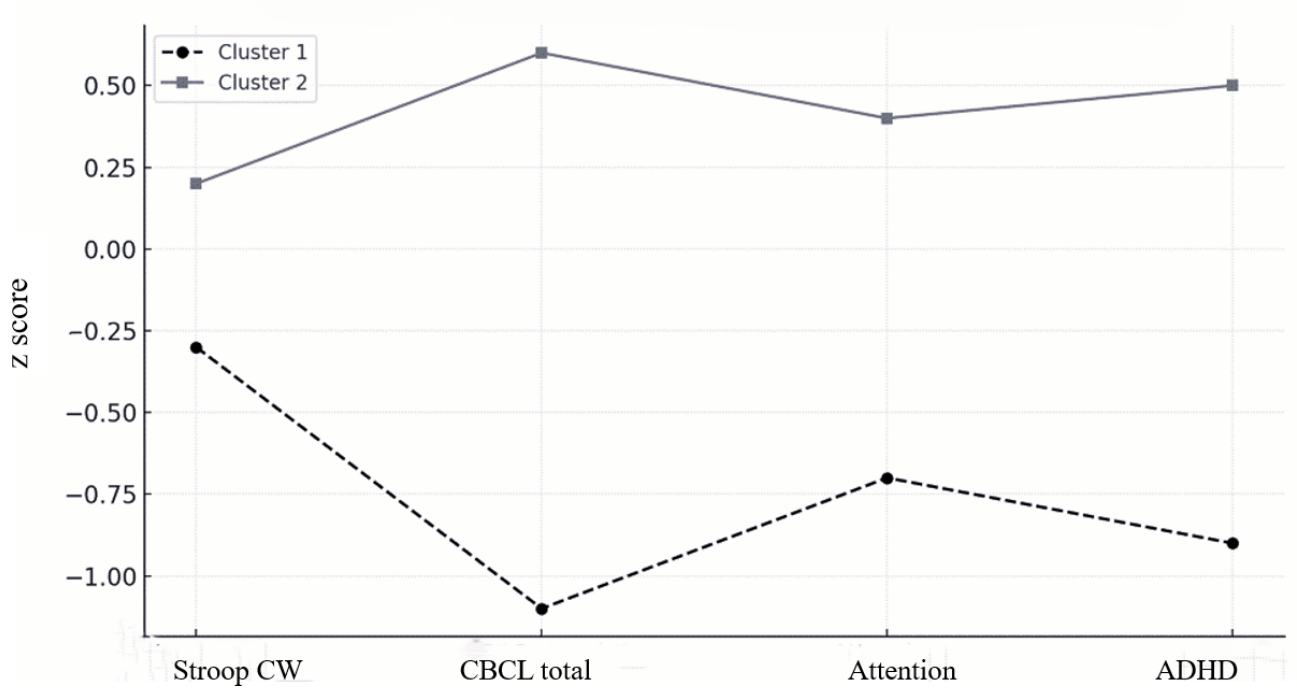
Variable (cluster)	Mean (SD)	*t* test (*df*)	*P* value
1	0.8 (0.505)		
2	0.6 (0.460)		

[a]K-WISC-IV: Korean Wechsler Intelligence Scale for Children, Fourth Edition.

[b]RT: reaction time.

[c]Statistically significant at $P<.05$.

Figure 4. Clusters identified based on *z* scores of changes from pretest to follow-up. ADHD: attention-deficit/hyperactivity disorder; CBCL: Child Behavior Checklist; CW: color-word



Discussion

Principal Findings

This pilot study provides preliminary evidence that a novel, at-home VR cognitive training game can significantly improve cognitive control and parent-reported ADHD symptoms in children. Notably, these therapeutic gains were sustained at a 3-month follow-up, and an analysis of a nonintervention group confirmed that the improvements were not solely attributable to test-retest effects. The study also demonstrated high feasibility. The integration of a telemonitoring system was effective in maintaining excellent adherence to the 20-day protocol, overcoming common challenges associated with remote interventions.

However, the Flanker test from the NIH toolbox and the CTT did not show significant training effects. This lack of significant findings may stem from the nature of these tasks, which primarily assess more automatic attentional processes, in contrast to the Stroop test, which targets controlled attention. Prior research has suggested that basic attention networks can exhibit unstable changes with repeated testing, making such measures potentially less sensitive to short-term training improvements [41]. A k-means clustering analysis was conducted based on changes observed in the Stroop Color-Word test, CBCL total behavioral scores, attentional problems, and ADHD symptom scores. This analysis revealed distinct patterns of training response among the identified clusters. Overall, the 2 clusters displayed contrasting trends: one group demonstrated a positive training effect, while the other showed no clear improvement. Notably, there were no significant differences in age and IQ indices between the clusters, suggesting that age and general intelligence did not account for the observed variability in training outcomes. Interestingly, the positively responding cluster exhibited longer correct response times and lower correct response ratios compared to the nonresponsive group. Although these findings appear counterintuitive, they may reflect greater engagement or more sincere participation, indicated by a higher number of total trials and longer reaction times, which could underlie the observed improvements. Notably, a significant association was found between the participant source (clinical vs community) and training response, with the community sample being less responsive to the training than the clinical sample. While the baseline assessment showed no significant differences between the 2 groups in IQ, age, or attention-related problems, the difference in training outcomes may suggest lower motivation in the community sample. However, given the small size of the community group, this interpretation is speculative and requires further investigation.

XSL•FO
RenderX

Limitations

Despite these compelling findings, several critical limitations must be acknowledged. First, the study lacked a control group, which limits the ability to draw causal conclusions about the effects of the training. The within-subjects design, without a parallel control, restricts the interpretation of training efficacy in a more systematic and rigorous manner. Second, the relatively small sample size (N=29), along with imbalanced participant characteristics, particularly in terms of gender distribution and medication status, reduces the generalizability and statistical power of the findings. Third, the study did not assess higher-order cognitive functions, such as executive functioning. Incorporating such measures could have provided a more comprehensive understanding of the relationship between neuropsychological test performance and parent-reported behavioral outcomes.

Conclusion

In conclusion, the newly developed VR-based cognitive control game, enhanced with a modified adaptive staircase algorithm and supported by a telemonitoring system, demonstrated its potential as an accessible and effective at-home intervention for children with ADHD symptoms. Building on research showing that user characteristics influence engagement with tele-mental health services [42], an important next step is to explore which specific user profiles benefit most from this VR-based intervention.

Acknowledgments

This study was funded by the Bio & Medical Technology Development Program of the National Research Foundation funded by the Korean government (Ministry of Science and ICT; grant 2017M3C7A1031974) and the Korea Health Technology R&D Project through the Korea Health Industry Development Institute, funded by the Ministry of Health & Welfare, Republic of Korea (grant HI22C0775). The funding agencies had no role in the study design; the collection, analysis, and interpretation of data; the writing of the report; and the decision to submit the article for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Comparisons between clinical and community participants.
[DOCX File, 19 KB - pediatrics_v8i1e66617_app1.docx]

Multimedia Appendix 2
Institutional review board approval.
[PDF File, 120 KB - pediatrics_v8i1e66617_app2.pdf]

Multimedia Appendix 3
Correlations between game behavior and difference scores of major measurements.
[DOCX File, 18 KB - pediatrics_v8i1e66617_app3.docx]

Multimedia Appendix 4
Contingency tables of cluster memberships.
[DOCX File, 18 KB - pediatrics_v8i1e66617_app4.docx]

References

1. Zipfel S, Lutz W, Schneider S, Schramm E, Delgadillo J, Giel KE. The future of enhanced psychotherapy: towards precision mental health. Psychother Psychosom 2024;93(4):230-236. [doi: 10.1159/000539022] [Medline: 38934154]
2. Kollins SH, DeLoss DJ, Cañadas E, et al. A novel digital intervention for actively reducing severity of paediatric ADHD (STARS-ADHD): a randomised controlled trial. Lancet Digit Health 2020 Apr;2(4):e168-e178. [doi: 10.1016/S2589-7500(20)30017-0] [Medline: 33334505]
3. Ziegler DA, Anguera JA, Gallen CL, Hsu WY, Wais PE, Gazzaley A. Leveraging technology to personalize cognitive enhancement methods in aging. Nat Aging 2022 Jun;2(6):475-483. [doi: 10.1038/s43587-022-00237-5] [Medline: 35873177]
4. Ressler KJ, Williams LM. Big data in psychiatry: multiomics, neuroimaging, computational modeling, and digital phenotyping. Neuropsychopharmacol 2021 Jan;46(1):1-2. [doi: 10.1038/s41386-020-00862-x]
5. Dwivedi YK, Hughes L, Baabdullah AM, et al. Metaverse beyond the hype: multidisciplinary perspectives on emerging challenges, opportunities, and agenda for research, practice and policy. Int J Inf Manage 2022 Oct;66:102542. [doi: 10.1016/j.ijinfomgt.2022.102542]

XSL•FO
RenderX

6. Li J, Yang H, Li F, Wu J. Application of virtual reality technology in psychotherapy. Presented at: 2020 International Conference on Intelligent Computing and Human-Computer Interaction (ICHCI); Dec 4-6, 2020; Sanya, China p. 359-362. [doi: 10.1109/ICHCI51889.2020.00082]
7. Rizzo AS, Shilling R. Application of virtual reality technology in psychotherapy. Curr Psychiatry Rep 2017;19(11). [doi: 10.1007/s11920-017-0846-9]
8. Ball C, Huang KT, Francis J. Virtual reality adoption during the COVID-19 pandemic: a uses and gratifications perspective. Telemat Inform 2021 Dec;65:101728. [doi: 10.1016/j.tele.2021.101728] [Medline: 34887619]
9. David EJ, Beitner J, Võ MLH. The importance of peripheral vision when searching 3D real-world scenes: a gaze-contingent study in virtual reality. J Vis 2021 Jul 6;21(7):3. [doi: 10.1167/jov.21.7.3] [Medline: 34251433]
10. Riva G. Virtual reality in clinical psychology. In: Comprehensive Clinical Psychology, 2nd edition: Elsevier; 2022, Vol. 10:91-105. [doi: 10.1016/B978-0-12-818697-8.00006-6]
11. Carl E, Stein AT, Levihn-Coon A, et al. Virtual reality exposure therapy for anxiety and related disorders: a meta-analysis of randomized controlled trials. J Anxiety Disord 2019 Jan;61:27-36. [doi: 10.1016/j.janxdis.2018.08.003] [Medline: 30287083]
12. Jeong E, Ham Y, Lee SJ, Shin JH. Virtual reality-based music attention training for acquired brain injury: a randomized crossover study. Ann N Y Acad Sci 2024 Nov;1541(1):151-162. [doi: 10.1111/nyas.15249] [Medline: 39476208]
13. Xu D, Liu Y, Zeng Y, Liu D. Virtual reality in adolescent mental health management under the new media communication environment. Humanit Soc Sci Commun 2025;12(1):201. [doi: 10.1057/s41599-025-04528-1]
14. Bioulac S, Micoulaud-Franchi JA, Maire J, et al. Virtual remediation versus methylphenidate to improve distractibility in children with ADHD: a controlled randomized clinical trial study. J Atten Disord 2020 Jan;24(2):326-335. [doi: 10.1177/1087054718759751] [Medline: 29562853]
15. Evans SW, Owens JS, Bunford N. Evidence-based psychosocial treatments for children and adolescents with attention-deficit/hyperactivity disorder. J Clin Child Adolesc Psychol 2014;43(4):527-551. [doi: 10.1080/15374416.2013.850700] [Medline: 24245813]
16. Baweja R, Soutullo CA, Waxmonsky JG. Review of barriers and interventions to promote treatment engagement for pediatric attention deficit hyperactivity disorder care. World J Psychiatry 2021 Dec 19;11(12):1206-1227. [doi: 10.5498/wjp.v11.i12.1206] [Medline: 35070771]
17. Spooner DM, Pachana NA. Ecological validity in neuropsychological assessment: a case for greater consideration in research with neurologically intact populations. Arch Clin Neuropsychol 2006 May;21(4):327-337. [doi: 10.1016/j.acn.2006.04.004] [Medline: 16769198]
18. Corrigan N, Păsărelu CR, Voinescu A. Immersive virtual reality for improving cognitive deficits in children with ADHD: a systematic review and meta-analysis. Virtual Real 2023 Feb 18;27:1-20. [doi: 10.1007/s10055-023-00768-1] [Medline: 36845650]
19. Gratton G, Cooper P, Fabiani M, Carter CS, Karayanidis F. Dynamics of cognitive control: theoretical bases, paradigms, and a view for the future. Psychophysiology 2018 Mar;55(3):e13016. [doi: 10.1111/psyp.13016] [Medline: 29044552]
20. Miller EK. The prefrontal cortex and cognitive control. Nat Rev Neurosci 2000 Oct;1(1):59-65. [doi: 10.1038/35036228] [Medline: 11252769]
21. Nyberg L. Cognitive control in the prefrontal cortex: a central or distributed executive? Scand J Psychol 2018 Feb;59(1):62-65. [doi: 10.1111/sjop.12409] [Medline: 29356013]
22. Carr L, Henderson J, Nigg JT. Cognitive control and attentional selection in adolescents with ADHD versus ADD. J Clin Child Adolesc Psychol 2010;39(6):726-740. [doi: 10.1080/15374416.2010.517168] [Medline: 21058121]
23. Solomon M, Ozonoff SJ, Cummings N, Carter CS. Cognitive control in autism spectrum disorders. Int J Dev Neurosci 2008 Apr;26(2):239-247. [doi: 10.1016/j.ijdevneu.2007.11.001] [Medline: 18093787]
24. Zhu Y, Liu L, Yang D, et al. Cognitive control and emotional response in attention-deficit/ hyperactivity disorder comorbidity with disruptive, impulse-control, and conduct disorders. BMC Psychiatry 2021 May 4;21(1):232. [doi: 10.1186/s12888-021-03221-2] [Medline: 33947370]
25. Durston S, de Zeeuw P, Staal WG. Imaging genetics in ADHD: a focus on cognitive control. Neurosci Biobehav Rev 2009 May;33(5):674-689. [doi: 10.1016/j.neubiorev.2008.08.009] [Medline: 18789356]
26. Friedman NP, Robbins TW. The role of prefrontal cortex in cognitive control and executive function. Neuropsychopharmacology 2022 Jan;47(1):72-89. [doi: 10.1038/s41386-021-01132-0] [Medline: 34408280]
27. Everard G, Vermette M, Dumas-Longpré E, et al. Self-adaptive over progressive non-adaptive immersive virtual reality serious game to promote motor learning in older adults - A double blind randomized controlled trial. Neuroscience 2025 Apr 6;571:7-18. [doi: 10.1016/j.neuroscience.2025.02.053] [Medline: 40021077]
28. Sarai G, Jayaraman PP, Tirosh O, Wickramasinghe N. Exploring virtual reality and exercise simulator interventions in patients with attention deficit hyperactivity disorder: comprehensive literature review. JMIR Serious Games 2025 Jan 29;13:e57297. [doi: 10.2196/57297] [Medline: 39879092]
29. Fang H, Fang C, Che Y, Peng X, Zhang X, Lin D. Reward feedback mechanism in virtual reality serious games in interventions for children with attention deficits: pre- and posttest experimental control group study. JMIR Serious Games 2025 Feb 24;13:e67338. [doi: 10.2196/67338] [Medline: 39993290]

XSL•FO
RenderX

30. Song H, Yi DJ, Park HJ. Validation of a mobile game-based assessment of cognitive control among children and adolescents. PLoS ONE 2020;15(3):e0230498. [doi: 10.1371/journal.pone.0230498] [Medline: 32196531]
31. Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods 2007 May;39(2):175-191. [doi: 10.3758/bf03193146] [Medline: 17695343]
32. Kwak KJ, Oh SW, Kim CT. Korean Version Wechsler Intelligence Scale for Children-IV: HakJiSa; 2011.
33. Koo HJ, Shin MS. Korean Color Trails Test Children's Version: HakJiSa; 2008.
34. Shin MS, Park MJ. Korean Color and Word Test Children's Version: HakJiSa; 2006.
35. Toolbox for assessment of neurological and behavioral function. National Institutes of Health. 2012. URL: https://www.healthmeasures.net/explore-measurement-systems/nih-toolbox [accessed 2025-08-06]
36. Oh K, Lee H, Hong K, et al. Korean Version of Child Behavior Checklist (K-CBCL): Chungang Aptitude Publishing Co. Ltd; 1997.
37. Achenbach TM. Child behavior checklist and related instruments. In: Maruish ME, editor. The Use of Psychological Testing for Treatment Planning and Outcome Assessment: Lawrence Erlbaum Associates, Inc; 1994:517-549.
38. The jamovi project. Jamovi (Version 23). 2023. URL: https://www.jamovi.org [accessed 2025-08-06]
39. Wickham H, Chang W, Henry L, et al. Ggplot2: create elegant data visualisations using the grammar of graphics. CRAN. 2018. URL: https://CRAN.R-project.org/package=ggplot2 [accessed 2025-08-06]
40. Patil I. Ggstatsplot: "ggplot2" based plots with statistical details. CRAN. 2018. URL: https://CRAN.R-project.org/package=ggstatsplot [accessed 2025-08-06]
41. The unstability of attentional network in the schizophrenic patients. Kor J Clin Psychol 2007 Aug;26(3):693-702. [doi: 10.15842/kjcp.2007.26.3.009]
42. Neumann A, König HH, Hajek A. Determinants of patient use of telemental health services: representative cross-sectional survey from Germany. JMIR Ment Health 2025 Jun 13;12:e70925. [doi: 10.2196/70925] [Medline: 40513010]

Abbreviations

ADHD: attention-deficit/hyperactivity disorder
CBCL: Child Behavior Checklist
CTT: Color Trails test
K-CBCL: Korean Child Behavior Checklist
K-WISC-IV: Korean Wechsler Intelligence Scale for Children, Fourth Edition
NIH: National Institutes of Health
PRI: perceptual reasoning index
PSI: processing speed index
PSI: processing speed index
VCI: verbal comprehension index
VR: virtual reality
WMI: working memory index

Edited by S Badawy; submitted 18.09.24; peer-reviewed by KP Wong, OR Runswick, S Persky; revised version received 11.07.25; accepted 18.07.25; published 19.09.25.

Please cite as:
Song H, Oh Y, Choi J, Ohm SY
Effectiveness of Virtual Reality–Based Cognitive Control Training Game for Children With Attention-Deficit/Hyperactivity Disorder Symptoms: Preliminary Effectiveness Study
JMIR Pediatr Parent 2025;8:e66617
URL: https://pediatrics.jmir.org/2025/1/e66617
doi:10.2196/66617

© Hyunjoo Song, Yunhye Oh, JongIn Choi, Seong-Yong Ohm. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 19.9.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Evaluating Telepsychiatric Assessment Satisfaction in Children and Adolescents With Autism Spectrum Disorder and Attention-Deficit/Hyperactivity Disorder and Their Caregivers: Randomized Controlled Trial

Shunya Kurokawa[1*], MD, PhD; Yuko Kawade[2*], MD; Kensuke Nomura[2], MD, PhD; Nana Hosogane[3], MD; Takashi Nagasawa[4], MD; Yu Matsumoto[2], MD; Shuichi Morinaga[5], MD; Yuriko Kaise[5], MA; Ayana Higuchi[5], MA; Akiko Goto[6], MD, PhD; Naoko Inada[7], MA, PhD; Masaki Kodaira[3], MD, PhD; Taishiro Kishimoto[1], MD, PhD

[1]Center for the Promotion of Interdisciplinary Research in Medicine and Life Science, Keio University School of Medicine, Mori JP Tower F7, 1-3-1, Azabudai, Minato-ku, Tokyo, Japan

[2]Department of Child Psychiatry, Shimada Ryoiku Medical Center for Challenged Children, Tokyo, Japan

[3]Department of Child and Adolescent Mental Health, Aiiku Clinic, Tokyo, Japan

[4]Department of Child and Adolescent Psychiatry, Tokyo Metropolitan Children's Medical Center, Tokyo, Japan

[5]Department of Neuropsychiatry, Keio University School of Medicine, Tokyo, Japan

[6]Tsurugaoka Garden Hospital, Tokyo, Japan

[7]Department of Clinical Psychology, Taisho University, Tokyo, Japan

[*]these authors contributed equally

Corresponding Author:
Taishiro Kishimoto, MD, PhD
Center for the Promotion of Interdisciplinary Research in Medicine and Life Science, Keio University School of Medicine, Mori JP Tower F7, 1-3-1, Azabudai, Minato-ku, Tokyo, Japan

Abstract

Background: Children and adolescents with attention-deficit/hyperactivity disorder (ADHD) and autism spectrum disorder (ASD) often face structural and psychological barriers in accessing medical care, including economic costs, long wait times, and stress of attending new medical environments. The COVID-19 pandemic accelerated the adoption of telehealth services to overcome these challenges. However, few studies have assessed the satisfaction levels of children and adolescents diagnosed with neurodevelopmental disorders and their caregivers when they use telepsychiatry, particularly in Japan.

Objective: This study aimed to evaluate satisfaction by conducting telepsychiatric assessments in children and adolescents diagnosed with ADHD or ASD and their caregivers and to identify factors associated with higher satisfaction levels.

Methods: A total of 68 patients aged 6 - 17 years with a confirmed diagnosis of ADHD or ASD and their caregivers participated in this study. The participants were recruited from Keio University Hospital and four collaborating institutions in Japan. Each patient and their caregiver underwent two assessment sessions, one face-to-face and the other via telepsychiatric assessment (a remote video tool), in a randomized order. Upon completing both assessments, the participants completed a satisfaction questionnaire using a 5-point Likert scale that covered aspects such as audio and video quality, seamless communication, perceived warmth, reduced burden, and the ability to behave naturally. Spearman rank correlation coefficients and multiple regression analyses were performed to identify factors associated with overall satisfaction.

Results: Among the patients, 70% (47/67) reported being “satisfied” or “very satisfied” with the telepsychiatric assessment, and 88% (60/68) of caregivers reported similar satisfaction levels. Multiple regression analysis showed that in children, high satisfaction was associated with seamless viewing of the screen, reduced burden of hospital visits, and the ability to speak naturally during the assessment. For caregivers, visual clarity and the child’s natural behavior were crucial factors.

Conclusions: Telepsychiatric assessments are an effective and practical option to provide care for children and adolescents diagnosed with ADHD or ASD and their caregivers, offering high levels of satisfaction. Technical reliability and reduced travel burden significantly contributed to positive experiences. However, ensuring that children and adolescents behave naturally and feel a sense of warmth during remote assessment is crucial to maximizing their satisfaction. Telepsychiatric services can enhance the quality of health care, making them valuable supplementary tools for clinical practice.

Trial Registration: UMIN Clinical Trials Registry UMIN000039860; https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000045415

XSL•FO
RenderX

(JMIR Pediatr Parent 2025;8:e69791) doi:10.2196/69791

KEYWORDS

attention-deficit/hyperactivity disorder; autism spectrum disorder; telepsychiatry; telehealth; caregivers; ADHD; ASD; mobile phone

Introduction

Neurodevelopmental disorders, including attention-deficit/hyperactivity disorder (ADHD) and autism spectrum disorder (ASD), are complex disorders caused by genetic and environmental factors. Early detection and intervention are crucial to prevent comorbidities, such as anxiety and depression [1,2]. Children and adolescents with neurodevelopmental conditions and their families frequently encounter structural and psychological barriers to obtaining medical treatment.

Structural barriers include economic costs [3,4], taking time off work [5], lack of treatment availability owing to a shortage of trained psychiatrists [6,7], and long-distance travel to specialized clinics [8]. Psychological barriers that impede engagement with neurodevelopmental disorder services include direct caregiver distress, the stigma associated with ASD and ADHD and their treatment [9,10], and low self-efficacy in accessing and implementing treatment [11]. For children and adolescents with neurodevelopmental disorders, traveling to medical appointments and being in unfamiliar medical settings can worsen behavioral problems and increase psychological stress [12].

In recent years, the development of information and communication technology has led to the widespread adoption of telehealth, in which individuals communicate via video calls over long distances. During the COVID-19 pandemic, in-person medical care was limited owing to the increased risk of infection from face-to-face contact. As an alternative, telepsychiatry proved to be an effective method in psychiatric care. This is attributable to most psychiatric assessments and treatments relying on medical interviews, behavioral observations, and patient conversations.

Numerous studies have reported high satisfaction with the use of telepsychiatry in the field of psychiatry [13,14]. However, few studies have focused on children with neurodevelopmental disorders. The treatment setting for children with ASD conditions and intellectual developmental disorders at a pediatric hospital in the United States during the COVID-19 pandemic received a 91% satisfaction rate for telepsychiatric health assessments [8]. Reisinger et al [15] investigated the satisfaction of telehealth assessments in children with ASD. They found that 88% of caregivers reported being satisfied with the assessments, with some implications for factors related to satisfaction. Galvin et al [16] surveyed caregivers of children with ADHD in Ireland regarding their satisfaction with the remote consultations they had received. Most participants (62.3%) reported being comfortable communicating with their health care professionals via telehealth consultations, and only 34.4% reported that their child was comfortable communicating through their telehealth experience. However, responses were not directly obtained from the children.

Despite the above reports, few studies have investigated satisfaction with telepsychiatry among children with ASD and ADHD and their caregivers, particularly in Japan. Studies on the advantages and disadvantages of using remote assessment for neurodevelopmental disorders in children remain limited, particularly regarding the satisfaction of children undergoing the assessment. Previously, we reported the reliability of remote ADHD assessment compared to face-to-face assessment in children with ASD or ADHD and their caregivers [17]. We used intraclass correlation coefficients to confirm that the assessments conducted remotely were comparable to those conducted face-to-face. This study aimed to examine the acceptance of remote evaluations by end users, particularly children with ASD or ADHD and their caregivers, and identify the factors associated with higher satisfaction.

Methods

Participants

Kurokawa et al [17] provide a detailed description of the related research methodologies. Patients were recruited at the Keio University Hospital and four collaborating institutions (Shimada Ryoiku Medical Center for Challenged Children, Aiiku Clinic, Tokyo Metropolitan Children's Medical Center, and Tsurugaoka Garden Hospital). The inclusion criteria were as follows: (1) confirmation of the Diagnostic and Statistical Manual of Mental Disorders diagnoses of ADHD and ASD, (2) age 6 - 17 years at the time of obtaining consent, and (3) stable treatment for 3 months before obtaining consent. The exclusion criteria were as follows: (1) either the child or caregiver had a hearing or visual impairment that made it challenging to use remote tools, even with corrective devices, such as glasses or hearing aids; (2) caregivers did not have the information related to the participants' early childhood; (3) comorbid symptoms, such as hallucinations and delusions, made it challenging to involve the participants in the study, as determined by the clinician; and (4) there were plans to initiate new treatments, such as pharmacotherapy or psychotherapy, during the observation period. This study was conducted in line with CONSORT (Consolidated Standards of Reporting Trials) guidelines (Checklist 1).

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and the Ethical Guidelines for Medical and Health Research Involving Human Subjects (Japan). Informed consent was obtained from all the caregivers. For children, an informed consent form that was tailored to their age and understanding was used, and written confirmation of their consent was obtained after careful explanation. Regarding confidentiality, a designated data manager assigned each participant a unique study

XSL•FO
RenderX

identification number and managed all records exclusively under this number thereafter. The correspondence table linking personal identifiers to study IDs was stored either in a locked cabinet within the Department of Psychiatry and Neurobiology at Keio University School of Medicine or on a password-protected computer with restricted access. All subsequently collected data and background patient information (eg, diagnosis, sex, and age) were handled solely by study ID and were completely separated from personal identifiers, such as participants' names, dates of birth, patient numbers, or addresses. The study protocol was approved by the Ethics Committee of Keio University School of Medicine (20190301). This study is registered in the UMIN Clinical Trial Registry (UMIN000039860).

Study Procedure

For baseline evaluation, the Autism-Spectrum Quotient–Japanese version for children, Conners 3 Japanese version to evaluate ADHD symptoms by caregivers, Strengths and Difficulties Questionnaire to assess social adaptation, and Short Sensory Profile to assess sensory characteristics were administered. Background information and data such as age, sex, diagnosis, medication, duration of illness, and intelligence test results were collected from medical records.

Patients and caregivers underwent assessments twice on different days, either face-to-face or remotely, in randomized order. The remote smartphone assessment tool "Curon" (MICIN Co Ltd) was used for the telepsychiatric assessment. The participants were seated in front of a smartphone in their homes and introduced to a remote evaluator. Remote evaluators administered their evaluations from a room at the Keio University Hospital using a personal computer. Assessments began after confirming the absence of interruptions in the video or audio environment. None of the raters was involved in the participants' assessments or treatment during their usual visits.

Upon completing the face-to-face and remote assessments, the participants were provided with a questionnaire to report their satisfaction with the assessment.

Satisfaction Questionnaire

The survey assessed the levels of satisfaction and feasibility associated with the use of telehealth tools during assessment interviews. A 5-point Likert scale ranging from 1=strongly disagree to 5=strongly agree was used to collect responses. The questions covered include: (1) audibility during telehealth assessments, (2) clarity of video presentation, (3) communication issues compared to in-person assessments, (4) lack of warmth or personal touch that made the patient feel uneasy, (5) perceived benefits of less time and burden compared to in-person hospital visits, and (6) whether the child could behave naturally compared to a face-to-face assessment. The participants were allowed to provide free-text comments on each item to illustrate their experiences.

Statistics

Analyses were conducted to identify the crucial factors related to overall satisfaction with the telehealth tools used by patients and their caregivers. Spearman rank correlation coefficients were used to identify factors strongly associated with overall satisfaction with remote assessment among patients and caregivers. These factors included age, sex, diagnosis, severity of ASD and ADHD, other survey items, waiting time for the initial consultation, and travel time to clinic appointments. The Wilcoxon rank sum test was used for binary categorical data.

Subsequently, multiple regression analysis was conducted to examine the factors associated with overall satisfaction. Variables showing strong correlations in the preliminary exploratory data analyses and those based on theoretical grounds were selected using a forced-entry method to develop the models. Separate models were developed for the patients and caregivers. For patients, the analysis included age, sex, main diagnosis, clarity of auditory and visual reception, difficulty in expression, sense of warmth, perceived reduction in time and psychological burden compared with usual care, and seamless speaking naturally. The variance inflation factor was calculated to address multicollinearity, with variables exceeding a variance inflation factor of 10 being excluded from the model. Data analysis was performed using SPSS Statistics (version 28; IBM Corp). The significance level was set at .05. All statistical tests were 2-tailed.

Results

The study initially enrolled 75 participants but concluded with 74, as one participant dropped out owing to scheduling conflicts over the 3-month period. Upon excluding 16 individuals for whom comprehensive satisfaction survey data were not obtained, 68 children and their caregivers were included in the analysis (Figure 1).

XSL•FO
RenderX

Figure 1. CONSORT diagram of participant flow through the study. ADHD: attention-deficit/hyperactivity disorder; ASD: autism spectrum disorder; CONSORT: Consolidated Standards of Reporting Trials.

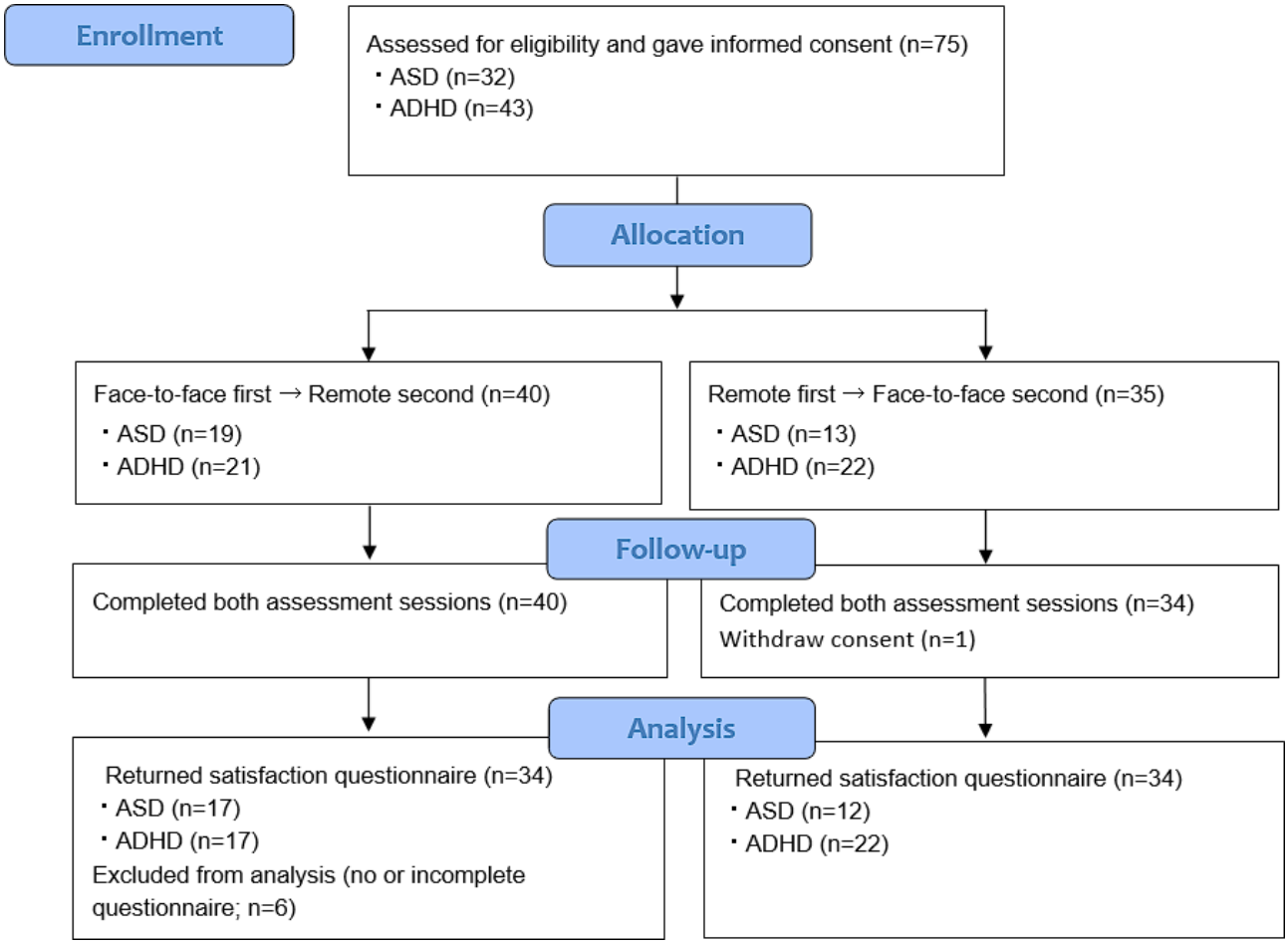


Table 1 presents the mean data. The sex distribution was predominantly male, with 53 (78%) male and 15 (22%) female participants. The primary clinical diagnoses were ASD in 29 (43%) individuals and ADHD in 39 (57%), with 18 (27%) participants having comorbid ASD and ADHD.

XSL•FO
RenderX

Table . Participant demographics.

	All (n=68)	ADHD[a] (n=39)	ASD[b] (n=29)	*P* value
Sex (female), n (%)	15 (22)	10 (26)	5 (17)	.41
Age (years), mean (SD)	10.2 (2.4)	10.5 (2.4)	9.8 (2.2)	.19
SDQ[c], mean (SD)	21.52 (4.88)	20.55 (4.99)	22.68 (4.57)	.09
AQ[d], mean (SD)	24.30 (7.32)	22.42 (6.47)	26.86 (7.75)	.02
Conners 3, mean (SD)	110.35 (37.05)	104.24 (67.60)	117.79 (35.64)	.15
SSP[e], mean (SD)	70.65 (20.60)	66.84 (20.63)	75.52 (19.87)	.09
CARS-2[f] (face-to-face), mean (SD)	36.15 (4.95)	34.36 (4.61)	38.50 (4.43)	<.001
ADHD-RS-IV[g] total (face-to-face), mean (SD)	27.29 (10.02)	26.55 (10.57)	28.29 (9.33)	.48
ADHD-RS-IV hyperactivity/impulsiveness (face-to-face), mean (SD)	7.91 (6.20)	7.63 (6.68)	8.29 (5.58)	.67
ADHD-RS-IV total inattention (face-to-face), mean (SD)	19.38 (5.31)	18.92 (5.47)	20.00 (5.11)	.41

[a]ADHD: attention-deficit/hyperactivity disorder.

[b]ASD: autism spectrum disorder.

[c]SDQ: Strengths and Difficulties Questionnaire.

[d]AQ: Autism Spectrum Quotientt.

[e]SSP: short sensory profile.

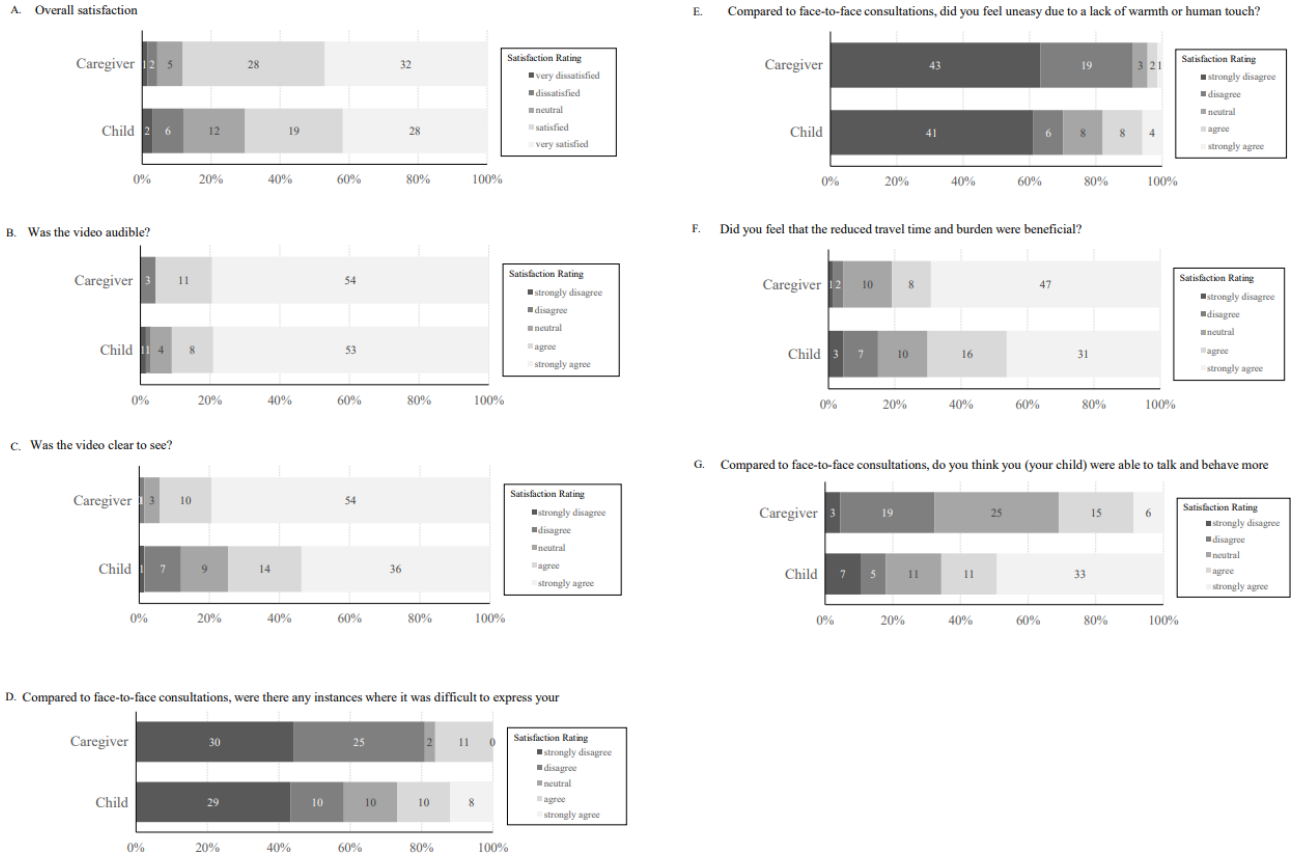
[f]CARS-2: Childhood Autism Rating Scale-2.

[g]ADHD-RS-IV: attention-deficit/hyperactivity disorder rating scale-IV.

Figure 2 shows the responses of patients and their caregivers to each question. Additionally, 70% (47/67) of children reported being “satisfied” or “very satisfied.” Among caregivers, 88% (60/68) reported being “satisfied” or “very satisfied.” Regarding seamless hearing, 91% (61/67) of the children answered that they could “hear well,” “hear very well.” For caregivers, 96% (65/68) responded with “hear well” or “hear very well.” Regarding screen visibility, 75% (50/67) of children found it “easy to see” or “very easy to see.” Similarly, 94% (64/68) of caregivers found the screen “easy to see” or “very easy to see.” Regarding difficulties in communicating during the interviews, 58% (39/67) of children responded “not at all” or “no” regarding whether it was challenging to express themselves compared to face-to-face assessments. Among caregivers, 81% (55/68) responded “not at all” or “no.”

XSL•FO
RenderX

Figure 2. Responses of patients and their caregivers to each question. (A) Overall satisfaction, (B) seamless hearing (voice), (C) seamless seeing (video), (D) comparison of face-to-face consultation with seamless expression of message, (E) comparison of face-to-face consultation with warmth or physical touch, (F) comparison of face-to-face consultation with reduced time travel, and (G) comparison of face-to-face consultation with children's ability to walk and behave naturally.



When asked if they felt uneasy owing to a lack of warmth or connection compared to face-to-face assessments, 70% (47/67) of children answered "not at all" or "no." For caregivers, 91% (62/68) responded "not at all" or "no."

Regarding the reduced time and burden of traveling for appointments, 70% (47/67) of children felt it was "beneficial" or "very beneficial." Among caregivers, 81% (55/68) reported it was "beneficial" or "very beneficial." Regarding their feeling that they could act naturally, 66% (44/67) of children responded "agree" or "strongly agree." However, only 31% (21/68) of the caregivers responded "agree" or "strongly agree." Regarding security concerns, 76% (52/68) of the caregivers responded "not at all" or "no."

In the free text, responses highlighted that for some children and caregivers, being at home facilitated relaxation during the assessment interviews, indicating that the home environment positively affected the participants' experience.

Many responses from the free text indicated that the caregivers were relieved about saving time. They reported that they had to consider the time for the patient's appointment, as well as the travel time, while managing other children's schedules. Some caregivers expressed psychological stress as follows: "I have to take my child out of school for appointments, and I always struggle with whether I must prioritize their medical care or their education because the visits are often on weekdays."

The caregivers had different opinions, including how "the child's behavior was too relaxed during the remote assessment and differed from their in-person assessment," whereupon they questioned the validity of the assessment. The difficulty of securing a private space yielded dissatisfaction with remote assessments. Some caregivers expressed difficulty with regard to the child exhibiting abnormal behavior in the presence of other family members owing to the lack of privacy during remote assessment.

Subsequently, the factors correlated with overall satisfaction were examined using the Spearman rank sum test. In children, the results indicated that factors associated with satisfaction included "seamless hearing" (r=0.315; P=.09), "visual clarity" (r=0.501; P<.001), "seamless expression of oneself" (r=−0.357; P=.03), "feel warmth and human touch" (r=−0.254; P=.04), "reduced burden of hospital visits" (r=0.357; P=.03), "ability to act naturally" (r=0.514; P<.001), and "conners scores" (r=−0.292; P=.02) reflecting lower ADHD severity. The Mann-Whitney U test showed that girls had higher satisfaction levels than boys (P=.04), and children with a primary diagnosis of ADHD reported higher satisfaction (P=.005).

Factors correlating with overall satisfaction among caregivers were examined using the Spearman rank sum test. The results showed that the factors associated with caregivers' satisfaction included "seamless hearing" (r=0.308; P=.01), "visual clarity" (r=0.503; P<.001), "ability to express oneself" (r=−0.341; P=.004), and "the child's ability to act naturally and as usual"

XSL•FO
RenderX

(r=0.284; P=.02). No correlations were found between categorical factors.

Finally, a multiple regression analysis including these factors showed that, for children, "visual clarity" (β=.361; t_{53}=3.353; P=.001), "reduced burden of hospital visits" (β=.238; t_{53}=2.475; P=.02), and "ability to speak naturally and as usual" (β=.243; t_{53}=2.272; P=.03) were crucial factors that influenced their level of satisfaction (adjusted R^2=0.508). For caregivers, "visual clarity" (β=.352; t_{63}=2.954; P=.004) and "the child's ability to act naturally and as usual" (β=.223; t_{63}=2.086; P=.04) were found to be significant (adjusted R^2=0.265).

Discussion

Principal Findings

This study evaluated the satisfaction levels with telepsychiatry among children with ADHD and ASD and their caregivers and identified factors associated with satisfaction. Satisfaction with telepsychiatry was high, with 88% (60/68) of caregivers reporting being "satisfied" or "very satisfied." The acceptance of telehealth remained favorable despite the lower satisfaction rate (47/67, 70%) among children. For children, the factors most strongly associated with high satisfaction included "seamless visibility," "reduced burden of travel," and "ability to speak naturally and be themselves." For caregivers, the items most closely related to high satisfaction were "seamless visibility" and "the child being able to behave naturally and as they usually would."

The children and caregivers reported high satisfaction with the "seamless hearing" and "clarity of the video," confirming the technical reliability of telepsychiatry tools. These findings are consistent with those of previous studies [15], suggesting that the technical aspects of telepsychiatry significantly contribute to overall satisfaction.

In previous studies, symptom severity was associated with satisfaction. This study did not yield similar results. However, the study results showed that children with weaker ADHD traits reported higher levels of satisfaction. This result contradicts that of a previous study, suggesting that the children in this study were in stable condition during treatment. When ADHD symptoms were less severe, the children found it easier to concentrate, even in a web-based setting with various environmental distractions at home, which might otherwise hinder engagement.

The responses also indicated that the children experienced significant relief and satisfaction from the reduced time burden associated with travel. This is in agreement with that of a previous study [16]. Considering the long-term nature of treatment for children with neurodevelopmental disorders, reducing caregiver burden is crucial.

Responses from the free text indicated that caregivers had to consider the time for the patient's appointment and the travel time while managing other children's schedules, highlighting the difficulties they experienced. Some caregivers also expressed psychological stress from having to take their children out of school for appointments, reflecting the challenge they faced in balancing medical visits. This was often on weekdays with academic responsibilities. However, with telepsychiatry, appointments can be scheduled after school, eliminating the need to choose between education and medical care, thus reducing the burden on caregivers.

A critical factor that influenced the satisfaction of children and caregivers was their ability to "act naturally" during telepsychiatric assessments. Children who reported feeling less natural or perceived a lack of warmth during remote assessments had lower satisfaction levels. This highlights a potential limitation of telepsychiatry, where the absence of direct human interaction can negatively impact the patient experience. Previous studies highlighted similar concerns, underscoring the importance of addressing the psychological aspects of telehealth to improve patient engagement [5]. Additionally, it has been established that using telehealth as a supplementary tool after a relationship has been established with an assessor or physician is essential.

The assessment of this "natural behavior" was based on subjective self-report or caregiver report using a Likert scale, inherently limiting the objective understanding of specific behavioral manifestations in a remote setting. Therefore, incorporating objective behavioral observation (eg, clinician ratings or video analysis) in future research is important to better define this critical concept and inform the development of more effective remote assessment practices.

As represented in the free-text questionnaire, caregivers faced difficulty sustaining their psychological safety during the assessment interviews when discussing sensitive topics, owing to the fear of being overheard by children in the adjacent room. This is a crucial consideration in many Asian countries, particularly in small households and high household density. When securing a sufficiently soundproof private room at home is impossible, it is crucial to provide an external setting that allows the child and caregiver to be separated and conduct the assessment in a safe and secure environment.

Limitations

This study has several limitations. First, the sample size was insignificant, and the data were collected from specific hospitals in Japan, limiting the generalizability of the results. Second, the results were based on the extent to which telepsychiatric assessments were conducted only once. The satisfaction with using telepsychiatry over a longer period was unclear. Third, the participants in this study were children who had already been diagnosed, and as stated in the inclusion criteria, were relatively stable with no plans to start new medications or psychotherapy within the next 3 months. Therefore, these findings may not be applicable to cases in which the child is undiagnosed and attending consultation for the first time or to patients in the acute phase. Fourth, a selection bias existed because the participants in this study were individuals who were already interested in remote assessments or telepsychiatry. Fifth, while smartphone ownership rates are high in Japan, a significant portion of the population remains unfamiliar with digital devices, as noted by the concept of "digital divide." Therefore, caution must be exercised when generalizing these results.

XSL•FO
RenderX

Comparison With Prior Work

Compared with previous studies, Reisinger et al [15] reported that 88% of caregivers of children with ASD were satisfied with remote assessments. Similar to this study, high satisfaction was observable. However, the participants were limited to children with ASD and their caregivers. Galvin et al [16] reported that 62.3% of caregivers of children with ADHD felt comfortable with telemedicine, whereas the children's comfort level was significantly lower at 34.4%. This study offers novelty compared to previous studies by directly evaluating the satisfaction of children themselves.

In this study, factors associated with children's satisfaction included "seamless viewing of the screen," "reduction in the burden of clinic visits," and "the ability to speak naturally." For caregivers, "seamless viewing of the screen" and "the child's ability to behave naturally" influenced their satisfaction. This finding aligns with those of Reisinger et al [15], which also showed that satisfaction is affected by technical reliability and seamless use.

However, children with mild ADHD symptoms were reportedly more satisfied. This point was not indicated in previous studies, suggesting that telemedicine is challenging for children with difficulty concentrating.

This study focused on Japan and demonstrated the acceptability of telemedicine in contexts with different cultural and social backgrounds. Considering many previous studies focused on Western countries, data from Japan are valuable and may contribute to improving health care access and reducing the burden on caregivers. Moreover, this study demonstrated that children with mild ADHD symptoms were more satisfied with telemedicine, a finding that has not been reported in previous studies.

Conclusions

This study examined the acceptance of remote evaluations by end users, particularly children with ASD or ADHD and their caregivers, identifying the factors associated with higher satisfaction. Each child and their caregiver underwent two assessment sessions, one face-to-face and the other via telepsychiatry (a remote video tool), in a randomized order. The results revealed that telepsychiatry is an effective and practical option for children with ADHD and ASD and their caregivers. Technical reliability and reduced travel burden are the crucial factors that contribute to satisfaction. Applying the findings of this study to clinical practice requires strengthening the support system to help children feel at ease and experience warmth during remote assessments, which is essential for enhancing the quality of telepsychiatric services, particularly for children with pronounced ADHD symptoms. With suitable environmental adjustments, telepsychiatry can be a valuable supplementary option.

Acknowledgments

This study was supported in part by the Japan Science and Technology Agency Program on Open Innovation Platform with Enterprises, Research Institute, and Academia (JST-OPERA; grant JPMJOP1842) and by MICIN Inc, Tokyo, Japan.

Conflicts of Interest

KN has received speaker's honoraria from Takeda, Janssen, Eli Lilly, Eisai, MSD, Otsuka, and Shionogi. MK has received honoraria from Takeda and Shionogi. TK has received consultant fees from Dainippon Sumitomo, Novartis, and Otsuka; speaker's honoraria from Banyu, Eli Lilly, Dainippon Sumitomo, Janssen, MSD, Novartis, Otsuka, and Pfizer; and grant support from Takeda, Dainippon-Sumitomo, and Otsuka.

Checklist 1
CONSORT checklist.
[DOC File, 226 KB - pediatrics_v8i1e69791_app1.doc]

References

1. Aoki A, Niimura M, Kato T, et al. Trajectories of healthcare utilization among children and adolescents with autism spectrum disorder and/or attention-deficit/hyperactivity disorder in Japan. Front Psychiatry 2021;12:812347. [doi: 10.3389/fpsyt.2021.812347] [Medline: 35126213]
2. Zahid S, Bodicherla KP, Eskander N, Patel RS. Attention-deficit/hyperactivity disorder and suicidal risk in major depression: analysis of 141,530 adolescent hospitalizations. Cureus 2020 May 4;12(5):e7949. [doi: 10.7759/cureus.7949] [Medline: 32509475]
3. Cummings JR, Lynch FL, Rust KC, et al. Health services utilization among children with and without autism spectrum disorders. J Autism Dev Disord 2016 Mar;46(3):910-920. [doi: 10.1007/s10803-015-2634-z] [Medline: 26547921]
4. Kuhlthau K, Payakachat N, Delahaye J, et al. Quality of life for parents of children with autism spectrum disorders. Res Autism Spectr Disord 2014 Oct;8(10):1339-1350. [doi: 10.1016/j.rasd.2014.07.002]
5. Baweja R, Soutullo CA, Waxmonsky JG. Review of barriers and interventions to promote treatment engagement for pediatric attention deficit hyperactivity disorder care. World J Psychiatry 2021 Dec 19;11(12):1206-1227. [doi: 10.5498/wjp.v11.i12.1206] [Medline: 35070771]

XSL•FO
RenderX

6. Penner M, Anagnostou E, Ungar WJ. Practice patterns and determinants of wait time for autism spectrum disorder diagnosis in Canada. Mol Autism 2018;9:16. [doi: 10.1186/s13229-018-0201-0] [Medline: 29541438]
7. McKenzie K, Forsyth K, O'Hare A, et al. Factors influencing waiting times for diagnosis of Autism spectrum disorder in children and adults. Res Dev Disabil 2015;45-46:300-306. [doi: 10.1016/j.ridd.2015.07.033] [Medline: 26280693]
8. Rosen V, Blank E, Lampert E, et al. Brief report: telehealth satisfaction among caregivers of pediatric and adult psychology and psychiatry patients with intellectual and developmental disability in the wake of COVID-19. J Autism Dev Disord 2022 Dec;52(12):5253-5265. [doi: 10.1007/s10803-022-05712-x] [Medline: 35987932]
9. Bailey RK, Owens DL. Overcoming challenges in the diagnosis and treatment of attention-deficit/hyperactivity disorder in African Americans. J Natl Med Assoc 2005 Oct;97(10 Suppl):5S-10S. [Medline: 16350600]
10. Liao X, Lei X, Li Y. Stigma among parents of children with autism: a literature review. Asian J Psychiatr 2019 Oct;45:88-94. [doi: 10.1016/j.ajp.2019.09.007] [Medline: 31542694]
11. Weiss JA, Tint A, Paquette-Smith M, Lunsky Y. Perceived self-efficacy in parents of adolescents and adults with autism spectrum disorder. Autism 2016 May;20(4):425-434. [doi: 10.1177/1362361315586292] [Medline: 26019305]
12. Gabellone A, Marzulli L, Matera E, et al. Expectations and concerns about the use of telemedicine for autism spectrum disorder: a cross-sectional survey of parents and healthcare professionals. J Clin Med 2022 Jun 8;11(12):3294. [doi: 10.3390/jcm11123294] [Medline: 35743364]
13. Shaker AA, Austin SF, Storebø OJ, et al. Psychiatric treatment conducted via telemedicine versus in-person modality in posttraumatic stress disorder, mood disorders, and anxiety disorders: systematic review and meta-analysis. JMIR Ment Health 2023 Jul 5;10:e44790. [doi: 10.2196/44790] [Medline: 37277113]
14. Hagi K, Kurokawa S, Takamiya A, et al. Telepsychiatry versus face-to-face treatment: systematic review and meta-analysis of randomised controlled trials. Br J Psychiatry 2023 Sep;223(3):407-414. [doi: 10.1192/bjp.2023.86] [Medline: 37655816]
15. Reisinger DL, Hines E, Raches C, Tang Q, James C, Keehn RM. Provider and caregiver satisfaction with telehealth evaluation of autism spectrum disorder in young children during the COVID-19 pandemic. J Autism Dev Disord 2022 Dec;52(12):5099-5113. [doi: 10.1007/s10803-022-05576-1] [Medline: 35579789]
16. Galvin E, Gavin B, Kilbride K, et al. The use of telehealth in attention-deficit/hyperactivity disorder: a survey of parents and caregivers. Eur Child Adolesc Psychiatry 2024 Dec;33(12):4247-4257. [doi: 10.1007/s00787-024-02466-y] [Medline: 38753037]
17. Kurokawa S, Nomura K, Hosogane N, et al. Reliability of telepsychiatry assessments using the attention-deficit/hyperactivity disorder rating scale-IV for children with neurodevelopmental disorders and their caregivers: randomized feasibility study. J Med Internet Res 2024 Feb 19;26:e51749. [doi: 10.2196/51749] [Medline: 38373022]

Abbreviations

ADHD: attention-deficit/hyperactivity disorder
ASD: autism spectrum disorder
CONSORT: Consolidated Standards of Reporting Trials

Edited by S Badawy; submitted 09.12.24; peer-reviewed by J Abua, VS Kishore Kancharla, Y Kakisaka; revised version received 02.06.25; accepted 04.06.25; published 05.09.25.

Please cite as:
Kurokawa S, Kawade Y, Nomura K, Hosogane N, Nagasawa T, Matsumoto Y, Morinaga S, Kaise Y, Higuchi A, Goto A, Inada N, Kodaira M, Kishimoto T
Evaluating Telepsychiatric Assessment Satisfaction in Children and Adolescents With Autism Spectrum Disorder and Attention-Deficit/Hyperactivity Disorder and Their Caregivers: Randomized Controlled Trial
JMIR Pediatr Parent 2025;8:e69791
URL: https://pediatrics.jmir.org/2025/1/e69791
doi:10.2196/69791

©Shunya Kurokawa, Yuko Kawade, Kensuke Nomura, Nana Hosogane, Takashi Nagasawa, Yu Matsumoto, Shuichi Morinaga, Yuriko Kaise, Ayana Higuchi, Akiko Goto, Naoko Inada, Masaki Kodaira, Taishiro Kishimoto. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 5.9.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Development of an eHealth Intervention in Pediatric Home Infusion Therapy: Interview Study of Needs and Preferences of Parents and Health Care Professionals

Helena Hansson[1,2], RN, MSc, PhD; Charlotte Castor[3], RN, PhD; Hanne Bækgaard Larsen[1,2,4], RN, MSc, PhD; Martha Krogh Topperzer[5], RN, MSSc, PhD; Mette Linnet Olesen[6], RN, MPH, PhD

[1]Department of Paediatrics and Adolescent Medicine, Copenhagen University Hospital Rigshospitalet, Blegdamsvej 9, Copenhagen, Denmark

[2]Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark

[3]Department of Health Sciences, Lund University, Lund, Sweden

[4]The Paediatric Oncology Research Laboratory, Copenhagen University Hospital Rigshospitalet, Copenhagen, Denmark

[5]Department of Education, Copenhagen University Hospital Rigshospitalet, Copenhagen, Denmark

[6]Department of Gynaecology, Fertility and Obstetrics, Copenhagen University Hospital Rigshospitalet, Copenhagen, Denmark

Corresponding Author:
Helena Hansson, RN, MSc, PhD
Department of Paediatrics and Adolescent Medicine, Copenhagen University Hospital Rigshospitalet, Blegdamsvej 9, Copenhagen, Denmark

Abstract

Background: With the provision of home infusion therapy in children with acute or long-term illness on the rise, eHealth technologies have the potential to bridge the transition between hospital and home. However, eHealth interventions intended to support parents in managing home infusion therapy are sparse. Gaining insight into the needs and experiences of parents and health care professionals is crucial to developing feasible and sustainable eHealth interventions that target their needs. This study describes the first phase of a research study designed to develop and evaluate an eHealth intervention to support home infusion therapy.

Objective: This study aimed to identify the experiences and needs of parents and health care professionals during home infusion therapy and their preferences for digital features in a future eHealth intervention.

Methods: A qualitative study was conducted at 3 pediatric departments at a university hospital in Denmark. We individually interviewed 17 parents of 14 children who had received home infusion therapy with a portable pump. In addition, 5 focus groups were conducted with 15 health care professionals. We conducted a qualitative content analysis of the data, which we collected from February to July 2020.

Results: We identified 6 subthemes that we merged into 3 main themes: increasing safe self-management at home; adapting information and responsibility to individual changing needs; and requesting digital features to ensure skill level, safety, and quality of care. The analysis showed that parents and health care professionals had corresponding needs and preferences, for example, a need for a high sense of safety and easier ways to communicate during home infusion therapy. Both groups emphasized the need for digital features to improve problem-solving and communication as a supplement to existing care to promote a safe environment, self-management, and quality of care. A vital issue was that an eHealth intervention should be aligned with the workflow of health care professionals and comply with regulations regarding confidentiality in communication and data sharing.

Conclusions: Our study highlights the needs that parents and health care professionals have for increased safety and easier access to communication when receiving and providing home infusion therapy. The findings will be used to help develop an eHealth intervention supporting home infusion therapy tailored to individual needs.

(JMIR Pediatr Parent 2025;8:e63260) doi:10.2196/63260

KEYWORDS

pediatrics; digital; interventions; eHealth; home care; intravenous infusion; qualitative research

Introduction

Home infusion therapy for children with acute or long-term illnesses is becoming increasingly common due to its benefits, such as supporting children and their families in maintaining their everyday lives and improving the child's health outcomes [1]. This therapy can be provided by nurses in hospitals or municipalities, home care agencies, or by nonprofessional

XSL•FO
RenderX

caregivers such as parents or guardians. Transitioning care tasks from a hospital to a home setting is complex and requires well-functioning, coordinated collaboration between health care professionals and parents [2]. Parents have reported feeling anxious and insecure if they lack support, experience with, or knowledge about care tasks such as administering medications and observing symptoms that they must manage at the hospital and at home [3]. Furthermore, studies show that parents' administration of oral medication at home is a high-risk area for medication errors [4-7]. Thus, it is vital to ensure that parents are comfortable and confident when managing care tasks at home.

eHealth interventions can be a means to support parents since they provide digital resources for managing home infusion therapy. According to the World Health Organization [8], eHealth can increase communication and data sharing between health care professionals and patients and improve accessibility and patient participation by electronic technologies. The use of eHealth expanded radically during the COVID-19 pandemic [9], but various barriers remain before integration into pediatric clinical practice is completely successful [10-13]. Studies have reported that the use of eHealth in pediatric clinical care can bridge the transition from hospital to home and increase interaction between the two by efficiently and conveniently providing information and communication [14-16]. This helps promote confident self-management among parents in treating and caring for children with various medical needs at home [2,15-17], improve symptom control in the child, and reduce parental worries and insecurity [2,18-22]. However, the availability of eHealth interventions for families of children with acute or long-term health conditions as well as the evidence supporting eHealth in pediatric clinical practice, remains still limited [23-25].

At the outset of this study, children and adolescents were given the opportunity to start antibiotic infusion therapy using a portable pump at a university hospital in Denmark and then continue treatment at home. Parents were trained by nurses and supported with printed materials and resources on the hospital's website. The provision of home infusion therapy began to expand to include other types of medications and delivery methods, thereby placing greater responsibility on the parents. No eHealth interventions were available to support home infusion therapy and there was uncertainty about the extent of parents' and health care professionals' needs and the specific content that they may need for eHealth support. Previous research have shown that extensive support is essential when parents perform caregiving tasks at home [3,26]. However, less is known about how parents and health care professionals employed at hospitals perceive their needs and preferences related to home infusion therapy and eHealth support. According to Medical Research Council's framework [27], exploring the needs of intervention users is a crucial first step in developing an intervention. Applying a participatory design [28], future users are involved to gain an understanding of their situation and respond to their experiences, needs, and preferences. This approach ensures that a future eHealth intervention would target their needs and be sustainably implemented [11,28-30]. Therefore, the aim of this study was to identify the experiences and needs of parents and health care professionals regarding home infusion therapy, in addition to their preferences for including digital features in the development of a future eHealth intervention.

Methods

Design

An exploratory qualitative design was applied to get relevant input from the users to the future development of a supportive eHealth intervention. This study is a part of the developmental phase of a larger research program with the overall goal of developing and testing an eHealth intervention to support parents and health care professionals during pediatric home infusion therapy. The Medical Research Council's framework for the development and evaluation of complex interventions [27] and a participatory design [28] framed the overall research project. The framework guides researchers through 4 interconnected phases, development, feasibility, evaluation, and implementation. Engaging the users of the eHealth intervention throughout the research study ensured the developmental relevance of our study and its feasibility in clinical practice, improving the probability of successful implementation [26].

Setting

The study was conducted in 3 pediatric departments at a university hospital in Copenhagen, Denmark, 1 specializing in oncology and hematology (20 in-patient beds), 1 in organ and infection diseases (12 in-patient beds), and 1 day hospital (7 beds), with around 2000 combined admissions annually.

Home Infusion Therapy

In 2018, the departments started offering home infusion therapy with portable pumps as an option to children with diagnoses such as cancer or with an acute infection with no underlying condition. The therapy was primarily used for intravenous antibiotic treatment and always initiated during hospitalization at an in-patient ward or in an out-patient setting. The children had a central venous catheter or midline catheter. A nurse informed and trained primarily one of the child's parents before home infusion therapy was initiated and administered the portable pump to the child at the hospital before discharge. The child returned the following day to the hospital to receive a new dose in the pump or to discontinue treatment. The parent's task was to clinically observe the child, the pump and infusion at home, and react if problems arose, such as reactions to the medicine or a pump alarm sounding. If the child had a serious reaction, the parent was instructed to immediately call an ambulance. Health care professionals also taught some parents how to change the pump medication or replace the elastomeric pump with a new one to allow the family to stay at home 1 or 2 additional days before returning to the hospital,

Participants

A purposeful sampling strategy of children, parents, and health care professionals was used to obtain rich and varied data on the home infusion therapy [31]. Inclusion criteria for children were 0 to 18 years of age, having received home infusion therapy with a portable pump with any type of medication,

XSL•FO
RenderX

having the parent living with the child part or full time, and the parent speaking Danish or English. Most children receiving the therapy had an underlying long-term illness, but children with an acute infection with no underlying condition were also approached. In total, 14 children and their parents were informed about the study, and all agreed to participate. The children were invited to participate in an interview together with their parent, which resulted in 13 children participating, 2 of whom actively joined in. In 3 families, both parents participated and were interviewed jointly or separately (Table 1). Inclusion criteria for health care professionals were: (1) nurse or a physician, (2) working at one of the 3 departments, and (3) had experience with providing home infusion therapy. A total of 15 health care professionals were approached, and all agreed to participate.

XSL•FO
RenderX

Table . Demographic and clinical characteristics of children and parents.

Characteristic			Participant, n
Children (n=14)			
	Age (years)		
		0 - 5	5
		6 - 11	6
		12 - 14	1
		15 - 18	2
	Sex		
		Male	11
		Female	3
	Primary diagnosis		
		Cancer	10
		Congenital lung disease	2
		Congenital autosomal disorder	1
		Stroke caused by virus infection	1
	Ethnicity		
		Danish	11
		Other	3
	Cohabiting with siblings (n)		
		0	2
		1	9
		2 - 4	3
Parents (n=17)			
	Sex		
		Female	12
		Male	5
	Partner relations		
		Cohabiting with partner	16
		Single parent	1
	Age (years)		
		31 - 40	11
		41 - 50	3
		Unknown	3
	Occupational status		
		Employed	5
		Unemployed	1
		Paid leave due to child's illness full time	10
		Paid leave due to child's illness part time	1

Data Collection

Data were collected from February to July 2020. Parents were interviewed based on a 2-part exploratory semistructured interview guide. The first part covered experiences and needs regarding home infusion therapy in terms of provision of and responsibility for it, preparation and training, and sense of safety, worries, and challenges. The second part presented concrete

XSL•FO
RenderX

examples of digital features to generate ideas on how technology could address the needs and preferences of the child and parent, in addition to focusing on how an eHealth intervention could support home infusion therapy. We asked which digital features to include, such as possible advantages and disadvantages, experience with digital technologies, and what features are important to have in an eHealth intervention. The eHealth Literacy Framework provided the underlying inspiration for the questions in the second part to understand user needs and prerequisites when new digital health services are introduced [32]. The interviews were conducted by the first author (n=16), at one of the pediatric departments in a meeting room or an in-patient room lasting and lasted 30 to 120 minutes, though 1 was done by phone.

Health care professionals were interviewed in 5 separate focus groups with a semistructured interview guide corresponding to the guide for parents though tailored to their professional role. The focus group interviews, which lasted 60 to 90 minutes, were held in a meeting room at one of the pediatric departments. The interviews were recorded and transcribed verbatim.

Data Analysis

A qualitative content analysis of the transcribed interviews was used comprising a 5-step iterative and inductive approach based on Graneheim and Lundman [33] to identify any patterns and variations in participant experiences. First, 2 authors [HH and MLO] read the text independently to gain an overall understanding. Second, they identified meaning units in terms of words, sentences, and paragraphs that related to the study aim. Next, the meaning units were condensed, organized, and coded using NVivo software (Lumivero). Fourth, the codes were compared with identify similarities and differences, before being organized into subthemes. Finally, the subthemes were compared and analyzed, after which they were merged into main themes. The defined main themes had a consistent pattern of underlying meaning in terms of the condensed meaning units, codes, and subthemes. To strengthen the trustworthiness of the study, the same 2 authors discussed the meaning units, codes, subthemes, and themes throughout the analysis until reaching consensus. Initially, individual and focus group interviews were analyzed separately as 2 datasets. During the data analysis, it became apparent that the subthemes overlapped, and data were analyzed together. In the last phase of the analysis, all authors reflected on and discussed the main themes and subthemes.

Trustworthiness

The authors discussed the analysis, interpretations, and themes at seminars and presentations with key health care professionals involved in home infusion therapy and other researchers to enhance credibility. The authors also discussed their preunderstanding to consider how it may influence data collection and analysis, all of us are experienced in conducting qualitative studies. The first author [HH], who is a nurse, has experience with implementing home infusion therapy at the 3 departments but did not have any clinical contact with the families before the interviews. The health care professionals knew HH, which may have hampered them from freely expressing themselves, but her knowledge of home infusion therapy may also have made them feel confident enough to provide in-depth responses to the interviews.

Ethical Considerations

The Danish Protection Agency approved the study (P-2019 - 392), while approval from the Regional Research Ethics Committees for the Capitol Region of Denmark was not required since it only assesses studies that collect biological material. The study adhered to the Declaration of Helsinki, International Ethical Guidelines for Health-Related Research Involving Humans, and current Swedish and European law. All participants were assured that participation was voluntary and that they could withdraw from the study at any time without affecting their child's treatment or the health care professionals' work. All participants provided written informed consent and were assured confidentiality. When applicable, the children received age-appropriate information about the study based on their cognitive abilities, language skills, and legal guardian's preferences.

Results

Overview

The amount of experience parents and health care professionals had with home infusion therapy ranged from doing it a few to multiple times. The parents expressed that it enhanced their child's well-being and the whole family's due to having a greater opportunity to spend everyday life together more at home. They were willing to take on the additional caregiving tasks and responsibility due to the benefits associated with doing so. The health care professionals also described how the child and family benefited and how important the option of home infusion therapy was.

Three main themes were identified comprising six subthemes: (1) increasing safe self-management at home, (2) adapting information and responsibility to individual changing needs, and (3) requesting digital features to ensure skill level, safety, and quality of care (Textbox 1). The themes and subthemes were bound together in an overarching theme "managing the extended responsibility of home infusion therapy." This theme encompasses the core experience of the increased responsibility parents take on when managing the therapy and the health care professionals being responsible for therapy taking place outside the hospital. Digital features were described as means to support that responsibility.

The first and second themes describe the needs of parents and health care professionals based on current experiences with home infusion therapy, while the third main theme present the digital features proposed to meet the needs of both groups in a future eHealth intervention (Figure 1).

XSL•FO
RenderX

Textbox 1. Main themes and subthemes.

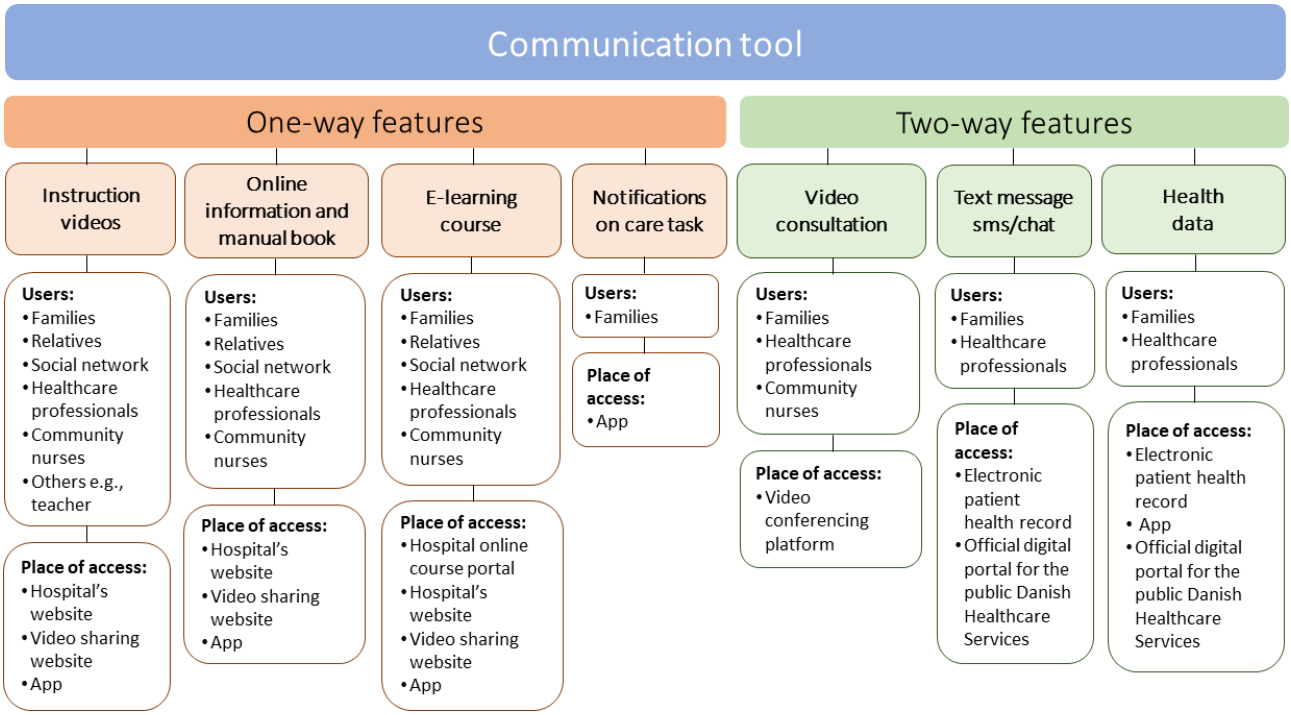
Overarching theme:

- Managing the extended responsibility of home infusion therapy

Main themes and their subthemes:

- Increasing safe self-management at home
  - Need for standardized information, training, and shared problem-solving
  - Being in control of home infusion therapy and feeling safe
- Adapting information and responsibility to suit individual needs
  - Repeating individualized information and training
  - Desire to share the responsibility
- Requesting digital features to ensure skill level, safety, and quality of care
  - Access to online one-way communication of knowledge and training
  - Access to interactive communication and support

Figure 1. Digital features proposed by parents and health care professionals for a future eHealth intervention.



Theme 1. Increasing Safe Self-Management at Home

Subtheme: Need for Standardized Information, Training, and Shared Problem-Solving

Overall, parents described that they were confident about the information and training they had received on how to manage home infusion therapy, and they had not experienced any problems with the pump or the child's health. But some felt that the information and training were too sparse. They appreciated the information booklet, even though they did not always have it with them when they needed it. The hospital website provided information and guidelines, but finding either one was sometimes difficult and time-consuming if immediate support was required.

Some parents thought that the information and training they received was inconsistent, making both them and their child feel insecure. They requested uniform guidelines and training regardless of which health care professionals or department taught them about managing the care tasks. They also felt unsure if they called for assistance and spoke with a health care professional who lacked the skills to provide support, sometimes forcing families to travel to the hospital.

> *I felt stressed when it [pump] sounded an alarm that showed 'low reservoir volume'. I think it was actually*

XSL•FO
RenderX

> *when the infusion bag was full. And then I called the ward after trying everything I could do at home. But when you call in the evening, there isn't necessarily anyone at work who knows much about the pump. So, they didn't know what I should do either.* [Mother 232]

Health care professionals who seldom had the task of giving parents information and training about managing the portable pump worried about how to maintain their professional skill level, making them feel insecure professionally and concerned about how that could affect the children and parents.

> *We don't provide home infusion that much at our ward and the more you physically deal with it [pump] in your hands, the better, safer, and more familiar you get with it when you teach the parents.* [Health care professional 113]

Subtheme: Being in Control of Home Infusion Therapy and Feeling Safe

The parents described that the pump was easy to manage and that they did not experience many problems related to the pump and infusion, or that their child experienced adverse effects. If a pump alarm went off, they were mostly able to manage the issue at home. They felt particularly worried if an alarm sounded due to air bubbles in the infusion set. In such situations they expressed a need for different interaction than a telephone call with the health care professionals because it had the potential to resolve problems and thereby avoiding a hospital visit.

> *I think, I think that there's a need for extra support in those kinds of situations when it [pump] acts up.* [Mother 73]

Parents described how they wanted to take on responsibility for their child's home infusion therapy as it was a way to have control over their situation. Even though they generally felt secure about the information, training, and support they received, some parents still worried about something unexpected happening, making them feel vulnerable about being home alone without a health care professional nearby. They stated that they would appreciate more support to improve their sense of safety and control of the situation.

The health care professionals also described the need to have more control when discharging a child to home infusion therapy, mentioning that they felt an extended sense of responsibility toward the child and home treatment that they sometimes found difficult to fulfill since they were unable to monitor the child's condition in the same way as at the hospital. The health care professionals lacked having a sense of the family's capacity at home; for example, they could not assess whether the procedures and observations the parents took on had been performed correctly. This lack of control preoccupied them as they worried about the risk of medication errors and adverse events. The health care professionals needed reassurance that the parents had conducted the necessary observations and procedures to help increase their feeling of control concerning the treatment they had initiated, especially because they felt responsible for the child's well-being, treatment, observations, and transferring such specialized care tasks to the parents without their presence to safeguard them at home.

> *And then there's the issue of whose responsibility it is when you hand it [therapy] over to the parents? Because I agree that they only want the best for their child. There's no doubt about that.* [Health care professional 117]

Theme 2. Adapting Information and Responsibility to Suit Individual Needs

Subtheme: Repeating Individualized Information and Training

Parents described feeling mentally burdened by their child's illness, especially those whose child had long-term illness. They had difficulty remembering and comprehending information and training, causing them to request the possibility to repeat information and training once they returned home.

> *You're bombarded with things that I, as a parent, must be able to gain an overview of, including how the pump works. Then, when you get home you think: "God, what was it that they said about that?" And in that situation, it would be really nice if you could seek help [digitally/online]: "Could you tell me again, what I should do, when I should do this and that?"* [Mother 173]

The health care professionals also worried that the parents did not always have the mental surplus to handle new or additional tasks in relation to home infusion therapy. They expressed a need for providing more individualized support to parents at home as they saw the parents' mental surplus as changing over time. It was important for them to ensure that the parents felt safe and were not additionally burdened by managing home infusion therapy.

> *Maybe we could come by to force them to accept it [home infusion], because we've been used to that. Then there's a psychological aspect to it, where you constantly have to determine where they are in the treatment trajectory: "Do you still feel secure about doing home care?" Because I think the families experience a tremendous number of mental ups and downs.* [Health care professional 262]

Subtheme: Desire to Share the Responsibility

The parents described that they would like to involve other caregivers and professionals in the home infusion therapy to share the responsibility, also their child if the child wanted to be involved. Often only one parent was trained to manage the pump and medicine, leaving them with the sole responsibility. One parent said that her partner did not want to help with it due to how unsure it made him feel.

> *He's perhaps afraid of ending up doing something wrong [with the pump] that may harm our son, which I think might paralyze him a little in terms of his ability to act.* [Mother 196]

Another parent described how the partner, who had not been trained at the hospital, panicked at home when an alarm on the

XSL•FO
RenderX

pump went off. Parents also emphasized the need for additional support to facilitate training and guidance at home to increase the sense of safety and control for the child and other caregivers with the therapy and to support shared responsibility. Like the parents, the health care professionals supported and emphasized the need for parents to share the responsibility for managing home infusion therapy, for example, with grandparents and daycare staff.

> *One of the disadvantages of home treatment is that all of the responsibility lies with one parent, or two, to manage it [the pump]. It's a great deal to have to take care of regularly.* [Health care professional 270]

However, the health care professionals found that letting the parents supervise others was challenging because they worried that training others might put an additional burden on the parent or potentially be problematic regarding quality of care and safety.

Theme 3. Requesting Digital Features to Ensure Skill Level, Safety, and Quality of Care

Subtheme: Access to Online One-Way Communication of Knowledge and Training

Parents suggested that online information, guidelines, and instruction videos would be helpful and should be easily accessible in one place, for example, the hospital's website or an app, making it more straightforward and quicker to find information and training, which would potentially allow parents to solve technical problems themselves.

> *I've actually thought of something that could be really nice, being able to watch a short video, if there's something that's tricky, instead of having to read about it. Because you can't be sure that you'll have the peace of mind to understand it [written information] when you're in the middle of a crisis.* [Mother 29]

> *Sometimes they call and say that they can't find it. They've lost their information material and manual, so they ask: "What should we do when she gets a fever or becomes flush or?"* [Health care professional F2]

If information on paper got misplaced or was forgotten, a digital version would always be available. Parents suggested that explanatory instruction videos could be developed to show how to solve the most common problems, for example, removing air bubbles in the infusion set or resolving other practical technical issues related to the pump. The health care professionals supported the idea of having information, guidelines, and instruction videos available online to provide professional reassurance that the parents could find information targeted their needs and skills. They explained that instruction videos could also meet their own needs for maintaining their skill level, along with e-learning. Furthermore, both parents and health care professionals expressed how online material would ensure that the information and skills the parents acquired were aligned with the health care professionals. However, the health care professionals had concerns about how to regularly keep online material and instruction videos updated based on the newest evidence-based practices.

Parents and health care professionals described how online guidelines and instruction videos could help bolster sharing responsibility for managing home infusion therapy for those who did not receive training at the hospital. Parents also expressed that this would be useful for children interested in self-managing their therapy, also because they were already familiar with using digital platforms with videos. Instruction videos also represent a useful tool for those who learn better visually, just as they can be subtitled or dubbed into different languages, improving access to allow more families to receive home infusion therapy.

Subtheme: Access to Interactive Communication and Support

Parents also mentioned the benefits of video consultations for receiving guidance in managing the pump and resolving any issues with the pump at home to avoid traveling to the hospital. Video consultations would also provide visual advantages that were absent in ordinary telephone conversations in terms of guidance and preventing misunderstandings.

> *A support feature would be very good to have. If you [nurses] had a smartphone available to make video calls to film what the pump says, because my wife panicked a little bit and the communication on the phone with the nurse [at the hospital] was not that great; the nurse and my wife misunderstood one another. So, I just drove him to the hospital.* [Father 112]

Health care professionals also requested the option of using video consultations to reassure parents that their observations were relevant and to guide them in shared problem-solving. Video consultations could potentially improve their sense of safety and professional control by allowing them to assess the child's condition and the parent's management of the therapy.

> *You're sure that the parents know how to change the infusion bag. And if you're in doubt at home, it's evening and you call and you can't be guided on the phone, then it would be nice be able to see it to avoid any misunderstandings.* [Health care professional 208]

However, the health care professionals had concerns. Even though the child was visible on video, they could not use their clinical judgment based on all their senses compared with face-to-face clinical observations at the hospital. They were uneasy about care becoming too digital.

> *I think it's a good idea [home care], but I also worry about not seeing the children: "How are you doing and how do you look?" Can the parents always assess that? The nursing loses something; it simply becomes too digital. That involves using your eyes, touch, and sense of smell and whatever else we run around doing.* [Health care professional 133]

Both parents and health care professionals stressed that the work procedures and settings for digital interactions would require

XSL•FO
RenderX

aligning expectations. For example, video consultations include specific requirements, such as the need for computers with the right equipment, setting up consultations in a confidential setting, and how to manage scheduling consultations, also in the evening and at night, not to mention having skilled health care professionals available to provide support 24/7.

Parents were also interested in being able to send data to the hospital, such as their child's blood pressure or pictures of skin changes to reassure the parents and health care professionals regarding the parents' observations. However, some parents had misgivings about perhaps feeling pressured to provide more data than they could manage. In addition, parents and health care professionals alike were uneasy about when and who was responsible for assessing and reacting to the data at the hospital, and the timespan in which parents could expect to receive an answer. Managing incoming measurements would be required for this to succeed and make all parties feel safer. Furthermore, parents and health care professionals suggested that the parents could also receive notifications to ensure that care tasks like taking their child's temperature and assessing intravenous access were performed at the right time.

Discussion

Principal Findings

We found that parents and health care professionals largely had corresponding needs for safety in home infusion therapy but that their preferences for digital features in a future eHealth intervention to meet those needs were based on different rationalities. It was vital that everyone felt safe about using home infusion therapy, and they suggested various digital features to meet their needs to have consistent knowledge, problem-solving skills, reassurance that the parents could manage the home infusion therapy and their child's well-being, maintain their skill level, and share responsibility with more than one parent. They emphasized the need for an eHealth intervention that provides additional communication support to existing care to enhance safety, self-management, and quality of care.

Comparison With Previous Work

A key finding was how home infusion therapy was linked to the extended responsibility of the parents and health care professionals, the former at home without the presence of a nurse, and that latter in terms of having the professional responsibility without being present in the child's home. We suggest that this extended responsibility generates specific needs and preferences for the digital features a future eHealth intervention should have.

Parents found their responsibilities manageable and felt greater sense of control when they had adequate information and training, along with access to skilled health care professionals when contacting the hospital without these resources, they felt unsure. Two other studies describing the parents' experiences of insecurity and fear of overlooking something important when their child received home intravenous therapy suggested improvements to decrease worries, such as enhanced preparation, alignment of expectations, and accessible visually based and text-based information [3,34]. Another study also found that parental management of care for their child after surgery at home felt insecure, for example, they were unable to identify postoperative complications [35]. The information they had received was partially incomplete, and there was a gap in support at home, such as some health care professionals lacking the right knowledge to provide support contacted by parents [35]. Even though the parents in our study had some similar experiences, they were generally satisfied overall but would like to see digital features bolster existing support.

Another aspect of the extended responsibility was the health care professionals' concerns about their ability to clinically assess the child's condition and to know how the parent was managing home infusion therapy. These concerns challenged their professionalism and ethics. For them, the setup comprised nursing at a distance, causing them to worry about how to ensure quality of care. They suggested that various digital features could bridge this distance and had to correspond to the parents' needs. Both parents and health care professionals suggested monitoring, such as sending temperature data to the hospital and notifications to parents to remember tasks. These features would help meet their need for reassurance and increase their sense of safety. One study showed that participants valued notifications as reminders for activities to be carried out at home [36], while another study on designing a home monitoring system for children with a medically complex condition showed how parents preferred to track symptoms to identify early changes in their child's health that could lead to an appropriate intervention [37]. However, parents in our study also worried that they would feel pressured to provide more monitoring and data than they could manage. As a result, adjusting the amount of monitoring and continuously assessing how parents manage at home is important to avoid increased caregiver stress.

The suggestions parents and HCPs provided in our study are comparable with the study by Nkoy et al [37] on the needs of caregivers for designing a home monitoring system for children with a medically complex condition. The parents wanted a mobile health tool that included features to track symptoms and report their child's symptoms that was user friendly, in addition to having the ability to report interventions provided at home, have direct access to hospital through text messaging, and real-time sharing of data, not to mention the capacity to upload a photo or video for the health care professionals [37]. Two studies in which parents managed nursing care for children after surgery or born prematurely developed a successful eHealth tablet for the aforementioned reasons [17,38]. The parents were given an eHealth tablet before their child was discharged from a highly specialized department and that allowed them chat, make video calls, send photos, write daily reports, and get feedback from health care professionals, which facilitated early detection of complications. These features provided support and easy access to communication with health care professionals, creating a sense of security that the parents highly appreciated [17,38]. Due to similarities with our study, this suggest that a corresponding eHealth intervention could support the families and health care professionals in our study.

However, the health care professionals were also concerned that digital features might exacerbate the distance between them

XSL•FO
RenderX

and the family, which is in line with a study on mobile health clinic appointments on parenteral nutrition at home done through a tablet [39]. Parents and health care professionals were very satisfied with how convenient and easy communication was, but the health care professionals reported that the inability to make accurate clinical assessments using the tablet was a significant challenge [39]. Research also shows that another concern is that telemedicine may depersonalize the patient and clinician relationship due to a lack of in-person interaction [11,40]. These key concerns must be taken into consideration when developing an eHealth intervention and will be explored further in the subsequent studies of the development and evaluation of the intervention in this research project.

Another concern was the reservations health care professionals had regarding workflow and setting, for example, how to organize and assess incoming data and chats at all times of day. Furthermore, organizational issues like maintaining confidentiality had to be considered when doing planned and unplanned video consultations. The study with the eHealth tablet showed that parents felt they had to wait too long to receive answers or feedback from health care professionals at the hospital [17]. Another study reported that clinicians emphasized the importance of having clear guidelines for scheduling and use of telemedicine in pediatric emergency settings [11]. Finally, a systematic review on factors concerning the success and failure of eHealth interventions also showed how workflow caused several barriers to success [41]. Accordingly, it is important to consider the needs of health care professionals, as motivating them to use telehealth can otherwise be challenging [42,43].

The extended responsibility that home infusion therapy entails emphasizes the importance of adjusting information and training, in addition to managing the capacity and needs of the individual child and parents. The parents' mental resources varied during their child's treatment, and research shows how parents obtain and act differently regarding health-related information concerning their child [35,44]. Both parents and health care professionals suggested that digital features could support the individualized aspects as the parents could, when necessary, repeat information and training, solve problems, and receive guidance. In addition, the parents and health care professionals in our study were preoccupied with sharing their responsibility with others to avoid distorting the amount of caregiving placed on one parent. Studies show that telemedicine can address these issues, by communication in greater alignment with the parents' own preferences and pace, not to mention that of families who live far from the hospital and wish to avoid the time and expense transportation and parking [17,38,45].

Strengths and Limitations

This study's strengths include its participatory design, which involved families and health care professionals at the beginning of the development process. The demographics and experiences of the sample of children with acute or long-term illness is also varied, just as both mothers and fathers were included, not to mention children to some extent. The child was invited to participate with their parent, and 13 children were present at the interview, 2 of whom participated actively. However, separate interviews would improve our understanding of the child's needs since the parent may withhold experiences and opinions due to the child's presence. Age-specific methods could have been used to involve and interview children, which would have provided additional insights into their unique needs and preferences. Children will be involved and interviewed in the evaluation study of this research project. The study is conducted in a specific geographic and health care setting, which may limit the generalizability of the findings to other countries and settings with different health care systems.

Data were collected during the early phase of the COVID-19 pandemic, and video consultations and other telehealth options were not used at the department on a regular basis at that time. This may have influenced participants' perceptions of eHealth and impacted the results in the sense that their technology readiness was limited. Since then, the use of telehealth has increased extensively in Denmark and abroad, perhaps causing our findings to appear obvious.

Conclusions

Our study highlights the need parents and health care professionals have for increased safety and easier access to communication when receiving and providing home infusion therapy. Their needs and preferences corresponded with each other, and they suggested key digital features for a pediatric eHealth intervention to provide consistent knowledge, skills, and problem-solving during home infusion therapy. The study emphasizes the need to increase access to home infusion therapy by using digital features, and our findings can provide clarity in terms of developing an eHealth intervention to support pediatric home infusion therapy tailored to individual needs.

Acknowledgments

The authors would like to express great gratitude to the participating families and health care professionals for sharing their experiences with us. This research is part of the research program eChildHealth supported by FORTE (R-257-A14720) and the research program iCOPE supported by European Regional Development Fund (2019-5934). The study was supported by grants from iCOPE and FORTE.

Conflicts of Interest

None declared.

References

XSL•FO
RenderX

1. Parab CS, Cooper C, Woolfenden S, Piper SM. Specialist home-based nursing services for children with acute and chronic illnesses. Cochrane Database Syst Rev 2013 Jun 15;2013(6):CD004383. [doi: 10.1002/14651858.CD004383.pub3] [Medline: 23771694]
2. Garfield CF, Kerrigan E, Christie R, Jackson KL, Lee YS. A mobile health intervention to support parenting self-efficacy in the neonatal intensive care unit from admission to home. J Pediatr 2022 May;244:92-100. [doi: 10.1016/j.jpeds.2022.01.004] [Medline: 35033562]
3. Roug LI, Jarden M, Wahlberg A, Hjalgrim LL, Hansson H. Ambiguous expectations of parent caregiving for the child and adolescent with cancer at the hospital and at home-an ethnographic study. J Pediatr Hematol Oncol Nurs 2023;40(2):100-110. [doi: 10.1177/27527530221140065] [Medline: 36628410]
4. Walsh KE, Dodd KS, Seetharaman K, et al. Medication errors among adults and children with cancer in the outpatient setting. J Clin Oncol 2009 Feb 20;27(6):891-896. [doi: 10.1200/JCO.2008.18.6072] [Medline: 19114695]
5. Walsh KE, Roblin DW, Weingart SN, et al. Medication errors in the home: a multisite study of children with cancer. Pediatrics 2013 May;131(5):e1405-e1414. [doi: 10.1542/peds.2012-2434] [Medline: 23629608]
6. Wong CI, Vannatta K, Gilleland Marchak J, et al. Preventable harm because of outpatient medication errors among children with leukemia and lymphoma: A multisite longitudinal assessment. Cancer 2023 Apr 1;129(7):1064-1074. [doi: 10.1002/cncr.34651] [Medline: 36704995]
7. Parand A, Garfield S, Vincent C, Franklin BD. Carers' medication administration errors in the domiciliary setting: a systematic review. PLoS ONE 2016;11(12):e0167204. [doi: 10.1371/journal.pone.0167204] [Medline: 27907072]
8. Digital health. World Health Organization. 2024. URL: https://www.who.int/europe/health-topics/digital-health#tab=tab_1 [accessed 2025-02-26]
9. Curfman A, McSwain SD, Chuo J, et al. Pediatric telehealth in the COVID-19 pandemic era and beyond. Pediatrics 2021 Sep;148(3):e2020047795. [doi: 10.1542/peds.2020-047795] [Medline: 34215677]
10. Olson CA, McSwain SD, Curfman AL, Chuo J. The current pediatric telehealth landscape. Pediatrics 2018 Mar;141(3):e20172334. [doi: 10.1542/peds.2017-2334] [Medline: 29487164]
11. Ray KN, Felmet KA, Hamilton MF, et al. Clinician attitudes toward adoption of pediatric emergency telemedicine in rural hospitals. Pediatr Emer Care 2017;33(4):250-257. [doi: 10.1097/PEC.0000000000000583]
12. Curfman AL, Hackell JM, Herendeen NE, et al. Telehealth: improving access to and quality of pediatric health care. Pediatrics 2021 Sep;148(3):e2021053129. [doi: 10.1542/peds.2021-053129] [Medline: 34462339]
13. Tully L, Case L, Arthurs N, Sorensen J, Marcin JP, O'Malley G. Barriers and facilitators for implementing paediatric telemedicine: rapid review of user perspectives. Front Pediatr 2021;9:630365. [doi: 10.3389/fped.2021.630365] [Medline: 33816401]
14. Slater PJ, Fielden PE, Bradford NK. The oncology family app: providing information and support for families caring for their child with cancer. J Pediatr Oncol Nurs 2018;35(2):94-102. [doi: 10.1177/1043454217741874] [Medline: 29161974]
15. Rabba AS, Dissanayake C, Barbaro J. Development of a web-based resource for parents of young children newly diagnosed with autism: participatory research design. JMIR Pediatr Parent 2020 Sep 30;3(2):e15786. [doi: 10.2196/15786] [Medline: 32996890]
16. Lakshmanan A, Sunshine I, Calvetti S, et al. Designing a mobile health solution to facilitate the transition from NICU to home: a qualitative study. Children (Basel) 2022 Feb 15;9(2):260. [doi: 10.3390/children9020260] [Medline: 35204980]
17. Lindkvist RM, Sjöström-Strand A, Landgren K, Johnsson BA, Stenström P, Hallström IK. "In A Way We Took the Hospital Home"-a descriptive mixed-methods study of parents' usage and experiences of eHealth for self-management after hospital discharge due to pediatric surgery or preterm birth. Int J Environ Res Public Health 2021 Jun 15;18(12):6480. [doi: 10.3390/ijerph18126480] [Medline: 34203985]
18. Azzuqa A, Chuo J, Zenge J. Tele-medicine: Innovative tools for a safe transition to home in neonatal care. Semin Perinatol 2021 Aug;45(5):151427. [doi: 10.1016/j.semperi.2021.151427] [Medline: 34006383]
19. Calcaterra V, Verduci E, Vandoni M, et al. Telehealth: a useful tool for the management of nutrition and exercise programs in pediatric obesity in the COVID-19 era. Nutrients 2021 Oct 20;13(11):3689. [doi: 10.3390/nu13113689] [Medline: 34835945]
20. Ray KN, Ashcraft LE, Mehrotra A, Miller E, Kahn JM. Family perspectives on telemedicine for pediatric subspecialty care. Telemed J E Health 2017 Oct;23(10):852-862. [doi: 10.1089/tmj.2016.0236] [Medline: 28430021]
21. Shah AC, O'Dwyer LC, Badawy SM. Telemedicine in malignant and nonmalignant hematology: systematic review of pediatric and adult studies. JMIR Mhealth Uhealth 2021 Jul 8;9(7):e29619. [doi: 10.2196/29619] [Medline: 34255706]
22. Pettit SE, Young E, Jung I. Systematic review of telemedicine in pediatric urology. J Pediatr Urol 2022 Feb;18(1):17-22. [doi: 10.1016/j.jpurol.2021.09.024] [Medline: 34642111]
23. Faiçal AVB, Mota LR, Monteiro LP, Souza ED, Terse-Ramos R. Telehealth for children and adolescents with chronic pulmonary disease: systematic review. Rev Paul Pediatr 2023;42:e2024111. [doi: 10.1590/1984-0462/2024/42/2022111] [Medline: 37194911]
24. Ferro F, Tozzi AE, Erba I, et al. Impact of telemedicine on health outcomes in children with medical complexity: an integrative review. Eur J Pediatr 2021 Aug;180(8):2389-2400. [doi: 10.1007/s00431-021-04164-2] [Medline: 34196791]

XSL•FO
RenderX

25. Mörelius E, Robinson S, Arabiat D, Whitehead L. Digital interventions to improve health literacy among parents of children aged 0 to 12 years with a health condition: systematic review. J Med Internet Res 2021 Dec 22;23(12):e31665. [doi: 10.2196/31665] [Medline: 34941559]
26. Beckmann NB, Dietrich MS, Hooke MC, Gilmer MJ, Akard TF. Parent caregiving experiences and posttraumatic growth following pediatric hematopoietic stem cell transplant. J Pediatr Oncol Nurs 2021;38(4):242-253. [doi: 10.1177/1043454221992306] [Medline: 33750237]
27. Skivington K, Matthews L, Simpson SA, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ 2021 Sep 30;374:n2061. [doi: 10.1136/bmj.n2061] [Medline: 34593508]
28. Clemensen J, Rothmann MJ, Smith AC, Caffery LJ, Danbjorg DB. Participatory design methods in telemedicine research. J Telemed Telecare 2017 Oct;23(9):780-785. [doi: 10.1177/1357633X16686747] [Medline: 28027678]
29. Black AD, Car J, Pagliari C, et al. The impact of eHealth on the quality and safety of health care: a systematic overview. PLoS Med 2011 Jan 18;8(1):e1000387. [doi: 10.1371/journal.pmed.1000387] [Medline: 21267058]
30. Taylor J, Coates E, Wessels B, Mountain G, Hawley MS. Implementing solutions to improve and expand telehealth adoption: participatory action research in four community healthcare settings. BMC Health Serv Res 2015 Dec 1;15:529. [doi: 10.1186/s12913-015-1195-3] [Medline: 26626564]
31. Patton Q. Qualitative Evaluation and Research Methods: Sage Publications Inc; 1990.
32. Kayser L, Karnoe A, Furstrand D, et al. A multidimensional tool based on the eHealth literacy framework: development and initial validity testing of the eHealth literacy questionnaire (eHLQ). J Med Internet Res 2018 Feb 12;20(2):e36. [doi: 10.2196/jmir.8371] [Medline: 29434011]
33. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. Nurse Educ Today 2004 Feb;24(2):105-112. [doi: 10.1016/j.nedt.2003.10.001] [Medline: 14769454]
34. Carter B, Fisher-Smith D, Porter D, et al. Paediatric outpatient parenteral antimicrobial therapy (OPAT): an e-survey of the experiences of parents and clinicians. PLoS ONE 2021;16(4):e0249514. [doi: 10.1371/journal.pone.0249514] [Medline: 33798226]
35. Nilsson S, Hylén M, Kristensson-Hallström I, Kristjánsdóttir G, Stenström P, Vilhjálmsson R. Parental access to healthcare following paediatric surgery-the precarious role of parents as providers of care in the home. Children (Basel) 2023 Sep 21;10(9):1578. [doi: 10.3390/children10091578] [Medline: 37761539]
36. Zucchelli F, Donnelly O, Rush E, Smith H, Williamson H, VTCT Foundation Research Team. Designing an mHealth intervention for people with visible differences based on acceptance and commitment therapy: participatory study gaining stakeholders' input. JMIR Form Res 2021 Mar 24;5(3):e26355. [doi: 10.2196/26355] [Medline: 33759791]
37. Nkoy FL, Hofmann MG, Stone BL, et al. Information needs for designing a home monitoring system for children with medical complexity. Int J Med Inform 2019 Feb;122:7-12. [doi: 10.1016/j.ijmedinf.2018.11.011] [Medline: 30623786]
38. Hylén M, Nilsson S, Kristensson-Hallström I, Kristjánsdóttir G, Stenström P, Vilhjálmsson R. Access to health care perceived by parents caring for their child at home supported by eHealth-a directed approach introducing aperture. BMC Health Serv Res 2022 Aug 8;22(1):1008. [doi: 10.1186/s12913-022-08398-0] [Medline: 35941653]
39. Smith CE, Spaulding R, Piamjariyakul U, et al. mHealth clinic appointment PC tablet: implementation, challenges and solutions. J Mob Technol Med 2015;4(2):21-32. [doi: 10.7309/jmtm.4.2.4] [Medline: 26604991]
40. Kodjebacheva GD, Culinski T, Kawser B, Amin S. Satisfaction with pediatric telehealth according to the opinions of children and adolescents during the COVID-19 pandemic: A literature review. Front Public Health 2023;11:1145486. [doi: 10.3389/fpubh.2023.1145486] [Medline: 37089475]
41. Granja C, Janssen W, Johansen MA. Factors determining the success and failure of eHealth interventions: systematic review of the literature. J Med Internet Res 2018 May 1;20(5):e10235. [doi: 10.2196/10235] [Medline: 29716883]
42. Gund A, Sjöqvist BA, Wigert H, Hentz E, Lindecrantz K, Bry K. A randomized controlled study about the use of eHealth in the home health care of premature infants. BMC Med Inform Decis Mak 2013 Feb 9;13:22. [doi: 10.1186/1472-6947-13-22] [Medline: 23394465]
43. Kruse CS, Krowski N, Rodriguez B, Tran L, Vela J, Brooks M. Telehealth and patient satisfaction: a systematic review and narrative analysis. BMJ Open 2017 Aug 3;7(8):e016242. [doi: 10.1136/bmjopen-2017-016242] [Medline: 28775188]
44. de Buhr E, Tannen A. Parental health literacy and health knowledge, behaviours and outcomes in children: a cross-sectional survey. BMC Public Health 2020 Jul 13;20(1):1096. [doi: 10.1186/s12889-020-08881-5] [Medline: 32660459]
45. Gleghorn EE, Hilk SS, Rothbaum R. Incorporation of telehealth into multidisciplinary clinics: visits via video offer advantages for team and families. J Pediatr Gastroenterol Nutr 2022 Apr 1;74(4):460-462. [doi: 10.1097/MPG.0000000000003392] [Medline: 35129154]

XSL•FO
RenderX

Edited by S Badawy; submitted 20.06.24; peer-reviewed by D Singh, EVD Velde; revised version received 21.11.24; accepted 26.11.24; published 13.03.25.

Please cite as:
Hansson H, Castor C, Larsen HB, Topperzer MK, Olesen ML
Development of an eHealth Intervention in Pediatric Home Infusion Therapy: Interview Study of Needs and Preferences of Parents and Health Care Professionals
JMIR Pediatr Parent 2025;8:e63260
URL: https://pediatrics.jmir.org/2025/1/e63260
doi:10.2196/63260

© Helena Hansson, Charlotte Castor, Hanne Bækgaard Larsen, Martha Krogh Topperzer, Mette Linnet Olesen. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 13.3.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Assessing the Impact of a Telemedicine Program on Caregivers of Children With Complex Chronic Conditions: Pre-Post Intervention Study

Aurora Madrid-Rodríguez[1,2], MD, PhD; María José Peláez-Cantero[1,2], MD, PhD; Alfonso Lendínez-Jurado[2,3,4], MD; Ana Suárez-Carrasco[1], BSN; Elena Godoy-Molina[1,2,3], MD, PhD; Antonia Gámez-Ruiz[1], BSN; Ana Corripio-Mancera[1], BSN; Yolanda Ramón-Telo[1], BSN; Ana García-Ruiz[4], MD; Isabel Leiva-Gea[2,3], MD, PhD

[1]Complex Chronic Patient and Palliative Care Unit, Department of Pediatrics, Regional University Hospital of Malaga, Málaga, Spain

[2]Instituto de Investigación Biomédica de Málaga y Plataforma en Nanomedicina-IBIMA Plataforma BIONAND, Calle Severo Ochoa, 35, Campanillas, Málaga, Spain

[3]Universidad de Málaga, Andalucía Tech, Campus de Teatinos, Málaga, Spain

[4]Distrito Sanitario Málaga-Guadalhorce, Málaga, Spain

Corresponding Author:
Alfonso Lendínez-Jurado, MD
Instituto de Investigación Biomédica de Málaga y Plataforma en Nanomedicina-IBIMA Plataforma BIONAND, Calle Severo Ochoa, 35, Campanillas, Málaga, Spain

Abstract

Background: The COVID-19 pandemic was a paradigm shift in global health care. This situation highlighted the role of telemedicine in adapting to the care requirements of pediatric patients and their families by facilitating remote consultations and ensuring continuity of care.

Objective: We aimed to establish the usefulness of a telemedicine program for caregivers of children with complex chronic conditions.

Methods: We performed a quasi-experimental pre-post intervention study of a telemedicine program, regarding health care system use and caregiver quality of life while comparing two periods: before and during the COVID-19 pandemic. This study included caregivers of children with complex chronic conditions followed-up in a specialized unit.

Results: A total of 34 families were included. The mean number of visits per year was higher in the preintervention period for both primary care consultations (*P*=.03) and hospital-specialized medical consultations (*P*=.03). The number of emergency room visits per year was lower in the pandemic period compared to the prepandemic period (*P*=.01). In both groups, an improvement in caregiver quality of life was detected at 12 months (*P*=.03). However, the Rosenberg self-esteem scale score for the primary caregiver was significantly lower at 3 months compared to the baseline (*P*=.03).

Conclusions: Our study demonstrates that the use of a telemedicine program resulted in decreased scheduled face-to-face care visits and a reduction in the number of emergency department visits. Regarding the caregiver quality of life, outcomes were poorer among families whose children were affected by neurological conditions or were diagnosed at an older age.

(JMIR Pediatr Parent 2025;8:e62953) doi:10.2196/62953

KEYWORDS

telemedicine; telehealth; complex chronic children; pediatrics complex chronic conditions; palliative care; COVID-19; caregivers; children; pediatrics; chronic; SARS-Cov-2; pandemic; global health; remote consultation; quasi-experimental; quality of life; primary care

Introduction

Technological advances and progress in medicine have reduced infant mortality [1,2]. These survival successes have contributed to an increase in the prevalence of incurable diseases and disability, which leads us to reassess the way we approach and organize health services to adapt them to these new care needs [3,4].

In high-income countries, children with a complex chronic condition (CCC) represent 0.67% - 5% of the pediatric population; however, they consume up to 40% of total health expenditure, involving a high level of care both in and out of hospital, primary care, and non-health services [5-9].

The prevalence of life-threatening or life-limiting illnesses has increased in recent decades, with an estimated 61.1 per 10,000 children aged 1 - 19 years in the United Kingdom. As reported,

XSL•FO
RenderX

approximately 30% of these children have cancer; the remaining 70% comprise a combination of conditions, mainly neurodegenerative, metabolic, and genetic. Of these, 50% children will require the specialized care of a pediatric palliative care unit [10,11].

Therefore, a new strategy is required to transform the current care model, which is focused on treatment—where the patient is a passive subject—into a proactive model more centered on the needs of patients and their caregivers. In this revised model, the patients have more information and autonomy to play an active role in managing the disease [12,13].

In this context, new information and communication technologies (ICTs) provide tools that enable access to a wide range of resources. Numerous studies have endorsed telehealth as a supplementary approach to in-person care for managing chronic diseases [14]. However, the effectiveness of telehealth as a replacement for face-to-face care in patients with chronic conditions remains unclear [15,16].

In 2020, the COVID-19 pandemic transformed medical care through telemedicine with a demand for remote health care and telehealth [17,18]. While the world faced an unprecedented pandemic, patients with chronic diseases required special attention on an ongoing basis and, if warranted, an adaptation of their usual care [19]. This need arose as health care systems were overwhelmed, with most resources diverted to manage COVID-19 patients and their associated complications. The resulting strain on primary and hospital care made in-person evaluations for patients with chronic conditions especially challenging [20].

In complex chronic patient and pediatric palliative care units, telemedicine provides an accessible and equitable tool. With these tools, families can remain in contact with professionals by establishing a schedule for specific services in a time-effective manner and adapted to the stage of the illness [21,22].

Due to the COVID-19 pandemic and considering the vulnerability and fragility of these patients, some of the tools offered by ICT for the continuity of care have become even more useful, as they allow nonface-to-face visits; but with a capacity comparable to face-to-face visits, minimizing the risk of infection, and reducing the need to travel to a medical center [23]. Moreover, these tools may enhance treatment adherence, prevent medication errors, and foster greater engagement in self-care practices [24].

This study aimed to develop and evaluate a telemedicine program for the care of children with CCCs or those receiving palliative care, both before and during the COVID-19 pandemic, within a specialized pediatric palliative care unit.

Methods

Study Design and Setting

We designed a quasi-experimental pre-post intervention study in the Complex Chronic Patient and Palliative Care Unit of a pediatric tertiary hospital.

The study population comprised children with CCCs or those needing palliative care and their families. Inclusion criteria required that children meet the definition of medical complexity algorithm defined by the Seattle Children's Hospital Group and score at least 6,5 points on the PedCom Scale [25,26]. Participants also had to be followed-up in the Complex Chronic Patient and Pediatric Palliative Care Unit of the hospital and had a high level of complexity, defined not only by the identification of the children as complex chronic patients but also by high consumption of resources: two or more hospital admissions, at least one admission to intensive care, or six or more visits to the emergency department in the last twelve months [27]. Patients older than 18 years or those whose families did not provide informed consent were excluded.

Ethical Considerations

The study protocol was in accordance with the Declaration of Helsinki. All caregivers were informed about the study and signed a consent form, with no financial compensation provided. All data were anonymized to ensure confidentiality. This study was approved by the Research Ethics Committee of Malaga in May 2017 (reference: PIN-0287 - 2016).

Telemedicine Program Description

The telemedicine program was remotely managed and controlled by the hospital and its technical support center. It comprised three main functionalities:

1. Communication: The technology used was an Android-based smart TV platform connected to a television, which allows access to advanced telecommunication and medical device management services. It allows videoconferencing between patient (through the TV) and hospital (via PC), or between the patient and the medical professional (via PC, tablet, or smartphone), based on session initiation protocol technology (ie, market standard).
2. Information and training: Through the platform, families accessed a menu of audiovisual contents. The contents were developed by the professionals of the unit. This includes: information including telephone numbers of interest for caregivers; individualized access to videos, according to specific CCCs, with recommendations, procedures, theoretical and practical workshops including specific training such as nutritional management for patients receiving enteral support, oxygen therapy, or cardiopulmonary resuscitation, and PowerPoint presentations on neonatal techniques and care, secretion aspiration, and monitoring and respiratory care; and information on the current vaccination schedule.
1. Health care: The platform allowed clinical assessment via video call, with the option of requesting tests (laboratory and radiological), modification of technological support parameters, and issuing electronic medical prescriptions.

During recruitment, to avoid selection bias caused by the digital divide for families who did not have internet access at home, it was provided through project funding.

XSL•FO
RenderX

Evaluation of the Program

The evaluation of the program was undertaken through the comparison of two one-year time periods; before the pandemic (March 2019 to February 2020) and during the pandemic (March 2020 to February 2021).

Sociodemographic variables described included age, gender, primary caregiver (parent or both parents), number of siblings, place of residence, and country of origin.

- Evaluation of face-to-face health care variables were categorized as follows: (1) scheduled: primary care consultations, hospital outpatient consultations per year, number of outpatient consultations in the Unit, number of home visits made by the Unit, number of scheduled hospital admissions; (2) urgent: number of emergency room visits, and number of urgent hospital admissions.
- Evaluation of telephone health care variables: (1) number of calls from the Unit to caregivers and (2) number of calls from caregivers to the Unit.
- Caregiver reported outcomes: (1) the Rosenberg Self-Esteem Scale [28,29], (2) the Positive and Negative Affect Schedule (PANAS) [30,31], (3) health-related quality of life of primary caregivers (EuroQol-5D-5L) [32], (4) short Zarit Caregiver Burden Interview (ZARIT) scale to assess primary caregiver burden [33,34].

The evaluation of the telemedicine program was carried out with periodic assessments (ie, baseline, 3, 6, and 12 months) of the health care variables and caregiver reported outcomes. The last assessment was carried out 12 months after the start of the intervention. The health care data was collected by telephone and the tests by mail and email.

Data Analysis

Data analysis was performed using free R software (version 4.0.2; R Foundation for Statistical Computing). The Shapiro-Wilk test analysis was performed to determine the normality of the study variables. Data were presented as mean (SD) values in normal distributions or as median (IQR) for non-normal distributions. For independent quantitative variables, Student one-tailed *t* test was used for normally distributed data, and the Mann-Whitney *U* test for not normal distributed data. The Wilcoxon signed-rank test was performed to analyze differences in the non-normal distributions, and the paired *t* test for normal distributed data. To compare qualitative variables, the χ^2 test was used for independent samples and McNemar test for related samples. A *P* value <.05 was considered statistically significant. *P* values were adjusted using the Benjamini-Hochberg correction to control for multiple comparisons.

Results

Study Population Characteristics

A total of 34 patients were included, ranging in age from 3 months to 14.2 years, with a median age of 4.9 years; 53% (18/34) were female participants. The most common CCC that affected our patients was neurological 73% (n=25), followed by gastrointestinal 71% (n=24), respiratory 50% (n=17), cardiovascular 41% (n=14), and oncological 21% (n=7). In addition, neurological CCCs were also the most frequent primary CCC in 47% (n=16), with cerebral palsy being the most prevalent neurological disease (11/16, 69%).

The primary caregiver was the mother in 82% (n=28) and 47% (n=16) of the families received social assistance; 91% of the families (n=31) received psychological care. A total of 29% (n=10) of the families were from a foreign country and 41% (n=14) had no other children; the number of children per family ranged from 0 to 5, with a median of 1.

Impact of the Telemedicine Program on Health Care Activity During the Pandemic

Regarding scheduled care, bivariate analysis showed that the mean number of visits to primary care consultations per year was higher in the pre-pandemic period (*P*=.03), as well as more hospital specialty consultations (*P*=.03) (Table 1).

In terms of emergency care, there were significant differences in the number of emergency department visits per year during the compared to the prepandemic period (*P*=.01), with fewer visits during the pandemic. No significant differences were found in emergency hospital admissions between the two periods (Table 1).

Regarding telephone care provided by the Unit, we noted a nonsignificant increase in the number of calls made by the Unit during the pandemic (*P*=.06). However, there was a significant increase in telephone calls made by caregivers to the Unit during the pandemic compared to the pre-pandemic period (*P*=.003) (Table 2).

There were no significant differences between the mean length of hospital stays (measured in days) before and during the pandemic.

Tables 1 and 2 display the variables related to the health care provided.

XSL•FO
RenderX

Table . Analysis of variables associated with face-to-face health care activity.

Type of care activity	Prepandemic period with telemedicine, mean (SD)	Pandemic period with telemedicine, mean (SD)	*P* value
Scheduled			
Primary care consultations	9.2 (9.9)	6.6 (5.9)	.03
Scheduled consultations hospital specialties	29.6 (19.2)	23.4 (19.2)	.03
Nurse consultations at CC[a] and PPC[b] Unit	8.3 (6.8)	10.1 (9.5)	.54
Pediatrician consultations at CC and PPC Unit	6.7 (5.6)	7.2 (5.6)	.77
Nursing home visits at CC and PPC Unit	3.1 (5.3)	2.4 (4.8)	.20
Pediatrician home visits CC and PPC Unit	2.8 (5.0)	2.1 (4.4)	.09
Scheduled admissions	0.6 (1.0)	0.6 (0.8)	.60
Urgent			
Emergency hospital visits	3.6 (4.0)	2.1 (2.1)	.01
Urgent hospital admissions	1.4 (1.5)	1.2 (1.5)	.19

[a]CC: complex chronic.

[b]PPC: pediatric palliative care

Table . Analysis of variables related to telephone health care activity.

Type of care activity	Pretelemedicine period, mean (SD)	Pandemic period with telemedicine, mean (SD)	*P* value
Unit calls to caregivers	36.4 (34)	48 (26)	.06
Caregivers calls to the Unit	6.2 (7.8)	10.5 (9.5)	.003

Impact of the Telemedicine Program on the Caregiver-Reported Outcomes

Significant differences were seen in the visual analogue scale (VAS) of the EuroQol five-dimension (EQ-5D) quality of life test of the primary caregivers at 12 months compared with baseline, with an increase in VAS scores at 12 months (*P*=.03).

The Rosenberg self-esteem scale scores of the primary caregivers were significantly lower at 3 months than at baseline (*P*=.03). There was a significant negative correlation between the short Zarit Caregiver Burden Interview (ZARIT) scale for primary caregiver burden at 6 months and the number of siblings (adjusted R^2=0.37; *P*=.009). The VAS score of the EQ-5D quality of life scale for primary caregivers at 12 months correlated negatively and significantly with age at diagnosis of the child's illness (adjusted R^2=0.24; *P*=.04).

The difference in the index value of the EQ-5D quality of life scale for primary caregivers from baseline to 3 months was negatively correlated with the age at patient admission (adjusted R^2=0.97; *P*=.007).

In the analysis of the relationship between caregiver quality of life and the different types of CCCs, the difference in index value of the EQ-5D quality of life scale for primary caregivers from baseline to 3 months was negatively correlated with neurological disease (adjusted R^2=0.89; *P*=.03).

Table 3 shows the results of the tests at baseline and at 3, 6, and 12 months.

XSL•FO
RenderX

Table . Analysis of quality of life test results.

Quality of life tests	0 months, mean (SD)	3 months, mean (SD)	6 months, mean (SD)	12 months, mean (SD)	*P* value
Rosenberg self-esteem scale	29.3 (5.2)	27.3 (6.4)	31.0 (4.2)	33.0 (4.8)	.03
Positive and negative affectivity scales (PANAS)					
Positive affect	29.1 (7.4)	29.5 (7.9)	33.1 (9.4)	33.8 (7.5)	.41
Negative affect	26.8 (8.8)	23.8 (6.8)	24.3 (7.1)	22.8 (6.2)	.34
Health-related quality of life (EuroQol-5D-5L)					
EQ-5D[b] value	0.814 (0.180)	0.766 (0.151)	0.838 (0.153)	0.838 (0.142)	.053
EQ-5D VAS score	76 (18)	75 (15)	78 (14)	75 (21)	.03
Short ZARIT[a] scale	20.1 (7.0)	24.3 (5.0)	20.8 (5.9)	19.8 (5.7)	.44

[a]ZARIT: Zarit Caregiver Burden Interview.

[b]EQ-5D: EuroQol-five dimension.

Discussion

Principal Findings

The development of telemedicine programs has transformed care for patients with chronic illnesses or those in palliative situations. Several studies including the one by Prabhakaran et al [35], highlights the effectiveness of a mobile health intervention in primary care settings within rural Indian communities. This initiative focused on preventing and managing cardiometabolic conditions, depression, and related risk factors among adults. In pediatrics, evidence-based studies, including the consensus developed by the Italian Societies of Telemedicine, Preventive and Social Pediatrics, and Pediatric Primary Care, among others, have demonstrated the critical role of telemedicine in managing patients with chronic conditions (eg, cardiology, respiratory, or neurology) or those requiring palliative care. These findings underscore the potential of telemedicine to enhance healthcare delivery by facilitating improved collaboration among multidisciplinary professionals and patients, creating innovative opportunities to optimize clinical outcomes and service quality [36].

In our study, the most common condition was neurological, which is the most frequent condition as described in literature indicating that neurological patients are the most prevalent. Our findings are in accordance with prior research, with neurological CCCs being the most frequent, followed by gastrointestinal and respiratory CCCs. Also coinciding with published findings, the mother most often fulfilled the role of the primary caregiver [13,37-41].

During the COVID-19 pandemic, as seen in other studies, a decrease was observed in both scheduled and urgent care for children with CCCs, similar to trends in the general pediatric population and among children with special health care needs [42-49].

The increase in telephone consultations during the pandemic, both initiated by the Unit and caregivers, especially the increase in calls from caregivers, may be explained by the decrease in face-to-face care in primary care and in specialized hospital care during this period. This finding highlights the support provided by the Unit via telephone to minimize the impact of the pandemic on children with CCCs, as described in several studies focused on specific care strategies aimed at this particularly vulnerable population [50].

In our study, the absence of significant differences in scheduled or urgent hospital admissions, has been described in other studies on telemedicine in children with CCCs [22]. This may be due to the high complexity of the patients included in this study, where pandemic-related factors may not have influenced the number of hospital admissions or the length of hospital stays.

Several studies have described the importance of the psychosocial needs of children with CCCs and their families and how these needs, especially concerning mental health increased during the pandemic [51,52]. To date, few studies have demonstrated improvements in the quality of life of caregivers from telemedicine programs, often due to the cross-sectional design of studies without multiple cut-off points. Our study highlights the importance of conducting studies that monitor the impact and benefits of these programs throughout the intervention to verify their usefulness [53-55].

In our study, a greater burden on primary caregivers was detected in families with more children, a demographic factor not previously described and one that should be considered to reinforce support for these families.

The quality of life of the primary caregivers measured by the VAS value of the EQ-5D scale at 12 months was poorer in those with children with CCCs diagnosed at an older age. Similarly, we found a negative correlation between the difference in the EQ-5D quality of life scale of the primary caregivers at 3 months, compared to baseline in children with CCCs who were older at admission to the Unit. Our analysis revealed that both the child's age at diagnosis and age at Unit admission were inversely associated with parental quality of life, showing the

XSL•FO
RenderX

most pronounced negative impact at 3- and 12-month follow-up during the pandemic. The influence of the age of the child with a CCC on the quality of life of the primary caregivers during the pandemic has not been examined previously and merits further investigation as a potential modulator of the quality of life of the parents.

Published studies on the impact of neurological diseases have shown an increased family, work, and economic burden on primary caregivers, specifically on caregivers of children with cerebral palsy [56]. In our study, a negative correlation was found between the index value of the EQ-5D quality of life scale of the primary caregiver at 3 months, compared to baseline with neurological CCCs, which was also the most frequent CCC observed.

The observed lower self-esteem among the primary caregivers at 3 months of the telemedicine program during the pandemic setting may be explained by the effects of full confinement, including reduced psychosocial and family support, adaptation of home care with a change in care support, and the increased care burden. This reduction in the quality of life of the primary caregiver at 3 months has not been evaluated in other studies and may be useful for reinforcing psychosocial support to families, considering this period as a turning point in caregiving. Conversely, the observed improvement in VAS of the EQ-5D quality of life test may reflect an increased quality of life at 12 months, which could be attributed to adaptation to the situation as well as decreased isolation measures one year after the pandemic.

It is important to leverage the growth of the ICTs during the pandemic for the benefit of patients, especially those who are most vulnerable and with specific care needs such as children with CCCs. Telemedicine provides equity in care and efforts should be made to evaluate the impact of telemedicine programs in patients, primary caregivers, and health care teams, taking into account the clinical, economic, and quality of life variables in patients and their families monitored over time.

Limitations

The use of telemedicine prior to the pandemic was demonstrated to be effective in children with CCCs, both in reducing the number of emergency department visits and costs [55,57-61]. However, in our study, it was challenging to determine with certainty whether the decrease in urgent or unscheduled care could be attributed to the COVID-19 pandemic or the telemedicine program intervention. During the pandemic, there was a decrease in emergency department visits, as many caregivers were afraid to go to hospitals to avoid infections in their children [43,45]. In addition, we must take into account the decrease in respiratory symptoms due to the confinement and isolation measures described in several studies [45,47,49]. Studies with larger and more homogeneous samples should be carried out after the pandemic to assess whether its effectiveness in terms of care is maintained without the interference caused by the pandemic.

Conclusions

In our study, the use of a telemedicine program during the pandemic resulted in a decrease in scheduled face-to-face care and a reduction in the number of emergency department visits compared to the prepandemic period. Conversely, we observed an increase in telephone support without any impact on hospital admissions. We identified the most vulnerable families in this group of patients, including those with a child affected by a neurological condition, those who had an older child when the disease was diagnosed, and families with a greater number of children. These insights allowed could help guide the redirection of limited resources. Our findings indicated that the telemedicine program was effective in the supporting care of children with CCCs and their families.

Acknowledgments

SmartHealth TV Solutions developed and provided the technology for the project. The authors acknowledge SmartHealth TV Solutions for supporting the project technology and its COVID-19 adaptations. The authors also thank Maria Repice for assistance with the English version of the manuscript.

This project was supported by the Andalusian Public Foundation for Health and Biomedicine Research of Malaga (FIMABIS); project title: *Implementation of a Telemedicine Program in the Care of Complex-Pluripathological Chronic Patients and Patients Receiving Palliative Care in a Pediatric Home Hospitalization Unit* (PIN-0287-2016). This project received the II Unicaja Award for Innovation in Biomedicine and Health, which enabled the improvement and continuity of the project in 2019.

Authors' Contributions

Conceptualization: AMR
Formal analysis: ILG, MJPC
Investigation: ASC, AGR, ACM, YRT
Methodology: ALJ, ILG
Resources: ALJ, ILG
Writing – original draft: ALJ, AMR, AGR, EGM
Writing – review & editing: ALJ, ILG

XSL•FO
RenderX

Conflicts of Interest

None declared.

References

1. Cooter R, Pickstone J. Medicine in the Twentieth Century: Taylor & Francis; 2000. [doi: 10.4324/9781003078456]
2. Porter R. The Greatest Benefit to Mankind: A Medical History of Humanity from Antiquity to the Present: Harper Collins; 1997. URL: https://pmc.ncbi.nlm.nih.gov/articles/PMC1112708/
3. Cohen E, Friedman J, Nicholas DB, Adams S, Rosenbaum P. A home for medically complex children: the role of hospital programs. J Healthc Qual 2008;30(3):7-15. [doi: 10.1111/j.1945-1474.2008.tb01137.x] [Medline: 18507235]
4. Busse R, Blümel M, Scheller-Kreinsen D, et al. Tackling chronic disease in europe: strategies interventions and challenges: observatory studies series no 20. World Health Organization-Regional Office for Europe, European Observatory on Health Systems and Policies. 2010. URL: https://iris.who.int/handle/10665/326484 [accessed 2022-02-07]
5. Berry JG, Hall M, Neff J, et al. Children with medical complexity and Medicaid: spending and cost savings. Health Aff (Millwood) 2014 Dec;33(12):2199-2206. [doi: 10.1377/hlthaff.2014.0828] [Medline: 25489039]
6. Braddock ME, Leutgeb V, Zhang L, Koop SE. Factors influencing recurrent admissions among children with disabilities in a specialty children's hospital. J Pediatr Rehabil Med 2015;8(2):131-139. [doi: 10.3233/PRM-150326] [Medline: 26409866]
7. Dunbar P, Hall M, Gay JC, et al. Hospital readmission of adolescents and young adults with complex chronic disease. JAMA Netw Open 2019 Jul 3;2(7):e197613. [doi: 10.1001/jamanetworkopen.2019.7613] [Medline: 31339547]
8. Simon TD, Berry J, Feudtner C, et al. Children with complex chronic conditions in inpatient hospital settings in the United States. Pediatrics 2010 Oct;126(4):647-655. [doi: 10.1542/peds.2009-3266] [Medline: 20855394]
9. Cohen E, Berry JG, Camacho X, Anderson G, Wodchis W, Guttmann A. Patterns and costs of health care use of children with medical complexity. Pediatrics 2012 Dec;130(6):e1463-e1470. [doi: 10.1542/peds.2012-0175] [Medline: 23184117]
10. Fraser LK, Gibson-Smith D, Jarvis S, Norman P, Parslow RC. Estimating the current and future prevalence of life-limiting conditions in children in England. Palliat Med 2021 Oct;35(9):1641-1651. [doi: 10.1177/0269216320975308] [Medline: 33323043]
11. IMPaCCT: standards for paediatric palliative care in Europe. European Journal of Palliative Care 2007;14(3):109-114. [doi: 10.1007/s00482-008-0690-4]
12. Institute of Medicine. Crossing the quality chasm: a new health system for the 21st century: The National Academies Press; 2001. [doi: 10.17226/10027]
13. Mead N, Bower P. Patient-centredness: a conceptual framework and review of the empirical literature. Soc Sci Med 2000 Oct;51(7):1087-1110. [doi: 10.1016/s0277-9536(00)00098-8] [Medline: 11005395]
14. Totten AM, Womack DM, Eden KB, et al. Telehealth: mapping the evidence for patient outcomes from systematic reviews: Rockville (MD): Agency for Healthcare Research and Quality; 2016. URL: www.ncbi.nlm.nih.gov/books/NBK379320/
15. Srinivasan M, Asch S, Vilendrer S, et al. Qualitative assessment of rapid system transformation to primary care video visits at an academic medical center. Ann Intern Med 2020 Oct 6;173(7):527-535. [doi: 10.7326/M20-1814] [Medline: 32628536]
16. Albritton J, Ortiz A, Wines R, et al. Video teleconferencing for disease prevention, diagnosis, and treatment : a rapid review. Ann Intern Med 2022 Feb;175(2):256-266. [doi: 10.7326/M21-3511] [Medline: 34871056]
17. Wosik J, Fudim M, Cameron B, et al. Telehealth transformation: COVID-19 and the rise of virtual care. J Am Med Inform Assoc 2020 Jun 1;27(6):957-962. [doi: 10.1093/jamia/ocaa067] [Medline: 32311034]
18. Barney A, Buckelew S, Mesheriakova V, Raymond-Flesch M. The COVID-19 pandemic and rapid implementation of adolescent and young adult telemedicine: challenges and opportunities for innovation. J Adolesc Health 2020 Aug;67(2):164-171. [doi: 10.1016/j.jadohealth.2020.05.006] [Medline: 32410810]
19. Low JK, Manias E. Use of technology-based tools to support adolescents and young adults with chronic disease: systematic review and meta-analysis. JMIR Mhealth Uhealth 2019 Jul 18;7(7):e12042. [doi: 10.2196/12042] [Medline: 31322129]
20. Pujolar G, Oliver-Anglès A, Vargas I, Vázquez ML. Changes in access to health services during the COVID-19 pandemic: a scoping review. Int J Environ Res Public Health 2022 Feb 3;19(3):1749. [doi: 10.3390/ijerph19031749] [Medline: 35162772]
21. Bird M, Li L, Ouellette C, Hopkins K, McGillion MH, Carter N. Use of synchronous digital health technologies for the care of children with special health care needs and their families: scoping review. JMIR Pediatr Parent 2019 Nov 21;2(2):e15106. [doi: 10.2196/15106] [Medline: 31750840]
22. Braun L, Steurer M, Henry D. Healthcare utilization of complex chronically ill children managed by a telehealth-based team. Front Pediatr 2021;9:689572. [doi: 10.3389/fped.2021.689572] [Medline: 34222153]
23. Shah AC, Badawy SM. Telemedicine in pediatrics: systematic review of randomized controlled trials. JMIR Pediatr Parent 2021 Feb 24;4(1):e22696. [doi: 10.2196/22696] [Medline: 33556030]
24. Vicente MA, Fernández C, Guilabert M, et al. Patient engagement using telemedicine in primary care during COVID-19 pandemic: a trial study. Int J Environ Res Public Health 2022 Nov 9;19(22):14682. [doi: 10.3390/ijerph192214682] [Medline: 36429402]

XSL•FO
RenderX

25. Simon TD, Cawthon ML, Stanford S, et al. Pediatric medical complexity algorithm: a new method to stratify children by medical complexity. Pediatrics 2014 Jun;133(6):e1647-e1654. [doi: 10.1542/peds.2013-3875] [Medline: 24819580]
26. Godoy-Molina E, Fernández-Ferrández T, Ruiz-Sánchez JM, et al. A scale for the identification of the complex chronic pediatric patient (PedCom Scale): a pilot study. In: Pediatr A, editor. An Pediatr (Engl Ed) 2022 Sep;97(3):155-160. [doi: 10.1016/j.anpede.2021.10.004] [Medline: 35871152]
27. Parente V, Parnell L, Childers J, Spears T, Jarrett V, Ming D. Point-of-Care complexity screening algorithm to identify children with medical complexity. Hosp Pediatr 2021 Jan;11(1):44-51. [doi: 10.1542/hpeds.2020-0066] [Medline: 33298458]
28. Rosenberg M. Society and the adolescent self-image: Princeton University Press,1965. URL: https://www.jstor.org/stable/j.ctt183pjjh [accessed 2025-05-12]
29. Atienza L, Moreno-Balaguer I. An analysis of the dimensionality of the Rosenberg self-esteem scale in a sample of Valencian adolescents [Spanish]. Universitas Tarraconensis 2000;22:34-45 [FREE Full text]
30. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. J Pers Soc Psychol 1988 Jun;54(6):1063-1070. [doi: 10.1037//0022-3514.54.6.1063] [Medline: 3397865]
31. Joiner TE Jr, Sandín B, Chorot P, Lostao L, Marquina G. Development and factor analytic validation of the SPANAS among women in Spain: (more) cross-cultural convergence in the structure of mood. J Pers Assess 1997 Jun;68(3):600-615. [doi: 10.1207/s15327752jpa6803_8] [Medline: 9170299]
32. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res 2011 Dec;20(10):1727-1736. [doi: 10.1007/s11136-011-9903-x] [Medline: 21479777]
33. Bédard M, Molloy DW, Squire L, Dubois S, Lever JA, O'Donnell M. The Zarit Burden Interview: a new short version and screening version. Gerontologist 2001 Oct;41(5):652-657. [doi: 10.1093/geront/41.5.652] [Medline: 11574710]
34. Gort AM, March J, Gómez X, de Miguel M, Mazarico S, Ballesté J. Escala de Zarit reducida en cuidados paliativos. Medicina Clínica 2005 May;124(17):651-653. [doi: 10.1157/13074742]
35. Prabhakaran D, Jha D, Prieto-Merino D, et al. Effectiveness of an mHealth-based electronic decision support system for integrated management of chronic conditions in primary care: the mWellcare cluster-randomized controlled trial. Circulation 2019 Jan 15;139(3):380-391. [doi: 10.1161/CIRCULATIONAHA.118.038192] [Medline: 30586732]
36. Esposito S, Rosafio C, Antodaro F, et al. Use of telemedicine healthcare systems in children and adolescents with chronic disease or in transition stages of life: consensus document of the Italian Society of Telemedicine (SIT), of the Italian Society of Preventive and Social Pediatrics (SIPPS), of the Italian Society of Pediatric Primary Care (SICuPP), of the Italian Federation of Pediatric Doctors (FIMP) and of the Syndicate of Family Pediatrician Doctors (SIMPeF). J Pers Med 2023 Jan 28;13(2):235. [doi: 10.3390/jpm13020235] [Medline: 36836469]
37. Climent Alcalá FJ, García Fernández de Villalta M, Escosa García L, Rodríguez Alonso A, Albajara Velasco LA. Children's medically complex diseases unit. a model required in all our hospitals. Anales de Pediatría (English Edition) 2018 Jan;88(1):12-18. [doi: 10.1016/j.anpede.2017.04.004]
38. Gordon JB, Colby HH, Bartelt T, Jablonski D, Krauthoefer ML, Havens P. A tertiary care-primary care partnership model for medically complex and fragile children and youth with special health care needs. Arch Pediatr Adolesc Med 2007 Oct;161(10):937-944. [doi: 10.1001/archpedi.161.10.937] [Medline: 17909136]
39. Berry JG, Agrawal R, Kuo DZ, et al. Characteristics of hospitalizations for patients who use a structured clinical care program for children with medical complexity. J Pediatr 2011 Aug;159(2):284-290. [doi: 10.1016/j.jpeds.2011.02.002] [Medline: 21429511]
40. Rehm RS. Nursing's contribution to research about parenting children with complex chronic conditions: an integrative review, 2002 to 2012. Nurs Outlook 2013;61(5):266-290. [doi: 10.1016/j.outlook.2013.03.008] [Medline: 23809600]
41. Macedo EC, da Silva LR, Paiva MS, Ramos MNP. Burden and quality of life of mothers of children and adolescents with chronic illnesses: an integrative review. Rev Lat Am Enfermagem 2015;23(4):769-777. [doi: 10.1590/0104-1169.0196.2613] [Medline: 26444180]
42. Onofri A, Pavone M, De Santis S, et al. Telemedicine in children with medical complexity on home ventilation during the COVID-19 pandemic. Pediatr Pulmonol 2021 Jun;56(6):1395-1400. [doi: 10.1002/ppul.25289] [Medline: 33524228]
43. Baumbusch J, Lloyd JEV, Lamden-Bennett SR, Ou C. The unintended consequences of COVID-19 public health measures on health care for children with medical complexity. Child Care Health Dev 2022 Nov;48(6):970-978. [doi: 10.1111/cch.12968] [Medline: 35043430]
44. Saqib MAN, Siddiqui S, Qasim M, et al. Effect of COVID-19 lockdown on patients with chronic diseases. Diabetes Metab Syndr 2020;14(6):1621-1623. [doi: 10.1016/j.dsx.2020.08.028] [Medline: 32889403]
45. Kadambari S, Abo YN, Phuong LK, Osowicki J, Bryant PA. Decrease in infection-related hospital admissions during covid-19: Why are parents avoiding the doctor? Pediatr Infect Dis J 2020 Nov;39(11):e385-e386. [doi: 10.1097/INF.0000000000002870] [Medline: 32852351]
46. Wilder JL, Parsons CR, Growdon AS, Toomey SL, Mansbach JM. Pediatric hospitalizations during the COVID-19 pandemic. Pediatrics 2020 Dec;146(6):e2020005983. [doi: 10.1542/peds.2020-005983] [Medline: 33144496]
47. Markham JL, Richardson T, DePorre A, et al. Inpatient use and outcomes at children's hospitals during the early COVID-19 pandemic. Pediatrics 2021 Jun;147(6):e2020044735. [doi: 10.1542/peds.2020-044735] [Medline: 33757994]

XSL•FO
RenderX

48. Gavish R, Levinsky Y, Dizitzer Y, et al. The COVID-19 pandemic dramatically reduced admissions of children with and without chronic conditions to general paediatric wards. Acta Paediatr 2021 Jul;110(7):2212-2217. [doi: 10.1111/apa.15792] [Medline: 33539565]
49. Markham JL, Richardson T, Teufel RJ, et al. Impact of COVID-19 on admissions and outcomes for children with complex chronic conditions. Hosp Pediatr 2022 Apr 1;12(4):337-353. [doi: 10.1542/hpeds.2021-006334] [Medline: 35257170]
50. Wong CA, Ming D, Maslow G, Gifford EJ. Mitigating the impacts of the COVID-19 pandemic response on at-risk children. Pediatrics 2020 Jul;146(1):e20200973. [doi: 10.1542/peds.2020-0973] [Medline: 32317311]
51. Geweniger A, Barth M, Haddad AD, et al. Impact of the COVID-19 pandemic on mental health outcomes of healthy children, children with special health care needs and their caregivers-results of a cross-sectional study. Front Pediatr 2022;10:759066. [doi: 10.3389/fped.2022.759066] [Medline: 35223688]
52. von Schulz J, Serrano V, Buchholz M, Natvig C, Talmi A. Increased behavioral health needs and continued psychosocial stress among children with medical complexity and their families during the COVID-19 pandemic. Infant Ment Health J 2022 Jan;43(1):111-126. [doi: 10.1002/imhj.21962] [Medline: 34973062]
53. Looman WS, Hullsiek RL, Pryor L, Mathiason MA, Finkelstein SM. Health-related quality of life outcomes of a telehealth care coordination intervention for children with medical complexity: a randomized controlled trial. J Pediatr Health Care 2018;32(1):63-75. [doi: 10.1016/j.pedhc.2017.07.007] [Medline: 28870494]
54. Perpiñá-Galvañ J, Orts-Beneito N, Fernández-Alcántara M, García-Sanjuán S, García-Caro MP, Cabañero-Martínez MJ. Level of burden and health-related quality of life in caregivers of palliative care patients. Int J Environ Res Public Health 2019 Nov 29;16(23):4806. [doi: 10.3390/ijerph16234806] [Medline: 31795461]
55. Ferro F, Tozzi AE, Erba I, et al. Impact of telemedicine on health outcomes in children with medical complexity: an integrative review. Eur J Pediatr 2021 Aug;180(8):2389-2400. [doi: 10.1007/s00431-021-04164-2] [Medline: 34196791]
56. Brehaut JC, Kohen DE, Raina P, et al. The health of primary caregivers of children with cerebral palsy: How does it compare with that of other Canadian caregivers? Pediatrics 2004 Aug;114(2):e182-e191. [doi: 10.1542/peds.114.2.e182] [Medline: 15286255]
57. Mosquera RA, Avritscher EBC, Pedroza C, et al. Telemedicine for children with medical complexity: a randomized clinical trial. Pediatrics 2021 Sep;148(3):e2021050400. [doi: 10.1542/peds.2021-050400] [Medline: 34462343]
58. McConnochie KM, Ronis SD, Wood NE, Ng PK. Effectiveness and safety of acute care telemedicine for children with regular and special healthcare needs. Telemed J E Health 2015 Aug;21(8):611-621. [doi: 10.1089/tmj.2014.0175] [Medline: 25839784]
59. McKissick HD, Cady RG, Looman WS, Finkelstein SM. The impact of telehealth and care coordination on the number and type of clinical visits for children with medical complexity. J Pediatr Health Care 2017;31(4):452-458. [doi: 10.1016/j.pedhc.2016.11.006] [Medline: 28017489]
60. Notario PM, Gentile E, Amidon M, Angst D, Lefaiver C, Webster K. Home-based telemedicine for children with medical complexity. Telemed J E Health 2019 Nov;25(11):1123-1132. [doi: 10.1089/tmj.2018.0186] [Medline: 30628860]
61. Milne Wenderlich A, Herendeen N. Telehealth in pediatric primary care. Curr Probl Pediatr Adolesc Health Care 2021 Jan;51(1):100951. [doi: 10.1016/j.cppeds.2021.100951]

Abbreviations

CCC: complex chronic condition
EQ-5D: EuroQol five-dimension
ICT: information and communication technologies
VAS: visual analogue scale

Edited by S Badawy; submitted 05.06.24; peer-reviewed by L Iliuta, M Wasilewski; revised version received 01.03.25; accepted 18.03.25; published 20.05.25.

Please cite as:
Madrid-Rodríguez A, Peláez-Cantero MJ, Lendínez-Jurado A, Suárez-Carrasco A, Godoy-Molina E, Gámez-Ruiz A, Corripio-Mancera A, Ramón-Telo Y, García-Ruiz A, Leiva-Gea I
Assessing the Impact of a Telemedicine Program on Caregivers of Children With Complex Chronic Conditions: Pre-Post Intervention Study
JMIR Pediatr Parent 2025;8:e62953
URL: https://pediatrics.jmir.org/2025/1/e62953
doi:10.2196/62953

XSL•FO
RenderX

© Aurora Madrid-Rodríguez, María José Peláez-Cantero, Alfonso Lendínez-Jurado, Ana Suárez-Carrasco, Elena Godoy-Molina, Antonia Gámez-Ruiz, Ana Corripio-Mancera, Yolanda Ramón-Telo, Ana García-Ruiz, Isabel Leiva-Gea. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 20.5.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Multilevel Factors and Indicators of Atypical Neurodevelopment During Early Infancy in Japan: Prospective, Longitudinal, Observational Study

Daigo Kato[1,2,3*], MD, PhD; Akiko Okuno[4*], PhD; Tetsuo Ishikawa[1,3,5,6], PhD; Shoji Itakura[4], PhD; Shinji Oguchi[3]; Yoshiyuki Kasahara[7], PhD; Kenji Kanenishi[8], MD, PhD; Yuzo Kitadai[9], MD; Yoshitaka Kimura[7], MD, PhD; Naoki Shimojo[10], MD, PhD; Kazushige Nakahara[11], MD, PhD; Akiko Hanai[1,3], PhD; Hiromichi Hamada[2], MD, PhD; Haruta Mogami[12], MD, PhD; Seiichi Morokuma[13], MD, PhD; Kazuhiro Sakurada[3,5], PhD; Yukuo Konishi[4†], MD, PhD; Eiryo Kawakami[1,3], MD, PhD

[1]Department of Artificial Intelligence Medicine, Graduate School of Medicine, Chiba University, Chiba, Japan

[10]Center for Preventive Medical Sciences, Chiba University, Chiba, Japan

[11]Department of Obstetrics and Gynecology, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan

[12]Department of Gynecology and Obstetrics, Kyoto University Graduate School of Medicine, Kyoto, Japan

[13]Department of Health Sciences, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan

[2]Department of Pediatrics, Graduate School of Medicine, Chiba University, Chiba, Japan

[3]Advanced Data Science Project, RIKEN Information R&D and Strategy Headquarters, 1-7-22 Suehiro-cho, Tsurumi-ku, Yokohama, Japan

[4]Center for Baby Science, Doshisha University, Kyoto, Japan

[5]Department of Extended Intelligence for Medicine, The Ishii-Ishibashi Laboratory, Keio University School of Medicine, Shinjuku, Japan

[6]Collective Intelligence Research Laboratory, Graduate School of Arts and Sciences, The University of Tokyo, Meguro, Japan

[7]Department of Maternal and Fetal Therapeutics, Graduate School of Medicine, Tohoku University, Sendai, Japan

[8]Department of Perinatology and Gynecology, Graduate School of Medicine, Kagawa University, Kita, Japan

[9]Department of Obstetrics, Fukuoka Children's Hospital, Fukuoka, Japan

[†]deceased

[*]these authors contributed equally

Corresponding Author:
Eiryo Kawakami, MD, PhD
Department of Artificial Intelligence Medicine, Graduate School of Medicine, Chiba University, Chiba, Japan

Abstract

Background: The early identification of developmental concerns requires understanding individual differences that may represent early signs of neurodevelopmental conditions. However, few studies have longitudinally examined how child and maternal factors interact to shape these early developmental characteristics.

Objective: We aim to identify factors from the perinatal to infant periods associated with early developmental characteristics that may precede formal diagnoses and propose a method for evaluating individual differences in neurodevelopmental trajectories.

Methods: A prospective longitudinal observational study of 147 mother-child pairs was conducted from gestation to 12 months post partum. Assessments included prenatal questionnaires and blood collection, cord blood at delivery, and postpartum questionnaires at 1, 6, and 12 months. The Modified Checklist for Autism in Toddlers (M-CHAT) was used to evaluate developmental characteristics that might indicate early signs of atypical neurodevelopment. Polychoric or polyserial correlation coefficients assessed relationships between M-CHAT scores and longitudinal variables. L2-regularized logistic regression and Shapley Additive Explanations predicted M-CHAT scores and determined feature contributions.

Results: Twenty-one factors (4 prenatal, 3 at birth, and 14 postnatal) showed significant associations with M-CHAT scores (adjusted *P* values<.05). The predictive accuracy for M-CHAT scores demonstrated reasonable predictive accuracy (area under the receiver operating characteristic curve=0.79). Key predictors included infant sleep status after 6 months (nighttime sleep duration, bedtime, and difficulties falling asleep), maternal Kessler Psychological Distress Scale scores, and Mother-to-Infant Bonding Scale scores after late gestation.

Conclusion: Maternal psychological distress, mother-infant bonding, and infant sleep patterns were identified as significant predictors of early developmental characteristics that may indicate emerging developmental concerns. This study advances our

XSL•FO
RenderX

understanding of early developmental assessment by providing a novel approach to identifying and evaluating early indicators of atypical neurodevelopment.

(JMIR Pediatr Parent 2025;8:e58337) doi:10.2196/58337

KEYWORDS

early developmental signs; neurodevelopmental screening; risk factors; prediction; early intervention; longitudinal study

Introduction

Early identification of neurodevelopmental disorders and timely intervention are crucial for optimizing developmental outcomes in children [1]. Children exhibit considerable individual differences in their developmental trajectories during the first year of life, particularly in preverbal social behavior skills [2]. These differences have emerged as crucial areas of study in neurodevelopmental research, as some behavioral characteristics observed during infancy may represent early indicators of developmental concerns [3-5]. Similar to how the concept of mild cognitive impairment has facilitated early intervention in preclinical stages of dementia [6], identifying early indicators of developmental concerns may enable more timely and effective support strategies. However, the complex nature of early development, with its inherent variability and multiple influencing factors, has made it challenging to identify and interpret these early indicators reliably.

Multiple factors influence early childhood neurodevelopment, including prenatal conditions such as maternal immune activation [7], stress [8], and nutritional status, as well as postnatal factors including parental depression [9,10] and early life experiences [11]. Recent research has also highlighted the importance of biological factors such as cytokine profiles [12-14] and sleep-wake rhythms [15-18] in early neurodevelopment. While these factors have been studied individually, their complex interactions across time and their cumulative impact on neurodevelopmental trajectories remain poorly understood.

This study is an exploratory longitudinal investigation conducted in Japan, following mothers and children from the perinatal period (20 weeks of gestation) to the end of infancy (12 months of age). Using an innovative explainable artificial intelligence methodology, we aimed to visualize and analyze how various longitudinal factors interact to influence individual neurodevelopmental trajectories during infancy. Specifically, we assessed preverbal social behavior skills at 12 months of age as potential early indicators of developmental concerns using the Modified Checklist for Autism in Toddlers (M-CHAT) [3,5], and systematically evaluated how multiple observed factors throughout the first year of life contributed to these developmental characteristics. This approach enables a comprehensive understanding of the temporal dynamics and relative importance of various factors in shaping early neurodevelopmental trajectories, potentially identifying key time points and factors for early intervention.

Methods

Recruitment

This study is part of an ongoing multicenter Japanese longitudinal research conducted by 6 collaborating institutions—namely, Kyushu University Graduate School of Medicine, Kagawa University School of Medicine, Tohoku University Graduate School of Medicine, Kyoto University School of Medicine, Fukuoka City Children's Hospital, and RIKEN. Pregnant women were recruited between October 2018 and June 2020 at 5 of the collaborating institutions (excluding RIKEN). Overall, 200 women who fulfilled the inclusion criteria (aged ≥20 years, pregnant with a gestational period of less than 26 completed weeks, and fetus in stable condition) agreed to participate. The exclusion criteria were the requirement for proxy consent or the inability to provide voluntary consent. These criteria were established by the Ethical Guidelines for Medical and Health Research Involving Human Subjects to ensure that severe comorbidities or extreme factors would not influence the results of this study. Participants were followed up by visiting the affiliated facilities at midgestation (24 - 26 weeks), late gestation (34 - 38 weeks), at birth, and 1 month post partum. Their children were enrolled at birth and followed up by mailing questionnaires at 1, 6, and 12 months of age. By November 2022, a total of 147 participants and their children had completed the 12-month follow-up. Two patients were excluded due to meeting the exclusion criteria for chromosomal abnormalities: 1 with trisomy 21 and another with an unspecified chromosomal abnormality. The third excluded patient was born at 25 weeks' gestation weighing 734 g, thus meeting both the criteria for very low birth weight (<1000 g) and extreme preterm birth (<30 weeks). These 3 cases were consequently removed from the study population. This study was prospectively registered in the UMIN Clinical Trials Registry (UMIN000034837) on November 9, 2018. While registered in a clinical trial registry, this research is an exploratory study, not a clinical trial. It uses nonpredefined analytical methods, which distinguishes it from traditional clinical trials with preset end points and analysis plans. The registration was carried out for transparency, despite the exploratory nature precluding a detailed prespecified analysis plan. This study was reported according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Maternal Assessment

Peripheral blood collected at mid- and late gestation and cord blood at birth was used to measure levels of 1,25-dihydroxyvitamin D, 25-hydroxyvitamin D, melatonin, and cytokines (interleukin [IL]-17A, IL-10, IL-1β, IL-6, and tumor necrosis factor). The participating mothers completed a series of questionnaires at mid- and late gestation and at 1 month

XSL•FO
RenderX

post delivery (Multimedia Appendix 1). Maternal hematological biomarkers (vitamin D, melatonin, and cytokines) were measured from blood samples collected during prenatal check-ups and from umbilical cord blood at delivery. While prenatal check-ups typically occur during daytime hours, we did not standardize the exact timing of blood collection. Similarly, as birth times vary unpredictably, umbilical cord blood collection times were inconsistent across subjects. Maternal sleep status was evaluated using the Pittsburgh Sleep Quality Index [19] to assess the quality of sleep and the 3D Sleep Scale (3DSS) [20] to assess sleep regularity (the "sleep phase" item). The Edinburgh Postnatal Depression Scale (EPDS) [21] and Kessler Psychological Distress Scale (K6) [22] were used to assess depression and anxiety disorders, respectively, during pregnancy and post partum. The late gestation questionnaire also included the Autism-Spectrum Quotient Japanese short version (AQ-J-10) [23]. At 1 month post partum, the Japanese version of the Mother-to-Infant Bonding Scale (MIBS-J) [24] was used to assess the mothers' feelings toward their babies.

Infant Assessment and Outcomes

When the children were 1, 6, and 12 months of age, mothers completed questionnaires regarding the children's sleep status (Multimedia Appendix 2). To assess early developmental characteristics in infants, we focused on the acquisition of standard preverbal social behavioral skills and the presence of behaviors commonly associated with autism spectrum disorder (ASD). Specifically, we administered the Japanese version of the M-CHAT at 12 months of age to systematically evaluate these early developmental characteristics. The M-CHAT—a parent-completed dichotomous questionnaire designed for children aged 16 - 30 months—is an effective primary screening tool for ASD and other developmental concerns in the general population [3,5]. In our study, we aimed to identify children showing potential developmental concerns at an earlier stage, specifically at 12 months of age. To achieve this, we developed a unique 10-item version of the M-CHAT, informed by age-specific achievement rates observed in a separate observational study of the general Japanese population. Given that prelinguistic social behaviors vary significantly with age, we included in our analysis 4 age-independent ASD-specific behavioral abnormalities (Q11, Q18, Q20, and Q22) and 6 prelinguistic social behaviors (Q1, Q2, Q4, Q10, Q12, and Q14) that are reported to be consistently achieved by 12 months of age in the general population [4]. The items included were as follows: (Q1) "enjoying being swung," (Q2) "interest in other children," (Q4) "enjoying peek-a-boo," (Q10) "eye contact," (Q11) "oversensitive to noise," (Q12) "response to smile," (Q14) "response to name," (Q18) "unusual finger movement," (Q20) "wonder if deaf," and (Q22) "stares at nothing." Children who fulfilled any of the 10 total M-CHAT items (M-CHAT score ≥1 point) were defined as the M-CHAT positive group.

Statistical Analysis

Descriptive statistics were used to investigate the characteristics of the participating mothers and their infants. Continuous variables—listed as the median and IQR—included maternal age, 1,25-dihydroxyvitamin D, 25-hydroxyvitamin D, melatonin, IL-17A, IL-10, IL-1β, IL-6, tumor necrosis factor, 3DSS (phase), Pittsburgh Sleep Quality Index global score (PSQIG), EPDS, K6, AQ-J-10, MIBS-J, and umbilical artery blood pH. Categorical variables—listed as frequencies and percentages—included the child's sex, maternal smoking history, educational level of parents, annual household income, gestational age at birth, birth weight, Apgar score at 5 minutes, delivery type, answers to sleep-related questions at each period, and the M-CHAT score. Thereafter, the correlation coefficients between the variables were calculated considering the aforementioned categorical variables and 3DSS (phase), PSQIG, EPDS, K6, AQ-J-10, and MIBS-J as ordinal variables. Polyserial correlation coefficients were computed for the relationships between ordinal and continuous variables; further, polychoric correlation coefficients were computed for the relationships between ordinal variables. These polychoric and polyserial correlation coefficients, as well as Pearson correlation coefficients for continuous variable pairs, were calculated using the lavCor function from the *lavaan* package in R software (R Foundation). Wald tests were performed to assess the statistical significance of each correlation. To address the issue of multiple comparisons arising from these correlation tests, false discovery rate correction [25] was subsequently applied to the resulting *P* values. This was performed using the p.adjust() function in R software. Adjusted *P* values (p.adjust) of <.05 were considered statistically significant.

Correlation Analysis

In this study, the relationships between variables affecting the M-CHAT score were represented by network structure. The nodes were variables that showed significant polychoric or polyserial correlations with the M-CHAT score ($|r| \geq .2$, p.adjust <.05). The nodes were arranged according to the data collection period.

Classification Model for the M-CHAT Positive Group

We implemented a classification model using a logistic regression algorithm with potential regularization in the scikit-learn Python package (version 3.1.2) to predict the M-CHAT positive group in infants aged 12 months. We used features of maternal and child demographics, laboratory values, and questionnaire results from the midgestation to 12 months post partum that exhibited a significant correlation (p.adjust<.05) and $|r| \geq .2$ with the M-CHAT score. This model, overall, used 20 features. The data obtained at 12 months of age had missing values, which were completed with missForest—a modern method based on random forests that efficiently addresses missing data imputation among multivariate data without cross-validating with the test data [26]. This method involves inherent randomness, potentially leading to variability in imputed datasets. In our study, we did not set a fixed seed during the missForest imputation. The mother-child dataset was divided into a training set (N=100) for training the prediction model and a test set (N=44) for evaluating the model's performance by using the train_test_split function in scikit-learn. To address the imbalanced nature of our dataset, we used the "stratify" parameter in the train_test_split function, specifying the binary M-CHAT outcome (positive or negative) as the stratification variable. This approach ensured that the distribution of M-CHAT

XSL•FO
RenderX

outcomes was maintained across both the training and test sets. The models were optimized by adapting a grid search method for the hyperparameter "C (regularization strength; 10^{-5}, 10^{-4}, 10^{-3}, 10^{-2}, 10^{-1}, 1, 10, 10^{2}, 10^{3}, 10^{4}, or 10^{5})," "penalty (norm of regularization; L1, L2, elastic net, or none)," and "solver (algorithm in optimization; "newton-cg," "lbfgs," "liblinear," "sag," "saga")." When specifying elastic net as the penalty, we validated by varying the l1_ratio from 0 to 1 in steps of 0.1. The performance of the logistic regression model was evaluated on the test set after ensuring missing data imputation. The model outputs class probabilities to predict the M-CHAT positive (M-CHAT score≥1) group. The optimal threshold for the model was determined by the Youden index.

The model's performance was evaluated using the area under the receiver operating characteristic and precision-recall curves. The relative importance of each feature for predicting M-CHAT scores was examined and visualized using Shapley Additive Explanations (SHAP) [27]. SHAP is a model-agnostic, game-theoretic, unified method that computes a Shapley value to account for each feature's contribution to a particular forecast. SHAP values are computed using an additive feature attribution method to approximate the Shapley value of the model's conditional expectation function. LinearExplainer [28] was used to calculate SHAP values for the logistic regression model. For the decision plotting that simulates the M-CHAT prediction pathway of each sample using SHAP, we specifically used samples with higher M-CHAT scores (M-CHAT scores 2 - 4) within the M-CHAT positive group to focus on cases that might represent early developmental concerns.

Data analysis was performed using the open-source software R (version 4.1.2) and Python (version 3.8.5; Python Software Foundation). The correlation analysis results were visualized using Cytoscape (version 3.9.1; Cytoscape Consortium).

Ethical Considerations

This study was approved by the Ethics Review Committee on Research Involving Human Subjects at Doshisha University (No. 22063) and, subsequently, by the Ethics Review Committees at each affiliated institution (No. 22064). Written informed consent was provided by each pregnant woman at the time of the visit at the affiliated facility. Data was deidentified immediately upon collection. A secure, separate database is maintained to connect study IDs with participant details, accessible only to authorized personnel. The research description clearly states the following points: (1) women are free to participate in the research and withdraw their consent, (2) refusal of participation in the research has no implications per disadvantages in medical care, and (3) participation in the research entails no increased cost burden or rewards.

Results

Description of the Sample

The characteristics and results for the 144 mother-child pairs included in the final analysis are presented in Table 1 and Multimedia Appendix 2. These maternal background and perinatal data were obtained by combining information from medical records and parents' reports up to the first month postpartum check-up. The median maternal age was 36 (IQR 32-29) years, and 3 (N=144, 2%) mothers had a smoking history during their current pregnancy. The most prevalent educational level for both parents was a university degree (48/144, 33% mothers and 64/144, 44% fathers). Annual household incomes varied among the participants, with the most common bracket being 4 to 6 million yen (approximately US $36,000 to US $56,000, based on a currency exchange rate of US $1=JP ¥107-112 that was applicable during the study period) per year, reported by 46 (N=142, 32% of the population) families. Of the children, 86 (N=144, 60%) were female, 129 (N=144, 90%) were born at 37 weeks or later, and 3 (N=144, 2%) were born between 30 and 33 weeks. Birth weight ranged from 3000 g to 3999 g in 122 (N=144, 85%) children; all 5-minute Apgar scores were 7 (N=144) or higher. The median umbilical artery blood gas pH was 7.29 (IQR 7.26 - 7.33). The delivery type was vaginal in 87 (N=144, 60%) cases (Table 1). Throughout the pregnancy, the 3DSS (phase) median score was 10 (IQR 9-12). From midgestation to 1-month postpartum, PSQIG exhibited an increasing trend with median scores of 5 (IQR 3-7), 6 (IQR 4.5-9), and 8 (IQR 6-10), respectively. This indicates that mothers' sleep conditions tended to worsen during the period up to 1 month after childbirth. The median EPDS scores were relatively low across all 3 time points: 3 points in midpregnancy, 4 points in late pregnancy, and 2 points at 1 month post partum. Similarly, K6 scores remained low at 1, 2, and 1, respectively. The median AQ-J-10 score at late gestation was 2 (IQR 1-3), and the median MIBS-J score at 1 month post partum was 1 (IQR 0-3; Multimedia Appendix 2).

XSL•FO
RenderX

Table . Demographic data for the 144 mother-child pairs included in the final analysis.

Characteristics		Longitudinal group
Maternal age (years; N=144), median (IQR)		36 (32-39)
Child's sex (N=144), n (%)		
	Female	86 (60)
	Male	58 (40)
Maternal smoking status (N=144), n (%)		
	Never or exsmoker	141 (98)
	Current smoker	3 (2.1)
Maternal education (N=144), n (%)		
	Junior high	3 (2.1)
	High school	28 (19)
	Technical college	5 (3.5)
	College	33 (23)
	Junior college	17 (12)
	University	48 (33)
	Master's degree	10 (6.9)
Paternal education (N=144), n (%)		
	Junior high	7 (4.9)
	High school	37 (26)
	Technical college	3 (2.1)
	College	15 (10)
	Junior college	0 (0)
	University	64 (44)
	Master's degree	18 (12)
Annual household income (JP ¥[a]; n=142), n (%)		
	<2 million	1 (0.7)
	2 - 3.9 million	29 (20)
	4 - 5.9 million	46 (32)
	6 - 7.9 million	32 (23)
	8 - 9.9 million	19 (13)
	10 - 11.9 million	11 (7.7)
	12 - 14.9 million	1 (0.7)
	15 - 19.9 million	3 (2.1)
Gestational age at birth (wk; N=144), n (%)		
	30 - 32	3 (2.1)
	33 - 36	12 (8.3)
	≥37	129 (90)
Birth weight (g; N=144), n (%)		
	<1500	1 (0.7)
	1500 - 2999	20 (14)
	3000 - 3999	122 (85)
	≥4000	1 (0.7)
Apgar score at 5 min (N=144), n (%)		

XSL•FO
RenderX

Characteristics		Longitudinal group
	7	1 (0.7)
	8	16 (11)
	9	116 (81)
	10	11 (7.6)
Umbilical artery blood pH (n=140), median (IQR)		7.29 (7.26 - 7.33)
Type of delivery (N=144), n (%)		
	Vaginal	87 (60)
	Cesarean	57 (40)

[a]A currency exchange rate of 107-112 JP ¥=US $1 was applicable during the study period.

The Distribution of the M-CHAT Score Among Children Aged 12 Months

The distribution of the M-CHAT scores among the 144 children aged 12 months was as follows: 105 (73%) children scored 0, 30 (21%) scored 1, 5 (3.5%) scored 2, 3 (2.1%) scored 3, and 1 (1%) scored 4. All 6 preverbal social behavior items (Q1, Q2, Q4, Q10, Q12, and Q14) used to score the M-CHAT in this study exhibited achievement rates of 95% or higher. Specifically, for the question on smiling response (Q12), only 1 parent reported that their child did not smile back when smiled at. Similarly, regarding concerns of hearing impairment (Q20), only 1 parent expressed concern that their child might be enduring hearing difficulties. Of the 39 children who scored 1 or more, 29 (74%) received scores for age-independent and ASD-specific behaviors (particularly Q11, Q18, and Q22; Multimedia Appendix 3).

Interrelationships Between M-CHAT Score and Each Variable

To examine the relationship between the M-CHAT score and other variables during each period, polychoric or polyserial correlation coefficients were calculated and presented in a heatmap (Figure 1). Using the correlation heatmap, variables that significantly correlated with the M-CHAT score were identified. The M-CHAT score was positively correlated with maternal serum melatonin levels in midgestation and cord blood IL-1β; the M-CHAT score showed a weak positive correlation with cord blood IL-10 (r=.18). By contrast, the M-CHAT score exhibited a negative correlation with maternal serum IL-1β levels in midgestation and cord blood IL-6 levels. The M-CHAT score was positively correlated with EPDS and K6 scores in late gestation and with K6 and MIBS-J scores at 1 month post partum. For infant sleep questions, the M-CHAT score was significantly correlated with shorter sleep duration, bedtime, and difficulty in falling asleep (moodiness and required time). Detailed correlation coefficients are presented in Multimedia Appendix 4.

Correlation analysis was performed to determine the interrelationships among factors potentially influencing early developmental characteristics as assessed by M-CHAT scores (Multimedia Appendix 5). Strong positive correlations (r≈1.0) were found between cord blood IL-6 and IL-1β levels and between weekday and holiday bedtimes of children aged 6 months. Nodes at late gestation, cord blood, and 1 month post partum were strongly and positively correlated with each other within the same observation period. In children aged 6 months, a negative correlation was found between “nighttime sleeping hours” and “bedtime,” and a positive correlation was found between “staying awake for ≥1 hour at nocturnal awakening” and “takes long (≥1 hour) to fall asleep.” A negative correlation was found between IL-1β levels in the midgestation period and “short sleep duration” in children aged 1 month; a positive correlation was observed between melatonin levels in midgestation and “takes long (≥1 hour) to fall asleep” in children aged 6 months. K6 and EPDS scores in the late gestation were positively correlated with K6 scores in 1 month post partum and also positively correlated with “staying awake for ≥1 hour at nocturnal awakening” in children aged 6 months. “Wakes up several times at night, does not sleep and takes several hands” in children aged 1 month was positively correlated with “takes long (≥1 hour) to fall asleep” in children aged 6 months. “Bedtime” among children aged 6 months was positively correlated with “bedtime on holidays” among children aged 12 months (Multimedia Appendix 5).

XSL•FO
RenderX

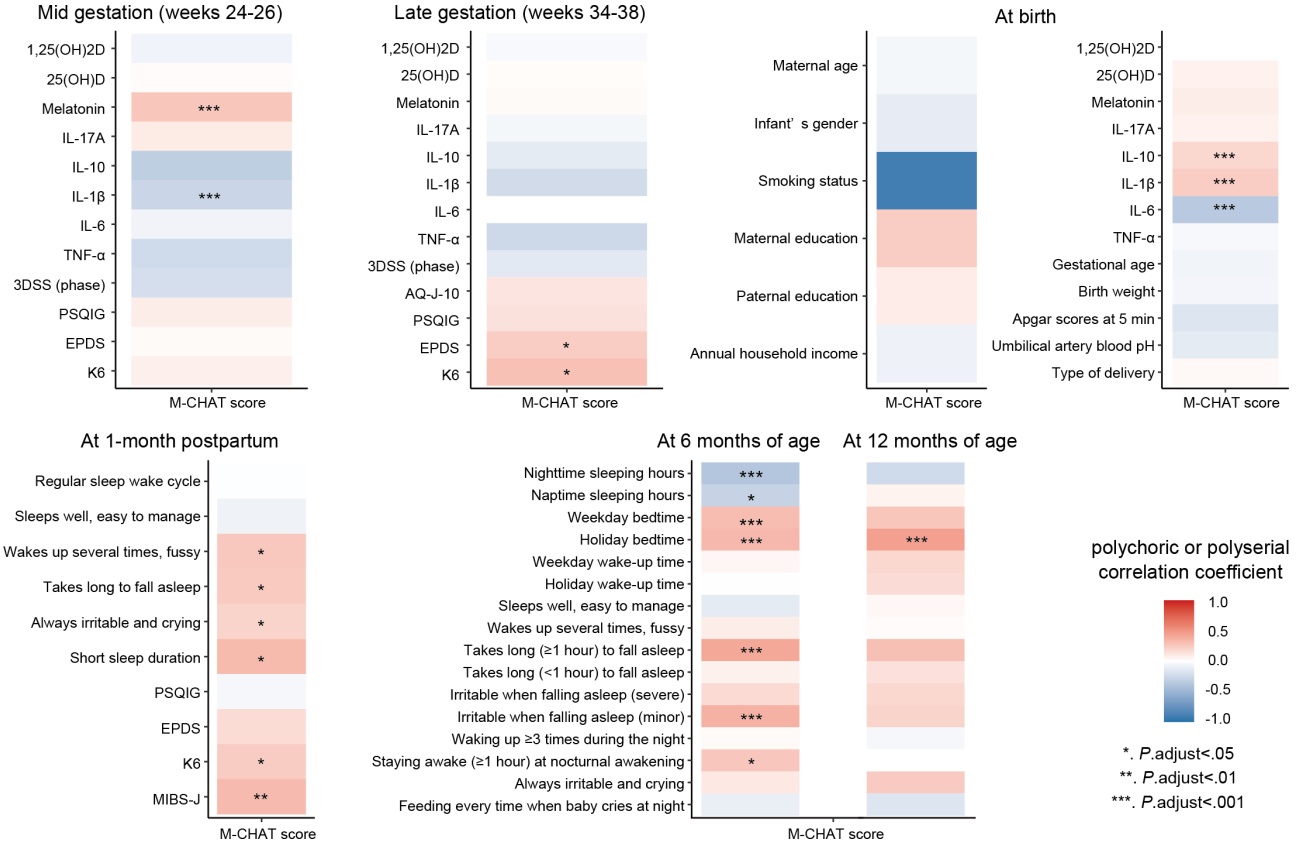


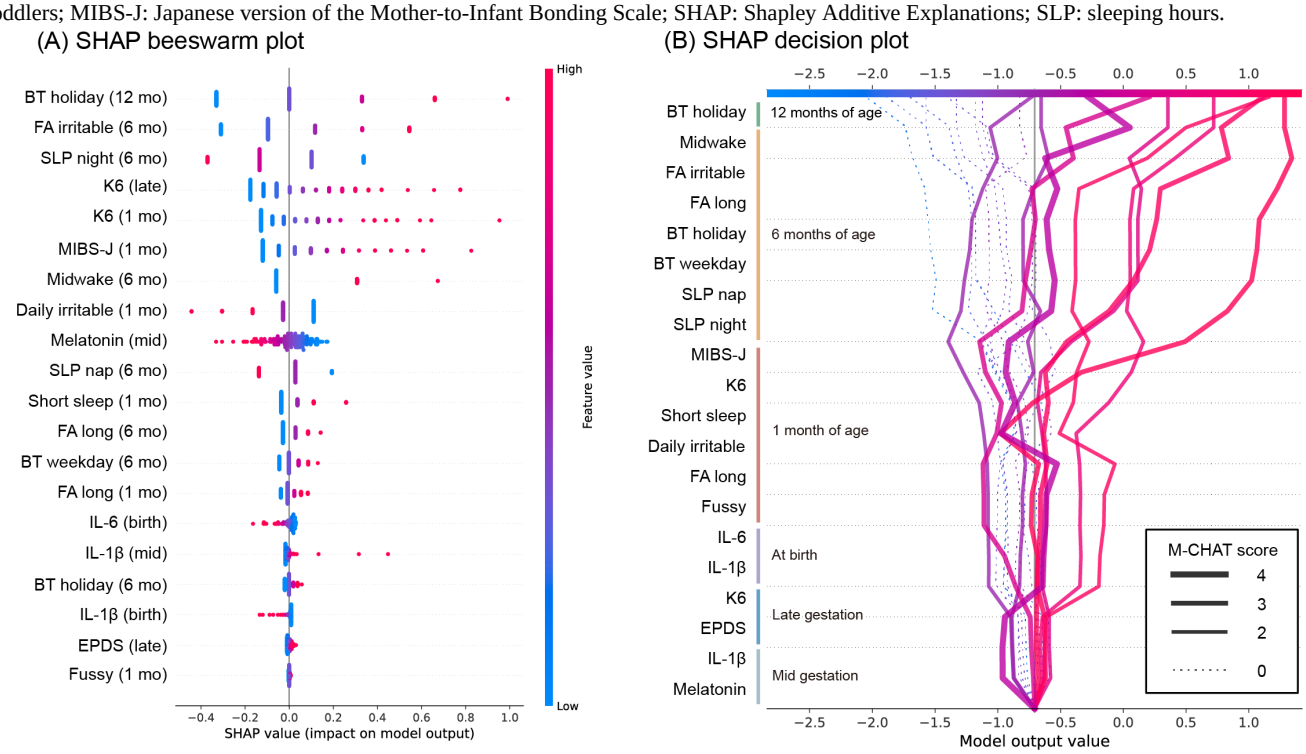
Figure 1. Heatmap of correlations between M-CHAT and each other variable. 1,25(OH)2D: 1,25-dihydroxyvitamin D; 25(OH)D: 25-hydroxyvitamin D; 3DSS: 3D Sleep Scale; AQ-J-10: Autism-Spectrum Quotient Japanese short version; EPDS: Edinburgh Postnatal Depression Scale; IL: interleukin; K6: Kessler Psychological Distress Scale; M-CHAT: Modified Checklist for Autism in Toddlers; MIBS-J: Japanese version of the Mother-to-Infant Bonding Scale; PSQIG: Pittsburgh Sleep Quality Index global score; TNF: tumor necrosis factor.

Assessment and Visualization of Factors Contributing to Early Developmental Characteristics

To assess longitudinal influences associated with early developmental characteristics as measured by M-CHAT scores, we conducted feature importance analysis using SHAP on a logistic regression model with L2 regularization ("C"=0.1, "penalty"="L2," "solver" = "liblinear," area under the receiver operating characteristic and precision-recall curves and the confusion matrix shown in Multimedia Appendix 6). The optimal threshold was determined by the Youden index to be 0.32. The logistic regression model attained reasonable predictive performance (area under the receiver operating characteristic curve=0.79, 95% CI 0.62 - 0.95; Multimedia Appendix 6). While the point estimate falls within the acceptable range (0.7 - 0.8), the CI extends below 0.7, indicating some uncertainty in its discriminative ability. The model's utility should therefore be interpreted within the context of the dataset and application. The SHAP beeswarm plot (Figure 2A) assesses the contribution of each feature of the total sample to the model. The order of the feature values obtained by SHAP and the contribution of each feature is high, and this ranking is relative, for example, it does not indicate which rank is particularly important. When examining variables in order of their contribution strength, we found high contributions from bedtime at 12 months, nighttime sleep duration and irritability at bedtime at 6 months, and maternal K6 and MIBS-J scores during late pregnancy and 1 month post partum. Specifically, later bedtimes, shorter nighttime sleep duration, higher K6 and MIBS-J scores, and irritability at bedtime promoted classification into the M-CHAT positive group. The characteristics that moderately contributed to such a classification were variables related to the sleep status of children aged 1-6 months and maternal melatonin levels. The 6 characteristics with the lowest influence were predominantly cytokine levels, EPDS score, "wakes up several times at night, does not sleep, and takes several hands" in children aged 1 month, and bedtime for children aged 6 months. The SHAP decision plot (Figure 2B) simulates the decision pathway for predicting classification into the M-CHAT positive or negative (M-CHAT score=0) groups in the order of observation period. All 9 randomly sampled cases with M-CHAT scores of 0 were correctly predicted to be the M-CHAT negative group. In some M-CHAT positive cases, the predictive risk began to increase owing to the deterioration of the maternal K6 and MIBS-J scores and infant sleep status for children aged 6 months. Conversely, there were cases in which the predictive risk did not change for maternal factors but increased rapidly for factors related to the child's sleep after 6 months of age.

XSL•FO
RenderX

Figure 2. (A) SHapley Additive exPlanations (SHAP) beeswarm plot of the logistic regression model. (B) SHAP decision plot of 9 samples with an M-CHAT score of 0 (random sampling) and 9 samples with an M-CHAT score of 2–4, for a total of 18 samples. BT: bedtime; EPDS: Edinburgh Postnatal Depression Scale; FA: fall asleep; IL: interleukin; K6: Kessler Psychological Distress Scale; M-CHAT: Modified Checklist for Autism in Toddlers; MIBS-J: Japanese version of the Mother-to-Infant Bonding Scale; SHAP: Shapley Additive Explanations; SLP: sleeping hours.



Discussion

Temporal Dynamics of Early Developmental Characteristics: Individual Patterns and Contributing Factors

In recent years, the number of cases of neurodevelopmental disorders has increased rapidly, becoming a significant social concern. While genetic factors have been extensively studied, identifying genes that correlate with symptoms alone is insufficient to understand developmental mechanisms. The clarification of how environmental factors interact with genetic predisposition in the developmental process remains an urgent research priority [29].

In this study, we assessed early developmental characteristics through social behavior patterns and analyzed how these patterns emerge during infancy. The SHAP analysis provided a novel approach to assess and visualize how multiple longitudinal factors contribute to individual neurodevelopmental trajectories. Specifically, our analysis focused on cases showing elevated M-CHAT scores (2 - 4 points), including those exceeding the conventional ASD screening cutoff value (M-CHAT score of 3+). This analysis revealed distinct temporal patterns in the emergence of early developmental characteristics. Some cases showed an increased risk of M-CHAT positive classification during late gestation, primarily associated with elevated maternal K6 scores. Other cases demonstrated increased risk due to disrupted infant sleep patterns after 6 months of age. Additionally, we observed cases where substantial increases in K6 and Mother-to-Infant Bonding Scale (MIBS) scores at 1-month postpartum markedly elevated the predicted probability of M-CHAT positive classification.

These results indicate that early developmental characteristics associated with elevated M-CHAT scores emerge through several distinct dynamic patterns, involving multiple interacting factors. The SHAP methodology enabled the quantification of each factor's relative contribution to these patterns. Based on our findings, we suggest that targeted follow-up assessments focusing on maternal anxiety disorders in late gestation and infant sleep characteristics at 6 months—particularly sleep duration, bedtime, irritability upon falling asleep, and extended periods of wakefulness—may be particularly valuable for the early identification of developmental concerns.

Temporal Relationships Between Early Developmental Characteristics and Longitudinal Factors

Correlation analysis revealed that relatively strong correlations between factors within the same period were observed between similar factors such as maternal physical and mental status, sleep difficulties in children, and inflammatory cytokines. However, correlations between factors with different observation periods were more limited than correlations within the same period. Our analytical method does not pursue a causal relationship.

Early Sleep Difficulties as Indicators of Emerging Developmental Characteristics

Recent research has established clear interactions between sleep patterns and neurodevelopment in young children. During early brain development, sleep patterns and neural maturation progress in parallel, significantly influencing cognitive performance [16,17]. Notably, studies have demonstrated associations between infant sleep patterns and brain structure, including hippocampal volume [18]. Children who later receive

XSL•FO
RenderX

neurodevelopmental disorder diagnoses often experience more persistent and complex sleep problems compared to their typically developing peers [30]. Several longitudinal studies have identified early sleep difficulties as potential risk indicators for diagnosis of later ASDs [18,30]. Specifically, shorter sleep duration, delayed sleep onset and wake times, and frequent midday awakenings have been associated with an increased likelihood of subsequent ASD diagnosis. The timing of sleep-related interventions appears crucial, with recommendations focusing on the period between 3 and 6 months of age, when circadian rhythms become established in the suprachiasmatic nucleus [15,31]. Our findings align with and extend this literature: M-CHAT scores at 12 months showed significant correlations with multiple sleep-related characteristics, including reduced sleep duration, later bedtime, and difficulties with sleep onset (including irritability and prolonged time to fall asleep). These results suggest that infants showing early signs of developmental concerns, as indicated by elevated M-CHAT scores, may already be experiencing sleep-related challenges. Early identification of these sleep patterns could provide opportunities for targeted interventions, potentially benefiting not only the infant's sleep and neurodevelopmental trajectory but also family functioning and overall cognitive outcomes.

Relationship Between Inflammatory Markers and Early Developmental Characteristics

Increasing evidence suggests that chronic inflammation plays a role in atypical neurodevelopment, although the underlying mechanisms remain unclear. For example, microglia, crucial for brain maturation and function, are increasingly recognized to play a decisive role in various developmental and cognitive conditions [32]. Microglia produce inflammatory mediators and reactive oxygen species, potentially leading to neuronal degeneration, white matter abnormalities, and decreased neurogenesis observed in conditions such as ASD or schizophrenia [32]. The secretion of signaling molecules and cytokines may promote crosstalk between microglia and astrocytes, leading to endothelial dysfunction and blood-brain barrier permeability impairment [33]. Multiple studies have reported increased concentrations of inflammatory cytokines such as IL-6 and IL-1β and a decrease in anti-inflammatory cytokines (IL-10 and transforming growth factor [TGF]-β) in the peripheral blood and cerebrospinal fluid of individuals with ASD [12,13,33]. The persistent elevation of these inflammatory cytokines may reflect ongoing inflammatory processes [14].

Maternal infections during pregnancy and early childhood are known to influence early development, and changes in cytokine profiles may be shaped by environmental exposures during prenatal and early childhood periods [32]. Typically, the maternal immune system shifts to a more tolerant state during pregnancy, characterized by a decrease in inflammatory cytokines and an increase in regulatory cytokines [12]. However, mothers whose children later receive neurodevelopmental diagnoses have been reported to have significantly higher levels of various inflammatory cytokines and chemokines, such as IL-1α, IL-4, IL-6, and interferon [IFN]-γ in serum during midpregnancy [34,35]. Studies have also reported alterations in melatonin secretion in individuals with ASD, particularly decreased secretion of melatonin and its metabolites at night and altered circadian rhythm [33]. Low maternal melatonin levels during pregnancy have been associated with an increased likelihood of subsequent ASD and intellectual disability diagnoses [36], although there is no consensus on this matter. Contrary to previous research, our study found associations between increased melatonin and decreased IL-1β and M-CHAT scores in midpregnancy. These associations were not observed in maternal blood in late pregnancy. Factors such as the intensity, timing, and duration of maternal inflammatory responses may be crucial for influencing the developing child's brain. Differences in sample processing and clinical sample variation may also contribute to these findings.

Higher levels of IL-1β in neonatal samples have been associated with an increased likelihood of ASD diagnosis [37]. Moreover, neonatal samples from infants later diagnosed with ASD showed decreased levels of many cytokines (IFN-γ, IL-2, IL-4, IL-6, and IL-10), suggesting reduced immune cell activity in the neonatal period [38]. Interestingly, consistent with previous studies, our analysis found significant correlations between increased IL-1β and decreased IL-6 in cord blood and M-CHAT scores. These results suggest 2 possibilities: first, the cytokine profile in umbilical cord blood samples may predict subsequent developmental characteristics similarly to neonatal samples; second, the M-CHAT assessment at 12 months may effectively identify early developmental concerns before formal diagnostic evaluations. However, these observed relationships between IL-1β and M-CHAT were derived using polychoric or polyserial correlation analysis, and statistical significance might be lost if other statistical methods accounting for outliers were applied. Given that these cytokine data showed very low predictive contribution to the model, and considering that IL-1β is a bioactive substance that can be unstable and challenging to measure in blood in clinical settings, the correlations found in this study should be interpreted with caution.

Maternal Psychological Well-Being as a Predictor of Early Developmental Characteristics

Focusing on maternal mental and physical status, it has been previously reported that persistent anxiety during pregnancy is significantly associated with ASD in children [8]; further, persistent depression is associated with developmental delay at 18 months [9]. Our study found correlations between K6, EPDS, and M-CHAT, consistent with previous reports. Notably, we identified a significant positive correlation between MIBS and M-CHAT scores at 1 month post partum. While previous studies have shown strong correlations between MIBS and EPDS from early postpartum through 12 months [10], our study is among the first to examine MIBS scores as an independent predictor of early developmental characteristics. Although enhanced parent-child bonding may not directly improve social functioning in children with ASD [39], our findings suggest that MIBS assessment may be valuable for the early identification of developmental concerns.

Our longitudinal analysis demonstrates that early postnatal maternal psychological measures—including emotional state (EPDS), psychological distress (K6), and MIBS—correlate with infant developmental characteristics as assessed by M-CHAT

XSL•FO
RenderX

scores. These findings emphasize the importance of comprehensive maternal psychological monitoring in the postpartum period. Even when EPDS scores do not indicate clinical depression, attention to other maternal psychological indicators, particularly MIBS and K6 scores, may provide valuable insights for early developmental screening.

Limitations

This study has several limitations. First, the pathogeneses of neurodevelopmental disorders are multifactorial; therefore, the presence of unobserved confounding factors cannot be excluded when interpreting the findings of this study. The interrelationship of various sleep and psychological measures (Pittsburgh Sleep Quality Index, K6, MIBS, EPDS, etc) assessed at different time points may introduce potential biases. Parental ratings of child sleep status are inherently subjective and could be influenced by parents' own psychological stress or sleep issues, potentially affecting the results. Additionally, the collection and measurement of maternal and cord blood biomarkers lack standardized timing protocols and do not account for diurnal variations, necessitating consideration of potential measurement errors in the analysis.

Second, the sample size is small, and the results are preliminary. Future studies should validate these findings using larger samples. Only Japanese participants were included in this study, and no analysis of cultural and social influences due to racial or ethnic differences was conducted. Furthermore, there was considerable variation in the number of mother-child pairs recruited across study sites. While recruitment was not intentionally biased, potential disparities in research resources and physician-patient relationships among facilities may have influenced informed consent rates. Of note is that our longitudinal study may not be fully representative of the Japanese population.

Third, the use of M-CHAT scores at 12 months as an indicator of early developmental characteristics has inherent limitations. While M-CHAT is a validated screening tool, our assessment was based on parent-reported scoring, and due to the short observation period, we were unable to confirm subsequent neurodevelopmental diagnoses. In an ongoing study, we plan to assess ASD using the Kinder Infant Development Scale and Social Responsiveness Scale 2nd edition at 36 months of age.

Conclusions

Understanding the characteristics of early development and their predictors is essential for improving strategies for early detection and support of neurodevelopmental problems.

Our study demonstrates that a systematic analysis of multiple longitudinal factors can reveal important patterns in early development, particularly in preverbal social behaviors as assessed by M-CHAT scores at 12 months. The results indicate that early developmental characteristics are influenced by several key factors, particularly maternal-infant bonding, maternal anxiety, and infant sleep patterns. The temporal dynamics of these relationships suggest that monitoring specific combinations of factors—including maternal psychological well-being and infant sleep patterns—may enhance our ability to identify early signs of developmental concerns. Future studies with larger and more diverse population samples are needed to validate these findings and establish their generalizability for clinical practice.

Acknowledgments

We would like to dedicate this paper to our wonderful colleagues, Y Konishi and Kiyomi Tsukimori, who died during the production of this paper. KS, Y Konishi, and EK designed this study. AO, SI, Y Kasahara, KK, Y Kitadai, Y Kimura, Y Konishi, KN, HM, and SM collected the data. DK wrote the first draft of this paper and made revisions. DK, AO, TI, SO, AH, and EK collated and analyzed the data. All the authors edited this paper. This work was supported by the Japan Society for the Promotion of Science (JSPS) KAKENHI (grant JP21K02356 to AO, TI, and SM). This work has been supported by RIKEN Healthcare and Medical Data Platform Project.

Data Availability

The data and code that support the findings of this study are available from the corresponding author, EK, upon reasonable request. The data are not publicly available as it contains information that could compromise the privacy of research participants.

Conflicts of Interest

Y Kimura received collaborative research funding and patent royalties from Atom Medical Inc. All other authors declare that they have no conflicts of interest.

Multimedia Appendix 1
Maternal and infant assessments with questionnaires.
[DOCX File, 62 KB - pediatrics_v8i1e58337_app1.docx]

Multimedia Appendix 2
Characteristics of participants.
[DOCX File, 44 KB - pediatrics_v8i1e58337_app2.docx]

XSL•FO
RenderX

Multimedia Appendix 3
Distribution of M-CHAT scores for 12-month-old children aged 12 months. M-CHAT: Modified Checklist for Autism in Toddlers.
[DOCX File, 98 KB - pediatrics_v8i1e58337_app3.docx]

Multimedia Appendix 4
Correlation between the M-CHAT scores and each variable. M-CHAT:Modified Checklist for Autism in Toddlers.
[DOCX File, 32 KB - pediatrics_v8i1e58337_app4.docx]

Multimedia Appendix 5
Correlation analysis.
[DOCX File, 555 KB - pediatrics_v8i1e58337_app5.docx]

Multimedia Appendix 6
Logistic regression model with L2 regularization predicting the DD positive group. DD: developmental diversity.
[DOCX File, 269 KB - pediatrics_v8i1e58337_app6.docx]

References

1. Cioni G, Inguaggiato E, Sgandurra G. Early intervention in neurodevelopmental disorders: underlying neural mechanisms. Dev Med Child Neurol 2016 Mar;58 Suppl 4:61-66. [doi: 10.1111/dmcn.13050] [Medline: 27027609]
2. Kucker SC, Zimmerman C, Chmielewski M. Taking parent personality and child temperament into account in child language development. Br J Dev Psychol 2021 Nov;39(4):540-565. [doi: 10.1111/bjdp.12379] [Medline: 33987860]
3. Robins DL. Screening for autism spectrum disorders in primary care settings. Autism 2008 Sep;12(5):537-556. [doi: 10.1177/1362361308094502] [Medline: 18805946]
4. Inada N, Kamio Y, Koyama T. Developmental chronology of preverbal social behaviors in infancy using the M-CHAT: baseline for early detection of atypical social development. Res Autism Spectr Disord 2010 Oct;4(4):605-611. [doi: 10.1016/j.rasd.2009.12.003]
5. Toh TH, Tan VWY, Lau PST, Kiyu A. Accuracy of Modified Checklist for Autism in Toddlers (M-CHAT) in detecting autism and other developmental disorders in community clinics. J Autism Dev Disord 2018 Jan;48(1):28-35. [doi: 10.1007/s10803-017-3287-x] [Medline: 28866856]
6. Anderson ND. State of the science on mild cognitive impairment (MCI). CNS Spectr 2019 Feb;24(1):78-87. [doi: 10.1017/S1092852918001347] [Medline: 30651152]
7. Doi M, Usui N, Shimada S. Prenatal environment and neurodevelopmental disorders. Front Endocrinol (Lausanne) 2022;13:860110. [doi: 10.3389/fendo.2022.860110] [Medline: 35370942]
8. Nishigori T, Hashimoto K, Mori M, et al. Association between maternal prenatal psychological distress and autism spectrum disorder among 3-year-old children: The Japan Environment and Children's Study. J Dev Orig Health Dis 2023 Feb;14(1):70-76. [doi: 10.1017/S2040174422000411] [Medline: 35801288]
9. Deave T, Heron J, Evans J, Emond A. The impact of maternal depression in pregnancy on early child development. BJOG 2008 Jul;115(8):1043-1051. [doi: 10.1111/j.1471-0528.2008.01752.x] [Medline: 18651886]
10. Kasamatsu H, Tsuchida A, Matsumura K, et al. Understanding the relationship between postpartum depression one month and six months after delivery and mother-infant bonding failure one-year after birth: results from the Japan Environment and Children's Study (JECS). Psychol Med 2020 Jan;50(1):161-169. [doi: 10.1017/S0033291719002101] [Medline: 31474232]
11. Walker SP, Wachs TD, Grantham-McGregor S, et al. Inequality in early childhood: risk and protective factors for early child development. Lancet 2011 Oct 8;378(9799):1325-1338. [doi: 10.1016/S0140-6736(11)60555-2] [Medline: 21944375]
12. Kordulewska NK, Kostyra E, Piskorz-Ogórek K, et al. Serum cytokine levels in children with spectrum autism disorder: differences in pro- and anti-inflammatory balance. J Neuroimmunol 2019 Dec 15;337:577066. [doi: 10.1016/j.jneuroim.2019.577066] [Medline: 31629288]
13. Saghazadeh A, Ataeinia B, Keynejad K, Abdolalizadeh A, Hirbod-Mobarakeh A, Rezaei N. Anti-inflammatory cytokines in autism spectrum disorders: a systematic review and meta-analysis. Cytokine 2019 Nov;123:154740. [doi: 10.1016/j.cyto.2019.154740] [Medline: 31228728]
14. Zhao H, Zhang H, Liu S, Luo W, Jiang Y, Gao J. Association of peripheral blood levels of cytokines with autism spectrum disorder: a meta-analysis. Front Psychiatry 2021;12:670200. [doi: 10.3389/fpsyt.2021.670200] [Medline: 34276441]
15. Miike T, Oniki K, Toyoura M, et al. Misalignment of sleep-wake circadian rhythm formation in infant/early childhood is a risk factor of future autism spectrum disorders (ASD). Preprint posted online on Feb 23, 2022 URL: https://papers.ssrn.com/abstract=4015092 [accessed 2025-03-13] [doi: 10.1007/978-3-031-42383-3_10]
16. Mason GM, Lokhandwala S, Riggins T, Spencer RMC. Sleep and human cognitive development. Sleep Med Rev 2021 Jun;57:101472. [doi: 10.1016/j.smrv.2021.101472] [Medline: 33827030]

XSL•FO
RenderX

17. Lokhandwala S, Spencer RMC. Relations between sleep patterns early in life and brain development: a review. Dev Cogn Neurosci 2022 Aug;56:101130. [doi: 10.1016/j.dcn.2022.101130] [Medline: 35779333]
18. MacDuffie KE, Shen MD, Dager SR, et al. Sleep onset problems and subcortical development in infants later diagnosed with autism spectrum disorder. Am J Psychiatry 2020 Jun 1;177(6):518-525. [doi: 10.1176/appi.ajp.2019.19060666] [Medline: 32375538]
19. Buysse DJ, Reynolds CF III, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res 1989 May;28(2):193-213. [doi: 10.1016/0165-1781(89)90047-4] [Medline: 2748771]
20. Matsumoto Y, Uchimura N, Ishida T, et al. Reliability and validity of the 3 Dimensional Sleep Scale (3DSS)--day workers version--in assessing sleep phase, quality, and quantity. Sangyo Eiseigaku Zasshi 2014;56(5):128-140. [doi: 10.1539/sangyoeisei.b13012] [Medline: 25048809]
21. Murray D, Cox JL. Screening for depression during pregnancy with the edinburgh depression scale (EDDS). J Reprod Infant Psychol 1990 Apr;8(2):99-107. [doi: 10.1080/02646839008403615]
22. Kessler RC, Andrews G, Colpe LJ, et al. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychol Med 2002 Aug;32(6):959-976. [doi: 10.1017/s0033291702006074] [Medline: 12214795]
23. Kurita H, Koyama T, Osada H. Autism-Spectrum Quotient-Japanese version and its short forms for screening normally intelligent persons with pervasive developmental disorders. Psychiatry Clin Neurosci 2005 Aug;59(4):490-496. [doi: 10.1111/j.1440-1819.2005.01403.x] [Medline: 16048456]
24. Yoshida K, Yamashita H, Conroy S, Marks M, Kumar C. A Japanese version of Mother-to-Infant Bonding Scale: factor structure, longitudinal changes and links with maternal mood during the early postnatal period in Japanese mothers. Arch Womens Ment Health 2012 Oct;15(5):343-352. [doi: 10.1007/s00737-012-0291-1] [Medline: 22733162]
25. Benjamini Y, Hochberg Y. Controlling the false discovery rate: a practical and powerful approach to multiple testing. J R Stat Soc Series B Stat Methodol 1995 Jan 1;57(1):289-300. [doi: 10.1111/j.2517-6161.1995.tb02031.x]
26. Stekhoven DJ, Bühlmann P. MissForest--non-parametric missing value imputation for mixed-type data. Bioinformatics 2012 Jan 1;28(1):112-118. [doi: 10.1093/bioinformatics/btr597] [Medline: 22039212]
27. Lundberg SM, Lee SI. A unified approach to interpreting model predictions. 2017 Presented at: 31st Conference on Neural Information Processing Systems (NIPS 2017); Dec 4-9, 2017; Long Beach, CA URL: https://proceedings.neurips.cc/paper_files/paper/2017/file/8a20a8621978632d76c43dfd28b67767-Paper.pdf [accessed 2025-03-13]
28. shapLinearExplainer — SHAP latest documentation. URL: https://shap.readthedocs.io/en/latest/generated/shap.LinearExplainer.html [accessed 2025-03-14]
29. Weintraub K. The prevalence puzzle: autism counts. Nature New Biol 2011 Nov 2;479(7371):22-24. [doi: 10.1038/479022a] [Medline: 22051656]
30. Halstead EJ, Joyce A, Sullivan E, et al. Sleep disturbances and patterns in children with neurodevelopmental conditions. Front Pediatr 2021;9:637770. [doi: 10.3389/fped.2021.637770] [Medline: 33738270]
31. Bruni O, Baumgartner E, Sette S, et al. Longitudinal study of sleep behavior in normal infants during the first year of life. J Clin Sleep Med 2014 Oct 15;10(10):1119-1127. [doi: 10.5664/jcsm.4114] [Medline: 25317093]
32. Matuleviciute R, Akinluyi ET, Muntslag TAO, et al. Microglial contribution to the pathology of neurodevelopmental disorders in humans. Acta Neuropathol 2023 Nov;146(5):663-683. [doi: 10.1007/s00401-023-02629-2] [Medline: 37656188]
33. Jiang CC, Lin LS, Long S, et al. Signalling pathways in autism spectrum disorder: mechanisms and therapeutic implications. Signal Transduct Target Ther 2022 Jul 11;7(1):229. [doi: 10.1038/s41392-022-01081-0] [Medline: 35817793]
34. Jones KL, Croen LA, Yoshida CK, et al. Autism with intellectual disability is associated with increased levels of maternal cytokines and chemokines during gestation. Mol Psychiatry 2017 Feb;22(2):273-279. [doi: 10.1038/mp.2016.77] [Medline: 27217154]
35. Goines PE, Croen LA, Braunschweig D, et al. Increased midgestational IFN-γ, IL-4 and IL-5 in women bearing a child with autism: a case-control study. Mol Autism 2011 Aug 2;2:13. [doi: 10.1186/2040-2392-2-13] [Medline: 21810230]
36. Jin Y, Choi J, Won J, Hong Y. The relationship between autism spectrum disorder and melatonin during fetal development. Molecules 2018 Jan 18;23(1):198. [doi: 10.3390/molecules23010198] [Medline: 29346266]
37. Krakowiak P, Goines PE, Tancredi DJ, et al. Neonatal cytokine profiles associated with autism spectrum disorder. Biol Psychiatry 2017 Mar 1;81(5):442-451. [doi: 10.1016/j.biopsych.2015.08.007] [Medline: 26392128]
38. Abdallah MW, Larsen N, Mortensen EL, et al. Neonatal levels of cytokines and risk of autism spectrum disorders: an exploratory register-based historic birth cohort study utilizing the Danish Newborn Screening Biobank. J Neuroimmunol 2012 Nov 15;252(1-2):75-82. [doi: 10.1016/j.jneuroim.2012.07.013] [Medline: 22917523]
39. Vivanti G, Nuske HJ. Autism, attachment, and social learning: three challenges and a way forward. Behav Brain Res 2017 May 15;325(Pt B):251-259. [doi: 10.1016/j.bbr.2016.10.025] [Medline: 27751811]

Abbreviations

3DSS: 3D Sleep Scale
AQ-J-10: Autism-Spectrum Quotient Japanese short version

XSL•FO
RenderX

ASD: autism spectrum disorder
EPDS: Edinburgh Postnatal Depression Scale
IFN: interferon
IL: interleukin
K6: Kessler Psychological Distress Scale
M-CHAT: Modified Checklist for Autism in Toddlers
MIBS: Mother-to-Infant Bonding Scale
MIBS-J: Japanese version of the Mother-to-Infant Bonding Scale
p.adjust: adjusted *P* value
PSQIG: Pittsburgh Sleep Quality Index global score
SHAP: Shapley Additive Explanations
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
TGF: transforming growth factor

Edited by S Badawy; submitted 13.03.24; peer-reviewed by M O'Hely, SJ Sheinkopf; revised version received 18.02.25; accepted 28.02.25; published 04.04.25.

Please cite as:
Kato D, Okuno A, Ishikawa T, Itakura S, Oguchi S, Kasahara Y, Kanenishi K, Kitadai Y, Kimura Y, Shimojo N, Nakahara K, Hanai A, Hamada H, Mogami H, Morokuma S, Sakurada K, Konishi Y, Kawakami E
Multilevel Factors and Indicators of Atypical Neurodevelopment During Early Infancy in Japan: Prospective, Longitudinal, Observational Study
JMIR Pediatr Parent 2025;8:e58337
URL: https://pediatrics.jmir.org/2025/1/e58337
doi:10.2196/58337

©Daigo Kato, Akiko Okuno, Tetsuo Ishikawa, Shoji Itakura, Shinji Oguchi, Yoshiyuki Kasahara, Kenji Kanenishi, Yuzo Kitadai, Yoshitaka Kimura, Naoki Shimojo, Kazushige Nakahara, Akiko Hanai, Hiromichi Hamada, Haruta Mogami, Seiichi Morokuma, Kazuhiro Sakurada, Yukuo Konishi, Eiryo Kawakami. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 4.4.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Co-Design and Development of the SmilesUp Text Messaging Intervention Using Behavioral Theory to Support Parents of Children With Early Childhood Caries: Mixed Methods Study

Rebecca Chen[1,2], BOH, MPH; Michelle J Irving[2], PhD, MHSc; Carrie Tsai[3], DCD, DMD, MPH; Bradley Christian[1], BDS, MDSc, CertDPH, PhD; Harleen Kumar[3,4], BDSc, DCD (Paed Dent); Angela Masoe[5], PhD, DipDT, MC&HD; Neeta Prabhu[3,6], BDS, MDSs (Paed Dent), MPhil; Woosung Sohn[1], DDS, PhD, DrPH; Heiko Spallek[3], DMD, Dr Med Dent, MSBA (CIS); Clara K Chow[2], MBBS, PhD, GAICD

[1]Population Oral Health, School of Dentistry, Faculty of Medicine and Health, University of Sydney, 2 Chalmers Street, Surry Hills, New South Wales, Australia

[2]Westmead Applied Research Centre, Faculty of Medicine and Health, University of Sydney, Surry Hills, Sydney, Australia

[3]School of Dentistry, Faculty of Medicine and Health, University of Sydney, Sydney, Australia

[4]Paediatric Dentistry Department, Sydney Dental Hospital, Oral Health Services, Sydney Local Health District, Surry Hills, Australia

[5]Centre for Oral Health Strategy, NSW Health Ministry of Health, St. Leonards, Australia

[6]Paediatric Dentistry Department, Oral Health Services, Western Sydney Local Health District, Westmead, Australia

Corresponding Author:
Rebecca Chen, BOH, MPH
Population Oral Health, School of Dentistry, Faculty of Medicine and Health, University of Sydney, 2 Chalmers Street, Surry Hills, New South Wales, Australia

Abstract

Background: Early childhood caries (ECC) remains a common childhood condition that affects 600 million children worldwide. Providing parents with support for oral health behavior change can address ECC risk factors and complement preventive clinical care. Mobile health (mHealth) text message programs that are co-designed and evaluated by parents and health professionals using behavior theory have been shown to be effective in improving oral health outcomes.

Objective: This study aimed to describe the co-design process, development, and content evaluation of a text message program designed to promote oral health behavior change among parents of children diagnosed with ECC using the Behavior Change Wheel (BCW) framework.

Methods: The *SmilesUp* mHealth program was co-designed with parents in 2 stages using the BCW, a widely used theoretical framework to underpin mHealth programs, recommended by the World Health Organization. Through focus groups with parents in phase 1, the BCW was used to understand parental perspectives by identifying barriers and enablers and selecting target behaviors that could be feasibly delivered within a mHealth intervention. Barriers and enablers were mapped to the relevant theoretical domains and behavior change technique (BCT) of the BCW. Phase 2 evaluated content acceptability, measured by understandability, usefulness, and appropriateness of the program through questionnaires with parents and health professionals. Highly rated messages were finalized into an algorithm for the SMS text message program.

Results: In phase 1, the overall target behavior was parental behavior change to support good oral health, including oral hygiene, reduced dietary sugar intake, and bedtime routines for their children. The 5 intervention functions focused on education, modeling, persuasion, environmental restructuring, and enablement, and 16 BCTs focused on addressing the motivational enablers and knowledge gap barriers identified by the parents. A total of 111 draft health messages were developed and mapped to the BCTs. In phase 2, a total of 2045 reviews of the 111 draft messages were completed by parents (14/31, 45.2%) and health professionals (17/31, 54.8%). Parents rated 77.4% (86/111) and health professionals rated 61.2% (68/111) of the messages as understandable, useful, and accepted. The messages that were considered understandable, useful, and appropriate by both groups were incorporated into the *SmilesUp* 12-week semipersonalized SMS message program.

Conclusions: The *SmilesUp* mHealth program uses behavioral theory to address knowledge gaps in tooth brushing, diet, and bedtime routines identified by parents. It provides parents with convenient, bite-sized nudges of information to support oral health–promoting behaviors in the home context. Robust content development and evaluation are crucial initial steps before further investments are made to conduct a clinical trial to assess the effectiveness of the program.

(JMIR Pediatr Parent 2025;8:e72107) doi:10.2196/72107

XSL•FO
RenderX

KEYWORDS

mobile health; mHealth; dental caries; prevention; co-design

Introduction

Early childhood caries (ECC) remains a complex childhood disease that affects 600 million children worldwide [1]. In Australia, children with the most severe cases of ECC may require hospital admission, impacting approximately one in every 250 children [2]. Parents play a key role in preventing ECC by changing known modifiable oral health lifestyle behaviors [3]. Providing mothers, fathers, carers, and parents (from here on referred to as "parents") with adequate and appropriate support for this behavior change remains key to sustainably improve oral health outcomes for their children across the life course [3]. ECC disease management approaches that focus on prevention and behavior change through motivational interviewing have been implemented over the past decade [4]. However, these strategies are time-intensive, costly, and have had limited population reach [5]. The widespread use of mobile phone technologies offers a valuable opportunity for modern health systems to increase the reach for prevention programs through prevention-focused digital health interventions [6]. These interventions can help drive sustainable oral health behavior change at scale [7,8]. While there are existing oral health mobile apps available, most focus only on tooth brushing and have been created for school-aged children or young adults [9,10]. These apps fail to comprehensively address the interrelated risk factors (oral hygiene, diet, and bedtime routines) specific to the prevention of ECC. Furthermore, many of these apps require the use of paid data, which can be prohibitive for some lower socioeconomic families, exacerbating potential disparities in digital health literacy [11,12]. Selecting an affordable medium to deliver digital health interventions can support equitable access to digital behavior change support among vulnerable populations [11]. Thoughtfully co-designed SMS interventions informed by behavioral theory have shown promise in improving general health behavioral outcomes, equitably and at scale [13-15]. To ensure practicability, mobile health (mHealth) programs should be compatible with any SMS text message systems used within existing digital health infrastructure. Making message delivery free or low cost will support equitable access to digital oral health interventions for diverse families at risk of ECC.

Involving and consulting consumers from the inception of the *SmilesUp* program development is crucial for developing effective content and features of the mHealth program [16]. Understanding the needs and preferences of parents enables health systems to develop mHealth interventions that genuinely support the health goals of the target population [17]. Furthermore, the latest World Health Organization (WHO) guidelines on mHealth emphasize the importance of a pragmatic approach, where developers of mHealth programs must balance consumer needs with the existing digital infrastructure and budget constraints within health systems [7]. Involving parents, health professionals, and policymakers early in the development process is crucial for creating feasible and scalable prevention-focused oral mHealth interventions [18].

Many co-designed mHealth programs supporting behavior change have used behavioral theory and content evaluation to ensure a robustly designed program [19-22]. The Behaviour Change Wheel (BCW) framework is a widely used theory for designing mHealth and digital health interventions [23-27]. It takes into account the broader social and legislative contexts, as well as societal limitations that may affect the desired outcomes of the target population [28]. Recently, the oral health academic community has recognized the importance of using the BCW to underpin the development and evaluation of behavior change interventions, including mHealth programs [29,30]. Similarly, the WHO guidelines emphasize the use of the BCW's Capability, Opportunity, Motivation-Behaviour (COM-B) model as the comprehensive behavior change theory of choice for intervention development [28]. By using behavioral theory and content evaluation, interventions can comprehensively address barriers and enablers related to oral health behaviors identified by both parents and health professionals within health systems to reduce the ECC burden[7]. This mixed methods study aimed to use BCW behavioral theory to co-design and evaluate the content acceptability of *SmilesUp*, an SMS-based mHealth intervention for parents of children with ECC.

Methods

Participants and Recruitment Setting

The study was conducted in public dental services in New South Wales (NSW), targeting families receiving care and the oral health staff working with these families at 2 tertiary pediatric referral centers. NSW Health public dental services offer a range of safety-net dental services, including general anesthetic appointments for children who meet an eligibility criterion [31]. The service also prioritizes emergency situations and vulnerable populations at highest risk of dental disease [31,32].

Recruitment of parents for the co-designed workshops was conducted through recruitment flyers in the waiting rooms of the pediatric dentistry tertiary centers. Health professionals were also recruited via a flyer that was circulated via email from the heads of departments at the 2 tertiary centers and the state-based health promotion and policy team. Purposive sampling of parents with a child diagnosed with ECC accessing NSW public dental services ensured representation of the end-user perspectives of the final *SmilesUp* program. Similarly, only health professionals who were working within NSW public dental clinics or for the state-wide oral health promotion team were invited to participate.

Ethical Considerations

Ethics approval was obtained and approved by the Western Sydney Local Health District Research ethics department (2022/ETH01920). As part of the recruitment process, all participants for both phases were given a participant information sheet and provided e-consent through Research Electronic Data Capture (REDCap) or via a paper consent form before joining

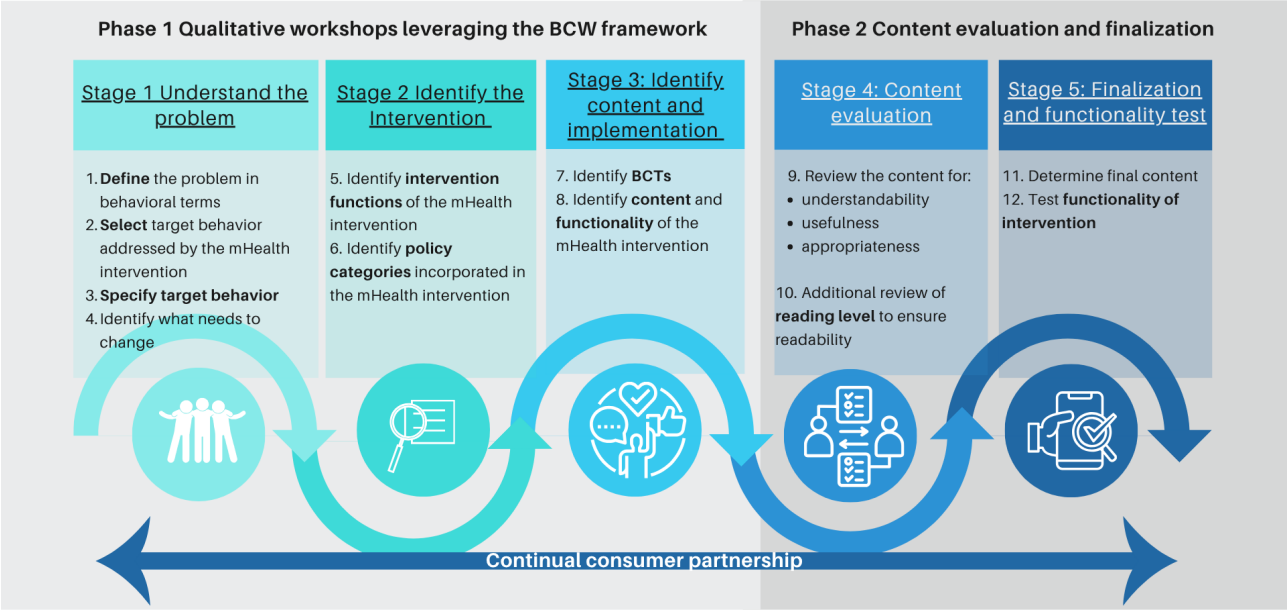
XSL•FO
RenderX

workshops, semistructured interviews, or completing the questionnaire. For participants attending in person focus groups, recurtiment flyers outlined that they would be reimbursed for their travel and parking expenses; no other compensation was provided. All research data collected were deidentified and procedures were conducted in alignment with the National Statement on Ethical Conduct in Human Research from the Australian National Health and Medical Research and the Declaration of Helsinki.

Overview of the Co-Design Process

This study used a 2-phase co-design approach, incorporating BCW and a mixed methods evaluation similar to previously published methodologies [21,33]. Phase 1 involved qualitative methods [34] to understand the oral health barriers and enablers faced by parents, identify target behaviors, and draft intervention content. Phase 2 focused on evaluating content validity by measuring understandability, usefulness, and appropriateness with both parents and health professionals (Figure 1).

Figure 1. SmilesUp mobile health (mHealth) intervention co-design process, including the Behaviour Change Wheel (BCW) framework and content evaluation and finalization. BCT: behavior change technique.



Phase 1: Qualitative Workshops Leveraging BCW

Overview of Phase 1

Phase 1 used all 3 stages of BCW (Figure 1) to understand parents' barriers and enablers, mapping these to intervention functions, behavior change techniques (BCTs), and text message content. Co-design workshops and semistructured interviews were conducted between February 2, 2023, and July 15, 2023. Data were collected by a trained qualitative researcher who had experience working within NSW Health public dental services, and sessions were conducted in person or via video calls if requested by participants. All workshop participants' anonymity was maintained through pseudonyms, and transcription was managed with the NVivo (Lumivero) qualitative data analysis software [35]. Parent and health professional sessions were held separately to reduce power dynamics and encourage open discussions [36,37].

Stage 1: Understanding the Problem

In the first stage, qualitative workshops and interviews were conducted with parents and oral health professionals to explore barriers and enablers related to 3 key oral health behaviors: oral hygiene, dietary sugar intake, and bedtime routines. These were mapped to the COM-B model to define a target behavior that could be supported by mHealth messaging.

Stage 2: Identifying the Intervention Options and Policy Areas

Stage 2 used the BCW mapping process to select intervention functions and policy areas to address the barriers and enablers identified in stage 1. These identified intervention functions also had to have the capacity to be incorporated into the format of the mHealth program.

Stage 3: Identifying BCTs and Drafting Content

In stage 3, BCTs were chosen based on the Acceptability, Practicability, Effectiveness, Affordability, Safety, and Equity (APEASE) [38] criteria, and content for the intervention was drafted and mapped to the original barriers and enablers. Within the BCW, the APEASE criteria ensures that the content is pragmatic and relevant for both the parents and the health system's existing digital infrastructure [28]. This process informed the content of the initial draft text message bank.

Phase 2: Content Evaluation and Final Functionality

Overview of Phase 2

Phase 2 developed the information gathered from the phase 1 co-design workshops by conducting a broader consultation with parents and health professionals to further evaluate the content (stage 4) before finalising the content and functionality of the *SmilesUp* program (stage 5).

XSL•FO
RenderX

Stage 4: Content Evaluation by a Broader Range of Parents and Health Professionals

A questionnaire based on previously published methodologies [15] was developed to measure the understandability, usefulness, and appropriateness of the draft content. This questionnaire was given to a wider group of parents and health professionals to assess the acceptability of SMS text message content [15]. We recruited until all messages were reviewed by at least 2 parents and 2 health professionals. The SMS text message content reviews were collected through questionnaires on REDCap and through paper forms when requested by parents [39]. To prevent survey fatigue, each participant was only required to provide feedback on the understandability, usefulness, and appropriateness of approximately 20 messages [15]. Additionally, to ensure the readability of the messages, a grade 5 reading level or below was set to ensure the readability of the program for our target population. All final messages were assessed using the Sydney Health Literacy Lab (SHeLL) reader to verify this reading level was met before they were included in the final set [40].

Stage 5: Finalization and Functionality Determination

In the finalization phase, messages were mapped back to the originally identified barriers and enablers (phase 1) to ensure that all identified needs and BCTs were addressed. Qualitative data were also analyzed to inform decisions about the program's functionality, including the duration, frequency, timing, and sequencing of the SMS text message schedule.

Results

Participants

Members included in the co-designed workshops were parents 30% (6/20) currently using public dental services, as well as health professionals 70% (14/20), including dental practitioners, health promotion policy officers, dietitians, and IT managers providing clinical services or developing programs for oral health services within NSW Health. This diverse group provided a broad perspective, shared existing high-quality digital health promotion resources (interactive websites or online videos) that could be incorporated into the program, and guided the features of the program to address target behaviors. The inclusion of various dental practitioners and dietitians ensured a comprehensive approach to oral health promotion information that addressed the specific barriers and enablers identified by parents. Additional parents (14/31, 45.2%) and health professionals (17/31, 54.8 %) were recruited for phase 2 to ensure a broader perspective beyond that of the initial co-design groups.

Phase 1: Co-Design Outcomes Using BCW

The results from the mixed methods data collection and analysis were progressive, integrated, and structured according to our methods (Figure 1). Phase 1 results are presented within the 3 stages set by BCW [28].

Stage 1: Understanding the Behavior

Workshops with parents and health professionals identified 15 enablers and 10 barriers to address 3 key oral health risk behavioral categories: oral hygiene, diet, and healthy bedtime routines. These barriers and enablers were mapped to BCW's COM-B model of behavior categories: *physical capability*, *psychological capability*, *physical opportunity*, *social opportunity*, *reflective motivation*, and *automatic motivation*. We found that while parents had the *physical capability* to perform oral health–promoting behaviors, they lacked specific knowledge (*psychological capability*) about selecting the best toothpaste, brushing techniques, and choosing low sugar snacks for their children. Most of the enablers were linked to *motivation* (*automatic*) and *capability* (*knowledge*) where parents sought reminders and information to help them develop consistent oral health habits.

Therefore, the problem was defined as the need to increase parents' oral health literacy encompassing both knowledge (*psychological capability*) and motivation (*automatic and reflective*) for adopting healthy oral behaviors to prevent ECC. A comprehensive tabulated description of the target behavior for the *SmilesUp* SMS text message program using BCW framework is found in Table 1.

XSL•FO
RenderX

Table . Using the Behavior Change Wheel (BCW) framework to identify the specific target behavior for the *SmilesUp* SMS text message program.

Question (BCW step)	Response
What is the target behavior?	Participation in a structured SMS messaging intervention to perform oral health–promoting behaviors in the home context.
Who needs to perform the behavior?	Parents of children with ECC[a], undergoing dental treatment within select NSW[b] Health public dental clinics, including but not limited to children waiting for a general anesthetic appointment for dental treatment.
What does the person need to do differently to achieve the desired change?	Participate in a co-designed and semipersonalized structured SMS messaging program that supports a range of healthy oral health behaviors, including oral hygiene, diet, and bedtime routines.
When will they do it?	Parents will engage with the SmilesUp 12-week program after their initial clinical appointment, which provides additional support to the oral hygiene and dietary advice provided by their clinicians, with messages sent at times nominated by the parents at the start of the program.
Where will they do it?	In the home context.
How often will they do it?	The program will be sent 2 - 3 times per week. However, most key behaviors related to ECC (eg, tooth brushing) will need to be conducted daily.
With whom will they do it?	With their children and other relevant members of their family.

[a]ECC: early childhood caries.

[b]NSW: New South Wales.

Stage 2: Intervention Options and Policy Areas Identified

Intervention options and policy areas from the BCW were identified based on the initial data around barriers and enablers collected from parents and clinicians. These were then mapped to the previously identified barriers and enablers (Multimedia Appendices 1 and 2). Parents and clinicians recommended incorporating 5 intervention functions and 10 theoretical domains into the *SmilesUp* mHealth intervention. The 5 intervention functions were education, persuasion, modeling, enablement, and environmental restructuring [38]. The 10 theoretical domains framework included knowledge, skills, beliefs about capabilities, optimism, beliefs about consequences, reinforcement, intentions, goals, memory, and social influences [38].

The *SmilesUp* program aligns with two specific policy areas identified in the BCW: (1) communication and marketing and (2) service provision [38]. The program sits at the intersection of these policies because it is delivered as a communication tool to support and encourage behavior change as part of the comprehensive, value-based clinicalservice provided to families with the NSW public dental service.

Stage 3: BCTs and Drafting Content Identified

Specific BCTs were determined using a feasibility lens based on the APEASE criteria with perspectives from parents and high-level stakeholders [28]. A total of 16 BCTs were identified and mapped to the 15 enablers and 10 barriers previously determined by the consumer co-designers in stages 1 and 2 (Multimedia Appendices 1 and 2). These BCTs were chosen for their feasibility and relevance to an mHealth intervention with the goal of enhancing parents' capability and motivation of oral health–promoting behaviors in the home context (Multimedia Appendices 1 and 2). The specific BCTs included were as follows: "1.4 Action planning"; "2.4 Self-monitoring of behavior"; "4.1 Instructions on how to perform behavior"; "5.1 Information about health consequences"; "5.3 Information about social and environmental consequences"; "5.6 Information about emotional consequences"; "6.1 Demonstration of the behavior"; "7.3 Reducing the prompts/cues"; "7.6 Satiation"; "8.2 Behavioral substitution"; "8.3 Habit formation"; "9.1 Credible source"; "12.1 Restructuring the physical environment"; "12.4 Distraction"; "13.1 Identification of self as a role model"; "15.1 Verbal persuasion about capability." An example of how the BCTs were comprehensively mapped to the barriers or enablers, theoretical domains framework, and policy functions is provided in Multimedia Appendices 1 and 2. This information informed the program's functionality, including the need for semipersonalization of the messages to include the child's name, and for parents to select the timing of the messages to suit their lifestyles, thereby supporting ongoing engagement and sustained long-term behavior change.

The draft content, co-designed with 20 participants including 6 (30%) parents and 14 (70%) health professionals, addressed the barriers and enablers and corresponded to the intervention functions and BCTs identified earlier. The draft message bank included 111 messages, some of which were adapted from the bank of messages from the WHO's *BeHealthy BeMobile* program, with locally relevant web-based links specific to the target population [7]. These web-based resources were in alignment with Australia's National Consensus Statement on Oral Health Messages [41] and were developed by government agencies and professional associations including NSW Health and the Australian Dental Association [41]. New messages were created to address specific knowledge barriers identified by the parents, such as the consumption of dried fruit and vitamin gummies that had been noted in stage 1. Additionally, BCTs were incorporated into the content and features of the mHealth program to support parents using the final *SmilesUp* program.

XSL•FO
RenderX

Phase 2: Content Evaluation and Final Functionality Determination

Stage 4: Content Evaluation Findings by a Broader Range of Parents and Health Professionals

In phase 2, of the 31 participants, 14 (45.2%) parents and 17 (54.8%) health professionals reviewed the 111 draft SMS text messages, providing a total of 2045 ratings, which included 805 (39.4%) parent reviews and 1240 (60.6%) health professional reviews. The sample size was determined by data saturation, which was reached when all messages were reviewed twice—once by a health professional and once by a parent consumer accessing NSW public dental clinics. For a message to be considered acceptable, it needed to receive a "yes" favorably on all 3 categories of understandability, usefulness, and appropriateness. Of the 111 draft messages, 86 (77.5%) messages were rated favorably by parents, while 68 (61.3%) messages were rated favorably by health professionals. A total of 56 (50.5%) messages were considered acceptable and useful by both parents and health professionals.

These 56 messages were further tested for readability using the SHeLL reader [40]. Two (1.8%) messages that exceeded the grade 5 reading level were removed.

Stage 5: Program Finalization and Functionality Determination

The final set of messages was mapped to oral health behaviors, barriers, enablers, intervention functions, and BCTs. Based on the final functionality determination, only 36 messages were required. Therefore, 18/56 (32%) messages that addressed similar barriers and enablers were removed to avoid redundancy. The final set included 12/36 (33.3%) messages addressing oral hygiene, 16/36 (44.4%) addressing dietary sugar intake, and 6/36 (16.7%) on bedtime routines. An example of how a barrier is mapped to an intervention function, a BCT and the SMS text message content for the program, is found in Table 2.

Table . Example of a barrier and enablers mapped to the Behaviour Change Wheel (BCW) framework and SMS text message content.

Barrier or enabler identified	COM-B[a]	TDF[b] and intervention function	Policy function	BCT[c]	Text message examples
Forgetfulness (barrier)	Motivation (automatic)	Reinforcement and enablement	Communication or marketing service provision	2.3 Self-monitoring of behavior; 4.1 Instructions on how to perform behavior; 13.1 Identification of self as a role model; 15.1 Verbal persuasion about capability	"Have you watched your children brushing their teeth today, did they do a good job? Brushing your teeth together can help them learn great habits @SMILESup"
Receiving reminders and tips (enabler)	Motivation (automatic)	Reinforcement and enablement	Communication or marketing service provision	8.3 Habit formation	"A little reminder for you to help [child name] brush their teeth before they go to bed. If they have clean teeth before they sleep, it will prevent tooth decay. @SMILESup"

[a]COM-B: Capability, Opportunity, Motivation-Behaviour.

[b]TDF: Theoretical Domains Framework.

[c]BCT: behavior change technique.

Finalizing the program's functionality included decisions about the duration, frequency, timing, and sequencing of the SMS text message algorithm. After consulting parents and considering the behavior change literature [42], the program was set for 12 weeks with an average of 3 messages per week, totaling 36 messages. Parents could semipersonalize the program by including their child's name in the messages and choosing the time they received the messages to best fit their lifestyles. The sequencing initially focused on bridging knowledge gaps identified by parents during the first month, with more reminders and messages targeting motivation scheduled for later in the program.

The message schedule and practice sequence were delivered using the Westmead Applied Research Centre's TextCare platform, a cloud-based system designed to semipersonalize the content and frequency of SMS text messages. TextCare includes built-in safety, privacy, and security systems with in-built data analytics, including an automated opt-out feature to measure engagement from parents. The messages are primarily 1-way, providing practical tips and strategies to prompt behavior change. The TextCare platform was monitored by a clinician researcher. RC tested the program for 1 month before delivering the program to parents.

Discussion

Principal Findings

This study reports the outcomes of a co-design and content evaluation of the *SmilesUp* SMS text message intervention, aimed at supporting parents of children with ECC in promoting oral health behavior change. Guided by the BCW, the intervention incorporates 16 BCTs to address motivation and knowledge gaps identified by parents. Of the 111 drafted messages, 56 (50.5%) text messages that were evaluated to be

XSL•FO
RenderX

understandable, useful, and acceptable by both parents and health professionals were programmed into the 12-week semipersonalized SMS text message program. This paper highlights the importance of involving parent end users at the beginning of the design process to ensure that the intervention addresses their needs in developing oral health–promoting behaviors for their children. This co-design work lays the foundation for future studies to test the effectiveness of the mHealth intervention for changing oral health behaviors [43].

Strengths and Limitations

A major strength of our study is the robust co-design process, structured around the BCW behavioral theory using mixed methods to incorporate perspectives from both parents and health professionals. The BCW, including the COM-B model of behavior change, ensured that the target behaviors were matched with the 16 BCTs to address identified barriers and enablers. The study aligns with the WHO's goal of optimizing digital technologies for oral health within its Draft Global Oral Health Action Plan (2023‐2030) and serves as an example of how a mHealth program can address ECC localized to the Australian context [44].

Methodologically, our study builds on the existing methods from other lifestyle-related behavioral studies [15,21,25,45-47] and is one of the few studies in the field of dentistry using a theory-driven design for mHealth programs focused on behavior change [48-50]. Our process was pragmatic, systematic, and grounded in behavioral theory. Although the formal triangulation of data was not conducted, qualitative findings informed content development, which subsequently guided the quantitative data collection. The quantitative insights were subsequently synthesized with the initial qualitative findings to ensure alignment with the original aims of the program. This iterative process led to the development of a distinctive program that addressed multiple oral health risk factors. Previous mHealth programs in oral health tended to focus on single risk behaviors, for example, on bedtime routines [49] or on diet [51]. Although specific to the Australian context, the robustness and adaptability of this program enables other countries to also co-design, adapt, and localize an mHealth program. This is especially important in lower resourced areas, including low- and middle-income countries in the Asia-Pacific region [52] and more globally [7,53]. Where both oral health consumers and practitioners are increasingly using digital technologies to enhance the preventive potential of oral health[54]. Furthermore, by using the BCW, this study contributes to the dental scientific community's understanding of effective BCT approaches used to improve oral health–related behaviors in the long term [20,29,30].

Raising the standard of mHealth design and involving end users in the design process is essential to ensure confidence in the impact that mHealth interventions can have on improving health outcomes. Continual consultation with parents shaped the content and functionality of the *SmilesUp* program, ensuring it was patient centered and designed for vulnerable families using NSW Health public dental clinics [18]. This approach aligns with value-based health care systems that prioritize the consumer voice [55] and enhances confidence in mHealth interventions and their potential impact. By using co-design and content evaluation, the *SmilesUp* program completed content acceptability testing to inform policy and funding decisions before further investments are made for efficacy testing.

A limitation of the current *SmilesUp* program is the 1-way SMS text messaging format. Although newer mobile health tools like mobile apps and wearables seem more advanced [56], our use of the APEASE framework and consumer consultation shows that SMS text messaging still remains an effective, equitable, and widely accepted option for patients and practical for health systems [15,57-60]. Furthermore, compared with standalone mobile apps, the TextCare platform enables analytics on message delivery and replies to assess the reach and engagement of the program. These data are critical for a process and feasibility evaluation before health systems make larger investments into digital health infrastructure to further embed programs like *SmilesUp* into their existing digital health management systems [56,61].

Future Directions

This co-design work is the first step before we conduct future research to test the effectiveness of the program in improving oral health behavioral outcomes, especially among parents of children at a high risk of ECC [43,62,63]. The effectiveness trial will be conducted in public dental care settings using the COM-B model to inform analytical strategies and outcome measures [43,64,65]. Future studies will also examine opportunities to expand the program for broader reach by translating the content to other languages and scaling the program to reach more families.

Conclusions

SmilesUp is a robust, co-designed, and behavioral theory–driven mHealth intervention developed to support parents, especially those from vulnerable and low socioeconomic families, to adopt key oral health behaviors to prevent ECC. By involving end-user parents in the co-design process, applying behavioral theory, and evaluating the content, the program ensures that it addresses specific knowledge gaps related to brushing, diet, and bedtime routines. This is a crucial first step before conducting a planned future trial to test the effectiveness of the mHealth intervention for behavior change and the prevention of ECC.

Acknowledgments

The authors would like to thank the consumers and health professionals at the Paediatric Dental Departments of the Sydney Dental Hospital, Sydney Local Health District, and the Westmead Centre for Oral Health, Western Sydney Local Health District, for their involvement in the study. No specific project funding was received for this study.

XSL•FO
RenderX

Data Availability

The datasets generated or analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Barriers identified by parents and health professionals mapped to the Behaviour Change Wheel framework.
[DOCX File, 23 KB - pediatrics_v8i1e72107_app1.docx]

Multimedia Appendix 2
Enablers identified by parents and health professionals mapped to the Behaviour Change Wheel framework.
[DOCX File, 17 KB - pediatrics_v8i1e72107_app2.docx]

References

1. Pitts NB, Baez RJ, Diaz-Guillory C, et al. Early childhood caries: IAPD Bangkok Declaration. J Dent Child (Chic) 2019 May 15;86(2):72. [Medline: 31395110]
2. Chen R, Schneuer FJ, Irving MJ, et al. Socio-demographic and familial factors associated with hospital admissions and repeat admission for dental caries in early childhood: a population-based study. Community Dent Oral Epidemiol 2022 Dec;50(6):539-547. [doi: 10.1111/cdoe.12708] [Medline: 34837420]
3. Ending childhood dental caries: WHO implementation manual. World Health Organization. 2020. URL: https://www.who.int/publications/i/item/ending-childhood-dental-caries-who-implementation-manual [accessed 2025-10-27]
4. Ng MW, Ramos-Gomez F, Lieberman M, et al. Disease management of early childhood caries: ECC collaborative project. Int J Dent 2014;2014:327801. [doi: 10.1155/2014/327801] [Medline: 24723953]
5. Faghihian R, Faghihian E, Kazemi A, Tarrahi MJ, Zakizade M. Impact of motivational interviewing on early childhood caries: a systematic review and meta-analysis. J Am Dent Assoc 2020 Sep;151(9):650-659. [doi: 10.1016/j.adaj.2020.06.003] [Medline: 32854867]
6. De la Torre K, Min S, Lee H, Kang D. The application of preventive medicine in the future digital health era. J Med Internet Res 2025 Feb 27;27:e59165. [doi: 10.2196/59165] [Medline: 40053712]
7. Mobile technologies for oral health: an implementation guide. World Health Organisation. 2021. URL: https://www.who.int/publications/i/item/9789240035225 [accessed 2025-10-27]
8. Poirier B, Jensen E, Sethi S. The evolution of the teledentistry landscape in Australia: a scoping review. Aust J Rural Health 2022 Aug;30(4):434-441. [doi: 10.1111/ajr.12874] [Medline: 35567780]
9. Chen R, Santo K, Wong G, et al. Mobile apps for dental caries prevention: systematic search and quality evaluation. JMIR Mhealth Uhealth 2021 Jan 13;9(1):e19958. [doi: 10.2196/19958] [Medline: 33439141]
10. Marshman Z, Ainsworth H, Chestnutt IG, et al. Brushing RemInder 4 Good oral HealTh (BRIGHT) trial: does an SMS behaviour change programme with a classroom-based session improve the oral health of young people living in deprived areas? A study protocol of a randomised controlled trial. Trials 2019 Jul 23;20(1):452. [doi: 10.1186/s13063-019-3538-6] [Medline: 31337437]
11. Yao R, Zhang W, Evans R, Cao G, Rui T, Shen L. Inequities in health care services caused by the adoption of digital health technologies: scoping review. J Med Internet Res 2022 Mar 21;24(3):e34144. [doi: 10.2196/34144] [Medline: 35311682]
12. Koh A, Swanepoel DW, Ling A, Ho BL, Tan SY, Lim J. Digital health promotion: promise and peril. Health Promot Int 2021 Dec 13;36(Supplement_1):i70-i80. [doi: 10.1093/heapro/daab134] [Medline: 34897444]
13. Chow CK, Redfern J, Hillis GS, et al. Effect of lifestyle-focused text messaging on risk factor modification in patients with coronary heart disease: a randomized clinical trial. JAMA 2015;314(12):1255-1263. [doi: 10.1001/jama.2015.10945] [Medline: 26393848]
14. Chow CK, Klimis H, Thiagalingam A, et al. Text messages to improve medication adherence and secondary prevention after acute coronary syndrome: the TEXTMEDS randomized clinical trial. Circulation 2022 May 10;145(19):1443-1455. [doi: 10.1161/CIRCULATIONAHA.121.056161] [Medline: 35533220]
15. Singleton A, Raeside R, Partridge SR, et al. Co-designing a lifestyle-focused text message intervention for women after breast cancer treatment: mixed methods study. J Med Internet Res 2021 Jun 14;23(6):e27076. [doi: 10.2196/27076] [Medline: 34125072]
16. Russell J, Fudge N, Greenhalgh T. The impact of public involvement in health research: what are we measuring? Why are we measuring it? Should we stop measuring it? Res Involv Engagem 2020 Oct 27;6:63. [doi: 10.1186/s40900-020-00239-w] [Medline: 33133636]
17. Greenhalgh T, Hinton L, Finlay T, et al. Frameworks for supporting patient and public involvement in research: systematic review and co-design pilot. Health Expect 2019 Aug;22(4):785-801. [doi: 10.1111/hex.12888] [Medline: 31012259]

XSL•FO
RenderX

18. Noorbergen TJ, Adam MT, Teubner T, Collins CE. Using co-design in mobile health system development: a qualitative study with experts in co-design and mobile health system development. JMIR Mhealth Uhealth 2021 Nov 10;9(11):e27896. [doi: 10.2196/27896] [Medline: 34757323]
19. Gould GS, Bar-Zeev Y, Bovill M, et al. Designing an implementation intervention with the Behaviour Change Wheel for health provider smoking cessation care for Australian Indigenous pregnant women. Implement Sci 2017 Sep 15;12(1):114. [doi: 10.1186/s13012-017-0645-1] [Medline: 28915815]
20. Kitsaras G, Asimakopoulou K, Henshaw M, Borrelli B. Theoretical and methodological approaches in designing, developing, and delivering interventions for oral health behaviour change. Community Dent Oral Epidemiol 2023 Feb;51(1):91-102. [doi: 10.1111/cdoe.12817] [Medline: 36749671]
21. Nelligan RK, Hinman RS, Atkins L, Bennell KL. A short message service intervention to support adherence to home-based strengthening exercise for people with knee osteoarthritis: intervention design applying the Behavior Change Wheel. JMIR Mhealth Uhealth 2019 Oct 18;7(10):e14619. [doi: 10.2196/14619] [Medline: 31628786]
22. Mummah SA, Robinson TN, King AC, Gardner CD, Sutton S. IDEAS (Integrate, Design, Assess, and Share): a framework and toolkit of strategies for the development of more effective digital interventions to change health behavior. J Med Internet Res 2016 Dec 16;18(12):e317. [doi: 10.2196/jmir.5927] [Medline: 27986647]
23. Michie S, Churchill S, West R. Identifying evidence-based competences required to deliver behavioural support for smoking cessation. Ann Behav Med 2011 Feb;41(1):59-70. [doi: 10.1007/s12160-010-9235-z] [Medline: 20936389]
24. Cooray N, Ho C, Bestman A, et al. Exploring the potential of a behavior theory-informed digital intervention for infant fall prevention: mixed methods longitudinal study. JMIR Pediatr Parent 2024 Jan 3;7:e47361. [doi: 10.2196/47361] [Medline: 38170580]
25. Brennan C, ODonoghue G, Keogh A, Rhodes RE, Matthews J. Developing an evidence- and theory-informed mother-daughter mHealth intervention prototype targeting physical activity in preteen girls of low socioeconomic position: multiphase co-design study. JMIR Pediatr Parent 2025 Jan 6;8:e62795. [doi: 10.2196/62795] [Medline: 39761561]
26. Ananya A, Tuuli J, Perowne R, Gutman LM. Barriers and facilitators to user engagement and moderation for web-based peer support among young people: qualitative study using the Behavior Change Wheel framework. JMIR Hum Factors 2025 Feb 5;12:e64097. [doi: 10.2196/64097] [Medline: 39908551]
27. Daniels K, Vonck S, Robijns J, et al. Exploring the feasibility of a 5-week mHealth intervention to enhance physical activity and an active, healthy lifestyle in community-dwelling older adults: mixed methods study. JMIR Aging 2025 Jan 27;8:e63348. [doi: 10.2196/63348] [Medline: 39869906]
28. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci 2011 Apr 23;6:42. [doi: 10.1186/1748-5908-6-42] [Medline: 21513547]
29. Buchanan H, Newton JT, Baker SR, Asimakopoulou K. Adopting the COM-B model and TDF framework in oral and dental research: a narrative review. Community Dent Oral Epidemiol 2021 Oct;49(5):385-393. [doi: 10.1111/cdoe.12677] [Medline: 34270110]
30. McNeil DW, Randall CL, Baker S, et al. Consensus statement on future directions for the behavioral and social sciences in oral health. J Dent Res 2022 Jun;101(6):619-622. [doi: 10.1177/00220345211068033] [Medline: 35043742]
31. Priority oral health program (POHP) and waiting list management. NSW Health. 2017. URL: https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2017_023 [accessed 2023-08-01]
32. Eligibility of persons for public oral health care in NSW. NSW Health. 2017. URL: https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2017_027 [accessed 2025-10-27]
33. Redfern J, Thiagalingam A, Jan S, et al. Development of a set of mobile phone text messages designed for prevention of recurrent cardiovascular events. Eur J Prev Cardiol 2014 Apr;21(4):492-499. [doi: 10.1177/2047487312449416] [Medline: 22605787]
34. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol 2013 Sep 18;13:117. [doi: 10.1186/1471-2288-13-117] [Medline: 24047204]
35. NVivo: leading qualitative data analysis software. Lumivero. URL: https://lumivero.com/products/nvivo/ [accessed 2025-10-27]
36. Fetters MD, Guetterman TC. Discovering and doing family medicine and community health research. Fam Med Community Health 2019;7(2):e000084. [doi: 10.1136/fmch-2018-000084] [Medline: 32148707]
37. Templeton AR, Young L, Bish A, et al. Patient-, organization-, and system-level barriers and facilitators to preventive oral health care: a convergent mixed-methods study in primary dental care. Implement Sci 2016 Jan 12;11:5. [doi: 10.1186/s13012-015-0366-2] [Medline: 26753791]
38. Michie S, Atkins L, West R. The Behaviour Change Wheel: A Guide to Designing Interventions: Silverback Publishing; 2014.
39. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019 Jul;95:103208. [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]

XSL•FO
RenderX

40. Ayre J, Bonner C, Muscat DM, et al. Multiple automated health literacy assessments of written health information: development of the SHeLL (Sydney Health Literacy Lab) health literacy editor v1. JMIR Form Res 2023 Feb 14;7:e40645. [doi: 10.2196/40645] [Medline: 36787164]
41. Welti R, Chinotti M, Walsh O, et al. Oral health messages for Australia: a national consensus statement. Aust Dent J 2023 Dec;68(4):247-254. [doi: 10.1111/adj.12973] [Medline: 37665214]
42. Lally P, van Jaarsveld CH, Potts HW, Wardle J. How are habits formed: modelling habit formation in the real world. Eur J Soc Psychol 2010;40(6):998-1009. [doi: 10.1002/ejsp.674]
43. Chen R, Irving M, Christian B, et al. SmilesUp text message intervention for early childhood dental caries prevention: a protocol for a randomised controlled trial. PLoS ONE 2024 Sep 30;19(9):e0310561. [doi: 10.1371/journal.pone.0310561] [Medline: 39348422]
44. Draft global oral health action plan (2023–2030). World Health Organization. 2023. URL: https://www.who.int/publications/m/item/draft-global-oral-health-action-plan-(2023-2030) [accessed 2025-10-27]
45. Chen J, Lieffers J, Bauman A, Hanning R, Allman-Farinelli M. Designing health apps to support dietetic professional practice and their patients: qualitative results from an international survey. JMIR Mhealth Uhealth 2017 Mar 31;5(3):e40. [doi: 10.2196/mhealth.6945] [Medline: 28363882]
46. Musgrave LM, Baum A, Perera N, Homer CS, Gordon A. Baby Buddy app for breastfeeding and behavior change: retrospective study of the app using the behavior change wheel. JMIR Mhealth Uhealth 2021 Apr 15;9(4):e25668. [doi: 10.2196/25668] [Medline: 33856351]
47. Fulton EA, Brown KE, Kwah KL, Wild S. StopApp: using the behaviour change wheel to develop an app to increase uptake and attendance at NHS stop smoking services. Healthcare (Basel) 2016 Jun 8;4(2):31. [doi: 10.3390/healthcare4020031] [Medline: 27417619]
48. Borrelli B, Henshaw M, Endrighi R, et al. An interactive parent-targeted text messaging intervention to improve oral health in children attending urban pediatric clinics: feasibility randomized controlled trial. JMIR Mhealth Uhealth 2019 Nov 11;7(11):e14247. [doi: 10.2196/14247] [Medline: 31710306]
49. Kitsaras G, Allan J, Pretty IA. Bedtime Routines Intervention for Children (BRIC) using an automated text messaging system for behaviour change: study protocol for an early phase study. Pilot Feasibility Stud 2020 Feb 6;6:14. [doi: 10.1186/s40814-020-0562-y] [Medline: 32047647]
50. Scheerman JF, van Meijel B, van Empelen P, et al. Study protocol of a randomized controlled trial to test the effect of a smartphone application on oral-health behavior and oral hygiene in adolescents with fixed orthodontic appliances. BMC Oral Health 2018 Feb 7;18(1):19. [doi: 10.1186/s12903-018-0475-9] [Medline: 29415697]
51. Goh CE, Zheng K, Chua WY, et al. Development of a dental diet-tracking mobile app for improved caries-related dietary behaviours: key features and pilot evaluation of quality. Digit Health 2024 Jan 31;10:20552076241228433. [doi: 10.1177/20552076241228433] [Medline: 38303969]
52. Maimanuku L, Piukala S, Tatui L, Tiim K, Benzian H. New leadership for WHO Western Pacific region: a call to prioritize oral health in the Pacific Islands. Front Public Health 2024 Jul 8;12:1388117. [doi: 10.3389/fpubh.2024.1388117] [Medline: 39040860]
53. Watt RG, Daly B, Allison P, et al. Ending the neglect of global oral health: time for radical action. Lancet 2019 Jul;394(10194):261-272. [doi: 10.1016/S0140-6736(19)31133-X] [Medline: 31327370]
54. Kengne Talla P, Inquimbert C, Dawson A, Zidarov D, Bergeron F, Chandad F. Barriers and enablers to implementing teledentistry from the perspective of dental health care professionals: protocol for a systematic quantitative, qualitative, and mixed studies review. JMIR Res Protoc 2023 Jul 26;12:e44218. [doi: 10.2196/44218] [Medline: 37494093]
55. Koff E, Lyons N. Implementing value-based health care at scale: the NSW experience. Med J Aust 2020 Feb;212(3):104-106. [doi: 10.5694/mja2.50470] [Medline: 31909479]
56. Willcox JC, Dobson R, Whittaker R. Old-fashioned technology in the era of “bling”: is there a future for text messaging in health care? J Med Internet Res 2019 Dec 20;21(12):e16630. [doi: 10.2196/16630] [Medline: 31859678]
57. Middleton T, Constantino M, McGill M, et al. An enhanced SMS text message-based support and reminder program for young adults with type 2 diabetes (TEXT2U): randomized controlled trial. J Med Internet Res 2021 Oct 21;23(10):e27263. [doi: 10.2196/27263] [Medline: 34524102]
58. Partridge SR, Raeside R, Singleton AC, et al. Text message behavioral intervention for teens on eating, physical activity and social wellbeing (TEXTBITES): protocol for a randomized controlled trial. JMIR Res Protoc 2020 Feb 18;9(2):e16481. [doi: 10.2196/16481] [Medline: 32130194]
59. Sutherland R, Brown A, Nathan N, et al. A multicomponent mHealth-based intervention (SWAP IT) to decrease the consumption of discretionary foods packed in school lunchboxes: type I effectiveness-implementation hybrid cluster randomized controlled trial. J Med Internet Res 2021 Jun 24;23(6):e25256. [doi: 10.2196/25256] [Medline: 34185013]
60. Raeside R, Todd A, Wardak S, et al. Striking the right balance: co-designing the Health4Me healthy lifestyle digital health intervention with adolescents. Res Involv Engagem 2023 Dec 7;9(1):114. [doi: 10.1186/s40900-023-00524-4] [Medline: 38062532]

XSL•FO
RenderX

61. Carrer F, Matuck BF, Lucena E, et al. Teledentistry and the unified health system: an important tool for the resumption of primary health care in the context of the COVID-19 pandemic. Pesqui Bras Odontopediatria Clín Integr 2020;20(suppl 1). [doi: 10.1590/pboci.2020.155]
62. Ng MW, Fida Z. Dental hygienist-led chronic disease management system to control early childhood caries. J Evid Based Dent Pract 2016 Jun;16 Suppl:20-33. [doi: 10.1016/j.jebdp.2016.01.015] [Medline: 27236993]
63. Kumar H, Kucera A, Nanayakkara S. Addressing Early Childhood Caries in Australia through chronic disease management. Int Dent J 2023 Sep;73(Supplement 1):S22-S23. [doi: 10.1016/j.identj.2023.07.247]
64. Keyworth C, Epton T, Goldthorpe J, Calam R, Armitage CJ. Acceptability, reliability, and validity of a brief measure of capabilities, opportunities, and motivations ("COM-B"). Br J Health Psychol 2020 Sep;25(3):474-501. [doi: 10.1111/bjhp.12417] [Medline: 32314500]
65. Balasubramanian M, Ghanbarzadegan A, Sohn W, et al. Primary school mobile dental program in New South Wales, Australia: protocol for the evaluation of a state government oral health initiative. BMC Public Health 2023 Feb 20;23(1):363. [doi: 10.1186/s12889-023-15241-6] [Medline: 36803579]

Abbreviations

APEASE: Acceptability, Practicability, Effectiveness, Affordability, and Equity
BCT: behavior change technique
BCW: Behaviour Change Wheel
COM-B: Capability, Opportunity, Motivation-Behaviour
ECC: early childhood caries
mHealth: mobile health
REDCap: Research Electronic Data Capture
SHeLL: Sydney Health Literacy Lab
WHO: World Health Organization

Edited by S Badawy; submitted 06.02.25; peer-reviewed by L Weinert, R Musa; revised version received 10.08.25; accepted 10.09.25; published 18.11.25.

Please cite as:
Chen R, Irving MJ, Tsai C, Christian B, Kumar H, Masoe A, Prabhu N, Sohn W, Spallek H, Chow CK
Co-Design and Development of the SmilesUp Text Messaging Intervention Using Behavioral Theory to Support Parents of Children With Early Childhood Caries: Mixed Methods Study
JMIR Pediatr Parent 2025;8:e72107
URL: https://pediatrics.jmir.org/2025/1/e72107
doi:10.2196/72107

© Rebecca Chen, Michelle J Irving, Carrie Tsai, Bradley Christian, Harleen Kumar, Angela Masoe, Neeta Prabhu, Woosung Sohn, Heiko Spallek, Clara K Chow. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 18.11.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Enhancing Access to Mental Health Services for Antepartum and Postpartum Women Through Telemental Health Services at Wellbeing Centers in Selected Health Facilities in Bangladesh: Implementation Research

Aniqa Tasnim Hossain[1], MSc; Md Hafizur Rahman[1], MSc; Ridwana Maher Manna[1], MBBS, MPH; Ema Akter[1], MS; SM Hasibul Islam[1], MBA; Md Alamgir Hossain[1], MSS, MPH; Tasnu Ara[1], MSc; Nasimul Ghani Usmani[1], MSc; Pradip Chandra[1], BPH; Maruf Ahmed Khan[2], MBBS; SM Mustafizur Rahman[2], MBBS; Helal Uddin Ahmed[3], MBBS, MD; Muhammad Kamruzzaman Mozumder[4], MSc, MPhil, PhD; Jesmin Mahmuda Juthi[1], MSc; Fatema Shahrin[1], MSc; Sadia Afrose Shams[1], MSc; Fahmida Afroze[1], MSc; Mukta Jahan Banu[1], MSc; Shafiqul Ameen[1], MBBS; Sabrina Jabeen[1], MBBS, MPH; Anisuddin Ahmed[1], MS; Mohammad Robed Amin[2], MBBS; Shams El Arifeen[1], MBBS, MPH, DrPH; Mohammad Sohel Shomik[1*], MBBS, MPH; Ahmed Ehsanur Rahman[1*], MBBS, MPH, PhD

[1]International Centre for Diarrhoeal Disease Research, Bangladesh, Dhaka, Bangladesh

[2]Director General of Health Services, Ministry of Health and Family Welfare, Dhaka, Bangladesh

[3]National Institute of Mental Health and Hospital, Ministry of Health and Family Welfare, Dhaka, Bangladesh

[4]Department of Clinical Psychology, University of Dhaka, Dhaka, Bangladesh

[*]these authors contributed equally

Corresponding Author:
Aniqa Tasnim Hossain, MSc
International Centre for Diarrhoeal Disease Research, Bangladesh
68 Shaheed Tajuddin Ahmed Sarani
Dhaka, 1212
Bangladesh
Phone: 880 1716543128
Email: aniqa.hossain@icddrb.org

Abstract

Background: Globally, 10% of pregnant women and 13% of postpartum women experience mental disorders. In Bangladesh, nearly 50% of mothers face common mental disorders, but mental health services and trained professionals to serve their needs are scarce. To address this, the government of Bangladesh's Non-Communicable Disease Control program initiated "Wellbeing Centers," telemental health services in selected public hospitals.

Objective: This study examines implementation outcomes, including adoption, accessibility, acceptability, feasibility, usefulness, need, experience, perception, and expectations of the Wellbeing Centers, with a focus on antepartum and postpartum women.

Methods: Between January 2023 and August 2024, we interviewed 911 antepartum and postpartum women receiving mental health services and 168 health care providers at 6 Wellbeing Centers in 4 districts in Bangladesh. Data collection involved both quantitative and qualitative methods. Implementation outcomes were measured following the World Health Organization's implementation research framework. Depression and anxiety symptoms were assessed using the Patient Health Questionnaire-9 and Generalized Anxiety Disorder-7 questionnaires. Descriptive statistics and adjusted odds ratios (aORs) with 95% CIs were used to evaluate the implementation outcomes. Qualitative information was obtained through in-depth interviews and key-informant interviews.

Results: Almost all health care providers (165/168, 98.2%) reported that the Wellbeing Centers were feasible to implement in their health facilities; however, about half (84/168, 50%) felt that trained staff to operate them were insufficient. Almost all women agreed that the Wellbeing Centers were acceptable (906/911, 99.8%), useful (909/911, 99.8%), and enhanced access to mental health care (906/911, 99.5%). Patients visiting district-level hospitals had higher odds of access (aOR 1.5, 95% CI 1.1-2.0) to Wellbeing Centers. Moreover, 77.4% (705/911) of women experienced depression symptoms, and 76.7% (699/911) experienced

XSL•FO
RenderX

anxiety symptoms. About 51.8% (472/911) experienced tiredness or lack of energy, 50.9% (464/911) felt nervous, anxious, or on edge, 57.2% (521/911) felt worried, and 3.8% (35/911) had suicidal ideation almost every day. Patients visiting district hospitals had higher odds (aOR 2.6, 95% CI 1.8-3.78) of depression and anxiety symptoms compared to the patients visiting subdistrict-level hospitals. Decreasing trends in Patient Health Questionnaire-9 scores (from mean 14.4, SD 0.47 to mean 12.9, SD 0.47) and Generalized Anxiety Disorder-7 scores (from mean 13.3, SD 0.49 to mean 12.5, SD 0.48) between 2 counseling sessions indicated improved mental health in the antepartum and postpartum women. The Wellbeing Centers' services were appreciated for their privacy and being free and accessible. However, stigma, postpartum illness, and long waiting times prevented some women from using these services.

Conclusions: To our knowledge, this is the first implementation research assessing telemental health in public health facilities involving trained psychologists and psychiatrists. Our study highlighted the increased accessibility, feasibility, acceptability, and utility of Wellbeing Centers for antepartum and postpartum women in Bangladesh, supporting their scale-up in similar settings.

(JMIR Pediatr Parent 2025;8:e65912) doi:10.2196/65912

KEYWORDS

Wellbeing Centers; antepartum; postpartum; depression; anxiety; implementation

Introduction

Background

Maternal mental health problems are common during pregnancy and after birth [1]. It is recognized as a global public health issue, as approximately 10% of antepartum and 13% of postpartum women experiencing some sort of mental health disorders [2]. The prevalence of maternal common mental disorders is high (49%) in Bangladesh, which underscores a need to screen for depression and anxiety symptoms during pregnancy and postpartum period [3,4]. Around 1 in 5 women experience depressive symptoms during pregnancy, and around 1 in 3 women experience anxiety in rural Bangladesh [4]. In a different study, postpartum women in rural Bangladesh reported that 11% had depressed symptoms, 35% had anxiety symptoms, and 3.4% had both depression and anxiety symptoms [5]. A recent study suggested that postpartum depression symptoms have been more common among impoverished rural mothers during the shutdown in Bangladesh [6-8].

Adverse Effects of Maternal Mental Disorders During the Antepartum and Postpartum Periods

Pregnant women with low education, history of economic difficulties, poor marital relationships, family history of any common mental disorder, poor social and partner support, bad obstetric history, current or previous exposure to violence, preference to have a male child, history of abortions, and disturbed family environment are more likely to report any kind of antepartum and postpartum mental disorders [4,9-13]. Maternal depression may cause negative health-related behaviors and adverse outcomes, including psychological and developmental disturbances in infants, children, and adolescents [14]. Women with severe mental disorders also have increased risks of pre-eclampsia, antepartum and postpartum hemorrhage, placental abruption, impaired intrauterine growth, abortion, and cesarean section, and stillbirths are associated with antepartum and postpartum depression and anxiety [14-19]. Severe mental disorders result in suicide, a leading cause of maternal death in pregnancy and the postpartum period, which contributes to maternal mortality and low quality of life [1,20,21].

Why Videoconference-Based Counseling Is Appropriate as an Intervention for Maternal Mental Disorders in the Context of Bangladesh

Early detection and treatments are necessary to address these maternal mental health issues. Maternal mental disorders are treatable using effective counseling and therapies [22]. However, the availability and access to mental health services are somewhat limited in rural Bangladesh. In addition, the number of available psychologists and psychiatrists is very low. Bangladesh has an estimated 260 psychiatrists, or approximately 0.16/100,000 population, as well as 700 nurses who provide mental health specialty care (0.4/100,000), and 565 psychologists (0.34/100,000) mostly concentrated in urban settings [23]. Providing in-person mental health care with limited capacities such as very low designated government facilities with few specialty service providers is difficult [23].

However, Bangladesh has very good network coverage, which can be used for telehealth counseling services. Telemental health services, which gained popularity during the COVID-19 pandemic, are also commonly used in Bangladesh [24]. Several studies have found that telephone-based treatment significantly improved short-term symptoms and considerably alleviated the advancement of postnatal depression [25,26]. Evidence suggests that digital psychological interventions for mental health problems in developing countries are effective when usual care for mental health problems is minimal [27]. Another study reported that mothers experienced less maternal depression after receiving videoconference-based counseling [28]. Videoconference-based counseling has emerged as a practical and efficient means of providing mental health treatment in resource-limited communities for reducing symptoms of psychiatric disorders and helping to improve quality of life [29-33].

Implementation of Wellbeing Centers in Collaboration With the Non-Communicable Disease Control Program of the Government of Bangladesh

Cognizant of this reality, the Non-Communicable Disease Control (NCDC) program of the government of Bangladesh (GoB) initiated the telemental health service called "Wellbeing Centers" in 6 public hospitals of Bangladesh to provide

XSL•FO
RenderX

telemental health services with facilitation support from the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). General patients along with women with maternal mental health disorders can take personalized and specialized counseling support from a pool of psychologists and psychiatrists through videoconference counseling at the Wellbeing Centers [34,35]. It is important to know whether these services are adequately benefitting the targeted population in a larger number of facilities for scaling up these Wellbeing Centers in other districts in Bangladesh since no study ever explored it in Bangladesh.

Aims

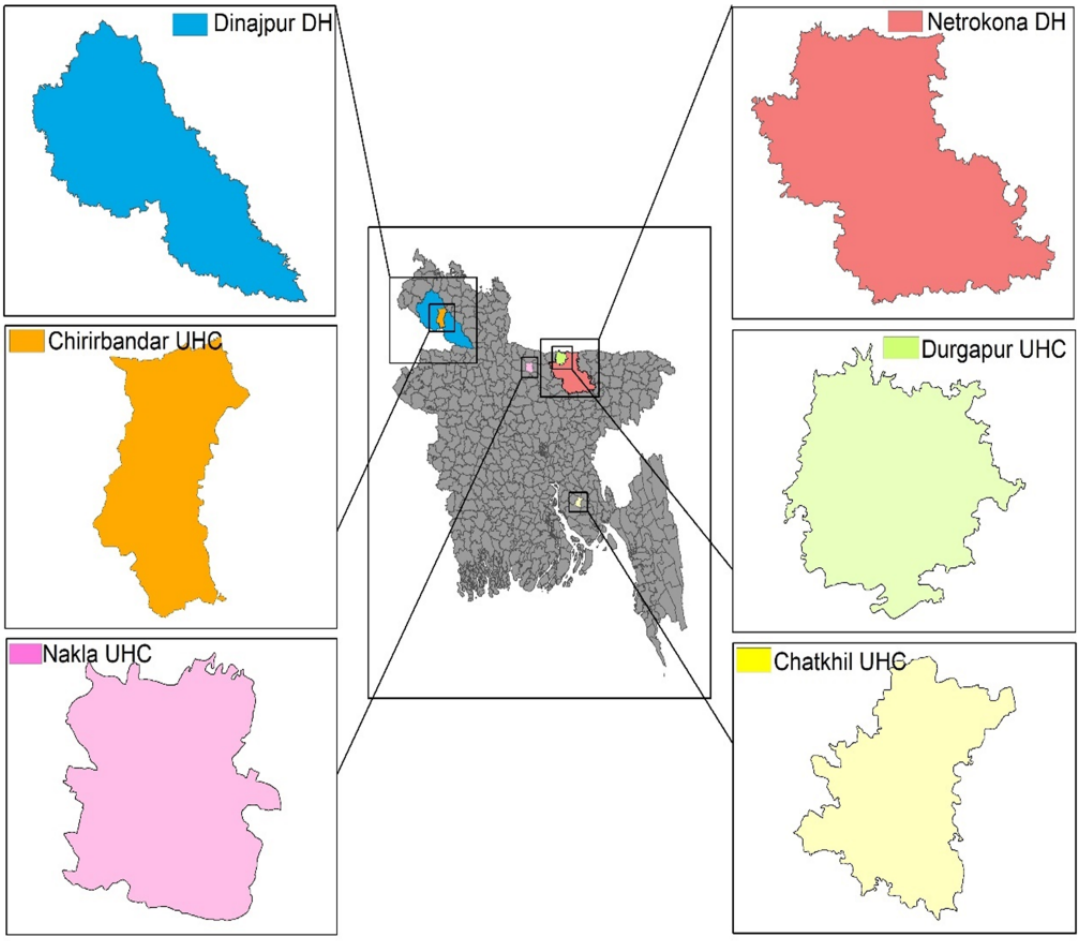
The primary aim of this study is to assess the implementation outcomes (feasibility, accessibility, adoption, acceptability, usefulness, need, experience, perception, and expectation) of the Wellbeing Centers in selected district and subdistrict hospitals of Bangladesh. We will also explore the prevalence of depression and anxiety symptoms in the targeted population as a secondary outcome for demonstrating the need for such mental health care.

Methods

Study Setting

A total of 6 Wellbeing Centers were implemented in district hospitals (DHs) and 4 *upazila* (subdistrict) health complexes (UHCs) in Dinajpur district of Rangpur division and Netrokona district of Mymensingh division. Two other subdistrict-level health care facilities were from Nakla in the Sherpur district and from Chatkhil in the Noakhali district. Selected health care facilities were Dinajpur DH, Netrokona DH, Durgapur UHC, Chirirbandar UHC, Nakla UHC, and Chatkhil UHC (Figure 1). The NCDC program of the Directorate General of Health Services suggested carrying out the Wellbeing Center services in these enlisted 6 health care facilities.

Figure 1. Study sites. DH: district hospital; UHC: upazila health complex.



Study Design

An implementation research study was conducted, where the NCDC program designed, developed, and demonstrated an implementation model to introduce Wellbeing Centers for providing telemental health services. The study used both quantitative and qualitative data collection. Implementation facilitation support was provided, and assessments were conducted by icddr,b, an international health research organization based in Bangladesh.

Study Participants

Antenatal and postnatal women who visited to the outpatient settings (mainly antenatal care [ANC] and postnatal care [PNC] corner) and received counseling from Wellbeing Centers of the 6 selected health care facilities were enrolled in this study. A total of 911 women in antepartum and postpartum periods

XSL•FO
RenderX

received care from the Wellbeing Centers, and 168 health care facility managers and providers directly involved in the implementation were surveyed and reincluded in this analysis. The health care facility managers and providers included civil surgeons of the corresponding districts, hospital superintendents of the corresponding DHs, subdistrict health and family planning officers of the corresponding UHCs, resident medical officers (RMOs) of corresponding DHs and UHCs, physicians, and gynecological consultants from the outpatient departments.

Development of the Wellbeing Centers at the Health Care Facilities

Overview

The NCDC program of the Directorate General of Health Services, Ministry of Health and Family Welfare of Bangladesh received implementation support from the icddr,b along with other institutions, such as the National Institute of Mental Health (NIMH) and Department of Clinical Psychology, University of Dhaka, to establish the Wellbeing Centers.

Creating a Pool of Psychologists and Psychiatrists

A pool of trained psychologists and psychiatrists has been formed to deliver mental health care services. This pool of psychologists and psychiatrists was guided and mentored by professional bodies from clinical and counseling psychology and psychiatry.

Establishment of the Wellbeing Centers

Equipment and technology recourses included a computer, an internet connection, and a webcam in each Wellbeing Center at the facility. To establish an internet connection, an internet router was provided. In cases of electrifying fall, an uninterrupted power supply was used. Psychologists and psychiatrists and patients were provided with headphones to cancel or isolate ambient noise. With the help of a digital platform, appointments were scheduled. Patients were connected with the psychologists through videoconferencing. In the hospital, a room was allocated for the Wellbeing Center. This room was dedicatedly used for telemental health, maintaining appropriate privacy and confidentiality. The webcam and video monitor were placed at the client's eye level to best approximate a face-to-face interaction.

Training

Health care administrators, expertise in mental health, along with facility managers partnered with icddr,b to facilitate training and workshops for district and subdistrict-level health care providers (such as RMOs, physicians, gynecological consultants, and health workers). Additionally, the implementation support team organized the orientation of both government and program-supported health workers to promote the Wellbeing Center activities. Training content covered the use of depression and anxiety screening tools, patient reception, appointment scheduling, communicable liaison, the integration of mental health services in outpatient settings, effective web-based patient engagement, the use of technology in delivering mental health services, patient referral processes, follow-ups, and crisis management.

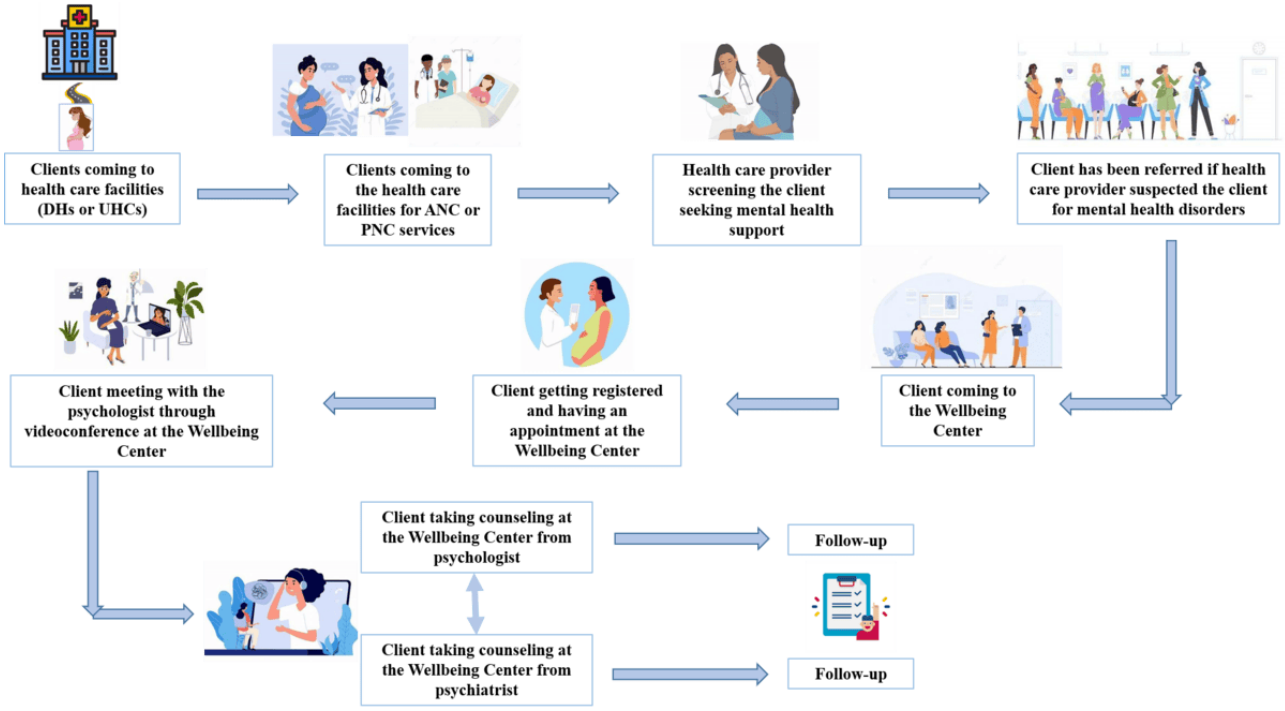
Service Provision

At first, women who came to seek health care service at ANC or PNC corners of the health care facilities were referred by the physicians or gynecological consultants to the Wellbeing Centers. Afterward, a health worker screened and redirected women of antepartum and postpartum to a Wellbeing Center and registered the client's through the digital platform using their name and phone number. The health worker noted the availability of psychologists, and an appointment was then fixed. By creating a digital meeting link, the patient's information and schedule were shared with the psychologists. Patients were supported by the health worker to prepare and make necessary arrangements for connecting to the psychologists through videoconference ensuring adequate privacy.

Psychologists assessed clients' mental health disorders using psychometric tools and then provided tailored counseling. Psychologists designed additional management plans and follow-ups based on the clients' improvement dimensions. When counseling proved insufficient to address moderate to severe instances, clients were referred to the NIMH's psychiatrists. Then, the health worker made an appointment and used videoconference-based counseling to connect with the psychiatrist for further treatment. Each client had a second screening by a health worker using the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder-7 (GAD-7) during follow-up sessions in order to measure the degree of change in their mental condition (Figure 2).

XSL•FO
RenderX

Figure 2. Mental health service delivery mechanism of Wellbeing Centers. ANC: antenatal care; DH: district hospital; PNC: postnatal care; UHC: upazila health complex.



Data Collection

Both quantitative and qualitative methods were undertaken to collect data. Quantitative data were collected using tablets, and qualitative interviews were done using audio recorders. We developed a data entry interface for this implementation research to manage data. A quantitative survey was conducted among women by trained health workers. A structured quantitative questionnaire was used to collect data on demographics [36,37], validate depression and anxiety symptom screening in outpatient settings [38-41], and assess implementation outcomes including acceptability, usefulness, and adoptability [42]. Assessment of feasibility among health facility managers was determined using the World Health Organization's (WHO) improving health system and services for mental health guideline [42]. Qualitative information was received by trained researcher using in-depth interviews (IDIs) and key informant interviews (KIIs). All data collection tools are presented in detail in Multimedia Appendices 1-4. About 10 qualitative IDIs were conducted on experiences, perceptions, and expectations regarding the videoconference-based mental health counseling among women who received ANC and PNC in the health care facilities at the Wellbeing Centers. Moreover, 15 KIIs were conducted among the health care facility managers, RMOs, physicians, psychologists, psychiatrists, and health workers. The number of antepartum and postpartum women who took follow-up sessions was 51.

Study Measures

Basic demographic information included age (years), types of care (ANC and PNC), religion, profession, education (years completed), household income (taka per month), and catchment area (subdistrict and district) were determined. The WHO's implementation research in health care guideline was followed in terms of defining acceptability, usefulness, feasibility, and adoption [42]. Table 1 provides detailed indicator information for all the implementation outcomes assessed in this study.

The PHQ-9 [43] and the GAD-7 scales [44] were used to evaluate depression and anxiety in outpatient settings, respectively [39,41]. The PHQ-9 is a 9-item questionnaire that assesses depression symptoms in a range of 0=not at all to 3=nearly every day. The PHQ-9 score ranges from 0 to 27, with mild, moderate, moderately severe, and severe depression symptoms equating to cutoff values of 5, 10, 15, and 20, respectively. The GAD-7 is a 7-item questionnaire that measures anxiety symptoms on a range of 0=not at all to 3=nearly every day. The GAD-7 scale has a score range of 0 to 21, with mild, moderate, and severe anxiety symptoms equating to cutoff values of 5, 10, and 15, respectively. Figure 3 presents the logical framework of the telemental health intervention in reducing the common mental health disorders among pregnant and postpartum women.

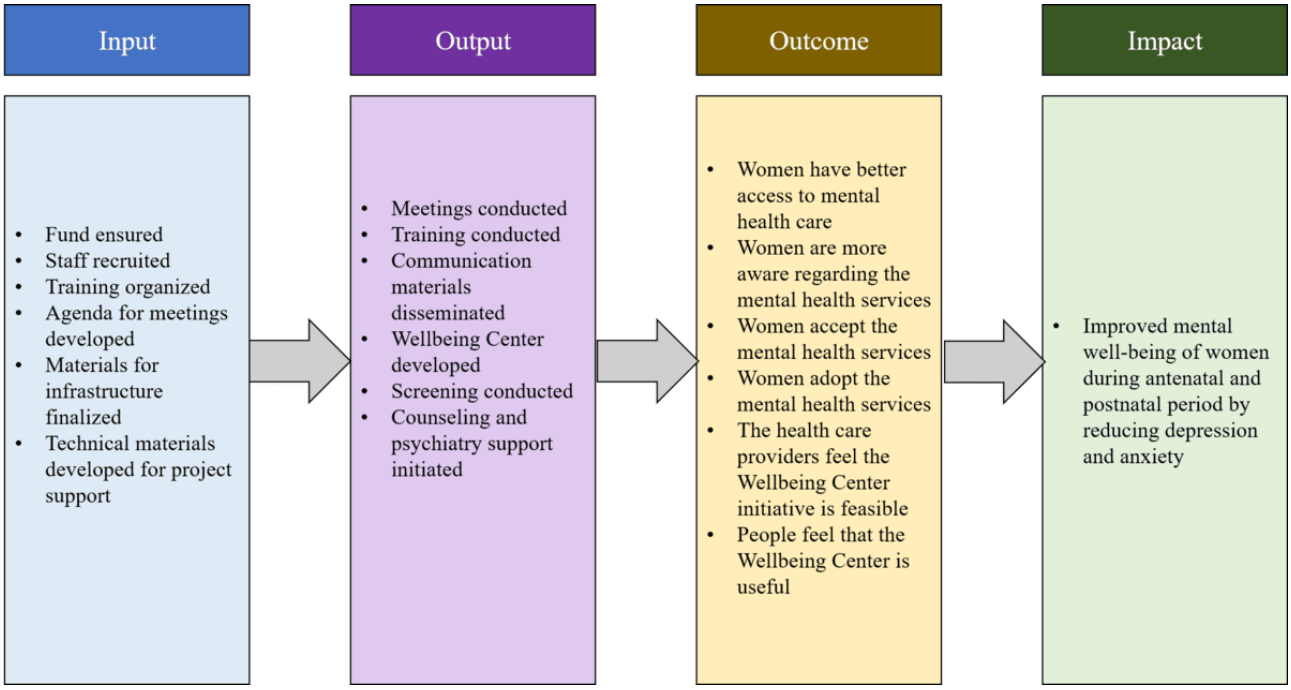
XSL•FO
RenderX

Table 1. Indicators according to the objectives for all the implementation outcomes assessed in the study.

Number	Objectives	Study method	Implementation outcome	Indicators or themes
1	To assess the feasibility of the Wellbeing Center at the district-level facility	Quantitative	Feasibility	• Percentage of facility managers who feel that Wellbeing Center is implementable in the facility • Percentage of facility managers who feel that they have sufficient trained staff in their facility to implement the Wellbeing Center
2	To assess the accessibility to mental health care among antenatal and postnatal women by introducing Wellbeing Center's telemental health care	Quantitative	Accessibility	• Percentage of users who agreed that Wellbeing Center has improved their access to mental health services
3	To assess the adoption of the Wellbeing Center at district-level facility for antepartum and postpartum women	Quantitative	Adoption	• Number of women receiving services from the Wellbeing Center
4	To assess the acceptability of the Wellbeing Center at district-level facility for antepartum and postpartum women	Quantitative	Acceptability	• Percentage of users who agreed that mental health services from the Wellbeing Center are acceptable to them
5	To assess the usefulness of the Wellbeing Center at district-level facility for antepartum and postpartum women	Quantitative	Usefulness	• Percentage of users who agreed that the Wellbeing Center is useful • Change in depression and anxiety symptoms scores from first follow-up to second follow-up
6	To assess the proportion of target women with symptoms of depression	Quantitative	Need	• Percentage of users who had depressive symptoms
7	To assess the proportion of target women with symptoms of anxiety	Quantitative	Need	• Percentage of users who had symptoms of anxiety
8	To assess the experience, perception, and expectation about the telemental health counseling at the district-level facility for the antepartum and postpartum women	Qualitative	Experience, perception, and expectation	• Experience, perception, and expectation about the Wellbeing Center

XSL•FO
RenderX

Figure 3. Logical framework of the telemental health intervention.



Data Analysis

Quantitative Analysis

Stata (version 15.0; StataCorp) was used for this analysis. We have presented descriptive statistics (frequency and percentage) with 95% CIs. For measuring the effect of various factors (age, types of care, religion, profession, education, household income, and catchment area) on the accessibility of the Wellbeing Centers and need-related indicators (depression, anxiety, and both depression and anxiety), 4 separate fitted models were constructed. Multiple logistic regression models were applied to compute the adjusted odds ratios (aORs) with 95% CI. In the adjusted models, accessibility was considered if a woman "strongly agreed" that the Wellbeing Center increased the accessibility of mental health services. Severe depression symptoms were coded as "1," and others (mild, moderate, and moderately severe depression) were coded as "0." For anxiety, severe anxiety symptoms were coded as "1," and mild and moderate anxiety symptoms were coded as "0." When a participant was found to have both severe anxiety and depression, we documented this as the co-occurrence of the 2 conditions using a binary response format (1 and 0). Wald statistics were used to assess the model adequacy. We presented the differences in depressive and anxiety symptoms of antepartum and postpartum women occurring nearly every day using radar plots. At the 5% level of significance, the statistical significance of the estimates has been reported.

Qualitative Analysis

All audio-recorded interviews, supplemented with field notes, were transcribed verbatim. The transcriptions were then read through several times by all the researchers to get more familiar with the data. The transcriptions were manually thematically analyzed using an inductive approach [45,46]. The three stages of the analysis included (1) reading the interview transcripts; (2) highlighting the related words, coding them in relation to the text, and thereafter classifying them; and finally, (3) identifying the themes with reflective notes. The data were coded and categorized according to the emerging themes. Data were analyzed by NVivo (QSR International) qualitative data analysis software. To respect the anonymity of each participant, no personal identifying information was presented in the result.

Ethical Considerations

The icddr,b Institutional Review Board granted the study ethics approval (protocol PR-22103). All the eligible women have given written informed consent prior to the enrollment. All data were anonymized or deidentified. No monetary compensation was provided to participants for this research. Consent has been granted from identifiable individual features of research participants or users in any images of the manuscript or supplementary material.

Results

Quantitative Findings

The selection process of the patients from the facilities with Wellbeing Center for antepartum and postpartum women is shown in Multimedia Appendix 5. Between January 2023 and August 2024, 16,203 patients visited the outpatient department, from whom 5863 general patients received services from Wellbeing Centers. Among them, 4450 women visiting the ANC and PNC corners received services from 6 Wellbeing Centers. We have considered only the 911 antepartum and postpartum women who received mental health services at the Wellbeing Center.

Table 2 presents the background characteristics of the antepartum and postpartum women who received services from Wellbeing Centers. The majority of the women were young adults aged 20-24 years. Most of the women (n=817, 89.7%) who received mental health services at the Wellbeing Centers and NIMH were referred during ANC visits. Only 2.2% (n=20)

XSL•FO
RenderX

of the women were involved in any income-generating activities. In total, 54.6% (n=497) of the women completed secondary-level education, and 46.9% (n=427) were from the low-income group. A total of 70.6% (n=643) of the counseling receiving women visited the subdistrict-level facility.

Figure 4 presents the WHO-guided implementation outcomes, feasibility, accessibility, acceptability, usefulness, and need of the Wellbeing Center. Among 168 providers, almost everyone (165/168, 98.2%) reported that the Wellbeing Center is implementable at the facilities. Half of the providers (84/168, 50%) agreed that the facilities have trained staff to maintain the Wellbeing Center. Among the users, almost all antepartum and postpartum women agreed that the Wellbeing Center is increasing accessibility, and it is acceptable and useful for them, as antepartum and postpartum women experience depression and anxiety throughout the period. Around three-fourths of the users had moderate to severe anxiety or depressive symptoms, which demonstrated the need for mental health care.

Figure 5 presents the percentage of women who experienced depressive and anxiety symptoms nearly every day in the past 2 weeks, as indicated by the PHQ-9 and GAD-7 scales. Half of the women (472/911, 51.8%) experienced a lack of energy nearly every day, and 36.6% (333/911) experienced a lack of interest and pleasure. Around one-third of women faced issues with trouble falling asleep or sleeping too much and poor appetite or overeating almost every day. In total, 3.8% (35/911) had suicidal ideation almost every day. Among the anxiety symptoms, 57.2% (521/911) worried too much about different issues, and 50.9% (464/911) experienced nervousness almost every day in the past 2 weeks.

The health care providers reported the need for telemental health in their respective facility:

> *Due to the shortage of well-trained psychiatrists nearby, we have to take treatment from the divisional level health facilities, which is time-consuming and costly. Ensuring proper mental health service district and upazila-level hospital requires service like tele-mental.* [KII-15, health worker, Nokla UHC, age 42 years]

Table 3 summarizes the effect of various factors on accessibility and need-related indicators. The odds of increased perceived accessibility were lower among patients receiving PNC compared to ANC with aOR 0.45 (95% CI 0.27-0.74). Women with lower education and lower income had higher perceived accessibility. Patients visiting DHs had higher odds of perceived accessibility (aOR 1.48, 95% CI 1.1-2.0). Patients visiting DHs had 3 times higher odds (aOR 2.58, 95% CI 1.82-3.68) of experiencing both depression and anxiety symptoms, expressing the need for mental health services through the Wellbeing Center.

Figure 6 presents the change in average scores of PHQ-9 and GAD-7 between the first and second counseling sessions of the antepartum and postpartum women. The average PHQ-9 score decreased from 14.4 (SD 0.47) to 12.9 (SD 0.47), and the average GAD-7 score decreased from 13.3 (SD 0.49) to 12.5 (SD 0.48) between these 2 sessions, indicating the usefulness of Wellbeing Center. These changes were statistically significant with $P<.001$.

The proportion of people taking follow-up counseling is shown in Multimedia Appendix 6. Only 15.1% (51/338 suggestions of follow-up visits) took follow-up counseling among the patients who were suggested a follow-up session.

XSL•FO
RenderX

Table 2. Background characteristics of the antepartum and postpartum women who received services from Wellbeing Centers (N=911).

Background characteristics	Participants, n (%)
Age (years)	
15-19	229 (25.1)
20-24	332 (36.4)
25-29	218 (23.9)
≥30	132 (14.5)
Type of contact care points at the facility	
ANC[a]	817 (89.7)
PNC[b]	94 (10.3)
Religion	
Muslim	848 (93.1)
Other[c]	63 (6.9)
Profession	
Housewife	856 (94)
Involved in income-generation activities	20 (2.2)
Other[d]	35 (3.8)
Education (years completed)	
No education	12 (1.3)
Primary	159 (17.5)
Secondary	497 (54.6)
Above secondary	243 (26.7)
Household income	
Low	427 (46.9)
Middle	217 (23.8)
High	267 (29.3)
Type of facility location	
Subdistrict	643 (70.6)
District	268 (29.4)

[a]ANC: antenatal care.

[b]PNC: postnatal care.

[c]Hindus, Buddhists, and Christians.

[d]Unemployed and unable to work due to disability.

XSL•FO
RenderX

Figure 4. Implementation outcomes of Wellbeing Centers according to the World Health Organization guidelines.

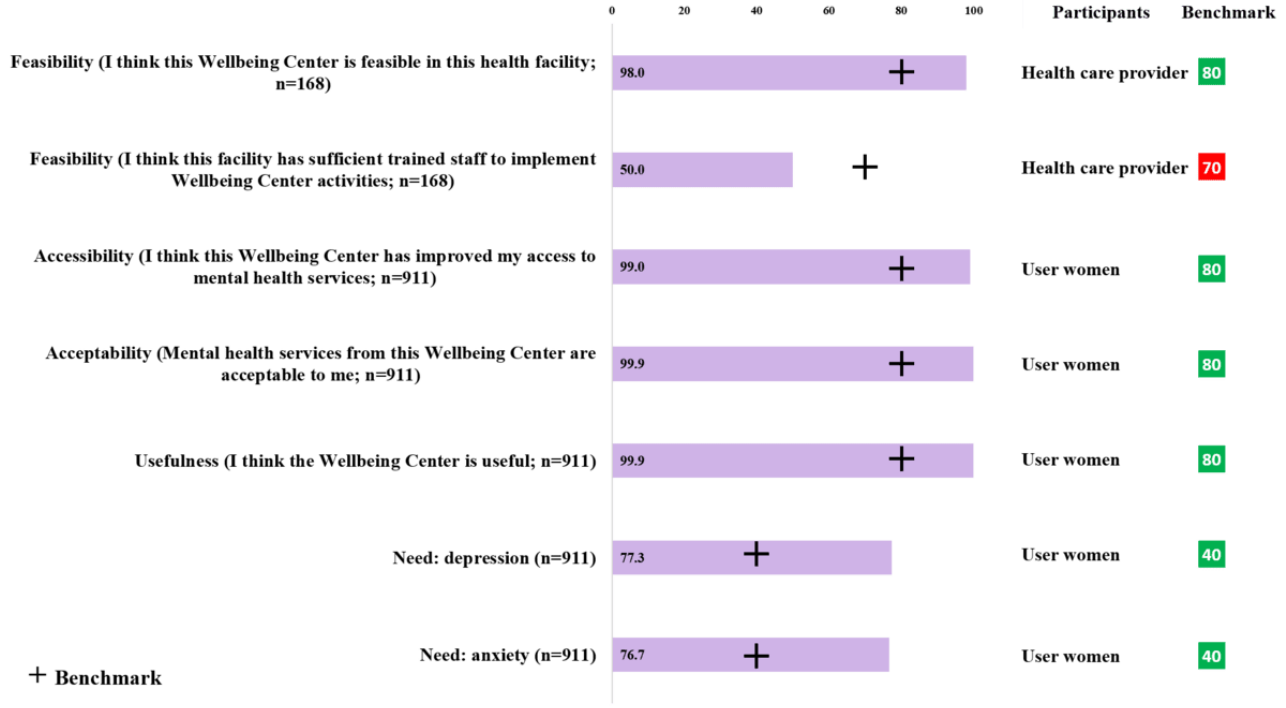
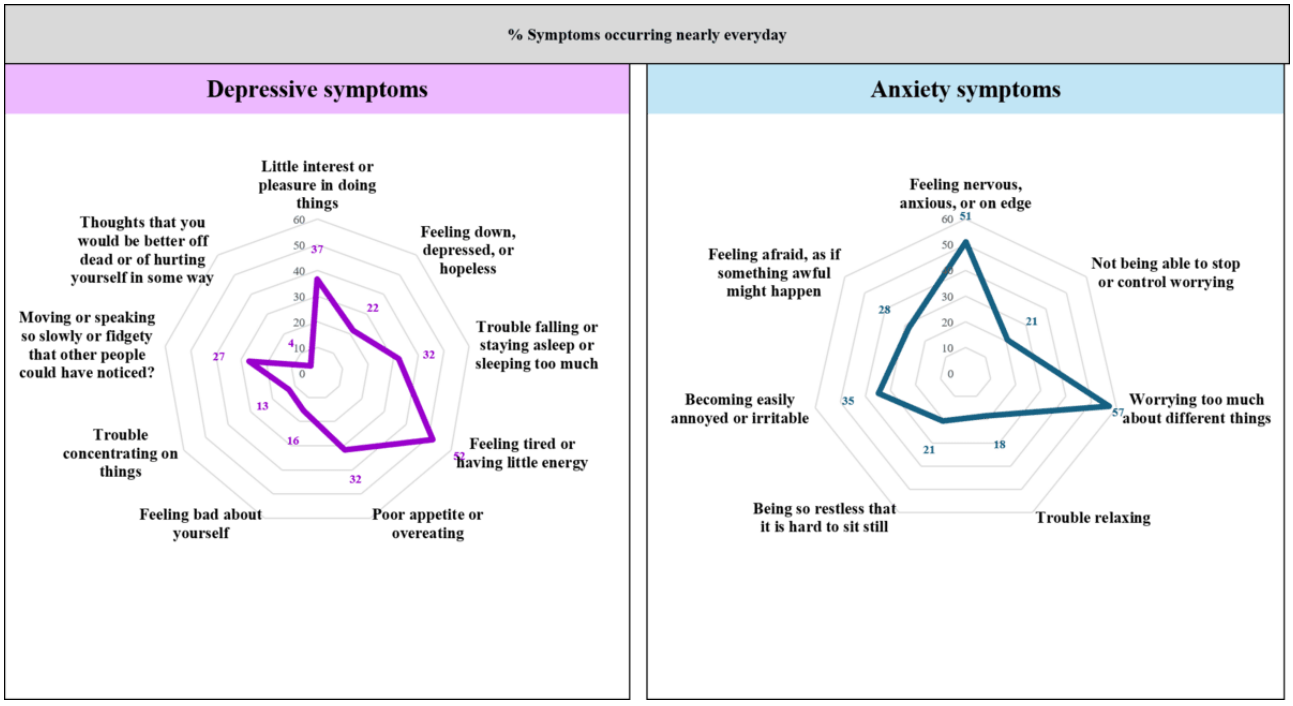


Figure 5. Need for Wellbeing Centers according to the frequency of depressive and anxiety symptoms.



XSL•FO
RenderX

Table 3. Factors associated with accessibility (strongly agree) and need (severe depression and anxiety symptoms) of Wellbeing Center.

	Accessibility		Both depression and anxiety	
	aOR[a] (95% CI)	*P* value	aOR (95% CI)	*P* value
Age (years)				
15-19	Reference	Reference	Reference	Reference
20-24	1.09 (0.76-1.57)	.63	1.42 (0.90-2.23)	.13
25-29	0.78 (0.52-1.17)	.22	1.01 (0.60-1.71)	.97
≥30	1.14 (0.72-1.81)	.57	0.87 (0.47-1.60)	.65
Type of contact care point at the facility				
ANC[b]	Reference	Reference	Reference	Reference
PNC[c]	0.45 (0.27-0.74)	.002	0.88 (0.48-1.62)	.68
Religion				
Muslim	Reference	Reference	Reference	Reference
Other[d]	0.56 (0.31-1.01)	.05	0.38 (0.15-0.99)	.047
Profession				
Housewife	Reference	Reference	Reference	Reference
Involved in incom- generation activities or other	1.04 (0.57-1.92)	.89	1.06 (0.48-2.32)	.89
Education				
No education or primary	Reference	Reference	Reference	Reference
Secondary	0.40 (0.27-0.58)	.001	1.02 (0.64-1.64)	.93
Above secondary	0.44 (0.28-0.69)	.001	0.89 (0.51-1.55)	.67
Household income				
Low	Reference	Reference	Reference	Reference
Middle	0.70 (0.49-0.99)	.047	0.97 (0.62-1.51)	.90
High	1.12 (0.81-1.56)	.50	1.07 (0.70-1.62)	.76
Type of facility location				
Subdistrict	Reference	Reference	Reference	Reference
District	1.48 (1.10-2.00)	.010	2.58 (1.82-3.68)	.001

[a]aOR: adjusted odds ratio.

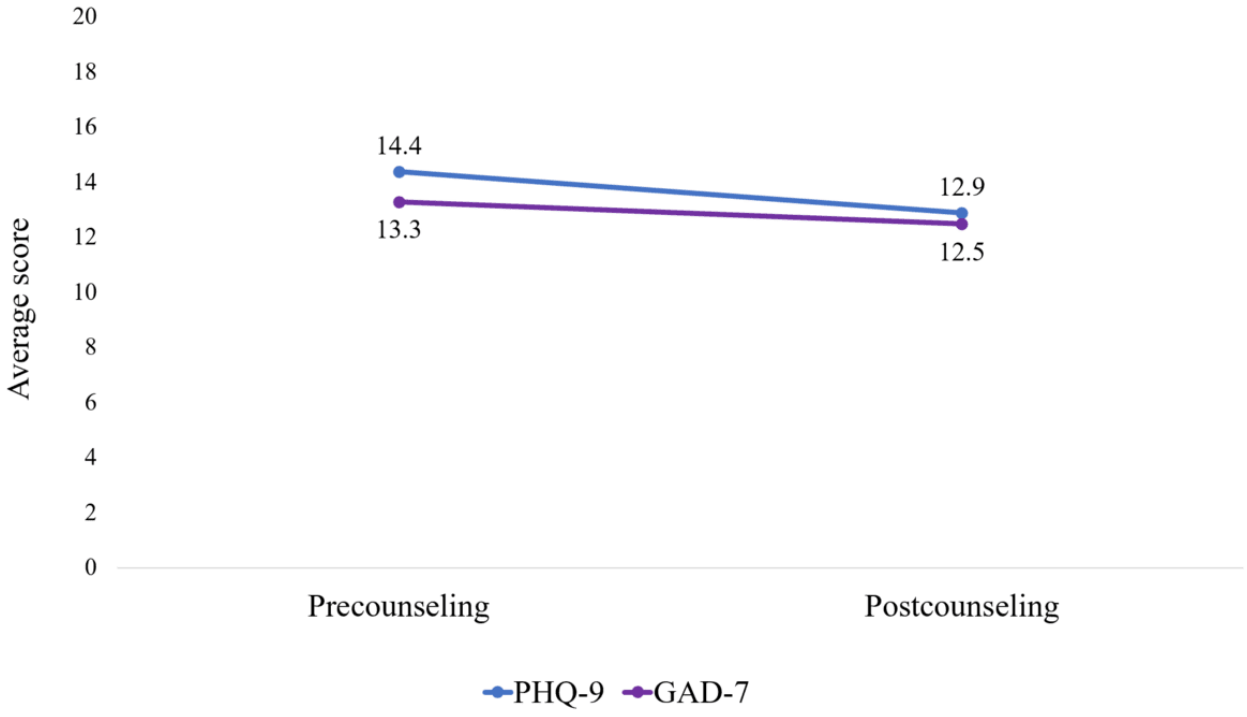
[b]ANC: antenatal care.

[c]PNC: postnatal care.

[d]Hindus, Buddhists, and Christians.

XSL•FO
RenderX

Figure 6. The usefulness of the counseling in reducing the average PHQ-9 and GAD-7 scores (n=51). GAD-7: Generalized Anxiety Disorder-7; PHQ-9: Patient Health Questionnaire-9.



Qualitative Findings

Perception and Experience Regarding Wellbeing Center Services During the Antepartum and Postpartum Periods

Positive Attitude of the Service Providers

The positive attitude of psychologists and health workers of the Wellbeing Centers strengthened the telemental health services compared to other health services. The health workers of the center cordially received the antepartum and postpartum women who were referred by the physicians. During the counseling session, psychologists listened to their problems and issues attentively and provided video counseling, which gives them better feelings about the service at the Wellbeing Center. A pregnant mother mentioned the following:

> *I feel scared to share my all problems with a physician! I just responded to what the doctor wanted to know. But in the audio-visual call, a counsellor gives a welcoming tone which influenced me to share my mental health issues clearly.* [IDI, female, age 32 years]

Cost and Accessibility

Earlier, antepartum and postpartum women who experienced mental health disorders had to get treatment from the regional medical college hospitals or have to go to specialized hospitals. Because of the Wellbeing Center, people can get mental support on their doorstep. From the Wellbeing Center, anyone can get free-of-cost and hassle-free treatment. Those who seek mental health treatment from private hospitals have to spend considerably more money on paying psychiatrist fees, unethical financial gain of clerks, medication, transportation costs, etc. Nevertheless, patients found videoconference-based counseling at the Wellbeing Centers more convenient than the traditional treatment system, as they do not require any treatment costs, and it provides easy treatment access at their doorsteps. A service receiver mentioned the following:

> *If I come here [Wellbeing Center] it will save my money and I get treatment from a good specialist that won't cost me money.* [IDI, female, age 22 years]

Privacy and Confidentiality

While the antepartum and postpartum women received counseling, nobody was present in the room to ensure privacy and confidentiality. Service receivers' privacy is a prime concern at the Wellbeing Centers, as patients receive services in a separate room that ensures privacy during the counseling. A service receiver said the following:

> *During in-person consultations, I did not freely communicate to the doctor [psychiatrist-private chamber] because of the other patient's presence in the waiting area. But in the Wellbeing Center, I do not have worries about violation of [my] privacy while getting audio-visual counseling in a separate room.* [IDI, female, age 24 years]

Name

The name of the mental health service center is Wellbeing Center to overcome the stigma and social taboo associated with psychological support needs. Whenever antepartum and postpartum women and their caregivers come to the corner, they do not hesitate to seek care. This may be due to the perception of a safe and supportive space that encourages open discussion of mental health issues without fear of judgment. The term "well-being" did not demonstrate any stigma. A health worker mentioned the following:

XSL•FO
RenderX

We do not use the term mental health corner, instead we use "Mon-Shastho Kendro" [Wellbeing Center] to avoid the stigma. When doctors refer them to the Wellbeing Centerthey do not feel hesitation. [KII, health workers, age 33 years]

Barriers to Using the Wellbeing Center Services

Stigmas and Taboos

During the pregnancy period, mothers experience numerous negative emotions. Though they can understand that their mental condition is changing, they cannot share their problems due to stigmas and taboos. Even more, they do not disclose their mental health problems to their husbands and family members. Fear of family violence and potential disruption of marriage often prevent pregnant women from disclosing their mental health issues. A pregnant mother mentioned the following:

> *I do not share my problems with my family members, if I share my mental problems with them then they may make any comments on this that will be very frustrating to me.* [IDI, pregnant mother, age 29 years]

Postpartum Illness

During the postnatal period, mothers are unable to receive mental health treatment from the Wellbeing Center for their physical illness and lack of support from the family. Moreover, after childbirth, the physician referred the mothers to the Wellbeing Center based on the mental health examination. However, sudden release from the hospital is a reason for not receiving the services. A health worker mentioned the following:

> *Within the 42 days [postnatal period], mothers were physically sick to come. Those who are referred by the physician, sometimes get a sudden release from the hospital. Therefore, they do not come for mental health services.* [KII, health assistant, age 33 years]

Long Waiting Times

During the follow-up visit, antepartum and postpartum women have to wait in the ANC and PNC corner for taking services. Some patients were in a rush to receive the service, but it was not possible to give them an opportunity, as other patients were also on the waiting list. This may be due to the patient load and the ANC and PNC corners operating on a first-come, first-served basis. A pregnant mother mentioned the following:

> *I feel unsteady while waiting for [receiving] the mental health service. There are only three seats in the waiting room, and three mothers already waiting there to receive the service. Therefore, I and my husband have to stand up for around thirty to forty minutes which causes the irritation.* [IDI, pregnant mother, age 18 years]

Discussion

Principal Findings

Our research demonstrated that telemental health services through the Wellbeing Center are feasible, acceptable, useful, and highly needed among women. It has increased accessibility to mental health services to pregnant or postpartum women with a lower level of income and education. The health care providers felt a need for more staff with appropriate training to implement this intervention at the hospitals, who are lacking in Bangladesh. The women visiting the DHs have a higher level of depression and anxiety symptoms, demonstrating a critical need for mental health services. Our follow-up assessment scores on depression and anxiety symptoms after the first counseling sessions demonstrated a decrease in the average scores, which indicted the effectiveness of the Wellbeing Centers. The service beneficiaries recommended the intervention because of the positive attitude of the service providers; the services being free of cost, private, and confidential; and its sensitive naming. However, they also mentioned some barriers to receiving care from Wellbeing Centers, which included social stigma, postpartum illness, and long waiting times at the facility to use the service.

To the best of our knowledge, this is the first implementation research that assessed the WHO implementation outcome variables of a facility-based telemental health intervention, the Wellbeing Centers, for antepartum and postpartum women that is operated by the GoB. We have pioneered in proposing an implementation model for mental health care including a pool of trained psychologists and psychiatrists who provided counseling and medications for mental health issues through videoconferencing in the Wellbeing Centers at the public health facilities in Bangladesh.

Some public hospitals in Bangladesh had initiated telemedicine units as a part of their routine care system. However, telemental health services through Wellbeing Centers differ from general telemedicine in several ways. Telemental health often involves specialized platforms designed to provide psychological assessments, therapy, and psychiatric consultations. In contrast, telemedicine includes a broader range of remote clinical services, including primary care, specialist consultations, and follow-up visits. Telemental health is a specialized subset of telemedicine focusing on mental health. While both telemental health and telemedicine use videoconferencing, phone calls, and other digital communication tools, telemental health platforms are tailored to address the unique needs of mental health care, such as ensuring patient privacy and providing a comfortable environment for discussing sensitive issues. This specialization can lead to better patient engagement and satisfaction in mental health care compared to general telemedicine [47]. This type of service is expected to vary according to the differences in context and health systems. Our research focused on the implementation outcomes of telemental health care. This provides evidence to support the scale-up of telemental health care through Wellbeing Centers.

Adoption and Acceptability

A significant proportion of Bangladeshi mothers have common mental health issues during the antenatal and postnatal period [4,48]. Most mental health care facilities are clustered around urban areas, while rural women do not have access to mental health care in Bangladesh. Since maternal mental distress among these rural mothers may cause adverse maternal and child health outcomes, appropriate interventions can address maternal mental distress among the Bangladeshi maternal population. Evidence supports the effectiveness of digital psychological interventions,

XSL•FO
RenderX

especially in low- and middle-income countries where mental disorders contribute significantly to the global burden of disease [49,50]. Globally, these services offer private, personalized support, connecting disparities in mental health care for those facing challenges accessing traditional services or face-to-face services [49]. Global evidence emphasizes the role of telemental health service as an equivalent and effective method, particularly in delivering mental health services to remote areas with limited resources. A significant number of users in our study provided strong evidence on the adoptability and acceptability of the telemental health services through Wellbeing Centers in Bangladesh. Services through Wellbeing Centers minimized travel, offering cost-effective and accessible psychological and psychiatric services.

Feasibility

The health care providers perceived that the telemental support through the Wellbeing Center is highly feasible. However, they also felt that the facilities lacked appropriately trained staff to maintain these centers. Banbury et al [51] stated that staff require comprehensive training to sustain and expand telehealth use in the facilities. These trainings should focus on knowledge, skills, and competencies in using telehealth as well as the broad factors of policies and understanding technologies to support the service providers [51]. Studies have discussed concerns around a lack of appropriate training to be able to conduct remote mental health care effectively and safely [52]. The government should ensure adequate training and supportive supervision for health providers (such as RMOs, physicians, gynecological consultants, and health workers) on mental health disorder assessments of pregnant and postpartum mothers, psychosocial services, as well as information and communication technology to maintain Wellbeing Center activities.

Accessibility

In the context of Bangladesh, mental health services face challenges due to limited resources and a shortage of professionals, relying heavily on the NIMH in Dhaka [53,54]. The new mental health policy of Bangladesh prioritizes community-based services, with nongovernment organizations contributing scalable models, including telemental health initiatives [55,56]. Access challenges still persist despite some voluntary counseling platforms, due to their lack of visibility [57,58]. These programs are not also integrated into the government system. Despite progress and current provisions for service delivery, issues like low help-seeking, inadequate service delivery, and persistent stigma emphasize the need for telemental health services on a larger scale [59]. Integrating telemental health services with these services is essential for improved mental health care [58]. Wellbeing Centers increased perceived accessibility among antepartum and postpartum women. Perceived accessibility was significantly higher among lower socioeconomic groups and lower educated groups. One of the reasons for this could be the free-of-cost facilities at public hospitals that are near their location.

Need

We looked into the need for well-being by looking at the depressive and anxiety symptoms prevalent among our targeted patients. Two-thirds of the women who sought services from the Wellbeing Center had moderate to severe indications of depression and anxiety. In addition, we observed a high level of anhedonia or lack of interest and tiredness among the women in the last 2 weeks. These highly prevalent symptoms indicated the need for Wellbeing Centers for the targeted mothers. El Sayed et al [60] reported that fatigue and anhedonia were prevalent and commonly reported in the post–COVID-19 period. A study by Costa et al [61] also reported that the prevalence of perinatal depression increased during the COVID-19 pandemic, which may be due to changes in the profile of specific depressive symptoms. Pearson et al [62] conducted a study where they reported that women experiencing anhedonic depressive symptoms during pregnancy had significantly larger systolic blood pressure responses toward infant distress than nondepressed pregnant women. Special attention should be given to anhedonia and fatigue-related symptoms of perinatal depression to ensure that they are adequately managed.

Among the other depressive symptoms, our finding that 3.8% (n=35) of patients experienced suicidal ideation is a significant concern, reinforcing the need for enhanced mental health interventions in Bangladesh. Scientific studies discussed the complexity of suicidal ideation, noting that it often goes unreported due to stigma and fear of judgment [63]. Suicidal ideation is influenced by a complex interplay of biological, psychological, and social factors. While some biomarkers have been identified to predict the risk of suicide, the underlying causes of suicide remain largely unclear. More research is needed to understand the root causes of suicidal ideation. Digital tools, such as mobile apps and telehealth services, can effectively monitor and reduce suicidal thoughts by providing real-time support [64]. Additionally, telehealth-supported decision-making has been found to significantly reduce suicidal ideation [65].

Our study also found that the level of worry and nervousness in the past 2 weeks was significantly higher among pregnant and postpartum women. More than half of the women experienced these symptoms of anxiety in the past 2 weeks almost every day. Tarafa et al [66] conducted a study in Ethiopia and assessed the factors associated with pregnancy-related anxiety among pregnant women attending ANC follow-up. Unwanted pregnancy, high perceived stress, young age, depression, low income, and poor social support were significantly associated with pregnancy-related anxiety. The overall prevalence of pregnancy-related anxiety in this study was slightly lower 32.7% [66]. It is worth noting that this study assessed only pregnancy-related anxiety while we included both pregnant and postpartum mothers. Appropriate intervention and focus are needed to address these worries and anxieties of pregnant women and postpartum mothers in Bangladesh through Wellbeing Center activities.

We report higher depression and anxiety and perceived accessibility among the women who took Wellbeing Center services at the district-level facilities compared to the subdistrict-level facilities. The reason can be regarded as an indirect effect of urbanization. A recent meta-analysis conducted by Cadman et al [67] assessed the influence of the urban environment in pregnancy and postpartum depression. Exposure

XSL•FO
RenderX

to air pollution and road traffic congestion may increase maternal depression. The urban family structure, with a lack of family support, may also induce higher levels of depressive and anxiety symptoms in Bangladesh. A study conducted on adolescents researched screen-related sedentary behavior, finding that the use of social media caused 2 times higher depression among urban adolescents [68]. A large proportion of our users of Wellbeing Centers were adolescents. Therefore, urgent initiatives should be taken to control the spread of depression and anxiety among the urban population, especially for mothers. In summary, at the district-level facilities, the need for mental health services was higher among the antepartum and postpartum women, which necessitated a strengthened focus on providing equitable services through the Wellbeing Centers in Bangladesh.

Usefulness

While we found the Wellbeing Centers to be feasible and acceptable, our study also indicated small improvements during the follow-up counseling sessions for the targeted patients. A review by Hilty et al [34] reported that telemental health is effective for diagnosis and assessment across many populations, including adults, children, older people, and people of different ethnicities, and for disorders in home and facility settings. This review urged that more research should be conducted on service models, specific disorders, issues regarding culture and language, and cost. Ensuring follow-up visits after the first counseling session is important for the sustained impact of telemental health services. However, we have not observed many women taking follow-up services in our Wellbeing Centers. Special initiatives such as follow-up phone calls or reminders should be ensured to increase follow-up sessions when needed and recommended.

Experience, Perception, and Expectation

Our research explored the experiences and perceptions regarding the Wellbeing Center activities, which revealed several strengths of and barriers to using these services. The users acknowledged the positive attitude and patience of the counselors during the service sessions. In Bangladesh, in-person psychiatric services are expensive and may not be affordable for underprivileged women. The Wellbeing Center services were completely free of cost, which attracted the targeted patients. Furthermore, these Wellbeing Centers ensured the privacy and confidentiality of the patients while providing psychological or psychiatric support. Many women were comfortable while expressing their problems and mental health issues, as they were reassured by this confidentiality. Finally, the women praised the naming of the service, which also addressed the stigma around mental health. The women also mentioned that existing stigmas and taboos on seeking mental health services prevented them from seeking care. However, almost all users of the Wellbeing Centers agreed that these services were acceptable to them. Further research is necessary to understand the actual state of stigma in the community regarding mental health care seeking.

Our quantitative data suggested that more women during pregnancy used Wellbeing Center services compared to postpartum women. Our qualitative finding echoed this finding as women reported postpartum illnesses were a barrier for them to seeking mental health care. Finally, few women mentioned that the long waiting time repelled them to receive services from the Wellbeing Centers. With the high demand and popularity, the system experienced a high patient load and struggled to satisfy all patients with timely services.

Comparison With Prior Studies

Recent studies on telemental health interventions have shown promising results, particularly in the context of the COVID-19 pandemic, which accelerated the adoption of remote mental health care. Research indicates that telemental health, including videoconferencing and phone-based therapy, is generally as effective as in-person care for a variety of mental health conditions [47]. Our research found similar results in terms of feasibility, utility, and effectiveness. A recent systematic review on implementation strategies for telemental health published in 2023 by Appleton et al [52] highlighted that telemental health can improve access to care, especially for individuals in remote or resource-limited areas. Our study echoed them in terms of the role of telemental health support in increasing the accessibility of mental health care in Bangladesh. While most studies on telemental health mentioned positive outcomes, one of the meta-analyses on mobile phone–based telemental health interventions by Goldberg et al [69] suggested that the effectiveness of these interventions can vary based on the specific mental health condition and the technology used. Our study could not compare the efficacy of the Wellbeing Centers compared to other phone-based or community-based methods. We recommend further research and trials to understand the actual benefits of using Wellbeing Centers compared to other types of services.

Strengths

Our study has several strengths, based on which we have identified the major findings discussed earlier. This study was conducted in 6 facilities, which provided us a reasonably large sample of pregnant and postpartum women attending antenatal and postpartum care. It involved a rigorous analysis using WHO-guided implementation variable, which ensured standardization with other global implementation research on telemental health services. Our intervention was provided through the government system; therefore, these findings will be valuable for the GoB for scaling up the intervention to a higher number of facilities. This paper focused on the pregnant and postpartum women. However, the services are also provided to general patients. Therefore, findings might provide additional evidence while assessing the implementation outcomes for general patients.

Limitations

We also acknowledge some limitations of our study. First, this study was conceptualized based on the WHO framework and implementation outcome variables. The WHO's implementation outcome variables may have limited the opportunities of capturing other potential outcome variables that may be important for assessing implementation aspects of the Wellbeing Centers. Second, we acknowledge the fact that we did not randomly select our demonstration sites for Wellbeing Centers. Therefore, the result may not be generalizable to the whole

XSL•FO
RenderX

country. In Bangladesh, there are regional variations that have an impact on access to health care as well as service quality. Our selected sites reasonably capture the variations of the service provision and quality. Third, we also acknowledge that we have selected the DHs based on their functionality. The inclusion of low-performing districts could make our results more generalizable. However, this was not possible because of implementation cost challenges. Fourth, in this analysis, we could not assess the rate of adoption of the Wellbeing Center services, as we could not capture the true denominator of how many women needed mental health support among those seeking ANC or PNC from the facilities. Finally, this analysis only assessed symptoms of depression and anxiety as mental health issue. Other disorders could also have been included to strengthen this study.

Conclusions

This implementation research study demonstrated the feasibility, acceptability, and usefulness of introducing the telemental health service Wellbeing Centers for antepartum and postpartum women at Bangladeshi facilities. We are confident in our conclusions, as we saw the services increased the perceived accessibility of mental health services with minimal influence from other factors. Appropriate staff training is required to maintain these centers. We recommend that psychologists and psychiatrists have patience and a positive attitude while maintaining the privacy of patients during the scale-up of the model. We also recommend future studies on cost-effectiveness and postimplementation follow-up to evaluate the sustainability, effectiveness, and impact over a longer time period. The experiences and learnings from this implementation research can support generating evidence-based decisions related to the introduction and scaling-up of the Wellbeing Centers in Bangladesh and other low- and middle-income countries.

Acknowledgments

This research protocol or activity or study was funded by the Department of Foreign Affairs, Trade and Development through Advancing Sexual and Reproduction Health and Rights (grant SGDE-EDRMS-#9926532, purchase order 7428855, project P007358). The International Centre for Diarrhoeal Disease Research, Bangladesh is also grateful to the governments of Bangladesh and Canada for providing core or unrestricted support.

Authors' Contributions

ATH developed the manuscript as the first author with support from AER. AER and MSS guided ATH in designing the study and developing the manuscript as joint senior authors. SEA and MRA reviewed the results and guided the team in interpreting the results. MHR, RMM, and EA contributed to data management and statistical analyses. MAH conducted the qualitative interviews, and TA, NGU, and PC supported in qualitative data management. SMHI supervised the implementation and field activities. HUA, MKM, JMJ, FS, SAS, FA, and MJB provided guidance in validating the psychological and psychiatric information of the study. MAK and SMMR provided support in developing the intervention strategy. SA, SJ, and AA reviewed the first draft of the paper. All authors contributed to the interpretation of the results and read and approved the final version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Quantitative data collection tools to assess depression, anxiety, adoption, accessibility, acceptability, and usefulness for antenatal and postnatal women.
[DOCX File , 38 KB - pediatrics_v8i1e65912_app1.docx]

Multimedia Appendix 2
Data collection tool for feasibility assessment among the health facility managers.
[DOCX File , 24 KB - pediatrics_v8i1e65912_app2.docx]

Multimedia Appendix 3
Interview guideline for in-depth interviews with antenatal and postnatal women to explore their experiences, perceptions, and expectations regarding the telemental health counseling.
[DOCX File , 21 KB - pediatrics_v8i1e65912_app3.docx]

Multimedia Appendix 4
Interview guideline for key informant interviews with the counselors and health care providers to explore their experiences, perceptions, and expectations regarding the telemental health counseling.
[DOCX File , 22 KB - pediatrics_v8i1e65912_app4.docx]

XSL•FO
RenderX

Multimedia Appendix 5
Flowchart of the selected antepartum and postpartum women.
[DOCX File , 50 KB - pediatrics_v8i1e65912_app5.docx]

Multimedia Appendix 6
Proportion of users who received follow-up counseling.
[DOCX File , 56 KB - pediatrics_v8i1e65912_app6.docx]

References

1. Jones I, Chandra PS, Dazzan P, Howard LM. Bipolar disorder, affective psychosis, and schizophrenia in pregnancy and the post-partum period. Lancet 2014;384(9956):1789-1799. [doi: 10.1016/S0140-6736(14)61278-2] [Medline: 25455249]
2. Maternal mental health. World Health Organization. URL: https://www.who.int/teams/mental-health-and-substance-use/promotion-prevention/maternal-mental-health [accessed 2024-01-31]
3. Nguyen PH, Saha KK, Ali D, Menon P, Manohar S, Mai LT, et al. Maternal mental health is associated with child undernutrition and illness in Bangladesh, Vietnam and Ethiopia. Public Health Nutr 2014;17(6):1318-1327 [FREE Full text] [doi: 10.1017/S1368980013001043] [Medline: 23642497]
4. Nasreen HE, Kabir ZN, Forsell Y, Edhborg M. Prevalence and associated factors of depressive and anxiety symptoms during pregnancy: a population based study in rural Bangladesh. BMC Womens Health 2011;11:22 [FREE Full text] [doi: 10.1186/1472-6874-11-22] [Medline: 21635722]
5. Edhborg M, Nasreen H, Kabir ZN. Impact of postpartum depressive and anxiety symptoms on mothers' emotional tie to their infants 2-3 months postpartum: a population-based study from rural Bangladesh. Arch Womens Ment Health 2011;14(4):307-316. [doi: 10.1007/s00737-011-0221-7] [Medline: 21626173]
6. Hossain SJ, Roy BR, Hossain AT, Mehrin F, Tipu SMMU, Tofail F, et al. Prevalence of maternal postpartum depression, health-seeking behavior and out of pocket payment for physical illness and cost coping mechanism of the poor families in Bangladesh: a rural community-based study. Int J Environ Res Public Health 2020;17(13):4727 [FREE Full text] [doi: 10.3390/ijerph17134727] [Medline: 32630173]
7. Saccone G, Florio A, Aiello F, Venturella R, De Angelis MC, Locci M, et al. Psychological impact of coronavirus disease 2019 in pregnant women. Am J Obstet Gynecol 2020;223(2):293-295 [FREE Full text] [doi: 10.1016/j.ajog.2020.05.003] [Medline: 32387321]
8. Hamadani JD, Hasan MI, Baldi AJ, Hossain SJ, Shiraji S, Bhuiyan MSA, et al. Immediate impact of stay-at-home orders to control COVID-19 transmission on socioeconomic conditions, food insecurity, mental health, and intimate partner violence in Bangladeshi women and their families: an interrupted time series. Lancet Glob Health 2020;8(11):e1380-e1389 [FREE Full text] [doi: 10.1016/S2214-109X(20)30366-1] [Medline: 32857955]
9. Fekadu Dadi A, Miller ER, Mwanri L. Antenatal depression and its association with adverse birth outcomes in low and middle-income countries: a systematic review and meta-analysis. PLoS One 2020;15(1):e0227323 [FREE Full text] [doi: 10.1371/journal.pone.0227323] [Medline: 31923245]
10. Dadi AF, Miller ER, Bisetegn TA, Mwanri L. Global burden of antenatal depression and its association with adverse birth outcomes: an umbrella review. BMC Public Health 2020;20(1):173 [FREE Full text] [doi: 10.1186/s12889-020-8293-9] [Medline: 32019560]
11. Dadi AF, Miller ER, Mwanri L. Postnatal depression and its association with adverse infant health outcomes in low- and middle-income countries: a systematic review and meta-analysis. BMC Pregnancy Childbirth 2020;20(1):416 [FREE Full text] [doi: 10.1186/s12884-020-03092-7] [Medline: 32698779]
12. Sahoo S, Gill G, Sikka P, Nehra R. Antenatal depression and anxiety in Indian women: a systematic review. Ind Psychiatry J 2023;32(2):222-233 [FREE Full text] [doi: 10.4103/ipj.ipj_156_22] [Medline: 38161466]
13. Joshi D, Shrestha S, Shrestha N. Understanding the antepartum depressive symptoms and its risk factors among the pregnant women visiting public health facilities of Nepal. PLoS One 2019;14(4):e0214992 [FREE Full text] [doi: 10.1371/journal.pone.0214992] [Medline: 30947251]
14. Gelaye B, Rondon MB, Araya R, Williams MA. Epidemiology of maternal depression, risk factors, and child outcomes in low-income and middle-income countries. Lancet Psychiatry 2016;3(10):973-982 [FREE Full text] [doi: 10.1016/S2215-0366(16)30284-X] [Medline: 27650773]
15. Rusner M, Berg M, Begley C. Bipolar disorder in pregnancy and childbirth: a systematic review of outcomes. BMC Pregnancy Childbirth 2016;16(1):331 [FREE Full text] [doi: 10.1186/s12884-016-1127-1] [Medline: 27793111]
16. Vigod SN, Kurdyak PA, Dennis CL, Gruneir A, Newman A, Seeman MV, et al. Maternal and newborn outcomes among women with schizophrenia: a retrospective population-based cohort study. BJOG 2014;121(5):566-574. [doi: 10.1111/1471-0528.12567] [Medline: 24443970]
17. McAllister-Williams RH, Baldwin DS, Cantwell R, Easter A, Gilvarry E, Glover V, et al. British Association for Psychopharmacology consensus guidance on the use of psychotropic medication preconception, in pregnancy and postpartum 2017. J Psychopharmacol 2017;31(5):519-552 [FREE Full text] [doi: 10.1177/0269881117699361] [Medline: 28440103]

XSL•FO
RenderX

18. Laursen TM, Munk-Olsen T. Reproductive patterns in psychotic patients. Schizophr Res 2010;121(1-3):234-240. [doi: 10.1016/j.schres.2010.05.018] [Medline: 20570491]
19. Nasreen HE, Pasi HB, Rifin SM, Aris MAM, Rahman JA, Rus RM, et al. Impact of maternal antepartum depressive and anxiety symptoms on birth outcomes and mode of delivery: a prospective cohort study in east and west coasts of Malaysia. BMC Pregnancy Childbirth 2019;19(1):201 [FREE Full text] [doi: 10.1186/s12884-019-2349-9] [Medline: 31200677]
20. Slomian J, Honvo G, Emonts P, Reginster J, Bruyère O. Consequences of maternal postpartum depression: a systematic review of maternal and infant outcomes. Womens Health (Lond) 2019;15:1745506519844044 [FREE Full text] [doi: 10.1177/1745506519844044] [Medline: 31035856]
21. Howard LM, Khalifeh H. Perinatal mental health: a review of progress and challenges. World Psychiatry 2020;19(3):313-327 [FREE Full text] [doi: 10.1002/wps.20769] [Medline: 32931106]
22. Alves SP, Costa T, Ribeiro I, Néné M, Sequeira C. Perinatal mental health counselling programme: a scoping review. Patient Educ Couns 2023;106:170-179. [doi: 10.1016/j.pec.2022.10.347] [Medline: 36376136]
23. Bangladesh: WHO special initiative for mental health situational assessment. World Health Organization. 2020. URL: https://www.who.int/docs/default-source/mental-health/special-initiative/who-special-initiative-country-report---bangladesh---2020.pdf?sfvrsn=c2122a0e_2 [accessed 2024-11-22]
24. Khan MM, Rahman SMT, AnjumIslam ST. The use of telemedicine in Bangladesh during COVID-19 pandemic. E-Health Telecommun Syst Netw 2021;10(01):1-19. [doi: 10.4236/etsn.2021.101001]
25. Huang L, Zhao Y, Qiang C, Fan B. Is cognitive behavioral therapy a better choice for women with postnatal depression? A systematic review and meta-analysis. PLoS One 2018;13(10):e0205243 [FREE Full text] [doi: 10.1371/journal.pone.0205243] [Medline: 30321198]
26. Barrera AZ, Wickham RE, Muñoz RF. Online prevention of postpartum depression for Spanish- and English-speaking pregnant women: a pilot randomized controlled trial. Internet Interv 2015;2(3):257-265 [FREE Full text] [doi: 10.1016/j.invent.2015.06.002] [Medline: 26273567]
27. Fu Z, Burger H, Arjadi R, Bockting CLH. Effectiveness of digital psychological interventions for mental health problems in low-income and middle-income countries: a systematic review and meta-analysis. Lancet Psychiatry 2020;7(10):851-864 [FREE Full text] [doi: 10.1016/S2215-0366(20)30256-X] [Medline: 32866459]
28. Wang L, Tsai H, Chen Y, Jhang J, Wu P, Huang Y, et al. A preliminary study of the effectiveness of video visitation on depression and stress in mothers with preterm infants during the pandemic. Pediatr Neonatol 2024 [FREE Full text] [doi: 10.1016/j.pedneo.2023.12.011] [Medline: 38910078]
29. Fernandez E, Woldgabreal Y, Day A, Pham T, Gleich B, Aboujaoude E. Live psychotherapy by video versus in-person: a meta-analysis of efficacy and its relationship to types and targets of treatment. Clin Psychol Psychother 2021;28(6):1535-1549. [doi: 10.1002/cpp.2594] [Medline: 33826190]
30. Zhao L, Chen J, Lan L, Deng N, Liao Y, Yue L, et al. Effectiveness of telehealth interventions for women with postpartum depression: systematic review and meta-analysis. JMIR Mhealth Uhealth 2021;9(10):e32544 [FREE Full text] [doi: 10.2196/32544] [Medline: 34617909]
31. Loughnan SA, Joubert AE, Grierson A, Andrews G, Newby JM. Internet-delivered psychological interventions for clinical anxiety and depression in perinatal women: a systematic review and meta-analysis. Arch Womens Ment Health 2019;22(6):737-750. [doi: 10.1007/s00737-019-00961-9] [Medline: 31101993]
32. Mu TY, Li YH, Xu RX, Chen J, Wang YY, Shen CZ. Internet-based interventions for postpartum depression: a systematic review and meta-analysis. Nurs Open 2021;8(3):1125-1134 [FREE Full text] [doi: 10.1002/nop2.724] [Medline: 33373101]
33. Huang S, Wang Y, Li G, Hall BJ, Nyman TJ. Digital mental health interventions for alleviating depression and anxiety during psychotherapy waiting lists: systematic review. JMIR Ment Health 2024;11:e56650 [FREE Full text] [doi: 10.2196/56650] [Medline: 39255015]
34. Hilty DM, Ferrer DC, Parish MB, Johnston B, Callahan EJ, Yellowlees PM. The effectiveness of telemental health: a 2013 review. Telemed J E Health 2013;19(6):444-454 [FREE Full text] [doi: 10.1089/tmj.2013.0075] [Medline: 23697504]
35. Bulkes NZ, Davis K, Kay B, Riemann BC. Comparing efficacy of telehealth to in-person mental health care in intensive-treatment-seeking adults. J Psychiatr Res 2022;145:347-352 [FREE Full text] [doi: 10.1016/j.jpsychires.2021.11.003] [Medline: 34799124]
36. Ackerman M, Greenwald E, Noulas P, Ahn C. Patient satisfaction with and use of telemental health services in the perinatal period: a survey study. Psychiatr Q 2021;92(3):925-933 [FREE Full text] [doi: 10.1007/s11126-020-09874-8] [Medline: 33389477]
37. Kılıç ST, Taşgıt A. Sociodemographic factors affecting depression-anxiety-stress levels and coping strategies of parents with babies treated in neonatal intensive care units during the COVID-19 pandemic. J Neonatal Nurs 2023;29(2):375-386 [FREE Full text] [doi: 10.1016/j.jnn.2022.07.027] [Medline: 35965613]
38. Dhira TA, Rahman MA, Sarker AR, Mehareen J. Validity and reliability of the Generalized Anxiety Disorder-7 (GAD-7) among university students of Bangladesh. PLoS One 2021;16(12):e0261590 [FREE Full text] [doi: 10.1371/journal.pone.0261590] [Medline: 34914811]

XSL•FO
RenderX

39. Kamrul-Hasan ABM, Hannan MA, Asaduzzaman M, Rahman MM, Alam MS, Amin MN, et al. Prevalence and predictors of diabetes distress among adults with type 2 diabetes mellitus: a facility-based cross-sectional study of Bangladesh. BMC Endocr Disord 2022;22(1):28 [FREE Full text] [doi: 10.1186/s12902-022-00938-3] [Medline: 35065623]
40. Naher R, Rabby M, Sharif F. Validation of Patient Health Questionnaire-9 for assessing depression of adults in Bangladesh. Dhaka Univ J Biol Sci 2021;30(2):275-281 [FREE Full text] [doi: 10.3329/dujbs.v30i2.54652]
41. Shih SCS, Chan ASM, Yeung EYY, Tsang AMY, Chiu RLP, Chu MHW, et al. Psychometric properties of Chinese version of work and social adjustment scale for outpatients with common mental disorders: classical test theory and Rasch analysis. East Asian Arch Psychiatry 2021;31(4):97-104 [FREE Full text] [doi: 10.12809/eaap20101] [Medline: 34987120]
42. Peters DH, Tran NT, Adam T. Implementation research in health: a practical guide. World Health Organization. 2013. URL: https://iris.who.int/bitstream/handle/10665/91758/9789241506212_eng.pdf [accessed 2024-11-28]
43. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001;16(9):606-613 [FREE Full text] [doi: 10.1046/j.1525-1497.2001.016009606.x] [Medline: 11556941]
44. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006;166(10):1092-1097. [doi: 10.1001/archinte.166.10.1092] [Medline: 16717171]
45. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
46. Thomas DR. A general inductive approach for analyzing qualitative evaluation data. Am J Eval 2006;27(2):237-246 [FREE Full text] [doi: 10.1177/1098214005283748]
47. Sugarman DE, Busch AB. Telemental health for clinical assessment and treatment. BMJ 2023;380:e072398. [doi: 10.1136/bmj-2022-072398] [Medline: 36646462]
48. Azad R, Fahmi R, Shrestha S, Joshi H, Hasan M, Khan ANS, et al. Prevalence and risk factors of postpartum depression within one year after birth in urban slums of Dhaka, Bangladesh. PLoS One 2019;14(5):e0215735 [FREE Full text] [doi: 10.1371/journal.pone.0215735] [Medline: 31048832]
49. Mishkind MC. How telemental health delivered to non-traditional locations helped prepare for responses to COVID-19. Mhealth 2021;7:17 [FREE Full text] [doi: 10.21037/mhealth-2020-4] [Medline: 33898586]
50. O'Brien M, McNicholas F. The use of telepsychiatry during COVID-19 and beyond. Ir J Psychol Med 2020;37(4):250-255 [FREE Full text] [doi: 10.1017/ipm.2020.54] [Medline: 32434596]
51. Banbury A, Taylor ML, Gray LC, Reid N, Smith AC. Sustaining and expanding telehealth activity: training requirements for Australian residential aged care front-line staff. PEC Innov 2023;2:100109 [FREE Full text] [doi: 10.1016/j.pecinn.2022.100109] [Medline: 37214526]
52. Appleton R, Barnett P, Vera San Juan N, Tuudah E, Lyons N, Parker J, et al. Implementation strategies for telemental health: a systematic review. BMC Health Serv Res 2023;23(1):78 [FREE Full text] [doi: 10.1186/s12913-022-08993-1] [Medline: 36694164]
53. Hasan MT, Anwar T, Christopher E, Hossain S, Hossain MM, Koly KN, et al. The current state of mental healthcare in Bangladesh: part 1—an updated country profile. BJPsych Int 2021;18(4):78-82 [FREE Full text] [doi: 10.1192/bji.2021.41] [Medline: 34747942]
54. Islam A. Mental health and the health system in Bangladesh: situation analysis of a neglected domain. AJPN 2015;3(4):57. [doi: 10.11648/j.ajpn.20150304.11]
55. Strengthening inclusive community based mental health support. Center for Disability in Development. URL: https://cdd.org.bd/2022/03/20/strengthening-inclusive-community-based-mental-health-support/ [accessed 2024-01-21]
56. Sharmin F, Chowdhury M. Initiating mental health and psychosocial support at the community level in Bangladesh. The Business Standards. 2023. URL: https://www.tbsnews.net/features/initiating-mental-health-and-psychosocial-support-community-level-bangladesh-750890 [accessed 2024-11-22]
57. Esho Nije Kori—Best Mental Health Organization in Bangladesh. 2016. URL: https://www.eshonijekori.com/about-us [accessed 2024-01-25]
58. Mental Health Service Directory 2023. ADD International Bangladesh. URL: https://add.org.uk/wp-content/uploads/2024/01/Bangladesh-Mental-Health-Service-Directory-in-English.pdf [accessed 2024-01-25]
59. Hossain MD, Ahmed HU, Chowdhury WA, Niessen LW, Alam DS. Mental disorders in Bangladesh: a systematic review. BMC Psychiatry 2014;14:216 [FREE Full text] [doi: 10.1186/s12888-014-0216-9] [Medline: 25073970]
60. El Sayed S, Shokry D, Gomaa SM. Post-COVID-19 fatigue and anhedonia: a cross-sectional study and their correlation to post-recovery period. Neuropsychopharmacol Rep 2021;41(1):50-55 [FREE Full text] [doi: 10.1002/npr2.12154] [Medline: 33332756]
61. Costa R, Pinto TM, Conde A, Mesquita A, Motrico E, Figueiredo B. Women's perinatal depression: anhedonia-related symptoms have increased in the COVID-19 pandemic. Gen Hosp Psychiatry 2023;84:102-111 [FREE Full text] [doi: 10.1016/j.genhosppsych.2023.06.007] [Medline: 37419029]
62. Pearson RM, Lightman SL, Evans J. Symptoms of depression during pregnancy are associated with increased systolic blood pressure responses towards infant distress. Arch Womens Ment Health 2012;15(2):95-105. [doi: 10.1007/s00737-012-0269-z] [Medline: 22382283]

XSL•FO
RenderX

63. Bruen AJ, Wall A, Haines-Delmont A, Perkins E. Exploring suicidal ideation using an innovative mobile app-strength within me: the usability and acceptability of setting up a trial involving mobile technology and mental health service users. JMIR Ment Health 2020;7(9):e18407 [FREE Full text] [doi: 10.2196/18407] [Medline: 32985995]
64. Toscos T, Coupe A, Flanagan M, Drouin M, Carpenter M, Reining L, et al. Teens using screens for help: impact of suicidal ideation, anxiety, and depression levels on youth preferences for telemental health resources. JMIR Ment Health 2019;6(6):e13230 [FREE Full text] [doi: 10.2196/13230] [Medline: 31228179]
65. O'Callaghan E, Mahrer N, Belanger HG, Sullivan S, Lee C, Gupta CT, et al. Telehealth-supported decision-making psychiatric care for suicidal ideation: longitudinal observational study. JMIR Form Res 2022;6(9):e37746 [FREE Full text] [doi: 10.2196/37746] [Medline: 36178727]
66. Tarafa H, Alemayehu Y, Nigussie M. Factors associated with pregnancy-related anxiety among pregnant women attending antenatal care follow-up at Bedelle general hospital and Metu Karl comprehensive specialized hospital, Southwest Ethiopia. Front Psychiatry 2022;13:938277 [FREE Full text] [doi: 10.3389/fpsyt.2022.938277] [Medline: 36213901]
67. Cadman T, Strandberg-Larsen K, Calas L, Christiansen M, Culpin I, Dadvand P, et al. Urban environment in pregnancy and postpartum depression: an individual participant data meta-analysis of 12 European birth cohorts. Environ Int 2024 Mar;185:108453 [FREE Full text] [doi: 10.1016/j.envint.2024.108453] [Medline: 38368715]
68. Anjum A, Hossain S, Sikder T, Uddin ME, Rahim DA. Investigating the prevalence of and factors associated with depressive symptoms among urban and semi-urban school adolescents in Bangladesh: a pilot study. Int Health 2022;14(4):354-362 [FREE Full text] [doi: 10.1093/inthealth/ihz092] [Medline: 31693088]
69. Goldberg SB, Lam SU, Simonsson O, Torous J, Sun S. Mobile phone-based interventions for mental health: a systematic meta-review of 14 meta-analyses of randomized controlled trials. PLOS Digit Health 2022;1(1):e0000002 [FREE Full text] [doi: 10.1371/journal.pdig.0000002] [Medline: 35224559]

Abbreviations

ANC: antenatal care
aOR: adjusted odds ratio
DH: district hospital
GAD-7: Generalized Anxiety Disorder
GoB: government of Bangladesh
icddr,b: International Centre for Diarrhoeal Disease Research, Bangladesh
IDI: in-depth interview
KII: key informant interview
NCDC: Non-Communicable Disease Control
NIMH: National Institute of Mental Health
PHQ-9: Patient Health Questionnaire-9
PNC: postnatal care
RMO: resident medical officer
UHC: upazila health complex
WHO: World Health Organization

Edited by S Badawy; submitted 30.08.24; peer-reviewed by H Badmus, J Lee; comments to author 09.10.24; revised version received 14.10.24; accepted 26.10.24; published 03.01.25.

Please cite as:
Hossain AT, Rahman MH, Manna RM, Akter E, Islam SMH, Hossain MA, Ara T, Usmani NG, Chandra P, Khan MA, Rahman SMM, Ahmed HU, Mozumder MK, Juthi JM, Shahrin F, Shams SA, Afroze F, Banu MJ, Ameen S, Jabeen S, Ahmed A, Amin MR, Arifeen SE, Shomik MS, Rahman AE
Enhancing Access to Mental Health Services for Antepartum and Postpartum Women Through Telemental Health Services at Wellbeing Centers in Selected Health Facilities in Bangladesh: Implementation Research
JMIR Pediatr Parent 2025;8:e65912
URL: https://pediatrics.jmir.org/2025/1/e65912
doi:10.2196/65912
PMID:

©Aniqa Tasnim Hossain, Md Hafizur Rahman, Ridwana Maher Manna, Ema Akter, SM Hasibul Islam, Md Alamgir Hossain, Tasnu Ara, Nasimul Ghani Usmani, Pradip Chandra, Maruf Ahmed Khan, SM Mustafizur Rahman, Helal Uddin Ahmed, Muhammad Kamruzzaman Mozumder, Jesmin Mahmuda Juthi, Fatema Shahrin, Sadia Afrose Shams, Fahmida Afroze, Mukta Jahan Banu, Shafiqul Ameen, Sabrina Jabeen, Anisuddin Ahmed, Mohammad Robed Amin, Shams El Arifeen, Mohammad

XSL•FO
RenderX

Sohel Shomik, Ahmed Ehsanur Rahman. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 03.01.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Pediatric Hearts and Minds: Reimagining Health Education Through Play and Narrative

Alina Yang

Scarsdale High School, 1057 Post Road, Scarsdale, NY, United States

Corresponding Author:
Alina Yang
Scarsdale High School, 1057 Post Road, Scarsdale, NY, United States

Related Article:

https://pediatrics.jmir.org/2025/1/e64814

(JMIR Pediatr Parent 2025;8:e72675) doi:10.2196/72675

KEYWORDS

congenital heart disease; children health literacy; health education; health education interventions; patient-centered care; design; pediatric; PRISMA

As a student advocate actively involved in heart health promotion among youth, I was interested in the study entitled "Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review" [1]. The authors identified a gap in age-appropriate educational tools for younger children in the interventions, highlighting the importance of using playful, developmentally tailored strategies to engage them in learning about their cardiac condition.

This insight dovetails precisely with the broader realm of pediatric health literacy, wherein the convergence of cognitive development and medical comprehension calls to attention unique barriers. Children with congenital heart disease (CHD) face difficulties in understanding abstract medical concepts and their condition [2]. Considering this, narrative medicine holds great potential in increasing the relatability, digestibility, and applicability of knowledge by reframing biomedical concepts into metaphorical storytelling. Thus, children with CHD may be able to internalize their medical journey in ways that align with their developmental stage and personal experiences, gaining a sense of agency and coherence.

Similarly, the role of ludic and entertaining pedagogical tools emerges as a pivotal mediator of developmental trajectories across cognitive, social, and emotional domains. Health care providers, especially pediatricians and family physicians, must actively ensure that play is healthy and safe [3]. Whether it be a story-driven game or a cardiac-themed toy, interactive tools may significantly advance educational interventions through tangible learning modalities that convert abstract principles into concrete experiences. As such, the cardiac health journey becomes one of engagement, where the child becomes a conscious, active participant in their medical education rather than a mere recipient of information.

The teddy bear hospital concept in particular exemplifies this symbiotic relationship between play and education, demonstrating efficacy in reducing children's health care–related anxiety, improving their health care knowledge, and enhancing their well-being through playful role-playing in a health care setting [4]. By softening the edges of medical procedures, this model dismantles the intimidating walls of the clinical environment, transforming it into a less foreign and more approachable space for younger children who are not as impacted by traditional educational interventions.

Yet another crucial dimension of children's play surfaces through physical activity. Children with CHD and their parents recognize the importance of physical activity, but uncertainty in their health environment contributes to inactivity despite minimal professional restrictions [5]. An area ripe for intervention, physical activity guidelines could incorporate real-time feedback mechanisms that build confidence and ensure safety to promote physical exercise as an act of healing and empowerment, rather than a source of anxiety.

In tailoring educational messaging by age, we can raise the effectiveness of CHD interventions, recognizing and respecting that children are not simply "mini teenagers" and much less "mini adults." Such an approach must, therefore, incorporate elements of embodied cognition, experiential learning, and psychological support to create a comprehensive educational framework that addresses the specific cognitive and emotional needs of children with CHD. Only in this way can we create immersive and engaging learning environments that make complex cardiac concepts accessible to the young minds often underrepresented while fostering psychological resilience and physical confidence.

XSL•FO
RenderX

Authors' Contributions

AY wrote, edited, revised, and reviewed this manuscript.

Conflicts of Interest

None declared.

Editorial Notice

The corresponding author of “Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review” declined to respond to this letter.

References

1. Barbazi N, Shin JY, Hiremath G, Lauff CA. Exploring health educational interventions for children with congenital heart disease: scoping review. JMIR Pediatr Parent 2025 Jan 24;8:e64814. [doi: 10.2196/64814] [Medline: 39854065]
2. Barbazi N, Shin JY, Hiremath G, Lauff CA. Developing assessments for key stakeholders in pediatric congenital heart disease: qualitative pilot study to inform designing of a medical education toy. JMIR Form Res 2025 Jan 27;9:e63818. [doi: 10.2196/63818] [Medline: 39869901]
3. Dag NC, Turkkan E, Kacar A, Dag H. Children’s only profession: playing with toys. North Clin Istanb 2021 Aug 20;8(4):414-420. [doi: 10.14744/nci.2020.48243] [Medline: 34585080]
4. Rashid AA, Cheong AT, Hisham R, Shamsuddin NH, Roslan D. Effectiveness of pretend medical play in improving children’s health outcomes and well-being: a systematic review. BMJ Open 2021 Jan 20;11(1):e041506. [doi: 10.1136/bmjopen-2020-041506] [Medline: 33472781]
5. Longmuir PE, Corey M, McCrindle BW. Interactions with home and health environments discourage physical activity: reports from children with complex congenital heart disease and their parents. Int J Environ Res Public Health 2021 May 4;18(9):4903. [doi: 10.3390/ijerph18094903] [Medline: 34064527]

Abbreviations

CHD: congenital heart disease

Edited by K Gandhi, TDA Cardoso; submitted 14.02.25; this is a non–peer-reviewed article;accepted 24.02.25; published 13.03.25.

Please cite as:
Yang A
Pediatric Hearts and Minds: Reimagining Health Education Through Play and Narrative
JMIR Pediatr Parent 2025;8:e72675
URL: https://pediatrics.jmir.org/2025/1/e72675
doi:10.2196/72675

© Alina Yang. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 13.3.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

A Holistic Digital Health Framework to Support Health Prevention Strategies in the First 1000 Days

Silvia Gabrielli[1], MSc, PhD; Oscar Mayora Ibarra[1], MSc, PhD; Stefano Forti[2], MSc

[1]Digital Health Research, Fondazione Bruno Kessler, Via Sommarive 18, Trento, Italy

[2]Center for Digital Health & Wellbeing, Fondazione Bruno Kessler, Trento, Italy

Corresponding Author:
Silvia Gabrielli, MSc, PhD
Digital Health Research, Fondazione Bruno Kessler, Via Sommarive 18, Trento, Italy

Abstract

The first 1000 days of a child's life, spanning from the time of conception until 2 years of age, are a key period of laying down the foundations of optimum health, growth, and development across the lifespan. Although the role of health prevention programs targeting families and children in the first 1000 days of life is well recognized, investments in this key period are scarce, and the provision of adequate health care services is insufficient. The aim of this viewpoint is to provide a holistic digital health framework cocreated with policy makers, health care professionals, and families to support more effective efforts and health care programs dedicated to the first 1000 days of life as the first line of prevention. The framework provides recommendations for leveraging on behavioral intervention technology and digital therapeutics solutions augmented by artificial intelligence to support the effective deployment of health prevention programs to families. The framework also encourages the adoption of a citizen science approach to co-design and evolve the digital health interventions with all relevant stakeholders in a real-world research perspective.

(JMIR Pediatr Parent 2025;8:e55235) doi:10.2196/55235

KEYWORDS

digital health; digital therapeutics; behavioral intervention technology; prevention; citizen science; first 1000 days

Introduction

The first 1000 days is a continuum that begins with pregnancy and ends at the child's second birthday. It is a unique period laying down the foundations of optimum health, growth, and development across the lifespan [1], but it can also represent a period of potential vulnerability where the way mothers and children are cared for has a profound influence on a child's ability to grow, learn, and thrive [2]. Although the role of the first 1000 days of life is well recognized [2,3], investments in this key period are scarce, and the provision of adequate health care services and interventions is insufficient [1].

In this viewpoint, we address current challenges and opportunities in the development of effective health care interventions for the first 1000 days, by leveraging on a holistic digital health (DH) framework that can help to optimize efforts in the cocreation of these interventions with the support of policy makers, health care professionals, and families. The framework leverages on state-of-the-art approaches and opportunities in the design of behavioral intervention technology (BIT) and artificial intelligence (AI)–augmented digital therapeutics (DTx) for prevention and care, such as the Integrate, Design, Assess, and Share (IDEAS) framework [4] and the DTx Real-World Evidence (RWE) framework [5]. It complements these approaches by stressing the importance of facing the design and validation challenges within a longitudinal perspective based on citizen science and real-world evidence, to cocreate and evolve the DH interventions in a more pragmatic and sustainable way.

Health Prevention Strategies and Challenges in the First 1000 Days

The first 1000 days are characterized by 3 main periods of intervention, preconception, pregnancy, and infancy, which are key for ensuring children's healthy growth [1,3]. Health prevention programs and strategies during the preconception period address biomedical, behavioral, and social risks factors that may affect a pregnant woman's health, by providing nutritional and physiological support; identification and prevention of risks, such as toxic exposures [6,7]; and support in the adoption of changes in lifestyle [3]. Health prevention programs and strategies should also be maintained in the interconception period, going from childbirth until the birth of a subsequent child [8]. During pregnancy, the main areas of prevention typically regard nutrition, stress, and exposure to environmental contaminants [3,9]. The Italian Ministry of Health identifies 11 thematic areas that focus on prevention in the first 1000 days, including nutrition, lifestyle, parental literacy and skills, and mental health [10].

In different countries, public health care programs and interventions have been developed to support families in the

XSL•FO
RenderX

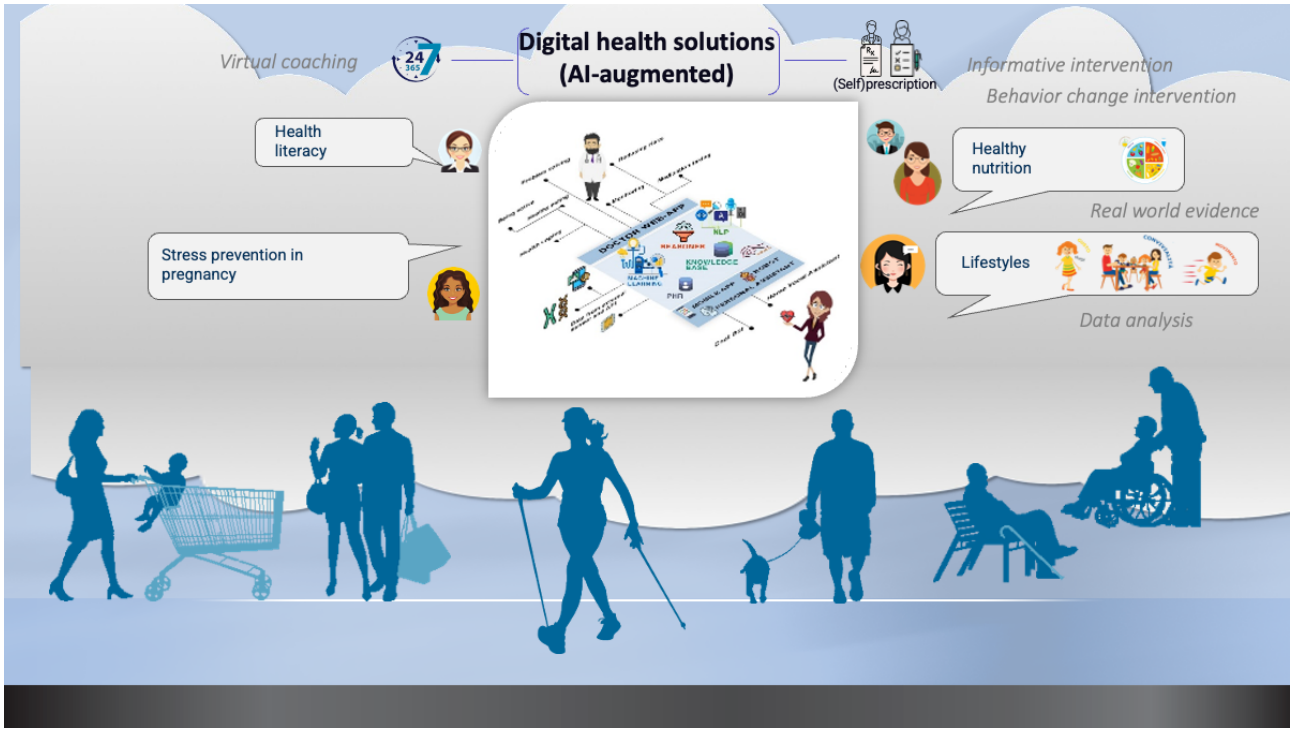
first 2 years after birth [11-14], promoting health literacy and behavioral change of parents in key areas such as nutrition, lifestyles, and mental health. Notwithstanding the large amount of data and guidelines supporting the importance of establishing efficient health care services in the first 1000 days, these health prevention strategies have not been efficiently converted into comprehensive and integrated programs enabling adequate support to parents and infants during this period [1,15,16].

In this viewpoint, we advocate that this gap is also due to a lack of deployment of DH solutions that support evidence-based educational and behavioral interventions for families and are designed for being acceptable, inclusive, engaging, equitable, scalable, and sustainable over the lifespan. Recent reviews of health professional-delivered interventions during the first 1000 days have shown that so far, most interventions were delivered in individual or group face-to-face sessions and that optimal intervention, in terms of timing, content, dose, mode of delivery, theory, and active ingredient, have yet to be established [15].

In our vision, DH technologies can play a key role in supporting the deployment of health prevention strategies and programs in the first 1000 days (as the first line of prevention) as well as over the individuals' lifespan. The kind of automation, engagement, and decisions supported by DH empowered by AI are commonly reviewed by domain experts before they can be implemented in a treatment plan, a process called augmented intelligence or intelligence amplification [17], wherein AI technology informs and augments, rather than replaces, health care professionals' experience and cognition [18].

As depicted in Figure 1, prevention programs addressing key areas of intervention, such as nutrition, lifestyle, mental health and well-being, health literacy, and education, may be more effectively translated into behavioral intervention solutions. These interventions should be informed by evidence-based theoretical approaches and a diversity of potential technologies to ensure a scalable, sustainable, accessible, and cost-effective delivery of prevention strategies. To address the challenges of effectively designing such solutions we call for a holistic DH framework helping to combine behavioral, technical, and methodological components in the intervention design process to ensure a translation of health strategies into better prevention and health outcomes for the target populations.

Figure 1. Digital health solutions delivering prevention programs in the first 1000 days and over the lifespan. AI: artificial intelligence.



A Holistic DH Framework for Cocreation With Stakeholders

Opportunities and Challenges of DH Deployment

Recent advances in the development of DH solutions provide unprecedented opportunities for deploying health prevention strategies and programs with the support of BITs or DTx. BITs typically include sensor-trackers (eg, heart rate and step count), AI-augmented chatbots (automated conversational agents), and momentary ecological assessments (which can repeatedly assess individual's behaviors and experience them in real time) [19-21].

DTx are defined as tools to deliver evidence-based health interventions (using, for example, cognitive behavioral theory as an active ingredient for treatment) through different types of potential technological solutions as excipients (eg, mobile health apps, web apps, chatbots, or virtual reality [VR] environments) [22-24].

Both BITs and DTx are DH solutions that can improve health outcomes, reduce burdens on health care professionals, and increase access to and usability of interventions [25,26]. Common goals of DH include improving lifestyle, by facilitating behavior change in diet, physical activity, or sleep, or improving mental health, such as care for depression, anxiety, or symptoms

XSL•FO
RenderX

of stress. DH solutions are often complex interventions [27], as they can include multiple components, such as goal-setting or problem-solving elements and AI algorithms that adapt provision of support to each person's changing needs. The goal of including these components in DH solutions is that they can simultaneously provide safe, effective, accessible, sustainable, scalable, and equitable support for individual and population health [28]. However, accomplishing an effective integration of these components in DH solutions is very difficult, and recent efforts have been made to provide guidance in the design, development, and assessment of these solutions by leveraging on the evidence offered by real-world data produced over usage of these digital tools, to better understand the trajectories of intervention outcomes over time [5].

The Framework Development

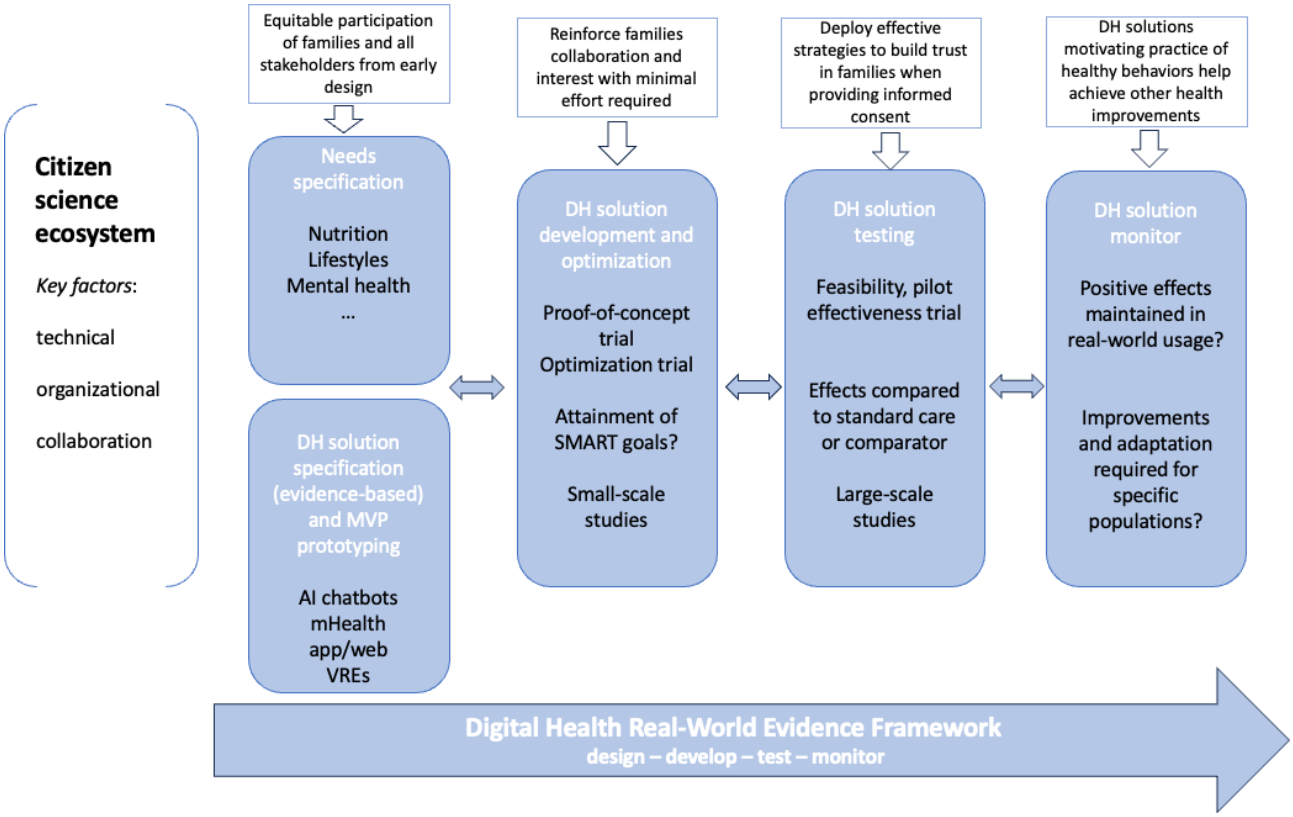
The holistic DH framework (Figure 2) is aimed at supporting the future deployment of DH solutions for prevention in the first 1000 days.

The authors of this paper first conducted a review of state-of-the-art frameworks relevant to inform the design and validation of these solutions. The review identified strengths and limitations of 4 main frameworks commonly deployed in the design of digital interventions: (1) the IDEAS framework, aimed at supporting the development of digital interventions for health behavior change and based on the IDEAS phases [4]; (2) the ORBIT (Obesity-Related Behavioral Intervention Trials) model [29], aimed at guiding the design of evidence-based behavioral treatments to prevent and treat chronic diseases, based on the 4 phases of design, preliminary testing, efficacy, and effectiveness research; (3) the MOST (Multiphase Optimization Strategy) model [30,31], aimed at optimizing the development of behavioral, biobehavioral, and biomedical interventions; and (4) the DTx RWE framework [5], inspired by ORBIT and based on the 4 phases model of development (design, develop, test, and monitor). The review also included the citizen science approach [32] as a relevant method informing the cocreation of DH solutions with the participation of all stakeholders. Citizen science has been defined as the general public engagement in scientific research activities, when citizens actively contribute to science either with their intellectual effort or surrounding knowledge or their tools and resources [33].

The holistic DH framework was then developed in a 2-way process. First, 1 author (SG) selected the combination of components from the DTx RWE framework and citizen science approach most relevant to provide a comprehensive overview of the research steps to be taken to design and deploy digital interventions for health prevention programs. In a second step, a draft version of the framework was discussed at length in a meeting among the 3 authors (SG, OMI, and SF) and revised based on the feedback provided.

We present the key components of the holistic framework in a case study providing guidance and recommendations for ensuring a more effective deployment of health prevention programs in the first 1000 days by, at the same time, leveraging on the potential of DH solutions.

Figure 2. Holistic DH framework to cocreate with stakeholders. AI: artificial intelligence; DH: digital health; mHealth: mobile health; MVP: minimum viable product; SMART: Specific, Measurable, Actionable, Realistic, Timely; VRE: virtual reality environment.



XSL•FO
RenderX

Application of the Holistic DH Framework

To illustrate the potential of the holistic DH framework in guiding the cocreation of effective prevention programs in the first 1000 days, we present examples of ongoing activities started by our research team in tackling the issues of digitizing prevention programs currently available to citizens in the Trentino region (Italy) for the pregnancy and infancy periods (birth path), working together with health professionals (gynecologists, obstetricians, and pediatricians) at the local health care system, with policy makers at the local Department of Health and Innovation, and with the target user populations (families). The main intervention areas addressed so far regard providing parental literacy to women and families during the first 1000 days (Figure 3), and providing pregnant women with healthy nutrition and psychoeducational DH programs for stress prevention from the 4th month of gestation [34-37]. The overall goal of introducing digital tools to support current prevention programs was to facilitate the adoption of a holistic strategy to target barriers in the delivery of these programs, such as reaching women living in rural areas having difficulties in accessing health care services or belonging to vulnerable populations, but also to improve ongoing prevention programs' development by incorporating holism, precision prevention, timeliness, and cost-effectiveness [19,38].

The design phase for these DH solutions started from a series of participatory sessions with all stakeholder groups (health professionals, policy makers, and families) to achieve an in-depth knowledge of the prevention needs in the target areas and to specify the requirements and prototyping of the DH tools by providing equitable consideration of the different stakeholders' perspectives, as well as building empathy and acknowledgment of any power differential [32].

From a technological point of view, it was decided to realize a secure and privacy-preserving DH platform providing virtual coaching functionalities by means of AI-augmented digital assistants available on mobile app (or coaching avatars in VR) each specialized for delivering DH intervention in a target prevention area.

Chatbot technology, using AI-augmented tools including machine learning and natural language processing, has been introduced into the health sector to address current health care challenges, such as shortage of health care providers and lack of health care access, showing several positive effects in supporting tailored intervention, which is better able to address users' needs over a digital treatment [39].

At the current stage of DH solutions development, a chatbot-based mobile app supporting women and families during the first 1000 days, named TreC-Mamma (Digital Health Research and Digital Health Innovation Lab, Fondazione Bruno Kessler), has already been released, and it is in use by more than 1000 users in the region. The aim of the TreC-Mamma solution is to provide an initial platform for collecting real-world evidence on the impact of DH solutions deployment during the first 1000 days, thus informing the development and refinement of more advanced AI-augmented digital assistants for the different intervention areas, by relying on a larger involvement and participation of families in the cocreation process. Parallel research activities are ongoing for assessing the developed proof-of-concept DH solution minimum viable products (MVPs) targeting healthy lifestyles and stress prevention during pregnancy. Specifically, virtual coaching on healthy nutrition and physical activity is provided to pregnant women by using microlearning and motivational modules validated by domain experts. For stress prevention, a chatbot-based solution deploying a digitally adapted version of the Self-Help+ protocol developed by WHO (World Health Organization) [40] has been implemented and preliminarily validated with mental health experts.

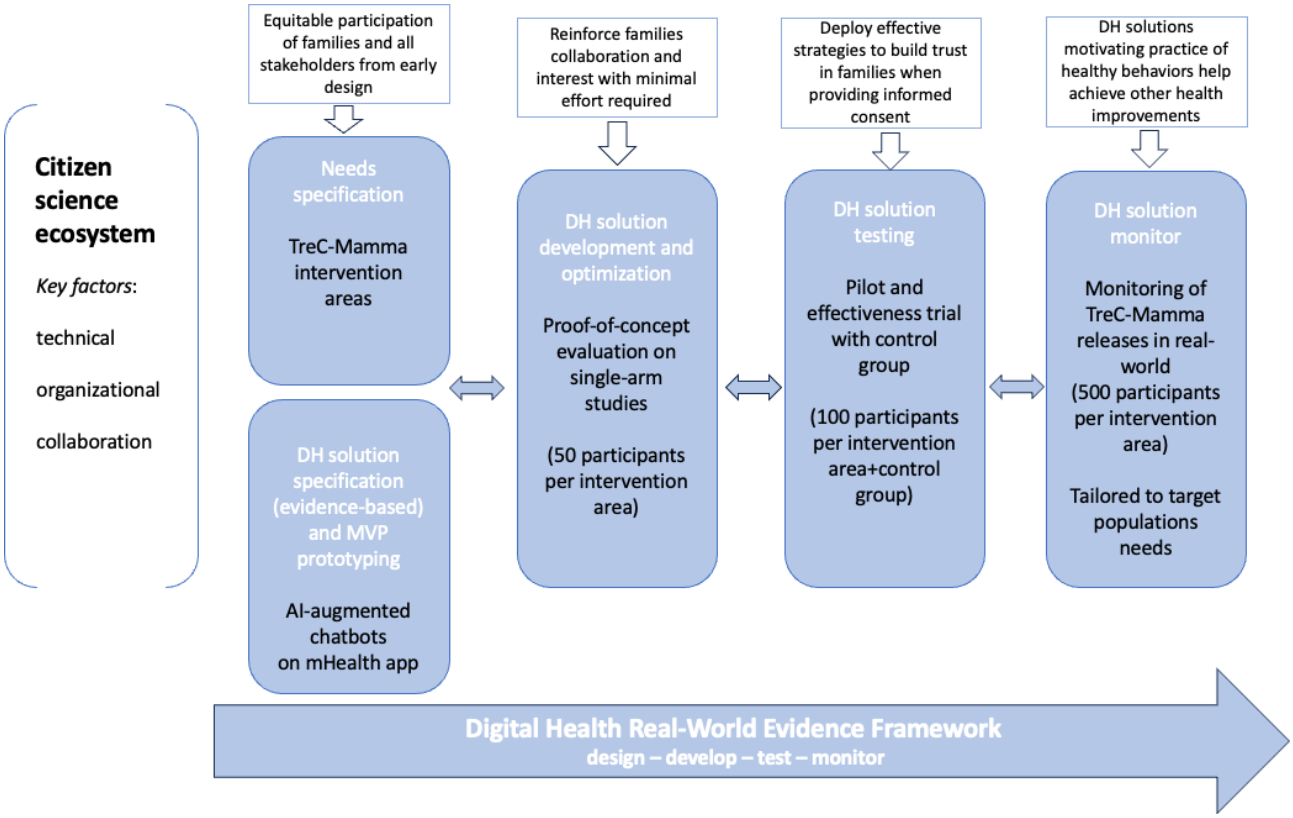
Small-scale studies are currently running to assess the MVPs' usability, acceptance, scalability, etc for further refinement and optimization based on the attainment of benchmark criteria such as the SMART (Specific, Measurable, Actionable, Realistic, Timely) goals [41]. These studies, typically involving small samples of pregnant women and their families, are also contributing to reinforce their collaboration and interest in the research project goals in the long-term, aiming to minimize the effort requested from citizens if they participate in the cocreation process.

Once the development and optimization phase of the digital assistants is completed, these DH solutions will be integrated into the TreC-Mamma platform and will be available for use by families to undergo more large-scale testing in the form of feasibility pilot trials or effectiveness trials. The ultimate goal of this testing phase is to compare the effects of the DH interventions with standard of care in the local health care system, with other relevant comparators, or by means of randomized controlled trials. In preparation of this testing phase, we are already devising an effective strategy to build trust in the project aim and solutions among families that are using the TreC-Mamma platform, facilitating the collection of their informed consent through the platform (asking them to sign a so-called "agreement with the citizen"), and clearly explaining the type of data and intended use of their data for a dynamic improvement of the platform in a citizen science perspective.

In a more long-term view, the TreC-Mamma platform will allow us to monitor the effects of our released DH interventions to assess whether their positive effects are maintained over real-world usage. In this monitoring phase, additional requirements and needs may arise from families and other stakeholders, leading to improvements and further adaptations of our solutions to fulfill evolving needs to address new areas of prevention or specific needs of target populations. As a positive side effect of deploying our DH solutions for motivating families to practice healthy behaviors in the first 1000 days, we foresee the potential achievement of health improvements in other prevention areas (eg, chronic disease prevention, such as gestational diabetes, type II diabetes, and depression) contributing to the realization of more comprehensive prevention goals and strategies.

XSL•FO
RenderX

Figure 3. Holistic DH framework applied to *first 1000 days* interventions. AI: artificial intelligence; DH: digital health; mHealth: mobile health; MVP: minimum viable product



Conclusions and Future Work

The holistic framework presented aims to provide guidance in the design and deployment of DH solutions supporting prevention strategies in the first 1000 days. It can be used to realize DH interventions in a more effective and participatory approach, leveraging on the contribution of the different stakeholders. It can help researchers in addressing the complex goal of realizing AI-augmented DH solutions by optimizing the resources available in the design process. This can be achieved by deploying a sociotechnical platform able to facilitate the engagement of citizens in the different stages of the intervention validation, as well as the effective use of real-world data for supporting the evolution and adaptation of the intervention to the target user populations.

Among the strengths of the framework presented is that it sheds light on unprecedented opportunities for deploying DH technologies in the attempt to realize more scalable, sustainable, and cost-effective solutions for prevention. It is also based on a concrete example of ongoing applied research for prevention in the first 1000 days that is supporting the feasibility of the approach proposed. We also believe that the framework illustrated can be of help in designing DH solutions for different application fields targeting health prevention and care with other target populations. By combining real-world evidence with citizen science research, it can help to overcome some limitations of previous DH frameworks like IDEAS by, for example, better supporting multidisciplinary teams' work beyond the initial intervention design and refinement, providing evidence for the adoption of the most effective behavioral strategies as derived from large-scale deployment of the digital solutions, and showcasing the sustainability of the digital solutions deployment, which may facilitate their more structural adoption and support by policy makers and users in the target communities.

However, there are also some limitations involved in the framework adoption and in its generalization to different contexts. Most of the real-world experience reported in the case study presented regards DH solutions design and development, while key outcomes derived from the test and monitor phases are still lacking. Therefore, more validation data on the framework application in real-world settings are needed, and this objective will be part of our future work. In addition, the AI-augmented features recommended to tailor the coaching of the digital assistants to the user needs require considerable design and development efforts, which may consume more tangible and intangible resources [42]. Key ethical considerations should also be considered when applying AI algorithms and techniques in DH solutions development, including bias minimization, transparency, and users' privacy and safety protection [43,44].

Notwithstanding these limitations, we think that grounding DH design efforts in a real-world evidence practice informed by a citizen science approach may contribute to establishing more productive dialogues among the stakeholders involved, as well as to facilitating faster innovation outcomes in the implementation of prevention programs.

XSL•FO
RenderX

Acknowledgments

This work was funded by Hub Life Science – Digital Health (LSH-DH) PNC-E3-2022-23683267 - Project DHEAL-COM - CUP C63C22001970001, Ministry of Health (Italy) under the Piano Nazionale Complementare al PNRR Ecosistema Innovativo della Salute (Code PNC-E.3).

Disclaimer

This publication reflects only the authors' views, and the Italian Ministry of Health is not responsible for any use that may be made of the information it contains.

Conflicts of Interest

None declared.

References

1. Indrio F, Dargenio VN, Marchese F, et al. The importance of strengthening mother and child health services during the first 1000 days of life: The foundation of optimum health, growth and development. J Pediatr 2022 Jun;245:254-256. [doi: 10.1016/j.jpeds.2022.03.001] [Medline: 35259398]
2. Brines J, Rigourd V, Billeaud C. The first 1000 days of infant. Healthcare (Basel) 2022 Jan 6;10(1):106. [doi: 10.3390/healthcare10010106] [Medline: 35052270]
3. Moore T, Arefadib N, Deery A, West S. The first thousand days: an evidence paper. Analysis and Policy Observatory. 2017. URL: https://apo.org.au/node/108431 [accessed 2022-02-14]
4. Mummah SA, Robinson TN, King AC, Gardner CD, Sutton S. IDEAS (Integrate, Design, Assess, and Share): a framework and toolkit of strategies for the development of more effective digital interventions to change health behavior. J Med Internet Res 2016 Dec 16;18(12):e317. [doi: 10.2196/jmir.5927] [Medline: 27986647]
5. Kim M, Patrick K, Nebeker C, et al. The Digital Therapeutics Real World Evidence Framework: an approach for guiding evidence-based DTx design, development, testing, and monitoring. Open Science Framework. Preprint posted online on Sep 9, 2022. [doi: 10.31219/osf.io/8t5xy]
6. Genuis SJ, Genuis RA. Preconception care: a new standard of care within maternal health services. Biomed Res Int 2016;2016:6150976. [doi: 10.1155/2016/6150976] [Medline: 27314031]
7. Genuis RA, Genuis SJ. Preconception care: the next frontier for improving maternal-child health care. Public Health 2017 Aug;149:57-59. [doi: 10.1016/j.puhe.2017.03.012] [Medline: 28551471]
8. Ratcliffe SD, Rosener SE, Frayne DJ. Preconception care. In: Paulman PM, Taylor RB, Paulman AA, Nasir LS, editors. Family Medicine: Principles and Practice, 7th edition: Springer International; 2017:127-139. [doi: 10.1007/978-3-319-04414-9_10]
9. Kim HW, Kim DH, Lee HY, Lee YJ, Ahn HY. Adult perceptions of healthy pregnancy: a focus-group study. Int J Environ Res Public Health 2020 Apr 3;17(7):2460. [doi: 10.3390/ijerph17072460] [Medline: 32260300]
10. Investire precocemente in salute: azioni e strategie nei primi mille giorni di vita - documento di indirizzo per genitori, operatori sanitari e policy maker, per la protezione e promozione della salute dei bambini e delle generazioni future. Ministero della Salute. 2019. URL: https://www.salute.gov.it/imgs/C_17_pubblicazioni_3120_allegato.pdf [accessed 2025-01-09]
11. Hamner HC, Nelson JM, Sharma AJ, et al. Improving nutrition in the first 1000 days in the United States: a federal perspective. Am J Public Health 2022 Oct;112(S8):S817-S825. [doi: 10.2105/AJPH.2022.307028] [Medline: 36122314]
12. Daníelsdóttir S, Ingudóttir J. The First 1000 Days in the Nordic Countries: Policy Recommendations: Nordic Council of Ministers; 2022.
13. Piano nazionale della prevenzione 2020-2025. : Ministero della Salute; 2020 URL: https://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf [accessed 2024-12-20]
14. Zambri F, Masè C, Chiodega V, Brolis R, Sforzini S, Giusti A. Percorso Nascita e nuovi modelli organizzativi in epoca COVID-19: l'esperienza della Provincia Autonoma di Trento [Article in Italian]. Prof Inferm 2021;74(4):235-240.
15. Hennessy M, Heary C, Laws R, et al. The effectiveness of health professional-delivered interventions during the first 1000 days to prevent overweight/obesity in children: A systematic review. Obes Rev 2019 Dec;20(12):1691-1707. [doi: 10.1111/obr.12924] [Medline: 31478333]
16. Juan J, Yang H. Early life 1000 days: opportunities for preventing adult diseases. Chin Med J (Engl) 2021 Dec 30;135(5):516-518. [doi: 10.1097/CM9.0000000000001920] [Medline: 34967791]
17. Kellogg KC, Sadeh-Sharvit S. Pragmatic AI-augmentation in mental healthcare: Key technologies, potential benefits, and real-world challenges and solutions for frontline clinicians. Front Psychiatry 2022;13:990370. [doi: 10.3389/fpsyt.2022.990370] [Medline: 36147984]
18. Bazoukis G, Hall J, Loscalzo J, Antman EM, Fuster V, Armoundas AA. The inclusion of augmented intelligence in medicine: A framework for successful implementation. Cell Rep Med 2022 Jan 18;3(1):100485. [doi: 10.1016/j.xcrm.2021.100485] [Medline: 35106506]

XSL•FO
RenderX

19. Zhang C, Przybylek S, Braksmajer A, Liu Y. An integrated conceptual framework of behavioral intervention technologies to promote healthcare utilization among socially-marginalized populations in the United States. J Nurs Stud Patient Care 2022;3(1):12-23. [Medline: 35727723]
20. Kim J, Marcusson-Clavertz D, Yoshiuchi K, Smyth JM. Potential benefits of integrating ecological momentary assessment data into mHealth care systems. Biopsychosoc Med 2019;13:19. [doi: 10.1186/s13030-019-0160-5] [Medline: 31413726]
21. Moskowitz DS, Young SN. Ecological momentary assessment: what it is and why it is a method of the future in clinical psychopharmacology. J Psychiatry Neurosci 2006 Jan;31(1):13-20. [Medline: 16496031]
22. Recchia G, Maria Capuano D, Mistri N, Verna R. Digital therapeutics-what they are, what they will be. Act Scie Medic 2020;4(3):01-09. [doi: 10.31080/ASMS.2020.04.0575]
23. Digital therapeutics (DTx). European Data Protection Supervisor. URL: https://www.edps.europa.eu/press-publications/publications/techsonar/digital-therapeutics-dtx_en [accessed 2025-01-09]
24. Digital therapeutics: combining technology and evidence-based medicine to transform personalized patient care. Digital Therapeutic Alliance. 2018. URL: https://www.dtxalliance.org/wp-content/uploads/2018/09/DTA-Report_DTx-Industry-Foundations.pdf [accessed 2025-01-09]
25. Patel NA, Butte AJ. Characteristics and challenges of the clinical pipeline of digital therapeutics. NPJ Digit Med 2020 Dec 11;3(1):159. [doi: 10.1038/s41746-020-00370-8] [Medline: 33311567]
26. Understanding DTx, a new category of medicine. Digital Therapeutics Alliance. 2022. URL: https://dtxalliance.org/understanding-dtx [accessed 2025-01-09]
27. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008 Sep 29;337:a1655. [doi: 10.1136/bmj.a1655] [Medline: 18824488]
28. Dang A, Arora D, Rane P. Role of digital therapeutics and the changing future of healthcare. J Family Med Prim Care 2020 May;9(5):2207-2213. [doi: 10.4103/jfmpc.jfmpc_105_20] [Medline: 32754475]
29. Czajkowski SM, Powell LH, Adler N, et al. From ideas to efficacy: The ORBIT model for developing behavioral treatments for chronic diseases. Health Psychol 2015 Oct;34(10):971-982. [doi: 10.1037/hea0000161] [Medline: 25642841]
30. Nahum-Shani I, Dziak JJ, Wetter DW. MCMTC: a pragmatic framework for selecting an experimental design to inform the development of digital interventions. Front Digit Health 2022;4:798025. [doi: 10.3389/fdgth.2022.798025] [Medline: 35355685]
31. Collins LM. Optimization of Behavioral, Biobehavioral, and Biomedical Interventions: The Multiphase Optimization Strategy (MOST): Springer; 2018. [doi: 10.1007/978-3-319-72206-1]
32. Petersen C, Austin RR, Backonja U, et al. Citizen science to further precision medicine: from vision to implementation. JAMIA Open 2020 Apr;3(1):2-8. [doi: 10.1093/jamiaopen/ooz060] [Medline: 32607481]
33. Green Paper on Citizen Science for Europe: Towards a Society of Empowered Citizens and Enhanced Research: European Commission; 2014.
34. Rizzi S, Poggianella S, Pavesi MC, et al. A mindfulness-based app intervention for pregnant women: protocol for a pilot feasibility study. JMIR Res Protoc 2024 May 10;13:e53890. [doi: 10.2196/53890] [Medline: 38567964]
35. Bolpagni M, Pardini S, Gabrielli S. Human centered design of AI-powered Digital Therapeutics for stress prevention: Perspectives from multi-stakeholders' workshops about the SHIVA solution. . 2024 Dec. [doi: 10.1016/j.invent.2024.100775]
36. Rizzi S, Pavesi MC, Moser A, et al. A mindfulness-based app intervention for pregnant women: study design, development, and preliminary testing of a prototype. JMIR Preprints. Preprint posted online on Mar 26, 2024. [doi: 10.2196/58265]
37. Fietta V, Rizzi S, De Luca C, et al. A chatbot-based version of the World Health Organization–validated self-help plus intervention for stress management: co-design and usability testing. JMIR Hum Factors. 2024 Oct 18. [doi: 10.2196/64614] [Medline: 39355954]
38. Gillman MW, Hammond RA. Precision treatment and precision prevention: integrating “below and above the skin”. JAMA Pediatr 2016 Jan;170(1):9-10. [doi: 10.1001/jamapediatrics.2015.2786] [Medline: 26595371]
39. Alpaydin E. Introduction to Machine Learning, 4th edition: MIT Press; 2020.
40. Self-help plus (SH+). World Health Organization. URL: https://www.who.int/publications/i/item/9789240035119 [accessed 2025-01-09]
41. SMART goals: A how to guide. University of California. 2016. URL: https://www.ucop.edu/local-human-resources/_files/performance-appraisal/How+to+write+SMART+Goals+v2.pdf [accessed 2025-01-09]
42. Roundtable on the Promotion of Health Equity and the Elimination of Health Disparities, Board on Population Health and Public Health Practice, Health and Medicine Division, National Academies of Sciences, Engineering, and Medicine. The Promises and Perils of Digital Strategies in Achieving Health Equity: Workshop Summary the Promises and Perils of Digital Strategies in Achieving Health Equity: Workshop Summary: National Academies Press (US); 2016.
43. Henderson P, Sinha K, Angelard-Gontier N, et al. Ethical challenges in data-driven dialogue systems. Presented at: AIES ’18: AAAI/ACM Conference on AI, Ethics, and Society; Feb 2-3, 2018; New Orleans, LA, USA. [doi: 10.1145/3278721.3278777]
44. Kearn M, Roth A. The Ethical Algorithm: The Science of Socially Aware Algorithm Design: Oxford University Press; 2019.

XSL•FO
RenderX

Abbreviations

AI: artificial intelligence
BIT: behavioral intervention technology
DH: digital health
DTx: digital therapeutics
IDEAS: Integrate, Design, Assess, and Share
MOST: Multiphase Optimization Strategy
MVP: minimum viable product
ORBIT: Obesity-Related Behavioral Intervention Trials
RWE: Real-World Evidence
SMART: Specific, Measurable, Actionable, Realistic, Timely
VR: virtual reality
WHO: World Health Organization

Edited by S Badawy; submitted 06.12.23; peer-reviewed by R Laws, T Baranowski; revised version received 14.06.24; accepted 26.10.24; published 16.01.25.

Please cite as:
Gabrielli S, Mayora Ibarra O, Forti S
A Holistic Digital Health Framework to Support Health Prevention Strategies in the First 1000 Days
JMIR Pediatr Parent 2025;8:e55235
URL: https://pediatrics.jmir.org/2025/1/e55235
doi:10.2196/55235

© Silvia Gabrielli, Oscar Mayora Ibarra, Stefano Forti. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 16.1.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Preventing Urgent Pediatric Readmissions: The Need for and Promise of Real-Time Monitoring

Isha Thapa[1], MS; Brian Han[2], MD; David N Rosenthal[2], MD; Stephen J Roth[2], MD, MPH; Andrew Y Shin[2], MD; Nicholas Bambos[1,3], PhD; David Scheinker[1,4,5,6], PhD

[1]Department of Management Science and Engineering, Stanford University, 475 Via Ortega, Stanford, CA, United States

[2]Division of Pediatric Cardiology, Stanford University School of Medicine, Stanford, CA, United States

[3]Department of Electrical Engineering, Stanford University, Stanford, CA, United States

[4]Division of Pediatric Endocrinology, Stanford University School of Medicine, Stanford, CA, United States

[5]Clinical Excellence Research Center, Stanford School of Medicine, Palo Alto, CADivision of Endocrinology, Department of Pediatrics, Stanford University School of Medicine, CA, United States

[6]Division of Hospital Medicine, Department of Medicine, Stanford University School of Medicine, CA, United States

Corresponding Author:
David Scheinker, PhD
Department of Management Science and Engineering, Stanford University, 475 Via Ortega, Stanford, CA, United States

Abstract

Urgent pediatric hospital readmissions are common, costly, and often preventable. Existing prediction models, based solely on discharge data, fail to accurately identify pediatric patients at-risk or urgent readmission. Remote patient monitoring (RPM) leverages wearable technology to provide real-time health data, enabling care teams to detect and respond to early signs of clinical deterioration. Emerging evidence suggests RPM may be a promising strategy to improve pediatric postdischarge outcomes and reduce urgent hospital readmissions.

(JMIR Pediatr Parent 2025;8:e60802) doi:10.2196/60802

KEYWORDS

medical information; remote patient monitoring; RPM; telehealth; pediatric readmissions; patient care management; chronic condition; readmission; disease management; intervention

Introduction

Untreated clinical deterioration in pediatric patients with chronic conditions can lead to urgent hospital readmissions, impacting the health of children, imposing a significant burden on health care systems, and delaying the care of others [1,2]. The rates of pediatric urgent readmissions, unplanned hospitalizations occurring within 30 days of discharge that require immediate medical intervention, vary from 3% to 19% across pediatric hospitals and up to 40% of them may be preventable [2]. The data available at discharge have not proved useful for predicting readmissions, especially for postdischarge causes such as medication-related failures [3]. Remote patient monitoring (RPM) may be a viable approach to detecting the early stages of clinical deterioration that ultimately lead to urgent readmission. A variety of wearable monitors enable the timely identification of deteriorating disease management and interventions to remediate it [4-6]. Used appropriately, wearable technology has the potential to help care teams reduce urgent readmissions. We argue that care models that leverage RPM have the most potential to allow care teams to reduce urgent hospital readmission for patient with chronic disease by identifying complications that may otherwise escalate into serious health concerns.

Challenges in Predicting Readmissions

Several studies have shown that predicting urgent pediatric hospital readmissions at the time of discharge is challenging, particularly for general- and for complex-subspecialty patient hospitalizations [2]. Initial efforts in this domain have concentrated on the identification of risk factors using odds ratios from data available at the time of discharge [3]. However, few of these studies have been externally validated or demonstrated to reduce readmissions in practice.

A systematic review of predictive models for 30-day unplanned pediatric readmissions found poor-to-moderate performance across most models [2]. Of the 37 models reviewed, all models except one had an area under the curve (AUC), a flawed but broadly recognized benchmark, below 0.8. The review assessed the quality of these studies to be moderate to low across all domains. Most studies lacked adequate representation of the broader pediatric population, often examining patients from only a single hospital. Many studies lacked sufficient consideration of potential confounders in their analyses.

XSL•FO
RenderX

Tools for predicting unplanned readmissions, such as the High Acuity Readmission Risk Pediatric Screen Tool, LACE (Length of stay, Acuity of admission, Comorbidity, Emergency department use), LACE-SDH (which adds Social Determinants of Health), LACE+, Epic's readmission risk model, and SQLAPE demonstrate only moderate performance, with AUCs ranging from 0.61 to 0.80 [7]. These modest performance metrics likely overstate the usefulness of such models for targeting limited resources to the relatively few patients with high risk of readmission [8]. Existing models likely fail to predict pediatric readmissions effectively because they rely on static data captured at the time of discharge, which does not reflect the evolving nature of recovery. Moreover, many are based on simple scoring systems or regression models that may inadequately account for the complexity of pediatric health trajectories.

It is not surprising that data available at the time of discharge are not sufficient to predict pediatric readmissions. Posthospitalization care is complex and lacks robust quality standards. Up to one-third of pediatric discharges may be associated with discharge-related care failures. Medication adherence serves as a prime example. A study of 157 caregivers revealed that 70% encountered medication-related failures [9]. These findings highlight the pressing need for improved postdischarge monitoring and/or interventions.

RPM

RPM offers promise for preventing readmissions. It is a technology-enabled approach to precision population health that facilitates the continuous capture and transmission of patient health metrics to medical practitioners when patients are not in the clinic. Portable devices have been validated for monitoring activity levels, sleep quality, heart rate, oxygen saturation, blood pressure, and glucose levels. Data from portable devices are often used to help manage chronic disease and detect deteriorating health in pediatric and adult populations [4-6,10,11]. Remote data acquisition and algorithm-supported analyses enable clinicians to detect health deterioration and adverse symptoms or health patterns when patients are not in the clinic. This enables timely investigation by the care team and, when appropriate, interventions to prevent the escalation of minor health concerns into serious complications.

Evidence for the effectiveness of RPM is already emerging in specific pediatric populations. An RPM intervention using continuous glucose monitors (CGMs) in pediatric patients with type 1 diabetes led to significant improvements in glucose control [6]. A small prospective study on pediatric patients receiving automated peritoneal dialysis resulted in a 45% reduction in hospitalization rates, significant increase in ultrafiltration, and significant reduction in systolic blood pressure [12]. RPM for children with single ventricle heart disease is now supported by the American Heart Association, after RPM contributed to mortality reductions of over 40% over an 8-year period [13]. RPM can also lead to more efficient workflows for health care providers, potentially reducing the time spent on routine checkups. For example, the conjunction of CGM with an automated tool was associated with improved outcomes and reduced provider screen time [6,14].

Health care systems adopting RPM will need to consider how to integrate workflows into existing clinical systems [15]. Effective implementation may include developing standardized protocols for alert management, integrating multiple monitoring devices into unified systems, and clearly defining care team responsibilities for responding to patient data. Implementing interoperability features that generate reports for inclusion into patients' medical records and import monitoring statistics into electronic medical record flowsheets can streamline clinical workflows [15]. A successful example comes from a CGM-based intervention that used a dashboard to prioritize patients for review, which was later adapted into a nationally available platform for broader adoption [15]. When an RPM system demonstrates efficacy within a single clinic, the standardized approach can facilitate expansion across multiple health care settings, creating opportunities for wider implementation and continuous improvement in patient care.

While RPM offers significant potential, barriers to access may affect its equitable implementation. Digital disparities, including limited internet access and device availability, could restrict RPM use [6,11]. Approximately 20% of US households lack access to a smartphone. In addition, variation in caregiver technological proficiency may affect adherence to monitoring protocols, and limited digital literacy can influence program engagement [11]. Addressing these challenges requires consideration of technology accessibility, device subsidization, user-friendly interfaces, and culturally appropriate education [6,11]. RPM programs "should be designed to accommodate populations with low health literacy and numeracy, with language preferences in mind" [11].

Proof-of-concept studies are necessary to determine how the implementation of RPM can reduce pediatric readmissions in the real clinical setting. Initial studies should focus on the assessment of technical feasibility within existing health care systems along with thoughtful mapping of how RPM would integrate into the clinical workflow of the care of the chronic pediatric patient. As these studies scale, outcome measures should capture not only clinical outcomes, but also include patient-reported outcomes and cost-effectiveness [16]. Pilot studies can then inform the design of larger randomized controlled trials comparing standard discharge protocols to those enhanced with RPM and allow scaling of its implementation [17].

Conclusions

Urgent pediatric hospital readmissions are common and preventable. Existing readmission prediction models are not sufficient to identify the patients at highest risk, especially those associated with care failures. RPM is a promising tool that offers real-time data transmission, streamlined operational procedures, and scalability. As RPM technology becomes more accessible, its potential to transform pediatric postdischarge care and reduce urgent readmissions warrants further investigation. Advancing this work may enable more proactive and effective strategies to improve health outcomes and reduce urgent readmissions.

XSL•FO
RenderX

Acknowledgments

This work was supported in part by the NIH via the Stanford Diabetes Research Center (1P30DK11607401) and grant no. R18DK122422 to D.S. Funding support was also received from the Helmsley Charitable Trust (grant no. G-2002-04251-2 to D.S.), the National Science Foundation (NSF) (grant no. 2205084 to I.T. and D.S.), and Stanford Human-Centered Artificial Intelligence (HAI) to I.T. and D.S.

Conflicts of Interest

None declared.

References

1. Kane JM, Hall M, Cecil C, et al. Resources and costs associated with repeated admissions to PICUs. Crit Care Explor 2021 Feb;3(2):e0347. [doi: 10.1097/CCE.0000000000000347] [Medline: 33623926]
2. Niehaus IM, Kansy N, Stock S, Dötsch J, Müller D. Applicability of predictive models for 30-day unplanned hospital readmission risk in paediatrics: a systematic review. BMJ Open 2022 Mar 30;12(3):e055956. [doi: 10.1136/bmjopen-2021-055956] [Medline: 35354615]
3. Zhou H, Roberts PA, Dhaliwal SS, Della PR. Risk factors associated with paediatric unplanned hospital readmissions: a systematic review. BMJ Open 2019 Jan 28;9(1):e020554. [doi: 10.1136/bmjopen-2017-020554] [Medline: 30696664]
4. King CE, Sarrafzadeh M. A survey of smartwatches in remote health monitoring. J Healthc Inform Res 2018 Jun;2(1-2):1-24. [doi: 10.1007/s41666-017-0012-7] [Medline: 30035250]
5. Tan SY, Sumner J, Wang Y, Wenjun Yip A. A systematic review of the impacts of remote patient monitoring (RPM) interventions on safety, adherence, quality-of-life and cost-related outcomes. NPJ Digit Med 2024 Jul 18;7(1):192. [doi: 10.1038/s41746-024-01182-w] [Medline: 39025937]
6. Prahalad P, Scheinker D, Desai M, et al. Equitable implementation of a precision digital health program for glucose management in individuals with newly diagnosed type 1 diabetes. Nat Med 2024 Jul;30(7):2067-2075. [doi: 10.1038/s41591-024-02975-y] [Medline: 38702523]
7. Bradshaw S, Buenning B, Chesnut S, Wichman L, Lee B, Olney A. A validation study of the high acuity readmission risk pediatric screen (HARRPS) tool©: Predicting readmission risk within the pediatric population. J Pediatr Nurs 2023;72:e139-e144. [doi: 10.1016/j.pedn.2023.06.020] [Medline: 37481388]
8. Saito T, Rehmsmeier M. The precision-recall plot is more informative than the ROC plot when evaluating binary classifiers on imbalanced datasets. PLoS ONE 2015;10(3):e0118432. [doi: 10.1371/journal.pone.0118432] [Medline: 25738806]
9. Philips K, Zhou R, Lee DS, et al. Caregiver medication management and understanding after pediatric hospital discharge. Hosp Pediatr 2019 Nov;9(11):844-850. [doi: 10.1542/hpeds.2019-0036] [Medline: 31582401]
10. Sasangohar F, Davis E, Kash BA, Shah SR. Remote Patient Monitoring and Telemedicine in Neonatal and Pediatric Settings: Scoping Literature Review. J Med Internet Res 2018 Dec 20;20(12):e295. [doi: 10.2196/jmir.9403] [Medline: 30573451]
11. Foster C, Schinasi D, Kan K, Macy M, Wheeler D, Curfman A. Remote monitoring of patient- and family-generated health data in pediatrics. Pediatrics 2022 Feb 1;149(2):e2021054137. [doi: 10.1542/peds.2021-054137] [Medline: 35102417]
12. Chan EYH, Liu MS, Or PC, Ma ALT. Outcomes and perception of cloud-based remote patient monitoring in children receiving automated peritoneal dialysis: a prospective study. Pediatr Nephrol 2023 Jul;38(7):2171-2178. [doi: 10.1007/s00467-022-05828-3] [Medline: 36449100]
13. Rudd NA, Ghanayem NS, Hill GD, et al. Interstage home monitoring for infants with single ventricle heart disease: Education and management: A scientific statement from the American Heart Association. J Am Heart Assoc Ovid Technologies 2020;9(16):e014548. [doi: 10.1161/JAHA.119.014548] [Medline: 32777961]
14. Scheinker D, Prahalad P, Johari R, Maahs DM, Majzun R. A new technology-enabled care model for pediatric type 1 diabetes. NEJM Catal Innov Care Deliv 2022 May;3(5):36544715. [doi: 10.1056/CAT.21.0438] [Medline: 36544715]
15. Kim GYK, Rostosky R, Bishop FK, et al. The adaptation of a single institution diabetes care platform into a nationally available turnkey solution. NPJ Digit Med 2024 Nov 6;7(1):311. [doi: 10.1038/s41746-024-01319-x] [Medline: 39506045]
16. Sugawara Y, Hirakawa Y, Iwagami M, Inokuchi R, Wakimizu R, Nangaku M. Metrics for evaluating telemedicine in randomized controlled trials: Scoping review. J Med Internet Res 2025 Jan 31;27:e67929. [doi: 10.2196/67929] [Medline: 39889298]
17. Ferstad JO, Prahalad P, Maahs DM, et al. Smart Start - designing powerful clinical trials using pilot study data. NEJM Evid 2024 Feb;3(2):EVIDoa2300164. [doi: 10.1056/EVIDoa2300164] [Medline: 38320487]

Abbreviations

AUC: area under the curve
CGM: continuous glucose monitor

XSL•FO
RenderX

LACE: Length of stay, Acuity of admission, Comorbidity, Emergency department use
LACE-SDH: Length of stay, Acuity of admission, Comorbidity, Emergency department use–Social Determinants of Health
RPM: remote patient monitoring

Edited by S Badawy; submitted 22.05.24; peer-reviewed by D Poddighe, J Nuñez, P Dunn; revised version received 29.04.25; accepted 20.05.25; published 23.06.25.

Please cite as:
Thapa I, Han B, Rosenthal DN, Roth SJ, Shin AY, Bambos N, Scheinker D
Preventing Urgent Pediatric Readmissions: The Need for and Promise of Real-Time Monitoring
JMIR Pediatr Parent 2025;8:e60802
URL: https://pediatrics.jmir.org/2025/1/e60802
doi:10.2196/60802

© Isha Thapa, Brian Han, David Rosenthal, Stephen Roth, Andrew Shin, Nicholas Bambos, David Scheinker. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 23.6.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Leveraging AI to Investigate Child Maltreatment Text Narratives: Promising Benefits and Addressable Risks

Wilson Lukmanjaya[1], BSc; Tony Butler[1], BSc, MSc, PhD; Sarah Cox[2], BSc, PhD; Oscar Perez-Concha[3], BSc, PhD; Leah Bromfield[2], BSc, PhD; George Karystianis[1], BSc, MSc, PhD

[1]School of Population Health, University of New South Wales Sydney, F25, Samuels Building, Samuel Terry Ave, Kensington, Sydney, Australia

[2]Australian Center for Child Protection, University of South Australia, Adelaide, Australia

[3]Centre for Big Data Resarch in Health, University of New South Wales Sydney, Sydney, Australia

Corresponding Author:
Wilson Lukmanjaya, BSc
School of Population Health, University of New South Wales Sydney, F25, Samuels Building, Samuel Terry Ave, Kensington, Sydney, Australia

Abstract

The trove of information contained in child maltreatment narratives represents an opportunity to strengthen the evidence base for policy reform in this area, yet it remains underutilized by researchers and policy makers. Current research into child maltreatment often involves the use of qualitative methodologies or structured survey data that are either too broad or not representative, thereby limiting the development of effective policy responses and intervention strategies. Artificial intelligence (AI) approaches such as large language models (AI models that understand and generate language) can analyze large volumes of child maltreatment narratives by extracting population-level insights on factors of interest such as mental health and treatment needs. However, when applying such methods, it is useful to have a framework on which to base approaches to the data. We propose a seven step framework: (1) data governance; (2) researcher vetting; (3) data deidentification; (4) data access; (5) feasibility testing of baseline methods; (6) large-scale implementation of black box algorithms; and (7) domain expert result validation for such exercises to ensure careful execution and limit the risk of privacy and security breaches, bias, and unreliable conclusions.

(JMIR Pediatr Parent 2025;8:e73579) doi:10.2196/73579

KEYWORDS

artificial intelligence; large language models; child maltreatment narratives; text mining; benefits and risks; research framework

Smarter Tech, Safer Kids

The World Health Organization estimates around 1 in 2 children worldwide experience physical, sexual, and emotional abuse and neglect [1]. In Australia, the monitoring of child maltreatment (ie, “all forms of physical and emotional ill-treatment, sexual abuse, neglect, and exploitation that results in actual or potential harm to the child’s health, development or dignity” [2,3]) relies on administrative data provided by child protection departments for local and national reporting purposes [4-6]. However, the structured nature of these data limits the reporting of more nuanced information such as maltreatment types, treatment needs, and mental health, preventing the ability to answer key questions. For example, the 2021 Australian Child Maltreatment Study [6] recorded the prevalence of physical abuse and sexual abuse at 32.0% and 28.5%, respectively, whereas the Australian Bureau of Statistics [5] in the same year reported that 1 in 7 (14%) children experienced physical and sexual abuse. Several factors contribute to such discrepancies, including the use of different methodologies (eg, self-report, cross-sectional surveys, and surveillance through administrative data), varying definitions of abuse and age ranges, and biases due to the small sample sizes and response rates [7-9]. While high-level reporting is important, both sources fail to provide a comprehensive picture of child maltreatment necessary for effective policy responses. Characteristics such as uncommon maltreatment subtypes and treatment needs are lacking. Indeed, the Australian Productivity Commission states that “with technological developments and advances in analytical techniques, not only is the volume of data being generated and collected growing, but so too is the scope to make use of data in innovative ways in every sphere of life” [10]. Child protection should be no exception to this.

Research in child maltreatment has predominantly utilized statistical and artificial intelligence (AI) approaches such as artificial neural networks and predictive risk modeling applied to structured child protection administrative data [11-15]. Studies on health administrative records focused on developing models to predict cases of sexual abuse [11], physical abuse [12], and overall maltreatment [13-15], with robust performance. Furthermore, information has been successfully extracted using text mining techniques such as word embeddings, bag-of-words, and feature selection from free-text health notes [16-19] to detect physical abuse.

XSL•FO
RenderX

Nevertheless, rarely tapped sources of unstructured information in this area are child maltreatment narratives containing detailed descriptive accounts of incidents or experiences of physical or emotional harm to a child. These document the initial reasons for coming to the attention of authorities (ie, intake report), descriptions of a child's experience of abuse or neglect, psychologists' assessments, police and medical records, and a detailed history of child protection involvement. They also describe abuse types, substance use and abuse, recorded injuries, mental and behavioral problems, physical health conditions, parental and family characteristics, and the types and conditions of the accommodation. Utilizing the information contained within the narratives could fill existing knowledge gaps by highlighting less common abusive behaviors (eg, social abuse, coercive control) and enriching definitions and measures of abuse types and mental illnesses [20-22]. A limited number of studies have used these narratives to automatically extract information. Victor et al [23] and Perron et al [24,25] applied machine learning algorithms such as random forest and k-nearest neighbors on caseworker summaries to identify domestic violence events and opioid-related maltreatment risks, respectively. In addition, Saxena et al [26] used topic modeling to explore the concept and definitions of "risk" on child maltreatment records with promising performance. Despite the advent of newer technologies to conduct text analysis such as large language models (LLMs; AI models that can understand and generate language), limited attempts have been made [27,28] to implement this approach. In particular, Perron et al [27] reported an F_1-score of 89% - 95% for their model to classify and extract substance-related problems, while more recently, Stoll et al [28] noted their approach to classify maltreatment subtype yielded a superior performance against human reviewers by 10%.

However, automatically mining information from child maltreatment records faces significant limitations [23-28]. Most importantly, the lack of sufficient training data restricts the AI model's capacity to learn complex patterns [29] such as nuanced indicators of abuse. In addition, the limited contextual understanding (even when using LLMs), along with the inconsistencies in narrative style and language, as caseworkers may document—or omit—events of child maltreatment through various terms, descriptions, and writing style, can lead to inaccurate outputs and falsehoods [26]. This is particularly critical when analyzing data related to Indigenous populations requiring a specific cultural lens through which to examine the data. Relying exclusively on one data type (eg, administrative data) can also skew the results and present an inaccurate picture [30].

Benefits Versus Risks

To manually process such voluminous and diverse information is extremely time consuming and not without significant challenges, including a lack of human resources to inspect large scale data and the associated high cost. AI pipelines, particularly applications of LLMs, offer a solution for efficiently processing vast amounts of child maltreatment narratives, comprehending the text for a broader range of tasks (ie, summarization, classification) [27,28,31], and offering potentially greater quality control due to its standardized approach compared to other (eg, qualitative) methods [32]. A primary concern of child protection services is to safeguard and monitor those in their care who may be at risk of maltreatment and neglect. Timely processing of many thousands of cases provides the possibility for professionals and policy makers to make faster decisions (eg, identifying clusters of abuse or mental illness using geographic areas) by predicting the severity of future abuse or allocating resources to high-prevalence communities and intervene earlier. Consequently, new evidence-based protocols for early intervention and prevention can be developed aimed at improving outcomes for children and families.

While appealing, AI applications come with security risks (eg, malware, data leakage), performance issues (eg, "AI hallucinations"), technical limitations (eg, black box bias), and ethical conundrums (eg, machine vs human decisions). Hidden malware or malicious code within unvetted AI algorithms with built-in third-party components could result in leaking sensitive information residing in child maltreatment narratives [33,34]. Child protection departments are extremely cautious about providing data access (making this data some of the most difficult to access) as children's data privacy risks could expose them to further harm. When the data involve Indigenous populations, additional cultural considerations for access, governance, and interpretation are required. Even with data access approval, challenges related to narrative data quality, such as data omission, will persist as researchers have limited control over these factors. Cultural and linguistic biases, as well as selection bias in the training data, also pose risks for misinterpretation of findings. In particular, LLM performance can be vulnerable due to "hallucinations" or misinformation with models generating inaccurate or false conclusions. This is further amplified by black box bias [35-37], since the decision-making process is not visible or understandable by humans and, therefore, it is hard to conduct any detailed error analysis.

For these reasons, AI-generated misinformation can have larger implications due to false positives and negatives, fabrication of summarization, and misclassifications. In child maltreatment cases, this could lead to the misidentification of mental health disorders, abuse and neglect misclassification, and unnecessary family separation [38-42]. Falsehoods could be interpreted as gold standards. Therefore, child maltreatment policies require a decision framework that draws conclusions from both machines and humans, with the final decision relying on human expertise. While some may propose automated approaches can reduce human errors, bias, and the time required to process reports, replacing human decision-making with AI-powered approaches requires ethical protocols to be in place. Relying exclusively on algorithms and their outputs should be discouraged as they lack the complexities and subtleties of human reasoning and decision making [43-47]. Human judgement needs to take priority over AI outputs [48] and adhere to research ethics and legal standards [49-51]. Machine-made choices bear potentially severe consequences when it comes to enhancing the evidence base and policy translation leading to social injustice and population oversurveillance [48]. Considering the inherent risk of biases [52,53] (ie,

XSL•FO
RenderX

underrepresented groups sampling bias) and the cost of hardware requirements, security protocols, and manual code inspection, it is difficult to apply such algorithms widely without the appropriate precautions.

Risk mitigation strategies are essential to ensure the appropriate application of automated approaches in areas such as child protection. First, using deidentified data and downloadable models from verified sources minimizes the risk of leaking private information. The incorporation of local LLMs could be set up using a virtual machine and offline to prohibit data access and the possibility of reidentifying personal records if information were to be siphoned off through hidden malware. False outcomes could be mitigated through improved quality of input data, further training to improve the model's understanding and designing clear, precise instructions for the model (ie, design prompt) that steer its response towards accurate information [47,48]. Governance infrastructures are also necessary to ensure appropriate handling of such sensitive data and the generated findings, especially if these data involve Indigenous populations, which would require input from key stakeholder groups and people with lived experience to ensure culturally sensitive analysis and interpretation. Finally, pipelines need to have expert-in-the-loop architecture to improve the quality and reliability of results. Ensuring that pipelines powered up by LLMs operate transparently with domain experts' input not only protects against biased decision-making but also aligns with efforts to safeguard personal data, as some algorithms can obscure the processes that may compromise fairness and privacy.

Proposed Framework

Existing research using AI approaches on child maltreatment narratives follows the establishment of the technical pipeline to extract information and obtain data access. Additional steps (eg, governance, data deidentification, researcher vetting) are also required to not only enhance the performance of such approaches but to limit security risks, ensure translatable outputs, and boost public confidence in such approaches. For these reasons, we propose a seven-step framework for processing child maltreatment narratives with LLMs or any black box algorithm: (1) data governance (including cultural considerations where appropriate), (2) researcher vetting, (3) data deidentification, (4) data access, (5) feasibility testing of baseline methods, (6) large-scale implementation of black box algorithms, and (7) domain expert result validation. These steps align with Gillingham's [48] principles of algorithmic accountability in social work and existing policy guidelines on AI for children [54,55] that prioritize children's safety, well-being, data privacy, and AI transparency. Although Gillingham's principles are rooted in decision support tools, they are relevant due to the generated results potentially contributing to policy making and translation.

The seven steps include:

1. Data governance: this foundational step focuses on establishing appropriate data governance infrastructures on both the child maltreatment data and the generated outputs. Key stakeholder agencies such as departments of child protection and information and communication technology services along with ethics committees must be engaged before any data analysis takes place. If the data relate to Indigenous populations, it is necessary to include relevant community representatives to ensure the analysis interpretation and dissemination of findings are culturally appropriate and align with Indigenous data sovereignty.
2. Researcher vetting: researchers need to be vetted (eg, have no track record of criminal activity, have previous experience with handling and analyzing sensitive data, be domestically based) to ensure responsible research, including a working with children government check. Signing a nondisclosure agreement can further minimize potential risks such as data privacy breaches and identity theft.
3. Data deidentification: as child protection data contains extremely sensitive information (eg, name, addresses, date of birth), to minimize privacy breaches, deidentification of child maltreatment narratives is recommended. Thus, in the unlikely event of data leakage, deidentification ensures that no identifiable information is exposed in the dataset.
4. Data access: accessing child protection data should be done within the vicinity of child protection agencies who can assign researchers limited access and maintain history logs of accessed or modified documents. Such an approach will ensure transparency and provide the capacity for tracking errors and auditability.
5. Feasibility testing of baseline methods: conducting a feasibility test before any large-scale implementation is important. Implementing simpler approaches that rely on lexical pattern identification (eg, rule-based) or traditional machine learning algorithms offers a controlled, auditable environment with enhanced security reducing the risk of unintended data exposure, allowing for more interpretability on potential errors (ie, false positives, false negatives) without requiring an extraneous number of resources and costs [56].
6. Large scale implementation of black box algorithms: the implementation of black box approaches or algorithms ensures efficient and effective large-scale processing of voluminous datasets. Evaluation metrics such as precision and recall ensure robust performance and support scalable research to address knowledge gaps in child maltreatment. Models such as LLMs can assist in the contextual understanding and scalability of the research to ultimately narrow the information gap within specific research aims in child maltreatment. These applications can be applied offline through a secure virtual machine environment. Through this approach, child protection organizations can ensure that researchers have no means of extracting and downloading identifiable data without explicit approval from participating governmental departments.
7. Domain expert result validation: the returned results need to be validated by domain experts in child maltreatment to ensure that the extracted or generated information does not lead to inaccurate or misleading conclusions. This can be done by manually checking a random sample of narratives and conducting interannotator agreement (via metrics such as Cohen κ coefficient) between 2 to 3 experts. Disagreements between domain experts regarding claims

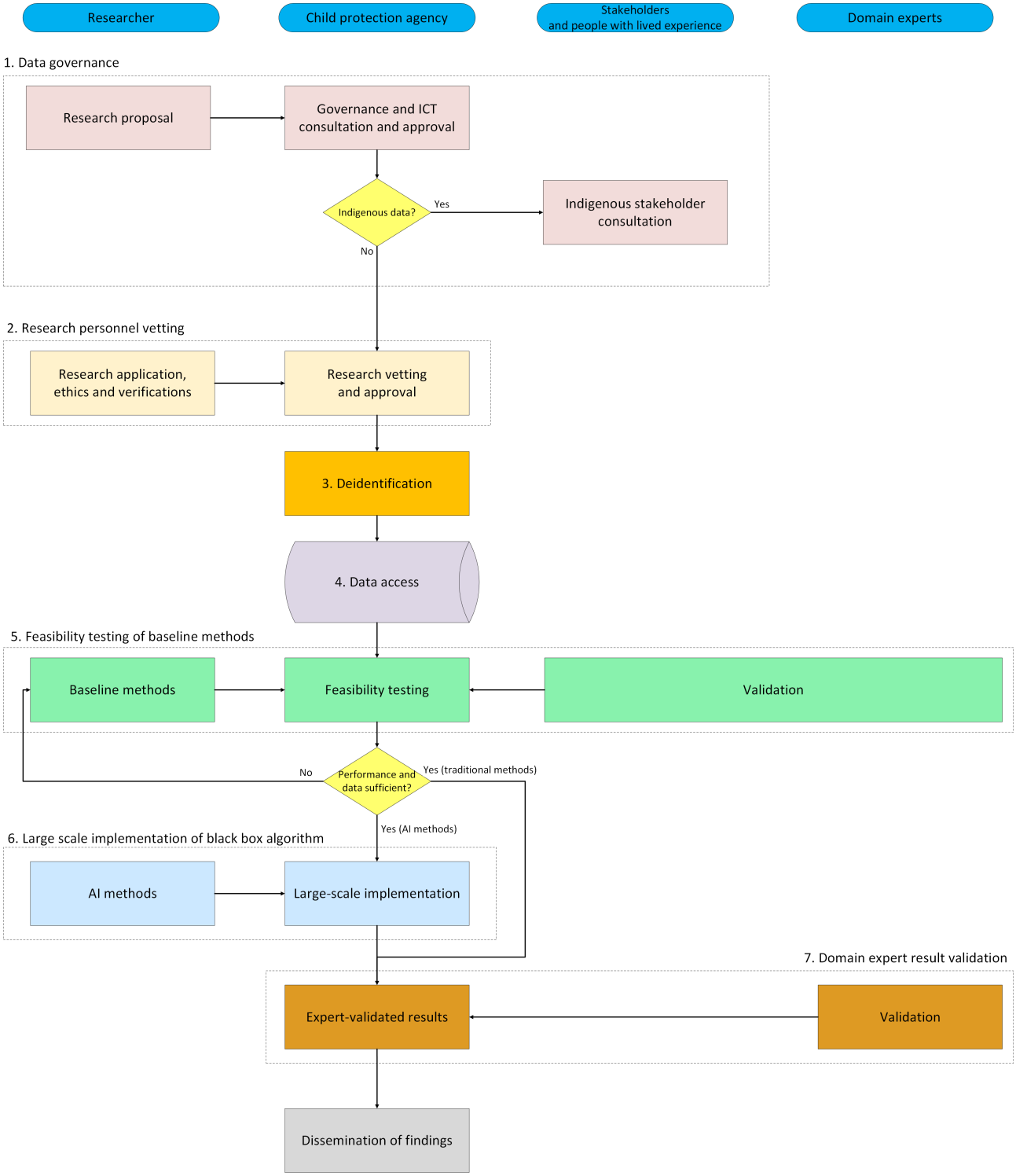
XSL•FO
RenderX

may require researchers to retrain and re-evaluate their method. This evaluation and validation process will ensure the findings' accuracy and relevancy are aligned with ethical standards such as the policy guidance for AI for children [54] or transnational frameworks for AI and children's rights and well-being [55], ensuring accuracy and fairness and limiting risks of potential harm before being used towards shaping existing or new policies and protocols.

Our proposed 7-step framework offers a novel research pipeline specific to ethical and secure use of AI in child maltreatment research. By introducing data governance, the inclusion of stakeholders with lived experience and structured deidentification processes and feasibility testing, the framework prioritizes both ethical and cultural safety while promoting analytical rigor. Incorporating domain expert validation further enhances the interpretability, contextual relevance, and ethical soundness of AI outputs—elements that are largely absent in the current literature. An illustrative example of a brief case scenario is presented in Figure 1. While it is understood that the framework may not apply to all contexts—given that protocols can vary across countries and may not have Indigenous cultures—the core principles are common. Adhering to these principles supports data privacy and cultural sensitivity and helps mitigate the uncaptured context problem and bias mitigation within the field through domain expert result validation [57].

XSL•FO
RenderX

Figure 1. Illustrative example of the proposed 7-step framework for responsible AI use in child maltreatment research. AI: artificial intelligence; ICT: information and communications technology.



Conclusions

As the complexity and scale of child maltreatment increases and the volume of information expands, an opportunity exists to apply new and sophisticated approaches that rely on AI to strengthen the evidence base by processing large volumes of narrative data. However, with this opportunity come risks that need to be minimized. The implementation of AI methods, particularly black box methods such as LLMs, should follow a framework of seven key steps—(1) data governance, (2) researcher vetting, (3) data deidentification, (4) data access, (5) feasibility testing of baseline methods, (6) large-scale implementation of black box algorithms, and (7) domain expert result validation—to ensure culturally sensitive governance, minimization of privacy risks, improvement data analysis, and optimization of AI usability in strengthening the evidence base for child maltreatment. Further research is needed to evaluate the framework's effectiveness and practice to improve policies and lead to better outcomes in child protection.

XSL•FO
RenderX

Data Availability

No generative artificial intelligence was used in any portion of the manuscript generation.

Authors' Contributions

WL conceived the study and conducted the drafting, literature review, revision, and submission of the manuscript. OP-C, LB, and SC drafted and revised the study. TB helped with the study design, revision, and supervision. GK helped with study conception and design, revision, and supervision.

Conflicts of Interest

None declared.

References

1. Hillis S, Mercy J, Amobi A, Kress H. Global prevalence of past-year violence against children: a systematic review and minimum estimates. Pediatrics 2016 Mar;137(3):e20154079. [doi: 10.1542/peds.2015-4079] [Medline: 26810785]
2. Daley SF, Gonzalez D, Bethencourt Mirabal A, Afzal M. Child abuse and neglect. In: StatPearls: StatPearls Publishing; 2025. [Medline: 29083602]
3. Child maltreat. World Health Organization. 2024. URL: https://www.who.int/news-room/fact-sheets/detail/child-maltreatment [accessed 2025-04-22]
4. Child protection Australia 2021-22. Australian Institute of Health and Welfare. 2023. URL: https://www.aihw.gov.au/reports/child-protection/child-protection-australia-2021-22 [accessed 2024-04-16]
5. 1 in 7 Australians have experienced childhood abuse. Australian Bureau of Statistics. 2023. URL: https://www.abs.gov.au/media-centre/media-releases/1-7-australians-have-experienced-childhood-abuse [accessed 2024-04-16]
6. Mathews B, Pacella R, Dunne M, et al. The Australian Child Maltreatment Study (ACMS): protocol for a national survey of the prevalence of child abuse and neglect, associated mental disorders and physical health problems, and burden of disease. BMJ Open 2021 May 11;11(5):e047074. [doi: 10.1136/bmjopen-2020-047074] [Medline: 33980529]
7. Mathews B, Pacella R, Scott JG, et al. The prevalence of child maltreatment in Australia: findings from a national survey. Med J Aust 2023 Apr 3;218 Suppl 6(Suppl 6):S13-S18. [doi: 10.5694/mja2.51873] [Medline: 37004184]
8. 4906055003 - personal safety survey, Australia: user guide, 2016: methodology. Australian Bureau of Statistics. 2017. URL: https://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4906.0.55.003main+features222016 [accessed 2025-04-22]
9. 4906.0.55.003 - personal safety survey, Australia: user guide, 2016: response rates. Australian Bureau of Statistics. 2017. URL: https://www.abs.gov.au/ausstats/abs@.nsf/Lookup/4906.0.55.003main+features242016 [accessed 2025-04-22]
10. Data availability and use. Productivity Commission. 2017. URL: https://www.pc.gov.au/inquiries/completed/data-access/report/data-access.pdf [accessed 2024-04-16]
11. Ucuz I, Ari A, Ozcan OO, Topaktas O, Sarraf M, Dogan O. Estimation of the development of depression and PTSD in children exposed to sexual abuse and development of decision support systems by using artificial intelligence. J Child Sex Abus 2022 Jan;31(1):73-85. [doi: 10.1080/10538712.2020.1841350] [Medline: 33206583]
12. Shahi N, Shahi AK, Phillips R, Shirek G, Lindberg DM, Moulton SL. Using deep learning and natural language processing models to detect child physical abuse. J Pediatr Surg 2021 Dec;56(12):2326-2332. [doi: 10.1016/j.jpedsurg.2021.03.007] [Medline: 33838900]
13. Vaithianathan R, Maloney T, Putnam-Hornstein E, Jiang N. Children in the public benefit system at risk of maltreatment: identification via predictive modeling. Am J Prev Med 2013 Sep;45(3):354-359. [doi: 10.1016/j.amepre.2013.04.022] [Medline: 23953364]
14. Horikawa H, Suguimoto SP, Musumari PM, Techasrivichien T, Ono-Kihara M, Kihara M. Development of a prediction model for child maltreatment recurrence in Japan: a historical cohort study using data from a Child Guidance Center. Child Abuse Negl 2016 Sep;59:55-65. [doi: 10.1016/j.chiabu.2016.07.008] [Medline: 27517122]
15. Choi J, Kim K. Predictive risk modeling for recurrence of child maltreatment using cases from the National Child Maltreatment Data System in Korea: exploratory data analysis using data mining algorithm. Prev Sci 2022 Nov;23(8):1517-1530. [doi: 10.1007/s11121-022-01446-5] [Medline: 36251208]
16. Amrit C, Paauw T, Aly R, Lavric M. Identifying child abuse through text mining and machine learning. Expert Syst Appl 2017 Dec;88:402-418. [doi: 10.1016/j.eswa.2017.06.035]
17. Jadhav P, Sears T, Floan G, et al. Application of a machine learning algorithm in prediction of abusive head trauma in children. J Pediatr Surg 2024 Jan;59(1):80-85. [doi: 10.1016/j.jpedsurg.2023.09.027] [Medline: 37858394]
18. Annapragada AV, Donaruma-Kwoh MM, Annapragada AV, Starosolski ZA. A natural language processing and deep learning approach to identify child abuse from pediatric electronic medical records. PLoS ONE 2021;16(2):e0247404. [doi: 10.1371/journal.pone.0247404] [Medline: 33635890]

XSL•FO
RenderX

19. Tiyyagura G, Asnes AG, Leventhal JM, et al. Development and validation of a natural language processing tool to identify injuries in infants associated with abuse. Acad Pediatr 2022 Aug;22(6):981-988. [doi: 10.1016/j.acap.2021.11.004] [Medline: 34780997]
20. Laajasalo T, Cowley LE, Otterman G, et al. Current issues and challenges in the definition and operationalization of child maltreatment: a scoping review. Child Abuse Negl 2023 Jun;140:106187. [doi: 10.1016/j.chiabu.2023.106187] [Medline: 37030235]
21. Brewsaugh K, Holmes AK, Richardson A, et al. Research and knowledge gaps in child welfare in the United States: a national survey of agency staff, allied disciplines, tribal leaders, and people who have experienced child welfare. Child Youth Serv Rev 2022 Jul;138:106496. [doi: 10.1016/j.childyouth.2022.106496]
22. Higgins DJ, Mathews B, Pacella R, et al. The prevalence and nature of multi-type child maltreatment in Australia. Med J Aust 2023 Apr 3;218 Suppl 6(Suppl 6):S19-S25. [doi: 10.5694/mja2.51868] [Medline: 37004183]
23. Victor BG, Perron BE, Sokol RL, Fedina L, Ryan JP. Automated identification of domestic violence in written child welfare records: leveraging text mining and machine learning to enhance social work research and evaluation. J Soc Social Work Res 2021 Dec 1;12(4):631-655. [doi: 10.1086/712734]
24. Perron BE, Victor BG, Bushman G, et al. Detecting substance-related problems in narrative investigation summaries of child abuse and neglect using text mining and machine learning. Child Abuse Negl 2019 Dec;98:104180. [doi: 10.1016/j.chiabu.2019.104180] [Medline: 31521909]
25. Perron BE, Victor BG, Ryan JP, Piellusch EK, Sokol RL. A text-based approach to measuring opioid-related risk among families involved in the child welfare system. Child Abuse Negl 2022 Sep;131:105688. [doi: 10.1016/j.chiabu.2022.105688] [Medline: 35687937]
26. Saxena D, Moon ESY, Chaurasia A, Guan Y, Guha S. Rethinking “risk” in algorithmic systems through a computational narrative analysis of casenotes in child-welfare. Presented at: CHI ’23: CHI Conference on Human Factors in Computing Systems; Apr 23-28, 2023; Hamburg, Germany. [doi: 10.1145/3544548.3581308]
27. Perron BE, Luan H, Victor BG, Hiltz-Perron O, Ryan J. Moving beyond ChatGPT: local large language models (LLMs) and the secure analysis of confidential unstructured text data in social work research. Res Soc Work Pract 2024. [doi: 10.1177/10497315241280686]
28. Stoll D, Wehrli S, Lätsch D. Case reports unlocked: harnessing large language models to advance research on child maltreatment. Child Abuse Negl 2025 Feb;160:107202. [doi: 10.1016/j.chiabu.2024.107202] [Medline: 39689392]
29. Hanson B, Stall S, Cutcher-Gershenfeld J, et al. Garbage in, garbage out: mitigating risks and maximizing benefits of AI in research. Nature New Biol 2023 Nov;623(7985):28-31. [doi: 10.1038/d41586-023-03316-8] [Medline: 37907636]
30. van Giffen B, Herhausen D, Fahse T. Overcoming the pitfalls and perils of algorithms: a classification of machine learning biases and mitigation methods. J Bus Res 2022 May;144:93-106. [doi: 10.1016/j.jbusres.2022.01.076]
31. Octoman O, Cox S, Arney F, Chong A, Tucker E. Narrative and fixed‐field data: are we underestimating the risk of family and domestic violence? Child Abuse Rev 2023 Jul;32(4):e2811. [doi: 10.1002/car.2811]
32. Taherdoost H. What are different research approaches? Comprehensive review of qualitative, quantitative, and mixed method research, their applications, types, and limitations. J Manag Sci Eng Res 2022;5(1):53-63. [doi: 10.30564/jmser.v5i1.4538]
33. Green BL, Ayoub C, Dym Bartlett J, et al. It’s not as simple as it sounds: problems and solutions in accessing and using administrative child welfare data for evaluating the impact of early childhood interventions. Child Youth Serv Rev 2015 Oct;57(40-49):40-49. [doi: 10.1016/j.childyouth.2015.07.015] [Medline: 26744551]
34. Martin I. Hackers have uploaded thousands of malicious files to AI’s biggest online repository. Forbes. 2024. URL: https://www.forbes.com/sites/iainmartin/2024/10/22/hackers-have-uploaded-thousands-of-malicious-models-to-ais-biggest-online-repository/ [accessed 2025-07-15]
35. Lupariello F, Sussetto L, Di Trani S, Di Vella G. Artificial intelligence and child abuse and neglect: a systematic review. Children (Basel) 2023 Oct 6;10(10):1659. [doi: 10.3390/children10101659] [Medline: 37892322]
36. Cohen D. Data scientists targeted by malicious hugging face ML models with silent backdoor. JFrog. 2024. URL: https://jfrog.com/blog/data-scientists-targeted-by-malicious-hugging-face-ml-models-with-silent-backdoor/ [accessed 2025-07-15]
37. Fluke JD, Tonmyr L, Gray J, et al. Child maltreatment data: a summary of progress, prospects and challenges. Child Abuse Negl 2021 Sep;119(Pt 1):104650. [doi: 10.1016/j.chiabu.2020.104650] [Medline: 32861435]
38. Zhou J, Zhang J, Wan R, et al. Integrating AI into clinical education: evaluating general practice trainees’ proficiency in distinguishing AI-generated hallucinations and impacting factors. BMC Med Educ 2025 Mar 19;25(1):406. [doi: 10.1186/s12909-025-06916-2] [Medline: 40108629]
39. Hatem R, Simmons B, Thornton JE. A call to address AI “hallucinations” and how healthcare professionals can mitigate their risks. Cureus 2023 Sep;15(9):e44720. [doi: 10.7759/cureus.44720] [Medline: 37809168]
40. Evans H, Snead D. Understanding the errors made by artificial intelligence algorithms in histopathology in terms of patient impact. NPJ Digit Med 2024 Apr 10;7(1):89. [doi: 10.1038/s41746-024-01093-w] [Medline: 38600151]
41. Hart LC, Viswanathan M, Nicholson WK, et al. Evidence from the USPSTF and new approaches to evaluate interventions to prevent child maltreatment. JAMA Netw Open 2024 Jul 1;7(7):e2420591. [doi: 10.1001/jamanetworkopen.2024.20591] [Medline: 38976263]

XSL•FO
RenderX

42. Timmons AC, Duong JB, Simo Fiallo N, et al. A call to action on assessing and mitigating bias in artificial intelligence applications for mental health. Perspect Psychol Sci 2023 Sep;18(5):1062-1096. [doi: 10.1177/17456916221134490] [Medline: 36490369]
43. Gillingham P. Predictive risk modelling to prevent child maltreatment and other adverse outcomes for service users: inside the “black box” of machine learning. Br J Soc Work 2016 Jun;46(4):1044-1058. [doi: 10.1093/bjsw/bcv031] [Medline: 27559213]
44. Schoech D, Jennings H, Schkade LL, Hooper-Russell C. Expert systems: artificial intelligence for professional decisions. Comput Hum Serv 1985;1(1):81-115. [doi: 10.1300/J407v01n01_06]
45. Hussey JM, Marshall JM, English DJ, et al. Defining maltreatment according to substantiation: distinction without a difference? Child Abuse Negl 2005 May;29(5):479-492. [doi: 10.1016/j.chiabu.2003.12.005] [Medline: 15970321]
46. Jent JF, Eaton CK, Knickerbocker L, Lambert WF, Merrick MT, Dandes SK. Multidisciplinary child protection decision making about physical abuse: determining substantiation thresholds and biases. Child Youth Serv Rev 2011 Sep 1;33(9):1673-1682. [doi: 10.1016/j.childyouth.2011.04.029] [Medline: 21804681]
47. Manion K, Renwick J. Equivocating over the care and protection continuum: an exploration of families not meeting the threshold for statutory intervention. Soc Policy J N Z 2008;33(70):94 [FREE Full text]
48. Gillingham P. Decision support systems, social justice and algorithmic accountability in social work: a new challenge. Practice (Birm) 2019 Aug 8;31(4):277-290. [doi: 10.1080/09503153.2019.1575954]
49. Hagendorff T. The ethics of AI ethics: an evaluation of guidelines. Minds & Machines 2020 Mar;30(1):99-120. [doi: 10.1007/s11023-020-09517-8]
50. Shaw J, Ali J, Atuire CA, et al. Research ethics and artificial intelligence for global health: perspectives from the global forum on bioethics in research. BMC Med Ethics 2024 Apr 18;25(1):46. [doi: 10.1186/s12910-024-01044-w] [Medline: 38637857]
51. Qadhi SM, Alduais A, Chaaban Y, Khraisheh M. Generative AI, research ethics, and higher education research: insights from a scientometric analysis. Information 2024;15(6):325. [doi: 10.3390/info15060325]
52. Beatty D, Masanthia K, Kaphol T, Sethi N. Revealing hidden bias in AI: lessons from large language models. arXiv. Preprint posted online on Oct 22, 2024. [doi: 10.48550/arXiv.2410.16927]
53. Holdsworth J. What is AI bias? IBM. 2023. URL: https://www.ibm.com/think/topics/ai-bias [accessed 2025-07-18]
54. Dignum V, Penagos M, Pigmans K, Vosloo S. Policy guidance on AI for children. UNICEF Innocenti. URL: https://www.unicef.org/innocenti/reports/policy-guidance-ai-children [accessed 2025-04-22]
55. Mahomed S, Aitken M, Atabey A, Wong J, Briggs M. AI, children’s rights, & wellbeing: transnational frameworks. The Alan Turing Institute. 2023. URL: https://www.turing.ac.uk/sites/default/files/2023-12/ai-childrens_rights-_wellbeing-transnational_frameworks_report.pdf [accessed 2025-04-22]
56. Karystianis G, Adily A, Schofield PW, et al. Surveillance of domestic violence using text mining outputs from Australian police records. Front Psychiatry 2021;12:787792. [doi: 10.3389/fpsyt.2021.787792] [Medline: 35222105]
57. Bhattacharya A, Stumpf S, De Croon R, Verbert K. Explanatory debiasing: involving domain experts in the data generation process to mitigate representation bias in AI systems. Presented at: CHI 2025: CHI Conference on Human Factors in Computing Systems; Apr 26 to May 1, 2025; Yokohama, Japan. [doi: 10.1145/3706598.3713497]

Abbreviations

AI: artificial intelligence
LLM: large language model

Edited by S Badawy; submitted 06.03.25; peer-reviewed by C Zheng, P Gillingham; revised version received 04.06.25; accepted 16.06.25; published 24.07.25.

Please cite as:
Lukmanjaya W, Butler T, Cox S, Perez-Concha O, Bromfield L, Karystianis G
Leveraging AI to Investigate Child Maltreatment Text Narratives: Promising Benefits and Addressable Risks
JMIR Pediatr Parent 2025;8:e73579
URL: https://pediatrics.jmir.org/2025/1/e73579
doi:10.2196/73579

© Wilson Lukmanjaya, Tony Butler, Sarah Cox, Oscar Perez-Concha, Leah Bromfield, George Karystianis. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 24.7.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is

XSL•FO
RenderX

properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Understanding Pediatric Patient Experiences with Urotherapy Tools: Qualitative Focus Group Study

Lola Bladt[1,2], MSc; Anka Nieuwhof-Leppink[3], PhD; Rose-Farah Blomme[1,2], MSc; Jiri Vermeulen[2], MSc; Alexandra Vermandel[4,5], PhD; Gunter De Win[5,6], MD, PhD; Lukas Van Campenhout[1], PhD

[1]Department of Product Development, Faculty of Design Sciences, University of Antwerp, Paardenmarkt 90/94, Antwerp, Belgium

[2]Department of Research and Development, Minze Health NV, Antwerp, Belgium

[3]Department of Urotherapy, Psychology and Urology, Wilhelmina Children's Hospital, University Medical Center Utrecht, Utrecht, The Netherlands

[4]Department of Rehabilitation Sciences and Physiotherapy, Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium

[5]Department of Urology, University Hospital Antwerp, Edegem, Belgium

[6]Antwerp Surgical Training, Anatomy and Research Centre (ASTARC), Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium

Corresponding Author:
Lola Bladt, MSc
Department of Product Development, Faculty of Design Sciences, University of Antwerp, Paardenmarkt 90/94, Antwerp, Belgium

Abstract

Background: Standard urotherapy for childhood incontinence involves traditional tools like paper bladder diaries, timer watches, wetting alarms, and uroflowmeters. However, little is known about how these tools are experienced by today's digitally native children.

Objective: This study aimed to explore how children undergoing urotherapy perceive and experience these commonly used tools, with the goal of informing more engaging and child-centered design approaches.

Methods: A qualitative focus group design was used with purposive sampling of children undergoing in-clinic urotherapy group training. In total, 19 participants (13 boys and 6 girls) aged 9-13 years took part in focus groups of 3 to 4 children, held at the hospital. A child-friendly focus group toolkit was used to facilitate discussion through creative and playful exercises. A total of 7 focus groups were conducted, including 2 repeated sessions, until thematic saturation was reached. All sessions were held in Dutch, video- and audio-recorded, and transcribed verbatim. An inductive conventional content analysis was conducted using a dual-coder approach to identify and iteratively refine emerging themes.

Results: Four themes emerged: (1) attitudes and motivation: ranging from willingness to engage in urotherapy and use tools to reluctance or resistance; (2) social acceptance: highlighting the impact of peer perception, fear of being bullied, and opportunities to break the taboo and reframe tools as socially desirable; (3) contextual influences: including dissatisfaction with school toilets and limited child involvement at doctor visits, contrasted with the positive peer support experienced during group therapy; and (4) digital integration: children saw many traditional tools as outdated and suggested gamified, smart alternatives. The drawings created by children during the exercises served as a creative reflection of these thematic findings.

Conclusions: Involving children in research and design is essential for creating interventions that are truly child-centered. Through creative, qualitative methods, this study uncovered rich insights into children's experiences with urotherapy tools, pointing to 4 key design priorities: personalization, stigma-free design, adaptability, and digital innovation.

(JMIR Pediatr Parent 2025;8:e79142) doi:10.2196/79142

KEYWORDS

child; urinary incontinence; urotherapy tools; qualitative research; focus groups; patient experience; child-centered care; digital health; gamification

Introduction

Background

Daytime urinary incontinence affects many school-aged children (5 - 13 y) [1,2], often leading to low self-esteem, feelings of shame, and stress, thereby negatively impacting the child's quality of life [3,4]. Standard urotherapy is the recommended first-line treatment for daytime urinary incontinence [5]. During standard urotherapy, children receive age-appropriate information and instructions on drinking and toileting habits, which need to be repeatedly practiced in order to reach optimal results [6,7]. There are a variety of tools designed to support

XSL•FO
RenderX

urotherapy, such as bladder diaries [8], timer watches [9], wetting alarms [7], and uroflowmeters [10].

Traditional bladder diaries consist of paper-based schedules where patients are required to manually record their urinary output (using a measuring cup), fluid intake, and incidents of urine leakage over a span of several days [1]. Bladder diaries provide the child, parent, and clinician with insights on symptoms and therapy progress and help to create self-awareness of voiding and drinking habits [5,11,12].

Timer watches sound an alarm at fixed time intervals to remind the child to drink and void regularly [9]. This tool encourages children not to postpone going to the toilet until they experience an urgent need or have accidents, but rather to urinate at set intervals with a more relaxed pelvic floor (ie,timed voiding).

Although primarily used for nighttime urinary incontinence, wetting alarms may also be used for children dealing with persistent daytime urinary incontinence [7]. These alarms involve specialized underwear with conductive material that triggers an alarm when wet. The purpose of the alarm is to restore a child's bladder signal awareness and promote an appropriate response to it.

Finally, traditional uroflowmeters consist of a weight-based sensor with a urine receptacle on top, placed under a commode chair with funnel. They measure urine flow during urination and can be used for real-time biofeedback [13,14]. Through this feedback, children can better understand their voiding function and work toward normalizing their uroflow patterns.

Study Rationale and Objectives

Despite its clinical potential, standard urotherapy is often challenged by low motivation and poor compliance [15]. Traditional tools may no longer align with the expectations of today's digitally native children [16]. Yet, little is known about how these tools are perceived by children or how they influence their overall experience with urotherapy.

This study aims to gain a deeper understanding of the experiences, needs, and desires of pediatric patients regarding urotherapy and its tools. The ultimate goal is to inform the development of more engaging and child-centered interventions and tools that better align with their expectations.

Methods

Study Design

The study used a qualitative focus group research design, following the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines. The focus group collected data on the experiences of pediatric patients with urotherapy and its tools.

Participants and Recruitment

A purposive sampling strategy was used to recruit participants who were undergoing in-clinic urotherapy group training (voiding school) at the Wilhelmina Children's Hospital of the University Medical Center Utrecht [17,18]. In this 10-day program, children are admitted to the hospital, staying overnight on weekdays and returning home over the weekend. The program includes a timed voiding and drinking schedule monitored through a bladder diary, along with the use of wetting alarms, repeated uroflowmetry biofeedback, and daily therapeutic sessions, all under the guidance of urotherapists.

All children who were enrolled in the program during the study period from February 2023 to April 2023 were considered eligible for participation in the focus group study. The inclusion and exclusion criteria were determined by the urotherapy program itself and included children aged 8 to 13 years with functional urinary incontinence that was refractory to standard urotherapy and who were fluent in Dutch. Children were excluded from the program if they had an anatomical or neurological cause for urinary incontinence, recurrent urinary tract infections, or unmanaged constipation. In addition, children were excluded if their cognitive functioning was below the level of a 6-year-old or if their IQ was below 60. These assessments were carried out by the clinical team of the Wilhelmina Children's Hospital. During the first intake, an extensive psychosocial history was taken by the urotherapist, including school functioning. Children were expected to attend at least grade 3 of primary school in the Netherlands, be able to read, tell time, follow instructions, and attend either regular or special primary education. If there was any doubt about IQ or developmental delay, a psychological report was requested.

Information about the study was presented to both the child and a parent in written and verbal forms at the initiation of the urotherapy program, upon hospital admission. A total of 19 participants (13 boys and 6 girls), aged between 9 and 13 years (Table 1), participated in the study after parental informed consent was obtained. In addition, children aged 12 and older provided written consent, while younger participants gave assent. The children took part in focus groups of 3 to 4 participants, corresponding to the group they were assigned to within the urotherapy program. One child discontinued participation early due to difficulties with concentration and behavior that disrupted the group dynamics.

XSL•FO
RenderX

Table . Participant characteristics (N=19).

Characteristic	Participants, n (%)
Sex	
Male	13 (68)
Female	6 (32)
Age group (years)	
<10	5 (26)
10 - 11	9 (47)
≥12	5 (26)
Diagnosis	
Overactive bladder	8 (42)
Voiding postponement	3 (16)
Dysfunctional voiding	2 (11)
Other	6 (32)
Comorbidities	
Neurodevelopmental or behavioral[a]	6 (32)
Other medical[b]	3 (16)
None	10 (53)

[a]Reported comorbidities included attention deficit disorder, attention deficit hyperactivity disorder, autism spectrum disorder, and dyslexia.

[b]Reported other medical comorbidities included hemophilia, leukemia and history of preterm birth.

Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki. The Medical Ethics Review Committee NedMec reviewed the study protocol (22/955; decision date: November 15, 2022) and determined that it did not fall within the scope of the Dutch Medical Research Involving Human Subjects Act (WMO). This decision was based on the nonexperimental nature of the study, which involved no medical intervention and focused solely on exploring children's experiences with existing urotherapy tools through focus group discussions. To ensure institutional oversight, the study was additionally reviewed and approved by the division management of the University Medical Center Utrecht.

Written informed consent was obtained from parents and from participants aged 12 years or older; younger participants provided assent. All data were pseudonymized before analysis. No compensation was provided for participation.

Data Collection

All focus group sessions were conducted at the Wilhelmina Children's Hospital during the in-clinic urotherapy program. The sessions were moderated by the first and third authors, both female researchers with no previous relationship to the participants. At the time of the study, the first author was a PhD candidate and the third author a master's student at the University of Antwerp, Faculty of Design Sciences. The first author received formal training in qualitative research and was responsible for organizing and moderating the session. The third author supported the session through observation and note-taking.

At the start of each session, the researchers introduced themselves, explained their roles, and shared the purpose of the study. It was explained that the researchers were interested in designing better tools and services for children with urinary incontinence. The first author disclosed her background in pediatric health design research and her professional role in a urology-focused medical device company, acknowledging a personal and professional motivation to improve urotherapy experiences.

To support the children's comfort at the start of the session, a urotherapist involved in their treatment was present. Once a safe and relaxed atmosphere was established, the urotherapist left the room, allowing the children to engage freely in the discussion with the researchers. Data collection was facilitated using a child-friendly focus group discussion toolkit, informed by existing literature and specifically designed for this study [19]. The goal was to create a safe and inspiring context where participating children could comfortably share personal experiences in a creative and playful manner (Figure 1). It consisted of an icebreaker and warm-up, collaging exercise, pen, and paper feedback, and a superhero character drawing (Table 2).

XSL•FO
RenderX

Figure 1. Child-friendly focus group discussion toolkit used in this study. (**A**) Collaging exercise where children shared emotions and personal experiences in various contexts. (**B**) Pen and paper exercise with cardboard toilet prop to share feedback and ideas on different urotherapy tools.

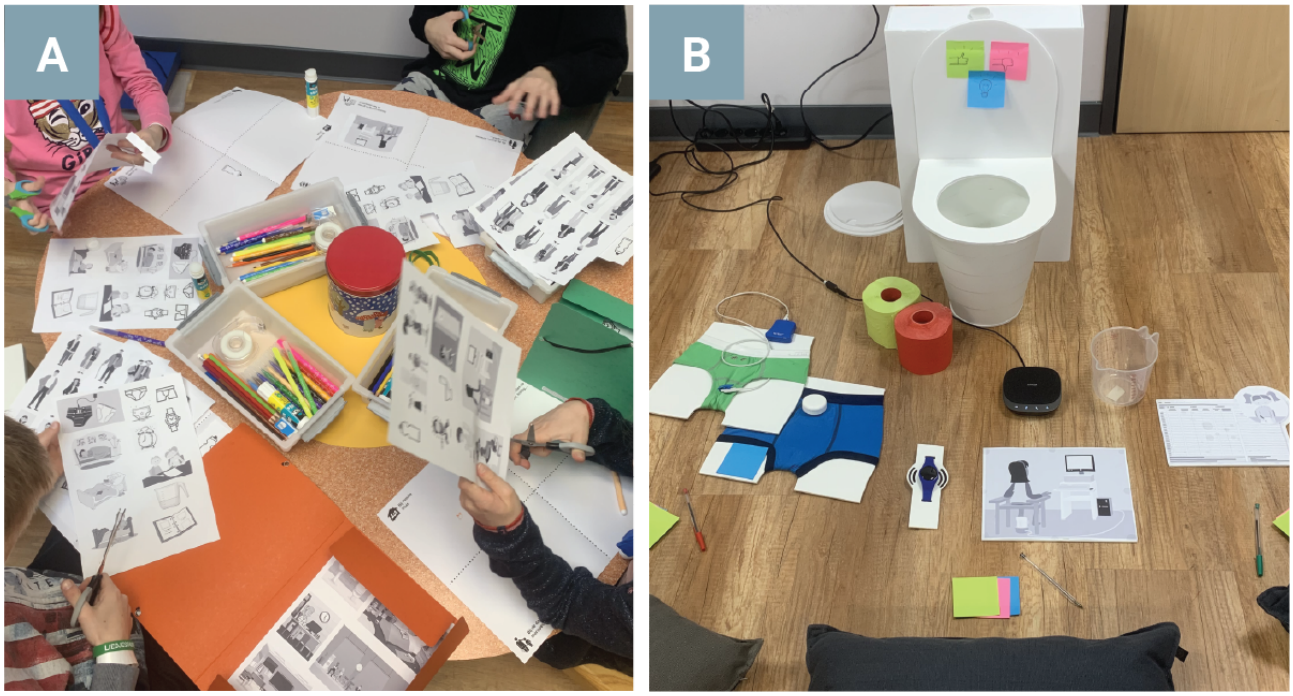


Table . Overview of focus group toolkit exercises.

Toolkit exercises	Description	Guiding questions
Icebreaker and warm-up	Children passed a toilet roll and shared personal facts. Followed by a group mind-mapping activity focused on drinking, going to the toilet, and bladder training.	"What is your name and age?," "What are your hobbies?," "When you hear the word ___, what comes to mind first?"
Collaging exercise	Children created collages about different settings (home, school, doctor visits, and group training) from the perspective of their bladder problems. They then presented their collages and discussed them in the group.	"What happens in those different contexts?," "How do you feel in those contexts?," "Who or what is there to support you?"
Pen and paper feedback	Children reflected on urotherapy tools (bladder diaries, timer watches, wetting alarms, and uroflowmeters) by drawing or writing their thoughts on paper. These were thrown into a cardboard toilet prop and then randomly drawn to prompt group discussion.	"What do you like and don't like about this tool?," "What ideas do you have to make it better?"
Superhero character drawing	Children drew a superhero who, like them, also happens to have a bladder problem. They then presented their superheroes and described their powers and coping strategies.	"What is your superhero's name?," "What superpowers do they have?," "How do they deal with their bladder problems?"

Each session lasted between 1.5 and 2 hours. Data collection concluded upon reaching "thematic saturation" (ie, when no new themes are uncovered by additional sessions) [20]. This saturation point was achieved after 7 focus groups, including 2 repeated sessions where 2 groups participated in an additional session on another day. These follow-up sessions were conducted to explore certain themes in more depth.

All focus group sessions were conducted in Dutch, video and audio recorded, and transcribed verbatim. The excerpts quoted in this paper were translated into English by the first author, with the aim of preserving the original meaning and tone. Due to the young age of participants, transcripts were not returned, and member checking was not conducted. However, to enhance the credibility and trustworthiness of the findings, they were cross-checked with health care professionals involved in the treatment of the participating children.

Data Analysis

A conventional content analysis [21] was used to inductively derive meaning from the focus group data, following three main phases: preparation, organization (including coding), and reporting.

In the preparation phase, the first author repeatedly watched the video recordings and read the transcripts to gain a comprehensive understanding. This phase allowed the researcher

XSL•FO
RenderX

to become familiar with the content and begin identifying meaningful units (segments of the text) of analysis.

In the organization phase, relevant segments of text were manually highlighted and open-coded using Microsoft Excel. Through several iterations of coding and code modification, a codebook was developed. The transcripts were then further coded by pairs of master's students, using a dual-coder approach to ensure consistency. As coding progressed, subcategories emerged and were iteratively grouped into broader themes, capturing patterns across the dataset. This hierarchical structure of codes, subcategories, and themes constituted the coding tree developed during analysis.

In the reporting phase, the first author prepared the preliminary structure of the emerging themes, which were then discussed and validated within the multidisciplinary research team, including a pediatric urologist, 2 urotherapists, and 2 medical product designers. This collaborative step ensured a diversity of viewpoints and enhanced the trustworthiness of the analysis. The final themes were defined based on consensus within the team and formed the basis for the study's results.

Results

Overview of Themes

Four main themes emerged from the analysis that provide insight into how children perceive and engage with urotherapy and its tools: (1) attitudes and motivation (2) social acceptance, (3) contextual influences, and (4) digital integration. The structure of the themes and subthemes is shown in Textbox 1.

Textbox 1. Theme structure.

Attitudes and motivation

- Willingness to engage in training and use tools
- Resistance or ignoring support
- Parental involvement and tension
- Fear of dependence and desire for autonomy

Social acceptance

- Need for discreet design
- Fear of being bullied
- Openness as a way to break taboo
- Reframing tools as socially desirable

Contextual influences

- Bladder behavior varies by setting
- Dissatisfaction with school toilets
- Disconnection at the doctor's office
- Peer support during group urotherapy

Digital integration

- Children are digital natives
- Traditional tools seen as outdated
- Ideas for gamified, smart solutions
- Awareness of digital pitfalls

Theme 1: Attitudes and Motivation

Children expressed diverse attitudes and varying levels of motivation toward engaging with urotherapy and its tools. For instance, a clear willingness to participate in training emerged, along with recognition of the value urotherapy tools could offer in managing their condition. Tools were described as useful for reminding them to go to the toilet, increasing awareness of bladder signals, and providing objective data to better understand their condition.

> *If your mom or dad don't remind you to go to the toilet, then you have to do it yourself. That's when the timer watch is really helpful.* [P3, male, 10 y]

> *When you wear the wetting alarm, you can actually feel what it's like when you leak. When it starts beeping, you know what that feeling means. Without it, you don't really know what to pay attention to.* [P11, male, 10 y]

> *A bladder diary helps you see how much you pee. If you just go to the toilet normally, you can guess, but you don't really know. But with a measuring cup, you know exactly. If it's very high or very low, the doctors*

XSL•FO
RenderX

> *can figure out if something's wrong or not, and then they can help you.* [P12, female, 9 y]

In contrast, expressions of reluctance or resistance were also observed. This included deliberately ignoring advice or recommendations like pretending to go to the toilet, disregarding alerts from reminder tools, or even ignoring their own bladder signals in favor of continuing preferred activities.

> *You can fake going to the toilet. Just go to the bathroom without actually peeing, and then come back.* [P3, male, 10 y]

> *I didn't always go to the toilet when the timer watch went off. Sometimes I just didn't feel like it and kept playing. I just turn off the alarm.* [P7, male, 8 y]

> *I'm pretty stubborn. I usually ignore my bladder signal. Even if an alarm goes off, I ignore it because I really want to finish my game. And then… well, I usually end up wet.* [P11, male, 10 y]

Children reported that in these situations parents became more involved in supporting their urotherapy routines. This involvement sometimes led to feelings of tension, frustration, or being controlled. The use of certain tools to enforce behavior was mentioned as a potential trigger for arguments between children and parents.

> *After I turned off the timer watch, my mom reprogrammed it to go off every thirty minutes and she turned up the volume so my teacher would hear it too and make sure I actually went to the bathroom.* [P1, male, 9 y]

> *Keeping a bladder diary at home is so annoying. Like, if you're mad at your mom and you need to go to the bathroom, you still have to fill it in, and then she'll yell, "Fill it in!"* [P13, female, 10 y]

> *My mom looks at my uroflow curves and then complains, like, "Such small voids!"* [P14, female, 13 y]

In addition, children expressed concerns about becoming dependent on certain urotherapy tools, emphasizing their desire for autonomy. They discussed how rigid, time-based routines set by tools like timer watches do not always align with real-life situations. They also described these tools as temporary aids to support their progress toward independent bladder control.

> *I don't like the timer watch because it makes you depend on it. When it beeps, you have to go, but what if you're busy and can actually hold it? Or what if you just don't need to go?* [P16, male, 12 y]

> *You don't have a uroflow toilet at home, so you can't really see how you pee. But in the end, you should be able to do it without one.* [P11, male, 10 y]

Theme 2: Social Acceptance

Social acceptance emerged as a significant theme, reflected in the importance participants placed on how they are perceived by peers. A recurring concern was that urotherapy tools were not discreet and could attract unwanted attention in social settings, leaving children feeling singled out.

> *If you're outside and the timer watch starts beeping every hour, your friends are like, "Why does he keep beeping?"* [P2, male, 11 y]

> *I had to keep a bladder diary at school once, but it was so annoying. Everyone in the class would look at me when I had to do it.* [P14, female, 13 y]

> *If you wear the alarm around your neck, everyone knows you're doing bladder training.* [P11, male, 10 y]

In addition, children reported being bullied for their bladder problems. To cope with this, they described efforts to hide symptoms and to be very selective about who they trusted with information about their condition.

> *I had an argument with my little brother and then I wet my pants, which happens more easily when I'm stressed. And then he yelled "Ew, gross! Run away! Run away!"* [P8, male, 11 y]

> *Only my teachers know. I don't tell anyone else, because I know I'll get bullied again. Like once during gym class, someone saw I had a wet spot. But I grabbed a glass of water and pretended to spill it on myself so they'd think it was just water.* [P2, male, 11 y]

In contrast, children expressed that openness about their bladder problems could serve as a way to break the taboo. For those who chose to do so, this openness was met with peer support and contributed to greater self-acceptance.

> *I did my school presentation about my bladder problem. That really helped me, because now my classmates support me. I also have a really good best friend who visits me a lot, and we often talk about it.* [P4, male, 9 y]

> *I think it's important that you can still fit in at school, even with this problem. Almost my whole class knows about it.* [P3, male, 10 y]

Timer watches were not always associated with stigma. Children described that, when designed in a playful, everyday style, the watches could attract desired attention. In these cases, the timer watch was seen as a stigma-free and unique accessory that could be proudly shown to peers.

> *I had one of those timer watches once in rainbow colors, and some kids said, "Wow you have a really cool watch!"* [P3, male, 10 y]

> *When the other kids in the class don't have a watch, they get really jealous.* [P4, male, 9 y]

Theme 3: Contextual Influences

The collaging exercise in particular revealed how various contexts influence children's bladder behavior (Figure 2). Different contexts, such as home, school, or sports, led to varying patterns of hydration, awareness of bladder signals, and incontinence frequency. Gaming and sports were identified as contexts where urine leaks occurred more frequently due to distraction, while school environments were associated with greater attentiveness and fewer incidents.

XSL•FO
RenderX

Figure 2. Example of a collage created by a participant (gray text represents the English translation).



At home I game a lot, and then it sometimes goes wrong. I get wet. Because while gaming, I don't really feel my signals. At school it goes better, because I pay attention to my bladder. I also drink less at home. [P11, male, 10 y]

I swear, when I get wet, it's usually during sports. It just leaks without me noticing. [P2, male, 11 y]

At school or with my friends, I drink a lot and then I go to the bathroom quickly. At home, I barely drink anything. I have to manage everything myself there, and then I forget. [P5, female, 9 y]

At school, I don't really drink anything, so I don't have to pee. [P15, female, 12 y]

Furthermore, specific contexts such as school toilets present their own unique challenges. Dissatisfaction with school toilets was a recurring theme, with children highlighting issues related to poor hygiene and restrictive policies.

At our school, the toilets smell really bad. [P15, female, 12 y]

The toilets at school are really, extremely gross. [P11, male, 10 y]

I got punished at school because I had to go to the toilet. [P8, male, 11 y]

I can go to the toilet at school whenever. Only sometimes they lock the entrance door. [P11, male, 10 y]

Similarly, the doctor's office presented its own challenges as a context. Children reported feeling disconnected during consultations, as interactions were often directed more toward their parents. In these situations, they described becoming disinterested, confused, or disengaged.

The doctor mostly talks to my mom. I just start playing with something, because I don't understand everything they're saying. Then my mom gets mad and says, "Hey, you have to pay attention!" [P11, male, 10 y]

We sometimes go to a doctor, but I don't really know what he does. [P6, female, 9 y]

When I'm at the doctor's office, I go to the toilet just because I don't like being there. [P13, female, 10 y]

In contrast, children described their experiences with in-clinic group therapy very positively. A key factor mentioned by children was the peer support they received from others going through similar challenges. Being part of a group was described as giving them a sense of belonging, trust, and shared understanding, which contrasted with the feelings of isolation often experienced at home or in other settings.

XSL•FO
RenderX

> *I really looked forward to it. It's actually like a sleepover. You can talk to each other 24/7. And it's just nice to be in a room together, play a game, or go gaming together. You sit next to each other, so you can see what's happening. At home, you're really just doing everything on your own.* [P11, male, 10 y]
>
> *It's just nice when someone you really trust and like has the same problem as you.* [P3, male, 10 y]

Theme 4: Digital Integration

As digital natives, the children are highly familiar with digital technologies. This was reflected in the focus groups through references to the regular use of smartphones, games, and other digital technologies.

> *Well, that's literally who I am: phone, selfies, calling.* [P15, female, 12 y]
>
> *At first, I only had two and a half hours of screen time on my phone, but now I'm just allowed to use it as much as I want.* [P17, male, 12 y]
>
> *At home I game a lot. Gaming is my hobby.* [P11, male, 10 y]
>
> *Everything is digital these days.* [P4, male, 9 y]
>
> *I'm not much of a writer.* [P14, female, 13 y]

In discussing urotherapy tools, children referred to their familiarity with digital platforms and contrasted this with traditional tools, such as paper-based bladder diaries or longstanding tools like wetting alarms and timer watches. They reported that these traditional tools were outdated, inconvenient, and misaligned with their digital preferences.

> *The wetting alarm and timer watch are old-fashioned!* [P9, male, 9 y]
>
> *It's annoying that you have to write everything down in your bladder diary. You just want to get on with what you're doing.* [P11, male, 10 y]
>
> *I'm okay with using the measuring cup, but not the paper chart. It's just inconvenient.* [P12, female, 9 y]
>
> *When the wetting alarm goes off, it just vibrates or beeps, but that's kind of basic and just makes you nervous. It should go off in some other, more fun way.* [P3, male, 10 y]

Children also came up with creative suggestions for smart, gamified solutions to enhance the appeal, engagement, and usability of urotherapy tools. These ideas included digitizing traditional tools such as bladder diaries.

> *The bladder diary should be digital so it's quicker to use.* [P3, male, 10 y]
>
> *There should be something that fills in the bladder diary automatically.* [P13, female, 10 y]
>
> *The timer watch should also let you record when you've been wet, like a bladder diary.* [P3, male, 10 y]

Among the ideas expressed were advanced features, such as smart algorithms capable of predicting when the bladder is full or when it is time to drink. It was also suggested that these systems could include self-learning capabilities, adapting over time based on user behavior and feedback.

> *Something that beeps when your bladder is full, instead of when you're already wet.* [P8, male, 11 y]
>
> *Something that predicts when you need to drink and pee using sensors that track how much you've drunk over time, and then tells you when you'll need to pee. You can see it in an app, and maybe even give feedback on whether the prediction was right or not.* [P16, male, 12 y]

Gamification also emerged as a strategy to increase engagement, with ideas such as turning uroflowmetry into a game through scoring systems that reward performance and progress.

> *There should be a mini game on the uroflow toilet. One time I set the record. I think it was 330 ml.* [P10, male, 10 y]
>
> *You could get a score for your uroflow graph, for example, 25 points for "Nice," 50 for "Good," 75 for "Perfect," and 100 for "Excellent." But it's important that the points always stay positive.* [P19, male, 13 y]

Finally, an interactive training buddy, such as a virtual animal or bottle avatar (Figure 3), was proposed as a way to provide age-appropriate encouragement and a sense of companionship.

XSL•FO
RenderX

Figure 3. Children's drawings illustrating concepts for a digital training buddy. (**A**) Little animal that walks across your uroflow curve; (**B**) little bear that reminds you to go to the toilet; (**C**) bottle that gets happier the fuller it gets to remind you to drink.



There could be a little animal, one you get to choose, that walks across your uroflow curve. [P6, female, 9 y]

If you haven't peed in a while, a little bear shows up in the game you're playing on your phone, taps the screen, and says, "You have to go to the toilet!" [P13, female, 10 y]

To help you drink more, there's a bottle on your phone that fills up and gets happier the fuller it gets. When it's completely full, it looks really happy. [P6, female, 9 y]

Despite enthusiasm for digital solutions, children also raised concerns. These included excessive phone use, technical malfunctions, or limitations, and the risk of fostering an overly competitive mindset through gamified features, which could result in disappointment.

If I start doing the bladder diary on my phone, I'll end up looking at other stuff and three hours later, I'm still on my phone. [P14, female, 13 y]

If there's a technical error, your data might not get saved. [P19, male, 13 y]

If you're out and forget your phone, and that's where the bladder diary app is, then you'd have to go back and get your phone. [P18, male, 11 y]

If you make it into a game, then you really want to win, but if you don't succeed, you might feel embarrassed or disappointed, and that's not really nice. [P11, male, 10 y]

Thematic Reflections in Children's Superhero Drawings

The superhero drawing exercise served as a creative and expressive validation of the findings from the focus groups, visually reflecting the core themes that emerged throughout the study. The characters children designed included elements that represented their attitudes, experiences, and desires.

The theme of attitudes and motivation included representations of superheroes who showed a willingness to participate in training and make use of urotherapy tools. For example, child 3 (male, 10 y) created "Captain Underpants," a popular Dutch children's book character, with a wetting alarm attached to his underpants (Figure 4A). Similarly, child 14 (female, 13 y) illustrated the "Time Controller," using tools like the timer watch to master toilet timing (Figure 4B). Child 2 (male, 11 y) envisioned a well-trained superhero with a powerful metal sphincter to prevent urine leakage.

In contrast, child 10 (male, 10 y) created "Diaperman," a robot with an infinite diaper supply (Figure 4C), and child 4 (male, 9 y) a superhero with laser eyes to remove the bladder. These superheroes may reflect a desire for convenience or unrealistic quick fixes rather than commitment to training, aligning with the subtheme of resistance toward training under the same theme of attitudes and motivation.

The theme of social acceptance also emerged through characters such as "Mister Pee" (child 8, male, 11 y), whose superpower is making bullies wet their pants so they can understand what it feels like (Figure 4D), an embodiment of the fear of being bullied. In contrast, characters like Spiderman with a wet spot (Figure 4E) or Superman with a diaper (child 11, male, 10 y) reinforced the idea that bladder problems can affect anyone,

XSL•FO
RenderX

even strong and popular superheroes, supporting the subtheme of openness as a way to break the taboo.

Child 12 (female, 9 y) designed different superhero accessories that grant the power to completely stop urination, but only when worn (Figure 4F). This drawing was categorized within the theme of contextual influences, as it illustrated how bladder control was imagined as dependent on specific situations or conditions.

Finally, many superheroes across drawings were equipped with tools and gadgets, hinting at the theme of digital integration, particularly the subtheme of gamified and smart solutions. These imaginative tools and gadgets often combined functionality with fantasy.

Figure 4. Children's superhero drawings. (**A**) "Captain Underpants" with wetting alarm; (**B**) "Time Controller" with timer watch to master toilet timing; (**C**) "Diaperman" with an infinite diaper supply; (**D**) "Mister Pee" with the power to make bullies wet their pants; (**E**) Spiderman with a wet spot; (**F**) Different superhero accessories to prevent urination while wearing them.



Discussion

Principal Findings

This qualitative focus group study revealed that children's experiences with urotherapy and its tools are shaped by a combination of (1) attitudes and motivations, (2) the need for social acceptance, (3) contextual influences, and (4) a strong desire for digital integration. As digital natives, children perceived many traditional urotherapy tools as outdated and misaligned with their expectations. They expressed a need for tools that support autonomy, discretion, and adaptability. Tools designed in a playful, everyday style were considered less stigmatizing and more socially acceptable. Their own innovative suggestions, ranging from smart predictive algorithms to gamified platforms and interactive training buddies, reflect a desire for more advanced, technology-driven solutions. At the same time, they acknowledged potential pitfalls, such as overuse or dependence on technology.

Strengths and Limitations

We conducted a qualitative study using a novel focus group discussion toolkit comprised of creative and playful exercises tailored to our objectives. While qualitative research in pediatric urology is an emerging field, its potential to capture the lived experiences of young patients is increasingly recognized [22]. The creative exercises used in this study enabled children to share personal and sensitive experiences in a child-friendly and expressive manner, demonstrating the potential of creative methodologies to enrich data quality and participant engagement. To our knowledge, no previous study has adopted such an approach in this field.

This study also has limitations. First, the focus group sessions were relatively long (1.5 to 2 h), which posed challenges in maintaining participants' attention and cooperation.

XSL•FO
RenderX

Nevertheless, the variety of creative and engaging exercises helped sustain children's attention. Second, the generalizability of findings is limited due to the purposive sampling of children undergoing the most intensive form of urotherapy, in-clinic group training in a tertiary care center. Despite this, we believe some transferability exists. These participants can be considered experts by experience, having undergone a broad spectrum of care ranging from outpatient to inpatient urotherapy. Moreover, their strong interest in advanced digital solutions likely reflects a broader trend among children growing up in a digitally native generation. Therefore, while findings should be interpreted within context, they provide valuable insights for improving urotherapy practices and inspiring the design of future urotherapy tools, particularly those involving smart, digital innovations.

Comparison With Prior Work

Our findings align with previous research demonstrating the social impact of peer dynamics, including a desire to conceal bladder problems and fear of bullying [23,24]. Similarly, our results are consistent with earlier studies highlighting contextual challenges, such as dissatisfaction with school toilets [25,26] and limited involvement during doctor consultations, in contrast to the positive influence of peer support experienced during group therapy [27]. Finally, children's interest in gamified, smart solutions aligns with the findings of our concurrent scoping review on innovative, technology-driven, digital tools for managing pediatric urinary incontinence [28]. Many of the tools identified in this review were described as engaging for children, improving patient compliance and leading to high levels of patient satisfaction and preference. Their gamification ideas aligned with the serious games described in the review, further validating the appeal of playful, story-driven engagement strategies. Similarly, the concept of prevoid alarms, which featured prominently in the review, was also proposed by children.

Both the scoping review and the focus group point to critical design features for future product development, including adaptability, personalization, and smart connected systems. What the focus group adds, however, is an important user-centered depth. To truly personalize treatment or tools, one must understand the child's individual context: attitudes, motivation, social context, and emotional needs. Yet, as the focus group revealed, children are not always actively involved during medical consultations, raising the question of how personalization can occur without their active participation. Importantly, the focus group study demonstrated that children can articulate their needs and preferences, especially when supported by creative, child-friendly methods. Their creative input provided a valuable entry point into co-design and communication strategies, as explored further in the Implications and Future Directions section.

Implications and Future Directions

Building on the children's creative ideas shared during the focus groups, we designed a conceptual smart urotherapy solution [29]. This concept incorporates smart algorithms capable of predicting bladder fullness and optimal drinking times by connecting a smart drinking bottle with a home-based uroflowmeter (Figure 5). These devices are linked through a reminder watch, which offers personalized voiding prompts based on the child's fluid intake and estimated bladder capacity. To reduce stigma and enhance social appeal, the design shifts the focus from urination to drinking and features playful, child-friendly esthetics. A digital training buddy, displaying various hydration and urgency states, provides companionship, support, and motivation throughout the therapy process.

Figure 5. Smart urotherapy concept: a smart drinking bottle, reminder watch, and home-based uroflowmeter are interconnected to deliver personalized voiding and drinking prompts via a digital companion on the watch.



Findings also highlight the need for improved child involvement during doctor visits. Children often lacked awareness of their care pathway, suggesting a need for more child-centered communication. The creative methods used, particularly the superhero drawing activity, proved effective in facilitating meaningful dialog and capturing children's emotions, motivations, and experiences. These insights have informed follow-up research focused on further analyzing the drawings to develop a "urotherapy superhero family," intended as a conversation tool during consultations (Figure 6). By inviting children to select a hero companion that represents them during treatment, the tool aims to enhance child engagement, support

XSL•FO
RenderX

emotional expression, and promote a more active role in their care trajectory.

Figure 6. A first design of a urotherapy superhero family, intended as a conversation tool between children and health care providers to promote engagement and a greater sense of child involvement.



Conclusions

This study's use of qualitative and creative methods enabled a rich understanding of how children engage with urotherapy and the tools that support it. It revealed that their experiences are shaped by a complex interplay of personal attitudes and motivations, social dynamics, contextual factors, and a strong desire for digital integration. These insights offer direction for developing future tools that prioritize personalization, stigma-free design, adaptability, and digital innovation. Including children's voices in research and design is essential to ensure that interventions are not only clinically effective but also meaningful and engaging, ultimately contributing to more child-centered care.

Acknowledgments

The generative artificial intelligence tool ChatGPT by OpenAI was used to improve language and readability. The tool provided inspiration on how to rephrase parts of the manuscript, but final edits and decisions were made by the authors. This research is part of a PhD project partially funded by the Flanders Innovation and Entrepreneurship Baekeland grant (project ID HBC.2021.0836) and the company Minze Health.

We also thank the urotherapists at the Wilhelmina Children's Hospital of the University Medical Center Utrecht for their collaboration, support, and for providing time for the sessions within their training program. A special thank you goes to the participants, with the support of their parents, for dedicating their valuable time and contributing to this work.

Data Availability

Full transcripts and recordings from the focus groups cannot be shared due to privacy and ethical reasons; however, anonymized excerpts or thematic summaries are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization of the study was carried out by LB, JV, GDW, AV, and LVC. The investigation was conducted by LB and RFB. LB was responsible for the formal analysis, data curation, and original draft preparation. Review and editing of the manuscript were undertaken by LB, GDW, AV, LVC, and ANL. Supervision was provided by GDW, AV, and LVC. Project administration was handled by ANL. The final manuscript was critically reviewed and approved by all authors.

XSL•FO
RenderX

Conflicts of Interest

GDW is a shareholder and LB, RFB and JV are employees of the digital health company Minze Health. However, the authors' affiliations with Minze Health did not influence the design of the study; the collection, analyses or interpretation of data; the writing of the manuscript; or the decision to publish the results. All other authors declare no conflicts of interest.

Checklist 1
COREQ checklist.
[PDF File, 384 KB - pediatrics_v8i1e79142_app1.pdf]

References

1. Austin PF, Bauer SB, Bower W, et al. The standardization of terminology of lower urinary tract function in children and adolescents: Update report from the standardization committee of the International Children's Continence Society. Neurourol Urodyn 2016 Apr;35(4):471-481. [doi: 10.1002/nau.22751] [Medline: 25772695]
2. Nieuwhof-Leppink AJ, Schroeder RPJ, van de Putte EM, de Jong T, Schappin R. Daytime urinary incontinence in children and adolescents. Lancet Child Adolesc Health 2019 Jul;3(7):492-501. [doi: 10.1016/S2352-4642(19)30113-0] [Medline: 31060913]
3. Thibodeau BA, Metcalfe P, Koop P, Moore K. Urinary incontinence and quality of life in children. J Pediatr Urol 2013 Feb;9(1):78-83. [doi: 10.1016/j.jpurol.2011.12.005] [Medline: 22236468]
4. Bower WF. Self-reported effect of childhood incontinence on quality of life. J Wound Ostomy Contin Nurs 2008;35(6):617-621. [doi: 10.1097/01.WON.0000341476.71685.78]
5. Chang SJ, Van Laecke E, Bauer SB, et al. Treatment of daytime urinary incontinence: a standardization document from the International Children's Continence Society. Neurourol Urodyn 2017 Jan;36(1):43-50. [doi: 10.1002/nau.22911] [Medline: 26473630]
6. Rivers CL. School nurse interventions in managing functional urinary incontinence in school-age children. J Sch Nurs 2010 Apr;26(2):115-120. [doi: 10.1177/1059840509356776] [Medline: 20065097]
7. Glad Mattsson G, Brännström M, Eldh M, Mattsson S. Voiding school for children with idiopathic urinary incontinence and/or bladder dysfunction. J Pediatr Urol 2010 Oct;6(5):490-495. [doi: 10.1016/j.jpurol.2009.11.004] [Medline: 19945349]
8. Ku JH, Jeong IG, Lim DJ, Byun SS, Paick JS, Oh SJ. Voiding diary for the evaluation of urinary incontinence and lower urinary tract symptoms: prospective assessment of patient compliance and burden. Neurourol Urodyn 2004;23(4):331-335. [doi: 10.1002/nau.20027] [Medline: 15227650]
9. Hagstroem S, Rittig S, Kamperis K, Djurhuus JC. Timer watch assisted urotherapy in children: a randomized controlled trial. J Urol 2010 Oct;184(4):1482-1488. [doi: 10.1016/j.juro.2010.06.024] [Medline: 20727552]
10. Yamanishi T, Yasuda K, Murayama N, Sakakibara R, Uchiyama T, Ito H. Biofeedback training for detrusor overactivity in children. J Urol 2000 Nov;164(5):1686-1690. [Medline: 11025748]
11. Maternik M, Krzeminska K, Zurowska A. The management of childhood urinary incontinence. Pediatr Nephrol 2015 Jan;30(1):41-50. [doi: 10.1007/s00467-014-2791-x] [Medline: 24615564]
12. Schäfer SK, Niemczyk J, von Gontard A, Pospeschill M, Becker N, Equit M. Standard urotherapy as first-line intervention for daytime incontinence: a meta-analysis. Eur Child Adolesc Psychiatry 2018 Aug;27(8):949-964. [doi: 10.1007/s00787-017-1051-6] [Medline: 28948380]
13. Schulman SL, Von Zuben FC, Plachter N, Kodman-Jones C. Biofeedback methodology: does it matter how we teach children how to relax the pelvic floor during voiding? J Urol 2001 Dec;166(6):2423-2426. [doi: 10.1016/s0022-5347(05)65607-8] [Medline: 11696803]
14. Klijn AJ, Uiterwaal C, Vijverberg MAW, Winkler PLH, Dik P, de Jong T. Home uroflowmetry biofeedback in behavioral training for dysfunctional voiding in school-age children: a randomized controlled study. J Urol 2006 Jun;175(6):2263-2268. [doi: 10.1016/S0022-5347(06)00331-4] [Medline: 16697850]
15. Nock MK, Photos V. Parent motivation to participate in treatment: assessment and prediction of subsequent participation. J Child Fam Stud 2006 Jun;15(3):333-346. [doi: 10.1007/s10826-006-9022-4]
16. Joiner R, Gavin J, Brosnan M, et al. Comparing first and second generation digital natives' internet use, internet anxiety, and internet identification. Cyberpsychol Behav Soc Netw 2013 Jul;16(7):549-552. [doi: 10.1089/cyber.2012.0526] [Medline: 23675995]
17. Vijverberg MAW, Elzinga-Plomp A, Messer AP, van Gool JD, de Jong T. Bladder rehabilitation, the effect of a cognitive training programme on urge incontinence. Eur Urol 1997;31(1):68-72. [doi: 10.1159/000474421]
18. Meijer EFJ, Nieuwhof-Leppink AJ, Dekker-Vasse E, de Joode-Smink GCJ, de Jong T. Central inhibition of refractory overactive bladder complaints, results of an inpatient training program. J Pediatr Urol 2015 Feb;11(1):21. [doi: 10.1016/j.jpurol.2014.06.024] [Medline: 25205144]
19. Bladt L, Nieuwhof-Leppink A, Broeck L, et al. The design of an engaging focus group discussion toolkit involving school-aged children following urotherapy. In: Connectivity and Creativity in Times of Conflict: Academia Press; 2023. [doi: 10.26530/9789401496476-078]

XSL•FO
RenderX

20. Guest G, Bunce A, Johnson L. How many interviews are enough? Field methods 2006 Feb;18(1):59-82. [doi: 10.1177/1525822X05279903]
21. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res 2005 Nov;15(9):1277-1288. [doi: 10.1177/1049732305276687] [Medline: 16204405]
22. Neuzil K, McCloskey K, Chan K. Qualitative research in pediatric urology. J Pediatr Urol 2023 Feb;19(1):92-97. [doi: 10.1016/j.jpurol.2022.10.034] [Medline: 36435681]
23. Whale K, Cramer H, Joinson C. Left behind and left out: the impact of the school environment on young people with continence problems. Br J Health Psychol 2018 May;23(2):253-277. [doi: 10.1111/bjhp.12284] [Medline: 29228510]
24. Malhotra NR, Kuhlthau KA, Rosoklija I, Migliozzi M, Nelson CP, Schaeffer AJ. Children's experience with daytime and nighttime urinary incontinence - a qualitative exploration. J Pediatr Urol 2020 Oct;16(5):535. [doi: 10.1016/j.jpurol.2020.10.002] [Medline: 33148456]
25. Lundblad B, Hellström AL. Perceptions of school toilets as a cause for irregular toilet habits among schoolchildren aged 6 to 16 years. J Sch Health 2005 Apr;75(4):125-128. [doi: 10.1111/j.1746-1561.2005.tb06656.x] [Medline: 15987005]
26. Jørgensen CS, Breinbjerg AS, Rittig S, Kamperis K. Dissatisfaction with school toilets is associated with bladder and bowel dysfunction. Eur J Pediatr 2021 Nov;180(11):3317-3324. [doi: 10.1007/s00431-021-04111-1] [Medline: 33999258]
27. Saarikoski A, Koppeli R, Salanterä S, Taskinen S, Axelin A. Voiding school as a treatment of daytime incontinence or enuresis: Children's experiences of the intervention. J Pediatr Urol 2018 Feb;14(1):56. [doi: 10.1016/j.jpurol.2017.09.009] [Medline: 29037865]
28. Bladt L, Vermeulen J, Vermandel A, De Win G, Van Campenhout L. Innovative, technology-driven, digital tools for managing pediatric urinary incontinence: scoping review. Interact J Med Res 2025;14:e66336. [doi: 10.2196/66336]
29. Bladt L, Blomme RF, Nieuwhof-Leppink AJ, Vermandel A, De Win G, Van Campenhout L. Design of a healthcare ecosystem to improve user experience in pediatric urotherapy. Proc Des Soc 2024 May;4:1567-1576. [doi: 10.1017/pds.2024.159]

Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research

Edited by S Badawy; submitted 16.06.25; peer-reviewed by G Raman, R Azar; revised version received 25.08.25; accepted 10.09.25; published 16.10.25.

Please cite as:
Bladt L, Nieuwhof-Leppink A, Blomme RF, Vermeulen J, Vermandel A, De Win G, Van Campenhout L
Understanding Pediatric Patient Experiences with Urotherapy Tools: Qualitative Focus Group Study
JMIR Pediatr Parent 2025;8:e79142
URL: https://pediatrics.jmir.org/2025/1/e79142
doi:10.2196/79142

© Lola Bladt, Anka Nieuwhof-Leppink, Rose-Farah Blomme, Jiri Vermeulen, Alexandra Vermandel, Gunter De Win, Lukas Van Campenhout. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 16.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Likelihood of Leveraging Augmented Reality Technology to Promote HIV Prevention and Treatment Among Adolescent Girls and Young Women in Cameroon: Cross-Sectional Survey

Zhao Ni[1,2], BMed, PhD; Intan Maharani Sulistyawati Batubara[1,2], MSN; Jackson Jr Nforbewing Ndenkeh[1], PhD; Georges Bediang[3,4], PhD, MD; Habakkuk Yumo[3,5], PhD; Xuehong Zhang[1], PhD; Sunyong Oh[1], MSN; Yuchen Zhao[6], MA; LaRon E Nelson[1,2], PhD

[1]School of Nursing, Yale University, 400 West Campus Drive, Orange, CT, United States

[2]Center for Interdisciplinary Research on AIDS (CIRA), Yale University, New Haven, CT, United States

[3]Research for Development (R4D) International Foundation, Yaounde, Cameroon

[4]Faculty of Medicine and Biomedical Sciences, University of Yaounde, Yaounde, Cameroon

[5]Transatlantic Health Solutions LLC, Mesquite, TX, United States

[6]School of Literature, Media, and Communication, Georgia Institute of Technology, Atlanta, GA, United States

Corresponding Author:
Zhao Ni, BMed, PhD
School of Nursing, Yale University, 400 West Campus Drive, Orange, CT, United States

Abstract

Introduction: Adolescent girls and young women in sub-Saharan Africa (SSA) represent 4 out of every 5 newly diagnosed HIV cases among adolescent girls and young women globally. Leveraging augmented reality (AR) technology for HIV prevention and treatment holds significant potential among young people. However, there is a knowledge gap regarding the acceptance of AR by adolescent girls and young women in SSA.

Objective: This study aimed to assess the likelihood of adolescent girls and young women in Cameroon using AR for HIV testing, prevention, and treatment. The study findings will lay the groundwork for developing AR-based interventions to prevent and treat HIV in Cameroon and beyond.

Methods: This was a cross-sectional survey conducted in Yaounde, Cameroon, in which 637 adolescent girls and young women were recruited using a combination of multistage cluster and snowball sampling techniques. We used an electronic survey to collect data on participants' knowledge, prior use of AR technology, and likelihood of using AR technology for HIV prevention and treatment, and associated factors. Multivariate ordinal regressions were used to analyze the factors associated with the likelihood of adolescent girls and young women using AR to prevent HIV.

Results: The study showed that 84% (536/637) of adolescent girls and young women had never heard of AR before this study, and only 8% (49/637) had prior experience using AR. Participants' median age was 22 (IQR 21 - 24) years, with the majority (362/637, 56.8%) aged between 21 and 25 years. Despite the low usage rate of AR among participants, there was a high likelihood of using AR to promote HIV prevention and treatment. Specifically, 72% (459/637) of participants reported that they were likely to use AR to visualize the HIV transmission process, while 73% (465/637) and 74% (471/637) reported the likelihood of using AR to learn about pre-exposure prophylaxis (PrEP) and how HIV medication lowers HIV viral load, respectively. More importantly, 54% (342/637) and 50% (319/637) of participants reported that they were extremely likely to use AR to learn the correct way of using condom and self-testing for HIV, respectively. The high likelihood of using AR to prevent and treat HIV was associated with a higher education level (P=.01), having ever tested for HIV (P=.03), and a history of previously using health apps or searching for health information on their phones (P<.001).

Conclusions: The likelihood of using AR technology to promote HIV prevention and treatment is high among adolescent girls and young women in Cameroon. Future research should focus on exploring the preferred features of AR-based digital health interventions and consider methods of implementing them in the context of Cameroon or SSA.

(JMIR Pediatr Parent 2025;8:e69471) doi:10.2196/69471

KEYWORDS

adolescent; augmented reality; AR; mHealth; mobile apps; HIV/AIDS; PrEP; women; pre-exposure prophylaxis

XSL•FO
RenderX

Introduction

In sub-Saharan Africa (SSA), the most vulnerable population for HIV is adolescent girls and young women [1]. Among adolescent girls and young women globally, 4 out of every 5 newly diagnosed HIV cases occur in SSA [2,3]. Cameroon, a lower-middle-income country with a population of 29 million, has the highest HIV prevalence rate in West Central Africa. Women, particularly those aged 15‐49 years, are disproportionately affected by the virus [4-7]. This health disparity among women is related to various factors, including limited access to health care resources, unbalanced power dynamics in sexual communication, reduced awareness of risk behaviors associated with HIV, and the absence of an enabling environment for women [8]. Consequently, the number of new infections among adolescent girls and young women in Cameroon is more than twice that of their male counterparts [9]. To eliminate the burden of HIV, the government of Cameroon has initiated national strategic plans aimed at reducing the HIV incidence by 65% by 2023 [7]. Although Cameroon is making progress in the fight against HIV, with a 50% decrease in HIV prevalence among people aged 15 to 64 years in the past 14 years, the 65% goal has not yet achieved [10]. This shortfall is associated with factors at individual, health system, and structural levels, including delays in diagnosis and linkage to HIV care, as well as insufficient engagement among persons who initiate care [11]. To end HIV in Cameroon, the national strategic plans of Cameroon emphasize the importance of providing adolescents and young people the right skills to protect themselves from HIV [7]. Under this backdrop, it is necessary to develop and test innovative, effective, and culturally appropriate approaches to enhance efforts in fighting against HIV in Cameroon, reduce health disparities, and promote HIV testing and pre-exposure prophylaxis (PrEP) use among adolescent girls and young women [12].

Innovative technologies, such as augmented reality (AR), have been integrated into mobile health (mHealth) interventions to promote user engagement, enhance interactive learning, and provide tailored health information [13]. AR is broadly defined as a technology, usable on devices such as smartphones, tablets, glasses, headsets, and so on, that overlays computer-generated information, such as avatars, images, and sounds, onto the users' real environment in real time to enhance users' interactive experience [13,14]. Additionally, a major technical limitation of conventional HIV prevention strategies is their lack of offering an interactive and immersive environment to enhance users' experience [15-17]. To young people who are more open to technology, AR-based mHealth interventions could offer innovative solutions, through its immersive and interactive qualities, to enhance HIV health education, communication for behavioral change, and reduce stigma. For example, studies have found that AR applications have the potential to significantly increase user engagement, promote information retention, and enhance users' satisfaction [18]. Furthermore, AR-based interventions have the capability to influence people's perceptions of HIV prevention, potentially revolutionizing health education and behavior change initiatives, with youth as the primary target audience [19].

Despite their potential, most AR-based mHealth interventions have been conducted in high-income countries, leaving insufficient evidence of their applicability in low-income settings [20]. Some AR-based interventions, including "Floating heart" 3D imaging [21], mLearning [22], BodyExplorer [23], and FlexAR [24,25], have demonstrated preliminary but significant outcomes in medical education. However, their application to improve HIV prevention (including condom use and HIV PrEP uptake) is very sparse. Also, implementing AR interventions in resource-limited settings often faces technical challenges, including the need for smartphones with AR capabilities and reliable internet connections. A previous analysis has highlighted a high ownership of smartphones and access to the internet among adolescent girls and young women in Yaounde, Cameroon [17], indicating a favorable environment for implementing digital health interventions like AR-based mHealth programs. Understanding how adolescent girls and young women in Cameroon perceive and engage with AR technology is crucial for designing effective, culturally tailored health interventions. To date, the usability and effectiveness of AR technology in HIV prevention among adolescent girls and young women in Cameroon and the SSA region is unknown. Therefore, this study aimed to assess the likelihood of adolescent girls and young women using AR for the promotion of HIV testing, prevention, and treatment. This study also sought to identify factors associated with the likelihood of adolescent girls and young women adopting AR-based health interventions, informing the design of future AR-based mHealth interventions in Cameroon and the SSA region.

Methods

Study Sample and Data Collection

This was a cross-sectional study conducted from February to June 2023, in which 637 participants were recruited from Yaounde, Cameroon, where a variety of adolescent girls and young women were residing. To be eligible to participate in this study, individuals must be cisgender women aged 18 to 30 years, able to understand the study questions, and mentally healthy enough to voluntarily give informed consent.

The study procedures have been published elsewhere [17]. In brief, participants were recruited using a multistage cluster sampling technique based on Cameroonian health districts and health areas, combined with a snowball sampling technique wherein a consenting participant referred other potential participants. This recruitment method was chosen to ensure the inclusion of participants with diverse demographic backgrounds within Cameroon. Data were collected as pseudonymized data using a survey questionnaire implemented on Yale Qualtrics, a secure electronic survey platform. The Qualtrics questionnaire was administered with the assistance of 2 well-trained enumerators, who could hand their phones to participants to select their own responses, especially for sensitive questions. For reasons of data protection and confidentiality, participants' identifier codes were only known to the 2 enumerators involved in fieldwork and JJNN, who possesses the signed inform consent forms.

XSL•FO
RenderX

Ethical Considerations

This study received ethical approvals from the Yale University Institutional Review Board (ID: 2000033713) and the Cameroonian Centre Regional Ethics Committee for Human Health Research (initial ID: CE number 02058/CRERSHC/2022, and extension ID: CE number 02058/CRERSHC/2023). Additionally, this study has received administrative authorization from the Cameroonian Centre Regional Delegation for Public Health. Data were pseudonymized and all participants provided informed consent.

Measures

Sociodemographic and Baseline Characteristics

Sociodemographic variables included age, monthly income, educational level, and geographical zone of origin. Other characteristics included sexual orientation, phone ownership and use, awareness of AR, and previous experience with AR. Specifically, phone ownership was measured by the question "Do you own or have access to the following devices on a daily basis (check all that apply: landline telephone, mobile phone without internet access, smartphone, tablet, laptop, and personal computer)?" Participants' awareness of AR was measured by the question "Have you ever heard about Augmented Reality (Yes or No)?" For those who were aware of AR, their previous experience with AR was measured by the question "Have you ever used Augmented Reality (Yes or No)?" For participants who had used AR, a follow-up question was asked to study the features of AR that they used: "Why do you use Augmented Reality in your daily life? Select all that apply (Immersive, interactive, virtual world, embodiment, sensory feedback, other, please specify)."

Likelihood of Using AR

The primary outcome variable was the likelihood of using AR for health purposes, measured as a composite score of 7 subscales. The seven subscales measured the likelihood of leveraging AR to (1) visualize the HIV transmission process, (2) demonstrate the correct way of using a condom, (3) introduce daily PrEP, (4) depict the HIV testing process in a clinical or NGO setting, (5) show the HIV self-testing process, (6) explain the process of receiving HIV treatment, and (7) illustrate how HIV medication lowers the HIV viral load. Participants' responses to each subscale were measured using a 5point Likert scale, ranging from 1 (extremely unlikely) to 5 (extremely likely). For example, the likelihood of leveraging AR to visualize the HIV transmission process was measured by the question: "If we build an Augmented Reality (AR) app for you to visualize the HIV transmission process, how likely would you be to use the AR?" and the likelihood of leveraging AR to demonstrate the correct way of using a condom was assessed by the question: "If we build an Augmented Reality (AR) app demonstrating the correct way of using condom, how likely would you be to use the AR?" A composite score was calculated for each participant as the mean score of the seven 5-point Likert subscales, rounded to the nearest whole number. Specifically, for each of the above subscales, we quantified their responses using a scale ranging from 1 to 5, followed by calculating the mean of these responses and rounded the results to the nearest whole number within the same Likert scale.

Statistical Analyses

Statistical analyses were conducted using R software version 4.3.1 (R Core Team). Categorical variables were presented as absolute and relative frequencies, as well as cross tabulations of the likelihood categories to use AR. Proportions of the likelihood to use AR for HIV prevention were calculated, where the numerators were the number of participants who selected any of the ordinal response categories (ie, extremely unlikely, somewhat unlikely, neither likely nor unlikely, somewhat likely, and extremely likely), and the denominator was the total number of study participants. To determine factors associated with the likelihood of using AR for health purposes, ordinal logistic regression was applied using the "*polr*" function. Univariate analyses were initially conducted to identify covariates of interest (with $P<.10$), which were then put together in a model to adjust for each other's effect in a multivariate analysis. The level of significance for the multivariate analysis was set at 5%. The exhaustive list of independent variables of the univariate analyses include: age group, region of origin, sexual orientation, education level, employment status, monthly revenue, marital status, housing condition, ownership of (or access to) smartphone or tablet with internet, history of health app use or phone for health information search, HIV testing situation, sexually transmitted infection diagnosis within past 6 months, vulnerable sexual behavior and PrEP awareness.

Results

Participant Characteristics

Participants' median age was 22 (IQR 21 - 24) years, with the majority (362/637, 56.8%) aged between 21 and 25 years. Most participants were heterosexual (599/637, 94%), unmarried (485/637, 76.1%), and were unaware of PrEP (519/637). We also found that 93.9% (598/637) of participants had access to a smartphone, 42.4% (270/637) had access to a laptop or personal computer, and 9.9% (63/637) owned a tablet or iPad [17]. Among the 637 participants, 84.1% (n=536) had never heard of AR, and only 7.7% (n=49) had used AR. Among those who had ever used AR, 51% (25/49) used virtual world, 20% (10/49) used embodiment features, 10% (5/49) used interactive elements, 10% (5/49) used sensory feedback, and 8% (4/49) used immersive features.

Likelihood to use AR for Health Purposes and Associated Factors

Overall, the likelihood of using AR for health purposes was high, with 72.8% (464/637) of participants somewhat or extremely likely to use AR, compared to 10.5% (67/637) of participants somewhat or extremely unlikely to use AR. It should be noted that for each of the health purposes, at least 45% (287/637) of participants were extremely likely to use AR, with 53.7% (342/637) preferring to use AR for learning condom use and 50.1% (319/637) preferring to use AR for learning the process of HIV self-testing (Table 1).

XSL•FO
RenderX

Table . Participants' likelihood to use augmented reality for health purposes (N=637).

Variable	Extremely unlikely, n (%)	Somewhat unlikely, n (%)	Neither likely nor unlikely, n (%)	Somewhat likely, n (%)	Extremely likely, n (%)
Likelihood to use AR[a] if it was built to visualize the HIV transmission process	19 (2.9)	55 (8.6)	106 (16.6)	169 (26.5)	288 (45.2)
Likelihood to use AR if it was built to demonstrating the correct way of using condom	18 (2.8)	47 (7.4)	80 (12.6)	150 (23.5)	342 (53.7)
Likelihood to use AR if it was built to introduce daily PrEP[b]	19 (2.9)	59 (9.3)	96 (15.1)	155 (24.3)	308 (48.4)
Likelihood to use AR if it was built to demonstrate the HIV testing process in a clinical or NGO[c] setting	17 (2.7)	60 (9.4)	99 (15.5)	150 (23.5)	311 (48.8)
Likelihood to use AR if it was built to demonstrate the HIV self-testing process	15 (2.4)	58 (9.1)	94 (14.8)	151 (23.7)	319 (50.1)
Likelihood to use AR if it was built to demonstrate the process of receiving HIV treatment	14 (2.2)	58 (9.1)	97 (15.2)	161 (25.3)	307 (48.2)
Likelihood to use AR if it was built to demonstrate how HIV medication lowers HIV viral load	14 (2.2)	57 (8.9)	95 (14.9)	162 (25.4)	309 (48.5)
Overall likelihood of using AR (a composite score of the above variables)	7 (1.1)	60 (9.4)	106 (16.6)	168 (26.4)	296 (46.5)

[a]AR: augmented reality.

[b]PrEP: pre-exposure prophylaxis.

[c]NGO: nongovernmental organization.

In unadjusted analyses of the ordinal logistic regression (Table 2), increasing likelihood to use AR for health purposes was associated with education level, sexual orientation, access to a smartphone or tablet, previous use of a health app or a phone for health-related information search, diagnosis of sexually transmitted infection within past 6 months, HIV testing, and awareness of PrEP.

XSL•FO
RenderX

Table . Factors associated with participants' likelihood to use augmented reality for health purposes (N=637).

Variables	OR[a] (95% CI)	*P*[b] value	aOR[c] (95% CI)	*P* value
Education level		<.001		.01
Uneducated or primary	1		1	
Secondary	3.3 (2.16 - 5.01)		2.0 (1.27 - 3.25)	
Higher	3.1 (1.89 - 5.28)		1.6 (0.85 - 2.88)	
Sexual orientation		.02		.047
Heterosexual or straight	1		1	
Bisexual or lesbian or other	0.5 (0.26 - 0.91)		0.5 (0.28 - 1.01)	
Employment status		.08		.24
Unemployed	1		1	
Employed	0.7 (0.5 - 1.04)		0.8 (0.49 - 1.2)	
Phone or Tablet with internet		.002		.48
No	1		1	
Yes	2.7 (1.46 - 4.97)		1.3 (0.65 - 2.46)	
History of health app use or phone health info search		<0.001		<0.001
No	1		1	
Yes	3.6 (2.28 - 4.95)		2.2 (1.41 - 3.42)	
HIV testing		<0.001		.03
Never	1		1	
>12 months	1.2 (0.85 - 1.71)		1.2 (0.8 - 1.7)	
≤12 months	2.02 (1.4 - 2.89)		1.7 (1.14 - 2.62)	
STI[d] in the past 6 months		.007		.21
No	1		1	
Yes	1.7 (1.15 - 2.42)		1.3 (0.86 - 1.98)	
Aware of PrEP		.002		.18
No	1		1	
Yes	1.9 (1.26 - 2.77)		1.3 (0.88 - 2.06)	

[a]OR: odds ratio

[b]Only variables with *P*<0.1 in univariate analaysis are shown in this table.

[c]aOR: adjusted odds ratio.

[d]STI: sexually transmitted infection.

Upon adjusting for all key covariates in a multivariate model, an increasing likelihood to use AR for health purposes was independently associated with a higher level of education (*P*=.01), having used a health-related app before or using a phone to search for health-related information (aOR 2.2, 95% CI 1.41 - 3.42; *P*<.001), and having tested for HIV, notably less than 12 months ago (aOR 1.7, 95% CI 1.41 - 2.62; *P*=.03), compared to those who have never undertaken an HIV test. Additionally, a decreasing likelihood to use AR for health purposes was independently associated with participants who identified as sexual minorities (aOR 0.5, 95% CI 0.28 - 1.01; *P*=.04), compared to heterosexual participants.

Discussion

Principal Findings

The integration of AR into HIV prevention strategies holds promise for enhancing education, improving accessibility, and ultimately reducing the spread of HIV. However, there is a knowledge gap regarding how AR technology, which garners increasing interest worldwide, can be best used for HIV prevention in resource-limited settings. This study seeks to address the literature gap on the feasibility of using AR technology for HIV prevention among adolescent girls and young women in the Cameroonian context. The findings of this study have provided valuable information on the likelihood of Cameroonian adolescent girls and young women to use AR to

XSL•FO
RenderX

learn about HIV testing, prevention, and treatment. Overall, there was a low prior knowledge of AR among adolescent girls and young women, accompanied by an even lower prior use of AR technology. Despite this, the likelihood of adolescent girls and young women using AR was high, with at least 45% indicating they were extremely likely to use AR interventions for HIV testing, prevention, and treatment, such as acquiring knowledge about HIV transmission, HIV testing, self-testing processes, correct condom use, HIV treatment, daily PrEP, and information on how HIV medication reduces viral load. This finding is particularly significant given that a study conducted in the Northwest region of Cameroon showed a high prevalence of inconsistent condom use among young women with HIV [26]. To end HIV in Cameroon and SSA, more comprehensive educational programs on sexual and reproductive health for adolescent girls and young women, including distribution and empowerment of female condom use, are necessary.

This study also indicated that leveraging AR is worth exploring in Cameroon. Globally, the awareness and use of AR for adolescent girls and young women in resource-limited settings is low compared to their counterparts in high-income settings [27]. This is mainly due to differences in access to AR technology, internet connectivity, and the integration of AR in education and entertainment [27]. Despite this, there have been a few commendable initiatives on the use of AR in SSA, notably in medical training, where it has shown to enhance the learning process and performance through more interactive and engaging experiences [28,29]. These initiatives, along with our study finding on the high likelihood of using AR among adolescent girls and young women, indicate that leveraging AR for HIV prevention in SSA is possible and should be given serious consideration.

This consideration is further justified by the interactive nature of AR technology. Compared with many early mHealth interventions, mobile apps embedded with AR technology can provide an immersive, interactive learning environment for people to receive real-time information, motivation, and behavioral skills. Considering the widespread adoption of smartphones among young people in resource-limited settings and the permeation of digital technologies in developing countries, AR-based mobile apps have significant potential for facilitating behavior change communication in HIV prevention efforts. For example, in a context where the ability of adolescent girls and young women to negotiate condom use during sexual acts is greatly influenced by a lack of comprehensive knowledge on HIV and cultural and social norms [30-32], AR technology, through interactive and educative role-play scenarios, may enhance their ability to effectively negotiate and correctly use condoms. Despite the lack of previous research on AR for HIV prevention among adolescent girls and young women, we believe that the expanded use and integration of technology-delivered interventions, such as mobile apps, websites, live chats, chatbots, vending machines, virtual reality and AR, when guided by theoretical frameworks, can assist adolescent girls and young women in engaging in self-care for HIV testing and prevention [33,34]. For instance, in 2018, the Joint United Nations Programme on HIV/AIDS (UNAIDS) teamed up with Google and Makhulu Media to release a series of virtual reality educational films on HIV testing. These films were distributed in clinics, schools, and communities across South Africa to encourage people to test for HIV, potentially reshaping attitudes and reducing HIV-related stigma [35].

Our study has identified several factors associated with the likelihood of adolescent girls and young women to use AR technology for health purposes. We observed that adolescent girls and young women with at least secondary education level were more likely to use AR for HIV prevention than those with less education. This might be because individuals with higher levels of education tend to have better digital literacy skills as education provides opportunities for engagement with digital technologies and developing necessary digital competencies [36,37]. We also observed that those who had previous exposure to mHealth apps and/or sought health-related information on mobile devices were more likely to accept AR use compared to those who did not use health apps or use their phones for health information inquiries. Given that mobile devices are integrated into everyday life, offering numerous opportunities to enrich the learning experience, prior exposure to smartphones in learning activities might have made them familiar and comfortable with technology-based health interventions [38].

In this study, we also found that adolescent girls and young women who had undergone HIV testing within the past 12 months had a higher likelihood of using AR for HIV prevention compared to those who had never been tested. This increased likelihood might be attributed to the counseling and education services related to HIV testing, which have raised awareness of HIV vulnerability and the preventive behavioral changes that should be adopted, thus increasing their openness to the potential role of AR technology in HIV prevention. Additionally, adolescent girls and young women who identified as sexual minorities (bisexual, lesbian, or other), compared to heterosexual, exhibited lower likelihoods to use AR for HIV-related services. This may be due to a lack of tailored HIV prevention that specifically address the needs and concerns of sexual minorities given the legal and social environment around same-sex relationships in Cameroon. It could also be due to stigma and discrimination based on sexual orientation, which may create barriers to accessing health care services, thus influencing the health care utilization and behavior of young female sexual minorities [39]. Furthermore, cultural and societal norms within certain communities in Cameroon may marginalize such populations [40].

Limitations

Although our study has contributed valuable knowledge to the field of leveraging AR in Cameroon to prevent HIV among adolescent girls and young women, its findings should be applied with consideration of the following limitations. First, although we used multistage cluster sampling that randomly selected 4 health districts followed by the selection of at least 2 health areas from each health district, which increased the representation of adolescent girls and young women from the various regions of Cameroon based in Yaounde, our study sample was ultimately recruited using the snowball technique, relying on referrals from participants' personal networks. This limits the generalizability of our study findings to all regions

XSL•FO
RenderX

of Cameroon notably semiurban and rural areas which potentially lack the infrastructure to effectively run digital interventions. Second, while investigating their likelihood of using AR technology, we provided participants with an AR definition but did not provide an actual AR device or intervention; therefore, participants' understanding of AR technology might be limited to only a conceptional level rather than with deeper user experience. This might have brought some biases within participant feedback and responses. Nonetheless, building on the findings of this study, our team aims to develop an AR-based mHealth intervention in the future to promote HIV prevention among adolescent girls and young women within the metropolitan cities of Cameroon.

Conclusions

Our study reveals that the likelihood of leveraging AR for HIV prevention among adolescent girls and young women in Cameroon is high, particularly among those with higher educational levels and those who have previously used mobile apps for health purposes. The findings lay the foundation for the necessity of developing and testing AR-based interventions to prevent HIV in Cameroon. These interventions should be based on behavioral theories, Cameroonian culture, and the preferences of adolescent girls and young women in Cameroon.

Acknowledgments

We thank the two enumerators, Apeh Alfred and Pepah Grace, for their time and efforts in helping collect data and in answering questions in our weekly Yale-Cameroon research project meetings. This study received funding from Yale University School of Nursing through the PRIME (Pilot Research, Innovation, and Maximum Health Equity / Excellence) Research Grant and the Faculty Research Support Fund for Zhao Ni.

Authors' Contributions

Conceptualization & methodology: ZN, IMSB, JJNN; funding acquisition: ZN; project administration: ZN, JJNN, LEN; formal analysis and visualization: ZN, IMSB, JJNN, XZ, SO, YZ; analysis review, revision and validation: ZN, IMSB, JJNN, GB, HY, XZ, SO, YZ, LEN; writing—original draft: ZN, IMSB, JJNN; writing—review & editing: ZN, IMSB, JJNN, GB, HY, XZ, SO, YZ, LEN.

Conflicts of Interest

None declared.

References

1. Murewanhema G, Musuka G, Moyo P, Moyo E, Dzinamarira T. HIV and adolescent girls and young women in sub-Saharan Africa: a call for expedited action to reduce new infections. IJID Reg 2022 Dec;5:30-32. [doi: 10.1016/j.ijregi.2022.08.009] [Medline: 36147901]
2. Mhungu A, Sixsmith J, Burnett E. Adolescent girls and young women's experiences of living with HIV in the context of patriarchal culture in sub-Saharan Africa: a scoping review. AIDS Behav 2023 May;27(5):1365-1379. [doi: 10.1007/s10461-022-03872-6] [Medline: 36318422]
3. HIV and adolescent girls and young women. UNAIDS. 2023. URL: https://thepath.unaids.org/wp-content/themes/unaids2023/assets/files/thematic_fs_hiv_girls_women.pdf [accessed 2025-04-03]
4. Alomepe J, Buseh AG, Awasom C, Snethen JA. Life with HIV: insights from HIV-infected women in Cameroon, Central Africa. J Assoc Nurses AIDS Care 2016;27(5):654-666. [doi: 10.1016/j.jana.2016.04.010] [Medline: 27260684]
5. Bekolo CE, Kouanfack C, Ateudjieu J, et al. The declining trend in HIV prevalence from population-based surveys in Cameroon between 2004 and 2018: myth or reality in the universal test and treat era? BMC Public Health 2023 Mar 13;23(1):479. [doi: 10.1186/s12889-023-15374-8] [Medline: 36915039]
6. Defo D, Kouotou EA, Nansseu JR. Failure to return to receive HIV-test results: the Cameroon experience. BMC Res Notes 2017 Jul 24;10(1):309. [doi: 10.1186/s13104-017-2632-7] [Medline: 28738886]
7. Cameroon's national strategic plan for fight against HIV/AIDS and stis, 2021-23. Cameroon Ministry of Public Health. 2021. URL: https://hivpreventioncoalition.unaids.org/en/resources/cameroon-national-strategic-plan-fight-against-hivaids-and-sti-2021-2023#:~:text=The%20Cameroon%202021%E2%80%932023%20national,as%20to%20ensure%20respect%20for [accessed 2024-10-03]
8. Sia D, Onadja Y, Hajizadeh M, Heymann SJ, Brewer TF, Nandi A. What explains gender inequalities in HIV/AIDS prevalence in sub-Saharan Africa? Evidence from the demographic and health surveys. BMC Public Health 2016 Nov 3;16(1):1136. [doi: 10.1186/s12889-016-3783-5] [Medline: 27809824]
9. Cameroon population-based HIV impact assessment CAMPHIA 2017. PHIA Project. 2018. URL: https://phia.icap.columbia.edu/wp-content/uploads/2018/07/3471CAMPHIA_Cameroon-SS_A4_v13_requests_7.25.18.pdf [accessed 2025-04-03]
10. Cameroon making progress in the fight against HIV. World Health Organization. 2023. URL: https://www.afro.who.int/countries/cameroon/news/cameroon-making-progress-fight-against-hiv [accessed 2024-10-07]

XSL•FO
RenderX

11. Parcesepe AM, Filiatreau LM, Ebasone PV, et al. Gender, mental health, and entry into care with advanced HIV among people living with HIV in Cameroon under a national "Treat All" policy. AIDS Behav 2021 Dec;25(12):4018-4028. [doi: 10.1007/s10461-021-03328-3] [Medline: 34091803]
12. HIV prevention among adolescent girls and young women 2016. UNAIDS. URL: https://www.unaids.org/sites/default/files/media_asset/UNAIDS_HIV_prevention_among_adolescent_girls_and_young_women.pdf [accessed 2024-10-07]
13. Augmented reality: enhancing healthcare and its powerful impact on patient outcomes. HYSCALER. URL: https://hyscaler.com/insights/augmented-reality-on-patient-outcomes [accessed 2024-10-07]
14. What is augmented reality (AR)? TechTarget. URL: https://www.techtarget.com/whatis/definition/augmented-reality-AR [accessed 2025-04-03]
15. Ni Z, Peng ML, Balakrishnan V, et al. Implementation of chatbot technology in bealth care: protocol for a bibliometric analysis. JMIR Res Protoc 2024 Feb 15;13:e54349. [doi: 10.2196/54349] [Medline: 38228575]
16. Peng ML, Wickersham JA, Altice FL, et al. Formative evaluation of the acceptance of HIV prevention artificial intelligence chatbots by men who have sex with men in Malaysia: focus group study. JMIR Form Res 2022 Oct 6;6(10):e42055. [doi: 10.2196/42055] [Medline: 36201390]
17. Ndenkeh JJN, Nelson LE, Bogning A, et al. The feasibility and acceptability of using mobile applications for HIV testing, prevention, and treatment among adolescent girls and young women in Cameroon: a cross-sectional study. J Assoc Nurses AIDS Care 2024;35(3):210-221. [doi: 10.1097/JNC.0000000000000469] [Medline: 38569188]
18. Kabir ZS, Kang K. The impact of augmented reality through user-platform interactions towards continuance intention with the effect of user generation. Information 2024;15(12):758. [doi: 10.3390/info15120758]
19. Paul Odenigbo I, AlSlaity A, Orji R. Augmented and virtual reality-driven interventions for healthy behavior change: a systematic review. Presented at: IMX '22; Jun 22-24, 2022; Aveiro, Portugal. [doi: 10.1145/3505284.3529964]
20. Alami H, Rivard L, Lehoux P, et al. Artificial intelligence in health care: laying the foundation for responsible, sustainable, and inclusive innovation in low- and middle-income countries. Global Health 2020 Jun 24;16(1):52. [doi: 10.1186/s12992-020-00584-1] [Medline: 32580741]
21. Chang YM, Lai CL. "Floating heart" application of holographic 3D imaging in nursing education. Inter Jour of Nurs Educ 2018;10(4):25. [doi: 10.5958/0974-9357.2018.00095.8]
22. Garrett BM, Jackson C, Wilson B. Augmented reality m-learning to enhance nursing skills acquisition in the clinical skills laboratory. Interactive Technology and Smart Education 2015 Nov 16;12(4):298-314. [doi: 10.1108/ITSE-05-2015-0013]
23. Wüller H, Behrens J, Garthaus M, Marquard S, Remmers H. A scoping review of augmented reality in nursing. BMC Nurs 2019;18:19. [doi: 10.1186/s12912-019-0342-2] [Medline: 31123428]
24. Mendez KJW, Piasecki RJ, Hudson K, et al. Virtual and augmented reality: implications for the future of nursing education. Nurse Educ Today 2020 Oct;93:104531. [doi: 10.1016/j.nedt.2020.104531] [Medline: 32711132]
25. Saenz M, Strunk J, Maset K, Seo JH, Malone E. FlexAR: anatomy education through kinetic tangible augmented reality. Presented at: ACM SIGGRAPH 2015 Posters; Aug 9-13, 2015; Los Angeles, CA. [doi: 10.1145/2787626.2792629]
26. Pilapil M, Morris L, Saito K, et al. Retrospective analysis of the prevalence of and factors associated with condom use among young HIV-infected women in Cameroon. SAGE Open Med 2016;4:2050312115626432. [doi: 10.1177/2050312115626432] [Medline: 26835019]
27. Fayda-Kinik FS. Augmented reality in education: an overview of research trends. Presented at: 10th International Eurasian Educational Research Congress; Jun 8-11, 2023; Ankara, Turkey.
28. Mbonye V, Ebrahim R. Integrating augmented reality in science education in South Africa: applications in the Mancosa iteachlab. Presented at: 2022 International Conference on Artificial Intelligence, Big Data, Computing and Data Communication Systems (icABCD); Aug 4-5, 2022; Durban, South Africa. [doi: 10.1109/icABCD54961.2022.9856083]
29. Oduor P, Mushila L, Cheta D, et al. Augmented reality for medical training in eastern Africa. Presented at: 2023 IEEE Conference on Virtual Reality and 3D User Interfaces Abstracts and Workshops (VRW); Mar 25-29, 2023; Shanghai, China. [doi: 10.1109/VRW58643.2023.00288]
30. Frimpong JB, Budu E, Adu C, et al. Comprehensive HIV/AIDS knowledge and safer sex negotiation among adolescent girls and young women in sub-Saharan Africa. J Biosoc Sci 2022 Nov;54(6):991-1003. [doi: 10.1017/S0021932021000493] [Medline: 34558397]
31. Zulu T, Musukuma M, Jacobs C, Musonda P. Factors associated with the ability of adolescent girls and young women (AGYW) in sexual unions to negotiate for safer sex. An analysis of data from the 2018 Zambia Demographic and Health Survey (ZDHS). PLOS Glob Public Health 2024;4(9):e0003614. [doi: 10.1371/journal.pgph.0003614] [Medline: 39231147]
32. Butts SA, Parmley LE, Alcaide ML, et al. Let us fight and support one another: adolescent girls and young women on contributors and solutions to HIV risk in Zambia. Int J Womens Health 2017;9:727-737. [doi: 10.2147/IJWH.S142232] [Medline: 29033613]
33. Muessig KE, Knudtson KA, Soni K, et al. "I didn't tell you sooner because I didn't know how to handle it myself." Developing a virtual reality program to support HIV-status disclosure decisions. Digit Cult Educ 2018;10:22-48. [Medline: 30123342]
34. Romero RA, Klausner JD, Marsch LA, Young SD. Technology-delivered intervention strategies to bolster HIV testing. Curr HIV/AIDS Rep 2021 Aug;18(4):391-405. [doi: 10.1007/s11904-021-00565-y] [Medline: 34109549]

XSL•FO
RenderX

35. UNAIDS teams up with Google and Makhulu Media to release virtual reality educational films about HIV testing. UNAIDS. URL: https://www.unaids.org/sites/default/files/20181120_UNAIDS_VR_launch.pdf [accessed 2024-10-17]
36. Smith EE, Storrs H. Digital literacies, social media, and undergraduate learning: what do students think they need to know? Int J Educ Technol High Educ 2023;20(1):29. [doi: 10.1186/s41239-023-00398-2] [Medline: 37220550]
37. Inan Karagul B, Seker M, Aykut C. Investigating students' digital literacy levels during online education due to COVID-19 pandemic. Sustainability 2021;13(21):11878. [doi: 10.3390/su132111878]
38. So HJ, Seow P, Looi CK. Location matters: leveraging knowledge building with mobile devices and Web 2.0 technology. Interactive Learning Environments 2009 Dec;17(4):367-382. [doi: 10.1080/10494820903195389]
39. Fisher CB, Fried AL, Desmond M, Macapagal K, Mustanski B. Perceived barriers to HIV prevention services for transgender youth. LGBT Health 2018;5(6):350-358. [doi: 10.1089/lgbt.2017.0098] [Medline: 30070960]
40. Ayhan CHB, Bilgin H, Uluman OT, Sukut O, Yilmaz S, Buzlu S. A systematic review of the discrimination against sexual and gender minority in health care settings. Int J Health Serv 2020 Jan;50(1):44-61. [doi: 10.1177/0020731419885093] [Medline: 31684808]

Abbreviations

AR: augmented reality
mHealth: mobile health
PrEP: pre-exposure prophylaxis
SSA: sub-Saharan Africa
UNAIDS: Joint United Nations Programme on HIV/AIDS

Edited by S Badawy; submitted 30.11.24; peer-reviewed by H Xie, JDD Tapsoba; revised version received 15.02.25; accepted 18.03.25; published 12.05.25.

Please cite as:
Ni Z, Batubara IMS, Ndenkeh JJN, Bediang G, Yumo H, Zhang X, Oh S, Zhao Y, Nelson LE
Likelihood of Leveraging Augmented Reality Technology to Promote HIV Prevention and Treatment Among Adolescent Girls and Young Women in Cameroon: Cross-Sectional Survey
JMIR Pediatr Parent 2025;8:e69471
URL: https://pediatrics.jmir.org/2025/1/e69471
doi:10.2196/69471

© Zhao Ni, Intan Maharani Sulistyawati Batubara, Jackson Jr Nforbewing Ndenkeh, Georges Bediang, Habakkuk Yumo, Xuehong Zhang, Sunyong Oh, Yuchen Zhao, LaRon Nelson. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 12.5.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

A Mobile Phone App to Support Self-Management and Transition to Adult Health Services in Young People With a Chronic Illness: Single-Arm Pilot Intervention Study

Shehani C Samarasinghe[1,2*], MPhil; Riham Al Na'abi[1,2*], MD; Hoi Lun Cheng[1,2], PhD; Jeffrey Yeung[1,2], MBChB; Katharine S Steinbeck[2], PhD

[1]Academic Department of Adolescent Medicine, The Children's Hospital at Westmead, Locked Bag 4001, Westmead, Australia

[2]Speciality of Child and Adolescent Health, Faculty of Medicine and Health, The University of Sydney, Westmead, Australia

[*]these authors contributed equally

Corresponding Author:
Hoi Lun Cheng, PhD
Academic Department of Adolescent Medicine, The Children's Hospital at Westmead, Locked Bag 4001, Westmead, Australia

Abstract

Background: Pediatric to adult health service (AHS) transition is a challenging time for many adolescents and young adults with chronic illness. As the responsibility of illness management shifts from parents to the young person themselves, many young people fail to transition in a timely manner, which has important health consequences. Mobile apps show potential in assisting young people to self-manage their condition during this vulnerable time, but empirical data on app uptake as well as efficacy with respect to transition outcomes and illness control are lacking.

Objective: This study aimed to evaluate the usage of a mobile app called "TransitionMate" (TMApp) by adolescents and young adults, which was purpose-built to support chronic illness self-management for youth undergoing transition. Secondary aims were to assess AHS attendance and changes in illness control over the first 12 months post transition. Upon demonstration of TMApp feasibility (49/70, ≥70% of participants using TMApp at least once a month), a randomized controlled trial was planned to test app efficacy in relation to transition and illness control outcomes.

Methods: Young people aged 16 - 19 years who were transitioning out of 2 major pediatric hospitals in Sydney, New South Wales, Australia, were recruited. Just before transition, participants' demographic and clinical details were collected, and TMApp was installed on their mobile devices. Participants were contacted by telephone at 6 and 12 months for information on self-reported usage, app usefulness, and other feedback. Quantitative cohort-level usage data, including the number of times specific app features were accessed, were tracked via mobile analytics. At 12 months, electronic medical records from participants' designated AHS were accessed for data on AHS attendances, measures of illness control, and unplanned hospitalizations.

Results: In total, 73 adolescents and young adults (30 male; median age 18, IQR 17-18 y) were recruited, with 1 withdrawing participation in the first month. Participants were primarily from 3 chronic illness subgroups—diabetes mellitus (n=23), inflammatory bowel disease (n=19), and cystic fibrosis (n=9). Of the total, 50% (36/72) of participants reported using TMApp at 1 month post transition. Self-reported usage rates fell to 25% and 11% at 6 and 12 months, respectively. Mobile analytics data broadly corroborated self-reported usage. Furthermore, 8 participants who continued to use TMApp for 12 months gave a median usefulness rating of 8/10. Over two-thirds (48/72, 68%) of participants successfully transitioned to their designated AHS by 12 months. Among the successful transitioners who had illness control data available on electronic medical records, over 80% (24/30) maintained a stable or improved illness status at 12 months.

Conclusions: TMApp was not used regularly enough by our young people to demonstrate feasibility and justify progression to a randomized controlled trial. Despite low app uptake, most participants successfully transitioned, suggesting that TMApp had minimal influence on transition outcomes.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12620000074998; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377349

International Registered Report Identifier (IRRID): RR2-10.1186/s12913-022-08536-8

(JMIR Pediatr Parent 2025;8:e67061) doi:10.2196/67061

KEYWORDS

adolescent; chronic illness; transition to adult care; self-management; mobile applications; pilot projects; diabetes mellitus; inflammatory bowel disease; cystic fibrosis; mobile phone

XSL•FO
RenderX

Introduction

Mobile phone technology is a significant part of everyday life and is seen as an attractive tool for both health care and health research. The management of chronic illness, where patients must maintain day-to-day routines to have good control of their condition, is a potential clinical situation where mobile apps might be useful.

One particular age group that may benefit from using mobile apps to manage their chronic condition is adolescents and young adults. First, young people, as digital natives, are confident users of mobile technology [1]. Second, adolescents undergo a challenging period of transition from pediatric to adult health services (AHS), whereby the responsibility of managing their chronic condition shifts substantially from the parent to the young person themselves [2]. Consequently, many young people neglect to monitor their health, adhere poorly to existing therapy, lose contact with any health care, and fail to transition in a timely manner [3,4]. Factors further contributing to suboptimal transition include inadequate communication between pediatric and adult services [5], decreased condition-specific illness knowledge in the AHS [6], and the lack of equivalent AHS [7]. Many of these issues are common among this age group, irrespective of chronic condition. Enhancing young people's capacity to competently and autonomously self-manage their condition is thus a key strategy to retaining them in the AHS and improving their transition experience [8,9]. Importantly, self-management skills are imperative for preventing loss of illness control and unplanned hospitalizations arising from acute morbidity [10,11].

While it is often assumed that adolescents and young adults will embrace mobile apps for managing their health, evidence to support this assumption is modest. In total, 2 systematic reviews to date have assessed the use of apps for youth self-management of chronic illness [12,13]. One of these reviews focused on transition and found some improvement in patient satisfaction related to self-management following the use of apps [13]. However, neither study was able to draw conclusions about app efficacy pertaining to transition outcomes, owing to insufficient and heterogeneous data. Other studies, such as those evaluating the "iManage" app (Cincinnati Children's Hospital Medical Center) for youth self-management of sickle cell disease [14-16], have generated useful information on app design, functionality, and acceptability with respect to consumer involvement, although efficacy data are yet to be available. Thus, knowledge gaps exist around understanding what role mobile apps play in the self-management of chronic illness for adolescents and young adults. Specifically, there is a need for more quantitative data on app usage and comparison of app uptake across different chronic conditions [17,18]. Empirical evidence on app efficacy with respect to transition outcomes and illness control is also lacking.

This study describes pilot testing of a mobile app called "TransitionMate" (TMApp), which was purpose-built to support adolescents and young adults in self-management during the vulnerable period of transition from pediatric to AHS. The app was designed as a generic (non–illness-specific) tool to address common issues around transition that could be used broadly across different health care settings and by patients with different conditions. The primary aim of this study was to evaluate young people's usage of TMApp. Secondary objectives were to assess AHS attendance and changes in illness control over the first 12 months post transition. The working hypothesis was that regular and long-term usage of TMApp would predict successful transition. Upon demonstration of app feasibility (defined as a minimum usage frequency of once a month by ≥70% [49/70] of participants based on power calculations), a randomized controlled trial was planned to test efficacy of TMApp in relation to transition and illness control outcomes [19]. Both the primary and secondary objectives were necessary before embarking on the randomized controlled trial.

Methods

TMApp

TMApp was developed from a prototype that was designed in collaboration with the University of Sydney School of Electrical Engineering, involving a team of medical professionals and software engineers [20].

A brief iterative participatory design process was used for developing the prototype. Initial ideas around what functionalities to include were informed by patient needs identified in the transition literature [21-23], through clinician experience, as well as experience from the software engineers who had previously built mobile apps for adult chronic illness. Furthermore, a focus group involving 10 adolescents and young adults with chronic illness was conducted to gain further insights into what young people wanted from a self-management app. Five required features were identified in this process, including automated reminders, the ability to log and view trends for illness data, a medication list, a mood tracking function, and a centralized repository for storing important contacts, referral letters, and medical histories as young people often struggled to recall this information when speaking to a new health care provider [24].

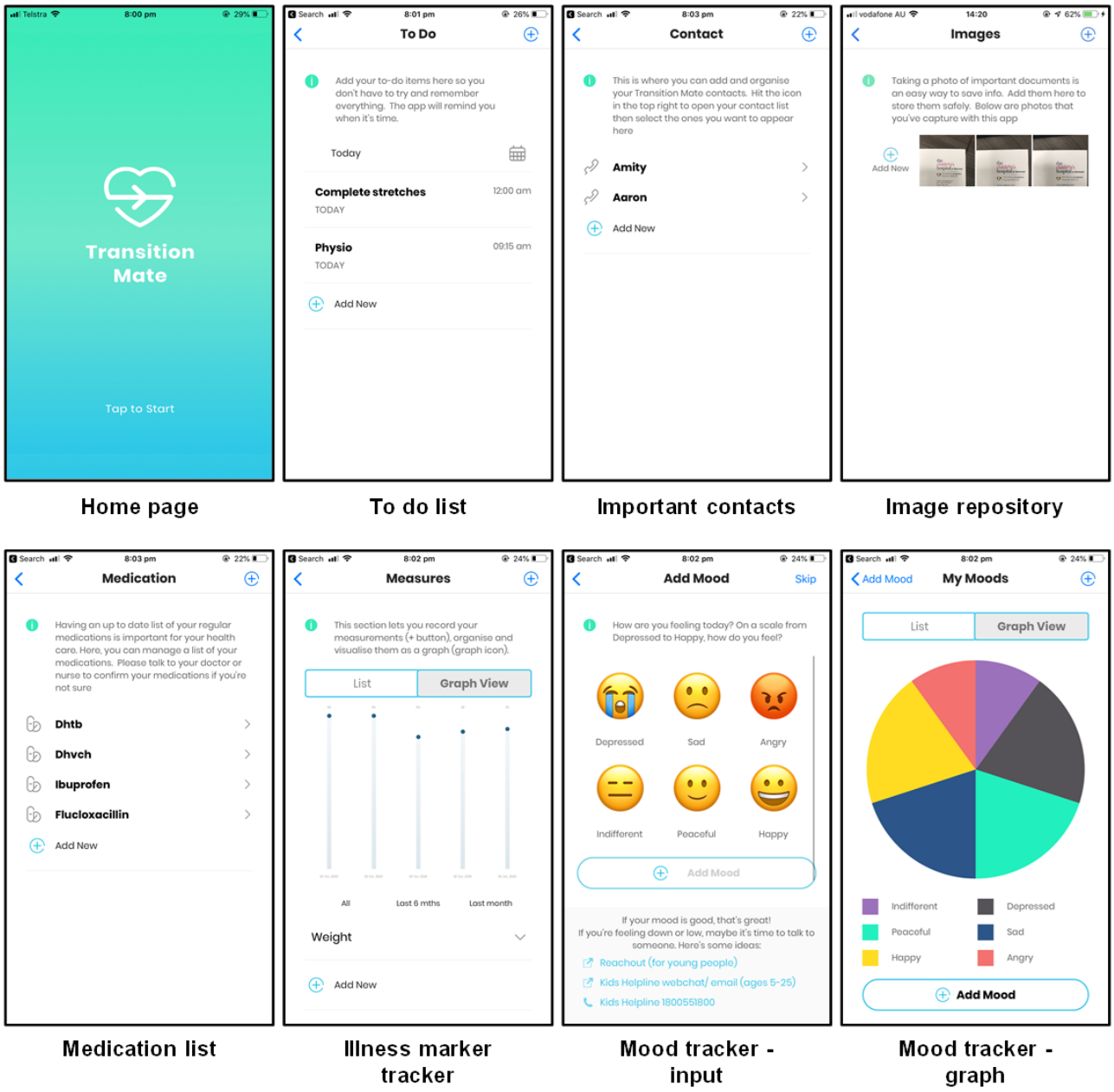
A prototype was subsequently built using the above information. Screenshots of each feature were presented to several clinicians and researchers with expertise in adolescent health, and further refinements were made accordingly. This review-and-refine process was repeated several times. Following this, the prototype was tested in a group of young adults with chronic illness who had recently undergone transition [25]. Feedback received from this user group was the need for a to-do list as well as customizable content and displays to suit individual illness management needs, among other improvements (eg, graphics and bug fixes). This feedback, along with the prototype, provided the framework for a commercial developer to build TMApp in its final form. Overall, the commercial app development process was lengthy, interrupted by insufficient funds, and resulted in the relatively simple TMApp, that again had user testing with further refinements.

The final version of TMApp had the following features: (1) to-do list; (2) reminders for health appointments and other health-related activities; (3) contact information for health care

XSL•FO
RenderX

and emergency professionals; (4) image repository for prescriptions, reports, results, and clinic letters; (5) medication list; (6) tracking of illness control markers; and (7) an emoji-based mood tracker (Figure 1). Participants received monthly automated notifications via the app to encourage use. These notifications included prompts for setting goals, checking medications, and obtaining new prescriptions, with no reply option available.

Figure 1. Screenshots of the main features on the TransitionMate mobile app.



TMApp was deployed on 2 major mobile operating systems—Apple iOS and Android (Google). For Apple iOS, TMApp was deployed through the App Store, whereby participants were given a promo code for free download onto their mobile device. To limit unintended downloads, it was made clear in the App Store that TMApp was intended for research participants only. For Android, deployment was through an Android Package Kit (.apk) file that was downloadable via a weblink emailed directly to participants. Technical support for TMApp was provided remotely by the commercial developer.

Study Design and Setting

This pragmatic, single-arm, pilot trial was conducted at 2 tertiary pediatric hospitals in Sydney, New South Wales, Australia—The Children's Hospital at Westmead and Sydney Children's Hospital, Randwick.

The main study time points were baseline, 6 months, and 12 months. The baseline visit occurred during the final routine clinic appointment at the pediatric hospital and involved the collection of patient demographic, clinical, and contact details, including an assessment of psychological distress and transition readiness. Installation and setup of TMApp also occurred during this visit. Follow-ups at 6 and 12 months involved a

XSL•FO
RenderX

telephone-administered semistructured questionnaire on (1) TMApp usage in the past month (daily, weekly, monthly, or never), (2) app features used most frequently and why, (3) AHS attendance (if they have attended or booked an appointment), and (4) illness control knowledge (if they could recall their markers of illness control and if any tests were done post transition). One additional question was included at 6 months, which asked participants to recall their TMApp usage during the first month of the trial. The 12-month questionnaire sought additional feedback, including a usefulness rating, whether TMApp was easy to use, whether they would recommend TMApp to others, and suggested improvements. Electronic medical record (eMR) data were sought from participants' designated AHS at 12 months, including (1) the number of AHS attendances in the past year; (2) primary, and if available, secondary measures of illness control; and (3) unplanned hospitalizations in the previous 12 months. Further details on the methodology are provided in the full trial protocol [19]. Reporting of this research study is in accordance with the CONSORT (Consolidated Standards of Reporting Trials) Pilot Trials checklist (Checklist 1).

Recruitment and Eligibility

Participants were recruited from May 2019 to May 2020 (between COVID-19 pandemic lockdowns). Adolescents with a chronic illness were approached with a study information pack by their treating teams during their penultimate routine clinic appointment. Patients were eligible if they were aged 16 - 19 years, undergoing transition to an AHS within the next 12 months, and consented to using TMApp and being contacted for study follow-up. Patients were excluded if they were non–English speaking, had no access to a personal smartphone, had an intellectual disability affecting questionnaire completion, had a primary diagnosis of mental health, active cancer, or were in a terminal state, or were using another transition-focused mobile app.

Transition Outcomes and Illness Control: Measurement and Definitions

Transition Outcomes

Using the eMR data obtained from AHS, we defined engagement as ≥1 recorded attendance at the participant's designated AHS within the first 6 months post transition. Retention was defined as ≥1 further attendance between 6 and 12 months post transition. If AHS appointments were expected to be annual, 1 attendance within the 12-month study period was defined as engagement. A participant was deemed to have transitioned successfully if they had ≥1 AHS attendance by 12 months. Unsuccessful transitioners were defined as those who did not engage with the AHS they were referred to or could not be contacted to ascertain if they had transitioned elsewhere.

Illness Control

Quantitative measures of illness control (primary and, if available, secondary) were obtained at baseline by accessing eMR data from the pediatric health service. At the end of the study, participants' designated AHS were contacted to obtain eMR data on subsequent measures of illness control and the number of unplanned hospitalizations.

Markers of illness control were specific to each chronic condition and were provided by clinicians from each pediatric specialty service, generally based on empirical evidence. Examples of common and clinically accepted markers of illness control are illustrated in Table 1. Participants were deemed to have experienced a deterioration in illness control if their primary or secondary markers showed a value that reflected a worse clinical state for their condition. Conversely, no change or a positive change in markers over time was indicative of stable or improved illness control.

XSL•FO
RenderX

Table . Clinically accepted markers of illness control and definitions for deterioration in illness control over 12 months.

Chronic illness and markers of illness control	Definitions for deterioration
Diabetes mellitus (type 1 and 2)	
HbA_{1c}[a]	≥1% increase
Cystic fibrosis	
FEV1[b]	≥10% decrease
Weight[c]	≥5% decrease
Inflammatory bowel disease	
CRP[d]	≥75% increase from ULN[e]
Weight[c]	≥5% decrease
Other chronic illnesses	
Hospitalization	≥1 unplanned hospitalization related to chronic illness

[a]HbA_{1c}: glycosylated hemoglobin.

[b]FEV1: forced expiratory volume (liters per second).

[c]Weight was considered a secondary illness marker for cystic fibrosis and inflammatory bowel disease.

[d]CRP: C-reactive protein.

[e]ULN: upper limit of normal (based on normative range defined by the laboratory providing the measure.

Psychological Distress and Transition Readiness

Participants completed the Kessler Psychological Distress scale (K10) and the Transition Readiness Checklist (TRC) at baseline. The K10 is a validated, 10-item scale that assesses an individual's mental distress related to depression and anxiety symptomatology [26]. The TRC is a 27-item tool developed by the Royal Children's Hospital (Melbourne, Australia) that assesses self-management skills covering the areas of illness knowledge, administrative and organizational capabilities, and self-advocacy [27].

Mobile Phone Analytics Data

Quantitative, cohort-level data on TMApp usage were obtained from Flurry Analytics (Flurry Inc). Variables of interest were the number of TMApp-active devices for each month of the study and the number of times each app feature was accessed. Due to privacy reasons, it was not possible to link mobile analytics data to individual user activity.

Statistics

Power Calculation

An estimated 70 participants were needed to achieve a minimum sample size of 49, with attrition predicted at 30%. A sample of 49 participants would have ≥80% power, based on a 1-sided significance level of 0.05, to detect an increase in the rate of successful transition from pediatric to adult care by 15% (eg, from 70% - 85%). This sample size was considered feasible given the number of adolescents with chronic illness who transition out of the 2 study hospitals annually.

Data Analyses

Results are presented as data aggregated for the entire cohort, except where sex differences were considered and when condition numbers were large enough for subgroup analyses. Normality was assessed via the Kolmogorov-Smirnov test. Associations between categorical variables were analyzed using chi-square tests. Mann-Whitney *U* tests were used to compare transition outcomes between subgroups. Significance was set at $P<.05$. Summary statistics are presented as means (SD) or median (IQR) for continuous variables, and frequency or percentage for categorical variables. Statistical analyses were performed using IBM SPSS Statistics version 24 (IBM Corp).

Ethical Considerations

The study was approved in 2017 by the Sydney Children's Hospital Network Human Research Ethics Committee (HREC/17/SCHN/385). Due to lack of human resources and a prolonged app development process, the study did not commence recruitment until 2019. Signed informed consent was sought from parents and carers or from adolescents and young adults if they had reached 18 years.

Participants did not receive compensation for their involvement in the research.

All hard copy data (including questionnaire, phone call, and interview data) are stored in a locked filing cabinet in The Children's Hospital at Westmead, Academic Department of Adolescent Medicine. Access to these data is restricted to staff involved in the research. Research data are deidentified upon receipt by the investigators using participant code numbers to preserve anonymity. Deidentified digital data are stored under password protection on a restricted-access network drive within the Sydney Children's Hospital Network. Only the principal investigators have access to the participant reidentification list, and this list is stored separately as hard copy data. All data collected for the study will be preserved for 7 years from the date of obtaining maturity for young people who are older than 18 years, or for 7 years after the completion of the study for those aged more than 18 years. The hard and soft copies will

XSL•FO
RenderX

be destroyed at this time under specific Human Research Ethics Committees protocols for destruction of paper and digital data.

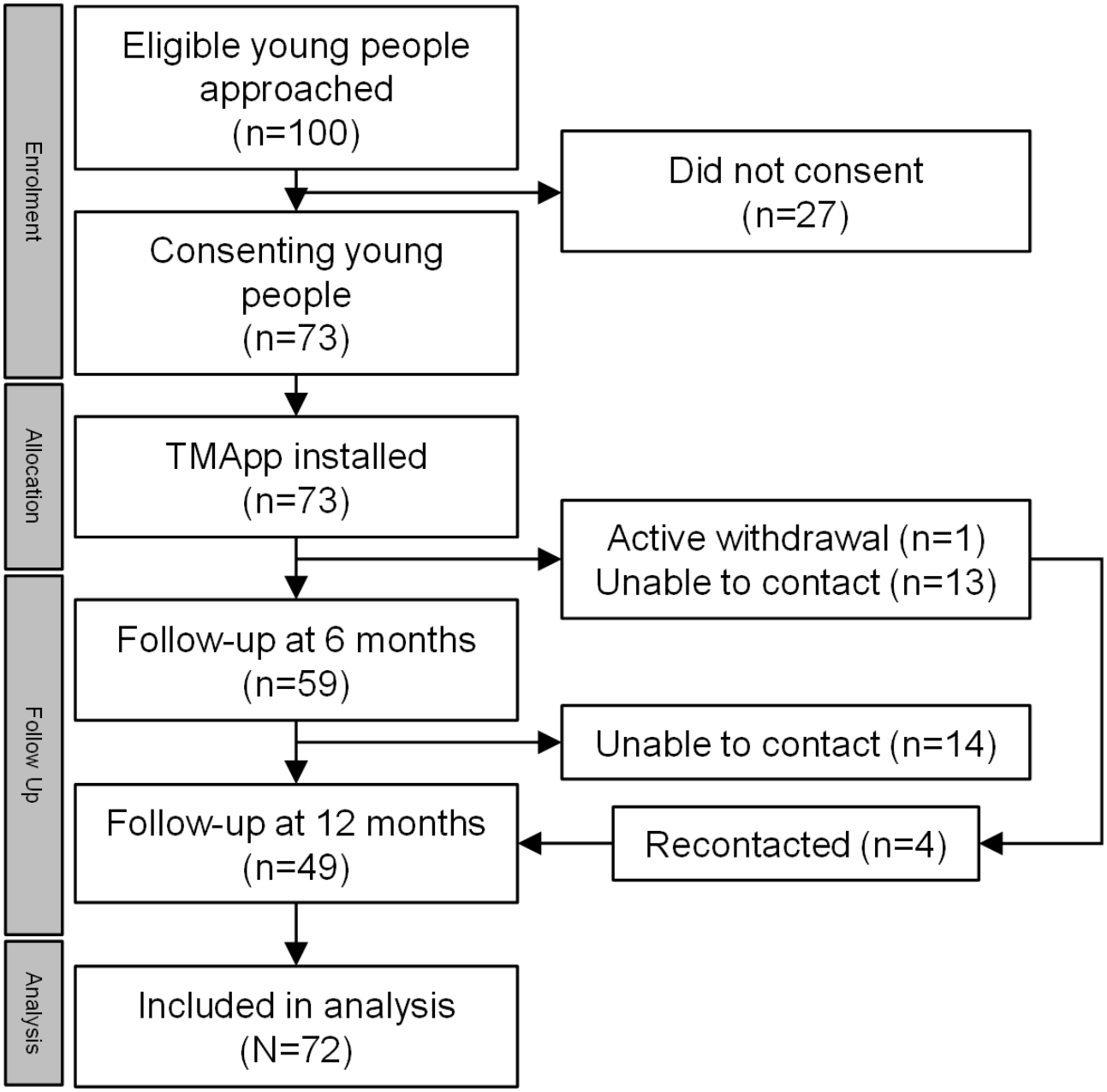
Results

Participant Characteristics

A total of 100 adolescent patients were approached, with 73 (30 male; median age 18, IQR 17-18 y) consenting to take part in this study. One participant withdrew within the first month of the study, citing lack of interest and was excluded from analyses. At 6 and 12 months, 83% (60/72) and 68% (49/72) of participants could be contacted for follow-up, respectively (Figure 2).

The majority (51/72, 70%) of participants were from 3 chronic illness subgroups: diabetes mellitus (type 1 and 2; n=23), inflammatory bowel disease (n=19), and cystic fibrosis (n=9). Other chronic conditions in the remaining participants are outlined in Table 2. Median scores for the K10 (17 out of 50) and TRC (70 out of 81) were, respectively, in the lowest category for mental distress and the highest category for transition readiness (Table 2).

Figure 2. Study flowchart. Of the 73 participants who consented to this research, only 1 was excluded from analysis due to withdrawal of consent. TMApp: TransitionMate app.



XSL•FO
RenderX

Table . Baseline participant characteristics. Data are presented as mean (SD) or median (IQR).

Participant characteristic	All (n=72)	Male (n=30)	Female (n=43)
Age (y), median (IQR)	18 (17 - 18)	18 (17 - 18)	18 (17 - 18)
Chronic illness, n			
Type 1 diabetes mellitus	20	6	14
Type 2 diabetes mellitus	3	0	3
Inflammatory bowel disease	19	11	8
Cystic fibrosis	9	5	4
Other[a]	21	7	4
Kessler Psychological Distress Scale (K10)[b,c], median (IQR)	17 (13 - 24)	14 (12 - 18)	20 (10 - 42)
K10 response categories, n			
Likely to be well	43	22	21
Mild	12	3	9
Moderate	8	2	6
Severe	8	1	7
Transition Readiness Checklist (TRC)[c,d]	Median 70 (IQR 66 - 76)	Mean 69 (SD 9)	Mean 69 (SD 8)
TRC categories, n			
Unlikely transition ready	4	2	2
Transition ready	67	26	41
Mobile operating system, n			
Android	53	23	30
Apple iOS	19	7	12

[a]Other conditions included: liver transplantation for congenital hepatic conditions (n=3); Duchenne muscular dystrophy (n=2); acromicric dysplasia (n=1); systemic lupus erythematosus (n=1); autoimmune thyroiditis (n=1); Grave's disease (n=1); repaired duodenal atresia with consequent Barrett's esophagus (n=1); bicuspid aortic valve with moderate aortic valve stenosis (n=1); neurofibromatosis type 1 (n=1); trichorhinophalangeal syndrome type 1 (n=1); epilepsy (n=1); glycogen storage disease pre-diabetes with severe metabolic syndrome (n=1); sinus node dysfunction with sinus arrest (n=1); constipation with fecal incontinence and megarectum (n=1); idiopathic megarectum (n=1); acquired brain injury (n=1); hereditary spastic paraplegia (n=1); undefined neurodegenerative disorder (n=1).

[b]Categories for K10 scores: Likely to be well (<20), mild mental disorder (20-24); moderate mental disorder (25-29), severe mental disorder (≥30).

[c]One participant had missing data for the K10 and TRC.

[d]Categories for TRC scores: Unlikely transition ready (27-54); Transition ready (55-81).

TMApp Usage

At 6 months, 36 of the 72 (50%) participants reported having used TMApp at least once in the first month post transition, with 4 daily and 5 weekly users (Figure 3). By 6 months, past-month TMApp usage decreased to 18 (25%) participants, with 2 daily and 7 weekly users. At 12 months, 8 (11%) participants reported past-month TMApp usage, with no daily and 1 weekly user.

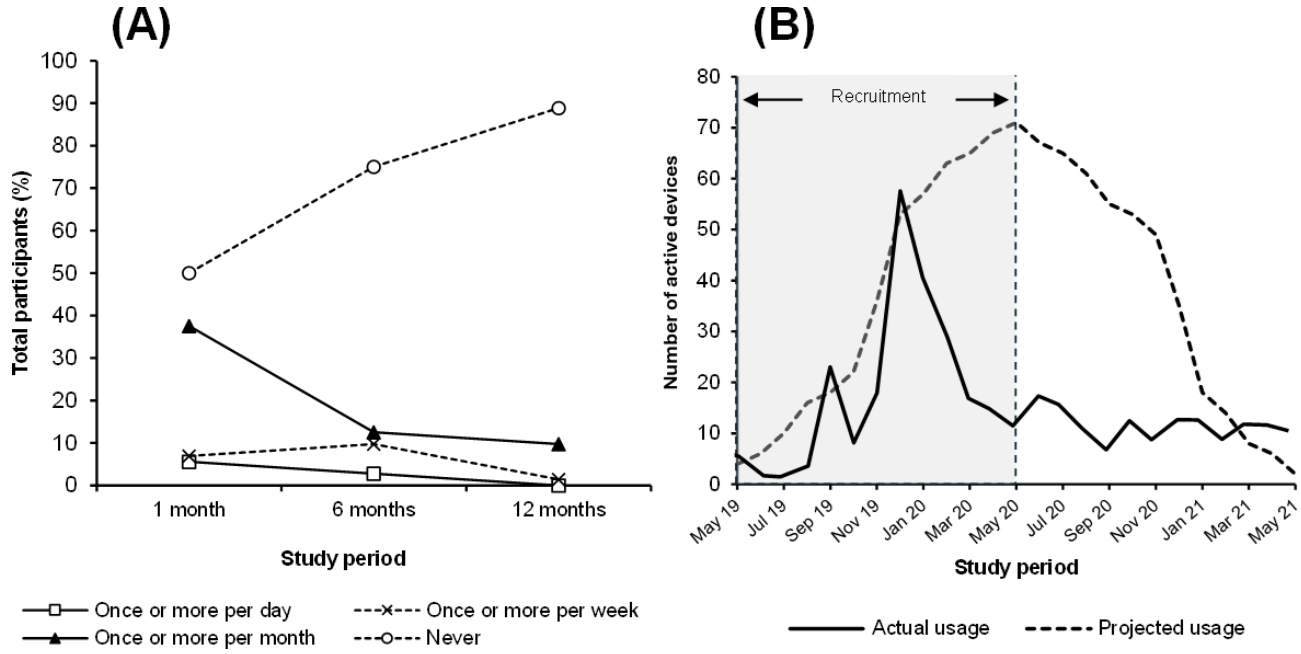
Aggregated usage data from mobile analytics showed peak usage at mid-recruitment, after which TMApp usage rates fell well below projected rates calculated based on monthly use by all participants (Figure 3). At study completion, TMApp was removed from the iOS App Store to limit unintended downloads and contamination of app usage statistics.

Across the chronic illness subgroups, self-reported TMApp usage was highest among participants in the "other" group (Figure 4). Diabetes, being the largest chronic illness subgroup, had the second lowest self-reported TMApp usage at 1 month (10/23, 43% reported use) and the lowest TMApp usage at 6 months (2/23, 9%). No participants with diabetes reported using the TMApp at 12 months.

The top 3 most used features reported by participants were the to-do list (n=14), medication (n=14), and mood tracker (n=11) functions. Mobile analytics data broadly corroborated participant self-reports, with the mood tracker recorded as the most accessed feature over 12 months, followed by the to-do list and medication functions (Figure 5).

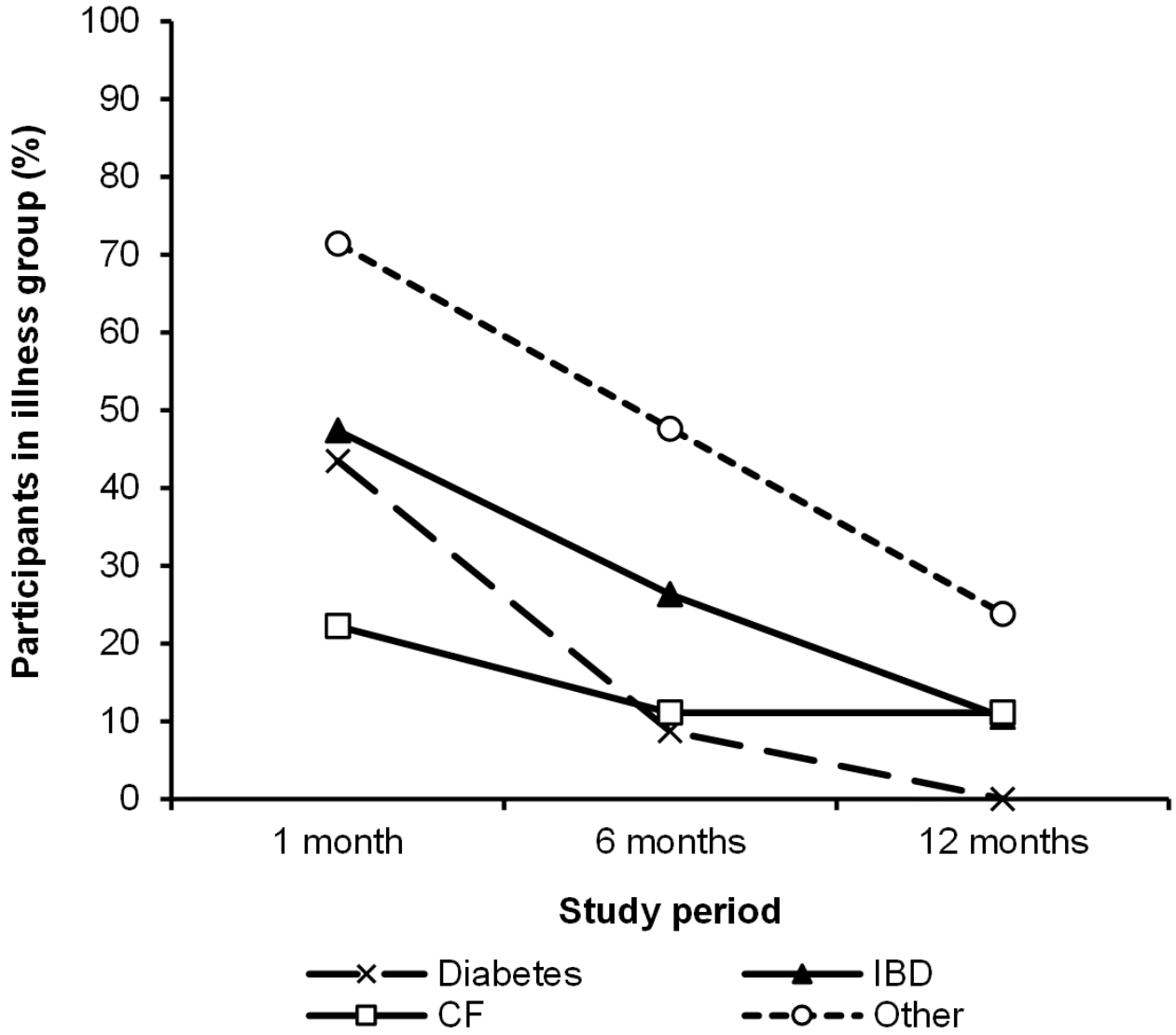
XSL•FO
RenderX

Figure 3. TransitionMate app usage data based on (A) self-reported frequency in the past month; and (B) mobile analytics data (black line) mapped against projected usage if every participant accessed the app on their device every month. (N.B. actual usage was higher than projected usage at some time points as mobile analytics data include user activity on researcher-held devices).



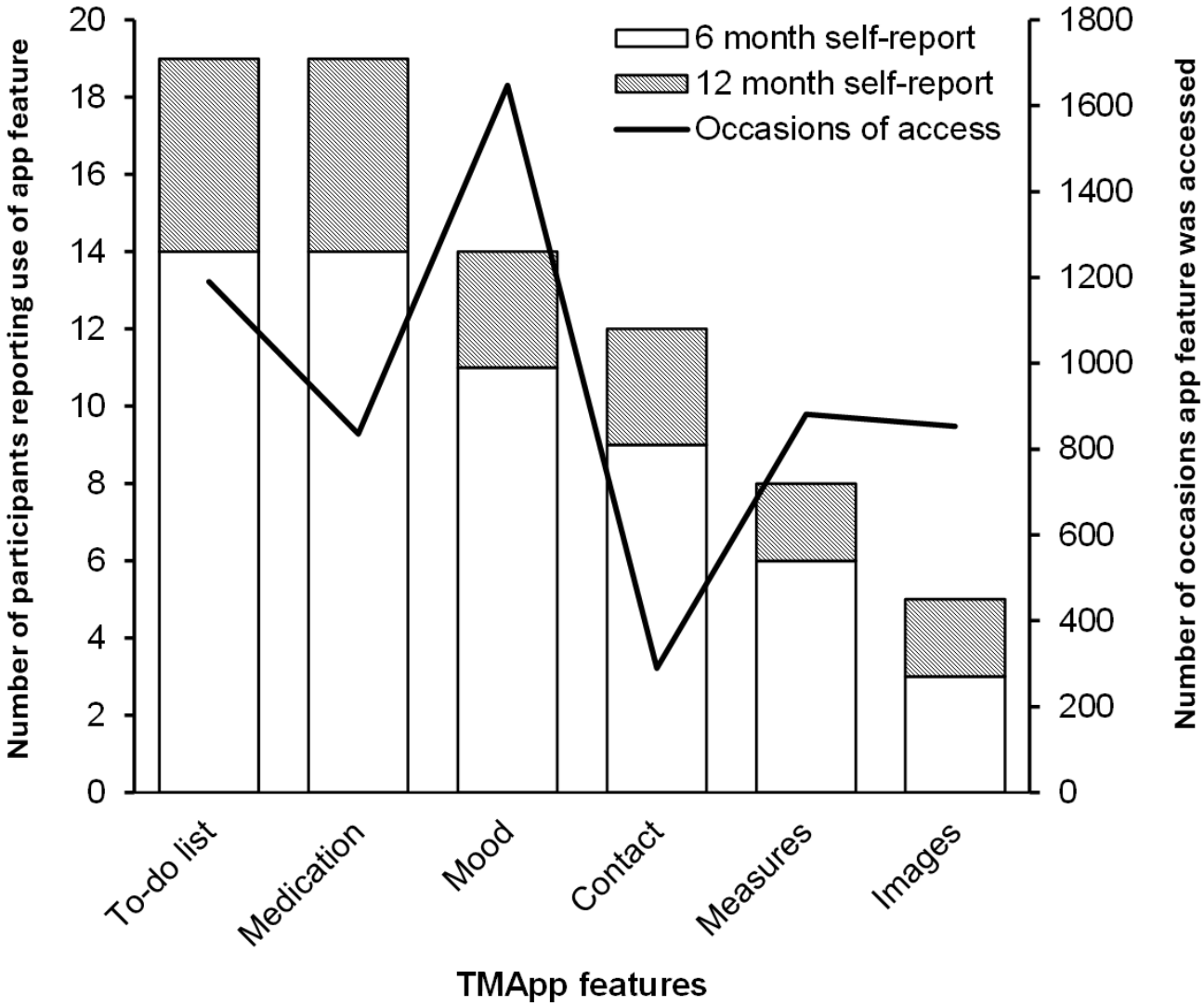
XSL•FO
RenderX

Figure 4. Proportion of participants within each illness subgroup who reported using the TransitionMate app at least once over the past month. CF: cystic fibrosis; IBD: inflammatory bowel disease.



XSL•FO
RenderX

Figure 5. Use of TransitionMate app features based on: self-report at 6 months (white bars), 12 months (hashed bars), and quantitative mobile analytics data (line). TMApp: TransitionMate app.



TMApp Usefulness and Other Feedback

The primary reason participants gave for not using TMApp was that they felt no need to use it (n=24). Other reasons were forgetting to use the app (n=5), changing phones (n=4), low app usefulness (n=3), lack of time (n=1), and preferring paper to apps (n=1). In terms of potential improvements, participants suggested the incorporation of health records, nutritional information, additional visual components, and a medication reminder alarm feature. Furthermore, 7 participants stated that the existing features were adequate. Among the 8 participants who continued to use TMApp at 12 months, a median usefulness rating of 8 out of 10 was given. In addition, 16 participants found TMApp easy to use and would recommend it to other young people with a chronic illness as they transition into adulthood.

6- and 12-Month Outcomes

The eMR data obtained from AHS showed that 49 out of the 72 participants successfully engaged with their designated AHS by 6 months. By 12 months, 48 of these participants were retained in the same AHS. Males exhibited a nonsignificant tendency for higher AHS engagement (23/29, 79% vs 26/43, 60%; P=.09) and retention (23/29, 79% vs 25/43, 58%; P=.06) compared with females. The proportion of successful (n=49) versus unsuccessful (n=23) transitioners did not differ between chronic illness subgroups (diabetes: 17/23, 74%; inflammatory bowel disease: 13/19, 68%; cystic fibrosis: 8/9, 89%; other: 11/21, 52%; P=.21). Similarly, K10 and TRC scores as well as primary markers of illness control at baseline did not differ between the successful and unsuccessful transitioners (Table 3).

Markers of illness control (obtained from AHS eMR) for the 3 major illness subgroups remained stable over the course of the study (Tables 4-6). Around 80% of participants (for whom follow-up eMRs were available) showed stable or improved illness status at 6 months (17/21) and 12 months (24/30). In total, 8 participants had unplanned hospitalizations recorded on eMR, including 5 with cystic fibrosis, 2 with diabetes, and 1 with inflammatory bowel disease. Furthermore, 1 participant with cystic fibrosis had 3 hospitalizations over the study period.

Of the 23 participants who had not engaged with their designated AHS by 12 months, 17 were contactable at follow-up. Reasons given for nonattendance were: (1) participant had not yet chosen an AHS to visit (n=3), (2) parents were arranging appointments

XSL•FO
RenderX

for a later date (n=2), (3) delaying transition until after their final school year examinations (n=2), (4) planning later transition (n=2), and (5) hesitancy over visiting a health service during the COVID-19 pandemic (n=2). Furthermore, 1 participant was uncertain how to schedule an appointment, and 5 did not offer an explanation.

Table . Comparison of baseline psychological distress and transition readiness scores and baseline markers of illness control between successful and unsuccessful transitioners. Data are presented as median (IQR). Statistical comparisons were performed using the Mann-Whitney *U* test.

Baseline measure	Successful transitioners[a] (n=49)		Unsuccessful transitioners[a] (n=23)		*P* value
	n	Median (IQR)	n	Median (IQR)	
Kessler Psychological Distress Scale (K10)[b]	48	16 (12 - 21)	23	21 (13 - 28)	.10
Transition Readiness Checklist (TRC)[c]	48	69 (66 - 76)	23	71 (64 - 76)	.60
Primary marker for illness group					
Diabetes mellitus (HbA_{1c}[d]; %)	17	7.2 (6.9 - 8.6)	6	7.7 (6.7 - 9.3)	.92
Cystic fibrosis (FEV1[e]; L/s)	8	2.9 (2.3 - 3.4)	1	3.4 (3.4-3.4)	—[f]
Inflammatory bowel disease (CRP[g]; mg/L)	12	1.2 (0.5 - 2.2)	6	1.0 (0.8 - 4.5)	>.99

[a]Successful transitioners were those who had ≥1 adult health service attendances on their electronic medical record at 12 months. Unsuccessful transitioners were those who did not have any recorded attendances at their designated adult health service at 12 months.

[b]Categories for K10 scores: Likely to be well (<20), mild mental disorder (20-24); moderate mental disorder (25-29), severe mental disorder (≥30).

[c]Categories for TRC scores: Unlikely transition ready (27-54); Transition ready (55-81).

[d]HbA_{1c}: glycosylated hemoglobin.

[e]FEV1: forced expiratory volume.

[f]Not applicable as there was only 1 person in this subgroup.

[g]CRP: C-reactive protein.

Table . Change in illness control for the diabetes subgroup based on eMR[a] data.

Diabetes mellitus	Primary illness marker	
	n	HbA_{1c}[b] (%), median (IQR)
Baseline	23	7.3 (6.9-8.6)
6 months[c]	10	8.3 (7.4-9.7)
Stable/improved, n	7	
Deteriorated, n	3	
12 months[c]	13	7.1 (6.8-8.9)
Stable/improved, n	10	
Deteriorated, n	3	

[a]eMR: electronic medical record.

[b]HbA1c: glycosylated hemoglobin.

[c]eMR records were only available for 37 participants due to limited data availability. A shift toward telehealth consultation in response to COVID-19 social distancing regulations wa as major contributor to missing data as many illness control assessments were not conducted.

XSL•FO
RenderX

Table . Change in illness control for the cystic fibrosis subgroup based on eMR[a] data.

Cystic fibrosis	Primary illness marker		Secondary illness marker	
	n	FEV1[b] (L/s), median (IQR)	n	Weight (kg), median (IQR)
Baseline	9	2.9 (2.3-3.4)	9	58.8 (52.5-62.8)
6 months[c]	1	2.3 (2.3-2.3)	1	59.2 (59.2-59.2)
Stable/improved, n	1		1	
Deteriorated, n	0		0	
12 months[c]	8	3.2 (2.1-3.6)	8	59.1 (53.5-65.4)
Stable/improved, n	5		6	
Deteriorated, n	3		2	

[a]eMR: electronic medical record.

[b]FEV1: forced expiratory volume (liters per second).

[c]eMR records were only available for 37 participants due to limited data availability. A shift toward telehealth consultation in response to COVID-19 social distancing regulations wa as major contributor to missing data as many illness control assessments were not conducted.

Table . Change in illness control for the inflammatory bowel disease subgroup based on eMR data.

Inflammatory bowel disease	Primary illness marker		Secondary illness marker	
	n	CRP[b] (mg/L), median (IQR)	n	Weight (kg), median (IQR)
Baseline	19	1.0 (0.6-2.1)	19	62.4 (55.1-74.7)
6 months[c]	10	1.4 (0.4-7.7)	10	64.5 (52.8-93.8)
Stable/improved (n)	9		9	
Deteriorated (n)	1		1	
12 months[c]	9	3.9 (1.0-4.0)	9	69.0 (55.5-83.0)
Stable/improved (n)	7		8	
Deteriorated (n)	1		1	

[a]eMR: electronic medical record.

[b]CRP: C-reactive protein (the most widely used serum indicator of inflammation).

[c]eMR records were only available for 37 participants due to limited data availability. A shift toward telehealth consultation in response to COVID-19 social distancing regulations was major contributor to missing data as many illness control assessments were not conducted.

Discussion

Principal Findings

To our knowledge, this is the first clinical trial to evaluate the uptake of a generic app to enhance pediatric to AHS transition in young people living with a chronic illness. This was designed as a feasibility study to determine usage over the vulnerable 12 months after young people leave wrap-around pediatric care and have more autonomy. Results from both the self-reported and quantitative usage data showed that TMApp was not used frequently enough to justify feasibility and efficacy testing in a randomized controlled trial. Not needing to use the app and forgetting to use the app were the top reasons given for nonuse. Other contributors to low usage may include the generic (ie, non–illness specific) design of the app, transition perceived as being of low priority, and TMApp's simple design compared with other commercial apps for managing chronic illness. The high usefulness ratings obtained from this study were likely to be biased, as feedback was only given by a small subset of highly engaged study completers. The nonanonymized nature of the follow-up interviews may have also yielded more positive but less truthful feedback. Given that we were unable to link the mobile analytics data to individual user activity, this study serves more as an observational study of the transition from pediatric to AHS.

TMApp was developed with input from adolescents and young adults to support transition in young patients with chronic illness. While the overall frequency of app usage was low with declining rates over time, TMApp was rated as useful and easy to use among those who did regularly access it to support their health service transition. This result is comparable with a pilot study of the "iManage" app for youth self-management of sickle cell disease. The iManage studies described challenges in maintaining user engagement despite observing improvements in self-efficacy and management of pain and mood [15]. Our attrition rates are also comparable with other studies of mobile health app use among adolescents and young adults [28,29]. Research suggests that enhancing brightness, color schemes, and gamification functions could boost health app usage among youth [30-32]. Other modifications, such as conversational style

XSL•FO
RenderX

interactions, speech bubbles, avatars, and illness-specific customizations (eg, importing of glucose monitor data), that were suggested by young adults during prototype testing could have also boosted usage rates in this study, although budgetary constraints precluded their inclusion in the final version of TMApp. Adding social interaction elements (either with the health care team or peers with similar conditions) was also suggested by young people who used the app. Such features may improve engagement and help strengthen social support systems for young patients [33,34], although these would introduce safeguarding and privacy issues. A full-time app moderator would have been required to manage the online interactions and respond promptly to any health emergencies that could have been communicated through the app. Our research team had neither the human nor the financial resources to support this. Finally, while our app development process incorporated some aspects of participatory design, a greater level of youth collaboration using youth-led and co-design principles would have allowed us to better understand their self-management needs, motivations for health technology use, and could have resulted in better usage rates.

Over two-thirds of the cohort (49/72, 68%) successfully transitioned to their designated AHS by 12 months. By comparison, varying rates of successful transition have been described in other studies, which range from approximately 20% to 90% [35-38]. Neither sex, chronic illness subgroup, nor baseline levels of distress and transition readiness were significantly predictive of successful transition in our small cohort, despite some research suggesting that AHS engagement is higher among young females [39-41]. Our relatively high rate of successful transition is likely attributed to the efficient local clinical protocols governing patient transition to adult care [42,43], especially for the main illness subgroups. Ongoing parental assistance in scheduling AHS appointments, as alluded to by some participants, also likely facilitated successful transition. Our current data suggest that implementation of the TMApp in conjunction with existing clinical procedures would have made minimal contributions to improving the transition process. For the 6 participants who did not engage with their designated AHS and were uncontactable at follow-up, it was not possible to ascertain whether they failed to transition or sought care from a different AHS, and this population requires further study. A unique barrier to transition experienced in this study was anxiety around attending medical appointments during the COVID-19 pandemic. The shift toward telehealth during pandemic lockdowns may have also delayed transition plans for some participants, given that many young people express a preference toward face-to-face over telehealth consultations [44,45].

The majority of participants who engaged with an AHS showed stable or improved illness markers and had low hospitalizations (except for one participant with cystic fibrosis). While we were unable to track illness control and hospitalizations in those who did not attend their designated AHS, our data support proactive follow-up for no-shows at AHS.

The key strengths of the study are, first, the follow-up methodology that involved obtaining posttransition eMR data on health service engagement and illness control, thus reducing reporter burden and error. Second, the mobile analytics data served as a valuable tool to quantify true app usage, despite only aggregate data being available due to user privacy restrictions. Third, TMApp was a generic mobile app designed to cover a wide range of chronic illnesses. This improves equity of access for individuals with rarer conditions where illness-specific self-management apps may not be available, but also limits the extent to which the app could be personalized. The major limitation was undoubtedly the low rates of usage, and the reasons for this have been discussed. Outsourcing app development to a commercial entity also introduced financial and logistical constraints that resulted in a relatively rudimentary TMApp design. Based on our current experiences, in-house development and maintenance are the only viable options for mobile health apps that have a small user base.

Conclusions

This pilot study did not demonstrate the feasibility of TMApp as it was not used regularly enough by adolescents and young adults with chronic illness in the first 12 months of transition. Over two-thirds of participants successfully transitioned despite low app usage, which is likely attributed to effective transition care protocols already in place, among other facilitators. Enhancing features, such as gamification and social networking capabilities, could help increase young people's app uptake and need to be tested. Importantly, future studies of mobile health apps for adolescents and young adults should include objective usage metrics like mobile analytics, as standard user feedback can be subject to considerable bias.

Acknowledgments

Initial funding for the development of the TMApp was provided by the New South Wales Health Agency of Clinical Innovation (ACI). ACI had no role in the design of the study, the collection, analyses and interpretation of data, and the preparation of this manuscript for publication. The research team would like to acknowledge the young people who took part in this study and provided valuable insights into the transition process. Further acknowledgments to Ms Tina Cunningham, Drs Sharon Medlow, Jane Ho, Vathsala Agarwalla, and Vhari Forsyth for their contributions at various stages of this study, all the medical specialty departments and staff who assisted with participant recruitment, as well as medical records staff at the adult hospitals for their assistance in adult health service data collection.

Data Availability

The datasets generated and analyzed during this study are available from the corresponding author on reasonable request.

XSL•FO
RenderX

Authors' Contributions

SCS, JY, and KSS designed the research; SCS, JY, and KSS conducted the research; SCS, RAN, HLC, and KSS analyzed and interpreted the data; RAN and SCS drafted the manuscript; HLC, JY, and KSS critically reviewed the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Checklist 1
CONSORT Pilot Trials checklist.
[PDF File, 94 KB - pediatrics_v8i1e67061_app1.pdf]

References

1. The digital lives of younger Australians. Australian Communications and Media Authority. URL: https://www.acma.gov.au/sites/default/files/2021-05/The%20digital%20lives%20of%20younger%20Australians.pdf [accessed 2025-08-16]
2. Badour B, Bull A, Gupta AA, Mirza RM, Klinger CA. Parental involvement in the transition from paediatric to adult care for youth with chronic illness: a scoping review of the North American literature. Int J Pediatr 2023;2023:9392040. [doi: 10.1155/2023/9392040] [Medline: 38045800]
3. Westwood A, Langerak N, Fieggen G. Transition from child- to adult-orientated care for children with long-term health conditions: a process, not an event. S Afr Med J 2014 Apr;104(4):310-313. [doi: 10.7196/samj.8201] [Medline: 25118562]
4. de Montalembert M, Guitton C, French Reference Centre for Sickle Cell Disease. Transition from paediatric to adult care for patients with sickle cell disease. Br J Haematol 2014 Mar;164(5):630-635. [doi: 10.1111/bjh.12700] [Medline: 24345037]
5. Pyatak EA, Sequeira PA, Whittemore R, Vigen CP, Peters AL, Weigensberg MJ. Challenges contributing to disrupted transition from paediatric to adult diabetes care in young adults with type 1 diabetes. Diabet Med 2014 Dec;31(12):1615-1624. [doi: 10.1111/dme.12485] [Medline: 24798586]
6. Lee A, Bailey B, Cullen-Dean G, Aiello S, Morin J, Oechslin E. Transition of care in congenital heart disease: ensuring the proper handoff. Curr Cardiol Rep 2017 Jun;19(6):55. [doi: 10.1007/s11886-017-0859-5] [Medline: 28477319]
7. Farre A, Wood V, Rapley T, Parr JR, Reape D, McDonagh JE. Developmentally appropriate healthcare for young people: a scoping study. Arch Dis Child 2015 Feb;100(2):144-151. [doi: 10.1136/archdischild-2014-306749]
8. Mahan JD, Betz CL, Okumura MJ, Ferris ME. Self-management and transition to adult health care in adolescents and young adults: a team process. Pediatr Rev 2017 Jul;38(7):305-319. [doi: 10.1542/pir.2016-0074] [Medline: 28667233]
9. Pollack AH, Backonja U, Miller AD, et al. Closing the gap: supporting patients' transition to self-management after hospitalization. Proc SIGCHI Conf Hum Factor Comput Syst 2016 May;2016:5324-5336. [doi: 10.1145/2858036.2858240] [Medline: 27500285]
10. White NH. Long-term outcomes in youths with diabetes mellitus. Pediatr Clin North Am 2015 Aug;62(4):889-909. [doi: 10.1016/j.pcl.2015.04.004] [Medline: 26210623]
11. Marrero F, Qadeer MA, Lashner BA. Severe complications of inflammatory bowel disease. Med Clin North Am 2008 May;92(3):671-686. [doi: 10.1016/j.mcna.2007.12.002] [Medline: 18387381]
12. Majeed-Ariss R, Baildam E, Campbell M, et al. Apps and adolescents: a systematic review of adolescents' use of mobile phone and tablet apps that support personal management of their chronic or long-term physical conditions. J Med Internet Res 2015 Dec 23;17(12):e287. [doi: 10.2196/jmir.5043] [Medline: 26701961]
13. Virella Pérez YI, Medlow S, Ho J, Steinbeck K. Mobile and web-based apps that support self-management and transition in young people with chronic illness: systematic review. J Med Internet Res 2019 Nov 20;21(11):e13579. [doi: 10.2196/13579] [Medline: 31746773]
14. Crosby LE, Ware RE, Goldstein A, et al. Development and evaluation of iManage: a self-management app co-designed by adolescents with sickle cell disease. Pediatr Blood Cancer 2017 Jan;64(1):139-145. [doi: 10.1002/pbc.26177] [Medline: 27574031]
15. Hood AM, Nwankwo C, Walton A, et al. Mobile health use predicts self-efficacy and self-management in adolescents with sickle cell disease. Transl Behav Med 2021 Oct 23;11(10):1823-1831. [doi: 10.1093/tbm/ibab041] [Medline: 33949674]
16. Crosby LE, Joffe NE, Kidwell KM, et al. Perceptions of a self-management intervention for adolescents with sickle cell disease. Clin Pract Pediatr Psychol 2022 Mar;10(1):79-90. [doi: 10.1037/cpp0000334]
17. Wesley KM, Fizur PJ. A review of mobile applications to help adolescent and young adult cancer patients. Adolesc Health Med Ther 2015;6(141-8):141-148. [doi: 10.2147/AHMT.S69209] [Medline: 26316835]
18. O'Connor A, Tai A, Carson-Chahhoud K. Isn't there an app for that? The role of smartphone and tablet applications for asthma education and self-management in adolescents. Children (Basel) 2021 Sep 9;8(9):786. [doi: 10.3390/children8090786] [Medline: 34572218]
19. Yeung J, Virella Pérez YI, Samarasinghe SC, Forsyth V, Agarwalla V, Steinbeck K. Study protocol: a pragmatic trial reviewing the effectiveness of the TransitionMate mobile application in supporting self-management and transition to adult

XSL•FO
RenderX

healthcare services for young people with chronic illnesses. BMC Health Serv Res 2022 Nov 29;22(1):1443. [doi: 10.1186/s12913-022-08536-8] [Medline: 36447255]
20. Calvo RA, Pardo A, Zhao Y, Klineberg E, Lam M, Steinbeck K. TransitionMate: a mobile application for chronic illness transition support. Presented at: OzCHI 2013; Nov 25-29, 2013; Adelaide, Australia p. 1-4.
21. Salama M, Shawish A. A comprehensive mobile-based companion for diabetes management. Presented at: 7th WSEAS European Computing Conference; 2013.
22. Ashurst EJ, Jones RB, Abraham C, et al. The diabetes app challenge: user-led development and piloting of internet applications enabling young people with diabetes to set the focus for their diabetes consultations. Med 20 2014 Nov 7;3(2):e5. [doi: 10.2196/med20.3032]
23. Harris LT, Tufano J, Le T, et al. Designing mobile support for glycemic control in patients with diabetes. J Biomed Inform 2010 Oct;43(5 Suppl):S37-S40. [doi: 10.1016/j.jbi.2010.05.004] [Medline: 20937484]
24. Steinbeck KS, Brodie L, Towns SJ. Transition care for young people with chronic illness. Int J Adolesc Med Health 2007;19(3):295-303. [doi: 10.1515/ijamh.2007.19.3.295] [Medline: 17937146]
25. Zhao Y, Calvo R, Pardo A, Gunn H, Steinbeck K. What we learned from transitionmate: a mobile app designed to support young people with chronic illness. Presented at: OzCHI 2015: The 27th Australian Conference on Human-Computer Interaction; 2015.
26. Kessler RC, Andrews G, Colpe LJ, et al. Short screening scales to monitor population prevalences and trends in non-specific psychological distress. Psychol Med 2002 Aug;32(6):959-976. [doi: 10.1017/s0033291702006074] [Medline: 12214795]
27. Transition care network resources. Agency for Clinical Innovation. URL: https://aci.health.nsw.gov.au/networks/transition-care/resources [accessed 2025-08-04]
28. Castensøe-Seidenfaden P, Husted GR, Jensen AK, et al. Testing a smartphone app (young with diabetes) to improve self-management of diabetes over 12 months: randomized controlled trial. JMIR Mhealth Uhealth 2018 Jun 26;6(6):e141. [doi: 10.2196/mhealth.9487] [Medline: 29945861]
29. Rudolf I, Pieper K, Nolte H, et al. Assessment of a mobile app by adolescents and young adults with cystic fibrosis: pilot evaluation. JMIR Mhealth Uhealth 2019 Nov 21;7(11):e12442. [doi: 10.2196/12442] [Medline: 31750841]
30. Bickmore T, Schulman D, Yin L. Maintaining engagement in long-term interventions with relational agents. Appl Artif Intell 2010 Jul 1;24(6):648-666. [doi: 10.1080/08839514.2010.492259] [Medline: 21318052]
31. Chan A, Kow R, Cheng JK. Adolescents' perceptions on smartphone applications (apps) for health management. Journal MTM 2017;6(2):47-55 [FREE Full text] [doi: 10.7309/jmtm.6.2.6]
32. Vaghefi I, Tulu B. The continued use of mobile health apps: insights from a longitudinal study. JMIR Mhealth Uhealth 2019 Aug 29;7(8):e12983. [doi: 10.2196/12983] [Medline: 31469081]
33. Wyatt TH, Bayless AK, Krauskopf P, Gaylord N. Using mHealth applications to promote self-managed health behaviors among teens. J Pediatr Nurs 2021;59:164-172. [doi: 10.1016/j.pedn.2021.04.025] [Medline: 33932646]
34. Jeminiwa RN, Hohmann NS, Fox BI. Developing a theoretical framework for evaluating the quality of mHealth apps for adolescent users: a systematic review. J Pediatr Pharmacol Ther 2019;24(4):254-269. [doi: 10.5863/1551-6776-24.4.254] [Medline: 31337988]
35. Hart LC, Pollock M, Brown A, et al. Where did they go? Tracking young adult follow-up during the transition from pediatric to adult-oriented care. Clin Pediatr (Phila) 2019 Oct;58(11-12):1277-1283. [doi: 10.1177/0009922819852980] [Medline: 31179741]
36. Reilly NR, Hammer ML, Ludvigsson JF, Green PH. Frequency and predictors of successful transition of care for young adults with childhood celiac disease. J Pediatr Gastroenterol Nutr 2020 Feb;70(2):190-194. [doi: 10.1097/MPG.0000000000002568] [Medline: 31978015]
37. Farrell K, Fernandez R, Salamonson Y, Griffiths R, Holmes-Walker DJ. Health outcomes for youth with type 1 diabetes at 18 months and 30 months post transition from pediatric to adult care. Diabetes Res Clin Pract 2018 May;139:163-169. [doi: 10.1016/j.diabres.2018.03.013] [Medline: 29534994]
38. van den Brink G, van Gaalen MAC, Zijlstra M, de Ridder L, van der Woude CJ, Escher JC. Self-efficacy did not predict the outcome of the transition to adult care in adolescents with inflammatory bowel disease. Acta Paediatr 2019 Feb;108(2):333-338. [doi: 10.1111/apa.14471] [Medline: 29926962]
39. Vargas G, Prunier L, Borus J. Gender differences in routine health maintenance examinations before and during the COVID-19 pandemic. J Adolesc Health 2023 Feb;72(2):300-302. [doi: 10.1016/j.jadohealth.2022.09.031] [Medline: 36473777]
40. Quine S, Bernard D, Booth M, et al. Health and access issues among Australian adolescents: a rural-urban comparison. Rural Remote Health 2003;3(3):245. [Medline: 15882102]
41. Jensen PT, Paul GV, LaCount S, et al. Assessment of transition readiness in adolescents and young adults with chronic health conditions. Pediatr Rheumatol Online J 2017 Sep 9;15(1):70. [doi: 10.1186/s12969-017-0197-6] [Medline: 28888223]
42. Bridgett M, Abrahamson G, Ho J. Transition, it's more than just an event: supporting young people with type 1 diabetes. J Pediatr Nurs 2015;30(5):e11-e14. [doi: 10.1016/j.pedn.2015.05.008] [Medline: 26044910]
43. West C, Brodie L, Dicker J, Steinbeck K. Development of health support services for adults with spina bifida. Disabil Rehabil 2011;33(23-24):2381-2388. [doi: 10.3109/09638288.2011.568664] [Medline: 21492059]

XSL•FO
RenderX

44. Mseke EP, Jessup B, Barnett T. A systematic review of the preferences of rural and remote youth for mental health service access: telehealth versus face-to-face consultation. Aust J Rural Health 2023 Jun;31(3):346-360. [doi: 10.1111/ajr.12961] [Medline: 36606417]
45. Barney A, Mendez-Contreras S, Hills NK, Buckelew SM, Raymond-Flesch M. Telemedicine in an adolescent and young adult medicine clinic: a mixed methods study. BMC Health Serv Res 2023 Jun 22;23(1):680. [doi: 10.1186/s12913-023-09634-x] [Medline: 37349720]

ABBREVIATIONS

AHS: adult health service
CONSORT: Consolidated Standards of Reporting Trials
eMR: electronic medical record
K10: Kessler Psychological Distress Scale
TMApp: TransitionMate
TRC: Transition Readiness Checklist

Edited by S Badawy; submitted 07.10.24; peer-reviewed by J Floch, M Peeples; revised version received 07.03.25; accepted 18.03.25; published 03.09.25.

Please cite as:
Samarasinghe SC, Al Na'abi R, Cheng HL, Yeung J, Steinbeck KS
A Mobile Phone App to Support Self-Management and Transition to Adult Health Services in Young People With a Chronic Illness: Single-Arm Pilot Intervention Study
JMIR Pediatr Parent 2025;8:e67061
URL: https://pediatrics.jmir.org/2025/1/e67061
doi:10.2196/67061

© Shehani C Samarasinghe, Riham Al Na'abi, Hoi Lun Cheng, Jeffrey Yeung, Katharine S Steinbeck. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 3.9.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Benefits and Barriers of Caregiver App Engagement for Supporting Diverse Children With Asthma: Mixed Methods Study

Kandia Lewis[1], PhD; Cynthia M Zettler-Greeley[2], PhD; Amy Milkes[3], MA; Kathryn V Blake[4], PharmD

[1]Virtual Health and Informatics, Nemours Children's Health, Wells Fargo Tower, 8th Floor, 1600 Rockland Road, Wilmington, DE, United States

[2]Virtual Health and Informatics, Nemours Children's Health, Jacksonville, FL, United States

[3]Center for Healthcare Delivery Science, Nemours Children's Health, Jacksonville, FL, United States

[4]Center for Pharmacogenomics and Translational Research, Nemours Children's Health, Jacksonville, FL, United States

Corresponding Author:
Kandia Lewis, PhD
Virtual Health and Informatics, Nemours Children's Health, Wells Fargo Tower, 8th Floor, 1600 Rockland Road, Wilmington, DE, United States

Abstract

Background: Asthma is one of the most common pediatric conditions affecting millions of US children. Digital health apps may provide children and their caregivers (parents or legal guardians) with ways to manage asthma and improve health and educational outcomes.

Objective: As digital health technology becomes more prevalent to help manage chronic conditions, like asthma, this study examined the reported benefits and barriers of caregiver interactions with an asthma-specific app. The app, created by physicians and digital health development professionals, was designed to educate, inform, and help caregivers manage the health of their child. We evaluated app logins and feature use (collectively defined as "app engagement") for caregivers of children with asthma aged 5 - 11 years. We examined whether (1) app engagement differed due to children's demographic and asthma health characteristics, (2) themes about app engagement emerged from caregiver-reported app experiences, (3) these themes correlated with demographic and asthma health characteristics, and (4) engagement with the app was associated with reduced school absences.

Methods: Eighty caregivers and their children with asthma participated between September 2019 and November 2020. Pretest (Time 1) and posttest (Time 2) data were collected over 6 months on caregiver and child demographic and health characteristics, health care usage, app engagement, and app experiences. Additionally, caregiver app engagement data and child health care data were collected retrospectively, 2 years prior to the start of the study. We used a mixed methods design, which included correlation, regression, chi-square, and content analysis to examine caregiver app engagement.

Results: Most caregivers were mothers (76/80, 95%) and had a college degree (45/80, 56%). Children's mean age was 8.76 (SD 1.79), and all were English speakers (80/80, 100%). About half of the participants were White children (43/80, 54%), and 26% (21/80) of them had uncontrolled asthma. Logistic regression revealed that caregivers of White children (OR [odds ratio] 8.57, 95% CI 1.68-43.65) with uncontrolled asthma (OR 17.81, 95% CI 2.36-134.24) who earned a college degree (OR 6.94, 95% CI 1.38-34.87) were statistically significantly more likely to use the app than caregivers of children of other races with controlled asthma without a college degree (P<.001). Qualitative findings support and expand on the logistic regression results. Five themes regarding app engagement emerged, including relevancy, acceptability and understandability, technology limitations, educational barriers, and information and communication benefits. Caregivers also identified specific app features that may promote child health and education.

Conclusions: Understanding caregiver and child experiences in using digital health technologies for managing asthma may inform ways to support app engagement among caregivers and their children in the effort to improve patient health outcomes.

(JMIR Pediatr Parent 2025;8:e69755) doi:10.2196/69755

KEYWORDS

digital health; pediatric asthma; app engagement; health care; education

XSL•FO
RenderX

Introduction

Current Knowledge of Asthma and Digital Health

Childhood asthma is a chronic lung disease that affects 4.7 million children in the United States [1]. Uncontrolled asthma can be disruptive and costly to families and payors. Approximately 60% of children with asthma between 5 and 11 years of age have an asthma exacerbation each year, resulting in school absences (52%), emergency department visits (19%), and hospitalizations (5%) [2]. Uncontrolled asthma also contributes to an annual economic burden on families and health care systems. In 2013, the estimated total direct costs of pediatric asthma in the United States approached 6 billion dollars, averaging between US $3076 and US $13,612 per child [3]. These health and economic burdens disproportionately affect children who are Black, Latinx, and from lower-income families, due in part to systemic racism and unequal access to quality health care, housing, and education [4,5].

Compounding the health and economic issues, children with asthma are at higher risk for educational difficulties stemming from chronic absenteeism [6]; asthma exacerbations contribute to about 10.5 million school absences each year [7]. As chronic absenteeism contributes to lower math and reading abilities compared to children who are not repeatedly absent [8], there is a need to develop tools to improve children's asthma to keep them healthy and in the classroom. One worthwhile approach to support improved asthma management may be to use digital health apps [9]. However, because a digital divide in usage exists based on race, ethnicity, income, and geographic location [10-14], the question remains as to whether digital health tools are appropriate for use across a diverse population of caregivers (parents or legal guardians) and their children.

Digital Health Apps: How to Support Asthma Management?

Leveraging digital health apps to improve pediatric asthma management may contribute to improved asthma health for children from underserved populations and those with uncontrolled asthma. Recent indications show digital health technologies may aid in addressing health equity concerns among marginalized patient populations as they frequently engage with specific app features [14]. Moreover, digital health tools are more likely to be used when children have uncontrolled asthma [9,10], as they often require frequent health care usage and engage with several digital health tools [14]. These tools may help improve children's health outcomes [15], as studies reveal these devices support medication adherence [16] and caregiver asthma knowledge [17], contributing to improved pediatric asthma health within 6 months [15,18]. As these patient populations have recently increased usage of mobile devices [19], including engagement with digital health apps [20], there is an opportunity to increase their access to health care and improve their health outcomes. Moreover, improved asthma health may reduce school absenteeism, thereby improving educational outcomes [21].

However, the reasons for app engagement are unclear, with studies highlighting potential barriers to app engagement; thus, further study is warranted. Access issues may include a lack of broadband internet or smartphone devices [22]. However, many individuals who have access to these technologies have suboptimal engagement due to a lack of knowledge, understanding, or guidance on how or why to use them for managing health needs [12]. Further, specific features may be more relevant for certain populations. For example, one study found that families receiving Medicaid—US government-funded health care services for low-income patients—accessed digital health educational resources more often than non-Medicaid recipients [14]. The authors posited that the frequent use of educational features among Medicaid recipients was due to a lack of access to health care information elsewhere. Further research is needed to understand these apparent contradictions in app use across patient populations.

Benefits and barriers of app engagement include whether patients consider the app relevant, understandable, and acceptable to use [23-25]. Moreover, as certain features may be considered more beneficial for certain populations [14], benefits and barriers may differ across diverse patient populations. As digital health tools become more widely implemented in pediatric health care institutions, it is vital to examine whether these technologies may yield equitable benefits for children. Consequently, it would be valuable to learn whether and why caregivers choose to use health apps for managing their child's health care. In addition to supporting health outcomes, this information could assist app developers in targeting users' needs, interests, and preferences, potentially motivating increased app engagement.

Purpose

The purpose of this study was to examine the benefits and barriers of digital health app engagement among caregivers of school-aged children with asthma. As such, we focused on children aged 5 - 11 years because after the age of 11 years, many children take responsibility for most of their asthma care [26]. Understanding factors that contribute to caregiver app engagement may help to uncover whether app engagement correlates with improved child health and education, including for those at risk for these poor outcomes. We explored four research questions:

1. Does app engagement differ based on demographic and asthma health characteristics? We hypothesized that (1) caregivers of White children and caregivers with higher socioeconomic status would be more likely to engage with the app than caregivers of children of other races and lower socioeconomic status [11,14], and (2) caregivers of children with uncontrolled asthma would be more likely to engage with the app than caregivers of children with controlled asthma [9,10,14,15].
2. Do app engagement themes emerge from caregiver-reported experiences about the app? We hypothesized that caregiver-reported experiences about app engagement would yield themes around relevancy, acceptability, and understandability [23-25].
3. Do app engagement themes correlate with demographic and asthma health characteristics? We wanted to understand whether identified themes related to benefits and barriers

XSL•FO
RenderX

of app engagement vary across diverse children with asthma. We hypothesized that (1) families with higher educational attainment would endorse more benefits of app engagement than less educated families [11,12] and (2) those of children with uncontrolled asthma would endorse more benefits of app engagement than families of children with controlled asthma [9,10,14,15].

4. Is app engagement related to reduced school absences? We hypothesized app engagement would help improve asthma management [15,18], thereby reducing chronic absenteeism.

Methods

Study Design and Procedure

This mixed methods, multisite, observational retrospective and prospective study included 6 months of active data collection and 2 years of retrospective data collection. Retrospective asthma health data were collected to avoid potential underreporting, as seasonality contributes to asthma management [27]. Moreover, obtaining 2 years of retrospective asthma control scores increased the likelihood of their collection, which are provided by caregivers and entered into the electronic health record (EHR) at scheduled patient care visits. Retrospective app engagement data, commensurate with asthma health data, and prospective data were recorded in the app. Prospective data were collected at study start (Time 1) and 6 months later (Time 2), consistent with previous digital health and asthma research [15,18].

Participants

Caregivers of children who were patients of Nemours Children's Health (NCH) and who had an asthma diagnosis were emailed recruitment notifications with access to a secure REDCap (Research Electronic Data Capture; Vanderbilt University) link to learn more about the study. Of the 154 caregivers who accessed the link, 148 (96%) were interested, and 126 (85%) of those interested were eligible for enrollment. Children were eligible if they were aged 5 - 11 years, had a diagnosis of asthma, and had a visit with a provider in the Nemours allergy or pulmonology departments within a year prior to consent. Caregivers were required to be a parent or legal guardian fluent in conversational English to match the language of the app. Families across Nemours US locations (Northeast and Southeast) were eligible whether they had the app or not. Per consent, we limited enrollment to 1 child per family. Almost two-thirds of eligible participants (64%, 80/126) consented to participate, 100% (80/80) completed all pretest study activities, and 80% (64/80) completed both pretest and posttest study activities.

Measures and Data Collection

Demographic Questionnaire

The Parent Research Questionnaire was a 28-item researcher-developed questionnaire about demographic characteristics (eg, income, race, ethnicity, and education level) and health characteristics (eg, family history of asthma). The questionnaire took about 10 minutes to complete. It has been used in previously published work [9], and it has asthma-specific items that were developed for study purposes, such as age of asthma diagnosis, family history of asthma, and asthma triggers. Data were collected at Time 1.

App Experience Survey

The App Experience survey was a 36-item researcher-developed questionnaire about caregiver app engagement (Section A in Multimedia Appendix 1) to understand caregiver engagement of a novel digital health app, which has been used in previously published work [9]. The survey took about 15 minutes to complete and included multiple-choice and open-ended items about feature engagement and app experiences (eg, reasons for using or not using the app, frequency of features used, and benefits and barriers of app use) and school absences due to asthma. Data were collected at Time 1 and Time 2.

Nemours App

Physicians and digital health development professionals at NCH developed a caregiver-facing digital health app, the "Nemours app," with features designed to support patients at NCH with asthma and their caregivers. Caregivers log in to the app via mobile devices or desktops and are logged out after 30 minutes of inactivity. The app has been in use since February 2018 and includes traditional portal mainstays, such as telehealth and messages, which can be used as frequently as desired, as well as asthma-specific features (Table 1). As this was an observational study, only resources provided by NCH were available, including contact information for technical support, an app demonstration video, and medication reminders (if selected by caregivers). Participants reported hearing about the app via emails, providers, family, friends, searches for digital health apps, and this study.

We defined "app engagement" as logging into the app at least once and using at least 1 identified app feature (Table 1). We defined a caregiver who did not log in or use any features during the study as a "nonapp engager" [28].

XSL•FO
RenderX

Table . App features.

Feature	Type	Description
Reminders	Asthma-specific	Set medication reminder notifications to support asthma medication adherence.
Medication images	Asthma-specific	View images to identify controller versus quick relief medications.
Medication videos	Asthma-specific	Watch videos demonstrating proper asthma medication usage.
Asthma educational resource	Asthma-specific	Read articles and terminology word banks to learn about asthma.
Asthma symptom tracker	Asthma-specific	Track asthma control levels, symptoms, limitations, and the air quality index. The data are linked to the electronic health care record so that providers may access patients' tracker entries between office visits.
Asthma action plan	Asthma-specific	Access individualized, provider-created, asthma action plans. Download and share it as a PDF or use it interactively to receive real-time feedback on actions that may help to resolve an exacerbation.
Air quality alerts	Asthma-specific	Receive alerts for dangerous levels of air quality to remind children to carry quick relief medication.
Telehealth	General	Participate in video visits with health care providers.
Messages	General	Communicate with health care providers.

Health Care Records

Data were obtained for asthma diagnosis and severity (as specified by the child's provider), asthma control, and health care usage (eg, asthma-related emergency department visits, urgent care visits, and hospitalizations) from the EHR. Asthma control was obtained from childhood asthma control test (C-ACT) scores in the EHR. Available C-ACT scores ranged from 0 to 9. Mean scores provided an average asthma control level per child. Scores above 19 were defined as "controlled," and scores of 19 or below were defined as "uncontrolled" [29].

Power Analysis

This study was part of a larger project for which we conducted an a priori power analysis to determine the sample size [9]. Sufficient power was estimated with n=40. To account for the 50% attrition typical in digital health research [30], we enrolled 80 caregivers and their children.

Data Analysis

We used a mixed methods approach to examine caregiver app engagement. We first conducted a preliminary correlation analysis to identify statistically significant (P<.05) demographic (eg, child age, government public assistance, parent learning problems, and transportation difficulties) and health characteristics (eg, family asthma history, asthma triggers, and health care usage) to include as predictors in the analysis for research question 1.

To address the first research question, we conducted logistic regression to evaluate the relation between the identified demographic and health characteristics and caregiver app engagement. Child race, maternal education level, and asthma control level were statistically significantly related to app engagement and were used as predictors in the regression model. The variables were dummy coded for the analysis: maternal education level (0=high school degree or less, 1=associate's, bachelor's degree or higher), child race (0=Other races, 1=White child), and asthma control level (0=controlled, 1=uncontrolled). Logistic regression was used because the outcome variable, app engagement, was dichotomous (0=nonapp engagement, 1=app engagement) [31]. Listwise deletion was used to address missing values for asthma control level in the analysis. As a result, 14 nonapp engagers and 13 app engagers were removed from the final regression analysis (n=53). For research question 1, missing data ranged between 0% and 34% (asthma control level missing at 27/80, 34%) and were missing completely at random per Little Missing Completely at Random test (χ^2_3=3.5; P=.33). Multiple imputation analyses were similar to the nonmultiply imputed analyses; thus, nonmultiply imputed findings are presented. For transparency, we included the multiply imputed findings (Section B in Multimedia Appendix 1).

We also conducted post hoc analyses because although all participants completed the Time 1 app experiences survey, 19% (15/80) of the data were missing for the Time 2 survey. Thus, we examined whether there was a difference between app engagers and nonapp engagers who completed the Time 2 survey. We also examined the relation between key demographic and health characteristics and completion of the Time 2 survey. Further, we examined whether frequency of app use was correlated with caregiver-child demographic and health characteristics.

XSL•FO
RenderX

For the second research question, content analysis was conducted to identify app engagement themes about caregiver app experiences. Caregiver responses were organized and coded in Excel (Microsoft) by the first author. Analysis of codes and themes was conducted in SPSS (IBM Corp). We used a combined approach. First, we used a deductive approach to examine a priori codes that were created to uncover themes regarding app benefits and barriers, including relevancy, understandability, and acceptability [23-25]. After that, we used an emergent approach because of the novelty of the Nemours app by using open coding in which additional codes could be added after initially reviewing the data [32]. We also used axial coding to combine related codes [33]. Coding was considered complete when only a few uncoded data remained [34,35]. Finally, the first and third authors double-coded 31% (5/16) of randomly selected caregiver open-ended response sections, which demonstrated strong percent agreement (0.92) and high interrater reliability (κ=0.87). For the third research question, we used nonparametric correlation analyses (Spearman) due to nonnormality to examine the extent to which themes about app relevancy, understandability, acceptability, benefits, and barriers were related to demographic and asthma health characteristics.

To address the fourth research question, we used chi-square analysis because both variables, app engagement (0=nonapp engagement, 1=app engagement), and school absences (0=none, 1=1 - 5, 2=6 - 10, 3=more than 10), were categorical. We examined whether app engagement was related to decreased school absences between Time 1 and Time 2. We calculated the difference score between school absences at Time 1 and Time 2. Initially, listwise deletion was used, resulting in 13 nonapp engagers and 3 app engagers being removed from the analysis (n=64). Overall, missing data ranged between 0% and 20% (school absences missing at 16/80, 20%). Data were missing not completely at random per Little Missing Completely at Random test (χ^2_1=15.0; P<.001), as nonapp engagers had more missing school absence data (13/31, 42%) than app engagers (3/49, 6%). As multiple imputation typically leads to less biased results than listwise deletion [36,37], we conducted these analyses and included predictor and covariate variables to help account for missingness [36]. The multiply imputed analyses yielded significant results, whereas the nonmultiply imputed analyses did not. As such, we present the nonmultiply imputed findings because it is likely a more conservative estimate. For transparency, we also included the multiply imputed findings (Section C in Multimedia Appendix 1). Additionally, we conducted post hoc analyses because, given that maternal education, race, and asthma control are associated with school absences [38], we examined whether these characteristics, plus app engagement, were related to a decline in school absences.

Ethical Considerations

The study was conducted between September 2019 and November 2020 and was approved by the Nemours Institutional Review Board (approval number 1422315). REDCap, a web-based app for secure data capture and storage [39,40], was used for study recruitment (via a rolling admission process), parental or legal guardian consent, data collection, and participant communication. Survey data were collected securely online via REDCap and items appeared in a consistent order. Page numbers varied from 4 to 7 because an adaptive format was used, and items ranged between 8 and 14 per page because of the variation in item format. Participants were informed of the study investigators, purpose, approximate time to complete surveys, security of data storage on password-protected files or servers, and the voluntary nature of participation. Quantitative data were obtained from multiple-choice survey items and qualitative data were obtained from open-ended survey items. A US $50 gift card was provided to incentivize participation. For additional information, see Lewis et al [9].

Results

Participant Characteristics

Participating children's race and ethnicity largely reflected that of pediatric patients with asthma in the US population, including a slight overrepresentation of White children and a slight underrepresentation of Latinx children [1]. The child sample, as identified by caregivers, and the US population, respectively, was 54% (43/80) and 44% (2,074,381/4,675,475) White, 24% (19/80) and 23% (1,058,310/4,675,475) Black, 12% (10/80) and 5% (221,110/4,675,475) multiracial, 1% (1/80) and 2% (108,819/4,675,475) Asian, and 9% (7/80) unreported; 12% of the child sample (10/80) and 24% (1,102,471/4,675,475) of the US population were Latinx. The 49 caregivers who engaged with the app logged in at least 3 times, exceeding our engagement criteria (at least one log in), and engaged with at least one of these features, including reminder notification (n=1, 2%), medication images (n=17, 35%), asthma symptom tracker (n=32, 65%), asthma action plan (n=11, 22%), air quality index (n=9, 18%), telehealth video visits (n=9, 18%), and messages (n=28, 57%). Child and caregiver demographic statistics are presented in Table 2. For additional information about participants, see Lewis et al [9].

XSL•FO
RenderX

Table . Child and caregiver demographic statistics by app use.

Characteristic	All (N=80)	Engage (n=49)	Nonengage (n=31)
Child age, mean (SD)	8.76 (1.79)	8.57 (1.79)	9.07 (1.77)
Mean C-ACT[a] score[b] , mean (SD)	20.84 (3.81)	20.18 (4.27)	22.24 (2.10)
English is primary language, n (%)	80 (100)	49 (100)	31 (100)
Child race, n (%)			
White	43 (54)	32 (69)	11 (41)
Black	19 (24)	9 (20)	10 (37)
Multiracial	10 (12)	4 (9)	6 (22)
Asian	1 (1)	1 (2)	0 (0)
Child ethnicity (Hispanic or Latinx), n (%)	10 (12)	4 (8)	6 (19)
Grade at Time 1, n (%)			
Daycare–Kindergarten	23 (29)	13 (27)	10 (32)
First–second	24 (30)	16 (33)	8 (26)
Third–fourth	22 (27)	11 (22)	11 (35)
Fifth–sixth	11 (14)	9 (18)	2 (6)
Asthma control, n (%)			
Uncontrolled[b]	21 (26)	19 (39)	2 (6)
Controlled[b]	32 (40)	17 (35)	15 (48)
Asthma severity, n (%)			
Intermittent	14 (18)	12 (24)	2 (6)
Persistent	66 (82)	37 (76)	29 (94)
Allergies	62 (78)	39 (80)	23 (74)
Asthma-related absences Time 1, n (%)			
None	28 (35)	20 (41)	8 (26)
1-5 days	36 (45)	20 (41)	16 (51)
More than 6 days	16 (20)	9 (18)	7 (23)
Asthma-related absences Time 2, n (%)			
None[c]	33 (41)	24 (49)	9 (29)
1-5 days[c]	23 (29)	17 (35)	6 (19)
More than 6 days[c]	8 (10)	5 (10)	3 (10)
Caregiver relationship to child, n (%)			
Mother	76 (95)	46 (94)	30 (97)
Father	2 (3)	1 (2)	1 (3)
Other (eg, grandparent)	2 (3)	2 (4)	0 (0)
Maternal highest degree, n (%)			
High school diploma or GED[d]	14 (18)	5 (10)	9 (29)

XSL•FO
RenderX

Characteristic	All (N=80)	Engage (n=49)	Nonengage (n=31)
Some college or trade school	21 (26)	11 (22)	10 (32)
Associate's or bachelor's degree	24 (30)	19 (39)	5 (16)
Graduate or professional school	21 (26)	14 (29)	7 (23)

[a]C-ACT: childhood asthma control test.

[b]Data for 27 children unreported.

[c]Data for 16 children unreported.

[d]GED: General Education Development.

Predicting App Engagement From Demographic Survey and Health Care Records

The full logistic regression model was statistically significant, (χ^2_3=24.5; *P*<.001), and well specified, as the Hosmer-Lemeshow Test was not statistically significant (*P*=.84). The model explained approximately 52% of the variance for app engagement (Nagelkerke R^2=0.52) and correctly classified 83% of the cases. Caregivers of White children were about 8.5 times more likely to engage with the app than caregivers of children of other races when controlling for maternal education and child asthma control level (OR [odds ratio] 8.57, 95% CI 1.68-43.65; *P*=.01). Caregivers with a college degree were nearly 7 times more likely to engage with the app than caregivers with a high school diploma when controlling for child race and asthma control level (OR 6.94, 95% CI 1.38-34.87; *P*=.02). Caregivers of children with uncontrolled asthma were almost 18 times more likely to engage with the app than caregivers of children with controlled asthma when controlling for maternal education and child race (OR 17.81, 95% CI 2.36-134.24; *P*=.01).

Post Hoc Analyses to Examine Survey Completion and Frequency of App Use

Responses about app engagement were skewed to those who engaged with the app, as they were statistically significantly more likely to complete the Time 2 survey than those who did not engage with the app (χ^2_1=17.9; *P*<.001). However, logistic regression and crosstabulations revealed no statistically significant relation between key participant characteristics and Time 2 app experience survey completion. Moreover, frequent app engagement (logged in ≥24 times) was not significantly correlated with (1) child and caregiver demographic characteristics including age, race, ethnicity, education, receiving public assistance, and transportation issues and (2) child health, including age diagnosed with asthma, family asthma history, asthma triggers, health care usage, and asthma control.

Themes That Emerged via the App Experience Survey

Nearly all caregivers (75/80, 94%) responded to at least one of the 16 open-ended response sections in the survey with an average of 28.31 (SD 17.58) responses per section. Five themes (2 a priori—relevancy and acceptability or understandability—and 3 emergent—technology limitations, educational barriers, and information and communication benefits—themes) from 408 coded comments resulted from the content analysis about caregiver app experiences (Table 3). One theme was whether the app was relevant for family use to manage asthma, with more caregivers stating the app was not relevant (eg, child's asthma was controlled; 12/80, 15%) than relevant (1/80, 1%). Another theme identified the "acceptability" and "understandability" of the app. More caregivers noted the app was easy to use and understand (56/80, 70%) relative to those who noted it was difficult to use and understand (23/80, 29%). Two themes were specifically related to barriers. First, caregivers noted technology limitations (17/80, 21%), such as difficulties with internet connection and technical issues (eg, during telehealth). Educational barriers (29/80, 36%) included being (1) unaware of the app or its features, (2) unclear about the app's potential benefits or purpose, and (3) unsure of how to use the app. The final theme pertained to the app's information and communication benefits (51/80, 64%), such as gaining information about child health and being able to communicate with a child's care team.

XSL•FO
RenderX

Table . App engagement themes.

Category (n=80)	Themes and examples	Caregivers, n	Total comments, n
Relevancy			
Benefits	• App Engager: "I don't think I was aware there was a newer app. [Her] asthma triggers have been a mystery so tracking her symptoms, good/bad days will be helpful."	1	1
Barriers	• App Engager: "Not sure how [the app] will help us. My daughter seems to be doing well." • Nonapp Engager: "She is inside more due to [COVID-19]." • Nonapp Engager: "I don't generally use the app. My providers haven't really made it into a tool we need..."	12	14
Acceptability or understandability (ease of use or clarity)			
Benefits	• App Engager: "I think this is very user friendly and everything in one place is very convenient." • App Engager: "On my phone and convenient." • App Engager: "It's easy to navigate and very comprehensive."	56	118
Barriers	• App Engager: "Difficult to understand and use." • Nonapp Engager: "Difficult to find things quickly."	23	43
Technology limitations			
Barriers	• App Engager: "Lack of a strong internet connection." • Nonapp Engager: "Having to pay for internet services." • Nonapp Engager: "It has technical issue with video appointments."	17	34
Educational			
Barriers	• App Engager: "I have no idea what I am supposed to use the app for in regards to my child's asthma." • App Engager: "Should be more education to parents about what we should be using the app for." • Nonapp Engager: "I wasn't aware of the videos and fun facts about learning more about asthma."	29	35
Information and communication			

XSL•FO
RenderX

Category (n=80)	Themes and examples	Caregivers, n	Total comments, n
Benefits	• App Engager: “Love the ability to message providers directly.” • App Engager: “A good way to get data and communicate with your provider.” • App Engager: “Easily shows doctor current health.”	51	163

Content analysis also revealed specific app features caregivers identified as a benefit to app engagement based on their experience with the app or based on app feature information shared via the study survey (Table 4). The most frequently reported beneficial app features were messages (25/80, 31%), access to health care records (24/80, 30%), and the asthma symptom tracker (19/80, 24%). These app features were often noted as beneficial for communication purposes and for gathering and sharing information about children’s asthma health.

Table . Caregiver-reported beneficial app features.

Features (n=80)	Examples	Caregivers, n	Total comments, n
Air quality index	• App Engager: “To check air Quality”	5	5
Asthma action plan	• Nonapp Engager: “To print action plan for schools and camp”	6	6
Telehealth video visits	• App Engager: “Having the option to stay home and still have a follow up visit with the doctor”	8	10
Medication reminders, refills, and education	• App Engager: “I use it for action plans and prescription renewals.”	9	11
Asthma symptom tracker	• App Engager: “I like the asthma tracker so that I can see if there is a pattern to when his asthma flares up.”	19	25
Health care records	• App Engager: “I can see details from all past appointments. I find it easier to use than [our] pediatricians so I use it if I have a question about her growth, asthma and medication history” • App Engager: “I like that I can refer back to this app after an appointment in case I forgot something the doctor said.”	24	32
Messages	• App Engager: “Love the ability to message providers directly.”	25	39

Correlation Between App Engagement Themes and Demographic and Health Characteristics

Statistically significant correlations were found between demographic and health characteristics and app engagement themes, specifically themes around relevancy, acceptability or understandability, educational barriers, and information and communication benefits (Table 5). Regarding relevancy, caregivers of children with dust allergies reported more benefits to understanding how the app could be helpful (ρ=0.23; *P*=.04), whereas caregivers with learning problems noted more barriers (ρ=0.27; *P*=.02). Regarding acceptability or understandability, caregivers of Asian children noted more benefits regarding the ease of use and clarity of the app (ρ=0.23; *P*=.04), whereas caregivers of children with pollen allergies (ρ=0.30; *P*=.01) and controlled asthma (ρ=−0.30; *P*=.03) shared more barriers. Caregivers of Asian children (ρ=0.28; *P*=.01) and of children with pollen allergies (ρ=0.24; *P*=.03) reported more app

XSL•FO
RenderX

educational barriers. Finally, caregivers of White children (ρ=0.30; *P*=.01) and caregivers who did not receive public assistance (ρ=–0.37; P<.001) reported more access to asthma-related health information and provider communication benefits because of their app engagement.

Table . Significant Spearman correlations between app themes and demographic and health characteristics.

Characteristic	Race-Asian		Race-White		Public assistance		Learning problems		Dust		Pollen		Asthma control	
	Spearman rank correlation (ρ)	*P* value	Spearman rank correlation (ρ)	*P* value	Spearman rank correlation (ρ)	*P* value	Spearman rank correlation (ρ)	*P* value	Spearman rank correlation (ρ)	*P* value	Spearman rank correlation (ρ)	*P* value	Spearman rank correlation (ρ)	*P* value
Relevancy–benefits	–0.02	.85	0.10	.38	–0.07	.52	–0.03	.78	0.23[a]	.04	0.08	.47	0.17	.22
Relevancy–barriers	–0.08	.47	0.15	.18	–0.20	.08	0.27[a]	.02	0.05	.69	0.08	.47	–0.05	.72
Acceptability or understandability–benefits	0.23[a]	.04	0.13	.24	–0.15	.19	–0.02	.84	0.08	.50	0.12	.29	–0.08	.55
Acceptability or understandability-barriers	0.03	.79	0.18	.11	–0.02	.89	–0.06	.62	0.22	.05	0.30[a]	.01	–0.30[a]	.03
Education barriers	0.28[a]	.01	0.11	.36	–0.12	.29	–0.03	.78	0.06	.60	0.24[a]	.03	0.10	.52
Information and communication benefits	0.03	.79	0.30[a]	.01	–0.37[a]	<.001	0.03	.82	0.17	.13	0.18	.12	0.04	.79

[a]Indicates statistically significant correlations.

Relation Between App Engagement and Caregiver-Reported School Absences

Chi-square analysis revealed that app engagement was not statistically significantly related to the school absence difference score (0=no change in absences, 1=absences reduced by 1 category, 2=absences reduced by 2 categories, 3=absences reduced by 3 categories) between Time 1 and Time 2 (χ^2_3=2.6; *P*=.46). As we did not find a statistically significant relation with this analysis, we also conducted a chi-square test to evaluate the difference in school absences for all children, regardless of app engagement. When examining this difference, we found a statistically significant decline in absences for all children between Time 1 and Time 2 (χ^2_9=99.9; *P*<.001). Further, we found that more caregivers reported “no absences” at Time 2 (33/80, 41%) than at Time 1 (28/80, 35%). We would expect fewer caregivers reporting “no absences” later in the year at Time 2, as we asked about cumulative school absences over the past year. These discrepancies suggest the results may be uninterpretable, warranting further research. We present this data, despite the limitations, because this was a planned study analysis. Additionally, as findings differed between nonmultiply imputed and multiply imputed data (Section C in Multimedia Appendix 1), the results must be interpreted with caution. Despite the discrepancies with the absentee data, for transparency, we included post hoc findings indicating child race and asthma control are statistically significantly related to school absences (Section D in Multimedia Appendix 1).

XSL•FO
RenderX

Discussion

Principal Findings

Understanding facilitators and challenges from caregivers and children who use digital health technology is key to uncovering ways to improve app engagement to potentially improve child health and educational outcomes. Using a mixed methods approach, this study demonstrated key demographic and health characteristics related to app engagement and revealed themes that further supported these findings. These themes may uncover factors that improve engagement among caregivers and children with diverse demographic and health characteristics. Three important findings were gleaned from this work, contributing to the nascent field of digital health research. First, quantitative and qualitative findings revealed racial, educational, and health-related differences in app engagement. Second, the app may have the potential to help improve communication between caregivers, children, and health care providers. Finally, caregivers identified app features that may help support child health and education.

Gaps in App Engagement

Caregivers of White children with uncontrolled asthma who earned a college degree were more likely to engage with the app than caregivers of children of other races with controlled asthma without a college degree. This suggests there may be an educational and racial gap in app engagement, consistent with previous research [12-14]. As a digital divide persists [9-14], care must be taken to understand potential reasons for this gap in app engagement. In this study, caregiver-reported app experiences supported the quantitative results and provided potential reasons for a divide between families of different racial and educational backgrounds.

Regarding educational and racial gaps, caregivers with a history of learning problems in school and caregivers of Asian children reported more educational barriers to app engagement. These caregivers reported receiving limited information about how to use the app to help manage their child's asthma or about the potential benefits of app engagement. This lack of education about the purpose and potential benefits of the app was well captured by this app engager's response: "I have no idea what I am supposed to use the app for in regards to my child's asthma." Video tutorials may be useful in addressing this educational barrier by facilitating app engagement among caregivers and children [23], whereby potential benefits of app engagement are highlighted, and app feature use is demonstrated. Video tutorials could also identify available features, such as access to health care educational resources, which may enhance interest among families who may perceive or experience a lack of access to these resources [14]. Additionally, creating digital health video tutorials may be particularly beneficial for families from low educational backgrounds because video tutorials are supportive of families with low literacy skills, thus reducing educational and literacy-related barriers to understanding how and why to use digital health apps [17,41]. Thus, integration of more educational supports, such as video tutorials, may improve engagement by making app engagement easier, potentially narrowing health disparities among racially, ethnically, and educationally diverse populations [12].

Findings from this study, consistent with our previous study [9], revealed that caregivers of children with uncontrolled asthma were more likely to use the app than caregivers of children whose asthma was controlled. Caregivers of children with controlled asthma shared more barriers, with understanding and using the app with comments such as, "Not sure how [the app] will help us. My daughter seems to be doing well," noting that the app is "Difficult to understand and use…" and "Difficult to find things quickly." These caregivers may be unsure why they should use it ("Not sure how [the app] will help us..."). Perhaps video tutorials could also be used to inform families of the potential benefits of continued monitoring of asthma symptoms, even when asthma appears under control, given that asthma can be unpredictable and seasonal [27]. Additionally, caregivers of children whose asthma is controlled may be less familiar with navigating the app because they do not engage with the app, or they engage with it less frequently than caregivers of children whose asthma is uncontrolled. This suggests a barrier to app use may be due to a lack of instruction, further suggesting an app video tutorial may be beneficial. Others have found that asthma interventions appear to be more effective for children with uncontrolled asthma, as these children are most at risk for poor health outcomes [15]. As such, a 2-pronged approach may be a worthwhile solution, in which informational video tutorials provide potential benefits of app engagement for all children with asthma and also highlight features that may best serve children with uncontrolled asthma, including enhanced communication opportunities with their child's asthma health care team.

App-Facilitated Communication

Pediatric asthma management may be facilitated by improved communication between health care providers and families. When providers and families engage in effective communication strategies, clinical decisions can be made jointly, thereby assisting treatment plan adherence [42]. Notably, using digital health technology is associated with improved communication between families and providers [9,43]. A randomized controlled trial found that children who received remote patient monitoring and health care provider feedback demonstrated statistically significantly higher asthma treatment adherence than children who only received remote patient monitoring [44]. Consequently, communication with the health care team in conjunction with digital health technology may be key for effectively improving treatment plan adherence. Similarly, results from our previous study indicated that 67% (33/49) of caregivers who used a digital health app reported that using the app led to improved communication with their child's health care team [9]. The qualitative results from this study further support this previous finding, as the most frequently reported app theme that emerged was about communication benefits. Specifically, 40% (163/408) of the comments referred to communication and information sharing as a benefit of app engagement. One app engager captured their experience with app-related communication by reporting it is, "A good way to get data and communicate with your provider." As such, this study highlights that app-facilitated communication may serve

XSL•FO
RenderX

to strengthen provider-family communication, which could help improve children's asthma health.

Two app features frequently reported as helpful and that could promote communication were the message system and the asthma symptom tracker. When reporting about messages, an app engager shared they "Love the ability to message providers directly." Another app engager noted the tracker is beneficial because they "…can see if there is a pattern to when [their child's] asthma flares up." These reports about app-facilitated communication features highlight tools that may support treatment adherence and improve asthma outcomes.

Potential Benefits of the App for Health Care and Education

In addition to app-facilitated communication features, messages, and asthma symptom tracker, caregivers identified several other app features as potentially beneficial. Unsurprisingly, the 3 most frequently reported beneficial app features, messages, health care records, and the asthma symptom tracker, aligned with the most prominent theme about app information and communication benefits. As noted, caregivers shared that engaging with messages and the asthma symptom tracker supported communication between themselves and their child's health care team. Caregivers also reported that having access to their child's health care records was informative. For instance, one app engager noted, "I like that I can refer back to this app after an appointment in case I forgot something the doctor said." Other features were also identified as informative, as caregivers reported that the air quality index helped them check the air quality, and app medication features could help with medication adherence. These features may help support asthma management and lead to improved health outcomes.

Despite the ambiguous school absence findings, many caregivers identified potential benefits of app features for school purposes, namely asthma-specific app features. For example, one non-app engager shared that they would "print action plan for schools and camp." Sharing asthma treatment plans, particularly asthma action plans, with schools is recommended by the National Heart, Lung, and Blood Institute to inform school personnel of child-related asthma needs and keep children safe in schools and may help reduce school absences or time away from the classroom [6]. We also found an overall reduction in school absences from Time 1 to Time 2. However, future research is necessary to explain the overall reduction in school absences. This study took place during the early period of the COVID-19 pandemic, during which childhood asthma morbidity was significantly reduced [45], as children were inside more frequently and perhaps exposed to fewer triggers. This explanation was supported by findings from this study, as one caregiver shared that the reason they were not engaging with the app was because "She is inside more due to [COVID-19]." Despite the historical and school absentee data limitations, most caregivers reported the benefits of app engagement and highlighted asthma-specific features that may be beneficial for their child's asthma-related health and education. As such, it is worthwhile for health care systems to consider that app engagement, particularly engagement with disease-specific app features, may be beneficial for the children and caregivers they serve.

Limitations and Future Research

As many people were using virtual technologies for health care and for schooling during the study time frame (from September 2019 to November 2020) due to the COVID-19 pandemic, this may have influenced caregivers' perspectives about engaging with digital health technology. Missing data were another limitation, as 20% (16/80) of school absentee data were missing at Time 2 and these data were not missing at random, likely because statistically significantly fewer nonapp engagers than app engagers completed the Time 2 survey. Post hoc analyses are consistent with previous research indicating that other characteristics, such as race and asthma control, are related to school absences [38]. However, we caution that the main and post hoc findings about school absences may be uninterpretable due to the history-related artifacts in the absentee data. Despite this limitation, we presented the data because assessing school absences was an important hypothesis to examine and part of the planned study analysis. Future digital health research is needed to examine the relationship among app engagement, absenteeism, and family characteristics to identify approaches that may help improve school attendance. A future study should also collect absentee data from school systems instead of relying on caregiver-reported data, which may help to limit any misreporting of the number of school days missed. For this observational study, we relied on existing data, using C-ACT data available in the EHR. Consequently, only a subsample of C-ACT scores was included in the analyses (53/80, 66%). Future research should collect these data directly for study purposes to limit the amount of missing data. Several biases must also be considered, as our findings may not generalize to a broader population. Although this study took place across the northeastern and southeastern United States, we examined a digital health app designed to support pediatric patients at a specific health care institution and developed a specific survey to obtain data about caregivers' app experience. As such, institutional biases may be present, and future research is warranted. However, many of the features examined, including the messages, tracker, and air quality index, are used in other pediatric digital health apps [18]. Thus, we expect findings from this study may be informative and relevant to other institutions, caregivers, and children. Despite a diverse racial, ethnic, and socioeconomic sample, most app engagers were White families and well-educated; thus, selection bias may be present. Sampling bias also may exist, even though most eligible participants consented.

Overall, findings from this study show initial relations between family characteristics and app engagement; however, a larger, more diverse study sample is needed to better understand the reasons underlying app engagement. Although we did not find significant correlations between frequent app engagement and participant characteristics, correlational results between app themes and these characteristics suggest they should be considered in future research. Future research should also consider using partial correlations to further examine the relation between app engagement themes and participant characteristics. Other caregiver characteristics, such as being a health care

XSL•FO
RenderX

professional and having previously engaged with digital health tools, should be considered, as this may indicate that these caregivers have greater knowledge of asthma and experience with digital health apps and may be more likely to engage with the app. Finally, post hoc analysis revealed responses about app engagement were skewed toward app engagers, as they were more likely to complete the Time 2 survey than nonapp engagers. Despite this skew, most participants completed the Time 2 survey (n=65). Furthermore, post hoc analysis revealed that race and maternal education were not statistically significantly related to completion of the Time 2 survey. Importantly, future digital health studies must work to engage a large, diverse patient population to ensure collecting a representative view of app engagement.

Conclusions

App engagement continues to demonstrate a digital divide in which children and their caregivers from lower educational and marginalized racial and ethnic backgrounds appear less likely to engage with these tools. Caregiver-reported reasons for not engaging with the app revealed gaps that health care systems need to address to improve the experience and potentially increase engagement of more diverse patient populations. A key finding from this study revealed technological and educational barriers to app engagement. These barriers may be reduced by use of video informational technologies to help better inform caregivers and their children about potential benefits of app engagement and to explain how to use the app. As apps become more ubiquitous in pediatric health care systems, these institutions must strive to ensure that the digital divide does not further exacerbate long-standing equity concerns. This study uncovers some barriers to app engagement and provides some recommendations to assist with reducing gaps in access to and use of digital health technology, which may potentially help improve health and educational outcomes for children.

Acknowledgments

The authors acknowledge the support of the Nemours Foundation, Nemours Virtual Health and Informatics, the research study team, and the caregivers and children who participated, without whom this research would not be possible.

Funding

The work was supported by the Nemours Foundation. Publication made possible in part by support from the Nemours Children's Health Grants for Open Access from Library Services (GOALS).

Data Availability

Datasets generated during this study may be available from the corresponding author on reasonable request.

Authors' Contributions

KL contributed to conceptualization, methodology, investigation, formal analysis, writing–original draft. CMZ-G and KVB handled conceptualization, methodology, writing–review, and editing. AM was involved in validation, investigation, writing–review, and editing.

Conflicts of Interest

The authors are employees of the health care institution that created and markets the freely available app described in this manuscript. Despite this, there is no competing financial interest.

Multimedia Appendix 1
App experience survey and supplementary analyses–multiply imputed and post hoc analyses.
[DOCX File, 33 KB - pediatrics_v8i1e69755_app1.docx]

References

1. Most recent national asthma data. Centers for Disease Control and Prevention. 2021. URL: https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm [accessed 2024-08-13]
2. Zahran HS, Bailey CM, Damon SA, Garbe PL, Breysse PN. Vital signs: asthma in children--United States, 2001–2016. MMWR Morb Mortal Wkly Rep 2018 Feb 9;67(5):149-155. [doi: 10.15585/mmwr.mm6705e1] [Medline: 29420459]
3. Perry R, Braileanu G, Palmer T, Stevens P. The economic burden of pediatric asthma in the United States: literature review of current evidence. Pharmacoeconomics 2019 Feb;37(2):155-167. [doi: 10.1007/s40273-018-0726-2] [Medline: 30315512]
4. Forno E, Celedón JC. Health disparities in asthma. Am J Respir Crit Care Med 2012 May 15;185(10):1033-1035. [doi: 10.1164/rccm.201202-0350ED] [Medline: 22589306]
5. Washington DM, Curtis LM, Waite K, Wolf MS, Paasche-Orlow MK. Sociodemographic factors mediate race and ethnicity-associated childhood asthma health disparities: a longitudinal analysis. J Racial Ethn Health Disparities 2018 Oct;5(5):928-938. [doi: 10.1007/s40615-017-0441-2] [Medline: 29188553]

XSL•FO
RenderX

6. Lim E, Davis J, Choi SY, Chen JJ. Effect of Sociodemographics, health-related problems, and family structure on chronic absenteeism among children. J Sch Health 2019 Apr;89(4):308-318. [doi: 10.1111/josh.12736] [Medline: 30843228]
7. Akinbami LJ, Moorman JE, Liu X. Asthma prevalence, health care use, and mortality: United States, 2005-2009. Natl Health Stat Report 2011 Jan 12;32(32):1-14. [Medline: 21355352]
8. London RA, Sanchez M, Castrechini S. The dynamics of chronic absence and student achievement. Educ Policy Anal Arch 2016;24(112):112. [doi: 10.14507/epaa.24.2471]
9. Lewis K, Zettler-Greeley CM, Blake KV, Milkes A. A digital health application for managing pediatric asthma: use and benefits. Inform Health Soc Care 2023 Oct 2;48(4):370-386. [doi: 10.1080/17538157.2023.2250435] [Medline: 37661853]
10. Lewis K, Zettler-Greeley CM. An mHealth app to support diverse school-age children with asthma. Presented at: National Association of School Psychologists Annual Convention; Feb 7-10, 2023.
11. Nelson LA, Mulvaney SA, Gebretsadik T, Ho YX, Johnson KB, Osborn CY. Disparities in the use of a mHealth medication adherence promotion intervention for low-income adults with type 2 diabetes. J Am Med Inform Assoc 2016 Jan;23(1):12-18. [doi: 10.1093/jamia/ocv082] [Medline: 26186935]
12. Smith B, Magnani JW. New technologies, new disparities: the intersection of electronic health and digital health literacy. Int J Cardiol 2019 Oct 1;292:280-282. [doi: 10.1016/j.ijcard.2019.05.066] [Medline: 31171391]
13. Walker DM, Hefner JL, Fareed N, Huerta TR, McAlearney AS. Exploring the digital divide: age and race disparities in use of an inpatient portal. Telemed J E Health 2020 May;26(5):603-613. [doi: 10.1089/tmj.2019.0065] [Medline: 31313977]
14. Tuan WJ, Mellott M, Arndt BG, Jones J, Simpson AN. Disparities in use of patient portals among adults in family medicine. J Am Board Fam Med 2022;35(3):559-569. [doi: 10.3122/jabfm.2022.03.210486] [Medline: 35641056]
15. Kosse RC, Bouvy ML, de Vries TW, Koster ES. Effect of a mHealth intervention on adherence in adolescents with asthma: a randomized controlled trial. Respir Med 2019 Mar;149:45-51. [doi: 10.1016/j.rmed.2019.02.009] [Medline: 30803885]
16. Foster JM, Usherwood T, Smith L, et al. Inhaler reminders improve adherence with controller treatment in primary care patients with asthma. J Allergy Clin Immunol 2014 Dec;134(6):1260-1268. [doi: 10.1016/j.jaci.2014.05.041] [Medline: 25062783]
17. Macy ML, Davis MM, Clark SJ, Stanley RM. Parental health literacy and asthma education delivery during a visit to a community-based pediatric emergency department: a pilot study. Pediatr Emerg Care 2011 Jun;27(6):469-474. [doi: 10.1097/PEC.0b013e31821c98a8] [Medline: 21629152]
18. Khusial RJ, Honkoop PJ, Usmani O, et al. Effectiveness of myAirCoach: a mHealth self-management system in asthma. J Allergy Clin Immunol Pract 2020 Jun;8(6):1972-1979. [doi: 10.1016/j.jaip.2020.02.018] [Medline: 32142961]
19. Anderson-Lewis C, Darville G, Mercado RE, Howell S, Di Maggio S. mHealth technology use and implications in historically underserved and minority populations in the United States: systematic literature review. JMIR Mhealth Uhealth 2018 Jun 18;6(6):e128. [doi: 10.2196/mhealth.8383] [Medline: 29914860]
20. Broffman L, Harrison S, Zhao M, Goldman A, Patnaik I, Zhou M. The relationship between broadband speeds, device type, demographic characteristics, and care-seeking via telehealth. Telemed J E Health 2023 Mar;29(3):425-431. [doi: 10.1089/tmj.2022.0058] [Medline: 35867048]
21. Joseph CLM, Peterson E, Havstad S, et al. A web-based, tailored asthma management program for urban African-American high school students. Am J Respir Crit Care Med 2007 May 1;175(9):888-895. [doi: 10.1164/rccm.200608-1244OC] [Medline: 17290041]
22. Kumar D, Hemmige V, Kallen MA, Giordano TP, Arya M. Mobile phones may not bridge the digital divide: a look at mobile phone literacy in an underserved patient population. Cureus 2019 Feb 20;11(2):e4104. [doi: 10.7759/cureus.4104] [Medline: 31057998]
23. Radparvar I, Ross MK. Barriers and facilitators of electronic patient portal uptake for asthma management. J Asthma 2023 Apr;60(4):635-646. [doi: 10.1080/02770903.2022.2087190] [Medline: 35726134]
24. Merchant RK, Inamdar R, Quade RC. Effectiveness of population health management using the Propeller Health asthma platform: a randomized clinical trial. J Allergy Clin Immunol Pract 2016;4(3):455-463. [doi: 10.1016/j.jaip.2015.11.022] [Medline: 26778246]
25. Zijp A, Versluis A, Joosse L, et al. Exploring the feasibility, acceptability, usability and safety of a digitally supported self-management intervention for uncontrolled asthma: a pre-post pilot study in secondary care. Digit Health 2024;10:20552076241292391. [doi: 10.1177/20552076241292391] [Medline: 39507014]
26. Orrell-Valente JK, Jarlsberg LG, Hill LG, Cabana MD. At what age do children start taking daily asthma medicines on their own? Pediatrics 2008 Dec;122(6):e1186-e1192. [doi: 10.1542/peds.2008-0292] [Medline: 19047221]
27. Akinbami LJ, Sullivan SD, Campbell JD, et al. Asthma outcomes: healthcare utilization and costs. J Allergy Clin Immunol 2012 Mar;129(3 Suppl):S49-S64. [doi: 10.1016/j.jaci.2011.12.984] [Medline: 22386509]
28. Angrist JD, Imbens GW, Rubin DB. Identification of causal effects using instrumental variables. J Am Stat Assoc 1996 Jun;91(434):444-455. [doi: 10.1080/01621459.1996.10476902]
29. Liu AH, Zeiger R, Sorkness C, et al. Development and cross-sectional validation of the Childhood Asthma Control Test. J Allergy Clin Immunol 2007 Apr;119(4):817-825. [doi: 10.1016/j.jaci.2006.12.662] [Medline: 17353040]

XSL•FO
RenderX

30. Hui CY, Walton R, McKinstry B, Jackson T, Parker R, Pinnock H. The use of mobile applications to support self-management for people with asthma: a systematic review of controlled studies to identify features associated with clinical effectiveness and adherence. J Am Med Inform Assoc 2017 May 1;24(3):619-632. [doi: 10.1093/jamia/ocw143] [Medline: 27694279]
31. Ngo FT, Govindu R, Agarwal A. Assessing the predictive utility of logistic regression, classification and regression tree, chi-squared automatic interaction detection, and neural network models in predicting inmate misconduct. Am J Crim Just 2015 Mar;40(1):47-74. [doi: 10.1007/s12103-014-9246-6]
32. Raskind IG, Shelton RC, Comeau DL, Cooper HLF, Griffith DM, Kegler MC. A review of qualitative data analysis practices in health education and health behavior research. Health Educ Behav 2019 Feb;46(1):32-39. [doi: 10.1177/1090198118795019] [Medline: 30227078]
33. Burnaford G. Teacher's work: methods for researching teaching. In: Burnaford G, Fischer J, Hobson D, editors. Teachers Doing Research: The Power of Action through Inquiry: Lawrence Erlbaum; 2001:49-82. [doi: 10.4324/9781410605641]
34. Merriam SB. Qualitative Research and Case Study Applications in Education: Jossey-Bass; 1998.
35. Lincoln YS, Guba EA. Naturalistic Inquiry: Sage; 1985.
36. Woods AD, Davis-Kean P, Halvorson MA, et al. Missing data and multiple imputation decision tree. PsyArXiv. Preprint posted online on Jan 8, 2025. [doi: 10.31234/osf.io/mdw5r]
37. Stavseth MR, Clausen T, Røislien J. How handling missing data may impact conclusions: a comparison of six different imputation methods for categorical questionnaire data. SAGE Open Med 2019;7:2050312118822912. [doi: 10.1177/2050312118822912] [Medline: 30671242]
38. Akinbami LJ, Parker JD, Merkle S. Factors associated with school absence among children with symptomatic asthma, United States, 2002–2003. Pediatr Allergy Immunol Pulmonol 2010 Sep;23(3):191-200. [doi: 10.1089/ped.2010.0013]
39. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381. [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
40. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019 Jul;95:103208. [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]
41. Sheridan SL, Halpern DJ, Viera AJ, Berkman ND, Donahue KE, Crotty K. Interventions for individuals with low health literacy: a systematic review. J Health Commun 2011:30-54. [doi: 10.1080/10810730.2011.604391] [Medline: 21951242]
42. Street RL, Makoul G, Arora NK, Epstein RM. How does communication heal? Pathways linking clinician–patient communication to health outcomes. Patient Educ Couns 2009 Mar;74(3):295-301. [doi: 10.1016/j.pec.2008.11.015]
43. Hamine S, Gerth-Guyette E, Faulx D, Green BB, Ginsburg AS. Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. J Med Internet Res 2015 Feb 24;17(2):1-15. [doi: 10.2196/jmir.3951] [Medline: 25803266]
44. Chen J, Xu J, Zhao L, Zhang J, Yin Y, Zhang F. The effect of electronic monitoring combined with weekly feedback and reminders on adherence to inhaled corticosteroids in infants and younger children with asthma: a randomized controlled trial. Allergy Asthma Clin Immunol 2020;16(1):1-8. [doi: 10.1186/s13223-020-00466-6] [Medline: 32922454]
45. Ulrich L, Macias C, George A, Bai S, Allen E. Unexpected decline in pediatric asthma morbidity during the coronavirus pandemic. Pediatr Pulmonol 2021 Jul;56(7):1951-1956. [doi: 10.1002/ppul.25406] [Medline: 33848402]

Abbreviations

C-ACT: childhood asthma control test
EHR: electronic health care record
NCH: Nemours Children's Health
OR: odds ratio
REDCap: Research Electronic Data Capture

Edited by S Badawy; submitted 09.01.25; peer-reviewed by J Thompson, M Sakamoto, NH Mohamad Zainal; accepted 14.10.25; published 04.12.25.

Please cite as:
Lewis K, Zettler-Greeley CM, Milkes A, Blake KV
Benefits and Barriers of Caregiver App Engagement for Supporting Diverse Children With Asthma: Mixed Methods Study
JMIR Pediatr Parent 2025;8:e69755
URL: https://pediatrics.jmir.org/2025/1/e69755
doi:10.2196/69755

XSL•FO
RenderX

© Kandia Lewis, Cynthia M Zettler-Greeley, Amy Milkes, Kathryn V Blake. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 4.12.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Validation and Acceptability of the Mobile App Version of the Control of Allergic Rhinitis and Asthma Test for Children (CARATKids): Cross-Sectional Study

Dulce Abreu da Mata[1*], MD; Inês Pais-Cunha[1*], MD; Sandra Catarina Ferraz[2], MD; Daniela da Rocha Couto[3], MD; Catarina Ferraz[1,4], MD; Sónia Silva[1], MD; José Carlos Valente[5], BSc; Pedro Vieira-Marques[6], PhD; João A Fonseca[5,6,7], PhD; Inês Azevedo[1,4], PhD; Cristina Jácome[6], PhD

[1]Unidade Autónoma de Gestão da Mulher e Criança, Pediatrics Department, Unidade Local de Saúde São João, Porto, Portugal

[2]Pediatrics Department, Unidade Local de Saúde do Alto Minho, Viana do Castelo, Portugal

[3]Pediatrics Department, Unidade Local de Saúde da Cova da Beira, Covilhã, Portugal

[4]RISE-Health, Departamento de Ginecologia Obstetrícia e Pediatria, Faculdade de Medicina, Universidade do Porto, Porto, Portugal

[5]MEDIDA – Serviços em Medicina, Educação, Investigação, Desenvolvimento e Avaliação, Porto, Portugal

[6]RISE-Health, MEDCIDS- Department of Community Medicine, Information and Health Decision Sciences, Faculty of Medicine, University of Porto, Rua Dr. Plácido da Costa, Porto, Portugal

[7]Allergy Unit, Hospital CUF Porto, Porto, Portugal

[*]these authors contributed equally

Corresponding Author:
Cristina Jácome, PhD
RISE-Health, MEDCIDS- Department of Community Medicine, Information and Health Decision Sciences, Faculty of Medicine, University of Porto, Rua Dr. Plácido da Costa, Porto, Portugal

Abstract

Background: The electronic version of the Control of Allergic Rhinitis and Asthma Test for Children (CARATKids) has the potential to enhance pediatric telemonitoring but has not yet been validated.

Objective: This study aimed to validate the electronic version of CARATKids against the paper-based version.

Methods: A cross-sectional study was conducted between April and December 2024 in a tertiary hospital in northern Portugal. Children with asthma or allergic rhinitis and their caregivers were recruited during pulmonology outpatient appointments. CARATKids comprises 13 yes or no questions, 8 addressed to the child and 5 to the caregiver, and the total score ranges from 0 to 13. The electronic CARATKids was made available through a mobile app. Both paper and electronic versions were administered in a randomized order before and after the appointment. In addition, participants' preferences between the two administration versions were assessed. Internal consistency (Cronbach α), reliability (intraclass correlation coefficient [ICC], Bland-Altman analysis), and convergent validity (Spearman coefficient) were analyzed following COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidelines.

Results: A total of 51 children (median 9, IQR 8-11 years; n=29, 57% male) and respective caregivers (median 41, IQR 7-45) years were included. The CARATKids total score was similar across the paper (median 5, IQR 3-8) and electronic (median 5, IQR 3-7) versions. The internal consistency was 0.79 for the paper version and 0.83 for the electronic version. The reliability between the two versions was excellent (ICC 0.95, 95% CI 0.91 - 0.97). The Bland-Altman analysis showed strong agreement between the two versions, with a mean difference of 0.04 (95% CI −1.99 to 2.07). The Spearman correlation between the two versions was 0.95 (P<.001). In total, 63% (n=32) of children and 61% (n=31) of caregivers were indifferent to the version used, while 33% (n=17) and 35% (n=18), respectively, preferred the electronic version.

Conclusions: The electronic version of CARATKids appears to be equivalent to the paper-based version of the questionnaire, with good acceptance by children and caregivers. CARATKids implementation in mobile health technologies has the potential to enhance remote child monitoring and optimize the management of asthma and allergic rhinitis.

(JMIR Pediatr Parent 2025;8:e73531) doi:10.2196/73531

KEYWORDS

asthma; rhinitis, allergic; pediatrics; telemedicine; mobile applications; patient-reported outcome measures; psychometrics; reliability; patient preference; mobile phone

XSL•FO
RenderX

Introduction

Asthma affects 5% - 6% of children worldwide and is a leading cause of disability among those aged 5 - 14 years old [1,2]. The condition significantly impacts the quality of life and productivity of both children and their caregivers, leading to substantial costs, with a disproportionate burden on ethnic minority groups and economically disadvantaged populations [3-5]. Allergic rhinitis, another common condition, often develops early in life, with a prevalence of 8.5% at ages 6 - 7, rising to 14.6% in those aged 13 - 14 years old [6]. The symptoms of allergic rhinitis have a profound negative impact on children's physical and emotional health, sleep quality, and daily activities [7]. Epidemiological and clinical studies have highlighted the strong link between asthma and allergic rhinitis, leading to the widely recognized concept of United Airways Disease, particularly evident in children [8]. Implementing effective monitoring strategies tailored to individual needs can optimize health outcomes for children with these conditions and their caregivers.

Patient-reported outcome measures (PROM) for asthma and allergic rhinitis assess key aspects of care and provide insights into patients' perceptions of treatment response over time [9,10]. The Control of Allergic Rhinitis and Asthma Test for Children (CARATKids) is the first questionnaire to simultaneously assess allergic rhinitis and asthma control in children aged 6 - 12 years old [11]. It is validated in 7 languages and is a recognized PROM used in clinical practice [11-16]. While the CARATKids paper version remains a valuable tool during scheduled in-person appointments, it often provides limited insight into the child's health trajectory in the period in-between appointments, as it relies on a recall period of 2 weeks. In this context, electronic patient-reported outcome measures (ePROMs) offer a complementary solution by enabling continuous long-term tracking and monitoring of symptoms, allowing health professionals to make more informed decisions based on real-life patient data [17-19]. This approach facilitates a more proactive and personalized approach to child care, allowing health professionals to identify trends and changes in a patient's condition over time [17,18,20]. In addition, ePROMs can offer numerous advantages, including greater patient acceptability, enhanced data quality, and higher response rates, while providing additional benefits for health systems and research [17,18,20,21].

The Allergic Rhinitis and its Impact on Asthma guidelines, implemented in over 70 countries, have evolved to include integrated care pathways with mobile technology for individualized and predictive medicine [22]. There is now an opportunity to increase access to asthma and allergic rhinitis care, ensure better disease control, bridge equity gaps, and control costs. A mobile app version of CARATKids could play a key role in integrating telemonitoring technologies to support remote management of pediatric asthma and allergic rhinitis.

The adult and adolescent version of the Control of Allergic Rhinitis and Asthma Test (CARAT) questionnaire has already been validated for mobile app use, demonstrating psychometric properties comparable to those of the paper version [23]. To date, CARATKids has only been validated in its paper version [11]. An electronic version of CARATKids should be validated comparing with the traditional paper-based questionnaire before being implemented in a clinical setting [24,25].

The primary objective of this study was to validate the electronic version of CARATKids for children with asthma or allergic rhinitis using a mobile app compared to the paper version. A secondary objective was to investigate the CARATKids preferred version, paper or electronic, by children and their caregivers.

Methods

Study Design

This cross-sectional study was conducted at the Pediatrics Department of Hospital de S. João, a public tertiary care hospital in northern Portugal, from April to December 2024. Children and their caregivers were invited to participate during scheduled pediatric pulmonology appointments. This study followed the guidelines on measurement properties for patient-reported outcomes of the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) initiative. This study was reported in compliance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guidelines [26].

Ethical Considerations

Ethical approval for this study was obtained from the Ethics Committee of São João Local Health Unit (approval 316/20; addendum dated April 19, 2024). Caregivers provided written informed consent, and informed assent was obtained from the children before data collection. Participants had the right to refuse to participate or to withdraw from the study at any time, without penalty or prejudice, and without needing to provide a reason. No financial compensation was provided to participants for their involvement in this study.

Participants

The sample size was set at a minimum of 50 children and their respective caregivers, following COSMIN guidelines [27]. Participants were selected by physicians based on convenience, specifically on days with a lighter appointment workload and when a researcher was available to assist with data collection. Children aged 6 to 12 years with a scheduled pediatric pulmonology appointment were included if they had a confirmed or suspected diagnosis of asthma or allergic rhinitis. Children were excluded if they had a major respiratory disease other than asthma or allergic rhinitis, or any other medical condition potentially contributing to respiratory symptoms. Caregivers were excluded if they were minors. Both children and caregivers with insufficient knowledge of the Portuguese language or unable to understand or answer self-reported questionnaires were excluded.

Data Collection

Demographic data from children (sex, age, height, weight, and school year) and their caregivers (sex, age, and level of education) were first collected in a paper case report form. In addition, to estimate the level of digital literacy, both children

XSL•FO
RenderX

and caregivers were asked about smart device ownership and whether they had ever downloaded and used a health or fitness app. The CARATKids questionnaire was administered in a randomized order, either as a paper version (pCARATKids) or an electronic version (eCARATKids), with one format completed before and the other after the pediatric pulmonology appointment. Time in-between the two assessments, pCARATKids and eCARATKids, was recorded. Following the administration of both versions, children and caregivers answered about their preference for the paper version, the electronic version, or their indifference between the two.

CARATKids

The Portuguese original version of CARATKids was used in this study [28]. The questionnaire comprises 13 yes or no questions, with 8 items directed to the child and 5 to the caregiver, referencing a recall period of the previous 2 weeks. Each positive response is assigned a score of 1 point, while a negative response is scored as 0. The total score, which ranges from 0 to 13, is calculated by summing the positive responses. Higher scores indicate poorer control of asthma and allergic rhinitis. Child, caregiver, and total scores were calculated. The CARATKids total score was categorized into 3 levels of disease control: controlled (<4), insufficiently controlled (4 or 5), or uncontrolled (>5) [11]. Throughout the study, participants were not informed of their scores or the corresponding disease control classification to prevent any potential influence on their responses. Participants completed both the pCARATKids (see Multimedia Appendix 1) and eCARATKids with support available from a researcher upon request. The eCARATKids was accessible through the InspirersKids mobile app (MEDIDA), which is available for both iOS- and Android-based devices, and was installed on the researchers' smartphones. With this mobile app, questions are presented one at a time rather than displaying the entire questionnaire at once (see Multimedia Appendix 2). A pop-up notification alerts users when the child's section is completed, and the caregiver's section begins. The app could be used offline (to facilitate its use in the clinical context) and, whenever an internet connection was available, the app automatically transferred the eCARATKids answer files to a secure server at Faculdade de Medicina da Universidade do Porto, from which the files could be accessed only by authorized researchers [29].

Data Analysis

Descriptive analyses, including the median (IQR) and the absolute and relative frequencies, were performed to characterize the children and their caregivers, as well as to describe CARATKids scores and version preferences.

Given the sample size, the Kolmogorov-Smirnov Test was conducted to assess the normality of the data. If the data followed a normal distribution, parametric methods were applied; otherwise, nonparametric methods were used.

The internal consistency of both pCARATKids and eCARATKids was assessed using Cronbach α. The relative reliability between the two versions was determined using the intraclass correlation coefficient (ICC), using both two-way mixed single measures, while the absolute reliability was evaluated through Bland-Altman plots. Convergent validity between the traditional paper-based version and the mobile app version of CARATKids was assessed through Spearman rank correlation coefficient. According to COSMIN methodology, Cronbach α, ICC, and Spearman correlation coefficients equal to or greater than 0.70 indicate good measurement properties [27].

All statistical analyses were performed using IBM SPSS Statistics (version 29.0.1.0), with the level of significance set at $P<.05$.

Results

Participants Characteristics

A total of 62 children and their respective caregivers were recruited; however, 2 dyads did not answer one of the CARATKids format due to lack of time, and 9 dyad answers to eCARATKids were lost due to failure in the transfer to the secure server and were excluded. Therefore, only 51 dyads were included in the final analysis. Table 1 presents the demographic and clinical characteristics of the participants. Children's median age was 9 years (IQR 8 - 11), and 57% (29/51) were boys. Caregivers' median age was 41 years (IQR 37-45), and 82% (42/51) were female. Children's median school year was 4th grade (IQR 2nd–6th), and 73% (37/51) of caregivers had at least secondary education.

Table . Demographic and clinical characteristics of the participants.

Characteristics	Children (n=51)	Caregivers (n=51)
Male, n (%)	29 (57)	9 (18)
Age (years), median (IQR)	9 (8-11)	41 (37 - 45)
Years of education, median (IQR)	4 (2-6)[a]	—[b]
Secondary education or higher, n (%)	—	37 (73)[a]
Smart device ownership, n (%)	45 (88)	50 (98)
Health or fitness mobile apps use, n (%)	12 (24)[a]	33 (65)

[a]1 missing value.

[b]Not applicable.

XSL•FO
RenderX

CARATKids Scores

The median total score was 5 (IQR 3-8) points for pCARATKids and 5 (IQR 3-7) points for eCARATKids. Disease was not controlled in 49% (25/51) of patients based on pCARATKids and in 45% (23/51) based on eCARATKids (see Table 2). A total of 24 (47%) children answered the eCARATKids first, and 4 children (8%) required assistance in reading the test in both paper and electronic versions. pCARATKids and eCARATKids were assessed with a median time interval of 41 (IQR 22-65) minutes. The time in-between assessments did not significantly influence the difference in total scores between the paper and app versions (see Multimedia Appendix 3).

Table . Control of Allergic Rhinitis and Asthma Test for children (CARATKids) scores and classification assessed on paper (pCARATKids)[a] and on the app (eCARATKids)[b].

Scores	pCARATKids (n=51)	eCARATKids (n=51)
Children's subscore, median (IQR)	4 (2-5)	4 (2-5)
Caregivers' subscore, median (IQR)	1 (0 - 2)	1 (0 - 2)
Total score, median (IQR)	5 (3-8)	5 (3-7)
Total score classification, n (%)		
Controlled	18 (35)	19 (37)
Insufficiently controlled	8 (16)	9 (18)
Uncontrolled	25 (49)	23 (45)

[a]pCARATKids: paper version of Control of Allergic Rhinitis and Asthma Test for Children.

[b]eCARATKids: electronic version of Control of Allergic Rhinitis and Asthma Test for Children.

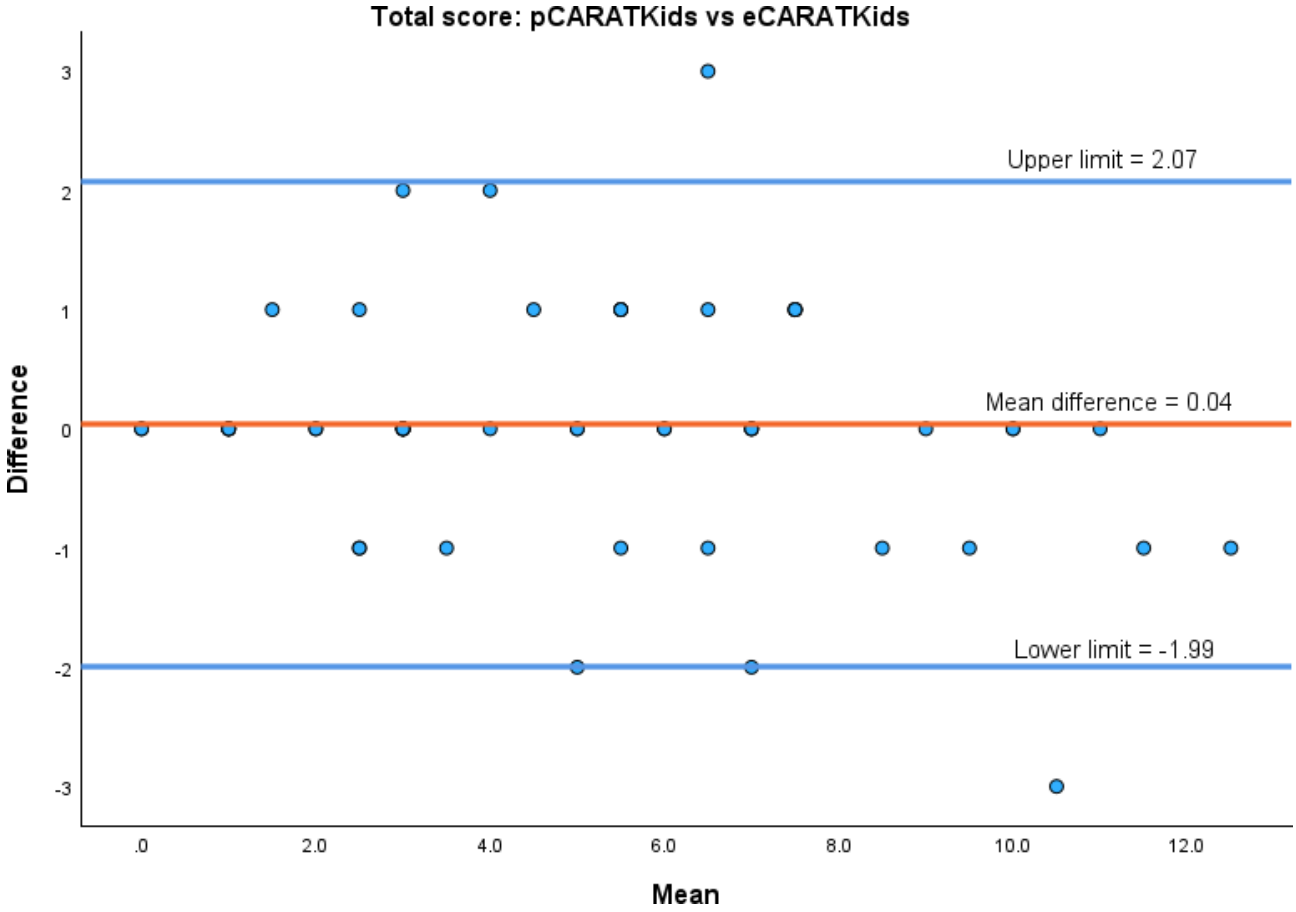
CARATKids Measurement Properties

The internal consistency of the CARATKids total score was above 0.7 in both versions (pCARATKids Cronbach α=0.79, 95% CI 0.56 - 1.00 and eCARATKids Cronbach α=0.83, 95% CI 0.62 - 1.00). The children's subscore had a Cronbach α of 0.65 (95% CI 0.30 - 1.00) for the paper version and 0.71 (95% CI 0.38 - 1.00) for the electronic version, while the caregivers' subscore had a Cronbach α of 0.75 (95% CI 0.32 - 1.00) for the paper version and 0.78 (95% CI 0.38 - 1.00) for the electronic version.

The CARATKids demonstrated an excellent relative test-retest reliability (ICC 0.95, 95% CI 0.91 - 0.97). This high reliability was maintained when CARATKids subscores were considered: children's subscore (ICC 0.90, 95% CI 0.83 - 0.94) or caregivers' subscore (ICC 0.94, 95% CI 0.90 - 0.97). The absolute reliability between the paper-based (pCARATKids) and electronic (eCARATKids) versions was good, with a mean difference between the two versions of 0.04 points and with 95% CI ranging from −1.99 to 2.07 (see Figure 1). The data points are evenly distributed around the mean difference line, with no significant proportional bias observed (see Figure 1 and Multimedia Appendix 4).

XSL•FO
RenderX

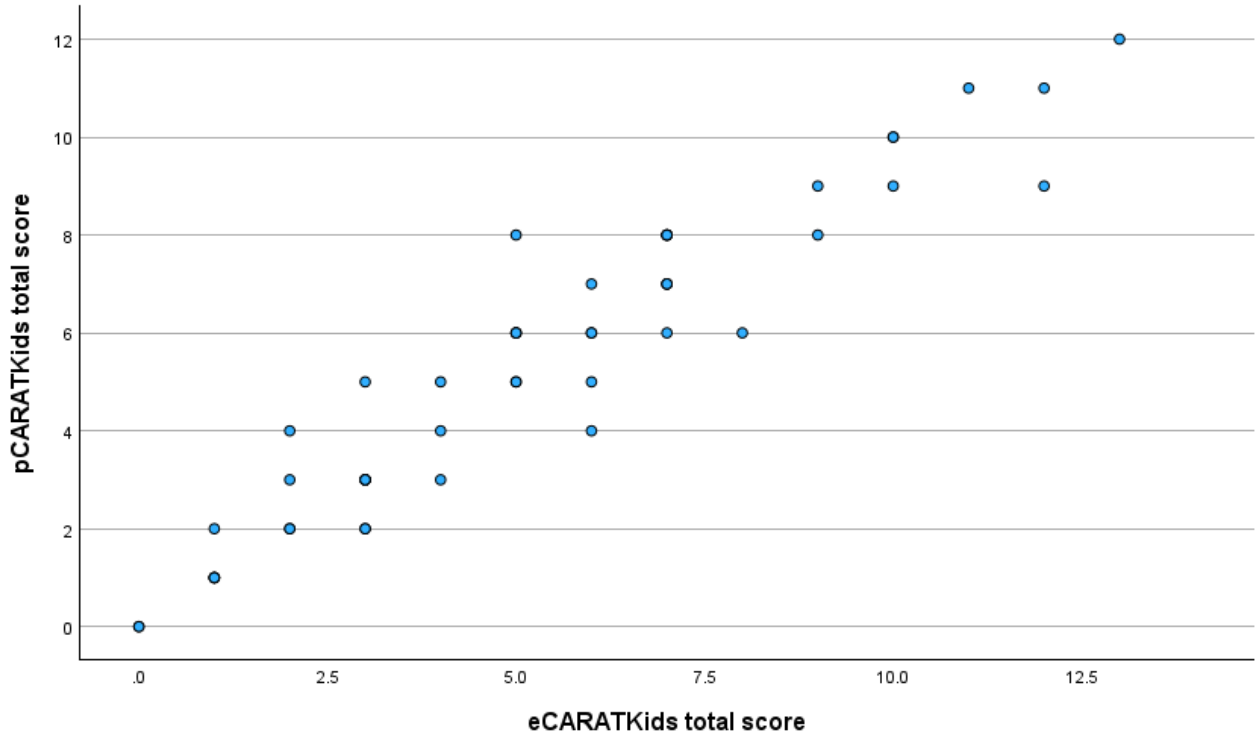
Figure 1. Bland-Altman plot of the total scores of Control of Allergic Rhinitis and Asthma Test for children (CARATKids), assessed on paper (pCARATKids) and on the app (eCARATKids). The blue lines represent the 95% CI.



Regarding convergent validity, the overall correlation between paper and mobile app scores was strong (ρ=0.95; *P*<.001; see Figure 2). When analyzed separately, both the children's (ρ=0.89; *P*<.001) and caregivers' (ρ=0.93; *P*<.001) subscores demonstrated strong positive correlations (see Multimedia Appendix 5).

XSL•FO
RenderX

Figure 2. Scatter plot showing the relationship between Control of Allergic Rhinitis and Asthma Test for children (CARATKids) total score on paper (pCARATKids) and on the mobile app (eCARATKids).



CARATKids Preferred Versions

Most of the children (63%, 32/51) and caregivers (61%, 31/51) reported being indifferent to the used versions, while 33% (17/51) of children and 35% (18/51) of caregivers preferred the electronic version (see Multimedia Appendix 6).

Discussion

Principal Findings

This study demonstrated that the electronic version of CARATKids, administered via a mobile app, is a valid and reliable alternative to the paper-based format for assessing asthma and allergic rhinitis control in children. The electronic version exhibited psychometric properties comparable to those of the traditional paper-based version, confirming its equivalence. Furthermore, the mobile app version was highly accepted by both children and caregivers, emphasizing its feasibility and user-friendliness.

Comparison With Previous Work

The internal consistency of CARATKids was evaluated using Cronbach α, which exceeded 0.7 for the total score in both the paper and electronic versions, meeting established psychometric standards [27]. The eCARATKids version demonstrated a Cronbach α of 0.83, comparable to that of the pCARATKids version in our study (Cronbach α=0.79). These findings are consistent with results from other studies using paper versions, including the multicenter Portuguese version of CARATKids (Cronbach α=0.80), as well as the Brazilian (Cronbach α=0.81), Turkish (Cronbach α=0.84), and Dutch (Cronbach α=0.81 - Cronbach α=0.85) validations [11,12,14,15]. Furthermore, the internal consistencies of the electronic versions of CARATKids and CARAT (Cronbach α=0.72 - Cronbach α=0.81) were found to be similar [23].

The intraclass correlation coefficient (ICC 0.95, 95% CI 0.91 - 0.97) further confirmed the strong test-retest reliability of the electronic version. In the validation of the mobile app's adult version, CARAT, the ICC between the paper and electronic versions ranged from 0.65 to 0.85 [23]. The reliability of the CARATKids results was further supported by Bland-Altman, which revealed a high level of agreement between the two versions. These apparently superior results may be attributed to the shorter time interval between administrations in this study (median 41 min, IQR 22-65 min) compared to the adult app validation study, in which 85% of participants completed both the paper and electronic versions on the same day, but still with a longer interval between administrations (median 0 d, IQR 0 - 2 d). Our study also revealed good convergent validity between pCARATKids and eCARATKids (ρ=0.95), indicating that both versions yield highly comparable results. In the validation of the adult mobile app version, the correlation was lower, ranging from 0.64 to 0.82 [23]. This difference may once again be explained by the shorter time interval between administrations in our study, which likely minimized variability due to changes in symptoms and increased recall bias. Furthermore, the response format may have contributed to this difference, as the children's version is based on a yes or no format, whereas the adult version is answered on a 4-point Likert scale [11,23].

Beyond psychometric validation, the study assessed patient and caregiver acceptability. Most children (63%, 32/51) and caregivers (61%, 31/51) were indifferent to the used version, and approximately one-third preferred the electronic version, while only 4% (2/51) favored the paper version. This distribution

XSL•FO
RenderX

suggests that eCARATKids does not introduce additional burden or complexity for users, as the relatively low preference for the paper version (4%) and the significant proportion favoring the electronic version (approximately one-third) indicate a notable openness to digital tools among this population. These findings align with trends observed in other pediatric studies evaluating preferences for ePROMs. For example, in orthopedic studies, 70% of participants preferred the electronic version, while in rheumatology, 83% were either indifferent or preferred the electronic version [30,31]. Furthermore, this high level of acceptability may further increase even more, considering that patients value features such as real-time progress tracking, motivational reminders, and personalized feedback [32].

Strengths and Limitations of the Study

The evaluation of the CARATKids questionnaire's reliability adhered to the COSMIN Risk of Bias guidelines, ensuring a methodologically robust approach [33]. Standardized measurement conditions were maintained throughout the study: both the paper-based and electronic versions were completed in the same controlled environment. Participants exclusively used the researcher's smartphone to complete the eCARATKids, with no use of personal devices, thereby minimizing variability in response conditions. To further reduce potential bias, the researchers responsible for administering and scoring the questionnaires were blinded to previous results. In addition, participants were not informed of their total scores after completing each questionnaire, preventing any potential influence on subsequent responses. The randomized administration of pCARATKids and eCARATKids—alternating before and after appointments—was designed to mitigate order bias and any potential influence of the clinical consultation on questionnaire responses.

Despite the promising findings, this study has several limitations that warrant consideration. First, the research was conducted at a single tertiary care hospital with the minimum recommended number of participants by COSMIN, which may restrict the generalizability of the results to other health care settings, such as primary care or community-based clinics. Although the order of questionnaire administration was randomized, we did not assess if answering the electronic version first had a role on the psychometric properties obtained. The short time interval between administrations also leaves open the possibility of learning effects, which could influence responses. In addition, eCARATKids was completed on the researchers' smartphones rather than on the participants' personal devices. While this approach streamlined the process by avoiding installation delays and bypassing internet restrictions in the clinical environment, the use of an unfamiliar device may have introduced unintended biases or usability challenges compared to responses provided on the child's or caregiver's own device.

To overcome these limitations, future studies should adopt a multicenter approach aiming to include at least 100 participants, ensuring a more diverse population and broader applicability using the patient's own device. In addition, a larger interval should separate pCARATKids and eCARATKids applications. According to COSMIN, the time interval in-between administrations should be long enough to prevent recall bias yet short enough to ensure that patients have not undergone changes in the construct being measured [27]. A time interval of about 48 hours or 1 week is often considered suitable for the evaluation of patient-reported outcomes instruments [23,34]. Future studies could benefit from the inclusion of additional reliability statistics recommended by COSMIN, such as the McDonald ω, and evaluate the responsiveness of eCARATKids over time, detecting changes in symptoms longitudinally. Future research could additionally explore the acceptability of eCARATKids among health care professionals, as this study focused primarily on children and caregivers.

Future Directions

Given these promising findings, eCARATKids emerges as a feasible alternative to paper-based assessments, reinforcing the growing adoption of ePROMs in pediatric asthma and allergic rhinitis care. Ongoing studies are assessing ePROMs' impact on chronic diseases, including in pediatric populations [35,36]. However, a systematic review on telemonitoring of pediatric asthma in outpatient settings identified a significant gap in the literature regarding technologies specifically designed for preschool children [37]. Further research and collaboration among healthcare providers, researchers, and technology developers are essential to advancing telemonitoring for pediatric asthma [37]. With this study, we contribute to bridging this gap.

To further improve eCARATKids, future versions of the app could include features such as biweekly reminders to encourage regular symptom tracking and improve adherence. Users could also receive immediate feedback after completing the questionnaire, including their total score and the corresponding classification of symptom control. Visual tools, such as an integrated dashboard with graphs or charts, could help caregivers track symptom changes over time, promoting better self-management. In addition, enabling users to easily share their results and symptom trends with their pediatrician would support remote consultations and personalized care. These updates could enhance patient engagement, streamline clinical decision-making, and ultimately improve asthma and allergic rhinitis management in children. Future studies could assess the impact of these features on adherence, symptom monitoring, and clinical outcomes.

Conclusions

This study demonstrated that eCARATKids is a valid and reliable alternative to the paper-based format for assessing asthma and allergic rhinitis control in children. With strong psychometric properties and high acceptability among children and caregivers, eCARATKids has the potential to enhance telemedicine strategies and facilitate remote pediatric monitoring. Its integration into mHealth platforms could further optimize disease management and contribute to improving health outcomes in pediatric asthma and allergic rhinitis care.

XSL•FO
RenderX

Acknowledgments

We extend our heartfelt gratitude to all the children and caregivers who participated in this study with enthusiasm and curiosity. This article was supported by national funds through FCT - Fundação para a Ciência e a Tecnologia, IP, within CINTESIS, R&D Unit (reference UIDB/4255/2020).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Control of Allergic Rhinitis and Asthma Test for Children (CARAT-Kids) paper version: children's questions (a); caregivers' questions (b).
[PDF File, 79 KB - pediatrics_v8i1e73531_app1.pdf]

Multimedia Appendix 2
The electronic version of the Control of Allergic Rhinitis and Asthma Test for Children (eCARATKids) is available through the InspirersKids mobile app, where questions are presented one at a time. A pop-up notification alerts users when the child's section is completed, signaling the start of the caregiver's section.
[MP4 File, 21634 KB - pediatrics_v8i1e73531_app2.mp4]

Multimedia Appendix 3
Scatter plot showing the relationship between minutes between assessments and difference in Control of Allergic Rhinitis and Asthma Test for Children (CARATKids) total scores (paper - pCARATKids - and electronic versions - eCARATKids).
[PNG File, 72 KB - pediatrics_v8i1e73531_app3.png]

Multimedia Appendix 4
Bland-Altman plot of the children's (a) and caregivers' (b) subscores of Control of Allergic Rhinitis and Asthma Test for Children (CARATKids), assessed on paper (pCARATKids) and on mobile app (eCARATKids). The blue lines represent the 95% limits of agreement.
[PNG File, 44 KB - pediatrics_v8i1e73531_app4.png]

Multimedia Appendix 5
Scatter plot showing the relationship between Control of Allergic Rhinitis and Asthma Test for Children (CARATKids) children's score (a), and caregivers' score (b) on paper (pCARATKids) and on mobile app (eCARATKids).
[PNG File, 44 KB - pediatrics_v8i1e73531_app5.png]

Multimedia Appendix 6
Control of Allergic Rhinitis and Asthma Test for Children (CARATKids) version preference: mobile app version (eCARATKids), paper version (pCARATKids), or indifference between the two.
[PNG File, 35 KB - pediatrics_v8i1e73531_app6.png]

References

1. García-Marcos L, Chiang CY, Asher MI, et al. Asthma management and control in children, adolescents, and adults in 25 countries: a Global Asthma Network Phase I cross-sectional study. Lancet Glob Health 2023 Feb;11(2):e218-e228. [doi: 10.1016/S2214-109X(22)00506-X] [Medline: 36669806]
2. Global burden of disease results. VizHub. URL: https://vizhub.healthdata.org/gbd-results/ [accessed 2025-02-06]
3. Dean BB, Calimlim BM, Kindermann SL, Khandker RK, Tinkelman D. The impact of uncontrolled asthma on absenteeism and health-related quality of life. J Asthma 2009 Nov;46(9):861-866. [doi: 10.3109/02770900903184237] [Medline: 19905909]
4. Fleming M, Fitton CA, Steiner MFC, et al. Educational and health outcomes of children treated for asthma: Scotland-wide record linkage study of 683 716 children. Eur Respir J 2019 Sep;54(3):1802309. [doi: 10.1183/13993003.02309-2018] [Medline: 31196949]
5. Perez MF, Coutinho MT. An overview of health disparities in asthma. Yale J Biol Med 2021 Sep;94(3):497-507. [Medline: 34602887]
6. Asher MI, Montefort S, Björkstén B, et al. Worldwide time trends in the prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and eczema in childhood: ISAAC Phases One and Three repeat multicountry cross-sectional surveys. Lancet 2006 Aug 26;368(9537):733-743. [doi: 10.1016/S0140-6736(06)69283-0] [Medline: 16935684]

XSL•FO
RenderX

7. Meltzer EO, Blaiss MS, Derebery MJ, et al. Burden of allergic rhinitis: results from the Pediatric Allergies in America survey. J Allergy Clin Immunol 2009 Sep;124(3 Suppl):S43-S70. [doi: 10.1016/j.jaci.2009.05.013] [Medline: 19592081]
8. Passalacqua G, Ciprandi G, Canonica GW. United airways disease: therapeutic aspects. Thorax 2000 Oct;55 Suppl 2(Suppl 2):S26-S27. [doi: 10.1136/thorax.55.suppl_2.s26] [Medline: 10992552]
9. Mosnaim G, Carrasquel M, Snedden M, Oppenheimer J, Lang D, Rathkopf M. Patient-reported outcomes in asthma. J Allergy Clin Immunol Pract 2024 Oct;12(10):2562-2572. [doi: 10.1016/j.jaip.2024.04.061] [Medline: 38796101]
10. Dykewicz MS, Wallace DV, Bandi S, Mahdavinia M, Sedaghat AR. Patient-reported outcome measures in rhinitis andchronic rhinosinusitis. J Allergy Clin Immunol Pract 2024 Oct;12(10):2574-2582. [doi: 10.1016/j.jaip.2024.06.049] [Medline: 39004415]
11. Linhares DVBR, da Fonseca JAL, Borrego LM, et al. Validation of control of allergic rhinitis and asthma test for children (CARATKids)--a prospective multicenter study. Pediatr Allergy Immunol 2014 Mar;25(2):173-179. [doi: 10.1111/pai.12218] [Medline: 24628568]
12. Amaral R, Carneiro AC, Wandalsen G, Fonseca JA, Sole D. Control of Allergic Rhinitis and Asthma Test for Children (CARATKids): validation in Brazil and cutoff values. Ann Allergy Asthma Immunol 2017 May;118(5):551-556. [doi: 10.1016/j.anai.2017.02.007] [Medline: 28366584]
13. Cilluffo G, Fasola S, Ferrante G, et al. Overrating classifier performance in ROC analysis in the absence of a test set: evidence from simulation and Italian CARATkids validation. Methods Inf Med 2019 Dec;58(S 02):e27-e42. [doi: 10.1055/s-0039-1693732] [Medline: 31746447]
14. Emons JAM, Flokstra BMJ, de Jong C, et al. Use of the Control of Allergic Rhinitis and Asthma Test (CARATkids) in children and adolescents: validation in Dutch. Pediatr Allergy Immunol 2017 Mar;28(2):185-190. [doi: 10.1111/pai.12678] [Medline: 27801950]
15. Batmaz SB, Tokgöz SA, Fonseca JA. Validity and the reliability of the Turkish version of the control of allergic rhinitis and asthma test for children (CARATKids). J Asthma 2019 Nov;56(11):1231-1238. [doi: 10.1080/02770903.2018.1534969] [Medline: 30407087]
16. Tran Ngoc Hieu N, Thi Dieu Thuy N, Cao Dong L. ng d ng c a b câu h i CARATkids trong ki m soát hen tr em hen ph qu n có viêm mũi d ng [Article in Vietnamese]. YDLS 2020 Mar 3;15(3) [FREE Full text]
17. Neame MT, Reilly D, Puthiyaveetil A, et al. Successful integration of an automated patient-reported outcome measure within a hospital electronic patient record. Rheumatol Adv Pract 2022;6(3):rkac065. [doi: 10.1093/rap/rkac065] [Medline: 36071947]
18. Aiyegbusi OL, Nair D, Peipert JD, Schick-Makaroff K, Mucsi I. A narrative review of current evidence supporting the implementation of electronic patient-reported outcome measures in the management of chronic diseases. Ther Adv Chronic Dis 2021;12:20406223211015958. [doi: 10.1177/20406223211015958] [Medline: 34104376]
19. Govindaraj R, Agar M, Currow D, Luckett T. Assessing patient-reported outcomes in routine cancer clinical care using electronic administration and telehealth technologies: realist synthesis of potential mechanisms for improving health outcomes. J Med Internet Res 2023 Nov 28;25:e48483. [doi: 10.2196/48483] [Medline: 38015606]
20. Meirte J, Hellemans N, Anthonissen M, et al. Benefits and disadvantages of electronic patient-reported outcome measures: systematic review. JMIR Perioper Med 2020 Apr 3;3(1):e15588. [doi: 10.2196/15588] [Medline: 33393920]
21. van der Veer SN, Anderson NE, Finnigan R, Kyte D. Electronic collection of patient-reported outcomes to improve kidney care: benefits, drawbacks, and next steps. Semin Nephrol 2024;44(3-4):151552. [doi: 10.1016/j.semnephrol.2024.151552] [Medline: 39164148]
22. Bousquet J, Hellings PW, Agache I, et al. ARIA 2016: Care pathways implementing emerging technologies for predictive medicine in rhinitis and asthma across the life cycle. Clin Transl Allergy 2016;6:47. [doi: 10.1186/s13601-016-0137-4] [Medline: 28050247]
23. Jácome C, Pereira R, Almeida R, et al. Validation of app and phone versions of the Control of Allergic Rhinitis and Asthma Test (CARAT). J Investig Allergol Clin Immunol 2021 Jun 22;31(3):270-273. [doi: 10.18176/jiaci.0640] [Medline: 32856596]
24. Campbell N, Ali F, Finlay AY, Salek SS. Equivalence of electronic and paper-based patient-reported outcome measures. Qual Life Res 2015 Aug;24(8):1949-1961. [doi: 10.1007/s11136-015-0937-3] [Medline: 25702266]
25. Kortbeek S, Pawaria A, Lee Ng V. Equivalence of pediatric paper and electronic-based patient-reported outcome measures: findings from a systematic review. Transplantation 2021;105(12S2):S3-S3. [doi: 10.1097/01.tp.0000812784.87703.d2]
26. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol 2008 Apr;61(4):344-349. [doi: 10.1016/j.jclinepi.2007.11.008]
27. Mokkink LB, Elsman EBM, Terwee CB. COSMIN guideline for systematic reviews of patient-reported outcome measures version 2.0. Qual Life Res 2024 Nov;33(11):2929-2939. [doi: 10.1007/s11136-024-03761-6] [Medline: 39198348]
28. Borrego LM, Fonseca JA, Pereira AM, Pinto VR, Linhares D, Morais-Almeida M. Development process and cognitive testing of CARATkids - Control of Allergic Rhinitis and Asthma Test for children. BMC Pediatr 2014 Feb 6;14:34. [doi: 10.1186/1471-2431-14-34] [Medline: 24502226]

XSL•FO
RenderX

29. Ferreira A, Almeida R, Muchagata J. How secure is your mobile health. 2019 Presented at: XV Mediterranean Conference on Medical and Biological Engineering and Computing – MEDICON 2019; Sep 26-28, 2019; Coimbra, Portugal. [doi: 10.1007/978-3-030-31635-8_168]
30. Sabatino MJ, Gans CV, Zynda AJ, et al. An electronic patient-reported outcomes measurement system in paediatric orthopaedics. J Child Orthop 2019 Aug 1;13(4):431-437. [doi: 10.1302/1863-2548.13.190053] [Medline: 31489051]
31. Yu JY, Goldberg T, Lao N, Feldman BM, Goh YI. Electronic forms for patient reported outcome measures (PROMs) are an effective, time-efficient, and cost-minimizing alternative to paper forms. Pediatr Rheumatol Online J 2021 May 3;19(1):67. [doi: 10.1186/s12969-021-00551-z] [Medline: 33941208]
32. Dumais KM, Dias N, Khurana L, et al. Preferences for use and design of electronic patient-reported outcomes in patients with chronic obstructive pulmonary disease. Patient 2019 Dec;12(6):621-629. [doi: 10.1007/s40271-019-00376-9] [Medline: 31313271]
33. Mokkink LB, Boers M, van der Vleuten CPM, et al. COSMIN Risk of Bias tool to assess the quality of studies on reliability or measurement error of outcome measurement instruments: a Delphi study. BMC Med Res Methodol 2020 Dec 3;20(1):293. [doi: 10.1186/s12874-020-01179-5] [Medline: 33267819]
34. Flokstra-de Blok BMJ, Baretta HJ, Fonseca JA, et al. Control of Allergic Rhinitis and Asthma Test with 1-week recall: validation of paper and electronic version. Allergy 2018 Dec;73(12):2381-2385. [doi: 10.1111/all.13564] [Medline: 30028515]
35. Hjollund NHI, Larsen LP, de Thurah AL, et al. Patient-reported outcome (PRO) measurements in chronic and malignant diseases: ten years' experience with PRO-algorithm-based patient-clinician interaction (telePRO) in AmbuFlex. Qual Life Res 2023 Apr;32(4):1053-1067. [doi: 10.1007/s11136-022-03322-9] [Medline: 36639598]
36. Tyack Z, Simons M, McPhail SM, et al. Improving the patient-centred care of children with life-altering skin conditions using feedback from electronic patient-reported outcome measures: protocol for a hybrid effectiveness-implementation study (PEDS-ePROM). BMJ Open 2021 Apr 9;11(4):e041861. [doi: 10.1136/bmjopen-2020-041861] [Medline: 33837095]
37. Pais-Cunha I, Fontoura Matias J, Almeida AL, et al. Telemonitoring of pediatric asthma in outpatient settings: a systematic review. Pediatr Pulmonol 2024 Oct;59(10):2392-2413. [doi: 10.1002/ppul.27046] [Medline: 38742250]

Abbreviations

CARAT: Control of Allergic Rhinitis and Asthma Test
CARATKids: Control of Allergic Rhinitis and Asthma Test for Children
COSMIN: COnsensus-based Standards for the selection of health Measurement INstruments
eCARATKids: electronic version of Control of Allergic Rhinitis and Asthma Test for Children
ePROM: electronic patient-reported outcome measure
ICC: intraclass correlation coefficient
pCARATKids: paper version of Control of Allergic Rhinitis and Asthma Test for Children
PROM: patient-reported outcome measure
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

Edited by S Badawy; submitted 06.03.25; peer-reviewed by JC Alchieri, R Vieira; revised version received 24.04.25; accepted 26.04.25; published 31.07.25.

Please cite as:
Abreu da Mata D, Pais-Cunha I, Ferraz SC, da Rocha Couto D, Ferraz C, Silva S, Valente JC, Vieira-Marques P, A Fonseca J, Azevedo I, Jácome C
Validation and Acceptability of the Mobile App Version of the Control of Allergic Rhinitis and Asthma Test for Children (CARATKids): Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e73531
URL: https://pediatrics.jmir.org/2025/1/e73531
doi:10.2196/73531

© Dulce Abreu da Mata, Inês Pais-Cunha, Sandra Catarina Ferraz, Daniela da Rocha Couto, Catarina Ferraz, Sónia Silva, José Carlos Valente, Pedro Vieira-Marques, João A Fonseca, Inês Azevedo, Cristina Jácome. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 31.7.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

An Information App (e-TOP) to Support Parents' Information Needs During the First Year at Home After Preterm Birth: Development and Usability Study

Monique Flierman[1,2,3], MSc; Eline L Möller[1,3], PhD; Vincent L Vijn[4], MSc; Raoul H Engelbert[1,2], Prof Dr; Martine Jeukens-Visser[1,3], PhD; Anton H van Kaam[1,5,6], Prof Dr Med; Daniel Bossen[2], PhD

[1]Department of Rehabilitation, Amsterdam Reproduction and Development, Amsterdam UMC Location University of Amsterdam, Meibergdreef 9, Amsterdam, The Netherlands

[2]Centre of Expertise Urban Vitality, Faculty of Health, Sports and Physical Activity, Amsterdam University of Applied Sciences, Amsterdam, The Netherlands

[3]Department of Rehabilitation, Amsterdam University Medical Centers, Amsterdam, The Netherlands

[4]Faculty of Digital Media and Creative Industry, Amsterdam University of Applied Sciences, Amsterdam, The Netherlands

[5]Amsterdam University Medical Center, Emma Kinderziekenhuis, Amsterdam, The Netherlands

[6]Department of Neonatology, Amsterdam Reproduction and Development, Amsterdam UMC Location University of Amsterdam, Amsterdam, The Netherlands

Corresponding Author:
Monique Flierman, MSc
Department of Rehabilitation, Amsterdam Reproduction and Development, Amsterdam UMC Location University of Amsterdam, Meibergdreef 9, Amsterdam, The Netherlands

Abstract

Background: Parents of preterm infants often face challenges in transitioning from hospital to home, requiring reliable and accessible information to support their caregiving. Mobile health interventions have the potential to supplement postdischarge education and empower parents by providing tailored, evidence-based information.

Objective: The primary objectives of this study were to develop an information app (e-TOP) using a participatory design approach, incorporating input from parents and health care professionals, and evaluate its usability.

Methods: A 2-phase, mixed methods design was used for this study. In Phase 1, the app was developed through iterative focus group discussions with parents of preterm infants, parents with limited health literacy, and TOP interventionists. In Phase 2, a usability study was conducted over 6 months with parents of preterm infants. Usability was assessed with a broad range of measurements: thinking aloud sessions, user engagement analytics, 2 questionnaires, the system usability scale (SUS), a customized satisfaction survey, open question sections, and semistructured interviews.

Results: The collaborative approach with end users and experts for the development led to a fully functional e-TOP app. Expert review and content validation ensured that information was clinically accurate, accessible, and relevant to parental needs. For the usability testing, a total of 58 families (116 participants) were recruited and 69 participants actively used the app. The median cumulative e-TOP usage per participant in 6 months (26 weeks) was 39 minutes (IQR 8.8 - 53.0). The median number of actions was 64.0 (IQR 33.5 - 88.0). The e-TOP app received a median SUS score of 75 (IQR 67.5 - 80.0), indicating good usability. Participants rated their overall median satisfaction at 7.0 (IQR 7.0 - 8.0) out of 10. While the app was perceived as useful for finding information on prematurity-specific topics, engagement declined over time. Qualitative feedback highlighted a need for improved navigation (eg, a search function), expanded content (eg, motor development and sensory processing), and more interactive features (eg, chat support and parental community forums).

Conclusions: The e-TOP app is a valuable digital resource that can supplement postdischarge care by providing tailored, evidence-based, and accessible information for parents of preterm infants. While usability scores were high, engagement trends and retrieved feedback suggest the need for enhanced retention strategies, such as push notifications, timeline-based navigation structure, interactive tools, and adding (practical) content. Future iterations to improve the inclusivity of the e-TOP app require strategies to engage fathers and parents with limited health literacy skills.

Trial Registration: ISRCTN Registry ISRCTN65709138; https://www.isrctn.com/ISRCTN65709138

(JMIR Pediatr Parent 2025;8:e75569) doi:10.2196/75569

XSL•FO
RenderX

KEYWORDS

mHealth; premature infants; postdischarge care; usability; user experience; parental support; app; mobile health

Introduction

Background

In the Netherlands, 6.9 % of the children are born prematurely (before 37 weeks of gestational age) [1]. Although advances in perinatal and neonatal care have significantly improved survival rates for preterm infants [2], preterm birth still accounts for 66% of all deaths occurring before or during the first month after birth [3]. Prematurity also has large adverse effects on children's motor, cognitive, and socioemotional development [4]. Giving birth to a premature infant is also a disruptive start for parents [5]. Parents of preterm infants often experience a range of mental health problems, such as anxiety and depression [6]. The dependency on medical and health professionals can challenge the formation of a secure infant-parent relationship and parents' self-efficacy in their ability to independently care for their infant [7]. The transition to home following discharge is known as challenging. Without the 24/7 access to health care professionals, parents of preterm infants feel unprepared for this new situation and lack confidence in their capacity to care for their infant [8]. Despite efforts to improve parents' readiness for discharge and the availability of follow-up services, many parents of preterm infants continue to experience unmet needs for support and practical information after leaving the hospital [9,10]. As the infant's care needs and developmental milestones evolve during the first year, the informational needs of parents of preterm infants also shift accordingly. Providing tailored information about the consequences of prematurity and the specific health, behavioral, and developmental needs of premature infants can strengthen parental self-efficacy, enhance their sense of security in caring for their infant, and potentially reduce health care use [11,12].

Search for Information

After returning home, parents of preterm infants search the internet for information on topics, such as infant crying, choice of formula, common illnesses, and developmental stages. While they use search engines, social media, or mobile health (mHealth) apps, finding appropriate and reliable information on the unique challenges of caring for a preterm infant at home remains difficult [8,9]. The use of mHealth could support a shift from time- and professional-dependent access to information toward a more autonomous approach, empowering parents to obtain information whenever and wherever they need it. However, for mHealth apps to be useful and effective, they must address the specific information needs of parents of preterm infants [13,14]. In addition, the app must be user-friendly [15] and the information accessible and easy to understand for parents across varying levels of education and health literacy [16].

mHealth Apps

mHealth education interventions for parents of premature infants were developed over the last decades. However, Richardson's evaluation of mobile apps targeting parents of infants in the neonatal intensive care unit (NICU) revealed that many apps are lacking quality and credibility or do not contain content identified by parents as important [17]. In contrast, the study on the NICU2HOME app provides high-quality information on infant and self-care during and after the NICU stay and showed promising results in enhancing parental self-efficacy and discharge preparedness [18]. Despite the rich body of literature regarding parental needs for information after discharge, available apps targeting the postdischarge period are limited. A systematic app review of mobile information apps for parents of preterm infants after hospital discharge found that, while the overall quality of the identified apps was acceptable, they insufficiently addressed key postdischarge concerns, such as information on transitions in nutrition, sleep patterns, or developmental stages [19]. This lack of targeted content may contribute to the limited usage and adoption of these apps, a common pitfall when end users and stakeholders are not adequately involved in the design process [20]. Participatory design approaches, such as the design thinking method, ensure that user requirements are accurately captured from the perspective of the end users, thereby enhancing usability and facilitating effective implementation [21-24].

The Dutch Context: TOP Program

In the Netherlands, a 1-year home-based responsive parenting intervention (TOP program) is standard care for very preterm infants and their parents and is currently expanded for moderate to late preterm infants. Pediatric physical therapists with an additional 1-year TOP training and affiliated with the Dutch Expertise Center for Premature Infants (EOP) carry out the TOP program. The strength-based and process-oriented intervention consists of 7 key strategies to enhance parental understanding of the infants' behavioral and developmental needs [25]. An important key strategy is to provide parents with information about their infant's behavioral and developmental needs. To enhance parents' knowledge and understanding of their infants' needs, TOP interventionists provide verbal information transfer and an individualized written parental report with strength-based recommendations accompanied by photos taken during the home visit. Despite the benefits of face-to-face care, there is a need for a complementary mHealth intervention that enhances information retention, supports parental confidence in managing their infant's care, and potentially reduces their reliance on health care professionals [9,14]. Therefore, we aim to complement and enhance the existing Dutch TOP program by addressing gaps in information retention and supporting professionals in delivering reliable information to parents. Before conducting more extensive research to measure its effectiveness, developing an information app that ensures that user requirements are effectively incorporated and is tailored to the specific needs of parents of preterm infants is crucial.

The aim of this study was two-fold: (1) to develop a postdischarge information app (e-TOP) for parents of premature infants and (2) to evaluate its usability.

XSL•FO
RenderX

Phase 1: Development of the e-TOP App

Phase 1 Methods

Setting

The study was performed between October 2021 and November 2023 by the EOP, affiliated with the Amsterdam University Medical Center, in collaboration with the Amsterdam University of Applied Sciences.

Ethical Considerations

The study was approved by the Medical Ethical Committee of the Stichting Amsterdam UMC (NL78996.018.21). All participants received an information letter detailing the study's objectives, timeline, content, target group, data management practices, and privacy considerations. Subsequently, informed consent forms were obtained. Participants were officially enrolled in the study upon providing written consent. Data were pseudonymized. Participants did not receive any compensation.

Participants

The user-centered design approach for the development of the prototype started with 3 focus groups, 1 with TOP interventionists and 2 with parents of preterm infants. A pragmatic sampling approach was used, drawing on available data from the EOP center to identify and invite participants (TOP interventionists) with relevant experience across different contexts [26]. For focus group 1, TOP interventionists with more than 5 years of experience, representing different geographic and socioeconomic regions, were approached. For the parent focus groups, participating TOP interventionists approached potential eligible and interested families within their caseload. Parents were included if they (1) participated in the TOP program for at least 3 months and (2) were able to understand and speak the Dutch language. Focus group 3 specifically involved parents of preterm infants with limited health literacy (LHL). These parents were identified and recruited by the TOP interventionist by using the following 2 additional criteria: (1) parents struggle with understanding and applying the information provided during the intervention or in the parent report and (2) fulfill the criteria for LHL according to the Dutch checklist to recognize LHL [27].

Focus Group Meetings

The script for the focus group meetings was developed collaboratively with the research team, guided by the 2 main objectives of the sessions (Multimedia Appendix 1). First, to verify the identified need for information on the 10 topics previously found in our qualitative research [13] and to enrich these with participants' personal experiences. Second, to elicit preferences regarding content, topics, design, and navigation of the app.

To address the first objective, the research team formulated open-ended questions and prompts for each of the 10 topics. These were designed to stimulate reflection, encourage sharing of personal experiences, and allow for the addition of new themes. Examples and short scenarios were incorporated to help participants relate the topics to their own context.

For the second objective, the script included guided activities involving visual and textual materials, such as screenshots of existing parenting apps, information cards, mock-ups, and text samples. These were selected and designed by the research team to support discussion on specific design features (eg, tone of voice, level of detail, and visual presentation) and to facilitate comparison between different styles. See Figure 1; information cards and Figure 2; mock-ups.

Figure 1. Information cards.



XSL•FO
RenderX

Figure 2. Mock-up.



The draft script was reviewed in 2 rounds by the research team to ensure alignment with the study objectives, clarity of language, and feasibility within the planned 2-hour sessions. Minor adjustments were made following pilot testing with a small group of colleagues to refine the sequence of questions and ensure smooth transitions between topics.

We conducted 3 focus group sessions. In the first meeting, 8 female TOP interventionists participated. Five interventionists worked in an urban setting with a diverse population in a challenging socioeconomic environment.

In the second focus group, 9 parents (5 mothers and 4 fathers) participated. Their mean age was 35.6 years (SD 5.8). For 5 parents, it was their firstborn, and for the other 4 parents, it was their second child. Their infants' mean gestational age was 30 weeks and 2 days (SD 19.0). In the third focus group meeting, 6 mothers with LHL participated with a mean age of 31.6 years (SD 2.2). For 5 mothers, it was their firstborn infant, and for 1 mother, her third child. Their infants' mean gestational age was 29 weeks and 1 day (SD 21.8).

The three 2-hour online focus group meetings were organized in the evenings, which was indicated by participants as the most convenient time. The focus groups were facilitated by an independent female researcher, MM. She was not involved in the study design or analysis. The first author (MF) attended the focus groups to take field notes but did not lead the discussions. The 3 focus group meetings were audio-recorded, relistened to, and summarized. Findings were discussed within the research team.

Phase 1 Results

Overview

The results of the focus group discussions with TOP interventionists and parents provided valuable insights that shaped the development of the e-TOP app, directly influencing its content and design refinements. TOP interventionists recommended not to use the age-based developmental norms strictly**,** as individual variation among preterm infants is substantial. Instead of providing medical guidance, the app should direct parents to contact their general practitioner or pediatrician when necessary. Additional topics identified by participants were the digestive system, reflux, constipation, medication management, sensory overload and stimulation, parent-infant attachment, and bonding. Parents expressed a preference for clear, supportive, and actionable information. Information should have a layered content structure, allowing simplified messages and scientifically substantiated information. A summary of these findings is provided in Table 1. We used them as a guideline for the further development of the e-TOP app.

XSL•FO
RenderX

Table . Results of focus group meetings.

Topics	Focus group 1[a]	Focus group 2[b]	Focus group 3[c]
Participants' associations with a digital information source.	• Reliable and user-friendly digital source aligns well with the needs of young parents.	• An app can offer practical guidance to support everyday care. • Given the limited experience of general practitioners and Dutch health services with prematurity, the app could also be a valuable source.	• Participants expressed curiosity and recognized the usefulness of an app in addressing their concerns.
What questions do parents have?	• Ten topics most frequently searched align with participants' concerns, validating the app's content. In addition, practical information on adequate sensory input and the use of slings is needed.	• Different experiences with gavage feeding at home, a need for more tailored information. • What can I do with my premature infant?	• Participants sought information on baby positioning, especially with the preferred head position. • In addition to the shown topics: reflux and gavage feeding tips. Information about constipation.
About which topics do parents seek additional information?	• Information about constipation, intestinal cramps, reflux, or medication.	• Feeding, sleep patterns, sensory overexcitability	• Inconsolable crying. • Psychological support for anxiety. • Premature clothes. • Information about long-term effects of oxygen.
What support do parents need?	• Finding psychological support for themselves.	• Need for a readily accessible professional after discharge.	• Information on available services, particularly for single moms.
Where do they look for information?	• Communities including Facebook groups and consumer association websites.	• Parents shared their favorite websites, but they are often not specific to premature infants.	• Forums such as 24baby are used. • Other parents with experiences serve as key sources of information.
Presentation of information	• Adaptability to literacy levels. Videos and animations in multiple languages for less literate parents.	• Varied content preferences. Different preferences: some participants liked text-based information, others favored videos.	• Preference for animation (visually oriented). • Practical demonstrations with videos for making the crib. • Interactive features such as a chat box for quick response. • Peer experiences. Some valued real-life success stories; others were not interested in fellow sufferers.
Navigation	• A structured topic design, with an FAQ chapter.	• Search button to improve content discoverability.	• Clicking through for more detailed information.
Information cards	• Reassuring and supportive tone is essential. • Normalizing and comforting tone of voice is important.	• Concise messages can raise questions. The messages should not oversimplify.	• Informative, necessity to be able to search further for more extensive information.
Text validation	• Be aware of the tone of voice, clarity of the information.	• Comforting information is important. An informal tone of voice is nice, it relates to parents and feels personal.	• Easy-to-read text, supplemented by practical examples on what to do. • Information can be more casually read, like you talk to a trusted friend or relative. • It needs to be valid information.

XSL•FO
RenderX

Topics	Focus group 1[a]	Focus group 2[b]	Focus group 3[c]
Depth of information	• Layered information structure. Parents need to be able to explore in-depth details or stay at a simpler level.	• Different headings can help to make content more accessible.	• Information should clearly explain the differences in care for premature infants.
Scope of information	• Coverage for the first year, aligning with the TOP program.	• Guidance on more complex cases should refer parents to the health care professionals. Potential integration with a hospital app could enhance usability.	• Developmental milestones per week. Receiving updates about what your baby is doing in relation to other infants (corrected for prematurity)

[a]TOP interventionist.

[b]Parents of preterm infants.

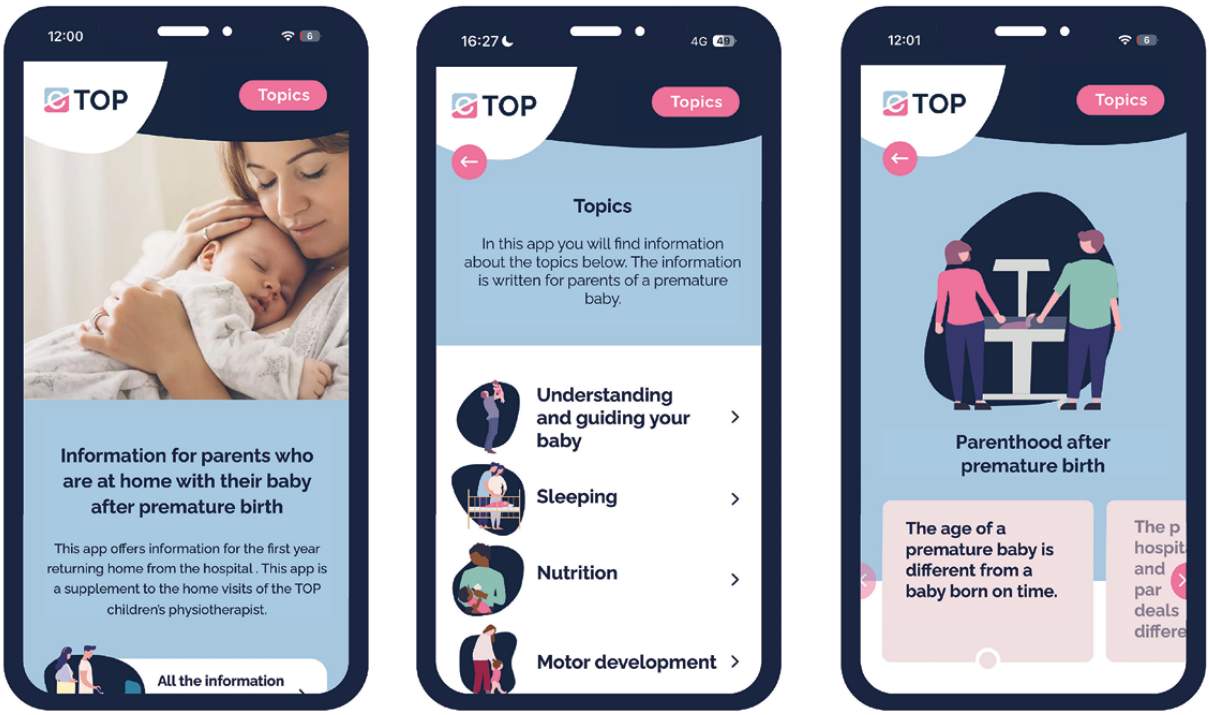
[c]Parents of preterm infants with limited health literacy.

From Prototype to a Functional e-TOP App

To create content for the app, experts were recruited through the researchers' network. Health care experts were selected based on their expertise regarding prematurity or related topics, such as feeding, sleep, or motor development. To address user needs, the following 4 steps were taken. First, the topics parents indicated in our prior research [13] were complemented with the findings of the focus group meetings. Experts drafted comprehensive information on these topics. Two members of the research team (MF and EM) finalized the content in 3 rounds of review and refinement. Second, the Dutch Expertise Center for reducing health inequities provided support to improve the readability, whereafter the text was simplified by the first 2 authors (MF and EM) to that of the reading ability to understand everyday health information (B1/B2). Key messages for each topic were formulated at level A2 for parents who prefer to read short sentences with familiar words[28]. In addition to text, a read-out-loud function was added. Third, the first 2 authors (MF and EM) included images and picture stories. Fourth, video content, either developed by health care experts from different fields or retrieved from the EOP library, was added. Videos consisted of interviews, demonstrations of parent-infant interaction, and explanations of infant behavioral signs. To clarify the content, videos had voice-overs and subtitles.

Simultaneously with creating content, we collaborated with a design company (ZIGT) to build a functional prototype of a web app accessible on smartphones, tablets, and desktop devices. The research team organized and posted all content leading to the final functional e-TOP app (see Figure 3).

Figure 3. e-TOP app.



XSL•FO
RenderX

Phase 2: Evaluation

Phase 2 Methods

Participants

For the evaluation of the e-TOP app, the sample was composed of parents with a very preterm born infant (below $32^{0/7}$ gestation) and moderate preterm born infants ($32^{0/7}$-$34^{6/7}$ weeks of gestation). Parents of very preterm infants received the TOP program (routine care, reimbursed by the basic package of insurers), and parents of moderate preterm infants received a shortened TOP program in a study context [29]. In addition to the home visits by the TOP interventionists, all participants received access to the e-TOP app.

Procedures

TOP interventionists were recruited using an invitation email distributed by the EOP center. Fifteen TOP interventionists responded to be available for participation in the study. They received a 1-day training in the intervention and research protocol including the informed consent procedure. The enrollment took place between November 2022 and March 2023. TOP interventionists introduced the study to eligible parents within their caseload. The requirement for parents to take part in the study was to be able to read and speak Dutch. When interested, parents received an information letter from the study center. If they agreed to participate, an informed consent visit was scheduled. Upon signing the informed consent, both parents received a unique access code and an animation video explaining how to install the e-TOP app. In addition, at the start (T0), parents were invited via email to complete a questionnaire on sociodemographic information including age, educational level, employment status, and family structure. Parents had continuous access to the app for the duration of 6 months. During this period, Matomo analytics was used to collect user data and thinking aloud tests were performed. At the end of this period (T1), parents received a follow-up invitation to complete questionnaires assessing their experiences, and 10 participants were invited for an interview.

Usability

For a comprehensive evaluation of the usability of the app, we used qualitative and quantitative measurements. User data provided insights into objective usage engagement, while qualitative data highlighted usability needs and identified issues for further improvement [30].

Usability Testing: Thinking Aloud

Thinking aloud tests were used to gain insights into the ease of use and navigation experiences with the app [31,32]. While navigating the app, parents were encouraged to express their thoughts, frustrations, questions, and feedback in real time. The tests were conducted by 2 students from the faculty of health of the University of Applied Sciences Amsterdam, supervised by author VV.

For the sample technique, a stepwise approach was used to ensure that the final participant list for the thinking aloud session included a varied sample across different levels of app engagement. The selection process involved the following steps: (1) all families were initially screened for e-TOP app installation. (2) For each participant, the total app usage time (in seconds) was calculated. (3) Quartiles of app usage time were determined, and participants were divided into 4 usage groups. (4) Each group was randomly ordered using a randomization tool. (5) Three participants per group (n=12) were approached by email for participation.

Participants were asked to complete 3 tasks: (1) determine when your infant can pick up a small object, (2) identify what actions you can take as a parent when your child is anxious about touch, and (3) calculate your infant's corrected age. After completing each task, participants rated the difficulty using the Single Ease Question [33], which scores task performance on a scale from 1 (very difficult) to 7 (very easy). Afterward, parents were asked questions regarding the content (eg, "Are there any topics you would like to add?"), usability (eg, "How was your experience with the e-TOP app?"), and comprehension (eg, "Did you understand the answers you found when searching for information?"). These sessions were screen-recorded, and audio transcripts were generated.

User Data

User data were monitored and analyzed with the web analytics tool Matomo [34]. Users were defined as those who accessed the e-TOP app more than once. The main metrics of interest were installs, visits, visit duration and change of usage over time, and visited topics.

To allow participants to provide immediate feedback on the app, the e-TOP app included a prompt at the end of each page asking, "Was this information helpful?" with 2 response options: yes or no. After selecting an option, a comment box appeared, allowing users to provide additional feedback.

Usability Questionnaires

The Dutch version of the system usability scale (SUS) was used [35]. The SUS is an easy-to-use, valid, and reliable questionnaire for usability assessment of mHealth apps. The scale consists of 10 statements, which can be completed within 10 minutes. All items are scored on a 5-point Likert scale from "strongly disagree" to "strongly agree." Scores per item are converted to an overall SUS score, which ranges from 0 to 100, with higher scores indicating better usability. Overall scores from 0 to 50 indicate "not acceptable," scores from 51 to 67 indicate a marginal level of usability, and scores from 68 to 100 indicate "acceptable to excellent" levels of usability [36].

To measure user experience and appropriateness of the content, a customized 10-item questionnaire was used. Seven statements were scored on a 5-point Likert scale from "strongly disagree" to "strongly agree." Two statement examples are: "The e-TOP app helps me to find information about premature birth" and "The pictures and videos help me to understand the information." Overall satisfaction with the app was scored on a numeric scale from 1 to 10 with 1 indicating very dissatisfied to 10 indicating extremely satisfied. Two open-response questions allowed participants to provide unrestricted and more subjective answers: "What information did you miss when using

XSL•FO
RenderX

the e-TOP app?" and "Do you have suggestions to improve the e-TOP app?"

Interviews

The interview guide was developed in collaboration with the research team. Questions were formulated to address predefined aspects considered critical for evaluating the app's usability. These aspects were derived from the study objectives and focused on identifying strengths, limitations, and opportunities for improvement.

To gain a more in-depth understanding of the experiences with the e-TOP app, a subgroup of participants (n=10) was invited for a semistructured interview with the first author (MF) to discuss their experiences with the e-TOP app in more detail. Purposeful sampling, including educational level, gender, and e-TOP app usage, was used to obtain a heterogeneous sample.

Interviews were scheduled at a time convenient for the parents (by phone or video call). The interview guide was set up to elicit direct, actionable feedback on app usage (Multimedia Appendix 2).

Data Analysis

Questionnaire data were collected using the Castor database (Electronic Data Capture, Ciwit BV, 2021). Descriptive statistics were used to describe the participants and the user data (installs, visits, visit duration and change of usage over time, and visited topics). Questionnaire data were checked for normal distributions using a graphical summary of data and descriptive statistics. The median score with IQR was used in case of skewed distributions.

For the qualitative data collected through thinking aloud sessions and interviews, a pragmatic thematic analysis approach was used [37]. For the thinking aloud analysis, initial open coding was analyzed and discussed within the project group and subsequently categorized into themes. Subthemes were then developed under each main theme to capture more specific insights. In addition, user comments and open questions from the questionnaires were evaluated and categorized by the first author (MF). Ultimately, the qualitative analysis resulted in 4 overarching themes: user experience, content, navigation, and functionality.

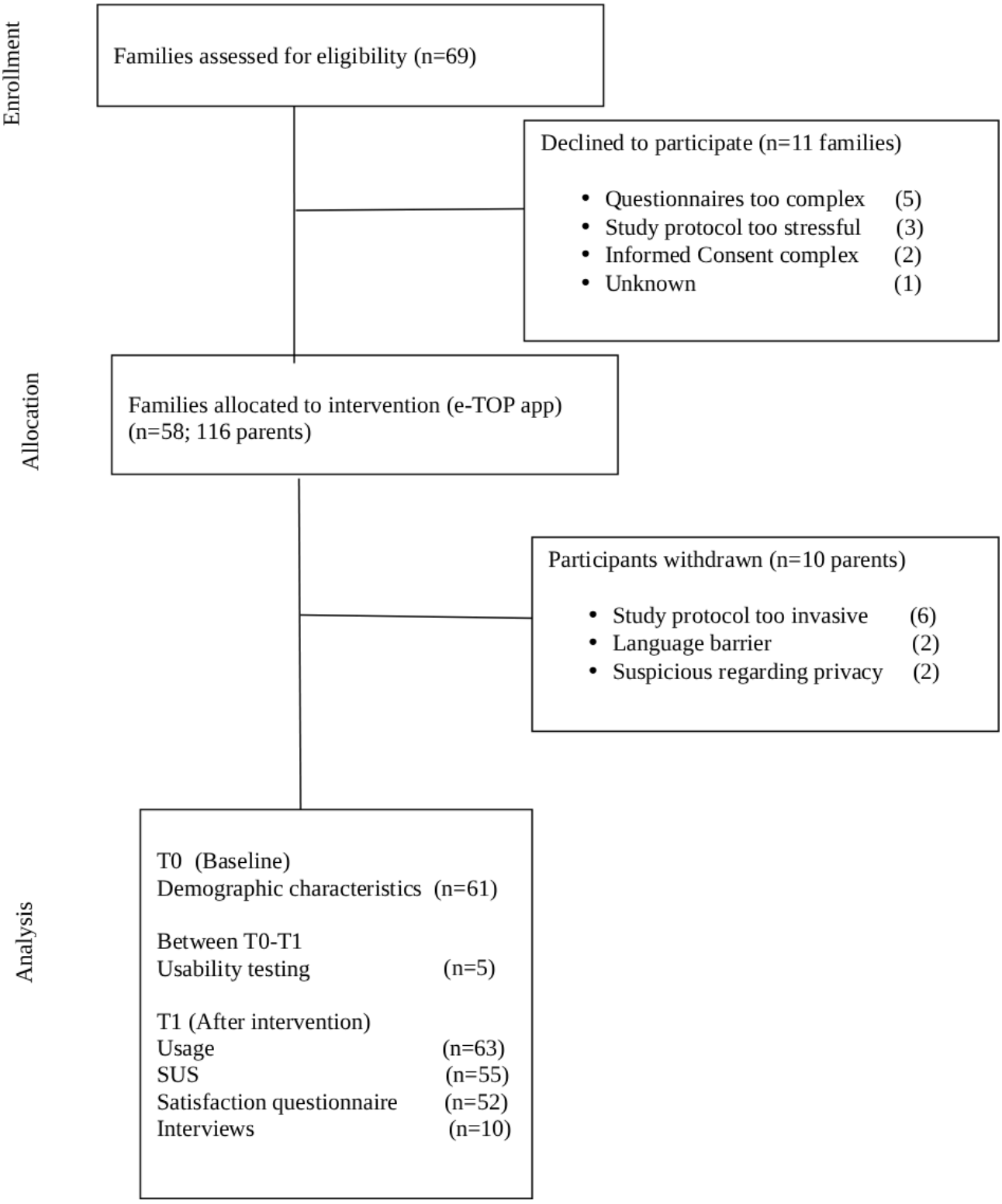
Phase 2 Results

Participants

A total of 69 families with a preterm infant were assessed for eligibility by 15 TOP interventionists. Of these, 58 eligible families, consisting of 58 fathers and 58 mothers, agreed to participate, signed informed consent, and received the access code for the e-TOP app. Five families (10 participants) withdrew from the study after signing informed consent and receiving the first questionnaires. At T0, 61 participants completed the demographic questionnaire (see Figure 4 for flow diagram). For participant characteristics, see Table 2.

XSL•FO
RenderX

Figure 4. Flow of participants. SUS: system usability scale.



XSL•FO
RenderX

Table . Participant characteristics.

Participant characteristics	Values, n (%)
Parent	
Mother	42 (69)
Father	19 (31)
Family status	
Firstborn child	37 (61)
Family status of 2 parents	61 (100)
Language	
Dutch language for health care information	60 (98)
Education[a]	
Lower	2 (3)
Intermediate	22 (36)
High	37 (61)
Employment	
Full-time	35 (57)
Part-time	25 (41)
No employment	1 (2%)

[a]Highest educational level completed: lower level education refers to primary school, vocational education, lower of middle general secondary education. Intermediate: refers to higher secondary general education, preuniversity education. High: higher vocational or university.

Usability Results

Thinking Aloud

Ultimately 5 participants (3 fathers and 2 mothers) were willing to schedule an appointment to perform the Thinking aloud tasks. The ease of use was rated as follows: Task 1 had a mean score of 6.4 (SD 0.55), Task 2 a mean of 6.0 (SD 0.89), and Task 3 a mean of 6.0 (SD 1.22) on a scale from 1 to 7, indicating that all 3 tasks were easy to perform. Participants appreciated the app, the tone of voice, and the understandability of the information. Participants provided explicit and actionable recommendations regarding content and functionality. For example, regarding content, participants expressed a desire for more information on health issues and medication. They also expressed interest in instructional videos on techniques, such as holding and carrying their baby. Regarding functionality, a home button, a scroll arrow, and a search function were missed.

User Data

In total, 69 participants (47 mothers and 22 fathers) used the personal access code to log in. Due to ad blockers, tracking data were available for 63 participants. The median cumulative e-TOP usage per participant during 6 months (26 weeks) was 39 minutes (IQR 8.8 - 53.0). The median number of actions was 64.0 (IQR 33.5 - 88.0). Most actions and the largest time spent on the app were registered during the 2 weeks after receiving the access code. See Figures 5 and 6 for further details. Multiple participants visited all 10 topics during the first 2 weeks. The total amount of visits per topic declined after this period with another peak in visits between weeks 11 and 17. The most visited topics in the app were nutrition, sleep, and correcting age for prematurity (Table 3).

XSL•FO
RenderX

Figure 5. Time spent per week.

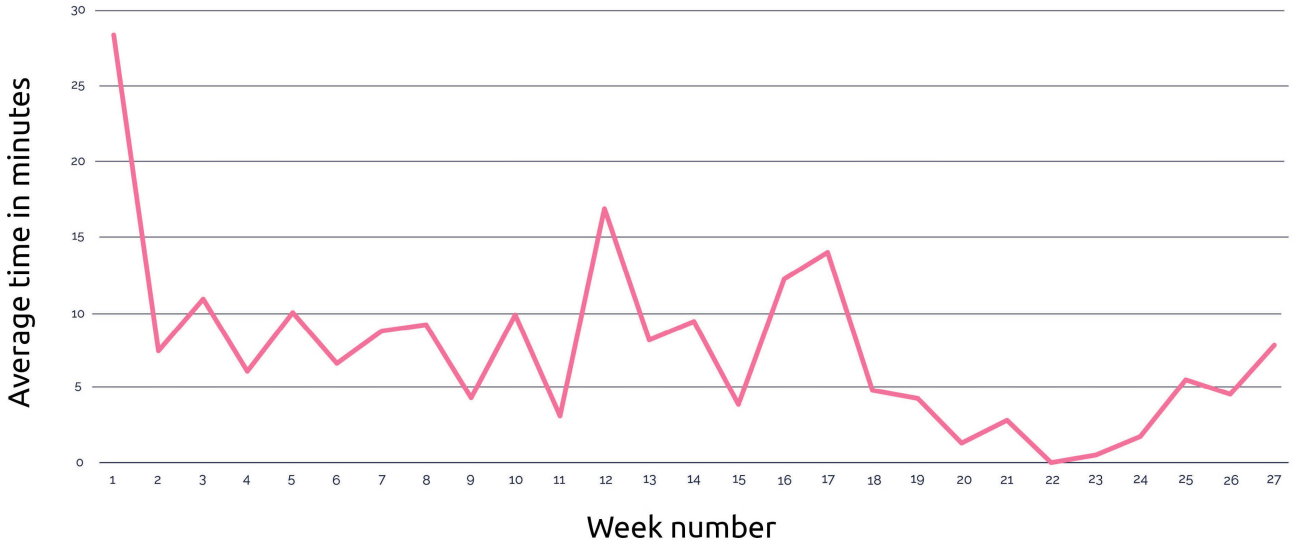


Figure 6. Actions per week.

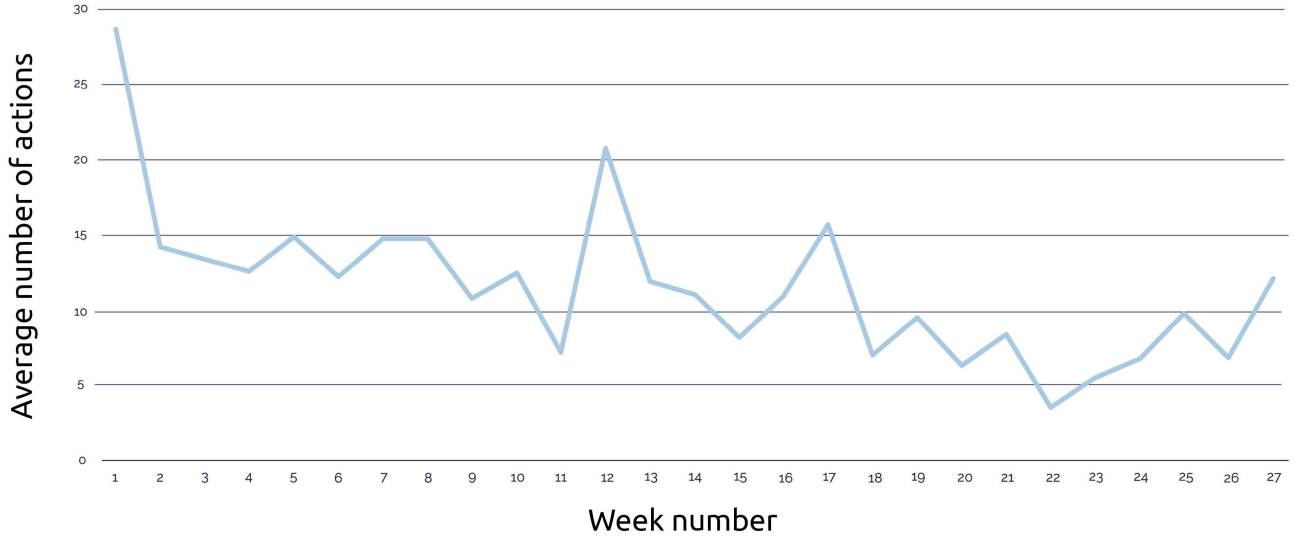


Table . Visited topics on the e-TOP app.

Topic	Total number of visits	Peak visits (week)
Nutrition	81	17
Sleep	79	6
Correcting age	54	3
Understanding your baby	49	4
Long-term consequences	44	14
Motor development	42	11
Returning to work	33	4
Parenting	25	4
Infant health	23	4
Follow-up	21	9

Usability Questionnaires

A total of 55 participants completed the SUS, yielding a median total SUS score of 75.0 (IQR 67.5 - 80.0), indicating generally good usability. The app was rated positively for its ease of use, functional integration, and user confidence.

Participants gave the app an overall satisfaction of 7.0 (IQR 7.0 - 8.0), on a scale of 1 - 10. Content satisfaction was rated

XSL•FO
RenderX

with a mean score of 3.7 (SD 0.89) and the app's appearance was considered attractive, with a mean score of 3.6 (SD 0.83) on a scale from 1 to 5. Participants found the pictures and videos particularly helpful (mean 4.0, SD 0.56) and expressed that the app was helpful in addition to face-to-face care from the TOP interventionist (mean 3.5, SD 0.99).

Qualitative Data

Data collected through thinking aloud sessions, interviews, and written comments from the app's comment box were categorized in 4 themes: user experience, content, navigation, and functionality (see Table 4).

Table . Integrated results matrix for quantitative and qualitative data.

Themes	Quantitative findings (questionnaires and thinking aloud)	Qualitative findings (interviews and comment box)	Meta-inference
User experience	• Overall satisfaction: median 7.0/10 (IQR 7-8) • Visual attractiveness: mean 3.6/5	Users appreciated the depth and specificity of information and the app's tone. However, they missed tailored responses and desired more interactive features.	Parents appreciate the user experience, yet desire more individualized and interactive features.
Content	• Content rating: mean 3.7/5 (SD 0.89) • Visual helpfulness: mean 4.0/10 (SD 0.56)	Content was viewed as highly relevant and unique to prematurity. Suggestions included more on motor development, practical care, and instructional videos.	Content meets core needs, but parents want more concrete, in-depth, and visually supported information tailored to daily care.
Navigation	• Median total SUS[a] score of 75.0 (IQR 67.5 - 80.0)	Parents found the app easy to use and appreciated its tone; they missed a search button and clearer navigation	Usability is high, but navigation challenges (especially in locating specific info) call for interface redesign and better structure.
Functionality	• Task ease thinking aloud: mean 6.1/7 (SD 0.89) • Usage: median 39 minutes (IQR 8.8-53) over 6 months	Parents appreciated the functions in the app, but had some suggestions for improvements.	Functionality is strong but could be elevated by improved orientation, content sharing, and age-specific organization (eg, timeline).

[a]SUS: system usability scale.

User Experience

Participants appreciated the specificity and depth of information provided yet expressed concerns about retrieving tailored answers to specific situations. As a participant in the interview stated, "The only thing I couldn't find was whether it's possible to swim with a premature baby and at what age that is safe". The app facilitated users' understanding of infant behavioral cues and sleep patterns. However, parents also preferred direct interaction with a TOP interventionist, indicating a desire for more personalized and human support. For example, a mother stated in the interview that "The TOP interventionist explained it to me personally, so I found that easier and more comfortable." Suggestions were given to incorporate interactive features, such as chat support or a parent community, indicating a preference for increased interactivity and social connection within the app.

Content

The content was generally deemed useful and relevant to the specific needs of parents with premature infants. As 1 participant noted in the comment box, "It gives information you cannot find on the internet, all content is related to premature birth." Suggestions for improvement emerged from both the interviews and the comment box. Requests for additional practical tips, along with more in-depth information on motor development and health-related concerns, highlighted opportunities to expand the scope of information. As a participant stated during the interview: "More information about motor development, like crawling, creeping, and sitting, would be helpful." Another parent expressed during the interview, "I would like there to be more concrete information, such as a chart with a baby weighing this much should drink this much." Videos were highlighted as particularly effective for conveying complex concepts, such as sleep patterns and infant signals.

Navigation

While users found the landing pages clear and well-organized, they reported difficulties with lengthy chapters and locating specific information. As a participant during the interview reported: "Searching for specific information is more difficult if you don't know under which chapter to search." Another participant reported in the comment box: "The sub-chapters contain too much information and not so easy to find answers to your questions." The need for enhanced navigation design, such as the inclusion of a search function, a home button, and scroll arrows, was suggested and could enhance information retrieval. A participant explained during the thinking aloud session: "If there was an arrow next to the app indicating that there's more room to scroll down, you might have looked further."

Functionality

A timeline-based structure reflecting the developmental stages of premature infants was suggested as a potential solution to improve content organization. One participant stated in the comment box: "It would also be helpful if there was a timeline showing what a child should do at each (corrected) age." The ability to share information easily with family members,

XSL•FO
RenderX

particularly regarding hygiene practices for visits, emerged as a key functional improvement.

Discussion

Overview

This study aimed to develop and evaluate a digital information source (e-TOP) to address the specific information needs of parents caring for preterm infants during the first year postdischarge.

Development of the App

To develop the e-TOP app, a user-centered design approach was used. The feedback from the 3 focus groups with TOP interventionists and parents of premature infants, including parents with LHL, directly influenced the app's content and design. The cocreation and iterative process between experts, the design company, and the research team was highly successful in shaping the app's functionality and refining its design and content. This collaborative approach ensured that the final prototype of the e-TOP app was both user-friendly and rich in relevant, evidence-based information, tailored to meet the diverse needs of its users. This methodology aligns with established practices in mHealth app development, emphasizing the importance of participatory design including health professionals to meet user needs [21-24].

Parents with LHL were actively engaged during the focus group meetings in the developmental phase of the e-TOP app. They expressed a need for clear, actionable information, preferably content in multiple formats, with an accessible tone and simplified messages. The app therefore incorporated features, such as simplified language (Level 1), multimedia content, and "read-out-loud" functionality to accommodate parents with LHL, with videos and text at different reading levels. This preference is supported by research indicating that visual-based interventions, particularly videos, are effective in improving health literacy and comprehension of health-related information [38].

Usage and Usability

Participants engaged with the app for a median total of 39 minutes (IQR 8.8-53.0) during the 6-month study period. The number of recorded actions per participant had a median of 64.0 (IQR 33.5-88.0), but usage varied significantly between participants. Differences in purpose, target groups, and the lack of user engagement metrics make comparison to other parenting apps challenging, as also described in Li's systematic review of commercial mHealth parenting apps [39]. The e-TOP app is designed as an additional information source; if we compare the results to educational health apps, longer but less frequent sessions are found [40]. This found gap calls for established standardized benchmarks for digital engagement in neonatal mHealth interventions.

While the app was perceived as useful for finding information on prematurity-specific topics, user data revealed a decline in engagement after the initial 2 weeks. These differences in intent to use versus lower nonusage attrition are found in other web-based parenting interventions [15]. The e-TOP engagement peaked at week 11 and week 16. Parents revisited the app at key developmental milestones, such as rolling over, reaching for toys, and the transition to solid foods. Integrating features such as search functionality, interactive (push notifications and chat function), and timeline-based navigation could enhance the e-TOP app's long-term utility [41,42].

SUS distribution with a mean SUS score of 68 is considered a suitable usability for Digital Health apps [43]. The e-TOP app demonstrated acceptable-to-good usability with a SUS score of 75.0 (IQR 67.5-80.0). By complementing the SUS with a customized satisfaction survey and data collected through thinking-aloud sessions, interviews, and written comments from the app's comment box, this study followed best practices of combining quantitative ratings with rich qualitative findings for the usability testing [30]. Participants provided actionable feedback across key areas. By integrating these improvements, the e-TOP app can enhance usability, ensuring it remains a valuable long-term resource for parents of preterm infants.

Limitations and Opportunities for Future Research

The total study period of 2 years and restricted finances necessitated pragmatic approaches to the evaluation of the usability. We used several qualitative and quantitative methods, but we had to make compromises impacting the study methodology, such as the reliance on a single author for qualitative data analysis which may introduce bias. Integrating multiple researchers into the thematic analysis process not only enriches the analysis through diverse perspectives but also enhances the credibility and trustworthiness of the research findings [44].

Although parents with LHL contributed to the development of the app, the study faced challenges in recruiting parents with LHL for the evaluation phase. Their limited representation in the evaluation phase underscores a broader challenge in engaging these parents in research [45]. Barriers such as complex consent processes and digital questionnaires have hindered participation in our study. Allowing parents to first establish a connection with the researchers or interventionists and using postponed consent is expected to promote inclusivity. Also, verbal consent or simplified forms could foster inclusivity. Although improved comprehension and trust may have positive effects on study enrollment, we emphasize the active involvement of the target group in the early stages of research projects when developing the study design, procedures, and the selection of measurements [46].

This study had a high attrition of the fathers; only 32% of the fathers used the app and 25% completed the usability questionnaires. In general, retaining participants in studies using mHealth apps has been described as challenging [47]. The finding of higher attrition among fathers aligns with the results of the study on the NICU2HOME app (Garfield [18]), in which high usability scores were similarly observed among mothers, but lower engagement among fathers was noted [10]. Xie [48] also found in her systematic review of digital interventions for fathers of infants from conception to 12 months postpartum that fathers have expressed the need and desire for access to relevant, accurate, and up-to-date information on infant care and challenges associated with new parenthood and called for

XSL•FO
RenderX

interventions that target father-identified priorities [49]. These studies and our findings highlight the importance of gaining a deeper understanding of perceived barriers to engaging fathers.

The usability evaluation confirms that the app was responsive to the needs of parents with a premature infant. Given the evidence supporting user-centered iterative development, we strongly advocate for proceeding with the implementation of the e-TOP app, ensuring it remains a valuable and available resource while integrating continuous user feedback by using real-time analytics, for example, engagement metrics [50,51]. Future research should focus on assessing the effectiveness by evaluating how app usage translates into improved parental confidence and decision-making in caregiving with the goal of reducing dependency on health care professionals and fostering parental autonomy.

Conclusion

The e-TOP app has demonstrated strong potential to complement information transfer to the face-to-face care after discharge and to bridge the information gap for parents when they leave the hospital. While usability findings are promising, continued development, customization, and integration of the app with health care systems are necessary to maximize its long-term impact. By addressing user engagement, content expansion, accessibility, and health care integration, future versions of e-TOP can become an essential tool for empowering parents of preterm infants and improving neonatal postdischarge care.

Acknowledgments

We would like to thank all involved parents and TOP interventionists for providing us with valuable feedback and photo and video material. We thank the experts for their uncompensated commitment to provide the e-TOP app content. We especially would like to thank our facilitator for the focus group meetings, Marion Matthijssen (MM), and the Dutch parent association Care4neo. This research was co-financed by Regieorgaan SIA, part of the Netherlands Organization for Scientific Research (NWO).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Focus group outline and key questions.
[DOCX File, 28 KB - pediatrics_v8i1e75569_app1.docx]

Multimedia Appendix 2
Interview guide for evaluating the e-TOP app.
[DOCX File, 27 KB - pediatrics_v8i1e75569_app2.docx]

References

1. Preterm birth: kerncijfers nederlandse geboortezorg 2021 [Report in Dutch]. : Perined; 2025 URL: https://assets.perined.nl/docs/a0978620-5d23-492f-a7f2-69fe7beff1a6.pdf [accessed 2025-06-29]
2. Preterm birth: fact sheet. World Health Organization. 2022. URL: https://www.who.int/news-room/fact-sheets/detail/preterm-birth [accessed 2025-06-29]
3. Information about public health and care. VZinfo. 2025. URL: https://www.vzinfo.nl [accessed 2025-06-29]
4. Allotey J, Zamora J, Cheong-See F, et al. Cognitive, motor, behavioural and academic performances of children born preterm: a meta-analysis and systematic review involving 64 061 children. BJOG 2018 Jan;125(1):16-25. [doi: 10.1111/1471-0528.14832] [Medline: 29024294]
5. Raap E, Weille KL, Flierman M, Jeukens-Visser M. “The Attitude Is Essential” The experience of two mothers with differing educational backgrounds receiving post-discharge intervention after very preterm delivery. Stud Clin Soc Work 2024 Apr 2;94(2):109-135. [doi: 10.1080/00377317.2023.2294903]
6. Vriend E, Leemhuis A, Flierman M, van Schie P, Nollet F, Jeukens-Visser M. Mental health monitoring in parents after very preterm birth. Acta Paediatr 2021 Nov;110(11):2984-2993. [doi: 10.1111/apa.16064] [Medline: 34375472]
7. George K, Rowe J, Barnes M, Kearney L, Feng GC. The Parenting Premmies Support Program: designing and developing a mobile health intervention for mothers of preterm infants. Cogent Soc Sci 2021 Jan 1;7(1). [doi: 10.1080/23311886.2020.1865617]
8. Green J, Fowler C, Petty J, Whiting L. The transition home of extremely premature babies: an integrative review. J Neonatal Nurs 2021 Feb;27(1):26-32. [doi: 10.1016/j.jnn.2020.09.011]
9. Davis-Strauss SL, Johnson E, Lubbe W. Information and support needs of parents with premature infants: an integrative review. J Early Interv 2021 Sep;43(3):199-220. [doi: 10.1177/1053815120957734]

XSL•FO
RenderX

10. Breivold K, Hjaelmhult E, Sjöström-Strand A, Hallström IK. Mothers' experiences after coming home from the hospital with a moderately to late preterm infant - a qualitative study. Scand J Caring Sci 2019 Sep;33(3):632-640. [doi: 10.1111/scs.12656] [Medline: 30715759]
11. Setiawan J, Mannix T, Sweet L. Understanding the effects of neonatal early discharge on parents: a literature review. J Perinat Neonatal Nurs 2019;33(2):170-188. [doi: 10.1097/JPN.0000000000000395] [Medline: 31021943]
12. Alderdice F, Gargan P, McCall E, Franck L. Online information for parents caring for their premature baby at home: a focus group study and systematic web search. Health Expect 2018 Aug;21(4):741-751. [doi: 10.1111/hex.12670] [Medline: 29380916]
13. Flierman M, Bossen D, de Boer R, et al. Parents' information needs during the first year at home with their very premature born child; a qualitative study. PEC Innov 2024 Dec;4:100270. [doi: 10.1016/j.pecinn.2024.100270] [Medline: 38495319]
14. Taylor K, Havinga J, Moore B, Tumin D, Bear K. Social media as a source of medical information for parents of premature infants: a content analysis of prematurity-related Facebook groups. Am J Perinatol 2023 Nov;40(15):1629-1637. [doi: 10.1055/s-0041-1736539] [Medline: 34666397]
15. Virani A, Duffett-Leger L, Letourneau N. Parents' use of mobile applications in the first year of parenthood: a narrative review of the literature. Health Technol 2021;5:14-14. [doi: 10.21037/ht-20-28]
16. Richardson A, Allen JA, Xiao H, Vallone D. Effects of race/ethnicity and socioeconomic status on health information-seeking, confidence, and trust. J Health Care Poor Underserved 2012 Nov;23(4):1477-1493. [doi: 10.1353/hpu.2012.0181] [Medline: 23698662]
17. Richardson B, Dol J, Rutledge K, et al. Evaluation of mobile apps targeted to parents of infants in the neonatal intensive care unit: systematic app review. JMIR mHealth uHealth 2019 Apr 15;7(4):e11620. [doi: 10.2196/11620] [Medline: 30985282]
18. Garfield CF, Kerrigan E, Christie R, Jackson KL, Lee YS. A mobile health intervention to support parenting self-efficacy in the neonatal intensive care unit from admission to home. J Pediatr 2022 May;244:92-100. [doi: 10.1016/j.jpeds.2022.01.004] [Medline: 35033562]
19. Jeukens-Visser M, Flierman M, Giezeman R, Vijn V, Engelbert R, Bossen D. A systematic review evaluating mobile education and support applications for parents of preterm infants post-discharge. Presented at: Conference proceedings of the 2023 Congress of the World Association for Infant Mental Health - Scientific abstracts 200450; Jul 16-19, 2023; Dublin, Ireland.
20. Noorbergen TJ, Adam MTP, Teubner T, Collins CE. Using co-design in mobile health system development: a qualitative study with experts in co-design and mobile health system development. JMIR mHealth uHealth 2021 Nov 10;9(11):e27896. [doi: 10.2196/27896] [Medline: 34757323]
21. Roberts JP, Fisher TR, Trowbridge MJ, Bent C. A design thinking framework for healthcare management and innovation. Healthcare (Basel) 2016 Mar;4(1):11-14. [doi: 10.1016/j.hjdsi.2015.12.002]
22. Garne Holm K, Brødsgaard A, Zachariassen G, Smith AC, Clemensen J. Participatory design methods for the development of a clinical telehealth service for neonatal homecare. SAGE Open Med 2017;5:2050312117731252. [doi: 10.1177/2050312117731252] [Medline: 28975028]
23. Schweitzer R, Schlögl S, Schweitzer M. Technology-supported behavior change-applying design thinking to mHealth application development. Eur J Investig Health Psychol Educ 2024 Mar 7;14(3):584-608. [doi: 10.3390/ejihpe14030039] [Medline: 38534900]
24. Molina-Recio G, Molina-Luque R, Jiménez-García AM, Ventura-Puertos PE, Hernández-Reyes A, Romero-Saldaña M. Proposal for the user-centered design approach for health apps based on successful experiences: integrative review. JMIR mHealth uHealth 2020 Apr 22;8(4):e14376. [doi: 10.2196/14376] [Medline: 32319965]
25. Jeukens-Visser M, Koldewijn K, van Wassenaer-Leemhuis AG, Flierman M, Nollet F, Wolf MJ. Development and nationwide implementation of a postdischarge responsive parenting intervention program for very preterm born children: the TOP program. Infant Ment Health J 2021 May;42(3):423-437. [doi: 10.1002/imhj.21902] [Medline: 33336859]
26. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. Adm Policy Ment Health 2015 Sep;42(5):533-544. [doi: 10.1007/s10488-013-0528-y] [Medline: 24193818]
27. Health and quality of care for everyone. Pharos. 2020. URL: https://www.pharos.nl/wp-content/uploads/2018/10/Checklist-HERKENNEN-laaggeletterdheid-maart-2022.pdf [accessed 2025-10-01]
28. The CEFR levels. Council of Europe. URL: https://www.coe.int/en/web/common-european-framework-reference-languages/level-descriptions [accessed 2024-07-23]
29. Flierman M, Möller EL, Engelbert RHH, van Kaam AH, Bossen D, Jeukens-Visser M. Feasibility of a Dutch post-discharge parenting intervention (TOP program) for moderate preterm born infants. Early Hum Dev 2024 Nov;198:106124. [doi: 10.1016/j.earlhumdev.2024.106124] [Medline: 39305832]
30. Inal Y, Wake JD, Guribye F, Nordgreen T. Usability evaluations of mobile mental health technologies: systematic review. J Med Internet Res 2020 Jan 6;22(1):e15337. [doi: 10.2196/15337] [Medline: 31904579]
31. Güss CD. What is going through your mind? Thinking aloud as a method in cross-cultural psychology. Front Psychol 2018;9:1292. [doi: 10.3389/fpsyg.2018.01292] [Medline: 30150948]

XSL•FO
RenderX

32. Hasso Plattner Institute of Design at Stanford University Stanford School. Stanford School. URL: https://dschool.stanford.edu/ [accessed 2024-12-03]
33. Hodrien A, Fernando TA. Review of poststudy and posttask subjective questionnaires to guide assessment of system usability. J Usability Stud 2021;16(3):203-232. [doi: 10.5555/3532758.3532762]
34. Web & app analytics for teams who demand accuracy. Matomo. URL: https://matomo.org/ [accessed 2022-10-03]
35. Ensink CJ, Keijsers NLW, Groen BE. Translation and validation of the System Usability Scale to a Dutch version: D-SUS. Disabil Rehabil 2024 Jan;46(2):395-400. [doi: 10.1080/09638288.2022.2160837] [Medline: 36573399]
36. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the System Usability Scale. Int J Hum Comput Interact 2008 Jul 29;24(6):574-594. [doi: 10.1080/10447310802205776]
37. Ramanadhan S, Revette AC, Lee RM, Aveling EL. Pragmatic approaches to analyzing qualitative data for implementation science: an introduction. Implement Sci Commun 2021 Jun 29;2(1):70. [doi: 10.1186/s43058-021-00174-1] [Medline: 34187595]
38. Galmarini E, Marciano L, Schulz PJ. The effectiveness of visual-based interventions on health literacy in health care: a systematic review and meta-analysis. BMC Health Serv Res 2024 Jun 11;24(1):718. [doi: 10.1186/s12913-024-11138-1] [Medline: 38862966]
39. Li K, Magnuson KI, Beuley G, Davis L, Ryan-Pettes SR. Features, design, and adherence to evidence-based behavioral parenting principles in commercial mHealth parenting apps: systematic review. JMIR Pediatr Parent 2023 Jun 1;6:e43626. [doi: 10.2196/43626] [Medline: 37261886]
40. Baumel A, Muench F, Edan S, Kane JM. Objective user engagement with mental Health apps: systematic search and panel-based usage analysis. J Med Internet Res 2019 Sep 25;21(9):e14567. [doi: 10.2196/14567] [Medline: 31573916]
41. Krishnamurti T, Moon R, Richichi R, Berger R. Integrating infant safe sleep and breastfeeding education into an app in a novel approach to reaching high-risk populations: prospective observational study. JMIR Pediatr Parent 2025 Jan 14;8:e65247. [doi: 10.2196/65247] [Medline: 39810395]
42. Amagai S, Pila S, Kaat AJ, Nowinski CJ, Gershon RC. Challenges in participant engagement and retention using mobile health apps: literature review. J Med Internet Res 2022 Apr 26;24(4):e35120. [doi: 10.2196/35120] [Medline: 35471414]
43. Hyzy M, Bond R, Mulvenna M, et al. System Usability Scale benchmarking for digital health apps: meta-analysis. JMIR Mhealth Uhealth 2022 Aug 18;10(8):e37290. [doi: 10.2196/37290] [Medline: 35980732]
44. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
45. Bader M, Zheng L, Rao D, et al. Towards a more patient-centered clinical trial process: a systematic review of interventions incorporating health literacy best practices. Contemp Clin Trials 2022 May;116:106733. [doi: 10.1016/j.cct.2022.106733] [Medline: 35301134]
46. Smits DW, van Meeteren K, Klem M, Alsem M, Ketelaar M. Designing a tool to support patient and public involvement in research projects: the Involvement Matrix. Res Involv Engagem 2020;6:30. [doi: 10.1186/s40900-020-00188-4] [Medline: 32550002]
47. Eysenbach G. The law of attrition. J Med Internet Res 2005 Mar 31;7(1):e11. [doi: 10.2196/jmir.7.1.e11] [Medline: 15829473]
48. Xie EB, Jung JW, Kaur J, Benzies KM, Tomfohr-Madsen L, Keys E. Digital parenting interventions for fathers of infants from conception to the age of 12 months: systematic review of mixed methods studies. J Med Internet Res 2023 Jul 26;25:e43219. [doi: 10.2196/43219] [Medline: 37494086]
49. Dick S, O'Connor Y, Thompson MJ, et al. Considerations for improved mobile health evaluation: retrospective qualitative investigation. JMIR mHealth uHealth 2020 Jan 22;8(1):e12424. [doi: 10.2196/12424] [Medline: 32012085]
50. Lupton D, Pedersen S, Thomas GM. Parenting and digital media: from the early web to contemporary digital society. Sociol Compass 2016 Aug;10(8):730-743. [doi: 10.1111/soc4.12398]
51. van Gemert-Pijnen J, Nijland N, van Limburg M, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res 2011 Dec 5;13(4):e111. [doi: 10.2196/jmir.1672] [Medline: 22155738]

Abbreviations

EOP: Dutch Expertise Center for Premature Infants
LHL: limited health literacy
mHealth: mobile health
NICU: neonatal intensive care unit
SUS: system usability scale

XSL•FO
RenderX

Edited by S Badawy; submitted 07.04.25; peer-reviewed by E Tella, L Weinert; revised version received 09.08.25; accepted 10.09.25; published 22.10.25.

Please cite as:
Flierman M, Möller EL, Vijn VL, Engelbert RH, Jeukens-Visser M, van Kaam AH, Bossen D
An Information App (e-TOP) to Support Parents' Information Needs During the First Year at Home After Preterm Birth: Development and Usability Study
JMIR Pediatr Parent 2025;8:e75569
URL: https://pediatrics.jmir.org/2025/1/e75569
doi:10.2196/75569

© Monique Flierman, Eline L Möller, Vincent L Vijn, Raoul H Engelbert, Martine Jeukens-Visser, Anton H van Kaam, Daniel Bossen. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 22.10.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Integrating Infant Safe Sleep and Breastfeeding Education Into an App in a Novel Approach to Reaching High-Risk Populations: Prospective Observational Study

Tamar Krishnamurti[1*], PhD; Rachel Moon[2*], MD; Rudolph Richichi[3*], PhD; Rachel Berger[1,4,5*], MPH, MD

[1]School of Medicine, University of Pittsburgh, Pittsburgh, PA, United States

[2]School of Medicine, University of Virginia, Charlottesville, VA, United States

[3]Statistical Analysis Management Consultants, Alexandria, VA, United States

[4]Child Advocacy Center, Department of Pediatrics, UPMC Children's Hospital of Pittsburgh, Pittsburgh, PA, United States

[5]Pennsylvania Office of Children, Youth and Families, Harrisburg, PA, United States

[*]all authors contributed equally

Corresponding Author:
Rachel Berger, MPH, MD
School of Medicine, University of Pittsburgh, Pittsburgh, PA, United States

Abstract

Background: Sudden unexpected infant death (SUID) is a leading cause of death for US infants, and nonrecommended sleep practices are reported in most of these deaths. SUID rates have not declined over the past 20 years despite significant educational efforts. Integration of prenatal safe sleep and breastfeeding education into a pregnancy app may be one approach to engaging pregnant individuals in education about infant care practices prior to childbirth.

Objective: This study aims to assess whether pregnant individuals would engage with prenatal safe sleep and breastfeeding education provided within a pre-existing pregnancy app. Secondary objectives were to compare engagement among those at high and low risk of losing an infant to SUID and to assess the importance of end user push notifications for engagement.

Methods: This prospective observational study was conducted from September 23, 2019 to March, 22 2022; push notifications were removed on October 26, 2021. TodaysBaby (University of Virginia, Boston University, and Washington University), a mobile health program in which safe sleep and breastfeeding video education was originally provided via texts, was embedded into the MyHealthyPregnancy app (Naima Health LLC). Pregnant mothers who received prenatal care within the University of Pittsburgh Medical Center hospital system were randomized to receive either safe sleep or breastfeeding education beginning at the start of the third trimester of pregnancy and ending 6 weeks post partum. Pregnant persons were designated as high risk if they lived in the 5% of zip codes in Allegheny County, Pennsylvania with the highest rates of SUID in the county. The primary outcome was engagement, defined as watching at least 1 video either in response to a push notification or directly from the app's learning center.

Results: A total of 7572 pregnant persons were enrolled in the TodaysBaby Program—3308 with push notifications and 4264 without. The TodaysBaby engagement rate was 18.8% with push notifications and 3.0% without. Engagement was highest in the initial weeks after enrollment, with a steady decline through pregnancy and very little postpartum engagement. There was no difference in engagement between pregnant persons who were low and high risk. The most viewed videos were ones addressing the use of pacifiers, concerns about infant choking, and the response of the body to the start of breastfeeding.

Conclusions: Integrating safe sleep and breastfeeding education within a pregnancy app may allow for rapid dissemination of infant care information to pregnant individuals. Birthing parents at high risk of losing an infant to SUID—a leading cause of infant death after 1 month of age—appear to engage with the app at the same rates as birth parents who are at low risk. Our data demonstrate that push notifications increase engagement, overall and for those in high-risk zip codes where the SUID education is likely to have the most impact.

(JMIR Pediatr Parent 2025;8:e65247) doi:10.2196/65247

KEYWORDS

SIDS; infant death; sleep; sudden infant death; US; United States; infant; infancy; baby; prenatal; safe sleep; breastfeeding; infant care; pregnancy; app; randomized controlled study; TodaysBaby; mobile health; mHealth; smartphone

XSL•FO
RenderX

Introduction

Sudden unexpected infant death (SUID) is a leading cause of death among US infants, with nonrecommended sleep practices reported in most of these deaths [1]. After a major decrease in the SUID rate immediately after the American Academy of Pediatrics released its 1992 recommendation that infants be placed on their backs to sleep, the rate has plateaued despite extensive educational efforts [2,3]. There continue to be racial and socioeconomic disparities in SUID, with rates higher among Black infants and infants who live in poverty [4-6]. The disparity can be marked, for instance, in Allegheny County, Pennsylvania in 2017 - 2022; 35% of all SUID occurred in 5.6% (7/124) of zip codes (Berger R, MPH, MD, unpublished data, personal communication, May 2024).

Parental education in the newborn nursery has been an important approach to reducing the risk of SUID [7-9]. Information about modifiable risk factors for SUID, including prone or side sleep position, not breastfeeding, sharing a sleep surface, use of soft bedding, and exposure to nicotine/smoking, alcohol, drugs, and illicit substances, when routinely incorporated into newborn education, can change parental practice [4,10]. In one 4-armed randomized controlled trial of hospital quality improvement (QI) and mobile health (mHealth) in 16 US hospitals, new parents were enrolled in an mHealth program (TodaysBaby; University of Virginia, Boston University, and Washington University). The videos in TodaysBaby were designed with parental input from mothers of young infants (our target population); mothers were involved design of the videos and provided suggestions before and during video production and provided feedback after video production [9]. Participants in the randomized controlled trial were randomized to receive emails or texts with links to short (<2 min) videos about either breastfeeding or safe sleep for 60 days. The videos were aimed at changing attitudes and dispelling misconceptions about safe sleep and breastfeeding. In this study, parents who received only safe sleep messaging were 10 percentage points more likely to use safe sleep practices than parents who received no safe sleep messaging. Additionally, racial and ethnic differences in reported safe sleep practices were eliminated in those who received safe sleep messaging. To our knowledge, this is the only randomized controlled trial evaluating video education as an approach to improving safe sleep practices.

The MyHealthyPregnancy (MHP; Naima Health LLC) app is a commercially available evidence-based patient-facing smartphone app and provider-facing portal developed to monitor and model individual risk during pregnancy and provide easy, actionable feedback to patients. The app also offers connection to relevant resources both within and outside the health care system and notifies the individual's care team if a critical risk (eg, preterm labor and suicidal ideation) is reported through the app. The primary goal of the app is to reduce unwanted outcomes both during pregnancy and in the early period after delivery through more timely risk detection and intervention [11-14]. End users were involved in the design, development, and deployment of the technology and the design approach was grounded in person-centered frameworks to advance reproductive health equity [11,15].

The primary objectives of this study were to assess whether the TodaysBaby educational program could be integrated into the MHP app, whether users of the app would engage with the TodaysBaby content, and whether there were differences in knowledge and attitudes related to safe sleep among pregnant persons who were assigned to the safe sleep versus breastfeeding education. A secondary objective was to assess whether parents of infants at the highest risk of SUID—as defined by zip code—were similar in their rates of engagement, knowledge, and attitude compared with those living in low-risk zip codes. TodaysBaby was the first infant-specific education to be integrated into the MHP app, which is otherwise entirely focused on pregnant persons' health and pregnancy.

Methods

Overview

Providers at prenatal clinics in the University of Pittsburgh Medical Center (UPMC) health system could prescribe the MHP app (iOS version 1.4.7, Android version 1.8) to pregnant patients at their first prenatal appointment as part of a prenatal care QI initiative sponsored by UPMC and at no cost to the patient. The internal protocol for prescribing MHP was to send a text-based invitation with a unique web link to the patient's phone, which allowed app users to download the app from the Android or Apple app store. App users electronically consented to share identifiable data with their health care provider and anonymized aggregate data for research. An additional specific consent was provided for enrolling in TodaysBaby. Participants did not receive financial compensation for app use or TodaysBaby participation. At the time of consent, patients were randomly assigned to the safe sleep or breastfeeding group in a 2:1 ratio. High-risk patients—defined by zip code as described below—were enrolled in a 3:1 ratio to the safe sleep group.

All participants were recruited during pregnancy at prenatal clinics. While we recognize that pregnant individuals and parents may be of any gender and that transgender men and gender-nonbinary people may also give birth, we did not collect additional information about biological sex or gender identity from participants. We refer to participants as pregnant persons throughout the manuscript.

MHP users completed an initial onboarding process in which they completed questions about demographics, medical history, and baseline risk factors. Throughout the course of their pregnancy, app users were offered the opportunity to answer questions about their experiences and symptoms through app-embedded screeners, questionnaires, and open-ended text entries. Starting at 32 weeks of pregnancy (based on the due date entered by the user), participants started receiving texts with links to videos ("push notifications" or "pushes") at predefined intervals. The decision to start TodaysBaby at 32 weeks was a change from the original TodaysBaby study, in which the education started at the birth of the infant [9]. We chose not to start earlier than 32 weeks to minimize the likelihood of pregnancy loss among study participants.

There were 21 pushes with 18 videos for each group (safe sleep and breastfeeding): 14 pushes in the prenatal period and 7 in

XSL•FO
RenderX

the postnatal period. A total of 12 short quizzes about intentions related to sleep and breastfeeding were pushed at similar intervals. All videos were also available to all users in both groups at any time in the app's learning center (LC), which was a section of the app providing educational articles and video links on a variety of pregnancy-related topics.

The video topics for both the safe sleep and breastfeeding groups are summarized in Textbox 1.

Textbox 1. Video topics for the safe sleep and breastfeeding groups.

Safe sleep

- Importance of sleep position
- Choking and sleep position
- Importance of sleep space
- Bed-sharing
- Handling advice from others
- Mattress safety
- Soft bedding
- Feeding baby in bed
- Pacifiers
- Dangers of smoking
- Infant sleep patterns

Breastfeeding

- Importance of breastfeeding
- How to start breastfeeding
- How often to breastfeed
- Hunger cues
- What to do if baby is always hungry
- Benefits of breast milk
- How long it takes for milk to come in
- Latching on
- Avoiding breast discomfort/pain
- Dealing with fussy baby
- Getting support from others
- Economics of breastfeeding
- Breastfeeding when returning to work

On October 26, 2021, the push notifications and videos were removed; the videos remained in the LC for pregnant persons who downloaded the MHP app.

Ethical Considerations

The project was approved by the UPMC QI Committee (reference number 1613). App users consented the publication of anonymized aggregate data during app onboarding. An additional consent was provided during app onboarding to a subset of MHP users to opt in to participation in the TodaysBaby program.

Statistical Analysis

The number of videos watched via push notification or from the LC was aggregated. Data from the push notifications indicated that some videos were possibly clicked, so the aggregation was done once for definitely clicked videos and separately to include both and possibly clicked videos. Partial viewings of a video were counted as a viewing of that video. Engagement was defined as watching at least 1 video either in the LC or in response to a push notification. A binary indicator of high- versus low-risk zip codes was created.

Descriptive statistics such as frequency and percentages were used to examine demographic factors for the entire sample as well as the high- and low-risk groups. Individual chi-square tests were used to examine 2 × 2 combinations by group (safe sleep vs breastfeeding), engagement, high-risk zip codes, and frequency of video viewership. A standard of 5% probability of type 1 error was used.

XSL•FO
RenderX

Results

Overview

Between September 23, 2019, and October 26, 2021, 43% (3635/8453) of pregnant persons who were prescribed the MHP app enrolled. Of these, 91% (n=3308) consented to receive TodaysBaby content—2407 in the sleep group and 901 in the breastfeeding group. There were no demographic differences between those who did or did not enroll in the MHP app [13]. The demographics of participants who enrolled in TodaysBaby are summarized in Table 1.

Table . Demographics of MyHealthyPregnancy app users who consented to TodaysBaby.

		Overall users (n=3308)	Pregnant person living in a higher SUID[a] rate area in Allegheny County (n=297)	Pregnant person living in a lower SUID rate area in Allegheny County (n=1562)
Maternal age (years), mean (SD)		29.8 (5.4)	30.3 (5.8)	30.7 (5.1)
Income (US $), n (%)				
	Under 10,000	282 (8.9)	43 (15.4)	105 (7.0)
	10,000-14,999	147 (4.6)	18 (6.4)	56 (3.7)
	15,000-19,999	107 (3.4)	11 (3.9)	39 (13.3)
	20,000-24,999	137 (4.3)	18 (6.4)	48 (3.2)
	25,000-34,999	233 (7.3)	21 (7.5)	86 (5.7)
	35,000-49,999	274 (8.6)	21 (7.5)	103 (6.9)
	50,000-69,999	351 (11.0)	28 (9.4)	140 (9.3)
	70,000-100,000	640 (20.1)	43 (15.4)	306 (20.4)
	>100,000	1011 (31.8)	77 (27.5)	618 (41.2)
Parity–Nulliparous, n (%)		1793 (54)	166 (56)	885 (57)
Maternal education, n (%)				
	Bachelor degree or higher	1881 (57)	158 (53)	1043 (67)
	Associate degree	356 (11)	29 (10)	137 (9)
	Grade school, some high school, high school, or GED[b]	1025 (31)	101 (34)	362 (23)
	Missing	46 (1)	9 (3)	20 (1)
Smoked tobacco, n (%)		219 (6.6)	20 (6.7)	70 (4.5)
Vaped, n (%)		64 (1.9)	3 (1.0)	24 (1.5)
Used marijuana, n (%)		104 (3)	18 (6.1)	39 (2.5)
Maternal race, n (%)				
	White	2608 (79)	164 (55)	1147 (73)
	Black	351 (11)	91 (31)	210 (13)
	East or South Asian	149 (5)	12 (4)	103 (7)
	Other	176 (5)	25 (8)	90 (6)
	No response	24 (0)	5 (2)	12 (1)

[a]SUID: sudden unexpected infant death.

[b]GED: General Educational Development.

Engagement

Video Watching in Response to a Push Notification

Overall, 11% (368/3308) of all participants clicked on at least one of the push notifications they received. Of those who clicked, 53% (194/368) clicked only 1, 26% (94/368) clicked on 2 unique notifications, and the remaining 21% (80/368) clicked on 3 or more unique push notifications (maximum 20 push notifications). An additional 36 participants clicked on at least 1 push notification but because they closed the app immediately after clicking on the notification, it is not possible to be sure whether they read the information provided. If the possible clicks are included, then 12.2% (404/3308) of all participants clicked on a push notification. By comparison, 9.0% (300/3308) of users clicked on at least 1 monthly mental health

XSL•FO
RenderX

push notification which was part of the MHP app but not part of TodaysBaby.

Video Watching From the LC

Overall, 10.4% (347/3308) watched at least 1 video directly from the LC and not in response to a push notification; 6.2% (206/3308) watched at least 1 breastfeeding video from the LC, and 7.4% (345/3308) watched at least 1 safe sleep video from the LC.

Overall Engagement Rate

Overall engagement, defined as watching at least 1 video either in response to a push notification or from the LC, was 18.8% (623/3308).

Video Watching

The frequency with which videos were watched ranged from 1% (35/3308) ("why you should not smoke around your baby") to 4.7% (154/3308) ("a reminder about pacifiers"). Over 9% (300/3308) watched at least 1 of 3 pacifier-related videos. Over 98% (613/623) of the watched videos were watched only once (Table 2).

Table . Frequency with which the 10 most popular safe sleep and breastfeeding videos were watched.

Video name	Number of views
A reminder about pacifiers	154
Should I give my baby a pacifier?	106
Will my baby choke on the stomach?	105
Will my body know what to do when I start breastfeeding?	98
Why sleep position matters	97
How often should I feed my baby?	90
What is the safest mattress?	89
How do I know when my baby is hungry	86
What about bedding and bumpers?	84
What makes a baby a good sleeper	70

Timing of Video Watching

Timing of video watching during pregnancy could only be assessed for app users for whom the TodaysBaby integration took place during their first pregnancy with the app. The "weeks gestation" field was not consistently accurate for users who had used the app with previous pregnancies because some had not logged the date when the first pregnancy ended.

Of the 3308, 43% (n=1431) users were using the app for the first time. The mean time during gestation, when videos were watched, ranged from 19 weeks of gestation ("How long should I breastfeed?" and "More about pacifiers") to 32 - 33 weeks ("What can I do when my baby is fussy" and "Breastfeeding can save you time and money"). Many of these videos were watched through the LC before the TodaysBaby curriculum was available (at 32 wk of gestation) on the MHP app.

Engagement Rate After Removal of Push Notifications

From October 27, 2021 to March 22, 2022, after the push notifications were stopped, of the 4264 participants who downloaded the MHP app, 3.0% (n=127) watched any TodaysBaby videos. Overall, 2.0% (n=85) watched at least 1 breastfeeding video, and 2.0% (n=85) watched at least 1 safe sleep video. The use of the LC was also significantly lower among pregnant persons who did not receive pushes versus those who did (127/4264, 3% vs 347/3308, 10.4%; $P<.001$).

Engagement of Participants in High-Risk Zip Codes in Allegheny County

Of the 3308 users, 58% (n=1859) were from Allegheny County; of these, 16% (297/1859) lived in a high-risk zip code and 84% (1562/1859) lived in a low-risk zip code. Demographic characteristics of the TodaysBaby participants from high-risk and low-risk zip codes are found in Textbox 1.

Among those with high-risk zip codes, 219 were randomized to safe sleep and 78 to the breastfeeding group. Overall engagement in this group was 21.5% (62/297), 10.8% (32/297) clicked on at least 1 TodaysBaby push notification, and 12.5% (37/297) watched at least 1 video from the LC. View rates of safe sleep and breastfeeding videos were similar for both high-risk and low-risk groups.

There was no difference in the engagement of users from high-risk and low-risk zip codes, with the push notifications (32/297, 10.8% vs 185/1562, 11.8%; $P=.60$) or the LC videos (182/1562, 11.6% vs 37/297, 12.5%; $P=.70$).

Quizzes

Overall, 12.0% (409/3308) of all users took at least 1 of the 12 quizzes. Of those who took at least 1 quiz, 54% (222/409) took only a single quiz. Except for quizzes 1 and 6, the completion rate was very low (Table 3). Quizzes 1 and 6 coincided with the user getting a push notification on the same day related to a change in the stage of fetal development. The push notification on the day of quiz 1 (32 weeks gestation) was "Pregnancy is full of many joys and challenges! Reflect on yours now with

XSL•FO
RenderX

your mental health check-in" and the one on the day of quiz 6 (35 weeks gestation) was "Welcome to week 35! Time to put that hospital bag next to your door! Visit MHP for a list of recommended items to pack." There was no difference in response rate between the safe sleep and breastfeeding groups or between high- and low-risk users.

Table . Number of responses to each of the 12 quizzes.

Quiz number	Number of responses
1	279
2	32
3	32
4	44
5	48
6	211
7	62
8	34
9	32
10	25
11	1
12	2

The responses to questions in quizzes 1 and 6 demonstrate that app users plan to breastfeed (83.2%), plan for their baby to sleep in a safe location (97.9%), and plan for their baby to sleep on his or her back (94.6%) (Table 4). There was no difference in the quiz responses between groups (safe sleep versus breastfeeding or high versus low risk).

Table . Responses to quizzes 1 and 6.

Quiz number and quiz question	Response
Q[a]1Ques[b]1: When I first bring my baby home, I plan to breastfeed	83.2% agree or strongly agree
Q1Ques2: When I first bring my baby home, I plan to have him/her sleep in an adult bed	2.1% agree or strongly agree
Q1Ques3: When I first bring my baby home, I plan to place him/her on the side to sleep	5.7% agree or strongly agree
Q1Ques4: When I first bring my baby home, I plan to place him/her on the stomach to sleep	3.9% agree or strongly agree
Q1Ques5: When I first bring my baby home, I plan to place him/her on the back to sleep	94.6% agree or strongly agree
Q1Ques6: When I first bring my baby home, I plan to give him/her a pacifier	34% agree or strongly agree
Q6Ques1: I will be taking a medication or substance that may make me sleep more deeply	10.9% yes or unsure
Q6Ques2: I am currently on prescribed opioids/pain medication/methadone or Subutex/suboxone	1.9% yes
Q6Ques3: I currently use tobacco products	7.6% yes

[a]Q: quiz.

[b]Ques: question.

Discussion

Principal Findings

This is the first study, to our knowledge, to evaluate the use of a mobile app as a means of delivering safe sleep education to pregnant persons with the goal of addressing the risk of SUID. While mHealth tools have been used to explicitly encourage breastfeeding and other care behaviors, the use of an mHealth tool to address safe sleep is novel [16,17]. Over the past 20 years, the way in which young adults receive information has shifted. Smartphone ownership is ubiquitous among reproductive-aged individuals in the United States, with similar distribution by race and ethnicity [18]. A vast majority of smartphone owners use their phones to access health

XSL•FO
RenderX

information, with pregnancy being one of the most popular health app domains [19-21].

In addition to their popularity as an information source, there are several clear advantages to the dissemination of information through a mobile app. An app allows for the dissemination of information much more broadly and quickly than face-to-face education or information via educational pamphlets. It also provides the opportunity for users to obtain the information at a time and place which is convenient for them and it allows for the education to be provided as many times as desired and for it to be provided in the same way each time. Receiving inconsistent information even within a single setting such as a primary care physician's office or newborn nursery can contribute to misinformation.

Timing of education is also critical. While previous safe sleep and breastfeeding education programs have focused on parents after childbirth, parents make many decisions about sleep and feeding practices during pregnancy. In a study by our group, we found that pregnant mothers often purchased cribs and made decisions about sleep practices in their third trimester (Berger R, MPH, MD, unpublished data, 2021). Much of the safe sleep and breastfeeding education in the health care system takes place in a physician's office or newborn nursery after birth, which may not coincide with when parents or other caretakers want or need to hear this information. For this reason, we included TodaysBaby within the MHP app starting at 32 weeks, which was a change from the original TodaysBaby study, in which the education started at the birth of the infant [9]. Our data demonstrated that many of the videos in the LC center were watched before any of the app users began receiving the TodaysBaby curriculum. The LC provides the opportunity for pregnant persons to find the information they are most eager and willing to learn and may be most amenable to incorporating new information. As a result of this finding, integration of the TodaysBaby curriculum earlier in the pregnancy is a possible future change.

One of the challenges of safe sleep education provided in a physician's office or birthing hospital is that there is a set curriculum; it would be very difficult to tailor education to each parent. In a recent study by our group, parents described interactions with their pediatricians related to safe sleep. Most parents reported that their pediatricians asked if they were practicing safe sleep and if they responded they were, there was no further conversation (Sahud H, unpublished data, personal communication, 2024). Here, an additional advantage of app-based content delivery is that the education can be tailored. Our study showed distinct differences in popularity (as determined by number of views) depending on the topic of the videos. This suggests that parents know the specific topics they are interested in or need additional information about (eg, pacifier use) and may not want to spend time learning about other (potentially already-familiar) infant-related topics even though each of the videos was <2 minutes in length.

This study also allowed us to see the natural engagement rate with the TodaysBaby content when deployed outside the context of a controlled study environment in a nonincentivized manner. Our approach allowed for dissemination to a large number of users which would not be possible with an in-person dissemination strategy. Since the field of digital health does not yet have a consensus definition of how to measure and report engagement [22], and very few published studies share engagement rates for specific embedded features and content within a larger intervention (eg, embedding TodaysBaby within the MHP app), it is difficult to interpret our engagement rate of 18.8%. Two studies evaluating specific intervention-embedded content in nonincentivized tool use demonstrated much lower engagement rates (eg, <1% of users completed all modules in 1 mHealth tool; approximately 3.5% completed a single assessment in another) than ours [23,24]. There may be an opportunity to increase engagement by focusing on high-interest video topics and beginning the TodaysBaby curriculum earlier in pregnancy when the overall engagement with the app is higher. Although fewer than half of the videos were watched in response to pushes, when the pushes were removed, the overall engagement dropped from 18% to 3%. Moreover, engagement with quizzes was highest when those quizzes coincided with push notifications containing fetal development information. This suggests that push notifications are critically important to engagement, and push notifications with time-sensitive or high-interest content may be leveraged to engage individuals with aspects of the tool that they would otherwise not seek out. The similar engagement rates between users living in communities with high and low rates of SUID are consistent with other data from the MHP app which has demonstrated that pregnant persons at the highest risk for pregnancy-related complications had similar or higher levels of engagement (Naima Health, unpublished data). This finding has important implications for SUID prevention and potentially for the identification of populations most likely to benefit from access to the MHP app. It is also encouraging that the engagement with videos about maternal health within the MHP app was watched as frequently as videos within the TodaysBaby curriculum since it suggests that mothers are equally willing to watch videos about their baby's health and their own health.

Limitations

There are limitations to this study. Those individuals who downloaded the app may not be representative of the larger pregnant population. For example, these individuals may be more comfortable with seeking out information through technology and may not reflect the population in greatest need of the TodaysBaby information. Because of the low response rate for the quizzes, it was not possible to assess whether engagement with the app correlated with changes in safe sleep or breastfeeding intentions. All participants were English-speaking; there is current work on an app that will be in both Spanish and English (Krishnamurti T, unpublished data, personal communication, June 2024).

Conclusions

Our data demonstrate that it is possible to embed safe sleep and breastfeeding education into an app designed to improve outcomes during pregnancy; that the engagement level is encouraging, especially when compared with other published studies of intervention-embedded education within a health-related app; and that this engagement was equally as

XSL•FO
RenderX

high among pregnant persons at the highest risk of an SUID. Using an app to disseminate information allows for widespread and rapid dissemination and provides users with the opportunity to choose which education they are interested in and when they are interested in receiving it. Simply having access to this education—as was available in the app LC—is not sufficient for engagement, and push notifications are critical for engagement. Future research should focus on assessing whether engagement with the app and TodaysBaby curriculum correlates with changes in safe sleep practices.

Acknowledgments

We thank Samantha Rodriguez, MS, and Laila Hayani, MS, for research assistance; Joybyte LLC for technical support; and Anthony DeFazio and Spencer Poston for administration support. The funding for this study was provided by the Hillman Foundation. The statements in this article are solely the responsibility of the authors and do not necessarily represent the views of the Pennsylvania Office of Children, Youth, and Families.

Conflicts of Interest

Naima Health LLC provided the data for this study. The authors did not receive any financial or material compensation for conducting this study. TK is a cofounder and equity holder of Naima Health LLC, but did not receive compensation for conducting this study or disseminating the MyHealthyPregnancy app.

References

1. Linked birth/infant death records. CDC WONDER online database. URL: https://wonder.cdc.gov/lbd.html [accessed 2024-05-08]
2. Carlin R, Moon RY. Learning from national and state trends in sudden unexpected infant death. Pediatrics 2018 Mar;141(3):2017-4083. [doi: 10.1542/peds.2017-4083] [Medline: 29440503]
3. Erck Lambert AB, Parks SE, Shapiro-Mendoza CK. National and state trends in sudden unexpected infant death: 1990-2015. Pediatrics 2018 Mar;141(3):e20173519. [doi: 10.1542/peds.2017-3519] [Medline: 29440504]
4. Moon RY, Carlin RF, Hand I, Task Force on Sudden Infant Death Syndrome and the Committee on Fetus and Newborn. Sleep-related infant deaths: updated 2022 recommendations for reducing infant deaths in the sleep environment. Pediatrics 2022 Jul 1;150(1):2022-057990. [doi: 10.1542/peds.2022-057990] [Medline: 35726558]
5. Boyer BT, Lowell GS, Roehler DR, Quinlan KP. Racial and ethnic disparities of sudden unexpected infant death in large US cities: a descriptive epidemiological study. Inj Epidemiol 2022 Mar 25;9(1):12. [doi: 10.1186/s40621-022-00377-7] [Medline: 35337375]
6. Colson ER, Levenson S, Rybin D, et al. Barriers to following the supine sleep recommendation among mothers at four centers for the women, infants, and children program. Pediatrics 2006 Aug;118(2):e243-e250. [doi: 10.1542/peds.2005-2517] [Medline: 16882769]
7. Goodstein MH, Bell T, Krugman SD. Improving infant sleep safety through a comprehensive hospital-based program. Clin Pediatr (Phila) 2015 Mar;54(3):212-221. [doi: 10.1177/0009922814566928] [Medline: 25670685]
8. Walcott RL, Salm Ward TC, Ingels JB, Llewellyn NA, Miller TJ, Corso PS. A statewide hospital-based safe infant sleep initiative: measurement of parental knowledge and behavior. J Community Health 2018 Jun;43(3):534-542. [doi: 10.1007/s10900-017-0449-x] [Medline: 29188464]
9. Moon RY, Hauck FR, Colson ER, et al. The effect of nursing quality improvement and mobile health interventions on infant sleep practices: a randomized clinical trial. JAMA 2017 Jul 25;318(4):351-359. [doi: 10.1001/jama.2017.8982] [Medline: 28742913]
10. Anderson TM, Lavista Ferres JM, Ren SY, et al. Maternal smoking before and during pregnancy and the risk of sudden unexpected infant death. Pediatrics 2019 Apr;143(4):e20183325. [doi: 10.1542/peds.2018-3325] [Medline: 30858347]
11. Krishnamurti T, Davis AL, Wong-Parodi G, Fischhoff B, Sadovsky Y, Simhan HN. Development and testing of the MyHealthyPregnancy app: a behavioral decision research-based tool for assessing and communicating pregnancy risk. JMIR Mhealth Uhealth 2017 Apr 10;5(4):e42. [doi: 10.2196/mhealth.7036] [Medline: 28396302]
12. Wang T, Krishnamurti T, Bernard M, Lopa S, Quinn B, Simhan H. Perceptions and knowledge of COVID-19 vaccine safety and efficacy among vaccinated and non-vaccinated obstetric healthcare workers. Behav Med 2023;49(3):258-270. [doi: 10.1080/08964289.2021.2023456] [Medline: 35057715]
13. Krishnamurti T, Davis AL, Quinn B, Castillo AF, Martin KL, Simhan HN. Mobile remote monitoring of intimate partner violence among pregnant patients during the COVID-19 shelter-in-place order: quality improvement pilot study. J Med Internet Res 2021 Feb 19;23(2):e22790. [doi: 10.2196/22790] [Medline: 33605898]
14. Krishnamurti T, Allen K, Hayani L, Rodriguez S, Davis AL. Identification of maternal depression risk from natural language collected in a mobile health app. Procedia Comput Sci 2022;206:132-140. [doi: 10.1016/j.procs.2022.09.092] [Medline: 36712815]

XSL•FO
RenderX

15. Krishnamurti T, Birru Talabi M, Callegari LS, Kazmerski TM, Borrero S. A framework for Femtech: guiding principles for developing digital reproductive health tools in the United States. J Med Internet Res 2022 Apr 28;24(4):e36338. [doi: 10.2196/36338] [Medline: 35482371]
16. Musgrave LM, Baum A, Perera N, Homer CS, Gordon A. Baby Buddy app for breastfeeding and behavior change: retrospective study of the app using the behavior change wheel. JMIR Mhealth Uhealth 2021 Apr 15;9(4):e25668. [doi: 10.2196/25668] [Medline: 33856351]
17. Demirci JR, Suffoletto B, Doman J, et al. The development and evaluation of a text message program to prevent perceived insufficient milk among first-time mothers: retrospective analysis of a randomized controlled trial. JMIR Mhealth Uhealth 2020 Apr 29;8(4):e17328. [doi: 10.2196/17328] [Medline: 32347815]
18. Sidoti O, Gelles-Watnick R, Faverio M, Atske S, Radde K, Park E. Mobile fact sheet. Pew Research Center. URL: https://www.pewresearch.org/internet/fact-sheet/mobile/?tabItem=d40cde3f-c455-4f0e-9be0-0aefcdaeee00 [accessed 2024-12-27]
19. Krebs P, Duncan DT. Health app use among US mobile phone owners: a national survey. JMIR Mhealth Uhealth 2015 Nov 4;3(4):e101. [doi: 10.2196/mhealth.4924] [Medline: 26537656]
20. Nguyen OT, Renfro CP, Hughes J, et al. Patients' use of smartphone apps for health record access in 2019: a cross-sectional study. Int J Med Inform 2022 Oct;166:104858. [doi: 10.1016/j.ijmedinf.2022.104858] [Medline: 36001919]
21. Hughson JAP, Daly JO, Woodward-Kron R, Hajek J, Story D. The rise of pregnancy apps and the implications for culturally and linguistically diverse women: narrative review. JMIR Mhealth Uhealth 2018 Nov 16;6(11):e189. [doi: 10.2196/mhealth.9119] [Medline: 30446483]
22. Amagai S, Pila S, Kaat AJ, Nowinski CJ, Gershon RC. Challenges in participant engagement and retention using mobile health apps: literature review. J Med Internet Res 2022 Apr 26;24(4):e35120. [doi: 10.2196/35120] [Medline: 35471414]
23. Baumel A, Muench F, Edan S, Kane JM. Objective user engagement with mental health apps: systematic search and panel-based usage analysis. J Med Internet Res 2019 Sep 25;21(9):e14567. [doi: 10.2196/14567] [Medline: 31573916]
24. Serrano KJ, Coa KI, Yu M, Wolff-Hughes DL, Atienza AA. Characterizing user engagement with health app data: a data mining approach. Transl Behav Med 2017 Jun;7(2):277-285. [doi: 10.1007/s13142-017-0508-y] [Medline: 28616846]

Abbreviations

LC: learning center
mHealth: mobile health
MHP: MyHealthyPregnancy
QI: quality improvement
SUID: sudden unexpected infant death
UPMC: University of Pittsburgh Medical Center

Edited by S Badawy; submitted 23.08.24; peer-reviewed by A Pease, L Musgrave; revised version received 31.10.24; accepted 07.11.24; published 14.01.25.

Please cite as:
Krishnamurti T, Moon R, Richichi R, Berger R
Integrating Infant Safe Sleep and Breastfeeding Education Into an App in a Novel Approach to Reaching High-Risk Populations: Prospective Observational Study
JMIR Pediatr Parent 2025;8:e65247
URL: https://pediatrics.jmir.org/2025/1/e65247
doi:10.2196/65247

© Tamar Krishnamurti, Rachel Moon, Rudolph Richichi, Rachel Berger. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 14.1.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Evaluating the Characteristics and Outcomes of Acute Pharmaceutical Exposure in Children: 5-Year Retrospective Study

Zhu Yan Duan[1*], MSc; Yan Ning Qu[1,2*], MSc; Rui Tang[3], MSc; Jun Ting Liu[4], PhD; Hui Wang[1], BS; Meng Yi Sheng[1], BS; Liang Liang Wang[1], BS; Shuang Liu[1], MSc; Jiao Li[3], PhD; Lin Ying Guo[1], MD; Si Zheng[3,5*]

[1]Emergency Department, Capital Center for Children's Health, Capital Medical University, No. 2 Yabao Road, Chaoyang District, Beijing, China

[2]Capital Institute of Pediatrics, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China

[3]Institute of Medical Information, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing, China

[4]Child Health Big Data Research Center, Capital Institute of Pediatrics, Beijing, China

[5]Department of Computer Science and Technology, Tsinghua University, Beijing, China

[*]these authors contributed equally

Corresponding Author:
Lin Ying Guo, MD
Emergency Department, Capital Center for Children's Health, Capital Medical University, No. 2 Yabao Road, Chaoyang District, Beijing, China

Abstract

Background: Acute pharmaceutical exposure in children can lead to severe health outcomes and contribute to the inefficient use of medical resources.

Objective: This study aimed to investigate the clinical characteristics and outcomes of children with acute pharmaceutical exposure to guide the development of preventive strategies and educational initiatives.

Methods: We analyzed real-world data from electronic medical records of children admitted to the emergency department of a pediatric hospital for acute pharmaceutical exposure between January 2019 and December 2023. Clinical data, including laboratory test results, interventions, and outcomes, were collected. We compared different exposure events and conducted logistic regression analysis to identify risk factors for hospitalization.

Results: A total of 653 children were included in the study. The most common drugs involved in exposure were vitamins (149/653, 22.8%), nonsteroidal anti-inflammatory drugs (92/653, 14.1%), and psychiatric drugs (74/653, 11.3%). In total, 74.3% (469/631) of patients with complete clinical manifestation data showed no symptoms after exposure, and 68.1% (445/653) of patients did not require specific therapy. Toxicology screening was performed for 11% (72/653) of the children, and 69.4% (50/72) of these tests were positive. Independent risk factors for hospitalization included multisystem involvement (odds ratio [OR] 4.575, 95% CI 1.709-12.251, *P*=.002), psychiatric drugs (OR 6.280, 95% CI 2.189-18.020, *P*=.001), and intentional poisoning (OR 12.892, 95% CI 2.222-74.796, *P*=.004).

Conclusions: Children with acute pharmaceutical exposure exhibit diverse clinical characteristics and outcomes, with most requiring no specific treatment. However, immediate toxicology screening and clinical intervention are essential for those exhibiting rapidly developing or multisystem symptoms, as well as those with intentional exposure or exposure to known highly toxic substances. Future pediatric health care policies should emphasize safe storage practices and public education on the prevention of pharmaceutical exposure.

(JMIR Pediatr Parent 2025;8:e66951) doi:10.2196/66951

KEYWORDS

acute pharmaceutical exposure; children; poisoning; characteristics; outcomes

Introduction

Acute poisoning is one of the major public health issues affecting children around the world [1,2]. It can cause severe harm to children and bring immense economic and emotional burdens to their families. As children always lack the ability to metabolize harmful substances, serious physiological and psychological impacts were often observed, even resulting in disability or death [3]. According to the World Health Organization (WHO) report, accidental poisoning is a major contributor to accidental injury-related deaths in children, particularly in limited-income countries, where the mortality from poisoning is more pronounced [4]. Recent studies reported a significant decline in overall childhood poison exposures, but a decrease in poisoning-related fatalities was not observed [5]. Surveys in China also indicate that poisoning events still

XSL•FO
RenderX

frequently occurred [5-8]. Meanwhile, acute poisoning has become a common reason for pediatric emergency visits in some regions, accounting for 0.1% - 0.5% of such visits [9,10]. Thus, acute poisoning remains a serious public health concern for pediatrics.

Children, particularly infants and preschoolers, spend the majority of their time at home. Children's strong curiosity, poor discernment ability, and weak protective awareness make them a high-risk group for pharmaceutical poisoning, often leading to acute poisoning incidents. In addition, unsafe storage of pharmaceuticals or chemicals, inadequate child supervision, nonauthoritative parenting, maternal employment, and lack of family support can also lead to pharmaceutical exposure and poisoning in children [11,12]. For example, Song et al [13] analyzed 586 cases of hospitalized children with acute poisoning and found that the main causes of poisoning included medications (37.7%), pesticides (28.5%), and rodenticides (29.9%). Li et al [14] showed that most poisoning incidents among children are accidental, with 70.4% occurring at home. Accidental poisonings are more common in young children, particularly in those aged 1 - 3 years, whereas intentional poisonings are more common among adolescents [15,16]. Furthermore, the clinical manifestations of acute poisoning in children are diverse, and some severe cases presenting consciousness disturbances and circulatory failure can be life-threatening.

Notably, a large proportion of studies focused on pediatric pharmaceutical exposures and related poisoning events have been carried out; however, the epidemiological characteristics and clinical manifestations or outcomes of exposed populations, as well as the toxic substance types and prevention efforts, are often limited to specific research geographical areas, cultural backgrounds, and time periods. Furthermore, with the continuous discovery and development of new drugs, the characteristics of exposed populations are constantly changing, necessitating continuous updates and expansions of the relevant knowledge to meet new challenges for preventing acute poisoning in pediatrics. Additionally, in cases of children with acute pharmaceutical exposure, most parents or caregivers are often unsure whether the drugs are truly dangerous to their children, leading them to immediately take the children to the emergency room. The excessive anxiety and lack of professional knowledge in this population may result in the unnecessary use of pediatric emergency resources. While some exposure incidents indeed require urgent medical intervention, in many cases, the exposure events do not immediately endanger life [17,18].

In light of the aforementioned information, in this study, we retrospectively analyzed the acute pharmaceutical exposure cases from the emergency department of a pediatric hospital located in northern China. By summarizing the epidemiological characteristics and clinical manifestations and outcomes of the patients, this study aims to explore the recent common drugs involved in acute pharmaceutical exposure and the related outcomes, and to propose recommendations for preventing and managing acute pharmaceutical exposure in children.

Methods

Sample Collection

This retrospective study included children with acute pharmaceutical exposure who were admitted to the emergency department of the Capital Center for Children's Health, Capital Medical University between January 1, 2019, and December 31, 2023. All participants were aged 18 years or younger. The inclusion criteria for the patient group were age at assessment between 0 and 18 years, and admission due to pharmaceutical exposure. The exclusion criteria were incomplete records (patients lacking key clinical information such as basic demographic data, type of pharmaceutical substance exposed to, or clinical outcomes), admission due to chronic pharmaceutical exposure, and repeat visits (repeated visit records refer to the follow-up visit records of children with acute pharmaceutical exposure who come to the hospital for further check-ups). Totally, 653 eligible patients were included.

Data Preprocessing and Variables Extraction

For the patients who met the inclusion criteria, more detailed clinical information was extracted from their anonymized electronic medical records. Specifically, the variables directly extracted from the structured fields of the electronic records included age, gender, residence, admission time, types of pharmaceutical substances (eg, vitamins, psychotropic drugs, and nonsteroidal anti-inflammatory drugs [NSAIDs]), reasons for acute pharmaceutical exposure (intentional, suicidal, or accidental ingestion), exposure location, exposure season, methods of arrival, caregiver's education level, and clinical outcomes (discharge without treatment, emergency observation, and hospitalization).

The following variables were manually extracted from the unstructured text in the electronic medical records: clinical manifestations (eg, no symptoms, gastrointestinal symptoms, and neurological symptoms), clinical interventions (eg, no specific therapy, gastric lavage, and specific antidotes), and laboratory test results (routine blood test, biochemical test, coagulation function test, and toxicology screening).

The extraction of unstructured data was performed by 4 pediatric emergency physicians with extensive experience. All physicians underwent training on the data extraction content and methods before the process to ensure the accuracy and consistency of the data collection.

All eligible patients were grouped into the following age categories: infancy (<1 year), toddler (≥1 to <3 years), preschool (≥3 to <6 years), school age (≥6 to <12 years), and adolescence (≥12 to <18 years). The pharmaceutical exposure reasons were categorized as intentional and unintentional. The types of drugs involved in acute pharmaceutical exposure were categorized into 13 groups, namely vitamins, NSAIDs (such as ibuprofen and acetaminophen), psychotropic drugs (eg, antidepressant, antiepileptic, and sedative), cardiovascular drugs (eg, antihypertensive and diuretics), antihistamines, respiratory drugs, topical skin drugs, antimicrobial drugs (eg, antibiotic, antiviral, and antifungal drug), endocrine drugs (eg, antidiabetic

XSL•FO
RenderX

and hormone), herbal medicine, digestive drugs, immunosuppressants, and others.

After completing the above variable extraction and transformation, 22 patients lacked clinical manifestation data. For laboratory tests, 435 children underwent routine blood tests (C-reactive protein, white blood cells, and platelets), 437 children underwent biochemical tests (liver enzymes, myocardial enzymes, and renal function), 418 children underwent coagulation function tests, and 72 patients underwent toxicology screening. Except for these, all other variables had no missing values. In this study, we did not perform imputation for the variables with missing values, and we only used the actual valid data for each variable for the following data comparison and statistical analysis.

Statistical Analysis

All analyses were conducted using SPSS (version 26.0; IBM Corp) and Python (version 3.11; Python Software Foundation). The mean level of numerical variables was measured as mean (SD), and differences between different groups were analyzed using 2-tailed *t* tests. Besides, categorical data were measured with frequencies or percentages, and differences between groups were analyzed using the chi-square test, and Fisher exact tests were used when more than 20% of theoretical frequency was less than 5. In addition, univariate and multivariate logistic regression were used and odds ratios (OR) with 95% CIs were calculated to define the risk factors associated with hospitalization for acute pharmaceutical exposure. A *P* value of <.01 was considered statistically significant.

Ethical Considerations

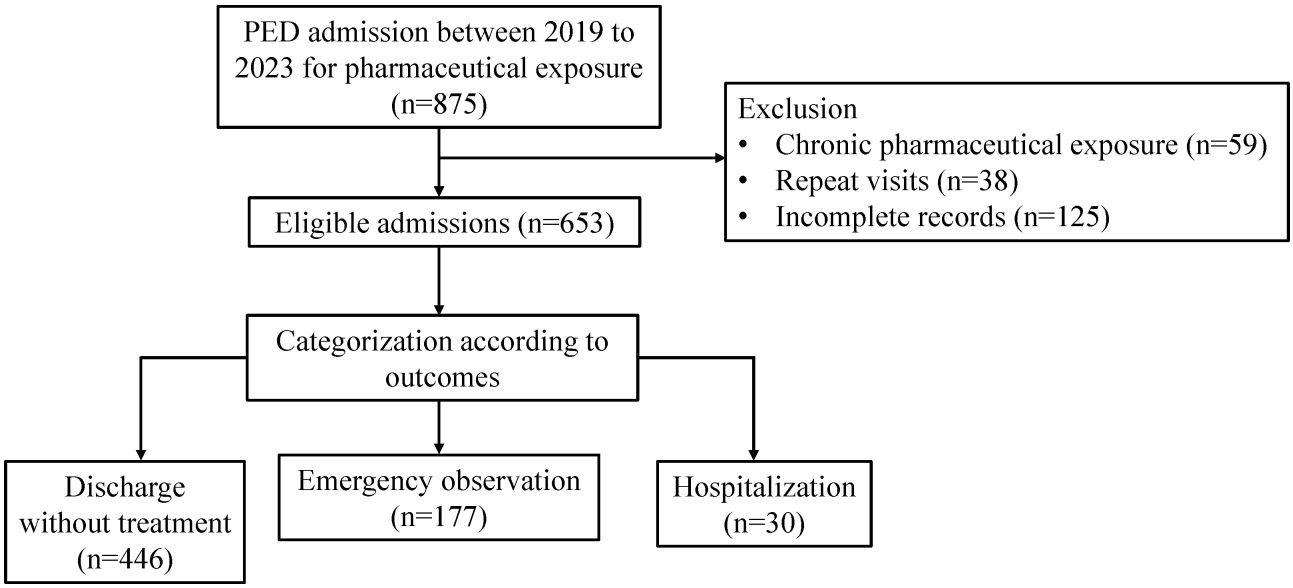
All methods were performed in accordance with the relevant guidelines and regulations. Since we used anonymized data, and this study did not constitute human subject research, the need for written informed consent was waived by the ethics committee of Children's Hospital Affiliated to Capital Institute of Pediatrics, due to the retrospective nature of the study (SHERLLM2024029).

Results

Characteristics of Children With Acute Pharmaceutical Exposure

From January 1, 2019, to December 31, 2023, 653 adequate pediatric patients with acute pharmaceutical exposure were admitted to our pediatric emergency department (PED; Figure 1). The male-to-female ratio among patients was 1.04:1, with a slightly higher proportion of males. The average age of the patients was 4.7 (SD 4.1) years, with toddlers aged 1 - 3 years old accounting for the highest proportion (253/653, 38.7%; Table 1). Analyzing the age distribution by gender, 56.9% (325/571) of the children under 12 years were male and 43.1% (246/571) were female. Among children aged 12 years and older, 11% (9/82) were male and 89% (73/82) were female, which indicated the gender ratio of patients varies across the 2 age groups.

Figure 1. The workflow of sample collection. PED: pediatric emergency department.



XSL•FO
RenderX

Table . Characteristics of children with acute pharmaceutical exposure admitted to the pediatric emergency department from 2019 to 2023 (N=653).

Demographic characteristics	Participants, n (%)
Sex	
Male	334 (51.1)
Female	319 (48.9)
Age group	
Infant	47 (7.2)
Toddler	253 (38.7)
Preschool	209 (32)
School age	62 (9.5)
Adolescence	82 (12.6)
Residence	
Urban	574 (87.9)
Rural	79 (12.1)
Exposure place	
Home	608 (93.1)
Others	45 (6.9)
Exposure time	
8 AM to 4 PM	231 (35.4)
4 PM to midnight	356 (54.5)
Midnight to 8 AM	66 (10.1)
Exposure season	
Spring	136 (20.8)
Summer	148 (22.7)
Autumn	175 (26.8)
Winter	194 (29.7)
Exposure reason	
Accidental	575 (88.1)
Intentional	78 (11.9)
Caregiver	
Parents	457 (70)
Grandparents	76 (11.6)
None	102 (15.6)
Others	18 (2.8)
Education level of caregiver	
High school or less	112 (17.1)
Undergraduate or vocational college degree	355 (54.4)
Master’s degree or above	132 (20.2)
Unclear	54 (8.3)

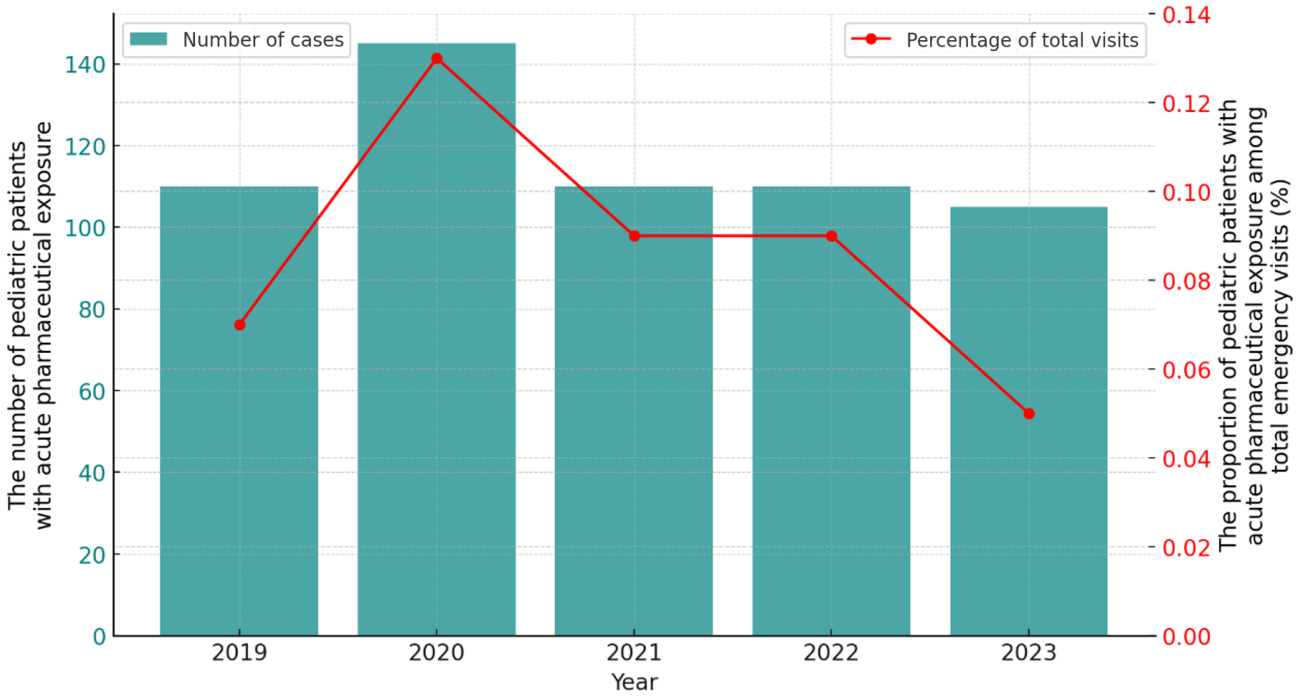
Most pharmaceutical exposure incidents primarily occurred at home, with the peak period mainly occurring between 4 PM and midnight (356/653, 54.5%). Regarding seasonal variations, the number of children visiting the PED for acute pharmaceutical exposure was highest in winter. The primary caregivers at the time of exposure events were parents, and 54.4% (355/653) of the caregivers were college or undergraduates. In addition, analysis of the exposure reasons showed that 11.9% (78/653) were intentional, while the remaining 88.1% (575/653) were accidental. There were 208 poisoning cases (31.9%) resulting from acute pharmaceutical exposure, with 31.3% (65/208) being intentional and the remaining 68.7% (143/208) accidental. In

XSL•FO
RenderX

our study, the diagnostic criteria for drug poisoning include the presence of corresponding clinical manifestations, abnormal laboratory results indicating organ damage, or toxicology tests showing drug concentrations reaching toxic levels.

In terms of changes over time, the annual number of emergency visits due to acute pharmaceutical exposure fluctuated between 107 and 149 over the past 5 years, with a significant increase in admissions in 2020 (Figure 2). The number of patients in other years did not show significant differences. This increase in the year 2020 may be attributed to prolonged home stays and heightened parental vigilance during the early stages of the pandemic, which led to more admissions related to acute pharmaceutical exposure. The annual proportion of admissions due to acute pharmaceutical exposure ranged from 0.05% to 0.13% of the total number of PED visits.

Figure 2. The annual number of pediatric patients with acute pharmaceutical exposure and its proportion in the total annual number of emergency department visits.

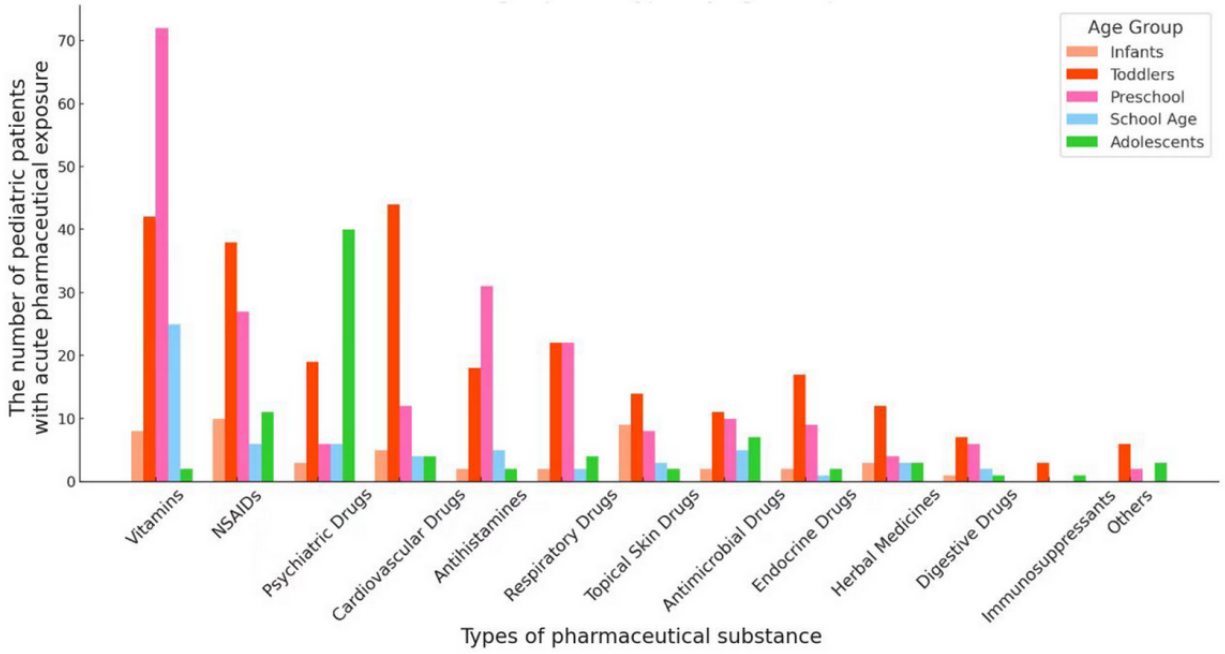


Types of Pharmaceutical Substances

In this study, the drugs involved in acute pharmaceutical exposure were categorized into 13 groups (Figure 3). Totally, vitamins emerged to be the most common in all patients (149/653, 22.8%), followed by NSAIDs (92/653, 14.1%; Table S1 in Multimedia Appendix 1). Notably, the proportion of psychotropic drugs is also high (74/653, 11.3%), of which antidepressants accounted for 64.8% (48/74). Besides, cardiovascular drugs (mainly antihypertensive; 56/69, 81.2%) and endocrine drugs (mainly hypoglycemic agents; 11/31, 35.5%) are also common exposure substances (Table S1 in Multimedia Appendix 1).

XSL•FO
RenderX

Figure 3. The distribution of pharmaceutical substances across different age groups.



Furthermore, the types of pharmaceutical substances varied across different age groups. NSAIDs (10/47, 21.3%) and topical skin drugs (9/47, 19.1%) were the most common substance in infants. While in toddlers, cardiovascular drugs (44/253, 17.4%), vitamins (42/253, 16.6%), and NSAIDs (38/253, 15%) were more prevalent. Preschool and school-age children were most frequently exposed to vitamins, accounting for 34.4% (72/209) and 40.3% (25/62), respectively. In adolescents, psychiatric medications were the most common type (40/82, 48.8%), followed by NSAIDs (11/82, 13.4%; Table S1 in Multimedia Appendix 1). It is worth noting that there were 29 patients (29/653, 4.4%) involved in multiple drug exposures, and 46.4% (12/29) of them were adolescents.

While the pandemic may have slightly influenced the absolute number of admissions (Figure 2), it did not substantially alter the underlying epidemiological trends of pediatric pharmaceutical exposures (Table S2 in Multimedia Appendix 1). Analysis of the types of pharmaceutical substances across different year groups showed temporal fluctuations. For example, between 2020 and 2022, the proportion of neuropsychiatric drug exposure was higher compared with both 2019 and 2023. Conversely, during the pandemic, the proportion of respiratory system drug exposure was lower than before and after the pandemic (5.7% vs 12.1% and 12.1%, respectively). However, the types of pharmaceutical substances involved remained largely consistent across these periods (chi-square test, P=.03; Table S2 in Multimedia Appendix 1).

Clinical Manifestations of Acute Pharmaceutical Exposure

In general, for the 631 patients with complete clinical manifestation data, 74.3% (469/631) did not exhibit obvious symptoms after acute pharmaceutical exposure, while the remaining patients showed one or more system involvements. For instance, 13% (82/631) of the patients showed the involvement of the gastrointestinal system, such as nausea, vomiting, abdominal pain, and diarrhea (Table 2). In total, 6.5% (41/631) of patients exhibited neurological symptoms like dizziness, drowsiness, and even coma in some severe cases; these children are mainly associated with excessive use of antidepressants and sedative overdoses. Cardiovascular symptoms were observed in 4.1% (26/631) of the children and manifested as pallor, sweating, and, in some severe cases, hypotension. In addition, multisystem involvement was noted in 9.5% (60/631) of the cases, and dermatological symptoms were observed in 1.4% (9/631) of the cases.

XSL•FO
RenderX

Table . Clinical manifestations and the abnormal laboratory test results for children with acute pharmaceutical exposure.

Clinical manifestations (n=631)	Participants, n (%)
No symptom	469 (74.3)
Gastrointestinal symptoms	82 (13)
Neurological symptoms	41 (6.5)
Cardiovascular symptoms	26 (4.1)
Dermatological symptoms	9 (1.4)
Hematological symptoms	1 (0.2)
Multisystem symptoms (>2 systems)	60 (9.5)
Abnormal laboratory test results	
Routine blood test (n=435)	
WBC[a]>12×10^9/L	58 (13.3)
CRP[b]>8 mg/L	31 (7.1)
WBC＜4×10^9/L	16 (3.7)
PLT[c]<100×10^9/L	5 (1.1)
Coagulation function test (n=418)	
Abnormal coagulation index (PT[d]>20 s or APTT[e]>50 s or FIB[f]<2 g/L)	32 (7.7)
Biochemical test (n=437)	
CKMB[g]>3.6 ng/mL	55 (12.6)
ALT[h]>40 U/L	22 (5.0)
Abnormal renal function (urea>7.1 mmol/L or CREA[i]>106 µmol/L)	7 (1.6)

[a]WBC: white blood cell.
[b]CRP: C-reactive protein.
[c]PLT: platelet.
[d]PT: prothrombin time.
[e]APTT: activated partial thromboplastin time.
[f]FIB: fibrinogen.
[g]CKMB: creatine kinase (CK)-MB.
[h]ALT: alanine transaminase.
[i]CREA: creatinine.

In our study, the majority of patients underwent basic laboratory tests, including routine blood tests, biochemistry tests, and coagulation profiles tests. Among these tested populations, as shown in Table 2, the most frequent abnormalities were white blood cell count elevation (58/435, 13.3%) and myocardial enzyme elevation (55/437, 12.6%). Relatively, creatine kinase-MB was frequent in patients exposed to psychiatric drugs (14/49, 28.6%), cardiovascular drugs (10/38, 26.3%), and antimicrobial drugs (6/27, 22.2%; Table S3 in Multimedia Appendix 1). In the antimicrobial drugs exposure group, the proportion of elevated white blood cells and CRP is high (both are 7/26, 26.9%). In addition, in our study, 72 patients underwent toxicology screening, and the total positive rate was 69.4% (50/72); the positive results indicate drug concentrations exceeding therapeutic levels (Table S4 in Multimedia Appendix 1).

Clinical Interventions and Outcomes of Acute Pharmaceutical Exposure

Before admission, 3.5% (23/653) of the children received emetic treatment, and 1.2% (8/653) of them received drainage from their parents or other caregivers. However, most children with acute pharmaceutical exposure were asymptomatic or showed mild symptoms; 68.3% (446/653) of them did not need specific treatment (discharge after a short observation or without treatment), while the remaining patients received one or more clinical interventions. Gastric lavage was the main treatment strategy for drug removal (145/653, 22.2%), followed by specific antidotes (39/653, 6%) and activated charcoal (38/653, 5.8%). In this study, respiratory support was provided in 1.1% (7/653) of the admitted children when airway protection was necessary due to respiratory or circulatory failure. Extracorporeal techniques like continuous renal replacement therapy,

XSL•FO
RenderX

hemoperfusion, or plasma exchange were used in 0.8% (5/653) of the patients (Table 3).

Table . Clinical interventions and outcomes of patients with acute pharmaceutical exposure (n=653).

Clinical interventions	Participants, n (%)
No specific therapy	445 (68.1)
Gastric lavage	145 (22.2)
Specific antidotes	39 (6.0)
Activated charcoal	38 (5.8)
Induction of vomiting	23 (3.5)
Catharsis	8 (1.2)
Respiratory support	7 (1.1)
CRRT[a]/hemoperfusion/plasma exchange	5 (0.8)
Outcomes	
Discharge without treatment (<6 hours)	446 (68.3)
Emergency observation (≥6 hours)	177 (27.1)
Hospitalization	30 (4.6)

[a]CRRT: continuous renal replacement therapy.

Comparison Between Intentional and Unintentional Acute Pharmaceutical Exposures

In this study, 11.9% (78/653) of the children experienced intentional acute drug exposure, with an average age of 13.6 years (Table 4). Of these, 88.5% (69/78) were female and 94.9% (74/78) had a history of depression. Psychotropic drugs were the most common pharmaceutical substances involved in exposure (42/78, 53.2%). In contrast, the average age for unintentional exposures was 3.3 years, with a relatively balanced gender ratio. For unintentional exposures, vitamins were the most common pharmaceutical substances involved in exposure (125/575, 21.7%). In addition, among patients with intentional exposure, 26 underwent toxicology screening, with a positive rate of 92.3% (24/26), which is significantly higher than the unintentional exposure groups (26/46, 56.5%; P=.004). Intentional exposures resulted in more severe clinical outcomes, with a significantly higher hospitalization rate compared with unintentional exposures (20.5% vs 2.4%, $P=1.486\times10^{-8}$). Detailed information is provided in Table 4.

XSL•FO
RenderX

Table . Comparison of patients with intentional and unintentional acute pharmaceutical drug exposure.

Characteristics	Intentional exposure (n=78)	Unintentional exposure (n=575)	*P* value[a]
Age (years), mean (SD)	13.6 (1.6)	3.3 (2.2)	—[b]
Gender, n (%)			<.001
Male	9 (11.5)	305 (53)	
Female	69 (88.5)	270 (47)	
Patients who were depressed, n (%)	74 (94.9)	0 (0)	
Toxicology screening[c], n (%)			.004
Positive	24 (92.3)	26 (56.5)	
Negative	2 (7.7)	20 (43.5)	
Multisystem involvement, n (%)			<.001
Yes	22 (28.2)	38 (6.9)	
No	56 (71.8)	515 (93.1)	
Hospitalization, n (%)			<.001
Yes	16 (20.5)	14 (2.4)	
No	62 (79.5)	561 (97.6)	

[a]*P* value was calculated with chi-square test, except for comparisons between different hospitalization outcomes, which were calculated with Fisher exact test.

[b]Not applicable.

[c]The total number of patients with toxicology screening results was 72.

Factors Influencing Hospitalization for Acute Pharmaceutical Exposure

Univariate analysis indicated that gender, ages 12 - 18 years, multisystem involvement, psychiatric drugs, multiple drug exposures, and intentional exposure were significant risk factors for hospitalization (*P*<.01; Table 5). The hospitalization rate was significantly higher for females (25/319, 7.8%) compared with males (5/334, 1.5%), patients over 12 years (20/82, 24.4%) compared with those under 12 years (10/571, 1.8%), patients with multisystem symptoms (19/60, 31.7%) compared with those without (11/593, 1.9%), psychiatric drug exposures (21/74, 28.4%) compared with other drugs (9/579, 1.6%), multiple drug exposures (7/29, 24.1%) compared with single drug exposures (23/624, 3.7%), and intentional poisoning (16/78, 20.5%) compared with accidental ingestion (14/575, 2.4%). For the variables that were significant in univariate analysis, further multivariate analysis was conducted. Further multivariate analysis showed that multisystem symptoms, psychiatric drug, and intentional exposure were independent risk factors for hospitalization (*P*<.01; Table 5).

XSL•FO
RenderX

Table . Univariate and multivariate logistic regression defined significant risk factors related with hospitalization for children with acute pharmaceutical exposure.

	Hospitalization, n		Univariate analysis[a]		Multivariate analysis	
	No	Yes	*P* value	Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)
Sex			.001	5.614 (2.122 - 14.855)	.42	1.709 (0.467 - 6.258)
Female	294	25				
Male	329	5				
Age group (years)			<.001	18.065 (8.091 - 40.330)	.25	0.344 (0.056 - 2.104)
12 - 18	62	20				
<12	561	10				
Multisystem involvement			<.001	23.592 (10.522 - 52.897)	.002	4.575 (1.709 - 12.251)
Yes	41	19				
No	560	11				
Types of pharmaceutical substances			<.001	25.050 (10.923 - 57.451)	.001	6.280 (2.189 - 18.020)
Psychiatric drug	53	21				
Others	570	9				
Number of drugs			<.001	8.300 (3.220 - 21.398)	.10	2.825 (0.805 - 9.908)
Multiple drugs	22	7				
Single drug	601	23				
Intentional exposure			<.001	27.680 (11.439 - 66.980)	.004	12.892 (2.222 - 74.796)
Yes	62	16				
No	561	14				

[a]For univariate analysis, only variables with *P* value <.05 were shown in the table.

Discussion

Principal Findings

This study provides a retrospective analysis of 653 cases with acute pharmaceutical exposure from 2019 to 2023. Our results suggest that toddler and preschool-age groups are more likely to be exposed to drugs. This finding also aligns with Soave et al's [19] study, which reported an average age of 30 months for poisoned children, highlighting the vulnerability of this age group to drug exposure. Following exposure, most children exhibited no symptoms and did not require specific therapy. The most common manifestations were gastrointestinal symptoms, along with elevated white blood cell counts, which were the most frequent abnormal laboratory test results. We also found that multisystem symptoms, psychiatric drugs, and intentional poisoning were associated with hospitalization after acute pediatric pharmaceutical exposure. Notably, female adolescents with mental health issues were more likely to experience intentional exposure, and positive toxicology screening rate, multisystem involvement, and hospitalization incidence were higher in intentional poisoning group [20].

Regarding regional distribution, this study reveals that 87.9% of the acute pharmaceutical exposure events occurred in urban areas, which could be attributed to the hospital's location. Research from different regions could show significant differences in the incidence and main types of poisoning in children. For example, studies in Zhejiang [7] and southwestern China [14] found poisoning was more common among rural children, with pesticides and insecticides being as the primary toxic substances. This difference may be due to the higher prevalence of agricultural activities and more frequent chemical use in these areas. In addition, 93.1% of pharmaceutical exposure in our study occurred at home, consistent with previous studies [21,22]. Urban families, especially those with young children, often stockpile medications for common illnesses, inadvertently increasing the likelihood of children accessing these drugs. This highlights the importance of safe storage practices at home. In addition, the peak times for exposure incidents were between 4 PM and midnight, likely due to lapses in parental supervision during this period, as children are more likely to access medications after school. Parents, who were the primary caregivers in 57.2% of cases, generally had a college or university degree, reflecting the central role of parents in our

XSL•FO
RenderX

studied area. Despite this, the frequency of pediatric drug exposure suggests a need for greater efforts in educating families about medication safety and preventive measures.

Various studies have indicated that psychiatric medications are commonly associated with acute poisoning in children. For instance, Vilaça et al [23] in Brazil found that anxiolytics (mainly benzodiazepines) were the primary drugs involved in poisoning, followed by analgesics. Anderson et al [24] in the United Kingdom reported that benzodiazepines accounted for 19% of poisoning cases, while Santiago et al [25] in Spain also found that benzodiazepines and detergents were the most commonly involved toxicants. These findings contrast with our results, where vitamins were the most common type of drug exposure, particularly among toddler, preschool and school-aged children. This discrepancy may be due to the fact that caregivers in our study population often keep vitamin supplements at home. However, these vitamins, often presented in candy or liquid form, can attract children and increase the risk of accidental ingestion. Caregivers tend to underestimate the risks associated with vitamins, considering them "harmless," even though high doses of certain vitamins (eg, vitamins A and D) can cause severe toxic reactions. Therefore, it is crucial to educate caregivers on the safe storage and proper use of vitamins. In the infant group, NSAID exposure was relatively high, aligns with other studies [23]. NSAIDs (eg, ibuprofen and acetaminophen) are commonly used to relieve fever and mild to moderate pain, and fever is prevalent among infants, leading to NSAIDs being a staple in homes. This increases the risk of accidental ingestion, with a significant proportion of infant exposure resulting from caregivers misusing doses, leading to overdose and poisoning incidents. In addition, our study also found that exposure events involving psychiatric medications, primarily antidepressants, were most common among adolescents.

It is also worth noting that 11.9% of the children were intentionally exposed to drugs, primarily among adolescents, with females accounting for 89% of this group. Intentional exposure typically involves larger doses or multiple drugs, resulting in more severe symptoms. Similar to previous studies [26,27], the rate of multiple drug ingestion was higher in adolescents, often linked to suicidal or self-harm intentions, reflecting the vulnerability of this age group to mental health issues. Studies from the United States, Singapore, Taiwan, Sri Lanka, and other regions [28-31] also indicate that adolescent girls face greater psychological and social pressures, making them more prone to emotional fluctuations and self-harm behaviors. Addressing intentional drug exposure requires strengthened psychological interventions and social support, especially mental health screening and intervention, to prevent poisoning incidents. Collaboration among schools, families, and society is crucial to help adolescents establish a healthy mental state. Furthermore, multivariate regression analysis identified psychiatric drug exposure, multisystem involvement, and intentional poisoning as key factors influencing hospitalization in children with acute drug exposure. Werner and Platt's study [32] in Brazil also showed that intentionality was associated with hospitalization. For these high-risk children, early identification, close monitoring, and proactive intervention are essential to optimize treatment and reduce the severity and mortality of poisoning. More research is needed to refine and validate these factors to guide clinical practice and improve early management of acute drug poisoning.

In our study, most children exposed to drugs showed no clinical symptoms, indicating that many ingested drugs were in small doses or of lower toxicity. Symptoms, when present, primarily affected the digestive and nervous systems, followed by the circulatory system, with multisystem involvement in 9.5% of cases. This is consistent with a study in Chongqing, China [13]. Clinical manifestations in children are closely related to the type and dose of ingested drugs. Higher rates of involvement in the digestive, nervous, and circulatory systems are mainly due to the accidental ingestion of NSAIDs, psychiatric medications, and antihypertensive drugs, which are more likely to cause significant clinical symptoms. Laboratory tests are crucial for diagnosing and guiding treatment in children with acute pharmaceutical exposure. In this study, the majority of the children underwent laboratory tests, with common abnormal results including elevated white blood cell counts and myocardial enzymes. The former likely reflects an inflammatory response rather than an adverse drug reaction. Elevated myocardial enzymes suggest potential myocardial damage from acute drug poisoning, particularly with nervous system drugs, antihypertensive drugs, and NSAIDs [33,34], indicating these drugs have a higher likelihood of causing myocardial damage. In addition, some children exhibited coagulation abnormalities, while liver enzyme and kidney function abnormalities were relatively low, suggesting a lower risk of liver and kidney damage in this study. The study also found that almost all asymptomatic children had normal laboratory results, consistent with Wang et al's [35] study in the United States, which found no positive results in extensive screening and electrocardiography tests for asymptomatic children aged 12 years or younger. Therefore, the necessity of these tests in asymptomatic children with accidental drug overdoses remains debatable.

Clinical interventions for suspected drug poisoning include detoxification; specific antidotes; and, in severe cases, extracorporeal techniques such as continuous renal replacement therapy, hemoperfusion, and plasma exchange. However, only 0.8% of patients required these advanced treatments. Managing acute drug exposure in children necessitates a comprehensive approach, considering factors such as toxin type, ingestion time, dosage, clinical symptoms, and laboratory results. Toxicology screening, performed in 11% of cases with a 69.4% positive rate, is essential for identifying toxins and assessing the severity of exposure. Studies have shown that toxicology results can optimize treatment plans, preventing both overtreatment and undertreatment [36]. Despite this, 68.1% of children did not require specific treatment, suggesting a potential overuse of emergency services. Improving parental education and raising public awareness of the risks associated with drug exposure could help reduce unnecessary visits to the emergency department and optimize resource allocation. Most children with mild or no symptoms can be safely managed at home with proper guidance, while moderate to severe cases require medical observation or hospitalization. The average cost of a pediatric

XSL•FO
RenderX

emergency department visit, including laboratory tests, ranges from ¥1000 to ¥3000 (approximately US $140-US $420), placing a financial burden on families and straining hospital resources. This inefficiency may also contribute to delays in care for critically ill patients.

Generally, preventing accidental drug exposure in children is crucial for reducing poisoning incidents, easing emergency department pressure, and optimizing pediatric medical resource use. Families should store medications out of children's reach, preferably in locked cabinets, and avoid placing them in common areas like kitchens and bedrooms. Parents should also refrain from taking or handling medications in front of children to prevent curiosity and mimicry [37]. In addition, caregivers should be educated on recognizing early symptoms of poisoning and proper emergency response methods. Child-resistant packaging should be used to minimize the risk of accidental openings [38]. Public health departments should promote medication safety through community activities, brochures, and media campaigns. Schools should incorporate medication safety into health education curricula to teach children about proper medication use and potential dangers from an early age [39]. A comprehensive, multifaceted approach is essential to reducing unnecessary pediatric poisonings from pharmaceutical exposure.

Limitations

This study has several limitations. First, its single-center design limits the generalizability of the results, and multicenter studies are needed to validate these findings. Second, additional follow-up data are required to explore the long-term effects of pharmaceutical toxic exposures in children. Third, factors such as family health issues, dietary habits, and the pandemic-related lockdown measures were not considered in detail. The increased exposure to neuropsychiatric drugs may be linked to the significant rise in psychological stress faced by children and adolescents during the COVID-19 pandemic. Factors such as prolonged isolation, internet-based learning, and reduced social interactions likely contributed to a surge in anxiety, depression, and other mental health issues, which, in turn, increased the use and exposure to neuropsychiatric drugs. The preventive measures implemented during the pandemic, such as mask-wearing, social distancing, and limited outdoor activities, may have effectively reduced the transmission of respiratory infections, resulting in a decreased incidence of pediatric respiratory diseases and a significant reduction in respiratory drug exposure. Despite these limitations, our study provides valuable insights into the occurrence and outcomes of acute pharmaceutical exposures in children in recent years. Future research with larger sample sizes, longer time spans, and more follow-up data will allow for more comprehensive comparative analysis.

Conclusions

In conclusion, our study offers valuable insights into the epidemiological characteristics and clinical presentations of children with acute drug exposure. It also emphasizes the importance of ongoing education and preventive measures to reduce the risk of drug poisoning in children and optimize the use of emergency medical resources.

Acknowledgments

The study was supported by Capital Institute of Pediatrics Foundation for Youths (grant number: QN-2024-15) and Chinese Academy of Medical Sciences (CAMS) Innovation Fund for Medical Sciences (grant number: 2021-I2M-1-056).

Data Availability

The dataset analyzed during this study is not publicly available but could be available from the corresponding author upon reasonable request and with permission of Capital Center for Children's Health, Capital Medical University, by sending a request to the corresponding author.

Authors' Contributions

LYG and conceptualized the study and reviewed the manuscript. ZYD, YNQ, and SZ collected data, performed the analyses, and wrote the manuscript. JTL supervised data collection and data analyses. RT, HW, MYS, and LLW collected and preprocessed data. SL and JL revised the manuscript. All authors approved the final manuscript as submitted.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary materials on different types of pharmaceutical exposure in different age groups, the distribution of pharmaceutical substances in different year groups, abnormal laboratory test results in different pharmaceutical exposure groups, and positive toxicology screening results in different pharmaceutical exposure groups.
[DOCX File, 34 KB - pediatrics_v8i1e66951_app1.docx]

References

XSL•FO
RenderX

1. Azab SMS, Hirshon JM, Hayes BD, et al. Epidemiology of acute poisoning in children presenting to the poisoning treatment center at Ain Shams University in Cairo, Egypt, 2009-2013. Clin Toxicol (Phila) 2016;54(1):20-26. [doi: 10.3109/15563650.2015.1112014] [Medline: 26653953]
2. Zhang H, Huo Q, Jing R, Dong M. Clinical analysis of acute poisoning in children. BMC Pediatr 2024 Mar 25;24(1):212. [doi: 10.1186/s12887-024-04697-z] [Medline: 38528509]
3. Tobaiqy M, Asiri BA, Sholan AH, et al. Frequency and management of acute poisoning among children attending an emergency department in Saudi Arabia. Pharmacy (Basel) 2020 Oct 14;8(4):189. [doi: 10.3390/pharmacy8040189] [Medline: 33066543]
4. Wang L, Wu Y, Yin P, et al. Poisoning deaths in China, 2006-2016. Bull World Health Organ 2018 May 1;96(5):314-326A. [doi: 10.2471/BLT.17.203943] [Medline: 29875516]
5. Li H, Dodd-Butera T, Beaman ML, Pritty MB, Heitritter TE, Clark RF. Trends in childhood poison exposures and fatalities: a retrospective secondary data analysis of the 2009-2019 U.S. National Poison Data System Annual Reports. Pediatr Rep 2021 Nov 15;13(4):613-623. [doi: 10.3390/pediatric13040073] [Medline: 34842797]
6. Wang BS, Chen L, Li XT, Xu M, Zhu BL, Zhang J. Acute pesticide poisoning in Jiangsu Province, China, from 2006 to 2015. Biomed Environ Sci 2017 Sep;30(9):695-700. [doi: 10.3967/bes2017.094] [Medline: 29081347]
7. Yimaer A, Chen G, Zhang M, Zhou L, Fang X, Jiang W. Childhood pesticide poisoning in Zhejiang, China: a retrospective analysis from 2006 to 2015. BMC Public Health 2017 Jun 28;17(1):602. [doi: 10.1186/s12889-017-4505-3] [Medline: 28659131]
8. Hu J, Luo M, He L, Zhao Z. Analysis of characteristics and forecast of unintentional injury deaths of children under age 5 from 2013 to 2019 in Sichuan, China. BMC Public Health 2022 Nov 21;22(1):2133. [doi: 10.1186/s12889-022-14600-z] [Medline: 36411468]
9. Lee J, Fan NC, Yao TC, et al. Clinical spectrum of acute poisoning in children admitted to the pediatric emergency department. Pediatr Neonatol 2019 Feb;60(1):59-67. [doi: 10.1016/j.pedneo.2018.04.001] [Medline: 29748113]
10. Uwumiro F, Okpujie V, Olaomi OA, et al. Profile of childhood poisoning and its outcomes in the United States: a one-year nationwide study of emergency and inpatient admissions. Cureus 2023 Apr;15(4):e37452. [doi: 10.7759/cureus.37452] [Medline: 37181953]
11. Ramos CLJ, Barros HMT, Stein AT, Costa JD. Risk factors contributing to childhood poisoning. J Pediatr (Rio J) 2010;86(5):435-440. [doi: 10.2223/JPED.2033] [Medline: 20938596]
12. Alhaboob AA. Sociodemographic characteristics and risk factors for childhood poisoning reported by parents at a tertiary care teaching hospital. Cureus 2021 Feb 12;13(2):e13313. [doi: 10.7759/cureus.13313] [Medline: 33732565]
13. Song L, Yin NG, Tian WJ, Gu R, Jia YT. Clinical features of acute poisoning in hospitalized children: an analysis of 586 cases. Zhongguo Dang Dai Er Ke Za Zhi 2017 Apr;19(4):441-445. [doi: 10.7499/j.issn.1008-8830.2017.04.016] [Medline: 28407833]
14. Li Z, Xiao L, Yang L, Li S, Tan L. Characterization of acute poisoning in hospitalized children in Southwest China. Front Pediatr 2021;9:727900. [doi: 10.3389/fped.2021.727900] [Medline: 34956970]
15. Dayasiri M, Jayamanne SF, Jayasinghe CY. Patterns and outcome of acute poisoning among children in rural Sri Lanka. BMC Pediatr 2018 Aug 18;18(1):274. [doi: 10.1186/s12887-018-1246-0] [Medline: 30121087]
16. Corlade-Andrei M, Nedelea PL, Ionescu TD, et al. Pediatric emergency department management in acute poisoning-a 2-year retrospective study. J Pers Med 2023 Jan 3;13(1):106. [doi: 10.3390/jpm13010106] [Medline: 36675767]
17. Marano M, Rossi F, Ravà L, et al. Acute toxic exposures in children: analysis of a three year registry managed by a Pediatric poison control Center in Italy. Ital J Pediatr 2021 Jun 2;47(1):125. [doi: 10.1186/s13052-021-01071-y] [Medline: 34078407]
18. Mintegi S, Azkunaga B, Prego J, et al. International epidemiological differences in acute poisonings in pediatric emergency departments. Pediatr Emerg Care 2019 Jan;35(1):50-57. [doi: 10.1097/PEC.0000000000001031] [Medline: 28121975]
19. Soave PM, Curatola A, Ferretti S, et al. Acute poisoning in children admitted to pediatric emergency department: a five-years retrospective analysis. Acta Biomed 2022 Mar 14;93(1):e2022004. [doi: 10.23750/abm.v93i1.11602] [Medline: 35315415]
20. Frey M, Obermeier V, von Kries R, Schulte-Körne G. Age and sex specific incidence for depression from early childhood to adolescence: a 13-year longitudinal analysis of German health insurance data. J Psychiatr Res 2020 Oct;129:17-23. [doi: 10.1016/j.jpsychires.2020.06.001] [Medline: 32554228]
21. Soori H. Developmental risk factors for unintentional childhood poisoning. Saudi Med J 2001 Mar;22(3):227-230. [Medline: 11307108]
22. Picazo E, Palacios Treviño JL. Factors associated with accidental poisoning in children. Salud Publica Mex 1971;13(3):333-340. [Medline: 5164664]
23. Vilaça L, Volpe FM, Ladeira RM. Accidental poisoning in children and adolescents admitted to a referral toxicology department of a Brazillian emergency hospital. Rev Paul Pediatr 2020;38:e2018096. [doi: 10.1590/1984-0462/2020/38/2018096] [Medline: 31778403]
24. Anderson M, Hawkins L, Eddleston M, Thompson JP, Vale JA, Thomas SHL. Severe and fatal pharmaceutical poisoning in young children in the UK. Arch Dis Child 2016 Jul;101(7):653-656. [doi: 10.1136/archdischild-2015-309921] [Medline: 27185085]

XSL•FO
RenderX

25. Santiago P, Bilbao N, Martinez-Indart L, Mintegi S, Azkunaga B, Intoxications Working Group of the Spanish Society of Pediatric Emergencies. Epidemiology of acute pediatric poisonings in Spain: a prospective multicenter study from the Spanish Society of Pediatric Emergency Medicine. Eur J Emerg Med 2020 Aug;27(4):284-289. [doi: 10.1097/MEJ.0000000000000661] [Medline: 31855890]
26. Sheridan DC, Hendrickson RG, Lin AL, Fu R, Horowitz BZ. Adolescent suicidal ingestion: national trends over a decade. J Adolesc Health 2017 Feb;60(2):191-195. [doi: 10.1016/j.jadohealth.2016.09.012] [Medline: 27889404]
27. Choi YH, Choi YH, Lee DH, Lim JY, Kim K, Lee JH. Characteristics of adolescent patients admitted to the emergency department due to attempted suicide by poisoning; a brief report. Adv J Emerg Med 2020;4(2):e26. [doi: 10.22114/ajem.v0i0.268] [Medline: 32322794]
28. Larson EK, Johnson KP, Sheridan DC. Sources of medications used by children and adolescents for intentional ingestion: a retrospective chart review. Pediatr Emerg Care 2022 Apr 1;38(4):e1213-e1216. [doi: 10.1097/PEC.0000000000002553] [Medline: 34608059]
29. Tay EY, Tan GF, Yeo AWC, Tham EH. Intentional poisoning in pediatric patients: examining the risk factors. Pediatr Emerg Care 2021 Dec 1;37(12):e1510-e1514. [doi: 10.1097/PEC.0000000000002101] [Medline: 32304525]
30. Lin YR, Liu TH, Liu TA, Chang YJ, Chou CC, Wu HP. Pharmaceutical poisoning exposure and outcome analysis in children admitted to the pediatric emergency department. Pediatr Neonatol 2011 Feb;52(1):11-17. [doi: 10.1016/j.pedneo.2010.12.003] [Medline: 21385651]
31. Dayasiri K, Jayamanne SF, Jayasinghe CY. Accidental and deliberate self-poisoning with medications and medication errors among children in rural Sri Lanka. Emerg Med Int 2020;2020:9872821. [doi: 10.1155/2020/9872821] [Medline: 32832160]
32. Werner JGB, Platt VB. Acute exogenous intoxications in childhood: factors related to hospitalization. Rev Paul Pediatr 2023;42:e2023028. [doi: 10.1590/1984-0462/2024/42/2023028] [Medline: 38088677]
33. Ferdinandy P, Baczkó I, Bencsik P, et al. Definition of hidden drug cardiotoxicity: paradigm change in cardiac safety testing and its clinical implications. Eur Heart J 2019 Jun 7;40(22):1771-1777. [doi: 10.1093/eurheartj/ehy365] [Medline: 29982507]
34. Destere A, Merino D, Lavrut T, et al. Drug-induced cardiac toxicity and adverse drug reactions, a narrative review. Therapie 2024;79(2):161-172. [doi: 10.1016/j.therap.2023.10.008] [Medline: 37957054]
35. Wang GS, Deakyne S, Bajaj L, Yin S, Heard K, Roosevelt G. The limited utility of screening laboratory tests and electrocardiograms in the management of unintentional asymptomatic pediatric ingestions. J Emerg Med 2013 Jul;45(1):34-38. [doi: 10.1016/j.jemermed.2012.11.056] [Medline: 23561311]
36. Valli A, Ferretti VV, Klersy C, Lonati D, Giardini I, Papa P. Effectiveness of a reliable toxicological analysis for a correct diagnosis of acute intoxication in pediatrics: 2-year experience of an analytical toxicological laboratory. Pediatr Emerg Care 2022 Oct 1;38(10):e1601-e1605. [doi: 10.1097/PEC.0000000000002641] [Medline: 36173433]
37. Kendrick D, Majsak-Newman G, Benford P, et al. Poison prevention practices and medically attended poisoning in young children: multicentre case-control study. Inj Prev 2017 Apr;23(2):93-101. [doi: 10.1136/injuryprev-2015-041828] [Medline: 27815418]
38. Kendrick D, Young B, Mason-Jones AJ, et al. Home safety education and provision of safety equipment for injury prevention. Cochrane Database Syst Rev 2012 Sep 12;2012(9):CD005014. [doi: 10.1002/14651858.CD005014.pub3] [Medline: 22972081]
39. Orton E, Whitehead J, Mhizha-Murira J, et al. School-based education programmes for the prevention of unintentional injuries in children and young people. Cochrane Database Syst Rev 2016 Dec 27;12(12):CD010246. [doi: 10.1002/14651858.CD010246.pub2] [Medline: 28026877]

Abbreviations

NSAID: nonsteroidal anti-inflammatory drug
OR: odds ratio
PED: pediatric emergency department
WHO: World Health Organization

Edited by S Badawy; submitted 27.09.24; peer-reviewed by J Zheng, S Arsić; revised version received 27.03.25; accepted 23.04.25; published 17.06.25.

Please cite as:
Duan ZY, Qu YN, Tang R, Liu JT, Wang H, Sheng MY, Wang LL, Liu S, Li J, Guo LY, Zheng S
Evaluating the Characteristics and Outcomes of Acute Pharmaceutical Exposure in Children: 5-Year Retrospective Study
JMIR Pediatr Parent 2025;8:e66951
URL: https://pediatrics.jmir.org/2025/1/e66951
doi:10.2196/66951

XSL•FO
RenderX

© Zhu Yan Duan, Yan Ning Qu, Rui Tang, Jun Ting Liu, Hui Wang, Meng Yi Sheng, Liang Liang Wang, Shuang Liu, Jiao Li, Lin Ying Guo, Si Zheng. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 17.6.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Exploring the Association Between Behavioral Determinants and Intention to Use a Chatbot-Led Parenting Intervention by Caregivers of Adolescent Girls in South Africa: Cross-Sectional Study

Maria Da Graca Ambrosio[1], MD, MPH; Seema Vyas[1], PhD; Juliet Stromin[2], MA; Shallen Lusinga[2], PhD; Paula Zinzer[1], MA; Kanyisile Brukwe[3], MS; Zamakhanya Makhanya[1], MPH, MA; Hlengiwe Gwebu[4], MPH, PhD; Anne Schley[5], BA; Laurie Markle[6], MA; David Stern[7], PhD; Chiara Facciolà[7], PhD; G J Melendez-Torres[8], PhD; Frances Gardner[1], PhD; Jamie M Lachman[1,2,6], PhD

[1]Department of Social Policy and Intervention, University of Oxford, 32 Wellington Square, Oxford, United Kingdom

[2]Centre for Social Science Research, University of Cape Town, Cape Town, South Africa

[3]Clowns Without Borders, Cape Town, South Africa

[4]Department of Nursing and Public Health, University of Fort Hare, East London, South Africa

[5]mothers2mothers, Mbombela, South Africa

[6]Global Parenting Initiative, Oxford, United Kingdom

[7]IDEMS International Community Interest Company, Reading, United Kingdom

[8]Faculty of Health and Life Sciences, University of Exeter, Exeter, United Kingdom

Corresponding Author:
Maria Da Graca Ambrosio, MD, MPH
Department of Social Policy and Intervention, University of Oxford, 32 Wellington Square, Oxford, United Kingdom

Abstract

Background: While digital innovation, including chatbots, offers a potentially cost-effective means to scale public health programs in low-income settings, user engagement rates remain low. Barriers to participant engagement (eg, perceived difficulty of use, busyness, low levels of digital literacy) may exacerbate inequality when adopting digital-only interventions as alternatives to in-person programs.

Objective: This cross-sectional study nested within a 2×2 clustered factorial trial that followed the Multiphase Optimization Strategy principles investigated the relationship between behavioral determinants (ie, human and socioeconomic characteristics that facilitate the use of digital health interventions [DHIs]) and caregiver intention to use a digital public health intervention, ParentText, an open-source, rule-based parenting chatbot designed to promote positive parenting, improve adolescent health, and reduce risky behaviors.

Methods: Caregivers of adolescent girls (10 - 17 years; N=1034 caregivers) were recruited by implementation partners from a community-wide project aimed at HIV prevention in two districts of Mpumalanga, South Africa. A Digital Health Engagement Model was adapted from the technology acceptance model, the PEN-3 model theoretical frameworks, and the Theory of Planned Behavior to investigate the relationship between behavioral determinants and the intentions of caregivers to engage in ParentText. Community facilitators administered baseline surveys to caregivers during intervention onboarding. Regression models tested associations between behavioral determinants (ie, perceived ease of use, perceived usefulness, attitude, hedonic motivation, habit, price value, and social influence) and intentions of caregivers to use the parenting chatbot. Interaction effects were explored to examine whether individual-level sociodemographic and psychosocial characteristics moderate associations between overall behavioral determinants and intentions to use the chatbot.

Results: Caregivers reported a mean of 2.85 (SD 0.79) and 2.90 (SD 0.72) out of a maximum score of 4 regarding their intention to use their mobile data and to continue using ParentText in the future, respectively. Overall behavioral determinants predicted by 76% (odds ratio 1.76, 95% CI 1.72 - 1.81) the intentions of caregivers to spend mobile data and by 85% (odds ratio 1.85, 95% CI 1.81 - 1.90) their intentions to use ParentText in the future. Moderator analysis suggested the interaction effects of age, paternal absence, financial efficacy, and stress on the relationship between overall behavioral determinants and intention outcomes.

Conclusions: This is the first known study to investigate the associations between overall behavioral determinants and participant intentions to use a parenting chatbot in a low-income setting. This study identifies behavioral determinants of engagement for improved delivery of DHIs, considering the need to provide low-cost, scalable parenting support through digital platforms that

XSL•FO
RenderX

engage parents, especially those in low-income contexts. Future research should explore methods to investigate mechanisms that regulate behavior to enhance the development of DHIs.

Trial Registration: Open Science Framework (OSF); https://doi.org/10.17605/OSF.IO/WFXNE

International Registered Report Identifier (IRRID): RR2-10.2196/52145

(JMIR Pediatr Parent 2025;8:e76992) doi:10.2196/76992

KEYWORDS

digital health; engagement; adolescent health; behavioral determinants; chatbot-led parenting intervention.

Introduction

Background

Research demonstrates the benefits of delivering public health interventions through digital platforms. In recent years, chatbots have been used to address structural barriers to accessing evidence-based interventions delivered through in-person programs [1,2], with increasing evidence suggesting their effectiveness in improving a range of health and behavioral outcomes, including mental well-being [3], supporting weight loss [4,5], and positive parenting practices [6]. While digital innovation offers a potentially cost-effective means to deliver public health programs at scale within low-income settings, user engagement rates are typically low [7]. Some of the identified critical barriers to participant engagement in digital interventions include the difficulty of use, lack of culturally adapted content (including human-like illustrations), low levels of digital literacy, and socioeconomic disadvantage—all of which can potentially exacerbate inequality when adapting digital alternatives from in-person programs [6,8,9].

Engagement in digital health interventions (DHIs) is theorized to be influenced by various factors or behavioral determinants. These include enjoyment, motivation, aesthetics and design, personal relevance, and ease of use [10,11]. We define "Behavioral Determinants of Engagement" as any factor characterized by attitudes, ideologies, and belief systems of the individual and the socioeconomic environment that influences the use of digital applications for behavior change. Even though behavioral determinants of health have been broadly studied and have been shown to influence behavior change [12,13], there is a gap in understanding the role of behavioral determinants on engagement in DHIs implemented in low- and middle-income country settings. The study of behavioral determinants in DHIs provides a broader approach to investigating the pathways leading to engagement by helping to identify individual and societal characteristics, such as socioeconomic status, sex, age, and geographic location, that may facilitate users' uptake. Previous studies have evaluated user acceptance of DHIs by investigating participants' (1) intention to use [14] and (2) engagement (ie, actual use) of the health technology [15]. Although actual engagement may suggest user acceptance of DHIs, understanding predictors of intention to use is an important predecessor of engagement in many behavior change theoretical models.

Measuring the Behavioral Determinants of Engagement

We combined the following models to develop a Digital Health Engagement Model (DHEM) that uses a multilevel approach to study how behavioral determinants predict intention as well as moderate the relationship between intention to use and engagement with DHIs: the Theory of Planned Behavior, the Technology Acceptance Model, and the PEN-3 Model. Ajzen's Theory of Planned Behavior [16] explains how personal beliefs, namely attitude (ie, positive or negative beliefs about potential outcomes of the desired behavior), subjective norms (ie, normative expectations of others related to enrolling in the desired behavior), and perceived control (ie, individual's perceptions of the ease of difficulty in performing the desired behavior), predict and explain behavior of individuals. Davis's Technology Acceptance Model [17] suggests that intention is determined by an individual attitude toward using a technology, which is mediated by perceived usefulness (ie, the achievement of job-related or personal goals due to the usage of the technology) and perceived ease of use (ie, how flexible, simple, and compatible the technology is) [18,19].

We drew from the relationships and expectations domain of the PEN-3 model to conceptually map predictors of intention retrieved from the Theory of Planned Behavior, the Technology Acceptance Model, and previous literature on digital health studies. We labeled those factors as behavioral determinants of engagement. Airhihenbuwa's PEN-3 Model foregrounds the role of cultural factors in developing public health interventions and incorporates three domains: cultural empowerment, cultural identity, and relationships and expectations [20]. The domain of relationships and expectations includes the constructs of perceptions, nurturers, and enablers. In the context of DHIs, perceptions can be positive if they contribute to an individual's active engagement with it (eg, users may perceive the DHI as a reliable source for finding health information) and negative if they negatively affect their active engagement with the DHI (eg, users may perceive that it is hard to manipulate the DHI) [18,19]. Similarly, positive enablers are the institutional resources encouraging the use of DHIs, such as clearly engaged marketing materials, broad network coverage, and external human support (eg, in-person or remote staff coaching for health technology use and troubleshooting support) [21-23]. On the other hand, negative enablers may include unsupportive structures for an individual's access and use of DHI, such as poor network coverage and low access to cell phones and electricity. Nurturers are positive when an individual has family or peer support in the use of DHI or negative when unsupportive

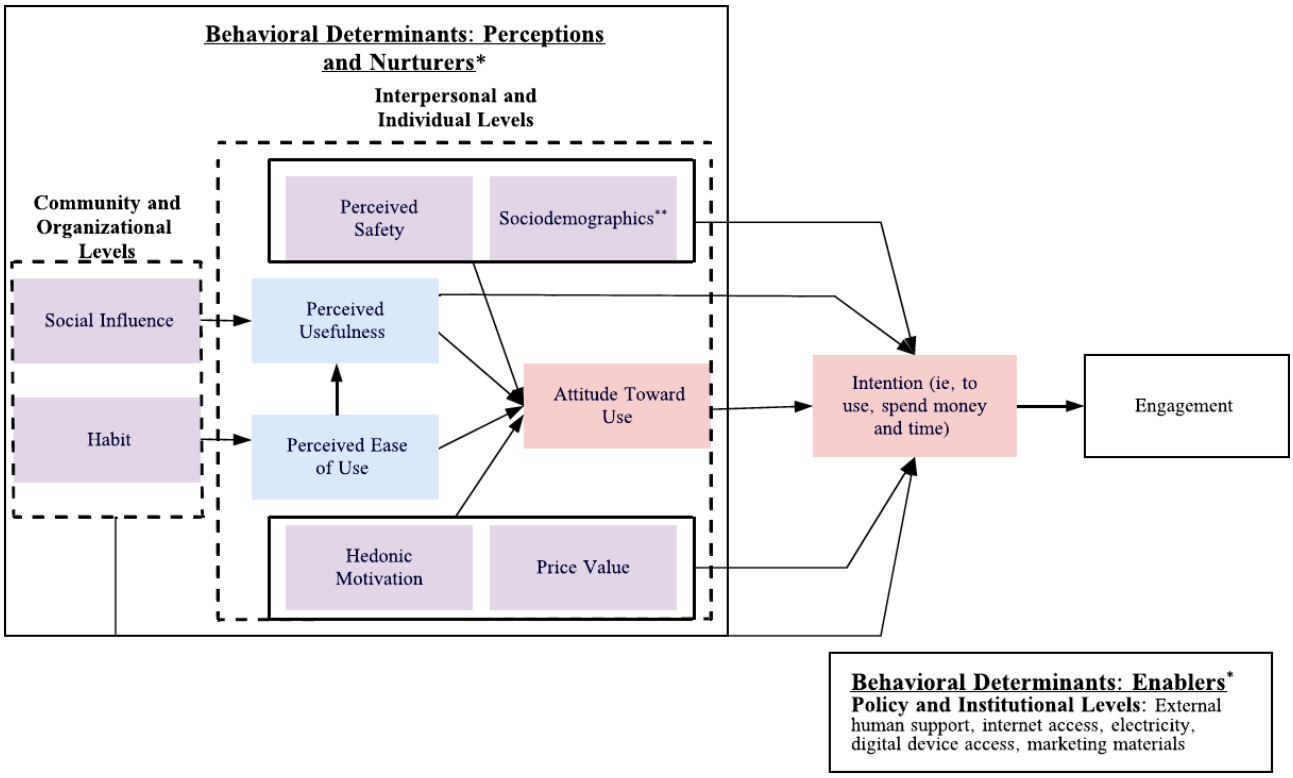
XSL•FO
RenderX

(eg, a user may be discouraged from using a parenting chatbot due to the negative opinions of their family members) [24].

The DHEM

The DHEM combines these theoretical frameworks by mapping behavioral determinants at three levels: (1) individual and interpersonal (eg, knowledge, attitudes, and beliefs affecting individual motivation toward the use of a DHI), (2) community and organizational (eg, beliefs and attitudes of close persons or groups toward the use of a DHI), and (3) policy and institutional levels (eg, resources within society and government promoting the use of DHI). In the DHEM, predictors of intention at the individual and interpersonal levels are perceived safety (ie, users' belief that their personal information is safe when accessing health technology), perceived usefulness, perceived ease of use, hedonic motivation (ie, enjoyment of the health technology), price value (eg, cost of health technology or network connection), attitude, and sociodemographics (eg, age, gender, income, education level, digital literacy). Predictors at the community and organizational levels are social influence (ie, user-perceived support from peers and family to use a DHI) and habit (eg, frequency of using digital technologies for communication and access to public services). In contrast, predictors at the policy and institutional levels are external human support, internet access, electricity, and digital device access (Figure 1).

Figure 1. The Digital Health Engagement Model. The blue boxes indicate variables that belong solely to the Technology Acceptance Model, the pink boxes indicate variables that belong to the Technology Acceptance Model and Theory of Planned Behavior, and the purple boxes indicate the external variables. The "*" indicates variables mapped under the Perceptions, Nurturers, and Enablers constructs of the PEN-3 model, while "**" indicates sociodemographics such as age, gender, income, education level, and digital literacy.



To guide the understanding of how the multidimensional aspects of intention may yield certain behavior outputs, the DHEM also incorporates a three-dimensional investigation of intention: (1) intention to use in the future, (2) intention to spend money (ie, pay to have access to DHI or network to use DHI), and (3) time to use in the future. The literature demonstrates that the intention–behavior relationship is dependent on time and contextual factors [25-27]. Therefore, in a low- and middle-income context where time and money constraints are often a reality, the three-dimensional study provides essential implications for advancing strategies for behavior change interventions, including those delivered digitally.

South African Context

South Africa makes for an interesting case study for exploring user engagement, given the growing presence of DHIs across its evolving digital landscape. There is promising evidence on the feasibility of implementing chatbot-led DHIs in the country [28,29]. In 2022, an estimated 70% of South Africa's population had internet access, and there were 162 mobile phone subscriptions per 100 people [30]. While chatbot-led public health interventions focused on health promotion and intimate partner violence prevention have been implemented in South Africa [28,29], evaluations of these interventions have documented no engagement rates. For instance, a South African chatbot-led study on intimate partner violence prevention reported no measure of user engagement [29].

Chatbot-led interventions, including those designed to promote positive parenting practices, have the potential to accelerate South Africa's progress toward achieving the United Nations Sustainable Development Goals 4 and 16 for children (such as increasing access to education, safety, responsive caring, and violence against children prevention strategies) [31]. Even though in-person parenting programs previously implemented

XSL•FO
RenderX

in South Africa have been shown to effectively target family factors (such as family relationship quality, abuse, and neglect) that influence adolescents' health and well-being and reduce the risk for early pregnancy and HIV infection [32,33], they remain difficult to scale at a national level. While low-cost, chatbot-led interventions offer a promising way to scale parenting programs, challenges related to user engagement and the limited research explicitly focused on this issue make it difficult to provide parenting support among those who may not be able to enroll in person due to access barriers such as employment, transportation, and childcare costs.

Study Objectives

The objectives of this study are as follows: first, to explore the factor structure for a locally adapted measurement of behavioral determinants; second, to examine how behavioral determinants of engagement are associated with the intention to use a chatbot delivered to parents and caregivers of adolescent girls as part of a hybrid-digital parenting intervention in South African low-income communities; and third, to investigate the moderating effect of individual-level sociodemographic and psychosocial characteristics on associations between determinants and intentions.

Methods

Study Design and Setting

This cross-sectional study was nested within a 2×2 clustered factorial trial (clusters were assigned to receive ParentText alone or combined with in-person sessions and a facilitated WhatsApp support group) that followed the Multiphase Optimization Strategy principles [34]. The trial aimed to optimize user engagement in the chatbot component of a hybrid digital parenting program developed by Parenting for Lifelong Health [34]. The program was implemented by mothers2mothers (m2m), a South African non-profit organization, as part of a large-scale HIV-prevention project "Children and Adolescents Are My Priority" (CHAMP) [34]. The CHAMP project was funded by the USAID (United States Agency for International Development) PEPFAR (US President's Emergency Plan for AIDS Relief) DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe) Initiative, which focuses on strengthening family relationships and communications and providing biomedical prevention resources and HIV treatment to 28,500 adolescent girls, aged 10 and 19 years, and young women [35]. This study was delivered from August to December 2023 across municipalities in the Ehlanzeni and Nkangala Districts of Mpumalanga Province, South Africa. Mpumalanga is characterized by high literacy and high unemployment [36], and the areas in which the trial was implemented were mostly rural and peri-urban zones, with agriculture, fishing, and mining as the primary economic sectors [37].

Eligibility Criteria

Caregivers recruited from the CHAMP community project were eligible if they (1) were aged 18 years or older and spoke English, isiZulu, or siSwati, (2) were caring for an adolescent girl aged between 10 and 17 years, (3) were already enrolled in CHAMP, (4) were living in the same household with the adolescent girl for a minimum of four nights over the previous 3 months, (5) had access to a mobile phone compatible with WhatsApp, (6) were willing to provide written informed consent to participate in the full study, and (7) were willing to enroll in the parenting chatbot and receive messages via WhatsApp. Caregivers with severe learning disabilities or mental health disorders were ineligible.

Data Collection Procedures

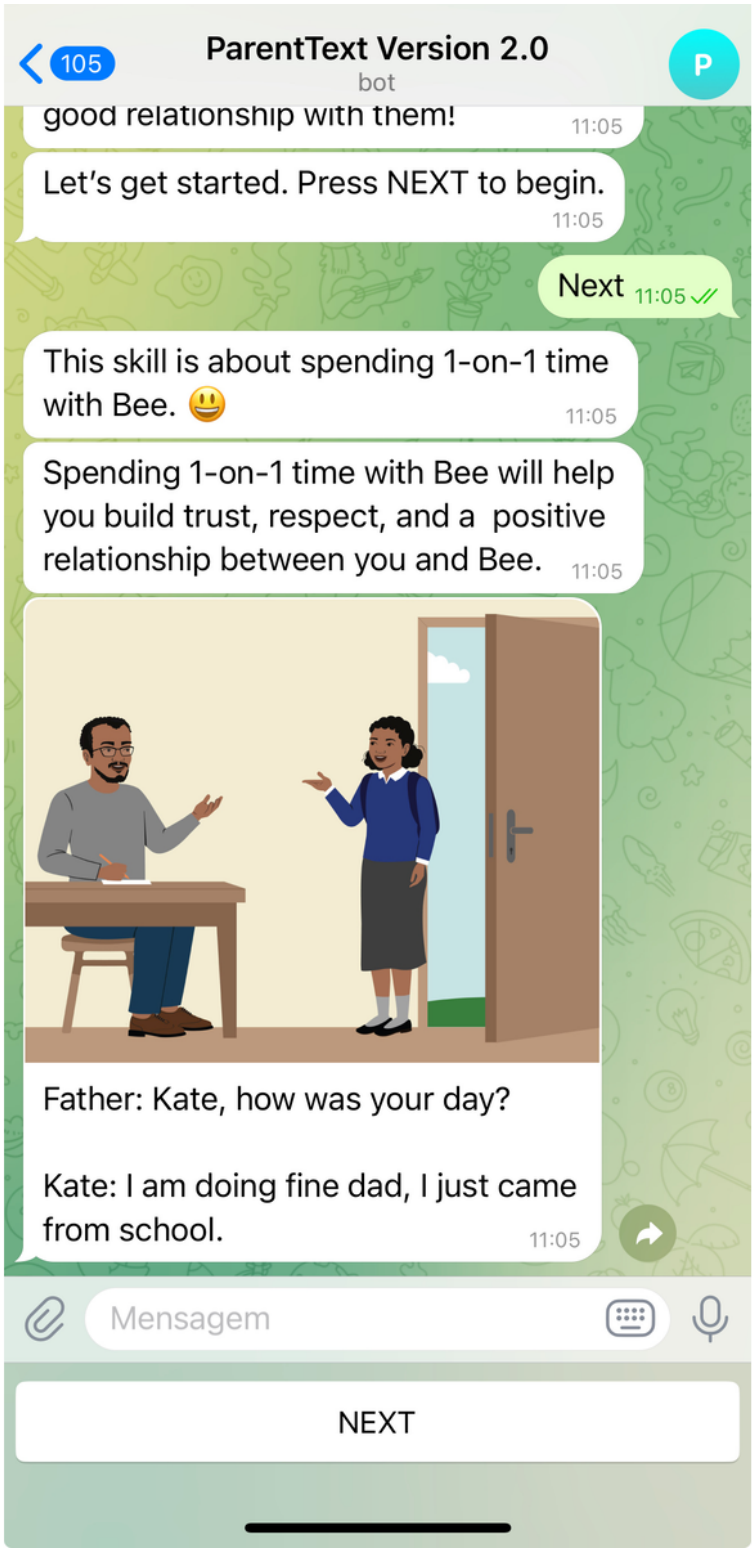
Data collection was conducted by trained m2m facilitators who were also responsible for recruiting participants into the trial and delivering the intervention. Baseline data were collected from caregivers and adolescent girls at community settings. Facilitators led participants through the chatbot registration and first parenting module (ie, approximately 10 min of user interaction). After completion of onboarding activities, caregivers completed the behavioral determinants and intention to use the chatbot survey. Data from paper-based questionnaires were abstracted by trained data capturers using Open Data Kit for analysis.

Digital Health Intervention

ParentText is a mobile rule-based chatbot adapted from the Parenting for Lifelong Health suite of programs to address barriers to access and scale of in-person programs [34]. It delivers personalized and gamified scheduled and on-demand messages through text, audio, and visual messages using UNICEF RapidPro, an open-source platform for building interactive messaging systems and delivered through social messaging apps such as WhatsApp (see Figure 2). While the overall content package includes messages based on development stages for caregivers of children aged 0 - 23 months, 2 - 9 years, and 10 - 17 years, this study only used the content targeting caregivers of children aged 10-17 years. ParentText delivers content over nine positive parenting goals composed of 37 learning modules aiming to improve parent–adolescent communication (Figure 2), improve engagement in learning, improve adolescent mental health, and reduce risky behaviors by establishing a healthy routine with clear instructions and rules [34]. Modules are described in Table S1 in Multimedia Appendix 1.

XSL•FO
RenderX

Figure 2. A display of a vignette in ParentText on a smartphone screen.



Initial piloting of ParentText in South Africa found low participant engagement, with the reported proportion of participants accessing the content delivered across four topics ranging from 20% (20/96) to 28% (27/96) of the sample [38]. Based on results from the pilot evaluation, the chatbot was subsequently revised to enhance the user experience by incorporating personalization features and adding tools to improve usability and support ongoing engagement [39]. ParentText is also being tested in the preschool system in Malaysia and the social welfare system in Mexico [40]. Delivery in South Africa was intended to support positive parent–adolescent relationships and prevent HIV risk behaviors as a key component of the CHAMP project.

Measures of Behavioral Determinants

Existing literature and the DHEM guided the instrument development used to measure behavioral determinants and intention to use. While previous studies have identified

XSL•FO
RenderX

associations between behavioral determinants (ie, perceived usefulness, perceived ease of use, attitude, hedonic motivation, habit, price value, and social influence) with intention to use [7,41-43], we found no existing questionnaires that specifically assess the behavioral determinants of potential users in the context of a chatbot-led parenting intervention. For this reason, we developed a questionnaire to measure caregivers' perceptions specific to the chatbot and their general usage frequency of WhatsApp, the platform on which ParentText was hosted. Given WhatsApp's role as a communication tool, caregivers' frequency of use can offer insights into its usability within their social networks (eg, family, neighbors, and friends).

The behavioral determinants and intention to use questionnaires consisted of 16 questions that were tested with the local research team for improved contextualization and translation. The outcome intention to use was assessed using two separate items that asked caregivers about their intention to use ParentText in the future and their intention to spend their mobile data to use ParentText. Both items were rated on a Likert scale ranging from 0 (strongly disagree) to 4 (strongly agree). Behavioral determinants were assessed using 14 items across seven domains derived from the Technology Acceptance Model and its extensions [17,19]. Perceived ease of use was measured using two items assessing caregivers' perceived understanding and capacity to interact with the chatbot. Perceived usefulness was measured using seven items (eg, "I think that ParentText would help me learn how to manage my child's behavior"). The remaining five domains, attitude toward use, hedonic motivation, price value, habit, and social influence, were each measured using a single item. All 16 items were rated on a Likert scale ranging from 0 (strongly disagree) to 4 (strongly agree). The items are described in Table S2 in Multimedia Appendix 2.

Covariates such as age, gender, and financial efficacy (ie, how confident caregivers are in their ability to manage their finances) were also assessed prior to administering the determinants and intention questionnaire. The choice of covariates was based on previous research reporting that age, gender, and financial status are associated with users' intentions to use DHIs [44-46]. In all questions, participants were given the option to select the response, "I do not want to answer." All measures (Table S2 in Multimedia Appendix 2) and ParentText content were translated from English into isiZulu and siSwati, the local home languages spoken by participants adopting back-translation procedures.

Moderators

Moderators included age, absence of the father in the house, financial efficacy, anxiety, depression, and stress. Age was measured in years, and the absence of the father in the house was a binary variable (yes and no). Financial efficacy was measured on a scale ranging from "not at all true" (0) to "exactly true" (3). Stress was measured using the parental stressors subscale (6 items) of the Parental Stress Scale on a scale of 0 to 20 and anxiety and depression using the 4-item Patient Health Questionnaire on a scale ranging from 0 to 12 [47,48].

Statistical Analyses

Data analysis was conducted using RStudio (R version 4.2.2) and Visual Studio Code (Python version 3.10.6) software. Missing data accounted for a maximum of 10% for predictor (n=91) and outcome (n=108) variables and was replaced using multiple imputation-chained equations following Graham and colleagues' recommendations [49]. Imputation was conducted using fully conditional specifications, predictive mean matching for numeric data, and polytomous regression for multicategory data. Twenty interactions were used to refine imputations, with five imputations created accounting for clustered standard errors. Beesley's stacked approach was conducted on the imputed datasets for weighing models and clustered standard errors to account for the between-cluster variance across the 32 clusters in the study [50]. Descriptive data was presented using frequencies and percentages for categorical variables and means and standard deviations for numeric variables.

To explore the factor structure of the behavior determinants measure, reliability analysis was performed on the extracted factors using Cronbach α and omega coefficients to assess the overall consistency, with $\alpha>.70$ representing high reliability, $.35>\alpha<.70$ representing medium reliability, and $\alpha<.35$ representing low reliability [51]. A collinearity test was conducted using Pearson's correlations and variance inflation factor (VIF), with VIF <1 representing no multicollinearity, 1>VIF <5 representing moderate collinearity, and VIF >5 representing high multicollinearity [52]. We also conducted principal component (PC) analysis to ensure that factors in the overall behavioral determinants composite construct contributed equally to it. PC analysis used individual scores of five factors (ie, attitude, hedonic motivation, habit, price value, and social influence) and the perceived usefulness (from 0 to 28) and the perceived ease of use (goes from 0 to 8) aggregate scores.

Next, to investigate how behavioral determinants and intentions to use are associated, ordered logistic regression models were applied to test for the predictive significance of behavioral determinants on both outcomes assessing caregiver intention to use ParentText. All four models (multivariable models with individual behavioral determinants and univariate models with the composite construct) included covariate adjustments for age, gender, and financial efficacy to account for confounding effects. Finally, to test the moderating effect of individual-level sociodemographic and psychosocial characteristics (ie, caregiver age, presence of the father in the house, financial efficacy, caregiver anxiety and depression, and caregiver stress), models with interactions between moderator and overall behavioral determinants construct were conducted. Results reports followed the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth (CONSORT-EHEALTH) checklist [53].

Ethical Considerations

Ethics approval for the study was granted by the University of Cape Town Center for Social Science Research Ethics Committee (reference: CSSR 2023/05), the University of Oxford Social Sciences and Humanities Interdivisional Research Ethics Committee (reference: R88177/RE001), and the Mpumalanga Department of Health and Department of Social Development (reference: R69569/RE003) [34]. Participants provided written informed consent prior to completing paper-based baseline surveys and were offered 50 ZAR internet bundles

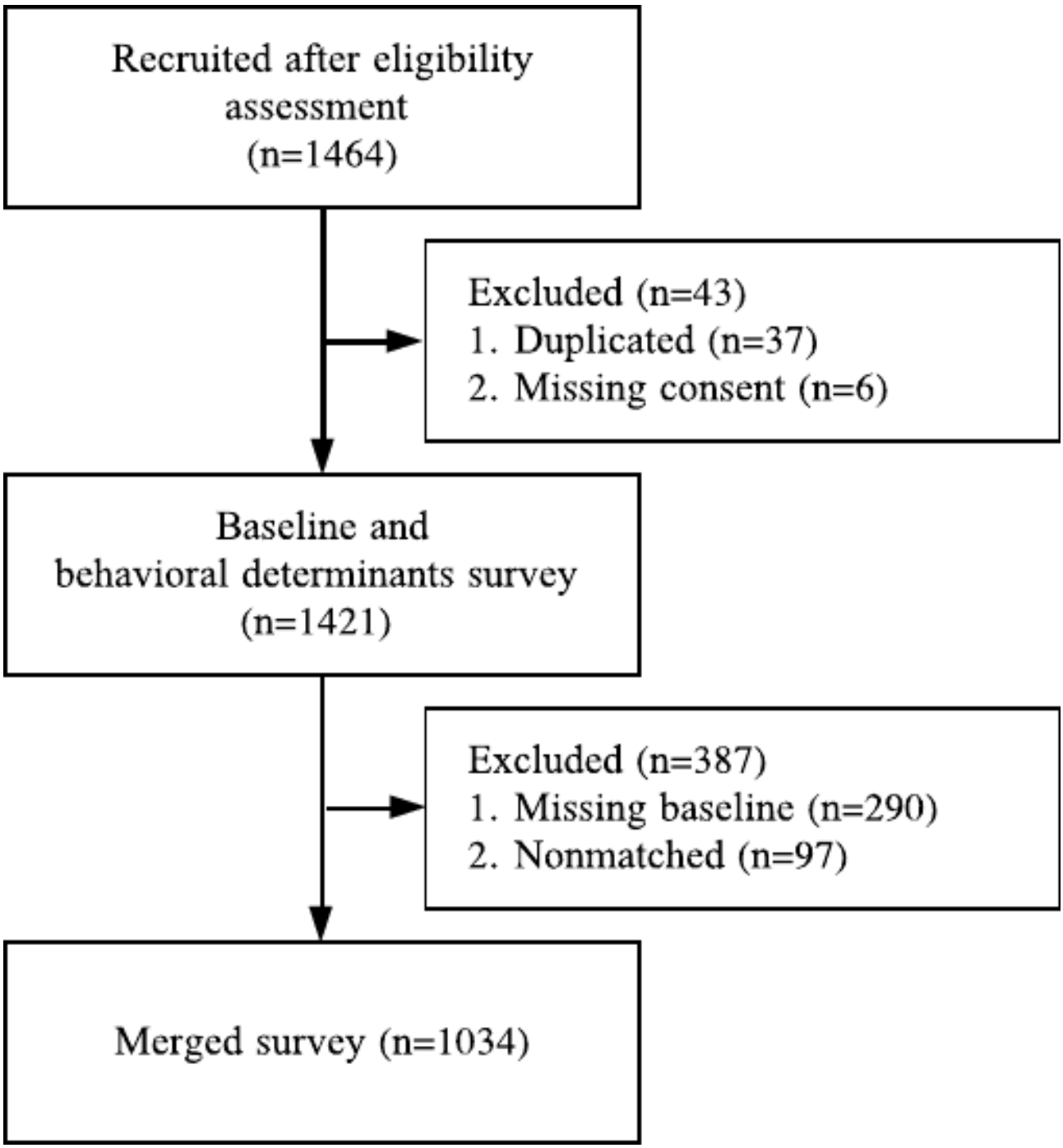
XSL•FO
RenderX

(approximately US $2.60) as an incentive to participate in the study [34]. Deidentified data sets were stored securely in a password-protected server at the University of Oxford and paper-based surveys stored by the m2m South Africa office in compliance with the South African Protection of Personal Information Act [34].

Results

Out of the 1464 caregivers recruited for eligibility, 1034 were included in this study with matched baseline demographic and behavioral determinant surveys (Figure 3).

Figure 3. Study recruitment.



Caregiver Baseline Characteristics

Participating caregivers were predominantly female (94%, 974/1034), and the average age was 38 years (SD 9). Almost two-thirds reported that they were in a relationship (64%, 665/1034). Reported paternal absence rates were 51% (537/1034), which were slightly below the national South African average (58%) [47]. Most caregivers were the biological parent (81%, 847/1034), and 10% (125/1034) reported that the adolescent girl in their care was a paternal orphan (Table 1).

XSL•FO
RenderX

Table . Baseline characteristics of participants (N=1034).

Characteristic	Value
Caregiver age, mean (SD)	38 (9)
Place of residence, n (%)	
Ehlanzeni	716 (69)
Nkangala	318 (30)
Caregiver gender, n (%)	
Female	974 (94)
Caregiver status, n (%)	
Biological parent	847 (81)
Relationship status, n (%)	
Partnered[a]	665 (64)
Financial efficacy, mean (SD)[b]	1.64/3 (1.09)
Absence of father in the house, n (%)[c]	537 (51)
Caregiver disability, n (%)	
Yes[d]	76 (7)
Child age, mean (SD)	12 (2.00)
Child gender, n (%)	
Female	1,034 (100.0)
Adolescent school enrollment (ie, school year), n (%)	
Grade 4 - 9	867 (83)
Grade 10 - 12	167 (16)
Caregiver anxiety and depression, mean (SD)	3.39/12 (3.21)
Caregiver stress, mean (SD)	8.60/20 (4.21)

[a]Partnered refers to married, civil, or noncivil partnership status.

[b]Higher values imply greater capacity to manage finances.

[c]Families where the father passed away or lives elsewhere.

[d]Includes caregiver-reported cognitive, learning, auditory, visual, physical (any motor limitations and difficulties in performing self-care activities such as getting dressed), and functional disabilities (any pre-existing non-communicable health conditions such as diabetes, cardiovascular disease, and cancer).

Descriptives of Behavioral Determinants and Intention

Caregivers reported a mean score of 2.99 (SD 0.55) out of 4 on their perceived usefulness of ParentText, a mean of 3.02 (SD 0.67) on their enjoyment, and a mean of 2.86 (SD 0.77) on perceived ease to interact with the chatbot. They also reported a mean of 2.91 (SD 0.70) on their perceptions that their peers and family would support them using ParentText and a mean of 2.81 (SD 0.78) on how worthwhile they believed it was to spend mobile data on the chatbot. The mean attitude of caregivers toward DHIs such as ParentText was 3.05 (SD 0.68) and WhatsApp usage habits was 2.76 (SD 0.85). Respondents also reported a mean of 2.85 (SD 0.79) and 2.90 (SD 0.72) regarding their intention to use their mobile data and to continue using ParentText in the future, respectively.

Psychometric Properties of Behavioral Determinants Measure

Principal Component Analysis

Results indicate that all seven items loaded relatively equally on the first PC, which accounted for 52% of the total variance of the overall behavioral determinant construct (52% PC1, 13% PC2, 9% PC3, 7% PC4, 6% PC5, 5% PC6, and 4% PC7). Using the scores from PC1, a summary composite score across all four subscales ranging from 0.67 to 18.64 was generated and used in the regression models (Table S3 in Multimedia Appendix 3).

Reliability Tests

The overall reliability of the instrument exceeded the acceptable threshold (α=.90; 95% CI 0.89 - 0.90; Ω=0.91). Reliability results for perceived usefulness, as measured by the α and omega coefficients, were also above 0.70 and thus considered high (Table S4 in Multimedia Appendix 3).

XSL•FO
RenderX

Association Between Behavioral Determinants and Intention to Use

Higher levels of overall behavioral determinants were positively associated with higher caregiver intention to use ParentText (intention to use in the future: odds ratio [OR] 1.85, 95% CI 1.81 - 1.90 and intention to use mobile data: OR 1.76, 95% CI 1.72 - 1.81; Tables 2 and 3). Individual behavioral determinant measures (ie, perceived usefulness and ease of use, attitude, hedonic motivation, habit) also emerged as positive predictors of both intention outcomes (Tables 2 and 3). Price value and perceived ease of use were not significantly associated with intention to use, while social influence was not significantly associated with intention to spend mobile data. The results of goodness-of-fit (Table S6 in Multimedia Appendix 3) indicate pseudo-R^2 values ranging from 17% to 37% in the overall behavioral determinants model and from 16% to 33% in the models with individual behavioral determinants, suggesting that the respective changes in the caregiver's intentions to use ParentText are well explained by all predictors. VIF indicated collinearity ranging from 1.02 to 2.95 (Table S5 in Multimedia Appendix 3). Tables S7 and S8 in Multimedia Appendix 3 report the results of multivariable logistic models conducted on unimputed data for sensitivity analysis.

Table . Multivariable logistic regression results testing associations between behavioral determinants and intention to use ParentText in the future[a].

Independent variable	OR[b]	95% CI	*P* value
Overall behavioral determinants	1.85 (0.01)	1.81 - 1.90	<.001
Perceived usefulness	1.10 (0.00)	1.08 - 1.12	<.001
Perceived ease of use	1.00 (0.02)	0.96 - 1.04	.99
Attitude	1.67 (0.03)	1.60 - 1.75	<.001
Hedonic motivation	1.77 (0.05)	1.66 - 1.87	<.001
Habit	1.25 (0.03)	1.18 - 1.31	<.001
Price value	1.02 (0.03)	0.97 - 1.08	.34
Social influence	2.08 (0.12)	1.85 - 2.34	<.001

[a]Note: All models included covariate adjustments for age, gender, and financial efficacy. Clustered standard errors in parentheses.
[b]Odds ratio.

Table . Multivariable logistic regression results testing associations between behavioral determinants and intention to spend mobile data to use ParentText in the future[a].

Independent variable	OR[b]	95% CI	*P* value
Overall behavioral determinants	1.76 (0.01)	1.72 - 1.81	<.001
Perceived usefulness	1.07 (0.00)	1.05 - 1.08	<.001
Perceived ease of use	1.05 (0.02)	1.01 - 1.09	<.001
Attitude	2.14 (0.06)	2.01 - 2.27	<.001
Hedonic motivation	1.26 (0.03)	1.19 - 1.33	<.001
Habit	1.17 (0.05)	1.08 - 1.28	<.001
Price value	2.15 (0.10)	1.97 - 2.36	<.001
Social influence	1.05 (0.03)	0.99 - 1.11	.05

[a]Note: All models included covariate adjustments for age, gender, and financial efficacy. Clustered standard errors in parentheses.
[b]Odds ratio.

Moderator Analyses

Moderator analysis suggested more relevance of behavioral determinants in predicting caregivers' intention to use in families where fathers were absent (OR 2.03, 95% CI 1.79 - 2.41) than those where fathers were present. A greater relevance of behavioral determinants in predicting caregivers' intention to use was observed among caregivers experiencing higher levels of stress compared to those with lower stress levels (OR 1.09, 95% CI 1.05 - 1.14). Behavioral determinants were also more relevant in predicting intentions to spend mobile data among older caregivers in comparison to younger caregivers (OR 1.04, 95% CI 1.03 - 1.05), financially stressed families in comparison to those more financially stable (OR 0.38, 95% CI 0.30 - 0.48), and in families where fathers were absent in comparison to those where fathers were present (OR 2.34, 95% CI 2.01 - 2.72). No moderating effects were observed on baseline levels of caregiver anxiety and depression (Table 4).

XSL•FO
RenderX

Table . Results of the interaction effect of sociodemographic and psychosocial characteristics on the associations between behavioral determinants and intention to use[a].

Moderator	Outcome	[b]OR	95% CI	*P* value
Age	Intention to use in future	1.00 (0.00)	0.99 - 1.00	.82
	Intention to spend mobile data	1.04 (0.00)	1.03 - 1.05	<.001
Absence of father in the house[c]	Intention to use in future	2.03 (0.07)	1.79 - 2.41	<.001
	Intention to spend mobile data	2.34 (0.10)	2.01 - 2.72	<.001
Financial efficacy	Intention to use in future	0.90 (0.12)	0.71 - 1.15	.43
	Intention to spend mobile data	0.38 (0.12)	0.30 - 0.48	<.001
Anxiety and depression	Intention to use in future	1.02 (0.04)	0.94 - 1.10	.59
	Intention to spend mobile data	0.96 (0.03)	0.89 - 1.02	.25
Stress	Intention to use in future	1.09 (0.02)	1.05 - 1.14	<.001
	Intention to spend mobile data	0.91 (0.03)	0.86 - 0.97	.007

[a]Note: Clustered standard errors in parentheses. Financial Efficacy range 0 - 3. Anxiety and depression range 0 - 12. Stress range 0 - 20.

[b]Odds ratio.

[c]Reference category: Present father.

Discussion

Evidence From the Theoretical Framework

Our findings highlight the positive associations between overall behavioral determinants and caregivers' intention to use the parenting chatbot, underscoring the strength of the composite construct in effectively capturing the seven underlying domains. For each one-unit increase in the overall behavioral determinants score, the odds of caregivers intending to spend mobile data on ParentText were 76% higher and the odds of intending to use ParentText in the future were 85% higher, compared to caregivers with lower scores. Similarly, individual behavioral determinant domains were also associated with intention, offering more nuanced insights into the context in which the chatbot was implemented.

Results demonstrated that perceived usefulness, attitude, and hedonic motivation were positively associated with intention to use, aligning with theory and with findings from previous research that reported such factors as positive predictors of intention to use [54,55]. Findings indicating positive associations between price value (ie, the perception that the chatbot was worth spending mobile data on) and intention to spend mobile data (Figure 4) warrant further discussion. Participants' prior knowledge that they would receive internet bundles to use ParentText may have influenced these observed positive associations. In low-income contexts such as rural and peri-urban South Africa, perceiving the value of ParentText and having a positive attitude toward DHIs may have influenced the intention of caregivers to use their data to interact with the chatbot instead of spending it on something else. There is ambiguity on the associations of financial cost to accessing a DHI with participants' intention to use, as some studies report negative [44,56], while others report no associations [57]. Our findings suggest that access to the internet, which, in the context of our study, has financial implications, may increase the acceptance of DHIs within low-income households.

XSL•FO
RenderX

Figure 4. Forest plot of logistic regression coefficients testing associations between behavioral determinants and intention to spend mobile data to use ParentText in the future.

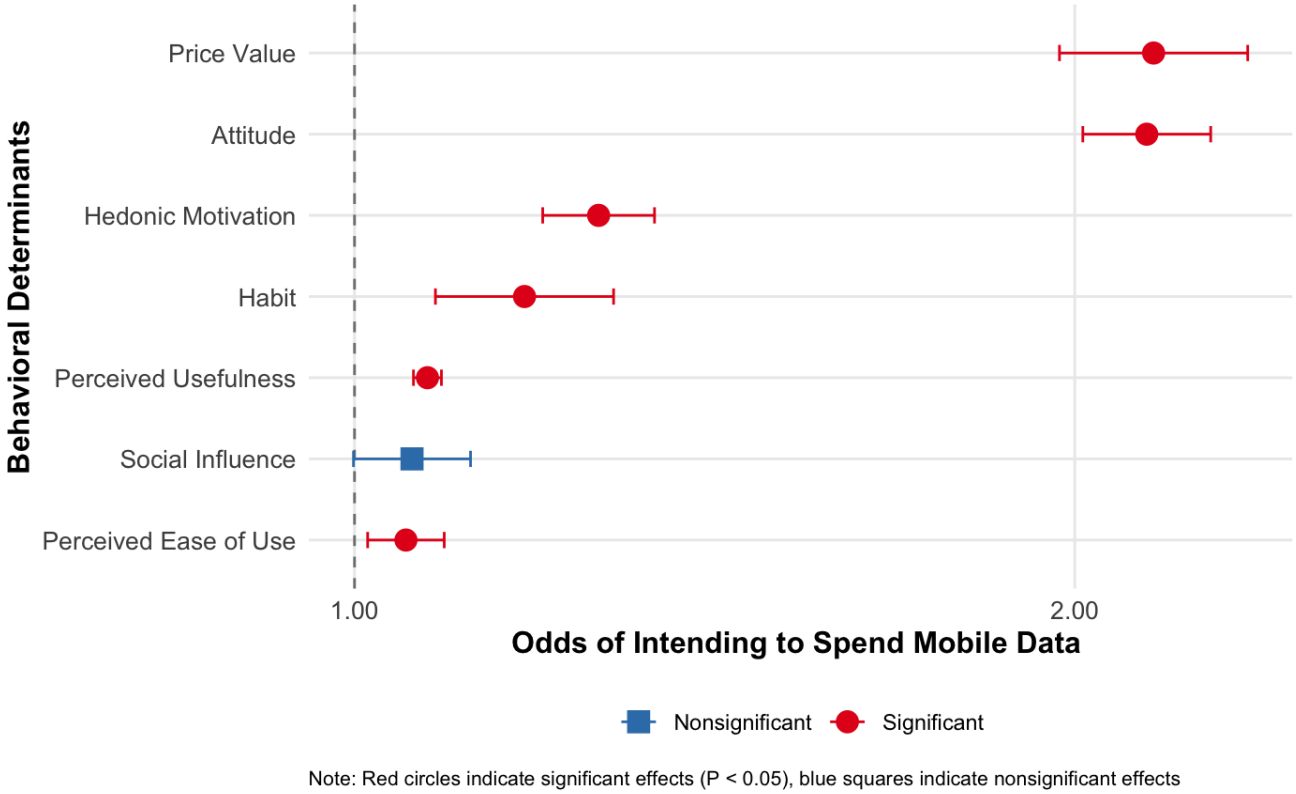
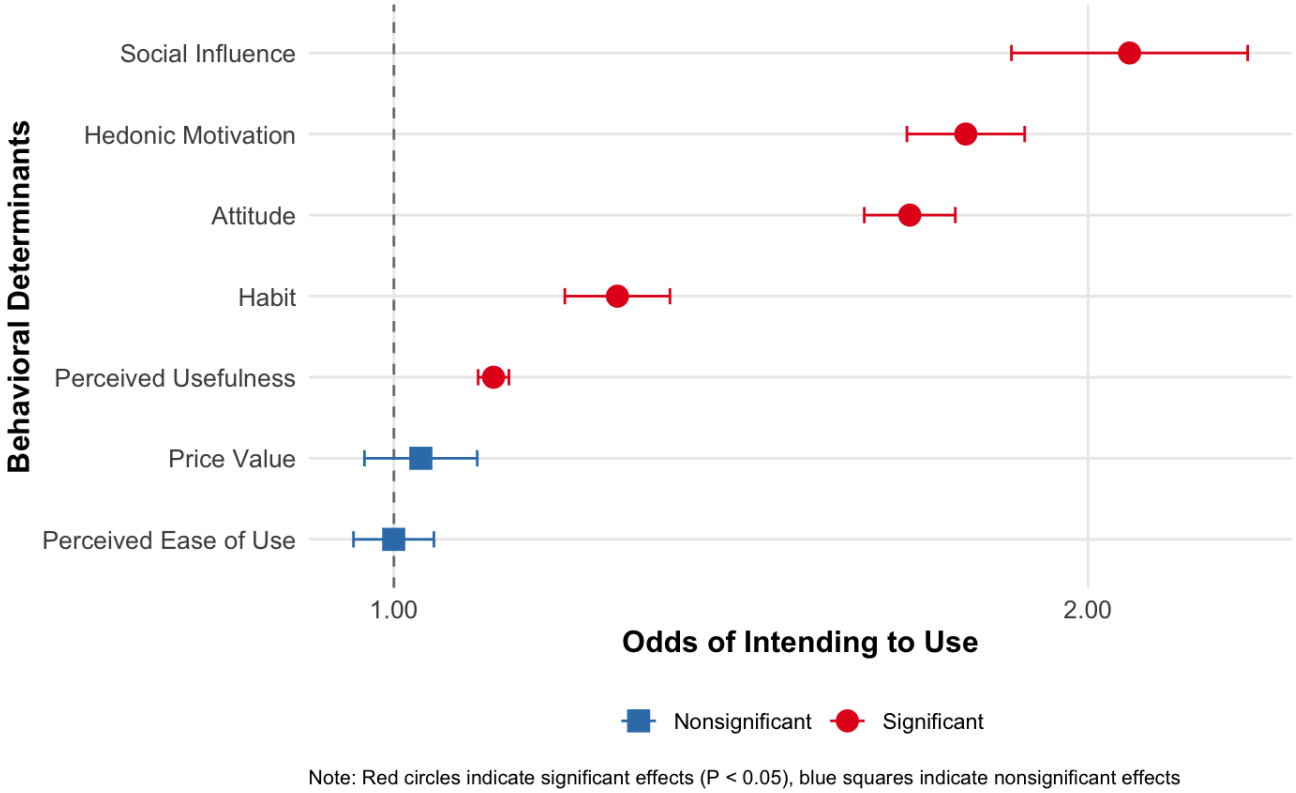


Figure 5. Forest plot of logistic regression coefficients testing associations between behavioral determinants and intention to use ParentText in the future.



Social influence, found in previous research to be associated with intention to use a DHI [57,58], was also positively associated with caregivers' intention to use ParentText (Figure 5,5), as measured by agreement with the statement, "People who are important to me think that digital tools such as ParentText could support me as a parent." In this study, participants responded to the questionnaire while in a group setting during onboarding, during which they may have been

XSL•FO
RenderX

aware of other caregivers' intentions toward using ParentText. Those factors may have positively influenced caregivers' impressions that their family and peers would support their usage of ParentText. In addition, results indicating positive associations between WhatsApp usage habits and intentions to use ParentText suggest the potential efficacy of adopting the most used and familiar communication platforms among potential DHI users to increase user acceptance.

Implication of Results in the South African Context

Our findings suggest that caregivers in South Africa who were introduced to the ParentText chatbot had positive intentions to continue to use it. Overall behavioral determinants became more relevant in predicting caregivers' intention to spend mobile data among families with older caregivers, families where the father was absent, and families that were less financially stable. These findings suggest that families with older caregivers, without fathers, or with greater levels of financial stress may require more structural support to engage in DHIs than those with younger caregivers, where fathers are present, and that are more financially stable. Therefore, there is great value in engaging fathers when delivering parenting chatbots, as previous research has reported their important role in families' health and well-being [59].

Study Strengths and Limitations

This study contributes to advancing the cycle of better development and implementation of DHIs by introducing a framework and a composite construct that explains the holistic role of behavioral determinants of engagement. In contexts where collecting data on all individual behavioral determinants is not feasible, the composite construct provides a practical alternative, allowing for the use of fewer items while still effectively capturing the multidimensional factors that influence users' intentions to engage with DHIs. Even though we could only investigate individual- and interpersonal-level factors and caregivers' personal impressions of community-level factors, their integration in the development and implementation stages can support good practices and help maximize DHI uptake.

Several limitations should be considered when interpreting our findings. First, selection bias may have influenced the results, as participants were caregivers already enrolled in the CHAMP program and owned WhatsApp-enabled phones, potentially representing a tech-savvy and intervention-positive subset of the population. Second, intention scores might have been skewed, as participants may have reported more positive intentions due to the provision of internet bundles, thereby confounding our results. Third, the cross-sectional design limited our ability to examine causal relationships between behavioral determinants and intention to use. Fourth, the behavioral determinants measurement did not capture policy-level enablers (eg, internet access, electricity), nor did we measure the participant's intention to spend time on the chatbot. Lastly, while we conducted face validity and tested the reliability of the behavioral determinant measures, we were unable to assess other types of validity due to the limited capacity of our research team.

Future Directions

Future research could employ a longitudinal or experimental design to investigate the relationships between behavioral determinants and intentions. It should also investigate how behavioral determinants and intentions are associated with engagement because a broader understanding of this pathway greatly supports efforts to improve the deployment of DHIs. Studies should also assess the construct, criterion, and content validity of the behavioral determinants and intention measurements and investigate the factors at the policy and institutional levels. Lastly, it is also essential to further investigate factors that are associated with positive intentions toward DHIs among those facing stress.

Conclusions

To the best of our knowledge, this is the first study to investigate how behavioral determinants of engagement are associated with the intention to use a parenting chatbot delivered in a low- and middle-income context. In conclusion, we recommend that developers and implementation scientists emphasize the value and quality of the DHIs while targeting aspects that enhance receptivity to social influence. Efforts to minimize network connection costs could also be provided through internet hotspots. The perception of affordability can trigger the sense that an individual is getting a good deal, which consequently leads to positive intentions. Similarly, implementation strategies that incorporate collaboration with community partners can foster positive normative influences toward DHIs, potentially leading to more favorable intentions toward use. The adoption of the most used communication platforms can also be prioritized to support positive intentions among potential users of chatbot-led interventions. While these early-stage findings suggest that chatbots may be effective platforms for overcoming barriers to accessing in-person programs in real-world settings, the generalizability of these results to other contexts remains uncertain.

Acknowledgments

The authors are grateful for the support received from mothers2mothers South Africa, Clowns Without Borders South Africa, Zoë-Life South Africa, the University of Cape Town, the Global Parenting Initiative, and all funders and partners who contributed to the implementation of this study. Similarly, the authors extend appreciation to the families and the community of Mpumalanga for participating in the study. This study is part of the Global Parenting Initiative, which is funded by The LEGO Foundation and Oak Foundation. This study also benefited from funding from the United States Agency for International Development (72067418CA00026) as part of the mothers2mothers South African Children and Adolescents Are My Priority project.

XSL•FO
RenderX

Data Availability

The datasets in this study are not currently publicly available due to ongoing analyzes. They will be made available via the Open Science Framework registration of the ParentText Optimization Study [60] upon study completion. In the interim, datasets are available from the principal investigators upon reasonable request.

Authors' Contributions

Conceptualization, development of the behavioral determinants of engagement survey, and creation of the behavioral determinants construct and digital health engagement model: MDGA; data curation: MDGA, JS, and SL; formal statistical analysis: MDGA; project implementation: AS, KB, SL, PZ, JS, ZM, HG, LM, DS, MDGA and CF; methodology: MDGA, GJMT, SV, FG, and JML; writing–original draft: MDGA; writing–review and editing: MDGA, SV, JML, and FG.

Conflicts of Interest

JML is the CEO and LM is the Chief of Solutions for Parenting for Lifelong Health (PLH), a charitable organization based in the United Kingdom that developed the ParentText, which is open access, licensed under a Creative Commons 4.0 Attribution Share-Alike license. JML has (and is participating) participated in several research studies involving the program, as an investigator, and the University of Oxford and University of Cape Town receive research funding for these. MDGA, JS, SL, ZM, FG, SV, HS, PZ, LM, and GJMT worked on other studies by PLH. The investigators will not benefit from any financial gains from implementing and disseminating this intervention. KB worked for Clowns Without Borders South Africa, a South African–based nonprofit organization responsible for providing capacity training and technical support on the delivery of PLH programs in Africa. The sponsor and funders did not influence any stage of the study design and were not involved in any stage of execution, data analysis, and dissemination of the study.

Multimedia Appendix 1
Intervention modules: ParentText content.
[DOCX File, 20 KB - pediatrics_v8i1e76992_app1.docx]

Multimedia Appendix 2
Items measuring behavioral determinants and intention to use.
[DOCX File, 22 KB - pediatrics_v8i1e76992_app2.docx]

Multimedia Appendix 3
Supplementary analyses.
[DOCX File, 29 KB - pediatrics_v8i1e76992_app3.docx]

References

1. David OA, The International Institute for the Advanced Studies of Psychotherapy and Applied Mental Health, Department of Clinical Psychology and Psychotherapy, Babeş-Bolyai University, The International Institute for the Advanced Studies of Psychotherapy and Applied Mental Health. The Rational Parenting Coach app: REThink parenting! A mobile parenting program for offering evidence-based personalized support in the prevention of child externalizing and internalizing disorders. JEBP 2019 Sep 1;19(2):97-108 [FREE Full text] [doi: 10.24193/jebp.2019.2.15]
2. Feil EG, Sprengelmeyer PG, Leve C. A randomized study of a mobile behavioral parent training application. Telemed J E Health 2018 Jun;24(6):457-463. [doi: 10.1089/tmj.2017.0137] [Medline: 29232180]
3. Ogilvie L, Prescott J, Carson J. The use of chatbots as supportive agents for people seeking help with substance use disorder: a systematic review. Eur Addict Res 2022;28(6):405-418. [doi: 10.1159/000525959] [Medline: 36041418]
4. Ly KH, Ly AM, Andersson G. A fully automated conversational agent for promoting mental well-being: a pilot RCT using mixed methods. Internet Interv 2017 Dec;10:39-46. [doi: 10.1016/j.invent.2017.10.002] [Medline: 30135751]
5. Gabarron E, Larbi D, Denecke K, Årsand E. What do we know about the use of chatbots for public health? Stud Health Technol Inform 2020 Jun 16;270:796-800. [doi: 10.3233/SHTI200270] [Medline: 32570492]
6. Klapow MC, Rosenblatt A, Lachman J, Gardner F. The implementation feasibility and acceptability of using a digital conversational agent (chatbot) for delivering parenting interventions: systematic review. JMIR Pediatr Parent 2024 Oct 7;7:e55726. [doi: 10.2196/55726] [Medline: 39374516]
7. van Kessel R, Roman-Urrestarazu A, Anderson M, et al. Mapping factors that affect the uptake of digital therapeutics within health systems: scoping review. J Med Internet Res 2023 Jul 25;25:e48000. [doi: 10.2196/48000] [Medline: 37490322]
8. Hasselberg MJ. The digital revolution in behavioral health. J Am Psychiatr Nurses Assoc 2020;26(1):102-111. [doi: 10.1177/1078390319879750] [Medline: 31587624]

XSL•FO
RenderX

9. Mee P, Gussy M, Huntley P, et al. Digital exclusion as a barrier to accessing healthcare: a summary composite indicator and online tool to explore and quantify local differences in levels of exclusion. medRxiv. Preprint posted online on 2023. [doi: 10.1101/2023.07.12.23292547]
10. Couper MP, Alexander GL, Zhang N, et al. Engagement and retention: measuring breadth and depth of participant use of an online intervention. J Med Internet Res 2010 Nov 18;12(4):e52. [doi: 10.2196/jmir.1430] [Medline: 21087922]
11. Brouwer W, Oenema A, Crutzen R, de Nooijer J, de Vries NK, Brug J. What makes people decide to visit and use an internet ‐ delivered behavior ‐ change intervention? Health Educ 2009 Oct 16;109(6):460-473. [doi: 10.1108/09654280911001149]
12. Green LW, Hiatt RA. Behavioral determinants of health and disease. In: Detels R, Beaglehole R, Lansang MA, Gulliford M, editors. Oxford Textbook of Public Health: Oxford University Press; 2009. [doi: 10.1016/j.mjafi.2012.05.002]
13. Trethewey SP, Reynolds EK, Trethewey CS. Behavioural determinants of health: individual versus societal responsibility. Br J Gen Pract 2021 Jul;71(708):301-302. [doi: 10.3399/bjgp21X716237] [Medline: 34319899]
14. AlQudah AA, Al-Emran M, Shaalan K. Technology acceptance in healthcare: a systematic review. Appl Sci (Basel) 2021;11(22):10537. [doi: 10.3390/app112210537]
15. Fitzpatrick KK, Darcy A, Vierhile M. Delivering cognitive behavior therapy to young adults with symptoms of depression and anxiety using a fully automated conversational agent (Woebot): a randomized controlled trial. JMIR Ment Health 2017 Jun 6;4(2):e19. [doi: 10.2196/mental.7785] [Medline: 28588005]
16. Ajzen I. The theory of planned behavior. Organ Behav Hum Decis Process 1991 Dec;50(2):179-211. [doi: 10.1016/0749-5978(91)90020-T]
17. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS Q 1989 Sep;13(3):319. [doi: 10.2307/249008]
18. Gagnon MP, Orruño E, Asua J, Abdeljelil AB, Emparanza J. Using a modified technology acceptance model to evaluate healthcare professionals' adoption of a new telemonitoring system. Telemed J E Health 2012;18(1):54-59. [doi: 10.1089/tmj.2011.0066] [Medline: 22082108]
19. Rondan-Cataluña FJ, Arenas-Gaitán J, Ramírez-Correa PE. A comparison of the different versions of popular technology acceptance models: a non-linear perspective. Kybernetes 2015 May 5;44(5):788-805. [doi: 10.1108/K-09-2014-0184]
20. Airhihenbuwa CO. A conceptual model for culturally appropriate health education programs in developing countries. Int Q Community Health Educ 1990 Jan 1;11(1):53-62. [doi: 10.2190/LPKH-PMPJ-DBW9-FP6X] [Medline: 20841220]
21. Rogers J, Gladstone T, Van Voorhees B, Bunge EL. The role of human support on engagement in an online depression prevention program for youth. Soc Sci (Basel) 2021;10(8):285. [doi: 10.3390/socsci10080285]
22. Day JJ, Sanders MR. Do parents benefit from help when completing a self-guided parenting program online? A randomized controlled trial comparing triple P online with and without telephone support. Behav Ther 2018 Nov;49(6):1020-1038. [doi: 10.1016/j.beth.2018.03.002] [Medline: 30316482]
23. Epstein M, Oesterle S, Haggerty KP. Effectiveness of Facebook groups to boost participation in a parenting intervention. Prev Sci 2019 Aug;20(6):894-903. [doi: 10.1007/s11121-019-01018-0] [Medline: 31124023]
24. Hsiao CH, Tang KY. Examining a model of mobile healthcare technology acceptance by the elderly in Taiwan. Journal of Global Information Technology Management 2015 Oct 2;18(4):292-311. [doi: 10.1080/1097198X.2015.1108099]
25. Maher JP, Dzubur E, Huh J, Intille S, Dunton GF. Within-day time-varying associations between behavioral cognitions and physical activity in adults. J Sport Exerc Psychol 2016 Aug;38(4):423-434. [doi: 10.1123/jsep.2016-0058] [Medline: 27634288]
26. Maher JP, Rhodes RE, Dzubur E, Huh J, Intille S, Dunton GF. Momentary assessment of physical activity intention-behavior coupling in adults. Transl Behav Med 2017 Dec;7(4):709-718. [doi: 10.1007/s13142-017-0472-6] [Medline: 28155108]
27. Pickering TA, Huh J, Intille S, Liao Y, Pentz MA, Dunton GF. Physical activity and variation in momentary behavioral cognitions: an ecological momentary assessment study. J Phys Act Health 2016 Mar;13(3):344-351. [doi: 10.1123/jpah.2014-0547] [Medline: 26284314]
28. Seebregts C, Tanna G, Fogwill T, Barron P, Benjamin P. MomConnect: an exemplar implementation of the health normative standards framework in South Africa. South Afr Health Rev :125-136 [FREE Full text]
29. De Filippo A, Bellatin P, Tietz N, et al. Effects of digital chatbot on gender beliefs and exposure to intimate partner violence among young women in South Africa. PsyArXiv. Preprint posted online on 2022. [doi: 10.31234/osf.io/n6rdj]
30. World Bank. Mobile cellular subscriptions (per 100 people)—South Africa | data. 2022. URL: https://data.worldbank.org/indicator/IT.CEL.SETS.P2?locations=ZA [accessed 2023-05-15]
31. Jamieson L, Berry L, Lake L. Broad Overview of the South African Child Gauge 2017: Children's Institute, University of Cape Town; 2017. URL: https://www.researchgate.net/publication/321609409 [accessed 2024-05-10]
32. Cluver L, Meinck F, Yakubovich A, et al. Reducing child abuse amongst adolescents in low- and middle-income countries: a pre-post trial in South Africa. BMC Public Health 2016 Jul 13;16(1):567. [doi: 10.1186/s12889-016-3262-z] [Medline: 27919242]
33. Cluver LD, Meinck F, Steinert JI, et al. Parenting for Lifelong Health: a pragmatic cluster randomised controlled trial of a non-commercialised parenting programme for adolescents and their families in South Africa. BMJ Glob Health 2018;3(1):e000539. [doi: 10.1136/bmjgh-2017-000539] [Medline: 29564157]

XSL•FO
RenderX

34. Ambrosio MDG, Lachman JM, Zinzer P, et al. A factorial randomized controlled trial to optimize user engagement With a chatbot-led parenting intervention: protocol for the ParentText optimisation trial. JMIR Res Protoc 2024 May 3;13:e52145. [doi: 10.2196/52145] [Medline: 38700935]
35. Bhana A, Petersen I, Mason A, Mahintsho Z, Bell C, McKay M. Children and youth at risk: adaptation and pilot study of the CHAMP (Amaqhawe) programme in South Africa. Afr J AIDS Res 2004 May;3(1):33-41. [doi: 10.2989/16085900409490316] [Medline: 25874981]
36. Data world. Mpumalanga spatial development framework. 2019. URL: https://cer.org.za/wp-content/uploads/2019/01/Phase1.pdf [accessed 2024-08-03]
37. South Africa Gateway. The economies of South Africa's nine provinces. 2018. URL: https://southafrica-info.com/infographics/animation-economic-sectors-of-south-africas-provinces [accessed 2024-08-03]
38. Schafer M, Lachman JM, Gardner F, et al. Integrating intimate partner violence prevention content into a digital parenting chatbot intervention during COVID-19: Intervention development and remote data collection. BMC Public Health 2023 Sep 4;23(1):1708. [doi: 10.1186/s12889-023-16649-w] [Medline: 37667352]
39. Klapow M, Zinser P, Lachman J, et al. Promoting family well-being at scale: optimising and re-designing a digital parenting programme for reducing violence against children in lmics using the 6squid framework. Popul Med 2023;5(Supplement). [doi: 10.18332/popmed/164209]
40. Cooper H, Nadzri FZM, Vyas S, et al. A hybrid digital parenting program delivered within the Malaysian preschool system: protocol for a feasibility study of a small-scale factorial cluster randomized trial. JMIR Res Protoc 2024 Apr 26;13:e55491. [doi: 10.2196/55491] [Medline: 38669679]
41. Wlasak W, Zwanenburg SP, Paton C. Supporting autonomous motivation for physical activity with chatbots during the COVID-19 pandemic: factorial experiment. JMIR Form Res 2023 Jan 25;7:e38500. [doi: 10.2196/38500] [Medline: 36512402]
42. Zin K, Kim S, Kim HS, Feyissa IF. A study on technology acceptance of digital healthcare among older Korean adults using extended TAM (Extended Technology Acceptance Model). Adm Sci 2023;13(2):42. [doi: 10.3390/admsci13020042]
43. Alsswey A, Naufal I, Bervell B. Investigating the acceptance of mobile health application user interface cultural-based design to assist Arab elderly users. IJACSA 2018;9(8). [doi: 10.14569/IJACSA.2018.090819]
44. Salgado T, Tavares J, Oliveira T. Drivers of mobile health acceptance and use from the patient perspective: survey study and quantitative model development. JMIR Mhealth Uhealth 2020 Jul 9;8(7):e17588. [doi: 10.2196/17588] [Medline: 32673249]
45. Dang S, Karanam C, Gómez-Orozco C, Gómez-Marín O. Mobile phone intervention for heart failure in a minority urban county hospital population: usability and patient perspectives. Telemed J E Health 2017 Jul;23(7):544-554. [doi: 10.1089/tmj.2016.0224] [Medline: 28051761]
46. Ngongo BP, Ochola P, Ndegwa J, Katuse P. The moderating role of top executives' sex, level of education and knowledge on adoption of mobile health applications by hospitals In Kenya. J Healthc Leadersh 2019;11:115-126. [doi: 10.2147/JHL.S226341] [Medline: 31807107]
47. Kroenke K, Spitzer RL, Williams JBW, Löwe B. An ultra-brief screening scale for anxiety and depression: the PHQ-4. Psychosomatics 2009;50(6):613-621. [doi: 10.1176/appi.psy.50.6.613] [Medline: 19996233]
48. Berry JO, Jones WH. The parental stress scale: initial psychometric evidence. J Soc Pers Relat 1995 Aug;12(3):463-472. [doi: 10.1177/0265407595123009]
49. Graham JW, Olchowski AE, Gilreath TD. How many imputations are really needed? Some practical clarifications of multiple imputation theory. Prev Sci 2007 Sep;8(3):206-213. [doi: 10.1007/s11121-007-0070-9] [Medline: 17549635]
50. Beesley LJ, Taylor JMG. A stacked approach for chained equations multiple imputation incorporating the substantive model. Biometrics 2021 Dec;77(4):1342-1354. [doi: 10.1111/biom.13372] [Medline: 32920819]
51. Nunnally JC. Psychometric theory—25 years ago and now. Educ Res 1975 Nov;4(10):7-21. [doi: 10.3102/0013189X004010007]
52. Shrestha N. Detecting multicollinearity in regression analysis. AJAMS 2020 Jan 15;8(2):39-42. [doi: 10.12691/ajams-8-2-1]
53. Eysenbach G, CONSORT-EHEALTH Group. CONSORT-EHEALTH: improving and standardizing evaluation reports of web-based and mobile health interventions. J Med Internet Res 2011 Dec 31;13(4):e126. [doi: 10.2196/jmir.1923] [Medline: 22209829]
54. Ngusie HS, Kassie SY, Zemariam AB, et al. Understanding the predictors of health professionals' intention to use electronic health record system: extend and apply UTAUT3 model. BMC Health Serv Res 2024 Aug 3;24(1):889. [doi: 10.1186/s12913-024-11378-1] [Medline: 39097725]
55. Tamilmani K, Rana NP, Prakasam N, Dwivedi YK. The battle of brain vs. heart: a literature review and meta-analysis of "hedonic motivation" use in UTAUT2. Int J Inf Manage 2019 Jun;46:222-235. [doi: 10.1016/j.ijinfomgt.2019.01.008]
56. Ben Arfi W, Ben Nasr I, Khvatova T, Ben Zaied Y. Understanding acceptance of eHealthcare by IoT natives and IoT immigrants: an integrated model of UTAUT, perceived risk, and financial cost. Technol Forecast Soc Change 2021 Feb;163:120437. [doi: 10.1016/j.techfore.2020.120437]
57. Cajita MI, Hodgson NA, Budhathoki C, Han HR. Intention to use mHealth in older adults with heart failure. J Cardiovasc Nurs 2017;32(6):E1-E7. [doi: 10.1097/JCN.0000000000000401] [Medline: 28248747]

XSL•FO
RenderX

58. Huang W, Ong WC, Wong MKF, et al. Applying the UTAUT2 framework to patients' attitudes toward healthcare task shifting with artificial intelligence. BMC Health Serv Res 2024 Apr 11;24(1):455. [doi: 10.1186/s12913-024-10861-z] [Medline: 38605373]
59. Yogman MW, Eppel AM. The role of fathers in child and family health. In: Handbook of Fathers and Child Development: Springer; 2022:15-30. [doi: 10.1007/978-3-030-75645-1_2]
60. Lachman JM, Zinzer P, Vyas S, Vallance I, Calderon F, Ambrosio MDG, et al. ParentText optimisation study—a factorial randomised controlled trial to optimise user engagement in a chatbot-led parenting intervention in South Africa: study protocol for the parent text optimisation trial. Open Science Framework. 2023. URL: https://osf.io/wfxne

Abbreviations

DHIs: digital health interventions
DHEM: Digital Health Engagement Model
CHAMP: Children and Adolescents Are My Priority
m2m: mothers2mothers
CONSORT-EHEALTH: Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth
VIF: variance inflation factor

Edited by S Badawy; submitted 06.05.25; peer-reviewed by J Igboanugo, S Yang; revised version received 30.06.25; accepted 17.08.25; published 22.09.25.

Please cite as:
Ambrosio MDG, Vyas S, Stromin J, Lusinga S, Zinzer P, Brukwe K, Makhanya Z, Gwebu H, Schley A, Markle L, Stern D, Facciolà C, Melendez-Torres GJ, Gardner F, Lachman JM
Exploring the Association Between Behavioral Determinants and Intention to Use a Chatbot-Led Parenting Intervention by Caregivers of Adolescent Girls in South Africa: Cross-Sectional Study
JMIR Pediatr Parent 2025;8:e76992
URL: https://pediatrics.jmir.org/2025/1/e76992
doi:10.2196/76992

© Maria Da Graca Ambrosio, Seema Vyas, Juliet Stromin, Shallen Lusinga, Paula Zinzer, Kanyisile Brukwe, Zamakhanya Makhanya, Hlengiwe Gwebu, Anne Schley, Laurie Markle, David Stern, Chiara Facciolà, G J Melendez-Torres, Frances Gardner, Jamie M Lachman. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 22.9.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Efficacy, Feasibility, and Acceptability of an Emotional Competence Tele-Intervention for Mandarin-Speaking Children Aged 5 to 7 Years With Developmental Language Disorder: Pilot Study With an Interrupted Time-Series Design

Hsin-Hui Lu[1,2], ClinPsy, PhD; Shih-Yuan Liang[3], SLPs, PhD; Yi-Chia Huang[4], ClinPsy, MD

[1]Division of Clinical Psychology, Graduate Institute of Behavioral Sciences, College of Medicine, Chang Gung University, Taoyuan City, Taiwan

[2]Department of Child Psychiatry, Chang Gung Memorial Hospital at Linkou, Taoyuan City, Taiwan

[3]Department of Psychology, National Chung Cheng University, Chaiyi, Taiwan

[4]Department of Child and Adolescent Psychiatry, Chang Gung Memorial Hospital, Kaohsiung Medical Center, Kaohsiung, Taiwan

Corresponding Author:
Hsin-Hui Lu, ClinPsy, PhD
Division of Clinical Psychology, Graduate Institute of Behavioral Sciences, College of Medicine, Chang Gung University
33302 No 259, Wenhua 1st Rd, Guishan Dist
Taoyuan City, 33302
Taiwan
Phone: 886 03 2118800
Email: hsinhuilupsy@gmail.com

Abstract

Background: Children with developmental language disorder (DLD) often experience language difficulties that hinder their ability to acquire emotional competence. Poor emotional competence is associated with emotional and behavioral problems in young children.

Objective: This research involved two studies focusing on (1) the emotional competence of Mandarin-speaking children aged 5 to 7 years with DLD and (2) the efficacy, feasibility, and acceptability of a tele-intervention designed to enhance their emotional competence in Taiwan.

Methods: Five children with DLD from study 1 declined to participate in study 2, the emotional competence tele-intervention, and were excluded from the analysis. We compared the emotional competence of 20 Mandarin-speaking children with DLD to that of 24 children with typical language development (TLD). The children with DLD were, on average, aged 5.79 (SD 0.47) years, whereas the children with TLD were, on average, aged 5.93 (SD 0.31) years. We assessed the children's emotional competence, nonverbal ability, verbal comprehension, vocabulary acquisition, and expressive language skills. In study 2, all children with DLD included in study 1 engaged in an emotional competence tele-intervention. An interrupted time-series design was used to examine their emotional competence. In total, 20 children with DLD provided data on emotional competence evaluated using the Emotional Lexicon Test. These data were individually collected at 3 time points after study 1 (time 1). These phases included baseline (time 1 to time 2), during the tele-intervention (time 2 to time 3), and follow-up (time 3 to time 4), spanning approximately 18 to 20 weeks from time 1 to time 4. Recruitment, retention, and attendance rates were calculated to evaluate the intervention's feasibility, and participant mood was evaluated after each session to calculate the intervention's acceptability.

Results: No significant changes in the children's ability to understand basic or complex emotional terms were observed during the baseline period. However, changes were observed during the tele-intervention period, and these changes remained throughout the follow-up period. With a recruitment rate of 80% (20/25), all participants completed 4 intervention sessions, with retention and attendance rates exceeding 95% (19/20). A total of 90% (18/20) of the participants deemed each session to be acceptable.

Conclusions: Mandarin-speaking children aged 5 to 7 years with DLD exhibited lower emotional competence compared with their counterparts with TLD. Tele-interventions are effective in enhancing the emotional competence of children with DLD, demonstrating feasibility and acceptability for these children and their parents in Taiwan.

(JMIR Pediatr Parent 2025;8:e60333) doi:10.2196/60333

XSL•FO
RenderX

KEYWORDS

language disorder; pediatrics; evidence-based intervention; telemedicine; tele-practice; visual support; mobile phone

Introduction

Background

According to the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (*DSM-5*) [1], language disorder (ie, developmental language disorder [DLD]) is a communication disorder that broadly refers to childhood language difficulties and is not associated with any known biomedical condition [2,3]. These language difficulties can hinder children's acquisition of emotional competence, including their understanding of the nature and causes of emotions, their own feelings, their physiological reactions to these feelings, and their cognition surrounding an emotion or emotive event [4-7]. Language is strongly associated with emotional competence, as evidenced in our use of prosody to interpret emotional cues, recognize emotions, and understand what others may feel in various situations [8]. When children experience communication difficulties, their opportunities for social learning diminish, making conversations harder to process, misunderstandings more likely, and participation in discussions or play activities more challenging, which can, in turn, hinder their emotional competence [9]. Language also provides access to mental terms such as *think* and *happy*, which help children mentalize and help them identify, understand, express, and regulate their emotions [10]. These capabilities facilitate social interactions and indirectly aid in understanding the mental states of others [11]. Therefore, children with language acquisition difficulties tend to struggle with using these mental terms to learn the emotional or cognitive aspects of theory of mind. Notably, verbal interactions with caregivers play a key role in the development of emotion regulation skills, primarily because discussing emotions helps children connect their emotions to events and learn how to manage these emotions [12]. As children with DLD grow, they struggle to develop the capacity to internally regulate their emotions, with language playing a crucial role in self-reflection, response inhibition, and guiding behavior [13]. Furthermore, in young children with typical language development (TLD), poor emotional competence has been shown to be associated with emotional and behavioral problems [14].

Previous research examining the emotional competence of children with DLD and children with TLD has rarely focused on children who speak Mandarin as their native language [4,11,15]. If studies indicate that the emotional competence of Mandarin-speaking children with DLD lags behind that of their peers with TLD, as is the case for non–Mandarin-speaking children with DLD, this finding will support the presence of cross-linguistic and cross-cultural consistency in the emotional challenges faced by children with DLD. In children with developmental delays, speech and language delays are the most common disabilities [16]. DLD is a highly prevalent neurodevelopmental disability in Mandarin-speaking children [17,18], highlighting the importance of focusing on the emotional competence of this population. Therefore, further research is needed to evaluate the emotional competence of Mandarin-speaking children with DLD and determine whether early intervention is necessary.

Tele-interventions constitute a promising tool that offers a timely, accessible, and cost-effective solution for overcoming barriers to medical service delivery, such as transportation issues, shortage of skilled therapists, and insufficient facilities in rural areas [19]. This approach is particularly significant given that the special needs of children with DLD living in rural areas are often less adequately addressed than those of children living in urban areas [20]. Adopting tele-practice for early interventions holds great potential to address these disparities and support the development of emotional competence in children with DLD in underserved rural areas [19]. In Taiwan, the procedures, advantages, and challenges associated with implementing such interventions remain unclear. Therefore, in this study, we examined the efficacy, feasibility, and acceptability of emotional competence tele-interventions designed for Mandarin-speaking children with DLD in Taiwan.

Multiple studies have indicated that social stories are an effective means to help children acquire emotional knowledge [21-23]. Social stories have been widely used in clinical practice for children with autism spectrum disorder (ASD) [24]; however, the application of these stories for children with DLD remain understudied. To the best of our knowledge, few studies have focused on children with pragmatic language impairments [25], language impairments [26], and pragmatic disorders with behavioral difficulties [24]. Among the key factors that contribute to the efficacy of a social story is the display of the protagonist's emotional state and social interactions [27], along with labeling affective, physical, and perceptual changes with words describing the protagonist's mental state. These labels help children understand that different experiences can fulfill the same function as long as these experiences are perceived as having the same meaning [28]. The use of visual aids such as pictures or videos can enhance the emotional representation of potential causes, subjective feelings, physiological responses, and cognition during social interactions [29]. Thought bubbles can also be used to clarify the protagonist's emotional state and thoughts within the social context [30,31]. Hence, emotional competence interventions conducted using social stories through remote interfaces, also referred to as social story tele-interventions (SSTIs), are expected to enhance the emotional competence of children with DLD.

Objectives

Preschool and early elementary school are critical periods in the development of a child's emotional competence; the child learns about self-regulation, and their level of emotional competence determines the severity and likelihood of behavioral problems [32,33]. In this research, we examined children in kindergarten and early elementary school. A total of 2 studies were conducted to explore 3 research questions. In study 1, our goal was to determine whether Mandarin-speaking children with DLD in Taiwan differ from those with TLD in emotional competence. We compared Mandarin-speaking children with

XSL•FO
RenderX

DLD to those with TLD in terms of the size and depth of their understanding of emotional terms at the ages of 5 to 7 years. We hypothesized that Mandarin-speaking children aged 5 to 7 years with DLD would exhibit lower performance in the size and depth of their understanding of emotional terms compared with their counterparts with TLD even with family language characteristics such as maternal educational level accounted for. In study 2, we used an interrupted time-series design to explore two questions: (1) Do SSTIs enhance the understanding of emotional language by Mandarin-speaking children aged 5 to 7 years with DLD relative to their baseline performance (ie, before the intervention)? (2) Are SSTIs a feasible and acceptable intervention for these children in Taiwan? We hypothesized that SSTIs would enhance the emotional competence of Mandarin-speaking children aged 5 to 7 years with DLD and that this tele-intervention would be both feasible and acceptable for them and their parents in Taiwan.

Study 1

Methods

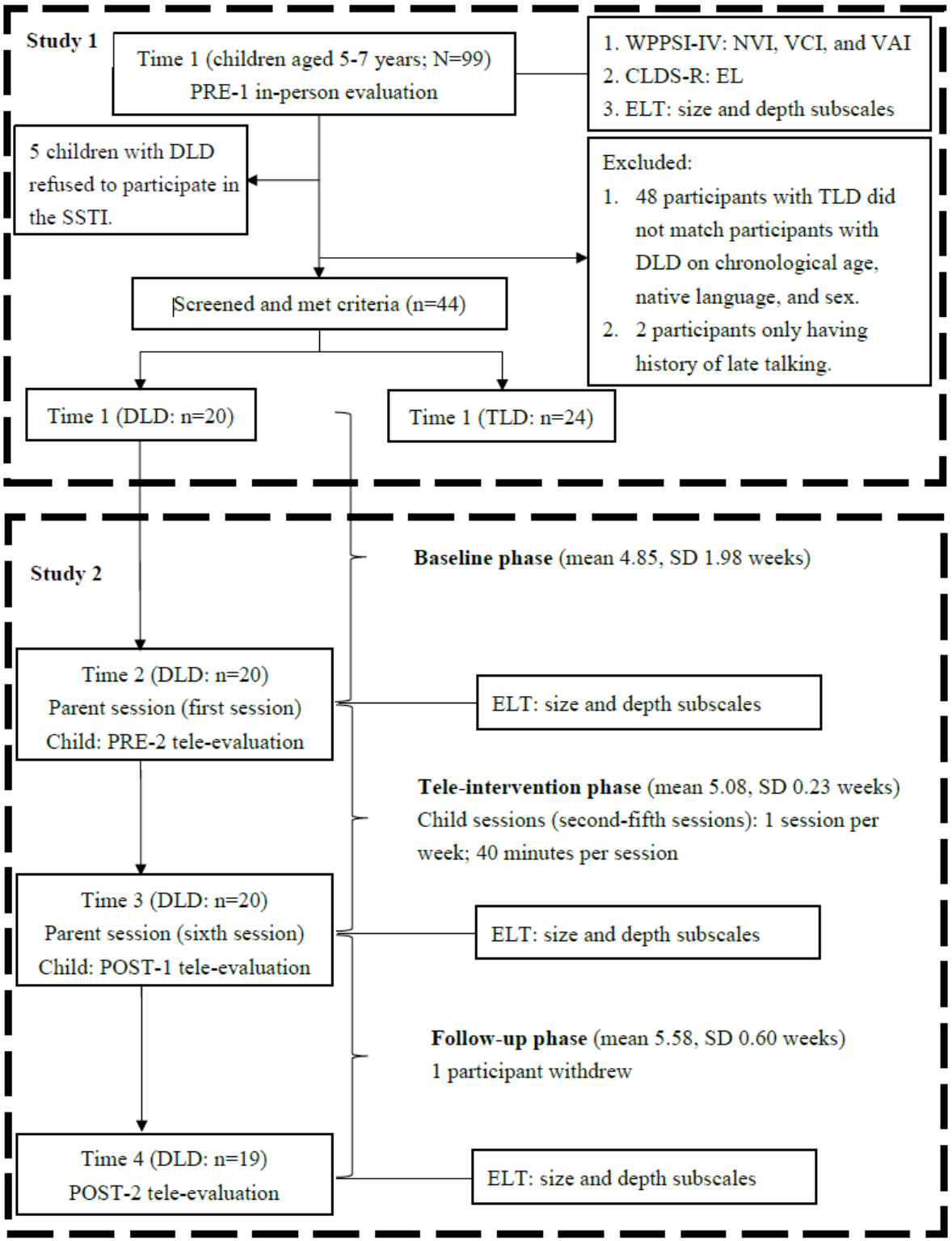
This case-control study was conducted to compare the emotional competence of children with DLD to that of children with TLD.

Participants

A total of 99 children aged 5 to 7 years were recruited from parenting websites and local pediatric clinics in northern and central Taiwan. Figure 1 shows the process of recruitment in study 1. Children with DLD meeting the following matching criteria were included in the study: being within 3 months of the specified age range, having Mandarin Chinese as their native language, and being of the same sex as their matched counterparts. If >1 participant with TLD met these criteria and could be matched with a participant with DLD, they were all included in the analysis. A total of 48 participants with TLD who did not meet the aforementioned criteria and who completed only the in-person evaluation at the preintervention 1 time point (time 1) were excluded from the final analysis. In addition, 2 participants with only a history of late talking who also completed only the in-person evaluation at the preintervention 1 time point (time 1) were excluded from the final analysis. A total of 5 parents refused to participate in the subsequent tele-intervention program. Therefore, of a total of 25 parents of children with DLD, only 20 (80%) participated. Furthermore, ultimately, 44 children were included in the final analysis in study 1: 20 (45%) in the DLD group (mean age 5.79, SD 0.47 years) and 24 (55%) in the TLD group (mean age 5.93, SD 0.31 years).

XSL•FO
RenderX

Figure 1. Flowchart of study 1 and study 2. CLDS-R: Child Language Disorder Scale–Revised; DLD: developmental language disorder; EL: expressive language; ELT: Emotional Lexicon Test; NVI: Nonverbal Index; POST-1: postintervention time point 1; POST-2: postintervention time point 2; PRE-1: preintervention time point 1; PRE-2: preintervention time point 2; SSTI: social story tele-intervention; TLD: typical language development; VAI: Vocabulary Acquisition Index; VCI: Verbal Comprehension Index; WPPSI-IV: Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition.



All participants with DLD had received a diagnosis based on the *DSM-5* criteria at the Early Developmental Evaluation Center, the official institution designated by the Ministry of Health and Welfare of Taiwan for identifying and evaluating children with developmental disorders before the age of 7 years. In Taiwan, the gold standard for diagnosing DLD requires confirmation through a converging evidence approach [34], which includes the assessment of delays in receptive and expressive language by board-certified speech and language pathologists using parental reports, standardized tests, and clinical observations. Clinical psychologists are required to confirm the absence of cognitive delays, and child psychiatrists and pediatric neurologists are required to determine whether any observed language delays are due to other

XSL•FO
RenderX

neurodevelopmental (eg, ASD) or neurological (eg, epilepsy) disorders. Establishing a DLD diagnosis through a converging evidence approach in clinical assessments and decision-making scenarios by medical professionals should be considered the gold standard. Participants with TLD had no known developmental or cognitive impairments.

Measurement

Family Characteristics

Data on family characteristics, including paternal and maternal mean age, paternal educational level and marital status, monthly family income, and number of siblings of the child participant, were collected from parent reports.

Child Characteristics

Data on child characteristics, including age, sex, developmental risk factors, and medical diagnoses, were also collected from parent reports. To confirm that the children met the inclusion criteria, their parents provided an early intervention assessment report issued by the Ministry of Health and Welfare. Among the developmental risk factors considered in this study were biological factors (eg, premature birth, low birth weight, genetic disorders, perinatal complications, and neurological conditions) and medical factors (eg, chronic diseases, infectious diseases, and hearing or vision impairments).

Evaluation of Nonverbal Ability

Nonverbal ability was measured using the Mandarin Chinese version of the Nonverbal Index (NVI) of the Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition [35]. The NVI has an internal consistency reliability of 0.94 to 0.96 across various age groups and a test-retest reliability of 0.85 [35].

Evaluation of Language Abilities

A total of 3 dimensions of language abilities were evaluated: verbal comprehension, vocabulary acquisition, and linguistic expressivity. Verbal comprehension and vocabulary acquisition were evaluated using the Mandarin Chinese versions of the Verbal Comprehension Index (VCI) and Vocabulary Acquisition Index (VAI), respectively, of the Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition [35]. The VCI and VAI have internal consistency reliability levels of 0.92 to 0.94 and 0.84 to 0.92, respectively, and both have a test-retest reliability of 0.86 [35]. Expressive language ability was evaluated using the Mandarin Chinese version of the Child Language Disorder Scale–Revised (CLDS-R) [36]. This subscale evaluates expressive language skills across multiple domains. These domains include (1) the ability to retrieve vocabulary or construct short phrases or sentences in response to questions that evaluate knowledge (eg, functions, general information, and analogies) acquired in the classroom and from one's lived environment; (2) phonological working memory, measured through sentence repetition tasks in which children verbally recall sentences of increasing length and grammatical complexity; and (3) narrative skills, evaluated through spontaneous image description and story retelling tasks with or without the aid of sequenced images. The internal consistency reliability of each CLDS-R subscale across different age groups ranges from 0.80 to 0.96, with a test-retest reliability ranging from 0.92 to 0.98 [36].

Evaluation of Emotional Competence

Emotional competence was evaluated using 2 subscales from the Emotional Lexicon Test (ELT) [37]: a depth subscale and a size subscale. Illustrations were drawn without displaying the facial expression of the protagonist to avoid influencing the children's responses. The depth subscale was used to evaluate the depth of understanding of basic emotional terms (BETs) and complex emotional terms (CETs). After the examiner read a story, they asked each child to label the emotional state of the protagonist and state the reasons underlying their responses (ie, explain the reasons underlying the protagonist's feelings in this context). This subscale evaluates the ability of children to retrieve emotional terms through a recall mechanism. Responses are rated depending on their quality on a scale with end points from 0 to 2, reflecting the varying degrees of children's understanding of emotional terms. In terms of interrater reliability, this subscale was evaluated by 2 raters, who reported a 95% agreement. Discrepancies in scores were discussed by the 2 raters to reach a consensus. The size subscale was used to evaluate the size of BETs and CETs. After the examiner read a story, they asked each child to determine which of 2 emotional state terms (eg, joyful vs fearful, scared vs ashamed, and delighted vs sad) better described the protagonist's emotional state. This subscale evaluates the ability of children to recognize emotional terms through a recognition mechanism. Each correct recognition response is assigned a score of 1 point, indicating the size of the child's emotional lexicon. These 2 subscales have been adopted in other emotional lexicon tests [38]. Each subscale consists of 14 cards with short illustrated stories, of which 6 feature basic emotions (joy, sadness, happiness, anger, fear, and disgust) and 8 feature complex emotions (shame, contempt, guilt, hate, envy, jealousy, pride, and loneliness). Hence, the scores on the depth subscale range from 0 to 28 points, and the scores on the size subscale range from 0 to 14 points. Each item in the ELT includes images to convey the story content, which in turn reduces the semantic comprehension load of the participating child. In this study, before the formal items were used, 2 questions and 1 example item were presented to determine whether the children could match the images with the oral content, indicating their understanding of the story. ELT has an adequate to high internal consistency (0.70-0.71) for CETs [39]. Its criterion-related validity scores with the Metacognitive Vocabulary Test and Peabody Picture Vocabulary Test–Revised are 0.80 and 0.74, respectively [40]. In addition, both hard- and soft-copy versions of the ELT were used. The hard-copy version was used for in-person evaluations, whereas the soft-copy version was used for tele-evaluations.

Procedure

After the children arrived at the laboratory with their parents, all parents were informed of the research procedures. All children successfully completed the 2 questions and 1 example item before the administration of the ELT proper, indicating their understanding of the story. All tests were conducted by licensed clinical psychologists and graduate students trained in child psychological assessment.

XSL•FO
RenderX

Ethical Considerations

The study design was approved by the institutional review board of Chung Shan Medical University Hospital in Taiwan (CS2-19046). During the in-person evaluation phase at the preintervention 1 time point (time 1), the researchers outlined the following: (1) study purpose, (2) data handling procedures, (3) privacy measures, and (4) participant rights, including the voluntary nature of participation and withdrawal options. All parents understood and provided their informed consent. This study was conducted in accordance with relevant guidelines and regulations for human participants. Privacy measures included secure data storage with access restricted to research team members only.

Data Analysis

Separate analyses of covariance (ANCOVAs) were conducted to determine the differences in the NVI, VCI, VAI, and linguistic expressivity scores between the 2 groups, with family characteristics used as a covariate. Chi-square and Fisher exact tests were used to compare group proportions with qualitative data for family characteristics (ie, parental educational level and marital status, monthly family income, and whether the child participant had siblings) and child characteristics (ie, sex and presence of developmental risk factors). In addition, a 3-way mixed-model multivariate ANCOVA was conducted, with group (TLD vs DLD) used as the between-group independent variable and emotion (basic vs complex) and understanding (size vs depth) used as the within-group independent variables, with maternal educational level used as a covariate. In case a statistically significant 3-way interaction was observed among group, emotion, and understanding, the simple main effects between TLD and DLD were examined. Effect sizes from ANCOVAs were calculated using the partial η_p^2, which could be directly translated into a percentage of explained variance. Using the basic framework by Cohen [41], we interpreted these effect sizes as small (η_p^2=0.01), moderate (η_p^2=0.06), or large (η_p^2=0.15). We also conducted a post hoc power analysis for ANCOVAs using G*Power (version 3.1.5) for a sample size of 44 participants, with α=.05 [42]. Post hoc power values of >0.8, between 0.6 and 0.8, and <0.6 were considered high, moderate, and low, respectively. All statistical analyses were conducted using SPSS Statistics (version 25.0; IBM Corp).

Results

Participant Characteristics

Table 1 presents the characteristics of the children and their parents in the TLD and DLD groups. Compared with the TLD group, the DLD group had a lower maternal educational level (N=44, χ^2_1=5.4, *P*=.04). Previous studies have found that mothers' educational level is related to children's social, emotional, and academic development [43]. Therefore, we controlled for this variable when conducting the ANCOVAs. However, no differences were observed between the 2 groups (*P*>.05) in terms of child characteristics (ie, mean age, sex, and risk factors) and family characteristics (ie, paternal and maternal mean age, paternal educational level and marital status, monthly family income, and whether the child participant had siblings).

Table 2 presents the NVI, VCI, VAI, and oral expression scores of the TLD and DLD groups during the evaluation at the preintervention 1 time point. No significant difference was observed in the NVI between the 2 groups (*P*>.05), as indicated by the ANCOVA results. However, compared with the TLD group, the DLD group exhibited significantly lower levels of verbal comprehension, vocabulary acquisition, and linguistic expressivity ($F_{1,\ 41}$=17.20, 11.89, and 10.91, respectively; *P*<.001, *P*=.001, and *P*=.002, respectively; η_p^2=0.30, 0.23, and 0.21, respectively; power=0.99, 0.94, and 0.92, respectively).

XSL•FO
RenderX

Table 1. Characteristics of the children and their parents.a

Variable	TLD[b] (n=24)	DLD[c] (n=20)	*P* value
Child's age (y), mean (SD)	5.93 (0.31)	5.79 (0.47)	.26
Father's age (y), mean (SD)	40.58 (4.72)	42.05 (5.16)	.34
Mother's age (y), mean (SD)	37.54 (3.75)	39.65 (4.20)	.09
Child characteristics, n (%)			
Sex			.76
Male	17 (71)	15 (75)	
Female	7 (29)	5 (25)	
Developmental risk factors			.15
Yes	13 (54)	15 (75)	
No	11 (46)	5 (25)	
Family characteristics, n (%)			
Father's educational level			>.99
Below university level	3 (12)	3 (15)	
At or above university level	21 (88)	17 (85)	
Mother's educational level			.04
Below university level	1 (4)	6 (30)	
At or above university level	23 (96)	14 (70)	
Parents married and living together			>.99
Yes	22 (92)	17 (85)	
No	2 (8)	3 (15)	
Monthly family income			.14
<NT $[d] 59,999 (US $1821.35)	10 (42)	13 (65)	
≥NT $ 60,000 (US $1821.38)	14 (58)	7 (35)	
Child participants having siblings			.50
Yes	8 (33)	4 (20)	
No	16 (67)	16 (80)	

[a]All *P* values were obtained from ANOVAs or chi-square or Fisher exact tests.

[b]TLD: typical language development.

[c]DLD: developmental language disorder.

XSL•FO
RenderX

Table 2. Nonverbal and language abilities of the participants[a].

Variable	TLD[b] (n=24), mean (SD)	DLD[c] (n=20), mean (SD)	*P* value
NVI[d] (CS[e])	103.71 (9.14)	98.15 (14.79)	.23
VCI[f] (CS)	112.83 (12.67)	93.65 (15.52)	<.001
VAI[g] (CS)	111.63 (11.21)	96.55 (13.92)	.001
EL[h] (*z* score)[i]	−0.08 (0.90)	−0.97 (0.61)	.002

[a]All *P* values were obtained from analyses of covariance.

[b]TLD: typical language development.

[c]DLD: developmental language disorder.

[d]NVI: Nonverbal Index.

[e]CS: composite score of the Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition, Chinese version.

[f]VCI: Verbal Comprehension Index.

[g]VAI: Vocabulary Acquisition Index.

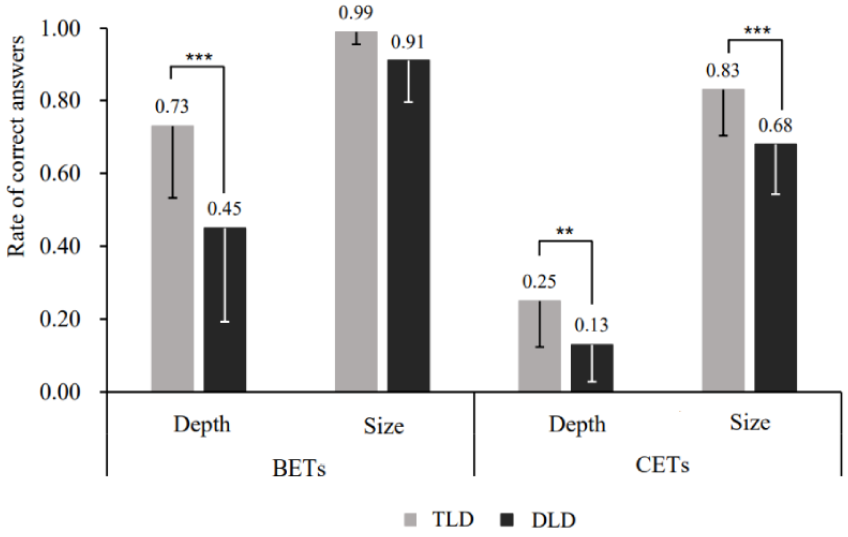
[h]EL: expressive language.

[i]*z* score of the Child Language Disorder Scale–Revised, Chinese version.

Emotional Competence Among Children With TLD and DLD

Figure 2 illustrates the size and depth of understanding of BETs and CETs for the TLD and DLD groups during the evaluation at the preintervention 1 time point. It also shows the main effects of emotion (Wilks $\lambda_{1, 41}$=34.17; *P*<.001; η_p^2=0.45; power=0.99) and understanding (Wilks $\lambda_{1, 41}$=72.97; *P*<.001; η_p^2=0.64; power=0.99). A post hoc analysis revealed that BETs outperformed CETs (*P*<.001), with the number of recognized emotional terms being greater than that of recalled emotional terms (*P*<.001). A statistically significant 3-way interaction was observed among group, emotion, and understanding (Wilks $\lambda_{1, 41}$=12.39; *P*=.001; η_p^2=0.23; power=0.66). Simple-simple main effect analysis revealed that the DLD group scored lower than the TLD group in terms of the depth of understanding of BETs and the size and depth of understanding of CETs ($F_{1, 164}$=37.20, 11.48, and 6.54, respectively; *P*<.001, *P*<.001, and *P*=.01, respectively; η_p^2=0.18, 0.07, and 0.04, respectively; power=0.86, 0.43, and 0.26, respectively).

Figure 2. Mean rate of correct answers for basic emotional terms (BETs) and complex emotional terms (CETs) for the typical language development (TLD) and developmental language disorder (DLD) groups during the evaluation at preintervention time point 1 (time 1). The vertical lines represent error bars with 1 SD. The asterisks indicate the significant simple main effects of group, revealing a higher mean rate of correct answers for the TLD group than for the DLD group. **P<.01; ***P<.001.



Discussion

Principal Findings

Few studies have compared the emotional competence of Mandarin-speaking children with DLD to that of children with TLD. In this study, we controlled for child and family characteristics in our research design and statistical analysis while comparing children with DLD and TLD. This approach increased the validity of our findings, indicating a lag between children with DLD and those with TLD in terms of emotional competence. It also enhanced the validity of study 2, which

XSL•FO
RenderX

examined the improvement observed in emotional competence among children with DLD after undergoing a tele-intervention.

The size of understanding of BETs among children aged 5 to 7 years with DLD was similar to that among their counterparts with TLD, indicating that children with DLD can understand basic emotional states in typical social scenarios. However, the depth of understanding of BETs among children aged 5 to 7 years with DLD was considerably lower than that among their counterparts with TLD, indicating that the ability of children with DLD to express their emotions through BETs may be limited. In addition, children with DLD were slower in understanding CETs compared with children with TLD in kindergarten and early elementary school years, indicating the delayed development and mastery of such concepts. Overall, our findings are consistent with those of previous studies [5-7,14,44] indicating that Mandarin-speaking children with DLD also exhibit impaired emotional competence. These findings suggest that the lag observed in emotional competence in children with DLD is a universal characteristic across countries and ethnic groups [45]. These findings underscore the importance of early interventions in improving their conceptual knowledge of emotional states.

In this study, children with DLD exhibited language functioning within the low but normal range, although their scores were lower than those of their peers with TLD. The study explored whether these children experienced delays in their lexical, grammatical, or articulatory development. In study 1, all children had been diagnosed with DLD in accordance with *DSM-5* criteria at the Early Developmental Evaluation Center, an institution designated by the Ministry of Health and Welfare of Taiwan to evaluate developmental disorders in children aged <7 years. Diagnosing DLD through clinical assessments with a converging evidence approach for clinical decision-making is regarded as the gold standard in Taiwan. In this approach, no single method serves as the deciding factor in making diagnostic decisions regarding the receptive and expressive language skills of individuals with DLD. Converging evidence refers to the concept that multiple pieces of assessment data must align and point in the same direction to support a diagnostic decision [34]. In specific test areas, the cutoff score may vary to maximize sensitivity and specificity in identifying those who are at a high risk of developmental problems. Nevertheless, no consensus has been reached regarding the cutoff values for the VCI, the VAI, and the CLDS-R expressive language subscale required for determining whether a child has DLD. In this study, the VCI, the VAI, and the CLDS-R expressive language subscale were used only to evaluate the language capabilities of children with DLD and compare them to those of children with TLD. Our goal was to determine whether the language capabilities of children with DLD lagged behind those of children with TLD, unlike nonverbal capabilities, for which no differences were observed between the 2 groups. Notably, we did not use the VCI, the VAI, or the CLDS-R expressive language subscale for diagnostic purposes in this study.

According to Bishop [46], DLD involves heterogeneous language features. In this study, we examined only the verbal comprehension, vocabulary acquisition, and expressive language capabilities of children with DLD and did not evaluate their speech perception, phonological awareness, or understanding and use of grammar. Therefore, we could not confirm whether children with DLD lag in these language dimensions. In addition, no consensus has yet been reached regarding the definition of DLD in terms of whether receptive or expressive language should be scored at a threshold of <1 or 1.5 SDs in standardized language tests [47]. Of a total of 20 children with DLD, 6 (30%) had received physical therapy, 19 (95%) had received occupational therapy, 18 (90%) had received speech therapy, and 6 (30%) had received psychological therapy, indicating that these children continually underwent systematic and structured interventions implemented by medical professionals to optimize their development during sensitive periods [48-50]. Therefore, although DLD can be qualitatively defined in accordance with the *DSM-5* [1] in medical and research contexts, no consensus has yet been established regarding its quantitative definition, including which tests to conduct and which cutoff criteria to apply. Furthermore, each quantitative definition may have unique implications for specific contexts in different countries or cultures, presumably reflecting the use of different measurement tools and cultural perspectives on children's development and delays [51]. Bishop [46] emphasized the importance of establishing a consensus regarding the quantitative definition of DLD to facilitate cross-linguistic and cross-cultural comparisons of the characteristics, developmental changes, and emotional competence of children with DLD over time.

Conclusions

In this study, low power values were observed for the simple-simple main effects of the size and depth of understanding of CETs. According to Ryou et al [52], a lower power value indicates a higher risk of a type II error, also referred to as a false negative, in which a statistical test does not call for the rejection of the null hypothesis when the alternative hypothesis is true. However, our group comparisons for the size and depth of understanding of CETs were significant, with moderate effect sizes. These comparisons mitigated the risk of type II errors in comparison to scenarios in which group differences were not significant. Therefore, increasing the sample size in future studies may aid in achieving more robust results.

Study 2

Methods

In this study, we used a prospective 1-group interrupted time-series research design situated within the context of a response-to-intervention instructional framework [53]. This study comprised a baseline phase, a tele-intervention phase, and a follow-up phase.

Participants

The same 20 children with DLD who participated in study 1 were included in study 2.

SSTI Characteristics

Intervention Sessions

This 6-week emotional competence tele-intervention comprised 2 sessions for parents (first and sixth sessions) and 4 sessions

XSL•FO
RenderX

for children (second to fifth sessions). In the first parent session, the mechanism of SSTIs designed for children to acquire emotional competence skills was introduced, whereas in the last parent session, the SSTIs and children's emotional competence skills acquired during the sessions and on a daily basis were reviewed. No home practice was offered after the 2 parent sessions, and no children were involved in these sessions. Each child's session included the presence of their parents and comprised the following elements: (1) a parent-child interactive game, that is, the finger trap game; (2) a 4-panel physical story comic; (3) a social story video (Multimedia Appendix 1) played for the participating child 3 times; and (4) a talk practice (retelling, prompting, self-narration, and imitation).

In the finger trap game, each parent places their palm facing down, and each child places their index finger underneath their parent's palm. Once a specific word (eg, *three*) is presented in a series of words (eg, *three*, *four*, *six*, *two*, *three*...), the parent attempts to rapidly close their open palm to catch the child's finger. Two 4-panel physical story comics are presented. The first comic, used in the first and second child sessions, depicts a balloon being blown away by the wind, floating up into a tree, getting caught on a branch, and popping. The second comic, used in the third and fourth child sessions, depicts a clear, sunny day that later turns cloudy and then rains heavily.

The themes and language content of these intervention sessions corresponded to the titles of 4 researcher-edited social story videos, namely, "Great with others," "Play game," "Grab a toy," and "Give a gift." In these social story videos, external causes lead the protagonist to have an emotional experience. The social stories developed in this study included 4 types of mental state terms: cognitive state terms such as *know*; desire state terms such as *want*; perceptual state terms such as *feel*; and basic emotional state terms such as *happy*, *sad*, *angry*, and *fear* [54]. Table 3 presents the mental state terms and their frequencies in each social story. Thought bubbles are used to display the beliefs, desires, intentions, knowledge, and moods of the story's protagonist as they arise from the interpretation of environmental cues (Multimedia Appendix 1). As shown in Multimedia Appendix 1, panel 2 displays the mental state for desire, panels 4 and 5 display the mental state for belief, panel 7 displays the mental state for intention, and panels 3 and 6 display the mental states for moods associated with desire and belief.

Table 3. Mental state terms and frequency, words, and length in each social story.

Social story	Mental state terms (frequency)	Words, N[a]	Length (seconds)
Great with others	• Know (n=6) • Want (n=6) • Feel (n=6) • Happy (n=6) • Sad (n=6)	115	95
Play game	• Know (n=6) • Want (n=6) • Feel (n=6) • Happy (n=6) • Angry (n=6)	118	104
Grab a toy	• Know (n=6) • Want (n=6) • Feel (n=6) • Happy (n=6) • Fear (n=6)	112	93
Give a gift	• Know (n=3) • Want (n=3) • Feel (n=3) • Happy (n=3) • Sad (n=3) • Angry (n=3) • Fear (n=3)	101	91

[a]Chinese character count.

The following instructions were given to the children for the talking practice. For retelling, the instruction was as follows: "Tell me about the story you just heard." For prompting, the instruction was as follows: "I have a few questions to ask you about this story." For self-narration, the instruction was as follows: "After listening to this story, it's your turn to share a story about how you grabbed a toy with someone." For imitation, the instruction was as follows: "Tell me the story one more time—I'll say a sentence, and then you repeat it."

Each session lasted approximately 40 minutes. A total of 4 sessions were delivered over 4 weeks, with 1 session per week. The quantitative and qualitative aspects of this intervention program are consistent with those outlined by Frizelle et al [55], who emphasized that, in an intervention program, the concept of efficiency is central to "dosage," which includes both quantitative (number of sessions, frequency, and duration) and qualitative (form) constructs.

XSL•FO
RenderX

Tele-Intervention Information and Communications Technology

The technical setup used by the 3 interventionists in their workrooms included a laptop equipped with Google Meet, a broadband internet connection, a web camera, a flexible lighting device to achieve optimal lighting, and a backdrop of an image showing the name of the interventionist to ensure optimal visibility during the tele-intervention sessions. The technical setup used by the participants included their own personal desktop computer or laptop (9/20, 45%), tablet (3/20, 15%), or smartphone (8/20, 40%), all equipped with Google Meet; an internet connection; and a web camera. All parents reported having internet access at their homes (fixed line or 4G or 5G cellular internet). They also reported a sound level of 55 to 65 dB, measured using a sound meter app. Throughout the tele-intervention sessions, the participants were asked to keep the video call in full-screen mode. All interventionists used the screen-sharing tool to present visual stimuli for the social story video and prompt pictures during the talk practice stage.

Measurement

Assessment of Emotional Competence

In this study, the ELT was used to evaluate the emotional competence of children with DLD. The study 1 section provides more details regarding this test.

Assessment of the Feasibility and Acceptability of SSTIs

Feasibility was evaluated based on recruitment, retention, and attendance rates to each session, and acceptability was evaluated based on the outcomes of each session. The participants were asked to either select 1 of 4 affect categories (happiness, anger, fear, and sadness) or remain neutral. Reports of happiness and neutrality were considered acceptable.

Procedure

As shown in Figure 1, the DLD group completed the in-person evaluation at the preintervention 1 time point (time 1). After 5 to 6 weeks, the SSTIs were administered. The parents attended the first parent session, and the ELT was administered during the tele-evaluation at the preintervention 2 time point (time 2). After 1 week, the DLD group received the SSTIs, which lasted 4 weeks (second to fifth session). In the sixth session, the parents were evaluated, and the DLD group was administered the ELT again during the tele-evaluation at the postintervention 1 time point (time 3). Finally, 5 to 6 weeks after time 3, the DLD group was administered the ELT once again during the tele-evaluation at the postintervention 2 time point (time 4). Only 1 participant withdrew from the study during the tele-evaluation at the postintervention 2 time point. The mean number of weeks between time 1 and time 2 and between time 3 and time 4 was similar (P>.05). Figure 1 shows the participant recruitment process. The period from time 1 to time 4 spanned approximately 18 to 20 weeks for each participant with DLD.

Ethical Considerations

This study was conducted in accordance with relevant guidelines and regulations for human participants. Privacy measures included secure data storage with access restricted to research team members only. The study design was approved by the institutional review board of Chung Shan Medical University Hospital in Taiwan (CS2-19046).

Data Analysis

When the data suggest a nonlinear relationship, piecewise linear growth models can be used to divide growth trajectories into >2 linear components, such as in interrupted time-series data [56,57]. In this study, we used a piecewise linear growth model with 3 slopes for each outcome: slope 1 to evaluate changes from the preintervention 1 to preintervention 2 time points (baseline), slope 2 to evaluate changes from the preintervention 2 to postintervention 1 time points (tele-intervention), and slope 3 to evaluate changes from the postintervention 1 to postintervention 2 time points (follow-up). We also hypothesized that the tele-interventions would have an effect. Generally, the absence of an intervention effect for baseline and follow-up indicates that emotional competence did not increase during the baseline phase and did not decrease during the follow-up phase. The HLM software (version 7.03; Scientific Software International) [58] was used to fit the piecewise linear growth model. All other analyses were conducted using SPSS Statistics (version 25.0). Estimates of intraclass correlation coefficients (ICCs) are often used to analyze the power of piecewise linear growth models [59]. These coefficients measure the similarity between data points within the same cluster and those in different clusters. They typically range from 0 (no similarity between clusters) to 1 (complete similarity between clusters). ICCs of >0.20 indicate that the model can detect actual differences in growth rates across different time segments [60]. Sufficient power is essential for study accuracy, making piecewise linear growth models suitable for analysis. Effect sizes are typically calculated for each period using the Cohen *d* for repeated measures [61]. Values of 0.2, 0.5, and 0.8 indicate small, moderate, and large effects, respectively [62]. The Cohen *d* was calculated using G*Power (version 3.1.5) [63].

Results

Changes in Emotional Competence Among Participants With DLD

In this study, the ICCs for BET size, BET depth, CET size, and CET depth were <0.001, 0.34, 0.30, and 0.46, respectively. The ICCs for BET depth, CET size, and CET depth were >0.20, indicating that the piecewise linear growth model was suitable for analysis. Figure 3 shows the mean change trajectories for the size and depth of BETs and CETs. Table 4 presents the results of multilevel piecewise growth models for estimating mean changes in 4 emotion outcomes in the tele-intervention during the baseline (preintervention 1 to preintervention 2 time points), tele-intervention (preintervention 2 to postintervention 1 time points), and follow-up (postintervention 1 to postintervention 2 time points) phases. Regarding BET size, no statistically significant change was observed during the baseline, tele-intervention, or follow-up phase (P>.05). Regarding BET depth, the rate of correct answers significantly increased during the tele-intervention phase (P<.001), but no significant change was observed during the baseline or follow-up stage (P>.05). Regarding CET size, no statistically significant change was observed during any phase (P>.05). Regarding CET depth, the rate of correct answers significantly increased during the

XSL•FO
RenderX

tele-intervention phase (*P*<.001), but no significant change was observed during the baseline or follow-up phase (*P*>.05).

Figure 3. Mean change trajectories for the size and depth of basic emotional terms (BETs) and complex emotional terms (CETs) during the baseline, tele-intervention, and follow-up phases. D-BET: BET depth; D-CET: CET depth; POST-1: postintervention time point 1; POST-2: postintervention time point 2; PRE-1: preintervention time point 1; PRE-2: preintervention time point 2; S-BET: BET size; S-CET: CET size.

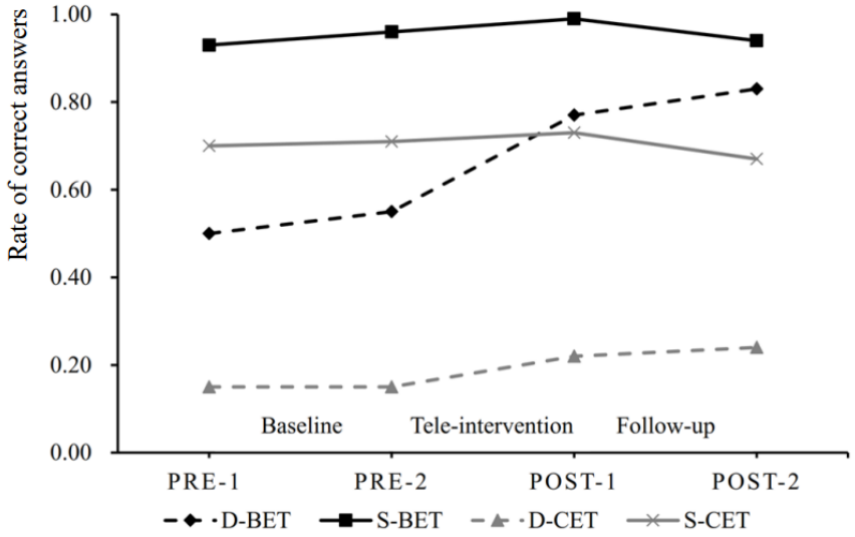


Table 4. Baseline, tele-intervention, and follow-up changes in multilevel piecewise models for emotional terms.

Variable	Size of BET[a], B (95% CI)[b]	Depth of BET, B (95% CI)[c]	Size of CET[d], B (95% CI)[e]	Depth of CET, B (95% CI)[f]
Fixed effect				
Intercept	0.93[g] (0.89 to 0.98)	0.50[g] (0.40 to 0.61)	0.69[g] (0.63 to 0.76)	0.15[g] (0.10 to 0.19)
Baseline	0.03 (–0.04 to 0.09)	0.05 (–0.03 to 0.13)	0.01 (–0.05 to 0.07)	0.00 (–0.05 to 0.05)
Tele-intervention	0.03 (–0.01 to 0.08)	0.21[g] (0.11 to 0.32)	0.03 (–0.05 to 0.10)	0.07[g] (0.04 to 0.10)
Follow-up	−0.02 (–0.04 to 0.00)	0.05 (–0.05 to 0.14)	0.001 (–0.09 to 0.09)	0.01 (–0.04 to 0.06)

[a]BET: basic emotional term.

[b]Random effect—intercept (U_0): χ^2_{19}=15.4; *P*>.50.

[c]Random effect—intercept (U_0): χ^2_{19}=116.3; *P*<.001.

[d]CET: complex emotional term.

[e]Random effect—intercept (U_0): χ^2_{19}=54.2; *P*<.001.

[f]Random effect—intercept (U_0): χ^2_{19}=98.6; *P*<.001.

[g]*P*<.001.

Table 5 presents the means and SDs of various emotional term measures at 4 measurement time points. The effect sizes for changes during the baseline period (from the preintervention 1 to preintervention 2 time points) were small (Cohen *d*=0.00-0.26), indicating that the depth and size of BETs and CETs slightly changed during this period. During the tele-intervention period (from the preintervention 2 to postintervention 1 time points), large effect sizes (Cohen *d*=0.88-0.94) were observed for the changes in depth of BETs and CETs, whereas small effect sizes (Cohen *d*=0.12-0.27) were observed for the changes in size of BETs and CETs. During the follow-up period (from the postintervention 1 to postintervention 2 time points), small effect sizes (Cohen *d*=0.01-0.39) were observed for the changes in depth and size of BETs and CETs.

XSL•FO
RenderX

Table 5. Means, SDs, and effect sizes for emotional term measures.

	Rate of correct answers (PRE-1[a]), mean (SD)	Rate of correct answers (PRE-2[b]), mean (SD)	Rate of correct answers (POST-1[c]), mean (SD)	Rate of correct answers (POST-2[d]), mean (SD)	Effect size, Cohen *d*		
					Baseline	Tele-intervention	Follow-up
D-BET[e]	0.50 (0.25)	0.55 (0.30)	0.77 (0.19)	0.81 (0.21)	0.26	0.88	0.18
S-BET[f]	0.93 (0.10)	0.96 (0.09)	0.99 (0.04)	0.97 (0.06)	0.19	0.27	0.39
D-CET[g]	0.15 (0.10)	0.15 (0.11)	0.22 (0.13)	0.22 (0.13)	0.00	0.94	0.03
S-CET[h]	0.69 (0.15)	0.71 (0.10)	0.73 (0.20)	0.73 (0.10)	0.14	0.12	0.01

[a]PRE-1: preintervention 1 time point.

[b]PRE-2: preintervention 2 time point.

[c]POST-1: postintervention 1 time point.

[d]POST-2: postintervention 2 time point.

[e]D-BET: depth of basic emotional term.

[f]S-BET: size of basic emotional term.

[g]D-CET: depth of complex emotional term.

[h]S-CET: size of complex emotional term.

Feasibility and Acceptability of SSTIs

Of the 25 parents of participants with DLD, 5 (20%) did not take part in this study. Therefore, the recruitment rate for the program was 80% (20/25). At the preintervention 2, postintervention 1, and postintervention 2 time points, the retention rates were 100% (20/20), 100% (20/20), and 95% (19/20), respectively. During the 4 sessions, the attendance rates were 100% (20/20), 100% (20/20), 95% (19/20), and 100% (20/20). All participants (20/20, 100%) completed the 4 tele-intervention sessions, with only 5% of missing data at the postintervention 2 time point.

During the 4 sessions, the percentages of participants who reported being happy were 90% (18/20), 79% (15/19), 85% (17/20), and 90% (18/20), and the percentages of participants who reported being neutral were 10% (2/20), 11% (2/19), 15% (3/20), and 5% (1/20). Overall, the acceptability rates were 100% (20/20), 89% (17/19), 100% (20/20), and 95% (19/20) during the 4 sessions.

Discussion

Principal Findings

Tele-interventions are not a novel concept in medicine. However, to the best of our knowledge, this is the first study to integrate a social story intervention with a remote format to improve the emotional competence of children with DLD. In this study, a 3-stage process was used to observe changes in emotional terms among children with DLD. We discovered that changes in emotional competence occurred only during the tele-intervention phase, with no changes observed during the baseline phase before the intervention. These effects remained during the follow-up period after the intervention. Overall, this research design enhanced the validity of the results.

Our results indicated that SSTIs helped children with DLD deepen their understanding of BETs. In these SSTIs, 4 BETs were repeatedly used in various social contexts to reflect different individuals' mental states. This approach enabled the participants to understand that a single emotion word may be applicable to a range of scenarios (ie, unspecific use). The earlier these terms are integrated into the active vocabulary of children, the more their use aligns with that of adults. These findings are consistent with those of Grosse et al [64] indicating that children who learn words about emotions through cross-context scenarios can understand and use such vocabulary as adults. In this study, thought bubbles were used to enhance the children's understanding of representational mental states associated with emotional terms.

Although our intervention was not designed to introduce new CETs, we hypothesized that children with DLD would not seek to increase the size of their CETs and would rather seek to improve their understanding of the CETs that they had already learned. Overall, our findings indicate that SSTIs, which are based on a thorough understanding of BETs, can help children with DLD gain a deeper understanding of the CETs that they have already learned. Further systematic studies of domain-specific vocabulary are required to determine the effectiveness of SSTIs, including the size of emotion vocabulary and the depth of understanding.

Although social stories are often applicable to patients with ASD, similar to the application of such stories to children with ASD, the social stories designed in this study included visualizations of the story context, which can influence social storytelling by reducing extraneous cognitive demands [65]. When social stories are used as an intervention for children with DLD, adjustments may be required depending on the children's language levels. In this study, we used the thought bubbles corresponding to mental state words, which can also be used to clarify the protagonist's emotional state and mental thoughts within a social context. In other words, by making hidden thoughts and feelings explicit, children with DLD can gain a deeper understanding of their own and others' emotions and acquire the emotional language necessary to reflect upon and

XSL•FO
RenderX

discuss these emotions [66]. Given that children with DLD represent a highly heterogeneous group, when social story interventions are implemented for these children, their language levels must be considered. In other words, the vocabulary, syntactic structures, and story elements included must be carefully planned to ensure that they are within the instructional level and not the frustration level [67]. These strategies have the potential to enhance the expressive language output of children for discussing emotional topics, processing targeted emotional components, and engaging in tele-interventions.

Among the indicators of feasibility for evaluating a pilot program are recruitment, retention, fidelity, acceptability, adherence, and engagement [68,69]. In this study, we evaluated the indicators of recruitment (proportion of parents who were willing to participate), retention (proportion of parents who did not withdraw), and attendance (proportion of parents who attended all 4 sessions). Retention rates are often used as evidence of feasibility in early intervention studies [70,71], particularly for pilot programs [69]. A high retention rate indicates that the program has promise for further development. Future research is required to evaluate the indicators of fidelity, adherence, and engagement to strengthen feasibility assessments.

According to Gartlehner et al [72], clinicians and policy makers tend to differentiate between efficacy and effectiveness. These 2 constructs exist on a continuum where efficacy and efficiency are about whether an intervention functions well under ideal and real-world conditions, respectively. This study was conducted under ideal conditions, supervised by a clinical researcher with expertise in children with DLD. The sample size was small, and the participants were carefully selected—only children with a confirmed diagnosis of DLD were included. The outcomes focused on specific aspects of emotional competence, such as the acquisition of emotional terms, rather than on broader health measures. A short-term intervention was implemented to provide initial evidence of efficacy, with strict protocols for both care providers and families. Future studies should explore the effectiveness of this program for Mandarin-speaking children with DLD, but first, it is necessary to establish the importance of continually evaluating its intermediate- and long-term efficacy. Chorpita et al [73] have argued that, even if >10 successful replications support a particular treatment, this information would not be sufficient to determine whether this treatment is more suitable for a particular child than a treatment supported by only 2 instances of replication assuming the absence of predictors of differences in outcomes. This assumption underscores the importance of conducting effectiveness studies to determine whether intervention programs can be widely implemented in clinical settings. Therefore, future studies should examine our program's real-world effects in hospital settings, including its acceptability, feasibility, and cost versus benefit. They should also explore broader mental health outcomes, such as increased self-regulation or decreased behavioral problems, of tele-interventions designed for Mandarin-speaking children with DLD.

Some parents raised concerns regarding their children facing difficulties focusing on their lessons and interacting with their instructors on-screen. Generally, in-person interventions involve physical contact and social interactions, such as high fives, contingency, eye contact, and joint attention, which can help children focus. In contrast, web-based interactions involve only visual support and behavioral management strategies to keep children engaged [74-76]. Despite these limitations, we discovered that the parents and children who participated in the intervention had high attendance rates and reported positive emotions after the intervention, indicating the feasibility and acceptability of SSTIs among them.

In the past few years, many hospitals were closed to the public because of the COVID-19 pandemic, thus preventing the implementation of in-person interventions. Early interventions for children with developmental delays were also suspended. These measures resulted in an increase in tele-evaluations and tele-interventions in medical scenarios. Although specialized hospitals are currently available for children, tele-practice interventions are particularly valuable for families living in rural areas, who tend to face challenges such as time constraints and lack of transportation. In these areas, enhancing the adoption of tele-practice requires software and hardware support because of these areas' limited internet access and lack of hardware [77]. Currently, Taiwan is striving to expand its 5G infrastructure (through platforms such as OpenGov Asia, the Ministry of Digital Affairs, and ComSoc Technology), particularly in remote areas such as Penghu, to improve digital accessibility and support tele-practice. Enhancing the degree of acceptance among health care professionals and parents is essential for promoting child language development and raising awareness of the benefits of tele-practice [78,79]. Finally, tele-interventions can also be used as a hybrid model in conjunction with in-person services to enhance learning experiences and make efficient use of resources.

This study has some limitations. First, emotional competence was exclusively measured by determining the number of emotional terms that children with DLD were aware of and examining the depth of their understanding of these terms. These measures did not reflect whether the children's emotional regulation strategies or behavioral problems improved as a result of our intervention. Therefore, further studies are required to explore these aspects of emotional competence. Second, the period during which we evaluated the effects of the intervention was short. Therefore, further long-term follow-up studies are required to determine the long-term and cumulative effects of our tele-intervention. Third, although the Italian version of the ELT has demonstrated strong psychometric characteristics [40] and assesses both basic and complex emotional competence in children, the Chinese version of this test lacks support from psychometric data. As in previous studies [38], we evaluated children's understanding of emotion-related words by making them listen to stories and choose the correct terms to determine the quantity of emotion words. We subsequently asked them to explain their choices to gauge their depth of understanding. This approach, which relies on a single test, limits the concept of emotional competence in children. Therefore, future studies should involve various additional measures such as the Emotional Competencies Scale for Young Children [80] or collect data through parent questionnaires or transcript analyses

XSL•FO
RenderX

to determine whether children use emotion words in different contexts [81,82].

Conclusions

Mandarin-speaking children aged 5 to 7 years with DLD exhibit lower emotional competence than those with TLD even after adjusting for child and family language characteristics. Although DLD can be qualitatively defined in accordance with the *DSM-5* [1] in medical and research contexts, no consensus has yet been established regarding its quantitative definition, including which tests to conduct and which cutoff criteria to apply. Therefore, further research is required to establish a quantitative definition for children with DLD across languages and cultures and enable comparisons of emotional competence in children with DLD from different linguistic and cultural backgrounds. In addition, emotional competence tele-interventions effectively improve the emotional competence of children with DLD. They are also feasible and acceptable for both children and their parents. These findings indicate that tele-interventions can be a viable option for individuals who lack access to in-person services due to hospital shutdowns or barriers related to transportation, location, or time. Visual materials such as images and videos of children's interactions, implicit thoughts, and emotions should be used to understand and discuss emotional situations, with a preference toward realistic content. In addition, the language used in SSTIs should match the language capabilities of children. Although the results of our tele-intervention approach are satisfactory, future studies should explore its effectiveness in hospital settings to determine its real-world impact and examine broader mental health outcomes of tele-interventions for children with DLD. Further research is also required to address unresolved concerns regarding assessment, diagnosis, telephone consultation, internet support systems, and inconsistent intervention outcomes. Addressing these concerns can facilitate the expansion of tele-interventions to enhance other competencies in children with DLD and include a broader population with different medical conditions. Overall, this emotional competence tele-intervention, which can be used on pediatric populations, should be conducted as a participatory process involving children and their parents, with technology used to increase the convenience of the intervention, provided that efficacy is achieved. The findings show that using remote technology in home-based tele-interventions is effective, feasible, and well accepted. These interventions improve emotional skills in children with DLD and help support their parents.

Acknowledgments

The authors would like to thank the research team members and Chung Shan Medical University for their assistance, as well as the children and parents who participated in this study. This study was financially supported by the National Science and Technology Council of Taiwan (grants NSTC 108-2410-H-040-010-MY3 and NSTC 111-2410-H-182-036-MY4 to H-HL).

Conflicts of Interest

None declared.

Multimedia Appendix 1
Example of a social story video.
[PNG File , 348 KB - pediatrics_v8i1e60333_app1.png]

References

1. American Psychiatric Publication. Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Washington, DC: American Psychiatric Association; 2013.
2. Bishop DV, Snowling MJ, Thompson PA, Greenhalgh T, The CATALISE-2 Consortium. Phase 2 of CATALISE: a multinational and multidisciplinary Delphi consensus study of problems with language development: Terminology. J Child Psychol Psychiatry 2017 Oct;58(10):1068-1080 [FREE Full text] [doi: 10.1111/jcpp.12721] [Medline: 28369935]
3. Bishop DV, Snowling MJ, Thompson PA, Greenhalgh T, CATALISE Consortium. CATALISE: a multinational and multidisciplinary Delphi consensus study. Identifying language impairments in children. PLoS One 2016;11(7):e0158753 [FREE Full text] [doi: 10.1371/journal.pone.0158753] [Medline: 27392128]
4. Samson AC, van den Bedem NP, Dukes D, Rieffe C. Positive aspects of emotional competence in preventing internalizing symptoms in children with and without developmental language disorder: a longitudinal approach. J Autism Dev Disord 2020 Apr;50(4):1159-1171 [FREE Full text] [doi: 10.1007/s10803-019-04336-y] [Medline: 31907729]
5. Spackman MP, Fujiki M, Brinton B. Understanding emotions in context: the effects of language impairment on children's ability to infer emotional reactions. Int J Lang Commun Disord 2006;41(2):173-188. [doi: 10.1080/13682820500224091] [Medline: 16546894]
6. Bahn D, Vesker M, Schwarzer G, Kauschke C. A multimodal comparison of emotion categorization abilities in children with developmental language disorder. J Speech Lang Hear Res 2021 Mar 17;64(3):993-1007. [doi: 10.1044/2020_jslhr-20-00413]
7. Aznar A, Tenenbaum HR. Spanish parents' emotion talk and their children's understanding of emotion. Front Psychol 2013;4:670 [FREE Full text] [doi: 10.3389/fpsyg.2013.00670] [Medline: 24069016]

XSL•FO
RenderX

8. Brinton B, Fujiki M, Hurst NQ, Jones ER, Spackman MP. The ability of children with language impairment to dissemble emotions in hypothetical scenarios and natural situations. Lang Speech Hear Serv Sch 2015 Oct;46(4):325-336. [doi: 10.1044/2015_lshss-14-0096]
9. Rieffe C, Dirks E, van Vlerken W, Veiga G. The empathic mind in children with communication impairments: the case of children who are deaf or hard of hearing (DHH); children with an autism spectrum disorder (ASD); and children with specic language impairments (SLI). In: Theory of Mind Development in Context. Milton Park, UK: Routledge; 2016.
10. Beck L, Kumschick IR, Eid M, Klann-Delius G. Relationship between language competence and emotional competence in middle childhood. Emotion 2012 Jun;12(3):503-514. [doi: 10.1037/a0026320] [Medline: 22148995]
11. Grau-Husarikova E, Sánchez Pedroche A, Mumbardó-Adam C, Sanz-Torrent M. How language affects social cognition and emotional competence in typical and atypical development: a systematic review. Int J Lang Commun Disord 2024 Apr 03;59(5):1788-1816. [doi: 10.1111/1460-6984.13032] [Medline: 38568167]
12. Yuill N, Little S. Thinking or feeling? An exploratory study of maternal scaffolding, child mental state talk, and emotion understanding in language-impaired and typically developing school-aged children. Br J Educ Psychol 2018 Jun 06;88(2):261-283. [doi: 10.1111/bjep.12194] [Medline: 28984350]
13. Salmon K, O'Kearney R, Reese E, Fortune CA. The role of language skill in child psychopathology: implications for intervention in the early years. Clin Child Fam Psychol Rev 2016 Dec 27;19(4):352-367. [doi: 10.1007/s10567-016-0214-1] [Medline: 27678011]
14. Kidwell SL, Young ME, Hinkle LD, Ratliff AD, Marcum ME, Martin CN. Emotional competence and behavior problems: differences across Preschool Assessment of Attachment classifications. Clin Child Psychol Psychiatry 2010 Jul;15(3):391-406. [doi: 10.1177/1359104510367589] [Medline: 20603426]
15. van den Bedem NP, Dockrell JE, van Alphen PM, Kalicharan SV, Rieffe C. Victimization, bullying, and emotional competence: longitudinal associations in (pre)adolescents with and without developmental language disorder. J Speech Lang Hear Res 2018 Aug 08;61(8):2028-2044. [doi: 10.1044/2018_jslhr-l-17-0429]
16. Chen HJ, Ko MHJ, Li ST, Chiu NC, Hung KL. Prevalence of preschool children developmental disabilities in northeastern Taiwan - screening with Taipei City Developmental Screening Checklist for Preschoolers, 2nd Version. J Formos Med Assoc 2020 Jul;119(7):1174-1179 [FREE Full text] [doi: 10.1016/j.jfma.2020.02.001] [Medline: 32089374]
17. Wu S, Zhao J, de Villiers J, Liu XL, Rolfhus E, Sun X, et al. Prevalence, co-occurring difficulties, and risk factors of developmental language disorder: first evidence for Mandarin-speaking children in a population-based study. Lancet Reg Health West Pac 2023 May;34:100713 [FREE Full text] [doi: 10.1016/j.lanwpc.2023.100713] [Medline: 37283967]
18. Sheng L, Yu J, Su P, Wang D, Lu TH, Shen L, et al. Developmental language disorder in Chinese children: a systematic review of research from 1997 to 2022. Brain Lang 2023 Jun;241:105268. [doi: 10.1016/j.bandl.2023.105268] [Medline: 37156064]
19. Fong R, Tsai CF, Yiu OY. The implementation of telepractice in speech language pathology in Hong Kong during the COVID-19 pandemic. Telemed J E Health 2021 Jan 01;27(1):30-38. [doi: 10.1089/tmj.2020.0223] [Medline: 32667859]
20. Lai DC, Tseng YC, Guo HR. Characteristics of young children with developmental delays and their trends over 14 years in Taiwan: a population-based nationwide study. BMJ Open 2018 May 08;8(5):e020994 [FREE Full text] [doi: 10.1136/bmjopen-2017-020994] [Medline: 29739783]
21. Test DW, Richter S, Knight V, Spooner F. A comprehensive review and meta-analysis of the social stories literature. Focus Autism Other Dev Disabl 2010 Jan 12;26(1):49-62. [doi: 10.1177/1088357609351573]
22. Leaf JB, Oppenheim-Leaf ML, Leaf RB, Taubman M, McEachin J, Parker T, et al. What is the proof? A methodological review of studies that have utilized social stories. Educ Train Autism Dev Disabil 2015 Jun;50(2):127-141.
23. Wahman CL, Pustejovsky JE, Ostrosky MM, Santos RM. Examining the effects of social stories™ on challenging behavior and prosocial skills in young children: a systematic review and meta-analysis. Top Early Child Spec Educ 2019 Aug 02;41(4):267-279. [doi: 10.1177/0271121419855692]
24. O'Connor KM, Hayes B. A real-world application of social stories as an intervention for children with communication and behaviour difficulties. Emot Behav Diffic 2019 Jun 02;24(4):323-338. [doi: 10.1080/13632752.2019.1625246]
25. Dessai RD. Effectiveness of social stories in children with semantic pragmatic disorder. Adv Life Sci Technol 2012;3:13-19 [FREE Full text]
26. Schneider N, Goldstein H. Social stories™ improve the on-task behavior of children with language impairment. J Early Interv 2009 Jul 07;31(3):250-264. [doi: 10.1177/1053815109339564]
27. Bernad-Ripoll S. Using a self-as-model video combined with social stories™ to help a child with Asperger syndrome understand emotions. Focus Autism Other Dev Disabl 2007 May 01;22(2):100-106. [doi: 10.1177/10883576070220020101]
28. Hoemann K, Xu F, Barrett LF. Emotion words, emotion concepts, and emotional development in children: a constructionist hypothesis. Dev Psychol 2019 Sep;55(9):1830-1849 [FREE Full text] [doi: 10.1037/dev0000686] [Medline: 31464489]
29. Zimmerman KN, Ledford JR, Gagnon KL, Martin JL. Social stories and visual supports interventions for students at risk for emotional and behavioral disorders. Behav Disord 2019 Sep 14;45(4):207-223. [doi: 10.1177/0198742919874050]
30. Wellman HM, Peterson CC. Deafness, thought bubbles, and theory-of-mind development. Dev Psychol 2013 Dec;49(12):2357-2367 [FREE Full text] [doi: 10.1037/a0032419] [Medline: 23544856]

XSL•FO
RenderX

31. Paynter J, Peterson CC. Further evidence of benefits of thought-bubble training for theory of mind development in children with autism spectrum disorders. Res Autism Spectr Disord 2013 Feb;7(2):344-348. [doi: 10.1016/j.rasd.2012.10.001]
32. Blair C, Diamond A. Biological processes in prevention and intervention: the promotion of self-regulation as a means of preventing school failure. Dev Psychopathol 2008 Jul 07;20(3):899-911. [doi: 10.1017/s0954579408000436]
33. Raver C. Emotions matter: making the case for the role of young children's emotional development for early school readiness. Soc Policy Report 2002 Sep;16(3):1-20. [doi: 10.1002/j.2379-3988.2002.tb00041.x]
34. Castilla-Earls A, Bedore L, Rojas R, Fabiano-Smith L, Pruitt-Lord S, Restrepo MA, et al. Beyond scores: using converging evidence to determine speech and language services eligibility for dual language learners. Am J Speech Lang Pathol 2020 Aug 04;29(3):1116-1132. [doi: 10.1044/2020_ajslp-19-00179]
35. Chen CI, Chen RH. Wechsler Preschool and Primary Intelligence Acale -Fourth Edition (Mandarin-Chinese version): Technical Manual. Taipei, Taiwan: Chinese Behavioral Science Corporation; 2013.
36. Lin BG, Huang YC, Huang GC, Hsuan CH. Child Language Disorder Scale-Revised (Preschool Version): Administration Manual. Taipei, Taiwan: Ministry of Education; 2008.
37. Grazzani I, Ornaghi V. How do use and comprehension of mental-state language relate to theory of mind in middle childhood? Cogn Dev 2012 Apr;27(2):99-111. [doi: 10.1016/j.cogdev.2012.03.002]
38. Sturrock A, Freed J. Preliminary data on the development of emotion vocabulary in typically developing children (5-13 years) using an experimental psycholinguistic measure. Front Psychol 2022 Jan 31;13:982676 [FREE Full text] [doi: 10.3389/fpsyg.2022.982676] [Medline: 36798644]
39. Grazzani I, Ornaghi V, Riva Crugnola C. Emotion comprehension and attachment: a conversational intervention with school-aged children. Eur Rev Appl Psychol 2015 Nov;65(6):267-274. [doi: 10.1016/j.erap.2015.10.004]
40. Grazzani IG, Ornaghi V, Piralli F. Theory of mind and children's comprehension of psychological lexicon: preliminary data from the validation of Test of Emotional Lexicon (TLE). Psicologia Clinica Dello Sviluppo 2011(1/2011):257-266. [doi: 10.1449/34606]
41. Cohen J. Statistical Power Analysis for the Behavioral Sciences. Cambridge, MA: Academic Press; 1969.
42. Verma JP, Verma P. Determining sample size in general linear models. In: Determining Sample Size and Power in Research Studies. Singapore, Singapore: Springer; 2020.
43. Letourneau NL, Duffett-Leger L, Levac L, Watson B, Young-Morris C. Socioeconomic status and child development: a meta-analysis. J Emot Behav Disord 2011 Dec 15;21(3):211-224. [doi: 10.1177/1063426611421007]
44. Streubel B, Gunzenhauser C, Grosse G, Saalbach H. Emotion-specific vocabulary and its contribution to emotion understanding in 4- to 9-year-old children. J Exp Child Psychol 2020 May;193:104790. [doi: 10.1016/j.jecp.2019.104790] [Medline: 31991263]
45. Causadias JM. A roadmap for the integration of culture into developmental psychopathology. Dev Psychopathol 2013 Dec 17;25(4pt2):1375-1398. [doi: 10.1017/s0954579413000679]
46. Bishop DV. Why is it so hard to reach agreement on terminology? The case of developmental language disorder (DLD). Int J Lang Commun Disord 2017 Nov 17;52(6):671-680 [FREE Full text] [doi: 10.1111/1460-6984.12335] [Medline: 28714100]
47. Ziegenfusz S, Paynter J, Flückiger B, Westerveld MF. A systematic review of the academic achievement of primary and secondary school-aged students with developmental language disorder. Autism Dev Lang Impair 2022 Jun 03;7:23969415221099397 [FREE Full text] [doi: 10.1177/23969415221099397] [Medline: 36382072]
48. Black MM, Walker SP, Fernald LC, Andersen CT, DiGirolamo AM, Lu C, et al. Early childhood development coming of age: science through the life course. The Lancet 2017 Jan;389(10064):77-90. [doi: 10.1016/s0140-6736(16)31389-7]
49. Britto PR, Lye SJ, Proulx K, Yousafzai AK, Matthews SG, Vaivada T, et al. Nurturing care: promoting early childhood development. The Lancet 2017 Jan;389(10064):91-102. [doi: 10.1016/s0140-6736(16)31390-3]
50. Guyer AE, Pérez-Edgar K, Crone EA. Opportunities for neurodevelopmental plasticity from infancy through early adulthood. Child Dev 2018 May;89(3):687-697 [FREE Full text] [doi: 10.1111/cdev.13073] [Medline: 29664997]
51. Causadias JM, Cicchetti D. Cultural development and psychopathology. Dev Psychopathol 2018 Nov 19;30(5):1549-1555. [doi: 10.1017/s0954579418001220]
52. Ryou HW, Lee MJ, Kim JK, Choe MS. Inadequate post-hoc statistical power analysis in Journal of the Korean Society of Emergency Medicine. J Korean Soc Emerg Med 2013 Aug;24(4):338-345.
53. Zvoch K. The use of piecewise growth models to estimate learning trajectories and RtI instructional effects in a comparative interrupted time-series design. Elementary School J 2016 Jun;116(4):699-720. [doi: 10.1086/686304]
54. Adrian JE, Clemente RA, Villanueva L, Rieffe C. Parent-child picture-book reading, mothers' mental state language and children's theory of mind. J Child Lang 2005 Aug 06;32(3):673-686. [doi: 10.1017/s0305000905006963] [Medline: 16220639]
55. Frizelle P, McKean C, Eadie P, Ebbels S, Fricke S, Justice LM, et al. Editorial perspective: maximising the benefits of intervention research for children and young people with developmental language disorder (DLD) - a call for international consensus on standards of reporting in intervention studies for children with and at risk for DLD. J Child Psychol Psychiatry 2023 Mar 20;64(3):474-479 [FREE Full text] [doi: 10.1111/jcpp.13694] [Medline: 36127873]

XSL•FO
RenderX

56. Kavussanu M, Barkoukis V, Hurst P, Yukhymenko-Lescroart M, Skoufa L, Chirico A, et al. A psychological intervention reduces doping likelihood in British and Greek athletes: a cluster randomized controlled trial. Psychol Sport Exerc 2022 Jul;61:102099. [doi: 10.1016/j.psychsport.2021.102099]
57. Blanton M, Stroud R, Stephens A, Gardiner AM, Stylianou DA, Knuth E, et al. Does early algebra matter? The effectiveness of an early algebra intervention in grades 3 to 5. Am Educ Res J 2019 Mar 10;56(5):1930-1972. [doi: 10.3102/0002831219832301]
58. Raudenbush S, Bryk A, Cheong Y, Congdon R, du Toit M. HLM 7: Hierarchical Linear and Nonlinear Modeling. Lincolnwood, IL: Scientific Software International; 2011.
59. Rhoads C. Coherent power analysis in multilevel studies using parameters from surveys. J Educ Behav Stat 2016 Nov 10;42(2):166-194. [doi: 10.3102/1076998616675607]
60. Chen CC, Barnhart HX. Comparison of ICC and CCC for assessing agreement for data without and with replications. Comput Stat Data Anal 2008 Dec;53(2):554-564. [doi: 10.1016/j.csda.2008.09.026]
61. Ise E, Schröder S, Breuer D, Döpfner M. Parent-child inpatient treatment for children with behavioural and emotional disorders: a multilevel analysis of within-subjects effects. BMC Psychiatry 2015 Nov 16;15(1):288 [FREE Full text] [doi: 10.1186/s12888-015-0675-7] [Medline: 26573683]
62. Aarts S, van den Akker M, Winkens B. The importance of effect sizes. Eur J Gen Pract 2014 Mar 30;20(1):61-64 [FREE Full text] [doi: 10.3109/13814788.2013.818655] [Medline: 23992128]
63. Zhang Z, Yuan KH. Practical Statistical Power Analysis using WebPower and R. Granger, IN: ISDSA Press; 2018.
64. Grosse G, Streubel B, Gunzenhauser C, Saalbach H. Let's talk about emotions: the development of children's emotion vocabulary from 4 to 11 years of age. Affect Sci 2021 Jun;2(2):150-162 [FREE Full text] [doi: 10.1007/s42761-021-00040-2] [Medline: 36043167]
65. De Koning BB, van der Schoot M. Becoming part of the story! Refueling the interest in visualization strategies for reading comprehension. Educ Psychol Rev 2013 Apr 12;25(2):261-287. [doi: 10.1007/s10648-013-9222-6]
66. Brinton B, Fujiki M. Emotion talk: helping caregivers facilitate emotion understanding and emotion regulation. Top Lang Disord 2011;31(3):262-272. [doi: 10.1097/TLD.0b013e318227bcaa]
67. Burns MK, Codding RS, Boice CH, Lukito G. Meta-analysis of acquisition and fluency math interventions with instructional and frustration level skills: evidence for a skill-by-treatment interaction. School Psychol Rev 2019 Dec 27;39(1):69-83. [doi: 10.1080/02796015.2010.12087791]
68. Bell ML, Whitehead AL, Julious SA. Guidance for using pilot studies to inform the design of intervention trials with continuous outcomes. Clin Epidemiol 2018 Jan;Volume 10:153-157. [doi: 10.2147/clep.s146397]
69. Teresi JA, Yu X, Stewart AL, Hays RD. Guidelines for designing and evaluating feasibility pilot studies. Med Care 2022 Jan 01;60(1):95-103 [FREE Full text] [doi: 10.1097/MLR.0000000000001664] [Medline: 34812790]
70. Keys EM, Norris JM, Cameron EE, Bright KS, Tomfohr-Madsen LM, Benzies KM. Recruitment and retention of fathers with young children in early childhood health intervention research: a systematic review and meta-analysis protocol. Syst Rev 2019 Dec 01;8(1):300 [FREE Full text] [doi: 10.1186/s13643-019-1215-1] [Medline: 31787109]
71. Liverpool S, Mota CP, Sales CM, Čuš A, Carletto S, Hancheva C, et al. Engaging children and young people in digital mental health interventions: systematic review of modes of delivery, facilitators, and barriers. J Med Internet Res 2020 Jun 23;22(6):e16317 [FREE Full text] [doi: 10.2196/16317] [Medline: 32442160]
72. Gartlehner G, Hansen RA, Nissman D, Lohr KN, Carey TS. A simple and valid tool distinguished efficacy from effectiveness studies. J Clin Epidemiol 2006 Oct;59(10):1040-1048. [doi: 10.1016/j.jclinepi.2006.01.011] [Medline: 16980143]
73. Chorpita BF, Daleiden EL, Ebesutani C, Young J, Becker KD, Nakamura BJ, et al. Evidence‐based treatments for children and adolescents: an updated review of indicators of efficacy and effectiveness. Clin Psychol Sci Pract 2011 Jun;18(2):154-172. [doi: 10.1111/j.1468-2850.2011.01247.x]
74. Frizelle P, McGill M. Prologue to the forum: speech and language tele-intervention: the future is now. Lang Speech Hear Serv Sch 2022 Apr 11;53(2):233-236. [doi: 10.1044/2022_lshss-21-00188]
75. Nelson LH, Rudge AM, Dawson P, Culianos D, Stredler-Brown A. Provider perspectives in serving children who are deaf or hard of hearing and their families using tele-intervention. J Early Hear Detect Interv 2022;7(2):22-32.
76. Rudge AM, Brooks BM, Stredler-Brown A. Working with families of young children who are deaf or hard of hearing through tele-intervention. J Early Hear Detect Interv 2022;7(2):2-8 [FREE Full text]
77. Lentejas KG, Lam JH, Tong SX. Professional training and therapeutic resources needed for the adoption of telepractice in the Philippines. Commun Disord Q 2022 Aug 29;44(4):257-265. [doi: 10.1177/15257401221119969]
78. Lowman JJ, Kleinert HL. Adoption of telepractice for speech-language services: a statewide perspective. Rural Special Educ Q 2017 Jun 20;36(2):92-100. [doi: 10.1177/8756870517712490]
79. Fairweather GC, Lincoln MA, Ramsden R. Speech-language pathology teletherapy in rural and remote educational settings: decreasing service inequities. Int J Speech Lang Pathol 2016 Dec 04;18(6):592-602. [doi: 10.3109/17549507.2016.1143973] [Medline: 27063692]
80. Wei WJ. Development and evaluation of an emotional lexicon system for young children. Microsyst Technol 2019 Jun 22;27(4):1535-1544. [doi: 10.1007/s00542-019-04425-z]

XSL•FO
RenderX

81. Chan M, Williams AI, Teng YP, Zhou Q. Links between parent-child emotion talk and preschoolers' socioemotional behaviors in Chinese-heritage families. Early Educ Dev 2022 Mar 09;34(2):366-386. [doi: 10.1080/10409289.2022.2048347]
82. Ogren M, Sandhofer CM. Emotion words in early childhood: a language transcript analysis. Cogn Dev 2021;60:101122 [FREE Full text] [doi: 10.1016/j.cogdev.2021.101122] [Medline: 34690421]

Abbreviations

ANCOVA: analysis of covariance
ASD: autism spectrum disorder
BET: basic emotional term
CET: complex emotional term
CLDS-R: Child Language Disorder Scale–Revised
DLD: developmental language disorder
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
ELT: Emotional Lexicon Test
ICC: intraclass correlation coefficient
NVI: Nonverbal Index
SSTI: social story tele-intervention
TLD: typical language development
VAI: Vocabulary Acquisition Index
VCI: Verbal Comprehension Index

Edited by S Badawy; submitted 07.05.24; peer-reviewed by YC Chen, J Hin Yan Lam, M Bryłka; comments to author 29.07.24; revised version received 02.10.24; accepted 26.11.24; published 11.02.25.

Please cite as:
Lu HH, Liang SY, Huang YC
Efficacy, Feasibility, and Acceptability of an Emotional Competence Tele-Intervention for Mandarin-Speaking Children Aged 5 to 7 Years With Developmental Language Disorder: Pilot Study With an Interrupted Time-Series Design
JMIR Pediatr Parent 2025;8:e60333
URL: https://pediatrics.jmir.org/2025/1/e60333
doi:10.2196/60333
PMID:

©Hsin-Hui Lu, Shih-Yuan Liang, Yi-Chia Huang. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 11.02.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Original Paper

Evaluating the Preliminary Efficacy of the TRUST Intervention on Alone-Time and Communication During Well-Adolescent Visits: Quasi-Experimental Study

Jyu-Lin Chen[1*], MSN, PhD; Marissa Raymond-Flesch[2*], MD, MPH; Thomas J Hoffmann[3], PhD; Chen-Xi Lin[4], PhD; Ling Xu[5], BSN; Kimberly A Koester[6], PhD

[1]Department of Family Health Care Nursing, School of Nursing, University of California, San Francisco, San Francisco, United States

[2]Division of Adolescent and Young Adult Medicine, Department of Pediatrics and the Philip R Lee Institute for Health Policy Studies, University of California, San Francisco, San Francisco, CA, United States

[3]Department of Biostatistics and Epidemiology, University of California, San Francisco, San Francisco, CA, United States

[4]School of Nursing, National Defense Medical Center, Taipei, Taiwan

[5]School of Nursing, University of California, San Francisco, San Francisco, CA, United States

[6]Division of Prevention Science, Department of Medicine, University of California, San Francisco, San Francisco, CA, United States

[*]these authors contributed equally

Corresponding Author:
Jyu-Lin Chen, MSN, PhD
Department of Family Health Care Nursing
School of Nursing
University of California, San Francisco
490 Illinois street
91P
San Francisco, 94143-0606
United States
Phone: 1 4155026015
Email: jyu-lin.chen@ucsf.edu

Abstract

Background: Alone time with health care providers is critical for adolescents, and several professional organizations recommend it. Alone time with providers promotes better utilization of health services, empowers adolescents to manage their health, and facilitates discussions on sensitive issues. However, only 40% of adolescents have private conversations with clinicians during visits. The advancement of mobile health technology provides an excellent opportunity to deliver effective interventions to promote adolescent-provider alone time with adolescents, parents, and providers.

Objective: This pilot study aims to explore the preliminary efficacy of a technology-based intervention designed to increase alone time with providers during well-adolescent visits and its impact on trustworthiness, parent-adolescent communication, sexual risk communication, parental monitoring, and parental support before and after the intervention.

Methods: A pre- and postintervention design was used. Participants were recruited through local clinics. After obtaining consent, participants accessed a study website to complete a baseline survey, independently interact with 4 educational modules on a website or cellphone, and complete a post-test survey 1 month after their well-adolescent visits. The surveys assessed alone time with providers, trustworthiness, parent-adolescent communication, sexual risk communication, parental monitoring, and parental support. Mixed model analysis and effect sizes were used to evaluate changes in these outcomes from pre- to postintervention.

Results: Thirty-two dyads (38 adolescents and 32 mothers) participated in this pilot study. About 86% (n=33) of adolescents and 87% (n=28) of mothers completed the pre- and post-test assessments and the intervention. This study found a trend toward an increase in alone time from 81.6% to 84.4%, albeit not statistically significant. Adolescents initiating alone time with providers rose from 6.45% (n=2) to 18.5% (n=5). Over 90% (n=26) of adolescents reported feeling comfortable in one-on-one interactions with providers postintervention. Mixed model analysis revealed significant improvements among adolescents in parental monitoring (z=2.93, P<.001), sexual risk communication (z=3.11, P<.001), parent-adolescent communication (z=3.11, P<.001), open family communication (z=2.00, P=.04), and parental support (z=2.87, P<.001). For mothers, significant improvements were found in parental monitoring (z=2.45, P<.001) and problem family communication (z=2.24, P=.03).

XSL•FO
RenderX

Conclusions: This pilot study demonstrates promising results regarding the preliminary efficacy of a technology-based intervention to increase alone time with providers during well-adolescent visits and to enhance communication and parenting practices. Improving access to alone time and strengthening communication between parents and adolescents facilitates discussions about sensitive topics, including parental monitoring, sexual and reproductive health, and may strengthen overall satisfaction with health care.

Trial Registration: ClinicalTrials.gov NCT07064070; https://clinicaltrials.gov/study/NCT07064070

(JMIR Pediatr Parent 2025;8:e71433) doi:10.2196/71433

KEYWORDS

alone time; technology-based intervention; well-child visits; parent-adolescent communication; sexual and reproductive health; parental monitoring; parental support

Introduction

Background

Despite notable improvements in several critical sexual and reproductive health (SRH) protective behaviors in recent years, young people remain considerably vulnerable to sexually transmitted infections (STIs), such as HIV, and unintended pregnancies [1,2]. Individuals aged 15-24 years account for 50% of all newly diagnosed STIs in the United States each year [3]. Adolescents face an elevated risk for STIs due to various factors, such as underutilization of SRH services, inadequate access to sexual health information, medical mistrust, privacy and confidentiality concerns, lack of awareness about their rights to confidential SRH services, and insufficient alone time with health care providers [3-6].

Alone time with health care providers promotes better utilization of health services and empowers adolescents to manage their health, express their emerging autonomy, and discuss sensitive health issues. The American Academy of Pediatrics and the Society for Adolescent Health and Medicine emphasize the importance of providing confidential health services and adolescent-provider alone time during well-adolescent visits [7,8]. Adolescents are more likely to seek health care and discuss sensitive topics when privacy is assured [9,10]. However, a recent medical expenditure panel survey analysis revealed that only 40% of adolescents had alone time with their clinicians during their last visit, and this rate was even lower among adolescents from low-income families, those without insurance, and those of Latinx ethnicity [11]. Another study published in 2022 reported that alone time increases adolescents' comfort discussing sensitive topics, yet only 31% of adolescents reported experiencing alone time with a provider [12]. A separate study, also published in 2022, showed that some clinics reported rates of adolescent-provider alone as low as 43% [13]. Despite this being a critical mechanism for improving confidential care, few intervention studies have explicitly focused on increasing alone time during well-adolescent visits [14].

Parents play a critical role in adolescents' health, including promoting alone time with health care providers. Understanding parents' perspectives on confidential adolescent health care is essential, and it can inform interventions to enhance the uptake of these services. A study found that 58% of parents believe adolescents should have alone time with their clinician [15]. Another study showed that while 89% of parents agreed that adolescents should be able to speak privately with their providers, 61% still preferred to be present in the examination room for the entire visit [6], When parents understand the role of alone time in adolescent health care they may advocate for their adolescent to have access to it, in the same way they might request vaccines or any other evidence-based preventative health service [9,10].

Research suggests that adolescents are accompanied to medical visits by their mothers in the majority of cases; therefore, it is essential to engage them in the intervention. Medical care for adolescents involves a triad of stakeholders, including adolescent health care providers, adolescent patients, and their parents [16]. It is essential to engage parents, especially mothers, in supporting their children's access to evidence-based health care and encourage alone time. Despite strong recommendations from professional organizations, few interventions focus on increasing alone time to adolescents. Research is needed to examine strategies to effectively increase alone time with health care providers during well-adolescent visits to improve health outcomes generally, as well as SRH outcomes, specifically.

Many parent-adolescent communication interventions focusing on sexual and reproductive health have shown improvements in parent-child communication and parent comfort with communication [17-20], with some resulting in reduced sexual risk behaviors among adolescents [18]. However, most interventions are resource-intensive and lack the feasibility to scale up in the real world. Research indicates that tailored, collaboratively developed communication messages delivered by optimal messengers (eg, peers and trusted adults) through youth-friendly communication channels can significantly encourage protective behaviors (eg, abstinence, consistent and correct condom use, and seeking confidential SRH services) among youth [21,22]. Technology-based interventions provide a promising model for delivering SRH messages and resources that can be scaled and accessed easily and have been proven to promote healthy behavior and can typically be easily accessed [23-25]. A recent web-based program for parents revealed that this type of intervention improved parent-adolescent communication quality and promoted a more positive attitude toward sexual health communication [26]. Another technology-based intervention study for adolescents also found that adolescents reported improvements in intentions for sexual communication, condom use, and self-efficacy to practice safer sex [27]. However, SRH technology-based interventions delivered to adolescents and their parents within the context of

XSL•FO
RenderX

primary care visits are limited, and none have focused on increasing alone time with providers.

Parents, especially mothers, can play a crucial role in guiding adolescents toward confidential SRH services and supporting effective communication with health care professionals. Developmentally and culturally tailored interventions that build parent and adolescent self-efficacy related to communicating about SRH, alone time, and parental monitoring are needed. In this study, we developed a technology-based intervention to increase alone time during well-adolescent visits and to promote alone time, communication, and parental monitoring among adolescents and their mothers to address this gap in the literature.

Theoretical Framework

The social-ecological model (SEM) was used to guide our study. The SEM emphasizes multiple levels of influence on the determinants of health. The levels include individuals (adolescents), interpersonal (mothers), organization (primary care clinics), community (cultural, values, and norms), and organizational (national guidelines) [28,29]. Given that health behaviors both shape and are shaped by the social environment, including interpersonal and organizational levels, the proposed intervention, technology-based resources to increase uptake of sexual health services for teens (TRUST), addressed adolescent's knowledge, attitude, and skill in navigating sexual health and SRH services, specifically accounting for interpersonal and social influences. The intervention also provided skill-building strategies for adolescents to advocate for alone time with their providers. Similarly, mothers received interactive advice about how to improve communication with adolescents related to SRH and parental monitoring. In addition to the SEM, this study considered the developmental stage of adolescents. Adolescence is a period of rapid physical, social, and cognitive development [30,31]. This dynamic period requires evolving approaches to sexual and reproductive health counseling. Because cognitive and physical development are different based on age, the TRUST intervention was tailored to the development stage of the adolescents enrolled.

Research Objective

The aim of this pilot study was to evaluate the preliminary efficacy of a technology-based intervention designed to increase adolescents' alone time with a health care provider during well-adolescent visits. The study also assessed secondary outcomes, including adolescent-mother trust, parent-adolescent communication, sexual risk communication, parental monitoring, and mother support before and after the intervention.

Methods

Ethical Considerations

The study was approved by the Institutional Review Board or Ethics Committee of the University of California, San Francisco (20-32013) on November 3, 2021. The clinical trial is registered on ClinicalTrials.gov (NCT07064070).

Study Design and Setting

The TRUST study used a pre-and post-test design to evaluate the preliminary efficacy of the TRUST intervention in increasing provider and adolescent alone time and improving parent-adolescent communication. All study procedures were carried out in the San Francisco Bay Area and included adolescent and pediatric clinical partners serving low-income and many non-English speaking patient populations, including families of Latinx and Chinese descent.

Inclusion Criteria

Adolescents could be included in the study if they were aged between 11 and 17 years, able to read and speak English, had access to the Internet (via phone or computer), and had a well-adolescent visit scheduled in the next 6 months. Mothers could be included if they had an adolescent enrolled in this study; spoke and read English, Cantonese, Mandarin, or Spanish; and had access to the Internet.

Recruitment

Recruitment was conducted at 3 primary care sites in the San Francisco Bay Area. A research champion at each study clinic assisted with recruitment, including by posting flyers in the common areas and exam rooms. Champions identified eligible adolescents with an upcoming well-adolescent visit. The study team sent a formal letter via email inviting the eligible family to enroll in the study. The invitation included (1) a description of the TRUST study objectives (ie, to promote adolescent health outcomes by increasing adolescent use of alone time), (2) a description of the intervention, and (3) details about the duration of the study and data collection, risk and benefits of participation, and safeguards for confidentiality. Interested adolescents and their mothers responded to the study invitation by email, phone, or text, or by accessing a screening form on the TRUST study website. All information was offered in English, Spanish, and Mandarin Chinese. A follow-up phone call or text message was made to interested participants to explain the study in greater detail, answer any questions, and assess eligibility.

Study Procedures

After obtaining assent from adolescents and consent from mothers, they were directed to the study website, where they could log in to complete the baseline survey assessment. Adolescents and their mothers completed the pretest assessment via a Qualtrics survey between 1 and 3 months before the scheduled well-adolescent visit. After completing the pretest assessment, participants had access to 4 interactive TRUST modules. Adolescents and their mothers were asked to complete these modules before the well-adolescent visit. About 1 month after completing their well-adolescent visit, another Qualtrics survey link was sent to the study participants for post-test assessment.

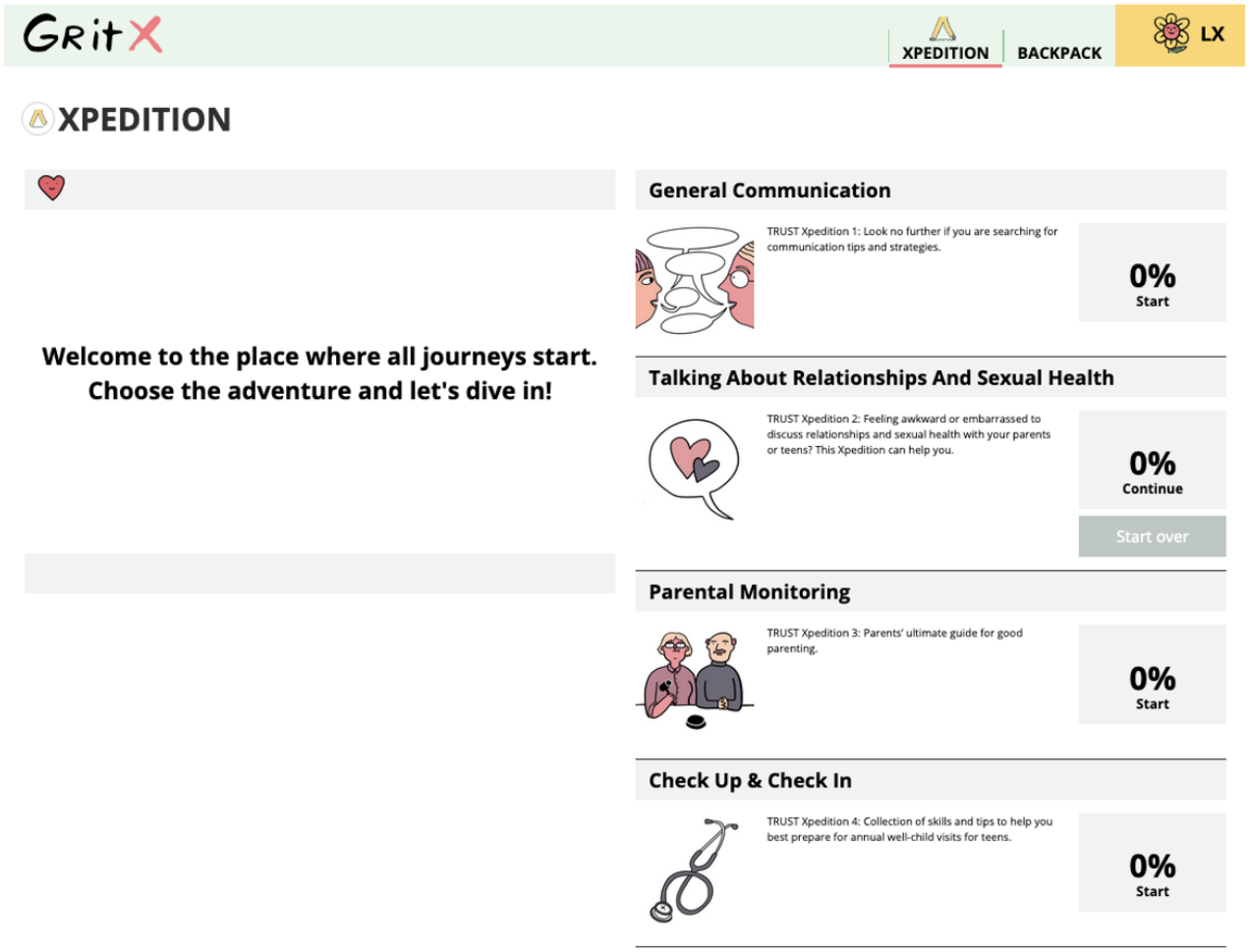
Intervention Description

The TRUST intervention includes interactive, evidence-based, culturally and developmentally appropriate modules to encourage adolescent alone time with a provider and improve parent-adolescent communication. It was hosted on the GritX website at the University of California, San Francisco [32]. Our modules were developed based on our work with the key stakeholders, including the youth advisory board, parent advisory board, and clinical partner advisory board (including

XSL•FO
RenderX

clinicians), and a review of the updated evidence [28]. The modules included: general communication, talking about relationships and sexual health, parental monitoring, and check-up and check-in (content focused on the importance of alone time). Modules were in English, Chinese, or Spanish (Figure 1).

Figure 1. Intervention modules.



Each interactive module consists of several key features and a roadmap: setting learning goals, assessment of knowledge and confidence, identifying learning topics, review of evidence-based guidelines and tips for the subject, opportunities for practicing skills, and a chance to save favorite information. Each module begins with learning goals and a simple assessment of knowledge on and confidence in the topic. For instance, participants were asked how much they knew about "why alone time between adolescents and health care providers is so important" and how confident they were to engage in "clear and respectful parent-adolescent communication." There is also a journal section where participants can write notes during their learning, and a virtual "backpack" where participants can store their favorite information. Virtual role-playing was used to engage participants in practicing different communication strategies. In addition, participants earned a badge after completing a module to encourage and motivate continued engagement. Each module took approximately 30-45 minutes to complete. Adolescents and their mothers could review and learn at their own pace and in the language of their choice (English, Chinese, or Spanish) using a smartphone or computer, and they could access resources via a password-protected website. If participants did not access a module within 2 weeks of enrolling in the study, a reminder text was sent to them. A detailed description of the intervention development has been published elsewhere [14].

Each participant received $20 after completing the baseline assessment, $20 after completing the well-adolescent visit, and $30 after completing the post-test assessment.

Measures

Adolescent Self-Reported Alone Time With Providers

To assess adolescents' alone time with their health care providers during well-adolescent visits, the research team used a specific item from the Young Adult Health Care Survey. The item asked, "Did you get a chance to speak with a doctor or other health provider privately during the last well-adolescent visit?" This question was clarified to mean one-on-one communication without parents or other individuals present in the room. The Young Adult Health Care Survey is a well-established survey that has demonstrated reliability and validity [33]. Participants also responded to who initiated the alone time with the primary care provider.

XSL•FO
RenderX

Measures of Trustworthiness

The construct of perceived trustworthiness was assessed using 3 items for adolescents and their mothers. The three items were as follows: (1) I can trust my mother/adolescent when we talk, (2) my mother/adolescent keeps her promises to me, and (3) my mother/adolescent is honest with me. Each item was rated on a 5-point Likert scale ranging from 1 (strongly agree) to 5 (strongly disagree). This scale allowed participants to express varying degrees of agreement or disagreement with each statement. The reliability and validity of these items are supported by previous research [34].

Parent-Adolescent Communication Scale

The parent-adolescent communication scale, developed by Olson (1985) [35], consists of 20 items that measure the quality of communication between adolescents and their parents. It is designed for both parents and adolescents to complete. Each item was rated on a 5-point Likert scale ranging from "strongly disagree" to "strongly agree," generating a total score and 2 subscale scores. The open family communication subscale reflects feelings of free expression and understanding in parent-adolescent interactions (eg, "When I ask questions, I get honest answers from my mother/father"). The problems in family communication subscale measures negative interaction patterns and hesitancy to disclose concerns (eg, "My mother/father tends to say things to me that would be better left unsaid"). Higher scores indicate better parent-adolescent communication. The parent-adolescent communication scale demonstrates good internal consistency [36,37].

Parent-Adolescent Sexual Risk Communication Scale III

The parent-adolescent sexual risk communication scale III, developed by Hutchinson [38], is an 8-item scale used to assess the extent of sexual risk communication between adolescents and their parents. The scale includes separate scales for adolescents to report communication with their mothers and fathers. In this study, we asked for communication with the mother only. Adolescents were asked to report how much information their mother communicated with them on a 5-point scale (1=none; 2=a little; 3=some; 4=a lot; and 5=extensive) and on the following topics between the ages of 10-18 years: birth control, sexually transmitted diseases (STDs), HIV/AIDS, condoms, how to protect yourself from HIV/AIDS, postponing or not having sex, peer pressure to have sex, and how to handle sexual pressure. The total scores range from 8 to 40, with higher scores indicating more extensive communication. Appropriate reliability and validity have been reported [38].

Parental Monitoring

This validated scale assesses the degree to which parents are informed about various aspects of their child's life [39]. This construct was measured using 9 questions that parents and adolescents answered on a 5-point Likert scale, ranging from 1 (no, never) to 5 (yes, almost always). Sample questions include, "Do your parents: know what you do during your free time? Know who you have as friends during your free time? Usually, know what type of homework you have? Know what you spend your money on?"

Parental Support (Mothers Only)

Mothers reported how often they support their child using a 3-item 4-point Likert scale (never to always). Sample items include, "How often do you let your child know you care about them?" and "How often do you listen to your child carefully?" Higher values indicate more supportive parenting. Adequate reliability has been reported [26].

Statistical Analysis

This pilot study aimed to explore the preliminary efficacy of the intervention. Descriptive statistics include the mean and proportion of participant demographic data and outcome variables. A mixed model analysis with intention to treat estimated the intervention's preliminary efficacy, controlling for age. This method allows us to use all available data, regardless of missing data. Six families with 2 adolescents were included in this study; family unit identification and individual unit identification were included as random effect parameters in the mixed model analyses. Effect sizes for pre- and postintervention outcome variables were assessed using the Cohen *d* index. Effect sizes were categorized as small (<0.20), medium (0.50), and large (>0.80). Statistical significance was determined with a *P* value set at <.05. All analyses were performed using Stata version 18.0.

Results

Sample Characteristics

Thirty-two dyads (38 adolescents and 32 mothers) participated in this study. The average age was 14.5 (SD 1.81) years and 49.06 (SD 7.9) years for adolescents and their mothers, respectively. Among the mothers, 10 out of 32 (31%) reported having a master's degree or higher, and 13 out of 32 (41%) had an annual household income greater than $120,001 (Table 1). Approximately 12 families identified themselves as European White (40%), 7 as Latinx (21.8%), and 13 as Asian (40.5%). Additionally, about 86% (n=33) of adolescents and 87% (n=28) of mothers completed the pre- and post-test assessments and the intervention (Table 2).

XSL•FO
RenderX

Table 1. Participant demographics.

Variable	Value
Age (years), mean (SD)	
Adolescents (n=38)	14.53 (1.81)
Mothers (n=32)	49.06 (7.83)
Occupation (mother), n (%)	
Administrative and office roles	7 (23)
Customer service	4 (13)
Education and training	4 (13)
Media and creative	2 (6)
Health care and therapy	3 (10)
Science and research	1 (3)
Business	5 (16)
Library clerk	1 (3)
Retired hairstylist	1 (3)
School crossing guard	1 (3)
Student	1 (3)
School bus driver	1 (3)
Annual household income, n (%)	
<$20,000	2 (6)
$20,000 to $80,000	10 (31)
$80,001 to $120,000	6 (19)
>$120,001	14 (44)
Education (mother), n (%)	
12th grade or below	6 (19)
Some college or vocational degree	3 (9)
Associate degree	3 (9)
Bachelor’s degree	9 (28)
Master’s degree or above	10 (31)
Refused	1 (3)

XSL•FO
RenderX

Table 2. Alone time reported by adolescents.

Variable	Baseline, n (%)	Follow-up, n (%)	Chi-square (*df*)	*P* value
Adolescent talks with a provider privately			0.10 (3)	.76
Yes	31 (82)	27 (84)		
No	7 (18)	5 (16)		
Initiated the alone time (adolescents)			2.02 (5)	.36
Provider	28 (90)	21 (78)		
Adolescent	2 (6)	5 (19)		
Mother	1 (3)	1 (4)		
How comfortable was it for you to be one-on-one with your provider			N/A[a]	N/A
Very comfortable	N/A	10 (36)		
Somewhat comfortable	N/A	16 (57)		
Somewhat uncomfortable	N/A	1 (4)		
Very uncomfortable	N/A	1 (4)		

[a]Not applicable.

Adolescent-Reported Alone Time and Comfort Level

In terms of alone time with providers, 27 out of 32 adolescents (84%) reported having alone time with the provider at their well-adolescent visit after the intervention, compared to 31 out of 38 (82%) at baseline (χ^2_3=.01, *P*=.76). The number of adolescents who initiated alone time with a provider increased from 2 out of 31 (6%) at baseline to 5 out of 27 (19%) at follow-up. The number of mothers who initiated alone time remained nearly the same: 1 out of 31 (3%) at baseline and 1 out of 27 (4%) at follow-up. Regarding adolescents' comfort levels in one-on-one interaction with the provider at follow-up, 16 out of 28 (57%) felt somewhat comfortable, and 10 out of 28 adolescents (36%) reported feeling very comfortable (Table 2).

Communication Outcome, Parental Monitoring, and Parental Support

Mixed model analysis controlling for age revealed significant improvements among adolescents in sexual risk communication (*z*=3.11, *P*<.001), parent-adolescent communication (*z*=3.11, *P*<.001), open family communication (*z*=2.00; *P*=.04), parental monitoring (*z*= 2.93, *P*<.001), and parental support (*z*=2.87, *P*<.001; Table 3). For mothers, significant improvements were found in parent-adolescent communication: problem family communication (*z*=2.24, *P*=.03) and parental monitoring (*z*=2.45, *P*<.001; Table 4).

XSL•FO
RenderX

Table 3. Mixed effects models results for adolescents.

Outcome	Coefficient (β)	Standard error	*z* score	*P* value	95% CI
Trustworthiness					
Time	0.61	0.39	1.54	.12	–0.16 to 1.37
Age	–0.17	0.17	–0.99	.32	–0.51 to 0.17
Parental monitoring					
Time	0.29	0.10	2.93	<.001	0.10 to 0.49
Age	–0.08	0.04	–2.10	.04	–0.16 to –0.01
Sexual risk communication					
Time	2.98	0.96	3.11	<.001	1.10 to 4.85
Age	0.76	0.69	1.09	.27	–0.60 to 2.12
Parent-adolescent communication					
Time	4.55	1.46	3.11	<.001	1.69 to 7.41
Age	–1.14	0.98	–1.16	.25	–3.06 to 0.78
Open family communication subscale					
Time	1.88	0.94	2.00	.04	0.04 to 3.73
Age	–0.80	0.58	–1.38	.17	–1.93 to 0.34
Problem family communication subscale					
Time	–0.41	0.94	–0.44	.66	–2.25 to 1.42
Age	–0.44	0.52	–0.85	.40	–1.47 to 0.58
Parental support					
Time	0.63	0.22	2.87	<.001	0.20 to 1.07
Age	–0.28	0.12	–2.28	.02	–0.52 to –0.04

XSL•FO
RenderX

Table 4. Mixed effects model results for mothers.

Outcome	Coefficient (β)	Standard error	*z* score	*P* value	95% CI
Trustworthiness					
Time	0.48	0.54	0.90	.37	–0.57 to 1.53
Age	–0.06	0.05	–1.28	.20	–0.15 to 0.03
Parental monitoring					
Time	0.46	0.13	3.45	<.001	0.20 to 0.72
Age	–0.01	0	–1.32	.19	–0.03 to 0.01
Parent-adolescent communication					
Time	2.80	2.00	1.40	.16	–1.12 to 6.72
Age	–0.23	0.22	–1.05	.30	–0.66 to 0.20
Open family communication subscale					
Time	–0.06	1.20	–0.05	>.99	–2.42 to 2.29
Age	–0.15	0.12	–1.24	.22	–0.37 to 0.08
Problem family communication subscale					
Time	2.64	1.18	2.24	.03	0.33 to 4.95
Age	–0.08	0.13	–0.66	.51	–0.34 to 0.17
Parental support					
Time	0.17	0.33	0.52	.60	–0.47 to 0.81
Age	–0.05	0.03	–1.85	.06	–0.10 to 0.00

Effect Size Analysis

A small effect was found for the alone time variable (Cramér V=0.05). The results indicated varying effect sizes on secondary outcomes based on the Cohen *d* index for pre- and post-tests. For adolescents, small effect sizes were found in trustworthiness, sexual risk communication, problem in the family communication subscale, parent-adolescent communication, and parental support total score. A medium effect size was observed in parental monitoring. For mothers, small effect sizes were found in several domains, including problem-free family communication, parent-adolescent communication total score, and parental support total score. A large effect size (Cohen *d*=1.05) was observed in parental monitoring (Table 5).

XSL•FO
RenderX

Table 5. Outcome data between baseline and follow-up.

Variable	Baseline (n=70)		Follow-up (n=59)		Effect size (Cohen *d*)[a]
	n	Mean (SD)	n	Mean (SD)	
Trustworthiness					
Adolescents	38	12.10 (2.31)	30	12.80 (2.10)	0.31
Mothers	31	12.87 (2.91)	27	13.33 (2.13)	0.18
Parental monitoring					
Adolescents	38	3.67 (0.57)	31	3.94 (0.51)	0.50
Mothers[b]	32	3.79 (0.48)	27	4.29 (0.47)	1.05
Sexual risk communication[a]					
Adolescents	37	17.86 (8.07)	31	20.48 (8.31)	0.32
Parent-Adolescent Communication					
Adolescents[b]	37	36.51 (7.83)	31	37.52 (6.04)	0.14
Mothers	31	37.81 (5.59)	27	38.26 (5.41)	0.08
Problem with family communication					
Adolescents	37	31.84 (6.64)	31	30.61 (5.72)	0.20
Mothers[b]	31	34.29 (5.42)	27	36.56 (6.14)	0.39
Open family communication					
Adolescents[b]	37	65.32 (12.43)	31	68.12 (10.61)	0.24
Mothers	31	72.10 (9.78)	27	74.81 (10.44)	0.27
Parental support					
Adolescents[b]	38	9.87 (1.66)	31	10.22 (1.48)	0.22
Mothers	32	10.28 (1.14)	27	10.63 (1.33)	0.28

[a]Small effect: Cohen *d*=0.2-0.49; medium effect: Cohen *d*=0.5-79; large effect: Cohen *d*=0.8-1.29; very large effect: Cohen *d*≥1.3.

[b]Significant at mixed model analysis.

Discussion

Principal Findings

This pilot study examined the preliminary efficacy of a technology-based intervention on alone time with a provider during well-adolescent visits by assessing trustworthiness, parent-adolescent communication, sexual risk communication, parental monitoring, and parental support before and after the intervention. We found an increase in reports of alone time with the provider at the last well-adolescent visit, increasing from 81.6% to 84.4%, although there was no statistical significance. We also found an improvement in the percentage of adolescents initiating alone time with a provider, which increased from 6.45% to 18.5%. Importantly, over 90% of adolescents reported feeling comfortable or very comfortable in one-on-one interactions with the provider after the intervention. In addition, this study revealed significant improvements in communication outcomes, parental monitoring, and parental support among adolescents. Small effect sizes were also noted in trustworthiness among adolescents. Significant improvements were also observed in parental monitoring and problem family communication among mothers. These findings suggest there is promise in using the technology-based TRUST intervention to improve adolescents' alone time at well-adolescent visits and improve parent-adolescent communication and parenting practices.

Empowering adolescents to have private conversations with health care providers is important because alone time during well-adolescent visits has been shown to facilitate discussions on sensitive health topics, including SRH, and ensure confidentiality in these matters [9,10,40]. Additionally, alone time with providers can enhance adolescents' satisfaction with their health care, which is crucial for ensuring continuity of care and better access to necessary health services [41]. Our pilot showed a particularly high level of reported alone time with primary care providers during well-adolescent visits at baseline, significantly surpassing the figures reported by Grilo et al [42], which ranged from 44% to 55% among nearly 2000 US youths. This suggests that our collaborating clinical sites adhere to professional recommendations to offer alone time. Despite this high baseline, we observed a 3% increase in alone time and a remarkable 12% increase in adolescents initiating alone time with their provider, suggesting the positive impact of the intervention. Although our intervention targeted adolescents and mothers, it may have indirectly influenced provider behavior by encouraging adolescent self-advocacy or maternal prompting.

XSL•FO
RenderX

In addition, while clinicians were not directly involved in accessing the intervention, we engaged them as an advisory group during its design phase to strengthen its impact. However, the factors driving provider-initiated alone time are complex and likely rooted in structural factors, clinic norms, and providers' own perspectives. Future studies should consider multilevel interventions that directly engage providers to enhance adolescent alone time during visits.

Our results reveal a low frequency of mother-initiated alone time, suggesting potential attitudinal or cultural influences. This underscores the importance of promoting the advocacy role of adolescents in requesting alone time. Future research should incorporate stronger parental components to better educate parents about the importance of encouraging adolescent-private time with health care providers.

In addition to the increase in alone time and the initiation of alone time by the adolescent, we also found improvements in various communication domains (parent and adolescent communication and SRH communication) and parenting areas (monitoring and support) reported by the adolescent after the intervention. Mothers reported an increase in parental monitoring and an increase in communicating about family problems. However, most observed effect sizes were small to medium. One possible explanation is the short interval between the intervention and follow-up, which may not allow sufficient time for meaningful changes to emerge in trust-building or established family communication patterns. Another possibility is that the brief, nonreinforced nature of the intervention may have limited its impact.

Strengthening communication skills between mothers and adolescents is particularly important. Improved parent-adolescent communication may enhance adolescents' ability to engage in appropriate SRH behaviors, use confidential health services when needed, and communicate more effectively with health care providers [15,19]. These findings are consistent with prior studies, suggesting that web-based programs for parents can improve the quality of parent-adolescent communication and foster a more positive attitude toward sexual health communication [26,27]. These results are consistent with 3 studies reporting an improvement in SRH communication after receiving the technology-based intervention [26,43,44], yet 2 studies found no significant difference [26,45].

Limitations

This pilot study reports the preliminary efficacy of a technology-based intervention, yet these results must be interpreted cautiously, as several limitations should be noted. First, the pilot study included a small sample size, comprising 32 dyads (38 adolescents and 32 mothers). This limited sample size may restrict the generalizability of the results to broader populations. Our study participants comprised mothers with high educational attainment, and a large portion reported high annual household income (41% earning over $120,001, the median household income in the San Francisco Area). This study sample may only reflect the San Francisco Bay Area population.

Second, our study used a quasi-experimental design without a control group; therefore, the results may be partially attributed to the intervention. The use of self-reported data may also increase potential bias. It is recommended that future studies include larger, more diverse samples and control groups, direct observation of alone time, and an extended follow-up period so that a comprehensive understanding of the intervention's efficacy can be established.

Third, while the TRUST intervention aimed to promote adolescent-provider alone time, it did not explicitly address psychological drivers of mistrust. The adolescent-mother trust, our secondary outcome, also did not show statistically significant improvement. Future studies should incorporate trust-building components to align more closely with the TRUST acronym.

Moreover, our baseline assessment of adolescent-provider interactions relied on retrospective self-reporting about participants' last health care encounter. This approach introduces methodological limitations such as potential recall bias due to varying time lapses between the actual encounter and survey completion. Future studies should implement real-time data collection after the actual encounter.

Finally, our study's high baseline alone time rate may reflect strong pre-existing clinic practices, as we mentioned earlier, which could have limited our ability to detect statistically significant changes, indicating a potential ceiling effect. Future studies should adopt a more diverse recruitment strategy to capture a wider range of baseline adolescents' behaviors.

Based on the literature and our clinical and research experiences, mothers are usually the primary caregivers of their adolescents. Therefore, this study included both adolescents and their mothers, forming a mother-adolescent dyad. A preliminary analysis indicated strong parental involvement from the mothers. However, due to the small sample size, it will be challenging to assess the impact of parental involvement on the outcomes. Future studies with larger sample sizes should include mediation analysis to evaluate the effect of parental involvement on outcomes. Despite these limitations, our technology-based, interactive intervention with tailored content actively equipped adolescents to advocate for alone time and improved adolescent-mother communication.

Conclusions

Our culturally grounded and technology-based intervention is one of the first aimed at improving rates of and comfort with provider-adolescent patient alone time. This pilot study demonstrates promising results regarding increased alone time with providers during well-adolescent visits and enhanced communication and parenting practices. These findings align with existing research on technology-based interventions and suggest that such approaches can effectively promote alone time with providers, strengthen communication, and support adolescents in engaging in private consultations, a foundational step toward promoting lifelong engagement in preventative health care.

XSL•FO
RenderX

Acknowledgments

This research was funded by the Centers for Disease Control and Prevention (grant 3 U48 DP006374-02S1). We thank all the study participants, clinical sites, and Scalable Care for technical support.

Conflicts of Interest

None declared.

References

1. Cuffe KM, Esie P, Leichliter JS, Gift TL. HIV services provided by STD programs in state and local health departments - United States, 2013-2014. MMWR Morb Mortal Wkly Rep 2017 Apr 07;66(13):355-358 [FREE Full text] [doi: 10.15585/mmwr.mm6613a2] [Medline: 28384128]
2. Martin JA, Hamilton BE, Osterman MJK, Driscoll AK, Drake P. Births: final data for 2017. Natl Vital Stat Rep 2018 Nov;67(8):1-50. [Medline: 30707672]
3. Sexually transmitted disease surveillance 2018. Centers for Disease Control and Prevention. URL: https://www.cdc.gov/sti-statistics/media/pdfs/2024/07/STDSurveillance2018-full-report.pdf [accessed 2025-08-20]
4. Steiner RJ, Pampati S, Rasberry CN, Liddon N. "Is it really confidential?" A content analysis of online information about sexual and reproductive health services for adolescents. J Adolesc Health 2019 Jun;64(6):725-731 [FREE Full text] [doi: 10.1016/j.jadohealth.2018.11.022] [Medline: 30850311]
5. Edman JC, Adams SH, Park MJ, Irwin CE. Who gets confidential care? Disparities in a national sample of adolescents. J Adolesc Health 2010 Apr;46(4):393-395. [doi: 10.1016/j.jadohealth.2009.09.003] [Medline: 20307830]
6. Gilbert AL, Rickert VI, Aalsma MC. Clinical conversations about health: the impact of confidentiality in preventive adolescent care. J Adolesc Health 2014 Nov;55(5):672-677. [doi: 10.1016/j.jadohealth.2014.05.016] [Medline: 25043835]
7. One-on-one time with the pediatrician. HealthyChildren.org. URL: https://www.healthychildren.org/English/ages-stages/teen/Pages/One-on-One-Time-with-the-Pediatrician.aspx [accessed 2025-08-20]
8. Ford C, English A, Sigman G. Confidential health care for adolescents: position paper of the Society for Adolescent Medicine. J Adolesc Health 2004 Aug;35(2):160-167. [doi: 10.1016/j.jadohealth.2004.03.002]
9. Ford CA, Thomsen SL, Compton B. Adolescents' interpretations of conditional confidentiality assurances. J Adolesc Health 2001 Sep;29(3):156-159. [doi: 10.1016/s1054-139x(01)00251-8] [Medline: 11524213]
10. McKee MD, Fletcher J, Schechter CB. Predictors of timely initiation of gynecologic care among urban adolescent girls. J Adolesc Health 2006 Aug;39(2):183-191. [doi: 10.1016/j.jadohealth.2005.11.022] [Medline: 16857529]
11. Adams SH, Park MJ, Twietmeyer L, Brindis CD, Irwin CE. Increasing delivery of preventive services to adolescents and young adults: does the preventive visit help? J Adolesc Health 2018 Aug;63(2):166-171 [FREE Full text] [doi: 10.1016/j.jadohealth.2018.03.013] [Medline: 29929838]
12. Allison BA, Rea S, Mikesell L, Perry MF. Adolescent and parent perceptions of telehealth visits: a mixed-methods study. J Adolesc Health 2022 Mar;70(3):403-413. [doi: 10.1016/j.jadohealth.2021.09.028] [Medline: 34756777]
13. Al-Shimari F, Kahn NF, McCarty CA, Parker EO, Richardson LP, Shafii T. Provider use of time alone with adolescents: differences by health concern. J Adolesc Health 2022 Oct;71(4):508-511 [FREE Full text] [doi: 10.1016/j.jadohealth.2022.05.021] [Medline: 35779999]
14. Richards A, Raymond-Flesch M, Hughes SD, Zhou Y, Koester KA. Lessons learned with a triad of stakeholder advisory boards: working with adolescents, mothers, and clinicians to design the TRUST study. Children (Basel) 2023 Mar 01;10(3):483 [FREE Full text] [doi: 10.3390/children10030483] [Medline: 36980041]
15. Miller VA, Friedrich E, García-España JF, Mirman JH, Ford CA. Adolescents spending time alone with pediatricians during routine visits: perspectives of parents in a primary care clinic. J Adolesc Health 2018 Sep;63(3):280-285. [doi: 10.1016/j.jadohealth.2018.01.014] [Medline: 29887486]
16. Urkin J, Bilenko N, Bar-David Y, Gazala E, Barak N, Merrick J. Who accompanies a child to the office of the physician? Int J Adolesc Med Health 2008;20(4):513-518. [doi: 10.1515/ijamh.2008.20.4.513] [Medline: 19230451]
17. Gavin L, Williams JR, Rivera MI, Lachance CR. Programs to strengthen parent-adolescent communication about reproductive health: a systematic review. Am J Prev Med 2015 Aug;49(2 Suppl 1):S65-S72 [FREE Full text] [doi: 10.1016/j.amepre.2015.03.022] [Medline: 26190849]
18. Santa Maria D, Markham C, Bluethmann S, Mullen PD. Parent-based adolescent sexual health interventions and effect on communication outcomes: a systematic review and meta-analyses. Perspect Sex Reprod Health 2015 Mar;47(1):37-50 [FREE Full text] [doi: 10.1363/47e2415] [Medline: 25639664]
19. Widman L, Choukas-Bradley S, Noar SM, Nesi J, Garrett K. Parent-adolescent sexual communication and adolescent safer sex behavior: a meta-analysis. JAMA Pediatr 2016 Jan;170(1):52-61 [FREE Full text] [doi: 10.1001/jamapediatrics.2015.2731] [Medline: 26524189]
20. Widman L, Evans R, Javidi H, Choukas-Bradley S. Assessment of parent-based interventions for adolescent sexual health: a systematic review and meta-analysis. JAMA Pediatr 2019 Sep 01;173(9):866-877 [FREE Full text] [doi: 10.1001/jamapediatrics.2019.2324] [Medline: 31355860]

XSL•FO
RenderX

21. New media interventions in youth sexual health promotion and HIV/STI prevention. University of California Berkley. URL: http://escholarship.org/uc/item/5xq4n2q8 [accessed 2025-08-20]
22. Brown W, Carballo-Diéguez A, John RM, Schnall R. Information, motivation, and behavioral skills of high-risk young adults to use the HIV self-test. AIDS Behav 2016 Feb 17;20(9):2000-2009. [doi: 10.1007/s10461-016-1309-x]
23. Chen J, Weiss S, Heyman MB, Cooper B, Lustig RH. The efficacy of the web-based childhood obesity prevention program in Chinese American adolescents (Web ABC study). J Adolesc Health 2011 Aug;49(2):148-154 [FREE Full text] [doi: 10.1016/j.jadohealth.2010.11.243] [Medline: 21783046]
24. Nigg CR. Technology's influence on physical activity and exercise science: the present and the future. Psychol Sport Exerc 2003 Jan;4(1):57-65. [doi: 10.1016/s1469-0292(02)00017-1]
25. Nguyen H, Wolpin S, Chiang KC, Cuenco D, Carrieri-Kohlman V. Exercise and symptom monitoring with a mobile device. AMIA Annu Symp Proc 2006;2006:1047 [FREE Full text] [Medline: 17238666]
26. Scull TM, Malik CV, Keefe EM, Schoemann A. Evaluating the short-term impact of media aware parent, a web-based program for parents with the goal of adolescent sexual health promotion. J Youth Adolesc 2019 Sep;48(9):1686-1706 [FREE Full text] [doi: 10.1007/s10964-019-01077-0] [Medline: 31304562]
27. Harper CR, Steiner RJ, Brookmeyer KA. Using the Social-Ecological Model to Improve Access to Care for Adolescents and Young Adults. J Adolesc Health 2018 Jun;62(6):641-642 [FREE Full text] [doi: 10.1016/j.jadohealth.2018.03.010] [Medline: 29784107]
28. One-on-one time with the pediatrician. healthychildren.org. URL: https://www.healthychildren.org/English/ages-stages/teen/Pages/One-on-One-Time-with-the-Pediatrician.aspx [accessed 2025-01-07]
29. Supporting one-to-one time with a health care provider. Centers for Disease Control and Prevention. URL: https://tinyurl.com/5y88edfk [accessed 2025-01-07]
30. Kar S, Choudhury A, Singh A. Understanding normal development of adolescent sexuality: a bumpy ride. J Hum Reprod Sci 2015;8(2):70-74 [FREE Full text] [doi: 10.4103/0974-1208.158594] [Medline: 26157296]
31. Galván A. Adolescent brain development and contextual influences: a decade in review. J Res Adolesc 2021 Dec;31(4):843-869. [doi: 10.1111/jora.12687] [Medline: 34820955]
32. GritX. URL: https://gritx.azureedge.net/ [accessed 2025-08-20]
33. Bethell C, Klein J, Peck C. Assessing health system provision of adolescent preventive services: the Young Adult Health Care Survey. Med Care 2001 May;39(5):478-490. [doi: 10.1097/00005650-200105000-00008] [Medline: 11317096]
34. Guilamo‐Ramos V, Jaccard J, Dittus P, Bouris AM. Parental expertise, trustworthiness, and accessibility: parent‐adolescent communication and adolescent risk behavior. J Marriage Fam 2006 Nov 15;68(5):1229-1246 [FREE Full text] [doi: 10.1111/j.1741-3737.2006.00325.x]
35. Barnes HL, Olson DH. Parent-adolescent communication and the circumplex model. Child Dev 1985 Apr;56(2):438. [doi: 10.2307/1129732]
36. White FA. Parent-adolescent communication and adolescent decision-making. J Fam Stud 2014 Dec 17;2(1):41-56. [doi: 10.5172/jfs.2.1.41]
37. Zapf H, Boettcher J, Haukeland Y, Orm S, Coslar S, Wiegand-Grefe S, et al. A systematic review of parent-child communication measures: instruments and their psychometric properties. Clin Child Fam Psychol Rev 2023 Mar;26(1):121-142 [FREE Full text] [doi: 10.1007/s10567-022-00414-3] [Medline: 36166179]
38. Hutchinson MK. The parent-teen sexual risk communication scale (PTSRC-III): instrument development and psychometrics. Nurs Res 2007;56(1):1-8. [doi: 10.1097/00006199-200701000-00001] [Medline: 17179868]
39. Stattin H, Kerr M. Parental monitoring: a reinterpretation. Child Dev 2000;71(4):1072-1085. [doi: 10.1111/1467-8624.00210] [Medline: 11016567]
40. Sieving RE, Mehus C, Gewirtz O'Brien JR, Steiner RJ, Wang S, Catallozzi M, et al. Correlates of sexual and reproductive health discussions during preventive visits: findings from a national sample of U.S. sdolescents. J Adolesc Health 2022 Mar;70(3):421-428 [FREE Full text] [doi: 10.1016/j.jadohealth.2021.10.013] [Medline: 34838444]
41. Brown JD, Wissow LS. Discussion of sensitive health topics with youth during primary care visits: relationship to youth perceptions of care. J Adolesc Health 2009 Jan;44(1):48-54 [FREE Full text] [doi: 10.1016/j.jadohealth.2008.06.018] [Medline: 19101458]
42. Grilo SA, Catallozzi M, Santelli JS, Yan H, Song X, Heitel J, et al. Confidentiality discussions and private time with a health-care provider for youth, United States, 2016. J Adolesc Health 2019 Mar;64(3):311-318. [doi: 10.1016/j.jadohealth.2018.10.301] [Medline: 30638752]
43. Chokprajakchad M, Phuphaibul R, Sieving RE, Phumonsakul S. Effectiveness of parent participation in a technology-based adolescent sexuality education program: a randomized control trial. Pac Rim Int J Nurs Res 2020;24(2):A-233. [doi: 10.5172/jfs.2.1.41]
44. Wirsiy FS, Atuhaire C, Ngonzi J, Cumber SN. A randomized controlled trial on mobile phone text messaging to improve sexo-reproductive health among adolescent girls in Cameroon. Contracept Reprod Med 2022 Jul 03;7(1):12 [FREE Full text] [doi: 10.1186/s40834-022-00180-1] [Medline: 35780241]

XSL•FO
RenderX

45. Scull TM, Kupersmidt JB, Malik CV, Keefe EM. Examining the efficacy of an mHealth media literacy education program for sexual health promotion in older adolescents attending community college. J Am Coll Health 2018 Apr;66(3):165-177 [FREE Full text] [doi: 10.1080/07448481.2017.1393822] [Medline: 29068772]

Abbreviations

SEM: social-ecological model
SRH: sexual and reproductive health
STI: sexually transmitted infection
TRUST: technology-based resources to increase uptake of sexual health services for teens

Edited by S Badawy; submitted 17.01.25; peer-reviewed by E von Scheven, J Guo, FY Chou; comments to author 20.05.25; revised version received 30.07.25; accepted 17.08.25; published 08.09.25.

Please cite as:
Chen JL, Raymond-Flesch M, Hoffmann TJ, Lin CX, Xu L, Koester KA
Evaluating the Preliminary Efficacy of the TRUST Intervention on Alone-Time and Communication During Well-Adolescent Visits: Quasi-Experimental Study
JMIR Pediatr Parent 2025;8:e71433
URL: https://pediatrics.jmir.org/2025/1/e71433
doi:10.2196/71433
PMID:

©Jyu-Lin Chen, Marissa Raymond-Flesch, Thomas J Hoffmann, Chen-Xi Lin, Ling Xu, Kimberly A Koester. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 08.09.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Body Fat and Obesity Rates, Cardiovascular Fitness, and the Feasibility of a Low-Intensity Non–Weight-Centric Educational Intervention Among Late Adolescents: Quasi-Experimental Study

Areeg Zuair[1], PhD; Fahad M Alhowaymel[2], PhD; Rola A Jalloun[3], PhD; Naif S Alzahrani[4], PhD; Khalid H Almasoud[5], Prof Dr; Majdi H Alharbi[6], BSN, RN; Rayan K Alnawwar[7], BSN, RN; Mohammed N Alluhaibi[7], BSN, RN; Rawan S Alharbi[4], BSN, RN; Fatima M Aljohan[8], BSN, RN; Bandar N Alhumaidi[1], PhD; Mohammad A Alahmadi[5], Prof Dr

[1]Department of Community Health Nursing, Taibah University, Janadah Bin Umayyah Road, Medina, Saudi Arabia

[2]Department of Nursing Science, Shaqra University, Shaqra, Saudi Arabia

[3]Department of Nutrition and Food Science, Taibah University, Medina, Saudi Arabia

[4]Department of Medical Surgical Nursing, Taibah University, Medina, Saudi Arabia

[5]Department of Sport Science and Physical Activity, Taibah University, Medina, Saudi Arabia

[6]Department of Nursing, Prince Mohammed Bin Abdulaziz Hospital, Medina, Saudi Arabia

[7]Department of Oncology, King Salman Bin Abdulaziz Medical City, Medina, Saudi Arabia

[8]Emergency Department, King Salman Bin Abdulaziz Medical City, Medina, Saudi Arabia

Corresponding Author:
Areeg Zuair, PhD
Department of Community Health Nursing, Taibah University, Janadah Bin Umayyah Road, Medina, Saudi Arabia

Abstract

Background: Obesity rates among Saudi adolescents are increasing, with regional variations highlighting the need for tailored interventions. School-based health programs in Saudi Arabia are limited and often emphasize weight and body size, potentially exacerbating body image dissatisfaction. There is limited knowledge on the feasibility of non–weight-centric educational programs in Saudi Arabia and their effects on health behaviors and body image.

Objectives: This study aimed to (1) assess the prevalence of obesity using BMI-for-age *z* score (BAZ) and fat percentage among Saudi adolescents; (2) evaluate key health behaviors, cardiovascular fitness, and health literacy; and (3) assess the feasibility and impact of a low-intensity, non–weight-centric educational intervention designed to improve knowledge of macronutrients and metabolic diseases, while examining its safety on body image discrepancies.

Methods: A quasi-experimental, pre-post trial with a parallel, nonequivalent control group design was conducted among 95 adolescents (58 boys and 37 girls; mean age 16.18, SD 0.53 years) from 2 public high schools in Medina City, Saudi Arabia. Participants were randomly assigned to either the weight-neutral Macronutrient + Non-Communicable Diseases Health Education group or the weight-neutral Macronutrient Health Education group. Anthropometry (BAZ and fat percentage), cardiovascular fitness, physical activity, and eating behaviors were measured at baseline. Independent *t* tests and χ^2 tests were conducted to compare group differences, and a 2-way mixed ANOVA was used to evaluate the effect of the intervention on macronutrient knowledge and body image discrepancies. A total of 69 participants completed the postintervention assessments.

Results: The prevalence of overweight and obesity based on BAZ was 37.9% (36/95), while 50.5% (48/95) of participants were classified as overfat or obese based on fat percentage. Students with normal weight status were significantly more likely to have had prior exposure to health education related to metabolic diseases than students with higher weight status (P=.02). The intervention significantly improved macronutrient-metabolic knowledge ($F_{1,64}$=23.452; P<.001), with a large effect size (partial η^2=0.268). There was no significant change in students' body image from pre- to postintervention (P=.70), supporting the safety of these weight-neutral programs. The intervention demonstrated strong feasibility, with a recruitment rate of 82.6% and a retention rate of 72.6%.

Conclusions: This study reveals a high prevalence of obesity among Saudi adolescents, particularly when measured using fat percentage. The significant improvement in knowledge and the nonimpact on body image suggest that a non–weight-centric intervention can foster better health outcomes without exacerbating body image dissatisfaction. Region-specific strategies that prioritize metabolic health and macronutrient education over weight-centric messaging should be considered to address both obesity and body image concerns in adolescents.

XSL•FO
RenderX

(JMIR Pediatr Parent 2025;8:e67213) doi:10.2196/67213

KEYWORDS

adolescent obesity; macronutrient education; cardiovascular fitness; body composition; health literacy; body image; macronutrient; educational; obesity; weight; overweight; fitness; nutrition; diet; patient education; student; school; youth; adolescent; teenager; metabolic; eating; physical activity; exercise

Introduction

Childhood obesity has become a significant public health concern globally, with projections indicating a continued upward trend in the coming decades. Obesity is expected to rise dramatically among children aged 5 - 19 years, from an estimated 158 million in 2020 to 254 million by 2030 [1], representing a 60% increase over just a decade. Global estimates suggest that the overall prevalence of childhood overweight and obesity could reach 30% by 2030, with boys (34.2%) surpassing girls (27.4%) [2]. This trend is particularly alarming in middle- and high-income countries, where childhood overweight and obesity rates are projected to reach 58.3% by 2030 [2].

In Saudi Arabia, the obesity epidemic has mirrored global trends, with a marked increase in prevalence among both adults and adolescents. National estimates indicate that obesity prevalence among Saudi adolescents ranges from 22.3% to 23.5%, with some studies suggesting that nearly 35% of adolescents are overweight and 20% are obese [3-5]. Although BMI is a common tool for assessing obesity, it has limitations in distinguishing between fat and muscle mass. Notably, recent findings in Saudi Arabia highlight that BMI can underestimate obesity prevalence compared with body fat percentage [6]. For instance, while BMI data indicated an obesity prevalence of 29% (102/348) in men and 53% (314/593) in women, body fat percentage assessments revealed significantly higher rates of 83.9% (292/348) in men and 97.3% (557/593) in women [6]. This underscores the importance of using body fat percentage to provide a more accurate representation of obesity, particularly when evaluating related health risks.

Regional disparities in obesity prevalence further complicate the issue. Urbanized areas in Saudi Arabia report higher rates of obesity, influenced by factors such as physical inactivity, Westernized diets, and socioeconomic conditions [7]. Conversely, rural regions often exhibit lower obesity rates due to more traditional lifestyles that incorporate higher physical activity and different dietary patterns [7]. These regional differences emphasize the need to address physical activity behaviors and dietary habits in specific contexts. While all forms of physical activity are beneficial, current evidence indicates that vigorous-intensity exercise may be particularly effective in improving body composition, cardiorespiratory fitness, and cardiometabolic health markers in adolescents [8,9]. Despite this, there remains a gap in studies exploring the relationship between physical activity behaviors and cardiovascular fitness among adolescents in Saudi Arabia.

Adding to the complexity, decreased health literacy and higher-income levels have been linked to increased obesity rates in Saudi Arabia. This contrasts with trends observed in the United States, where lower-income levels are more commonly associated with higher obesity rates [10,11]. This highlights the crucial role of health literacy as a determinant of obesity prevalence and the importance of tailored educational interventions.

Despite the alarming trends, evidence-based interventions targeting adolescents in Saudi Arabia, particularly late adolescents in school settings, remain limited [12,13]. Schools provide an ideal environment for implementing cost-effective and sustainable obesity interventions, especially when these programs are theory-driven and tailored to meet the specific needs of the target population [14]. A review of the literature shows that only 7 school-based obesity intervention studies have targeted adolescents in Saudi Arabia, with an average age range of 12 - 14 years, and none focusing on high school students [12,13,15]. Furthermore, only 3 of these studies used theory-based approaches [12], and all used weight-centric messaging.

Since 2020, more than 100 organizations worldwide, including scientific societies and academic institutions, have endorsed joint international statements to eliminate weight stigma [16]. Non–weight-centric approaches, which emphasize overall health and well-being rather than solely focusing on weight loss, have gained traction in school-based obesity interventions [17]. These programs encourage healthy behaviors and promote a positive body image without stigmatizing students, addressing the negative outcomes associated with weight stigma such as anxiety, disordered eating, and even weight gain [18,19]. However, designing obesity prevention programs that avoid weight-based stigma remains challenging, prompting calls for expanded research in non-Western cultural settings [16,20].

No study in Saudi Arabia has yet documented the development or efficacy of non–weight-centric interventions. This study focused on Medina City to examine the impact of healthy lifestyle factors on obesity rates among late adolescents and to assess the effectiveness and safety of a low-intensity, non–weight-centric, noncommunicable diseases (NCDs) educational intervention. This regional focus aims to provide insights that can inform targeted, culturally sensitive obesity prevention strategies.

In summary, this study sought to (1) identify the prevalence of obesity using both BMI-for-age *z* score (BAZ) and body fat percentage among Saudi late adolescents in Medina City; (2) characterize health-related behaviors, cardiovascular fitness, handgrip strength, and health literacy levels; and (3) evaluate the feasibility and safety of a low-intensity health educational intervention aimed at empowering adolescents with improved NCD knowledge while monitoring its effects on body image discrepancy. This research aims to contribute to the development of effective, culturally appropriate interventions that promote adolescent health without reinforcing weight stigma.

XSL•FO
RenderX

Methods

Design

This study used a quasi-experimental, pre-post trial with a parallel, nonequivalent control group design to assess baseline anthropometry, health-related cardiovascular fitness components, handgrip strength, physical activity, and eating behaviors, as well as the feasibility of a low-intensity, school-based educational intervention aimed at improving critical thinking about the relationship between macronutrients and NCDs among high school students, while tracking safety measures such as body image discrepancy.

Participants

A total of 115 high school students from 2 public schools (1 for males and 1 for females) in Medina City, Saudi Arabia, were invited to participate. These schools were selected by the ministry of education's school health department. Of the invited students, 95 (58 males and 37 females) completed anthropometry and body composition measurements. Baseline surveys were completed by 85 students (53 males and 32 females). Four classes (2 females and 2 males) were randomly assigned to 1 of 2 intervention groups: the Macronutrient+ NCDs Health Education group (n=31) or the Macronutrient Health Education group (n=38).

Intervention: Green Apple

Overview

The LEAF program, an 8-session structured intervention, was developed to enhance critical thinking regarding macronutrients and their relationship to body energy and the prevention of cardiometabolic diseases. For this study, a pilot version, titled Green Apple, was conducted over two 45-minute sessions for female students and one 60-minute session for male students due to scheduling constraints. The intervention was based on best practices derived from evidence-based research into health literacy and behavior change [21]. The program was grounded in the Health Belief Model [22] and Social Cognitive Theory [23], incorporating the Transtheoretical Model for behavior change [24].

These theories provided the framework for understanding how adolescents perceive their risk of NCDs (eg, diabetes, hyperlipidemia, liver disease, stroke, and hypertension) and motivated them to adopt healthier behaviors through education, muscle building, and dietary modifications. The Green Apple program aimed to reduce chronic metabolic NCD risk by promoting visceral fat reduction and muscle building without focusing on weight loss or obesity. Participants were encouraged to follow the MyPlate dietary guidelines [25], emphasizing fiber and whole food consumption and engaging in muscle-building exercises. The program avoided topics related to obesity and sedentary behavior, instead focusing on metabolic health improvements.

Intervention Groups

The Macronutrient+ NCDs Health Education group included 3 educational topics covering nutrition and metabolic diseases (eg, diabetes and cardiovascular disease), highlighting the impact of macronutrition on metabolic health.

The Macronutrient Health Education group included 2 educational topics focused solely on healthy nutrition principles, dietary guidelines, food groups, and balanced eating.

Both groups received identical macronutrient content.

Measurements

Demographics

Baseline demographic data included age, self-reported weight and height, parental education levels, and monthly family income. Parental education was categorized as high (college degree or above) or low (high school degree or below).

Anthropometry

Body weight and height was measured using a portable digital scale (Omron BF511) to the nearest 100 g and a stadiometer to the nearest 0.1 cm. BMI was calculated as weight (kg) divided by height squared (m^2), and BAZs were classified using the World Health Organization 2007 Growth Reference for children and adolescents aged 5 - 19 years [26]. The BAZ categories were thinness ($-3 \leq BAZ < -2$), normal weight ($-2 \leq BAZ \leq +1$), overweight ($+1 < BAZ \leq +2$), and obesity ($BAZ > +2$).

Fat percentage was assessed using a bioimpedance analyzer (Omron BF511). Classification was based on McCarthy's age- and sex-specific fat percentile references, with the 2nd, 85th, and 95th percentiles defining underfat, overfat, and obese, respectively [27].

Cardiovascular Fitness

The Queen's College Step Test, a submaximal exercise test, was used to estimate the maximal oxygen consumption (VO_2max). Participants stepped on a 30.5- cm box at a set rate for 3 minutes [28]. The 30.5-cm step height was chosen for its suitability for adolescents [28]. VO_2max estimation: The pulse rate was measured postexercise using a pulse oximeter, following McArdle's protocol [29]. The equations for estimating VO_2max were as follows: girls: $65.81 - (0.1847 \times \text{pulse rate})$ and boys: $111.33 - (0.42 \times \text{pulse rate})$ [28].

Handgrip Strength

Handgrip strength was measured using a Takei Kiki Kogyo dynamometer, and the highest value from 2 trials for the dominant hand was recorded. Classifications followed age- and gender-specific percentiles [30].

Physical Activity

Physical activity was assessed using the Arab Teen Lifestyle Study physical activity questionnaire subscale [31], calculating total weekly energy expenditure in metabolic equivalent tasks (METs), with vigorous activities (6 METs) and moderate activities (4 METs) expressed in minutes per week.

Eating Habits

Eating habits were evaluated using the Arab Teen Lifestyle Study eating habits subscale, which measured positive eating habits (eg, fruit or vegetable intake) and negative eating habits

XSL•FO
RenderX

(eg, sugary drinks or fast food) based on weekly frequency [31], with a total scores ranging from 0 to 28 for positive habits and 0 to 35 for negative habits.

Sedentary Behavior

Sedentary behavior was measured using the Arabic Sedentary Behavior Questionnaire (SBQ) for weekdays [32]. The questionnaire included 9 items, and a total sitting time was averaged over 5 weekdays. Sitting ≥7 hours per day was considered highly sedentary [33].

Exposure to NCDs Health Education

Exposure to health education on NCDs was assessed using 4 yes or no questions regarding prior education on chronic diseases. A total score (0 - 4) was calculated.

Macronutrient-NCDs Knowledge

Macronutrient and NCDs knowledge was measured using an 18-item true-or-false quiz developed based on the Green Apple content. A total score (0 - 18) was analyzed, with an urgent need for intervention indicated if 70% or fewer answered correctly, a considered need at 71% - 89%, and no need at 90% or more [34].

Body Image Discrepancy

Body image discrepancy was assessed using 4 body size silhouettes [35]. Participants selected their ideal and perceived current body images, with discrepancies indicating body image concerns. A negative score represented a drive for thinness, while a positive score reflected a drive for increased body weight [36].

Ethical Considerations

The study protocol was approved by the Shaqra University ethics committee (ERC_SU_20230005). Written informed consent was obtained from parents, and student participation was voluntary. To ensure privacy and confidentiality, participant data were anonymized using unique identifiers, and data access was limited to authorized personnel. Baseline assessments were conducted prior to the intervention. The intervention was delivered on different days for males and females due to scheduling constraints. Postintervention assessments for macronutrient-NCDs knowledge and body image discrepancy were conducted, and participants received a key chain medley as a token of appreciation for their involvement.

Statistical Analysis

Overview

Descriptive statistics (means, SDs, and frequencies) were calculated for all variables. Independent *t* tests were conducted to compare males and females and students with and with no overweight or obesity on continuous variables, while χ^2 tests were used for categorical variables. A 2-way mixed ANOVA design was used, with 1 between-subjects factor (intervention type: macronutrient-NCDs vs macronutrient) and 2 within-subjects factors (time: pre-test and post-test) for 2 dependent variables: macronutrient-NCDs knowledge and body image discrepancy. Gender was included as an additional between-subjects variable to assess potential interactions with time and intervention type.

Statistical significance was set at $P<.05$. Sample size calculations using G*Power 3.1 indicated a required sample size of 34 participants to detect medium effects ($f=0.25$) with 80% power. Although an initial plan accounted for a 30% attrition rate, the final sample size exceeded the minimum requirement for detecting a medium effect size with 80% power, ensuring sufficient study power.

A 2-way mixed ANOVA was conducted to evaluate the effect of the Green Apple intervention on students' macronutrient-NCDs knowledge scores before and after the intervention and to determine potential gender interaction effects, given the significant difference in mean scores between males and females at preassessment.

Two borderline outliers with studentized residuals of −3.02 and −3.03 were identified but retained in the analysis. The data were normally distributed, as assessed by the Shapiro–Wilk test ($P>.05$). Homogeneity of variances ($P>.05$) and covariances ($P>.001$) were confirmed by Levene test and Box M test, respectively, except for postintervention body image discrepancy, which required Welch ANOVA.

Missing Data

A missing data analysis was conducted, revealing that 4% of data were missing across all items, with a maximum of 7% missing for certain variables (eg, "minutes' walk per day," "number of stairs per day," and "SBQ-listening to music, using computer, crafting"). Little MCAR test was applied to assess the randomness of the missing data, yielding a nonsignificant result ($P>.05$), indicating that the data were missing completely at random [37]. Expectation-Maximization was used to impute missing data for variables with 5% - 7% missing values. For variables with <5% missing data, series mean and series median imputation methods were used.

Two items from the physical activity scale ("regular dancing" and "house cleaning") were excluded due to cultural factors that led to inconsistent responses between male and female participants. This decision was informed by a review of similar studies conducted in the region [38,39]. Furthermore, family income was excluded from analysis because female students were often unaware of this information, which is considered sensitive, and younger students may not accurately understand their family's financial status [40]. The high absenteeism rate among female students during the intervention (approximately 28%) also contributed to some missing data, consistent with previously reported absenteeism rates in Saudi schools [41].

Results

Baseline Characteristics and Prevalence of Overweight and Obesity

Table 1 shows the baseline characteristics of the 95 participants (37 girls and 58 boys). The mean age of the total sample was 16.18 (SD 0.53) years, with girls having a significantly higher mean age than boys ($P<.001$). The mean BAZ score for the total sample was 0.44 (SD 1.42), with a significant sex difference

XSL•FO
RenderX

(*P*=.03). Furthermore, girls had a higher mean fat percentage than boys (28.58% vs 22.65%), but this difference was not statistically significant (*P*=.37). The combined prevalence of overweight and obesity based on the BAZ classification was 37.9% (36/95), with 16.8% (16/95) of participants classified as overweight and 21.1% (20/95) of participants classified as obese. When considering fat percentage, the combined prevalence of overfat and obesity was 50.5% (48/95), with 11.6% (11/95) of participants classified as overfat and 38.9% (37/95) of participants classified as obese. For the BAZ and fat percentage percentile categories, no significant sex differences were observed. Table 2 shows descriptive statistics for the distribution of the participants' weight status (normal BAZ and high BAZ) across different levels. These results suggest that there was no statistically significant relationship between parental education level (both mother and father) and the participants' weight category.

Table . Descriptive statistics based on sex (mean [SD] or fat percentage).

Variables	All (N=95)	Girls (n=37)	Boys (n=58)	Sex (significance) difference[a]
Age (years), mean (SD)	16.18 (0.53)	16.38 (0.64)	16.05 (0.39)	<.001
BMI (kg/m^2), mean (SD)	23.46 (6.07)	23.25 (5.24)	23.59 (6.59)	.05
BAZ[b], mean (SD)	0.44 (1.68)	0.44 (1.42)	0.44 (1.84)	.03
Fat percentage, mean (SD)	24.96 (9.54)	28.58 (8.62)	22.65±9.44	.37
BAZ percentile, n (%)				.39
Underweight	7 (7.4)	2 (5.4)	5 (8.6)	
Normal weight	52 (54.7)	22 (59.5)	30 (51.7)	
Overweight	16 (16.8)	8 (21.6)	8 (13.8)	
Obese	20 (21.1)	5 (13.5)	15 (25.9)	
Fat percentage percentile, n (%)				.44
Underfat	5 (5.3)	3 (8.1)	2 (3.4)	
Normal	42 (44.2)	16 (43.2)	26 (44.8)	
Overfat	11 (11.6)	6 (16.2)	5 (8.6)	
Obese	37 (38.9)	12 (32.4)	25 (43.1)	
Exposure to metabolic NCDs[c] education, mean (SD)[d]	3.19 (1.006)	3.72 (0.523)	2.87 (1.093)	<.001
Macronutrient-metabolic NCDs knowledge, mean (SD)[d]	10.64 (3.638)	12.13 (2.472)	9.74 (3.943)	.50
Body image discrepancy, mean (SD)[e]	−0.36 (0.94)	−0.69 (0.74)	−0.13 (1.00)	.005

[a]Independent *t* tests were conducted to compare differences between the 2 groups. Two-sided *P* values are reported when no significant difference was found between the groups. One-sided *P* values are reported when the 1-directional hypothesis was supported.

[b]BAZ: BMI-for-age *z* score.

[c]NCD: noncommunicable disease.

[d]The n values for these data are as follows: All (n=85); Girls (n=32); Boys (n=53).

[e]The n values for these data are as follows: All (n=78); Girls (n=32); Boys (n=46).

XSL•FO
RenderX

Table . Weight category descriptive statistics (mean [SD] or fat percentage).

	All	Normal BAZ[a]	High BAZ	Significance[b]
Mother's education, n (%)				.99
Low education level	28 (34.6)	18 (34.6)	10 (34.5)	
High education level	53 (65.4)	34 (65.5)	19 (65.5)	
Father's education, n (%)				.07
Low education level	18 (21.7)	8 (15.4)	10 (32.3)	
High education level	65 (78.3)	44 (84.6)	21 (67.7)	
Fat percentage, mean (SD)	24.96 (9.54)	19.53 (6.10)	33.85 (7.16)	<.001
VO_2max (mL/kg/min), mean (SD)	53.33 (14.63)	53.68 (14.72)	52.77 (14.67)	.86
VO_2max boys (mL/kg/min), mean (SD)	62.65 (10.29)	63.43 (10.69)	61.46 (9.77)	.81
VO_2max girls (mL/kg/min), mean (SD)	37.90 (2.87)	38.84 (1.83)	36.10 (3.65)	.014
Handgrip strength max score (kg), mean (SD)	24.49 (7.85)	24.81 (8.81)	23.96 (6.04)	.15
Handgrip strength percentile, n (%)				.67
Low: ≤20	52 (54.7)	34 (57.6)	18 (50)	
Normal: 21 - 80	35 (36.8)	21 (35.6)	14 (38.9)	
High: >80	8 (8.4)	4 (6.8)	3 (11.1)	
Health-related behaviors based on weight status, mean (SD)				
Vigorous-intensity physical activity (METs[c] min/wk)	2038.91 (2560.25)	2360.92 (2914.76)	1505.56 (1743.45)	.047
Moderate-intensity physical activity (METs min/wk)	1038.90 (1219.13)	1009.073 (1174.13)	1088.286 (1307.99)	.39
Sedentary behavior per day during the week (h/d)	7.28 (3.93)	7.741 (3.11)	7.5064 (3.98)	.34
Positive eating behavior	16.43 (6.30)	16.838 (5.98)	15.7188 (6.84)	.22
Negative eating behavior	15.11 (6.62)	15.160 (6.22)	15.022 (7.34)	.46
Exposure to metabolic NCDs[d] health education topics	3.19 (1.01)	3.36 (0.76)	2.91 (1.28)	.02
Macronutrient-metabolic NCDs knowledge	10.64 (3.64)	10.90 (3.10)	10.13 (4.39)	.16
Need for educational intervention assessment, n (%)				.92
Urgent need	59 (69.4)	37 (69.8)	22 (68.8)	
Considered need	26 (30.6)	16 (30.2)	10 (31.3)	
No need	0 (0)	0 (0)	0 (0)	

[a]BAZ: BMI-for-age *z* score.

[b]Independent *t* tests were conducted to compare differences between the 2 groups. Two-sided *P* values are reported when no significant difference was found between the groups. One-sided *P* values are reported when the 1-directional hypothesis was supported.

[c]MET: metabolic equivalent task.

[d]NCD: noncommunicable disease.

XSL•FO
RenderX

Cardiovascular Fitness and Handgrip Strength

Overall cardiovascular fitness levels, as measured using VO_2max, did not significantly differ between individuals in the normal and high body weight categories. The boys in the normal BAZ group had a slightly higher VO_2max (63.43 mL/kg/min, SD 10.69) than the boys in the high BAZ group (61.46 mL/kg/min, SD 9.77). However, this difference was not statistically significant (*P*=.81). There was a notable and statistically significant difference between the girls in the normal BAZ group (38.84 mL/kg/min, SD 1.83) and those in the high BAZ group (36.10 mL/kg/min, SD 3.65), with a *P* value of .014. This indicates that girls with overweight or obesity had significantly lower cardiovascular fitness levels than their peers in the normal group, suggesting a potential negative impact of higher body weight on cardiovascular fitness among girls. However, the distribution of handgrip strength categories did not show a statistically significant association with the BAZ classification (*P*=.67) (Table 2).

Health-Related Behaviors Based on Weight Status

Activity Behavior

Participants with a high BAZ had lower levels of METs minutes per week from vigorous-intensity activity (1505.56, SD 1743.45) than those with a normal BAZ (2360.92, SD 2914.76), with a significant difference (*P*=.047). No significant differences were observed in METs from moderate-intensity activity (*P*=.39).

Sedentary Behavior

The difference in sedentary behavior between the 2 groups was not statistically significant (*P*=.68), indicating similar levels of sedentary time regardless of weight status.

Eating Behavior

Positive eating behaviors were marginally lower in the high BAZ group (15.72, SD 6.84) than in the normal BAZ group (16.84, SD 5.98), but the difference was not statistically significant (*P*=.23). Furthermore, negative eating behaviors showed no significant differences between the groups (*P*=.93).

Macronutrient-Metabolic NCDs Knowledge and Need for Intervention

The participants with a normal BAZ reported higher exposure to metabolic NCDs education (3.36, SD 0.76) than those with a high BAZ (2.91, SD 1.28), with a significant difference (*P*=.02). However, no significant differences were observed in the macronutrient-metabolic NCDs knowledge scores between the 2 groups (*P*=.16). The majority of the participants were classified as having an urgent need for an educational intervention (59/85, 69.4%), and 30.3% (26/85) were classified as having a need for an intervention, with no statistically significant distribution between the 2 groups (*P*=.92).

The Green Apple Intervention Effectiveness

The final sample consisted of 69 participants, with 23 females (intervention=13, control=10) and 46 males (intervention=18, control=28).

Effect on Macronutrient-Metabolic NCDs Knowledge

There was a significant main effect of time on students' macronutrient-metabolic NCDs knowledge ($F_{1,58}$=23.263; *P*<.001), with a large effect size (partial η^2=0.286). This indicates that knowledge significantly improved from pre- to postintervention, and the magnitude of the change was substantial. Also, a significant main effect was found for intervention type ($F_{1,58}$=19.756; *P*<.001), with a large effect size (partial η^2=0.254). The Macronutrient + NCDs intervention had a greater effect on improving knowledge (Table 3). The interaction between gender and intervention type was nonsignificant ($F_{1,58}$=0.002; *P*=.99), with a very small effect size (partial η^2=0.00), indicating that the effect of the interventions on knowledge was consistent across genders.

Table . Changes in macronutrient-noncommunicable disease (NCD) knowledge and body image discrepancy across intervention periods.

	Baseline, mean (SE)	95% CI	Follow-up, mean (SE)	95% CI
Effect on macronutrient-metabolic NCDs knowledge				
Nutrition+ NCD	11.16 (0.56)	10.03 to 12.29	13.39 (0.42)	12.55 to 14.24
Nutrition	11.53 (0.55)	10.45 to 12.63	13.04 (0.41)	12.22 to 13.86
Effect on body image discrepancy				
Nutrition + NCD	−0.38 (0.17)	−0.72 to −0.03	−0.53 (0.19)	−0.90 to −0.16
Nutrition	−0.50 (0.167)	−0.84 to −0.17	−0.41 (0.18)	−0.77 to −0.05

Body Image Discrepancy

The effect of time on body image was nonsignificant ($F_{1,58}$=0.150; *P*=.70), with a small effect size (partial η^2=0.003), suggesting no significant change in students' body image from pre- to postintervention. Similarly, the interaction between gender and intervention type was nonsignificant for body image ($F_{1,58}$=0.182; *P*=.73), with a very small effect size (partial η^2=0.002), meaning that the interventions had similar effects on body image for both males and females. The effect of gender on body image was marginally significant ($F_{1,58}$=6.157; *P*=.052), with a medium effect size (partial η^2=0.064), suggesting a slight difference in body image perception between males and females. However, Welch ANOVA was used due to unequal variances between males and females on postintervention body image discrepancy, and the findings suggest that gender does play a

XSL•FO
RenderX

role in postintervention body image, with a statistically significant difference detected between males and females (Welch $F_{1,66.977}$=5.385; P=.02). This suggests that after accounting for unequal variances (based on Levene test), gender does have a significant effect on postintervention body image.

The Green Apple Intervention Feasibility

The high recruitment rate indicates strong initial interest and willingness to participate in the intervention, with 82.6% (95/115) of invited students enrolling in the study. Nearly 90% (85/95) of the recruited participants were engaged enough to provide comprehensive baseline data. The overall retention rate, based on completion of the pre- and postintervention questionnaires, was 72.6% (69/95). This indicates that a significant majority of the participants remained engaged with the study through to its conclusion, although there was a drop-off of 27.4% (26/95) from baseline to the postintervention phase. This dropout rate highlights some challenges in maintaining participant engagement over the study period. The retention rate was notably higher among male participants (46/58, 79.3%) than among female participants (23/37, 62.2%). This disparity was related to high absenteeism in the female school. Furthermore, one of the key challenges encountered was scheduling conflicts, particularly in the male school. These constraints impacted the intervention delivery, reducing the planned 2 sessions over 2 weeks to a single session on 1 day.

Discussion

Principal Findings

This study aimed to assess the prevalence of obesity among late adolescents in Medina City, Saudi Arabia, using both BAZ and fat percentage, and to evaluate the feasibility and effectiveness of a low-intensity, non–weight-centric educational intervention focused on macronutrient-metabolic disease knowledge. The findings indicate a high prevalence of obesity in this population, surpassing national averages. The Green Apple intervention effectively improved students' macronutrient knowledge without negatively affecting body image discrepancy, demonstrating its potential as a health education tool.

The prevalence of overweight and obesity based on the BAZ classification was 37.9% (36/95), with 21.1% (20/95) classified as obese. When using fat percentage, the prevalence was even higher at 50.5% (48/95), highlighting that BMI alone may underestimate obesity rates. This aligns with regional data, indicating that adolescent obesity trends in Medina reflect broader patterns observed in the western region of Saudi Arabia [7]. The effectiveness of the Green Apple intervention in significantly improving macronutrient-metabolic NCDs knowledge without impacting body image discrepancy underscores the potential for brief educational programs to enhance adolescents' understanding of nutrition and health.

Our study's obesity prevalence rates are consistent with findings from prior research in the western region of Saudi Arabia. For instance, a 2019 study reported a 35.3% (121/342) obesity prevalence among university students in Medina [42], indicating a persistent trend across educational levels. A 2021 study also found a similar overweight and obesity prevalence of 38.5% (44,826/116,656) among participants aged 17 - 25 years across different Saudi regions [43]. The higher prevalence of obesity in males (15/58, 25.9%) than in females (5/37, 13.5%) aligns with national data showing higher obesity rates in male adolescents [10].

The use of fat percentage as an additional measure provided a more nuanced understanding, revealing an obesity rate nearly double that of the BAZ classification. This supports prior research suggesting that fat percentage often results in a higher reported prevalence of obesity compared with BMI, sometimes by 1.5-3 times [44-46]. BMI fails to distinguish between muscle and fat mass, making fat percentage a more accurate indicator of obesity [45,46].

The study also identified a significant difference in VO_2max scores between the normal and high BAZ groups among females, with the normal group demonstrating better cardiovascular fitness. This finding suggests an inverse relationship between BAZ and cardiovascular health, emphasizing the importance of maintaining a normal BAZ for better fitness. Similar studies have shown a negative relationship between BMI and cardiorespiratory fitness in Saudi youth aged 8 - 15 years [47]. Furthermore, while the normal BAZ group had higher handgrip strength, there was no significant difference in percentiles between groups, indicating that low muscle strength is common among adolescents regardless of BMI. Previous studies have also reported low muscle strength among Saudi male adolescents aged 17 years [48] and no significant association between BMI and strength in college-aged females [49]. This study is the first to report age- and sex-specific handgrip strength percentiles for this population, an essential aspect for future research [30].

Also, the lack of significant differences in dietary behaviors between weight groups suggests that suboptimal eating habits are widespread. Both groups showed low fruit and vegetable intake and high consumption of sugary drinks, aligning with global patterns [50]. Sedentary behavior was similar between groups, reinforcing the need for targeted physical activity interventions. Our finding that vigorous physical activity correlates with lower obesity rates aligns with the Green Apple program's emphasis on high-intensity activity for metabolic health [51]. Current evidence suggests that vigorous intensity exercise may be particularly effective for improving body composition and health outcomes in adolescents [8,9]. These modalities also show promise for improving adherence. However, proper supervision and safety considerations are important, especially for higher-intensity activities and more research is needed to determine optimal exercise prescriptions and implementation strategies for this age group [8,9].

Our findings further revealed significantly lower exposure to NCD education among students with overweight or obese status compared with those with normal weight, and male students reported lower exposure than females. This could be linked to lower NCD knowledge among male teachers, as suggested by a recent study in Saudi Arabia [52]. The lower awareness about NCDs among young adults highlights the need for targeted interventions to increase education and awareness [53,54]. Early

XSL•FO
RenderX

education can lead to better outcomes by promoting preventive measures [54,55].

The efficacy of low-intensity, non–weight-centric educational interventions in improving knowledge is crucial for preventing metabolic NCDs. By focusing on macronutrient education without emphasizing weight loss, the Green Apple program demonstrates a promising approach to improving metabolic health in adolescents without affecting body image. Research on educational interventions in Saudi Arabia and Gulf Cooperation Councilcountries is limited, with existing studies primarily focusing on obesity awareness and metabolic NCDs such as diabetes [12,56]. Our study contributes to this field by showing that even low-intensity interventions targeting macronutrient and NCD knowledge can enhance health literacy. Importantly, this study targeted late adolescents, addressing a significant gap as previous research has mainly focused on younger adolescents (aged 12 - 14 years) [12,56]. The Green Apple program, as a pilot derived from the larger LEAF program, suggests a scalable model that integrates educational and behavioral strategies to promote sustainable health improvements by focusing on visceral fat reduction and muscle mass development.

The significant improvement in students' knowledge aligns with recent literature highlighting the importance of early NCD education [57,58]. The observed large effect size (partial η^2=0.286) further supports the intervention's effectiveness. Contextualizing nutritional information to metabolic health may enhance learning by linking knowledge to practical outcomes. Also, the nonsignificant interaction between gender and intervention type indicates that the content was equally effective for both male and female students, which is significant in a cultural context where gender-specific education is common [59]. This suggests that balanced content can be effective across genders. Finally, the nonsignificant effect on body image supports literature advocating for weight-neutral interventions to avoid adverse body image outcomes [60]. However, the significant postintervention body image difference between genders highlights the need for considering gender-specific perceptions in future program designs [61].

Limitations and Recommendations

Despite the positive outcomes, challenges such as scheduling and gender-specific retention highlight the need for flexible strategies. Limitations include the relatively small, single-region sample size, which may limit generalizability, and the short intervention period, which may not capture long-term effects. Self-reported data could introduce bias. Future research should involve larger, more diverse samples and longer interventions and consider digital family-based education methods, such as webinars and web-based workshops, to enhance parental involvement [62-64]. Engaging parents in school health education could yield better adolescent health outcomes [63,64].

Conclusions

This study underscores the high prevalence of obesity among Saudi adolescents and highlights the potential of low-intensity educational interventions to improve macronutrient knowledge. By emphasizing metabolic health and muscle building, the Green Apple program offers a promising non–weight-centric strategy for preventing chronic metabolic diseases. Future programs should focus on high-intensity physical activity and neutral weight messaging to address obesity and mental health comprehensively.

Acknowledgments

The authors would like to express sincere gratitude to the Ministry of Education School Health Department in Medina and all the participating schools for their invaluable support. All authors have read and agreed to the published version of the manuscript.

Data Availability

The datasets generated and analyzed during this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

References

1. Zhang X, Liu J, Ni Y, et al. Global prevalence of overweight and obesity in children and adolescents: a systematic review and meta-analysis. JAMA Pediatr 2024 Aug 1;178(8):800-813. [doi: 10.1001/jamapediatrics.2024.1576] [Medline: 38856986]
2. Gao L, Peng W, Xue H, et al. Spatial-temporal trends in global childhood overweight and obesity from 1975 to 2030: a weight mean center and projection analysis of 191 countries. Global Health 2023 Aug 4;19(1):53. [doi: 10.1186/s12992-023-00954-5] [Medline: 37542334]
3. AlEnazi S, AlAjlan R, AlKhalaf H, et al. Prevalence of obesity among children and adolescents in Saudi Arabia: a multicenter population-based study. Saudi J Med Med Sci 2023;11(1):19-25. [doi: 10.4103/sjmms.sjmms_417_22] [Medline: 36909009]
4. Alhamed A, Al-Zeer A, Alsaawi F, et al. The shifting patterns of childhood obesity: insights from national school screening data. Saudi Pharm J 2023 Dec;31(12):101862. [doi: 10.1016/j.jsps.2023.101862] [Medline: 38028221]
5. Alluhidan M, Alsukait RF, Alghaith T, Shekar M, Alazemi N, Herbst CH. Overweight and Obesity in Saudi Arabia: Consequences and Solutions: International Development in Focus; 2022.

XSL•FO
RenderX

6. Alammar M, Alsoghayer S, El-Abd K, Alkhenizan A. Diagnostic accuracy of body mass index (BMI) when diagnosing obesity in a Saudi adult population in a primary care setting, cross sectional, retrospective study. Diabetes Metab Syndr Obes 2020;13:2515-2520. [doi: 10.2147/DMSO.S263063] [Medline: 32765030]
7. Wahabi H, Fayed AA, Shata Z, et al. The impact of age, gender, temporality, and geographical region on the prevalence of obesity and overweight in Saudi Arabia: scope of evidence. Healthcare (Basel) 2023 Apr 15;11(8):1143. [doi: 10.3390/healthcare11081143] [Medline: 37107976]
8. Chaabene H, Markov A, Schega L. Why should the next generation of youth guidelines prioritize vigorous physical activity? Sports Med Open 2024 Jul 30;10(1):87. [doi: 10.1186/s40798-024-00754-0] [Medline: 39080127]
9. Huang Z, Li J, Liu Y, Zhou Y. Effects of different exercise modalities and intensities on body composition in overweight and obese children and adolescents: a systematic review and network meta-analysis. Front Physiol 2023;14:1193223. [doi: 10.3389/fphys.2023.1193223] [Medline: 37497435]
10. Al-Hussaini A, Bashir MS, Khormi M, et al. Overweight and obesity among Saudi children and adolescents: where do we stand today? Saudi J Gastroenterol 2019;25(4):229. [doi: 10.4103/sjg.SJG_617_18]
11. Morales Camacho WJ, Molina Díaz JM, Plata Ortiz S, Plata Ortiz JE, Morales Camacho MA, Calderón BP. Childhood obesity: aetiology, comorbidities, and treatment. Diabetes Metab Res 2019 Nov;35(8):e3203. [doi: 10.1002/dmrr.3203]
12. Banany M, Kang M, Gebel K, Sibbritt D. A systematic review of school-based weight-related interventions in the Gulf Cooperation Council countries. Syst Rev 2024 Feb 14;13(1):66. [doi: 10.1186/s13643-024-02475-7] [Medline: 38355590]
13. Abdulwahab IJ, Alzahrani NA, Khouja JH. A comprehensive review of school-based lifestyle interventions to reduce childhood obesity in the eastern Mediterranean region. Cureus 2024 Jul;16(7):e64305. [doi: 10.7759/cureus.64305] [Medline: 39130893]
14. Dabravolskaj J, Montemurro G, Ekwaru JP, et al. Effectiveness of school-based health promotion interventions prioritized by stakeholders from health and education sectors: a systematic review and meta-analysis. Prev Med Rep 2020 Sep;19:101138. [doi: 10.1016/j.pmedr.2020.101138] [Medline: 32612906]
15. Almutairi N, Burns S, Portsmouth L. Barriers and enablers to the implementation of school-based obesity prevention strategies in Jeddah, KSA. Int J Qual Stud Health Well-being 2022 Dec;17(1):2135197. [doi: 10.1080/17482631.2022.2135197] [Medline: 36263729]
16. Rubino F, Puhl RM, Cummings DE, et al. Joint international consensus statement for ending stigma of obesity. Nat Med 2020 Apr;26(4):485-497. [doi: 10.1038/s41591-020-0803-x] [Medline: 32127716]
17. Motevalli M, Drenowatz C, Tanous DR, Khan NA, Wirnitzer K. Management of childhood obesity—time to shift from generalized to personalized intervention strategies. Nutrients 2021;13(4):1200. [doi: 10.3390/nu13041200]
18. Puhl RM, Lessard LM, Larson N, Eisenberg ME, Neumark-Stzainer D. Weight stigma as a predictor of distress and maladaptive eating behaviors during COVID-19: longitudinal findings from the EAT study. Ann Behav Med 2020 Oct 1;54(10):738-746. [doi: 10.1093/abm/kaaa077] [Medline: 32909031]
19. Nutter S, Ireland A, Alberga AS, et al. Weight bias in educational settings: a systematic review. Curr Obes Rep 2019 Jun;8(2):185-200. [doi: 10.1007/s13679-019-00330-8] [Medline: 30820842]
20. Nutter S, Eggerichs LA, Nagpal TS, et al. Changing the global obesity narrative to recognize and reduce weight stigma: a position statement from the World Obesity Federation. Obes Rev 2024 Jan;25(1):e13642. [doi: 10.1111/obr.13642] [Medline: 37846179]
21. Jacob CM, Hardy-Johnson PL, Inskip HM, et al. A systematic review and meta-analysis of school-based interventions with health education to reduce body mass index in adolescents aged 10 to 19 years. Int J Behav Nutr Phys Act 2021 Jan 4;18(1):1. [doi: 10.1186/s12966-020-01065-9] [Medline: 33397403]
22. Champion VL, Skinner CS. The health belief model. In: Glanz K, Rimer BK, Viswanath K, editors. Health Behavior and Health Education: Theory, Research, and Practice, 4th edition: Jossey-Bass; 2008:45-65.
23. Bussey K, Bandura A. Social cognitive theory of gender development and differentiation. Psychol Rev 1999 Oct;106(4):676-713. [doi: 10.1037/0033-295x.106.4.676] [Medline: 10560326]
24. Marshall SJ, Biddle SJ. The transtheoretical model of behavior change: a meta-analysis of applications to physical activity and exercise. Ann Behav Med 2001;23(4):229-246. [doi: 10.1207/S15324796ABM2304_2] [Medline: 11761340]
25. Post RC. A new approach to dietary guidelines communications: make MyPlate, your plate. Child Obes 2011 Oct;7(5):349-351. [doi: 10.1089/chi.2011.0500.post]
26. de Onis M, Onyango AW, Borghi E, Siyam A, Nishida C, Siekmann J. Development of a WHO growth reference for school-aged children and adolescents. Bull World Health Organ 2007 Sep;85(9):660-667. [doi: 10.2471/blt.07.043497] [Medline: 18026621]
27. McCarthy HD, Cole TJ, Fry T, Jebb SA, Prentice AM. Body fat reference curves for children. Int J Obes (Lond) 2006 Apr;30(4):598-602. [doi: 10.1038/sj.ijo.0803232] [Medline: 16570089]
28. Selland CA, Kelly J, Gums K, Meendering JR, Vukovich M. A generalized equation for prediction of VO2peak from a step test. Int J Sports Med 2021 Jul;42(9):833-839. [doi: 10.1055/a-1310-3900] [Medline: 33352603]
29. McArdle WD, Katch FI, Pechar GS, Jacobson L, Ruck S. Reliability and interrelationships between maximal oxygen intake, physical work capacity and step-test scores in college women. Med Sci Sports 1972;4(4):182-186. [doi: 10.1249/00005768-197200440-00019] [Medline: 4648576]

XSL•FO
RenderX

30. Saint-Maurice PF, Laurson KR, Kaj M, Csányi T. Establishing normative reference values for standing broad jump among Hungarian youth. Res Q Exerc Sport 2015 Jun 26;86 Suppl 1:S37-S44. [doi: 10.1080/02701367.2015.1042416] [Medline: 26054955]
31. Al-Hazzaa HM, Musaiger AO, ATLS Research Group. Arab Teens Lifestyle Study (ATLS): objectives, design, methodology and implications. Diabetes Metab Syndr Obes 2011;4:417-426. [doi: 10.2147/DMSO.S26676] [Medline: 22253540]
32. Alahmadi MA, Almasoud KH, Aljahani AH, et al. Validity and reliability of the Arabic sedentary behavior questionnaire among university students aged between 18-30 years old. BMC Public Health 2023 Jan 18;23(1):128. [doi: 10.1186/s12889-023-15030-1] [Medline: 36653773]
33. Chau JY, Grunseit AC, Chey T, et al. Daily sitting time and all-cause mortality: a meta-analysis. PLoS One 2013;8(11):e80000. [doi: 10.1371/journal.pone.0080000] [Medline: 24236168]
34. Marías YF, Glasauer P. Guidelines for Assessing Nutrition-Related Knowledge, Attitudes and Practices: Food and Agriculture Organization of the United Nations (FAO); 2014.
35. Simeon DT, Rattan RD, Panchoo K, Kungeesingh KV, Ali AC, Abdool PS. Body image of adolescents in a multi-ethnic Caribbean population. Eur J Clin Nutr 2003 Jan;57(1):157-162. [doi: 10.1038/sj.ejcn.1601515] [Medline: 12548311]
36. Latiff AA, Muhamad J, Rahman RA. Body image dissatisfaction and its determinants among young primary-school adolescents. J Taibah Univ Med Sci 2018 Feb;13(1):34-41. [doi: 10.1016/j.jtumed.2017.07.003] [Medline: 31435300]
37. Tabachnick BG, Fidell LS. Using Multivariate Statistics, 6th edition: Pearson Education; 2013.
38. Al-Hazzaa HM, Alrasheedi AA, Alsulaimani RA, et al. Prevalence of overweight and obesity among Saudi children: a comparison of two widely used international standards and the national growth references. Front Endocrinol (Lausanne) 2022;13:954755. [doi: 10.3389/fendo.2022.954755] [Medline: 36004353]
39. Al-Hazzaa HM, Al-Sobayel HI, Musaiger AO. Convergent validity of the Arab Teens Lifestyle Study (ATLS) physical activity questionnaire. Int J Environ Res Public Health 2011 Sep;8(9):3810-3820. [doi: 10.3390/ijerph8093810] [Medline: 22016718]
40. Chen X, Nunnery A. Profile of Very Low-and Low-Income Undergraduates in 2015-16 Stats in Brief: ERIC; 2019.
41. AlSayyari A, AlBuhairan F. Prevalence and correlations of school-absenteeism among intermediate and secondary students in Saudi Arabia. Child Youth Serv Rev 2020 Apr;111:104778. [doi: 10.1016/j.childyouth.2020.104778]
42. Alhazmi AH, Johani AA. Prevalence and associated factors of eating disorders among students in Taiba University, Saudi Arabia: a cross-sectional study. Malays J Public Health Med 2019;19(1):172-176. [doi: 10.37268/mjphm/vol.19/no.1/art.80]
43. Alghnam S, Alessy SA, Bosaad M, et al. The association between obesity and chronic conditions: results from a large electronic health records system in Saudi Arabia. Int J Environ Res Public Health 2021 Nov 24;18(23):12361. [doi: 10.3390/ijerph182312361] [Medline: 34886087]
44. De Paula Sena R, Caroline Santos I, De Souza Cerqueira B, et al. Establishing a normative table for classifying body fat percentage in adolescents. J Hum Growth Dev 2022;32(1):129-135. [doi: 10.36311/jhgd.v32.11542]
45. Woolcott OO, Seuring T. Temporal trends in obesity defined by the relative fat mass (RFM) index among adults in the United States from 1999 to 2020: a population-based study. BMJ Open 2023 Aug 17;13(8):e071295. [doi: 10.1136/bmjopen-2022-071295] [Medline: 37591649]
46. Chen KK, Wee SL, Pang BWJ, et al. Relationship between BMI with percentage body fat and obesity in Singaporean adults—the Yishun Study. BMC Public Health 2021 Jun 1;21(1):1030. [doi: 10.1186/s12889-021-11070-7] [Medline: 34074272]
47. Al-Asiri ZA, Shaheen AAM. Body mass index and health related physical fitness in Saudi girls and adolescents aged 8-15 years. Open J Ther Rehabil 2015;03(4):116-125. [doi: 10.4236/ojtr.2015.34016]
48. Alahmadi M. Health-related physical fitness among adolescent school boys in Madinah city, western Saudi Arabia. Int Sci J Phys Educ Sport Sci 2021 Mar 9;9(1):50-61. [doi: 10.21608/isjpes.2021.62927.1038]
49. Shalabi KM, AlSharif ZA, Alrowaishd SA, Al Ali RE. Relationship between body mass index and health-related physical fitness: a cross-sectional study. Eur Rev Med Pharmacol Sci 2023 Oct;27(20):9540-9549. [doi: 10.26355/eurrev_202310_34127] [Medline: 37916321]
50. Al-Hazzaa HM, Albawardi NM. Obesity, lifestyle behaviors, and dietary habits of Saudi adolescents living in Riyadh (ATLS-2 Project): revisited after a ten-year period. Life (Basel) 2021 Oct 13;11(10):1078. [doi: 10.3390/life11101078] [Medline: 34685449]
51. Posadzki P, Pieper D, Bajpai R, et al. Exercise/physical activity and health outcomes: an overview of Cochrane systematic reviews. BMC Public Health 2020 Nov 16;20(1):1724. [doi: 10.1186/s12889-020-09855-3] [Medline: 33198717]
52. Aljefree NM, Almoraie NM, Althaiban MA, Hanbazaza MA, Wazzan HA, Shatwan IM. Gender differences in knowledge, attitudes, and practices with respect to type 1 diabetes among Saudi public-school teachers. BMC Public Health 2023 Jan 17;23(1):118. [doi: 10.1186/s12889-023-15043-w] [Medline: 36650460]
53. Bendor CD, Bardugo A, Pinhas-Hamiel O, Afek A, Twig G. Cardiovascular morbidity, diabetes and cancer risk among children and adolescents with severe obesity. Cardiovasc Diabetol 2020 Jun 13;19(1):79. [doi: 10.1186/s12933-020-01052-1] [Medline: 32534575]
54. Bucholz EM, Gooding HC, de Ferranti SD. Awareness of cardiovascular risk factors in U.S. young adults aged 18-39 years. Am J Prev Med 2018 Apr;54(4):e67-e77. [doi: 10.1016/j.amepre.2018.01.022] [Medline: 29433955]

XSL•FO
RenderX

55. Akseer N, Mehta S, Wigle J, et al. Non-communicable diseases among adolescents: current status, determinants, interventions and policies. BMC Public Health 2020 Dec 14;20(1):1908. [doi: 10.1186/s12889-020-09988-5] [Medline: 33317507]
56. Al-Daghri NM, Wani K, Khattak MNK, et al. Cardiometabolic effects of a 12-month, COVID-19 lockdown-interrupted lifestyle education program for Arab adolescents. Front Pediatr 2022;10:887138. [doi: 10.3389/fped.2022.887138] [Medline: 35783315]
57. Colao A, Piscitelli P, Pulimeno M, Colazzo S, Miani A, Giannini S. Rethinking the role of the school after COVID-19. Lancet Public Health 2020 Jul;5(7):e370. [doi: 10.1016/S2468-2667(20)30124-9] [Medline: 32464100]
58. Hoffman JA, Miller EA. Addressing the consequences of school closure due to COVID-19 on children's physical and mental well-being. World Med Health Policy 2020 Sep;12(3):300-310. [doi: 10.1002/wmh3.365] [Medline: 32904951]
59. Barry A. Gender differences in academic achievement in Saudi Arabia: a wake-up call to educational leaders. Int J Educ Policy Leadersh 2019;15(15):1-17. [doi: 10.22230/ijepl.2019v15n15a890]
60. Kenney EL, Wintner S, Lee RM, Austin SB. Obesity prevention interventions in US public schools: are schools using programs that promote weight stigma? Prev Chronic Dis 2017 Dec 28;14:E142. [doi: 10.5888/pcd14.160605] [Medline: 29283880]
61. Kerner C, Prescott A, Smith R, Owen M. A systematic review exploring body image programmes and interventions in physical education. Eur Phy Educ Rev 2022 Nov;28(4):942-967. [doi: 10.1177/1356336X221097318]
62. De-Jongh González O, Tugault-Lafleur CN, Buckler EJ, et al. The Aim2Be mHealth intervention for children with overweight or obesity and their parents: person-centered analyses to uncover digital phenotypes. J Med Internet Res 2022;24(6):e35285. [doi: 10.2196/35285]
63. Nuss K, Coulter R, DeSilva B, et al. Evaluating the effectiveness of a family-based virtual childhood obesity management program delivered during the COVID-19 pandemic in Canada: prospective study. JMIR Pediatr Parent 2022;5(4):e40431. [doi: 10.2196/40431]
64. Ganserer A, Moliterno P, Neidenbach R, et al. Effect of a web-based nutritional and physical activity intervention with email support (the EDDY Program) on primary school children's BMI Z-score during the COVID-19 pandemic: intervention study. JMIR Pediatr Parent 2024 Sep 19;7:e50289. [doi: 10.2196/50289] [Medline: 39298741]

Abbreviations

BAZ: BMI-for-age *z* score
MET: metabolic equivalent task
NCD: noncommunicable disease
SBQ: Sedentary Behavior Questionnaire
VO_2max: maximal oxygen consumption

Edited by S Badawy; submitted 05.10.24; peer-reviewed by A Batrakoulis, M Alanazi; revised version received 15.11.24; accepted 28.11.24; published 24.01.25.

Please cite as:
Zuair A, Alhowaymel FM, Jalloun RA, Alzahrani NS, Almasoud KH, Alharbi MH, Alnawwar RK, Alluhaibi MN, Alharbi RS, Aljohan FM, Alhumaidi BN, Alahmadi MA
Body Fat and Obesity Rates, Cardiovascular Fitness, and the Feasibility of a Low-Intensity Non–Weight-Centric Educational Intervention Among Late Adolescents: Quasi-Experimental Study
JMIR Pediatr Parent 2025;8:e67213
URL: https://pediatrics.jmir.org/2025/1/e67213
doi:10.2196/67213

© Areeg Zuair, Fahad M Alhowaymel, Rola A Jalloun, Naif S Alzahrani, Khalid H Almasoud, Majdi H Alharbi, Rayan K Alnawwar, Mohammed N Alluhaibi, Rawan S Alharbi, Fatima M Aljohan, Bandar N Alhumaidi, Mohammad A Alahmadi. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 24.1.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Corrigenda and Addenda

Correction: Digital Health Program to Support Family Caregivers of Children Undergoing Growth Hormone Therapy: Qualitative Feasibility Study

Alba Jiménez-Díaz[1*], MSc; Maitena Pierantonelli[1*], BA; Patricia Morte Coscolín[2,3], MD; Amaia Salinas-Uhalte[2,3], MD; Silvia Quer-Palomas[4], PhD; Octavio Rivera-Romero[5,6], PhD; Rocío Herrero[7,8], PhD; Luis Fernández-Luque[4], PhD; Rosa Baños[1,8], PhD; Ricardo C Berrios[4], BSc; Antonio de Arriba Muñoz[2,3], MD, PhD

[1]Departamento de Personalidad, Evaluación y Tratamientos Psicológicos, Universitat de València, Valencia, Spain
[2]Unidad de Endocrinología Pediátrica, Hospital Universitario Miguel Servet, Zaragoza, Spain
[3]Instituto de Investigación Sanitaria de Aragón, Zaragoza, Spain
[4]Adhera Health Inc, Santa cruz, CA, United States
[5]Instituto de Ingeniería Informática, Universidad de Sevilla, Sevilla, Spain
[6]Electronic Technology Department, Universidad de Sevilla, Sevilla, Spain
[7]Departamento de Psicología y Sociología, Universidad de Zaragoza, Teruel, Spain
[8]CIBER of Physiopathology of Obesity and Nutrition (CIBEROBN), Madrid, Spain
[*]these authors contributed equally

Corresponding Author:
Antonio de Arriba Muñoz, MD, PhD
Unidad de Endocrinología Pediátrica
Hospital Universitario Miguel Servet
Paseo Isabel la Católica, 1
Zaragoza, 50009
Spain
Phone: 34 976765500
Email: luis@adherahealth.com

Related Article:

Correction of: https://pediatrics.jmir.org/2025/1/e55023

(JMIR Pediatr Parent 2025;8:e76508) doi:10.2196/76508

In “Digital Health Program to Support Family Caregivers of Children Undergoing Growth Hormone Therapy: Qualitative Feasibility Study” (JMIR Pediatr Parent 2025;8:e55023) the authors made one correction.

The following affiliation was added to authors RH and RB:

CIBER of Physiopathology of Obesity and Nutrition (CIBEROBN), Madrid, Spain

The correction will appear in the online version of the paper on the JMIR Publications website together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

XSL•FO
RenderX

Edited by P Kharbanda; submitted 25.04.25; this is a non–peer-reviewed article;accepted 25.04.25; published 18.07.25.

Please cite as:
Jiménez-Díaz A, Pierantonelli M, Morte Coscolín P, Salinas-Uhalte A, Quer-Palomas S, Rivera-Romero O, Herrero R, Fernández-Luque L, Baños R, Berrios RC, de Arriba Muñoz A
Correction: Digital Health Program to Support Family Caregivers of Children Undergoing Growth Hormone Therapy: Qualitative Feasibility Study
JMIR Pediatr Parent 2025;8:e76508
URL: https://pediatrics.jmir.org/2025/1/e76508
doi:10.2196/76508
PMID:40680275

©Alba Jiménez-Díaz, Maitena Pierantonelli, Patricia Morte Coscolín, Amaia Salinas-Uhalte, Silvia Quer-Palomas, Octavio Rivera-Romero, Rocío Herrero, Luis Fernández-Luque, Rosa Baños, Ricardo C Berrios, Antonio de Arriba Muñoz. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 18.07.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Correction: Sex Differences in the Joint Trajectories of Depressive Symptoms and Body Mass Index From Adolescence to Early Adulthood: Longitudinal Observational Study

Jing Chen[1], PhD; Rui Shan[1], MD; Wen Yuan[2], PhD; Qiong Wu[3], PhD; Yang Yang[1], MD; Yi-Hang Yang[1], MD; Jing-Yao Liu[1], MD; Wu-Cai Xiao[1], MD; Shanghang Zhang[4], PhD; Li-Ming Wen[5], PhD; Xiao-Rui Zhang[6*], PhD; Zheng Liu[1*], PhD; Yi Song[2], PhD

[1]Department of Maternal and Child Health, School of Public Health, Peking University, 38 Xueyuan Road, Haidian District, Beijing, China

[2]Institute of Child and Adolescent Health, School of Public Health, Peking University, Beijing, China

[3]Institute of Social Science Survey, Peking University, Beijing, China

[4]The School of Computer Science, Peking University, Beijing, China

[5]School of Public Health, The Faculty of Medicine and Health, University of Sydney, Sydney, Australia

[6]Department of Pediatrics, Peking University People's Hospital, Beijing, China

[*]these authors contributed equally

Corresponding Author:
Zheng Liu, PhD
Department of Maternal and Child Health, School of Public Health, Peking University, 38 Xueyuan Road, Haidian District, Beijing, China

Related Article:

Correction of: https://pediatrics.jmir.org/2025/1/e72722

Abstract

(JMIR Pediatr Parent 2025;8:e84632) doi:10.2196/84632

In "Sex Differences in the Joint Trajectories of Depressive Symptoms and Body Mass Index From Adolescence to Early Adulthood: Longitudinal Observational Study" [1], the authors noted two affiliation errors.

The affiliation for author XRZ has been changed to:

Department of Pediatrics, Peking University People's Hospital, Beijing, China

In addition, the affiliations for author YS have been amended so that the author is only affiliated with the following institution:

Institute of Child and Adolescent Health, School of Public Health, Peking University, Beijing, China

The correction will appear in the online version of the paper on the JMIR Publications website, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Reference

1. Chen J, Shan R, Yuan W, et al. Sex differences in the joint trajectories of depressive symptoms and body mass index from adolescence to early adulthood: longitudinal observational study. JMIR Pediatr Parent 2025 Jun 27;8:e72722. [doi: 10.2196/72722] [Medline: 40576329]

XSL•FO
RenderX

Submitted 22.09.25; this is a non–peer-reviewed article;accepted 22.09.25; published 30.09.25.

Please cite as:
Chen J, Shan R, Yuan W, Wu Q, Yang Y, Yang YH, Liu JY, Xiao WC, Zhang S, Wen LM, Zhang XR, Liu Z, Song Y
Correction: Sex Differences in the Joint Trajectories of Depressive Symptoms and Body Mass Index From Adolescence to Early Adulthood: Longitudinal Observational Study
JMIR Pediatr Parent 2025;8:e84632
URL: https://pediatrics.jmir.org/2025/1/e84632
doi:10.2196/84632

© Jing Chen, Rui Shan, Wen Yuan, Qiong Wu, Yang Yang, Yi-Hang Yang, Jing-Yao Liu, Wu-Cai Xiao, Shanghang Zhang, Li-Ming Wen, Xiao-Rui Zhang, Zheng Liu, Yi Song. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 30.9.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

The Effect of COVID-19 on Health Care Utilization Among Children with Medical Complexity: Retrospective Chart Review Study

Onur Asan[1], PhD; Ilse Super[1], MS; Stephen Percy[2], MD; Katharine N Clouser[2], MD

[1]Department of Systems and Enterprises, Stevens Institute of Technology, 1 Castle Terrace Dr, Hoboken, NJ, United States

[2]Hackensack Meridian School of Medicine, Hackensack University Medical Center, Hackensack, NJ, United States

Corresponding Author:
Onur Asan, PhD
Department of Systems and Enterprises, Stevens Institute of Technology, 1 Castle Terrace Dr, Hoboken, NJ, United States

Abstract

This study examines the trends, patterns, and potential health disparities in health care utilization among children with medical complexity, before and during COVID pandemic through a retrospective chart review. Our findings show significant differences in the average number of visits per patient over the years and support the adoption of telehealth consultations, while highlighting concerns about demographic disparities.

(JMIR Pediatr Parent 2025;8:e65751) doi:10.2196/65751

KEYWORDS

children with medical complexity; pediatric; children; health care utilization; telemedicine; telehealth; virtual care; virtual health; COVID-19; SARS-COV-2; coronavirus; respiratory; infectious; pulmonary; pandemic; chart review; chart review study; retrospective chart review; retrospective chart review study

Introduction

Children with medical complexity are defined as children and youth with chronic and severe health conditions and substantial functional limitations that require specialized medical services, frequent hospitalizations, and coordinated care from various health care providers [1,2].

Telehealth was one of the efficient and creative solutions for care for children with medical complexity during the pandemic [3]. These children face numerous barriers to health care (eg, multiple visits per day, limited access and availability of clinicians, high cost of transportation, day-to-day life disruptions) [4]. Telehealth visits or remote virtual consultations offered numerous benefits at the onset of the COVID-19 pandemic, such as limited exposure, fewer transfers, and minimum travel for several types of patients and specialists, while also increasing the availability of consultations [5]. This alternative to in-person visits has proven to be effective in resource-limited countries with geographical barriers and has reduced the burden of negative consequences for chronically ill children [6]. After its rapid implementation during the pandemic, the attention has shifted towards equity and safety for children with medical complexity postpandemic, while focusing on clinical model refinement and addressing potential health disparities [7,8]. We explored health care utilization patterns among children with medical complexity over 3 years, before and after the pandemic.

Methods

Study Design and Participants

We performed a retrospective chart review study using data from a large health care setting on the East Coast between January 1, 2019, and December 31, 2021. Patients that were included in the study (N=435) were children with medical complexity (<22 years of age), diagnosed with ≥3 chronic conditions [9]. All patient mortality cases (n=5) during the selected period were excluded due to incomplete data for comparison.

Ethical Considerations

This study used deidentified chart data retrieved from electronic health records using *ICD-10* codes to identify the population. The data were fully anonymized before analysis, and no personal or identifiable information was accessed. The study was conducted in compliance with all relevant data protection regulations, including the HIPPA (Health Insurance Portability and Accountability Act). Institutional Review Board approval was obtained (IRB ID: Pro2023-0385) from Hackensack Meridian Health.

Data Processing and Analysis

A demographic summary and descriptive statistics were computed to analyze the distribution of demographic variables, years, and health care visit types, including counts, means, and standard deviations. To evaluate associations between these variables, the Pearson χ^2 tests of independence were conducted.

XSL•FO
RenderX

For variables showing significant associations (P<.05), we reported the effect size using Cramer's V [5] to determine the strength of the relationship. Additionally, posthoc pairwise comparisons were performed using χ^2 tests with adjusted significance levels to identify specific category pairs contributing to the observed differences. All analyses were performed using Microsoft Excel and SPSS software (version 29; IBM Corp) to ensure accuracy and consistency.

Results

Demographic Summary

Table 1 presents the demographic summary of the patients included in the study.

Table . Demographic summary of patients.

Variables	Patients, n (%) (N=435)
Age	
Infants (1-2)	55 (12.6)
Children (3-11)	231 (53.1)
Adolescents (12-18)	104 (23.9)
Young Adults (18-21)	45 (10.3)
Race/ethnicity	
Asian	65 (14.9)
Black	65 (14.9)
Hispanic	82 (18.9)
NonHispanic White	85 (29.5)
Other	67 (15.4)
Unknown	71 (16.3)
Insurance method	
Managed Care	302 (69.4)
Private	99 (22.8)
Other	34 (7.8)

Statistical Analysis

Table 2 provides descriptive statistics for the entire dataset. The data reveal that the highest total average was 16.74 appointments per patient before the pandemic in 2019. In 2020, with the onset of COVID-19, telehealth became a viable means of communicating with patients, while other types of visits and inpatient admissions decreased, resulting in a total average of 10.34 appointments per patient. Although mean of all visit types, including inpatient admissions increased in 2021, they did not return to the 2019 levels, leading to an overall average of 13.22 appointments per patient.

XSL•FO
RenderX

Table . Data description and findings. This table describes the mean and standard deviations of the number of visits for each visit type (telehealth, outpatient, emergency department) and admissions per patient.

Demographic variables	Visit types															
	Telehealth visits, mean (SD)				Outpatient visits, mean (SD)				Emergency department visits, mean (SD)				Inpatient admissions, mean (SD)			
	2019	2020	2021	*P* value	2019	2020	2021	*P* value	2019	2020	2021	*P* value	2019	2020	2021	*P* value
Overall[a]	0 (0)	2.84 (2.02)	2.01 (1.41)	<.001	6.01 (1.98)	3.50 (1.09)	5.33 (2.31)	<.001	7.31 (2.28)	2.44 (1.70)	3.40 (2.21)	<.001	3.42 (2.30)	1.56 (1.11)	2.48 (1.69)	<.001
Age[b]				.78				.15				.45				.86
Young adults	0 (0)	2.44 (2.23)	2.22 (1.41)		5.91 (1.78)	3.96 (1.02)	4.91 (2.33)		7.07 (2.32)	2.69 (1.49)	4.07 (2.04)		3.71 (2.14)	1.60 (1.16)	2.27 (1.47)	
Children	0 (0)	2.99 (1.94)	1.99 (1.39)		5.81 (2.06)	3.50 (1.08)	5.37 (2.27)		7.32 (2.32)	2.45 (1.72)	3.42 (2.19)		3.31 (2.35)	1.61 (1.09)	2.45 (1.73)	
Adolescents	0 (0)	3.09 (2.07)	1.99 (1.43)		6.17 (1.94)	3.46 (1.10)	5.35 (2.37)		7.24 (2.25)	2.49 (1.67)	3.21 (2.23)		3.61 (2.35)	1.51 (1.12)	2.52 (1.70)	
Infants	0 (0)	2.05 (1.87)	1.98 (1.46)		6.62 (1.79)	3.24 (1.09)	5.45 (2.36)		7.62 (2.16)	2.11 (1.80)	3.11 (2.33)		3.31 (2.13)	1.40 (1.13)	2.73 (1.72)	
Race/ethnicity[b]				.30				.04				.86				.85
Asian	0 (0)	2.80 (2.03)	2.26 (1.47)		5.49 (1.80)	3.35 (1.02)	5.51 (2.37)		7.35 (2.34)	2.46 (1.71)	3.52 (2.03)		3.51 (2.24)	1.71 (1.10)	2.71 (1.68)	
Black	0 (0)	2.91 (2.26)	2.09 (1.51)		6.46 (1.76)	3.51 (1.09)	5.22 (2.23)		7.22 (2.26)	2.51 (1.69)	3.86 (2.24)		3.37 (2.22)	1.54 (1.13)	2.31 (1.66)	
Hispanic	0 (0)	2.52 (1.95)	1.79 (1.39)		5.98 (1.81)	3.45 (1.11)	4.96 (2.19)		7.63 (2.27)	2.66 (1.76)	3.24 (2.30)		3.72 (2.22)	1.61 (1.04)	2.44 (1.74)	
Non-Hispanic White	0 (0)	2.65 (1.93)	2.02 (1.37)		6.49 (2.07)	3.71 (1.14)	5.38 (2.33)		7.31 (2.08)	2.13 (1.54)	3.40 (2.24)		3.41 (2.21)	1.59 (1.14)	2.35 (1.82)	
Other	0 (0)	3.30 (2.04)	1.87 (1.28)		5.60 (2.11)	3.66 (1.05)	5.30 (2.41)		7.10 (2.57)	2.57 (1.79)	3.36 (2.31)		3.06 (2.42)	1.57 (1.05)	2.66 (1.67)	
Unknown	0 (0)	2.97 (1.93)	2.08 (1.44)		5.93 (2.13)	3.31 (1.08)	5.65 (2.37)		7.18 (2.26)	2.35 (1.71)	3.08 (2.09)		3.39 (2.36)	1.32 (1.18)	2.46 (1.56)	
Insurance methods[b]				.86				.44				.43				.17
Managed Care	0 (0)	2.81 (2.02)	1.99 (1.42)		6.06 (1.98)	3.52 (1.07)	5.23 (2.34)		7.32 (2.27)	2.44 (1.66)	3.42 (2.19)		3.39 (2.30)	1.56 (1.11)	2.43 (1.68)	
Private	0 (0)	2.78 (1.99)	2.04 (1.39)		5.92 (1.98)	3.59 (1.11)	5.63 (2.34)		7.28 (2.36)	2.38 (1.77)	3.35 (2.20)		3.40 (2.36)	1.49 (1.12)	2.55 (1.74)	
Other	0 (0)	3.26 (2.09)	2.09 (1.38)		5.85 (2.06)	3.15 (1.16)	5.29 (1.93)		7.29 (2.21)	2.62 (1.86)	3.32 (2.50)		3.74 (2.09)	1.74 (1.08)	2.76 (1.69)	

[a]Overall averages for each year with a *P* value for difference between the years

[b]Averages per year for each demographic group with a *P* value for the difference between demographic categories.

XSL•FO
RenderX

A χ^2 test of independence revealed significant differences between the years for telehealth visits (P<.001, Cramer's V=0.612), outpatient visits (P<.001, Cramer's V=0.396), emergency department visits (P<.001, Cramer's V=0.557), and inpatient admissions (P<.001, Cramer's V=0.405).

Among the demographic variables, a significant association was found between race or ethnicity and the number of outpatient visits for three years (P=.04, Cramer's V=0.008). Pairwise comparison for outpatient visits revealed three significant relationships between Asian (P=.02), Hispanic (P=.004), and other patients (P=.02) compared to nonHispanic White patients.

Discussion

Telehealth visits were introduced in 2020, and resulted in a notable decrease in other visit types and inpatient admissions, as reported in other studies [4]. Although 2021 saw an increase in these visit types compared to 2020, they did not return to prepandemic levels observed in 2019. This could be attributed to catch-up visits and admissions that were postponed due to safety reasons during the pandemic [10]. In addition, while many visits can be conducted via telehealth systems, some health care procedures require in-person visits; the safety of these in-person visits improved in 2021.

The reduction in in-person visits after introducing telehealth implementation aligns with another study showing lower hospitalization rates 3 months post discharge when telehealth was used for follow up [11]. Our study also found a reduction in emergency department visits after telehealth introduction, as shown in the literature [8]. Increasing the ease at which a family can access health care via telehealth can avoid some of the in-person struggles faced by families and improve satisfaction with health care interactions.

Our findings show that Asian, Hispanic, and other racial and ethnic groups, have significantly fewer outpatient visits, on average, than nonHispanic White patients. These findings partially align with recent research among Medicaid-insured children with medical complexity, which found that Black nonHispanic and Hispanic children had lower outpatient visit rates than nonHispanic White children [12]. Several reasons may contribute to lower out-patient visits among racial and ethnic minorities, including differential access to care [12], geographical dispersion, a reduced likelihood of receiving specialty referrals from primary care providers, and distrust in the health care system [13]. Significant differences in the number of visits could lead to health disparities, potentially disadvantaging minority groups, and should, therefore, be monitored and addressed.

The COVID-19 pandemic has shown the feasibility of telehealth visits. Although we found disparities based on race and ethnicity in outpatient visits, our findings support equity through telehealth visits for patients and reduced health care utilization. There was no increase in the need for inpatient services when using telehealth visits, which supports the idea that telehealth can be an effective solution for patients. Families can avoid transportation challenges and coordination issues when using telehealth visits.

Our study focuses on changes in health care utilization among children with medical complexity with 3 or more chronic conditions, providing valuable insights into trends within this population. However, we did not account for specific illnesses, clinical outcomes, or the quality of telehealth visits. Additionally, we did not consider environmental factors such as air pollution or pollen exposure, which could significantly influence utilization patterns among children with respiratory or allergic conditions [14]. To deepen our understanding, future research should include control groups or broader pediatric populations to contextualize these observed trends and address potential confounding factors. Additionally, qualitative analyses are needed to explore the reasons behind differences in utilization and disparities, offering a more comprehensive perspective on the challenges faced by this population.

In conclusion, our findings emphasize the need for continued adaptation and support for telehealth services among children, while monitoring demographic disparities in health care access. The introduction of telehealth at the onset of the pandemic coincided with significant decreases in in-person visits and inpatient admissions. Although health care utilization rebound in 2021, it remained below prepandemic levels, suggesting an ongoing adjustment in health care practices. Further, our findings indicate that racial and ethnic disparities persist in outpatient visit patterns. Continued support for telehealth implementation, coupled with targeted efforts to address disparities, are crucial for equitable health care access for all children with medical complexity.

Acknowledgments

This publication was supported by the Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health under Award Number 1R15HD109791-01.

Authors' Contributions

Conceptualization: IS, KNC, OA, SP
Methodology: IS, KNC, OA, SP
Writing – original draft: IS, OA
Writing – review & editing: IS, KNC, OA, SP

XSL•FO
RenderX

Conflicts of Interest

None declared.

References

1. Millar K, Rodd C, Rempel G, Cohen E, Sibley KM, Garland A. The clinical definition of children with medical complexity: a modified Delphi study. Pediatrics 2024 Jun 1;153(6):e2023064556. [doi: 10.1542/peds.2023-064556] [Medline: 38804054]
2. Cohen E, Berry JG, Sanders L, Schor EL, Wise PH. Status complexicus? The emergence of pediatric complex care. Pediatrics 2018 Mar;141(Suppl 3):S202-S211. [doi: 10.1542/peds.2017-1284E] [Medline: 29496971]
3. Elkourdi F, Asan O. Community caregivers' perspectives on health IT use for children with medical complexity: qualitative interview study. JMIR Pediatr Parent 2025 Feb 10;8:e67289. [doi: 10.2196/67289] [Medline: 39928943]
4. Lakhaney D, Matiz LA. Telemedicine for children with medical complexity during the COVID-19 pandemic: implications for practice. Clin Pediatr (Phila) 2023 Feb;62(2):89-91. [doi: 10.1177/00099228221116707] [Medline: 35941789]
5. Hageman JR. The emergence of pediatric telehealth as a result of the COVID-19 pandemic. Pediatr Ann 2020 Jul 1;49(7):e283-e284. [doi: 10.3928/19382359-20200626-01] [Medline: 32674163]
6. Mukusheva Z, Assylbekova M, Poddighe D. Management of pediatric rheumatic patients in Kazakhstan during the coronavirus disease 2019 (COVID-19) pandemic. Rheumatol Int 2020 Aug;40(8):1351-1352. [doi: 10.1007/s00296-020-04613-5] [Medline: 32514608]
7. Coller RJ, Berry JG, Kuo DZ, et al. Health system research priorities for children and youth with special health care needs. Pediatrics 2020 Mar;145(3):e20190673. [doi: 10.1542/peds.2019-0673] [Medline: 32024751]
8. Van Cleave J, Stille C, Hall DE. Child health, vulnerability, and complexity: use of telehealth to enhance care for children and youth with special health care needs. Acad Pediatr 2022 Mar;22(2S):S34-S40. [doi: 10.1016/j.acap.2021.10.010] [Medline: 35248246]
9. Feudtner C, Feinstein JA, Zhong W, Hall M, Dai D. Pediatric complex chronic conditions classification system version 2: updated for ICD-10 and complex medical technology dependence and transplantation. BMC Pediatr 2014 Aug 8;14(199):25102958. [doi: 10.1186/1471-2431-14-199] [Medline: 25102958]
10. Onofri A, Pavone M, De Santis S, et al. Telemedicine in children with medical complexity on home ventilation during the COVID-19 pandemic. Pediatr Pulmonol 2021 Jun;56(6):1395-1400. [doi: 10.1002/ppul.25289] [Medline: 33524228]
11. Ming DY, Li T, Ross MH, et al. Feasibility of post-hospitalization telemedicine video visits for children with medical complexity. J Pediatr Health Care 2022;36(2):e22-e35. [doi: 10.1016/j.pedhc.2021.10.001] [Medline: 34879986]
12. Ming DY, Jones KA, White MJ, et al. Healthcare utilization for Medicaid-insured children with medical complexity: differences by sociodemographic characteristics. Matern Child Health J 2022 Dec;26(12):2407-2418. [doi: 10.1007/s10995-022-03543-x] [Medline: 36198851]
13. Cai C, Gaffney A, McGregor A, et al. Racial and ethnic disparities in outpatient visit rates across 29 specialties. JAMA Intern Med 2021 Nov 1;181(11):1525-1527. [doi: 10.1001/jamainternmed.2021.3771] [Medline: 34279566]
14. Lee E, Rhee EH, Yu J, et al. Incidence of healthcare utilization for allergic and respiratory infectious diseases in children with asthma before and during the COVID-19 pandemic. Allergy 2024 Apr;79(4):1064-1067. [doi: 10.1111/all.15992] [Medline: 38140807]

Abbreviations

HIPPA: Health Insurance Portability and Accountability Act

Edited by S Badawy; submitted 25.08.24; peer-reviewed by D Poddighe, SW Lee; revised version received 10.01.25; accepted 13.01.25; published 28.02.25.

Please cite as:
Asan O, Super I, Percy S, Clouser KN
The Effect of COVID-19 on Health Care Utilization Among Children with Medical Complexity: Retrospective Chart Review Study
JMIR Pediatr Parent 2025;8:e65751
URL: https://pediatrics.jmir.org/2025/1/e65751
doi:10.2196/65751

© Onur Asan, Ilse Super, Stephen Percy, Katharine N Clouser. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 28.2.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete

XSL•FO
RenderX

bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

A Primary Care Group Resilience Intervention Promotes Child and Caregiver Behavioral Health

Joan Jeung[1], MD, MPH; Andrew Nguyen[2], MPH; Jennifer Martinez[3], BS; Li Zhang[2], PhD

[1]Department of Pediatrics, Division of Developmental Medicine, University of California San Francisco (UCSF) School of Medicine, 675 - 18th St, 2nd Floor, UCSF Box 3132, San Francisco, CA, United States

[2]Department of Medicine, University of California San Francisco (UCSF) School of Medicine, San Francisco, CA, United States

[3]Graduate Medical Sciences, Chobanian & Avedisian School of Medicine, Boston University, Boston, MA, United States

Corresponding Author:
Joan Jeung, MD, MPH
Department of Pediatrics, Division of Developmental Medicine, University of California San Francisco (UCSF) School of Medicine, 675 - 18th St, 2nd Floor, UCSF Box 3132, San Francisco, CA, United States

Abstract

This pilot study of the redesigned Resilience Clinic, a group-based psychoeducational intervention designed to promote relational health and child and family resilience provides preliminary evidence that participation in this intervention is associated with decreased caregiver stress, anxiety, and child behavioral concerns.

(JMIR Pediatr Parent 2025;8:e67638) doi:10.2196/67638

KEYWORDS

parenting education; parent-child relationship; adverse childhood experiences; child behavior; children; caregiver; caretaker; parenting; family; stress; anxiety; behavior; relational health; psychoeducation; psychological education; resilience intervention; group-based; pilot study

Introduction

Since adverse childhood experiences (ACEs) including child maltreatment, family violence, parental substance abuse, and parental mental illness may increase health and behavioral risks [1,2], further research into preventive early childhood interventions, before the onset of ACE-associated sequelae is required [3]. The Resilience Clinic (RC) [4] is a primary care-based group psychoeducational intervention promoting resilience among children exposed to significant adversity. Initially serving children of all ages, this program was redesigned based on significant parent feedback to focus on early childhood (ages 0 - 5); the curriculum incorporates Circle of Security-Parenting (building secure attachment) [5] and Dovetail Learning (mindful stress management) [6] in 6 weekly, hour-long group sessions. This study explored whether participation in RC decreased measures of (1) caregiver stress, anxiety, and depression, and (2) child behavioral challenges.

Methods

This pilot study analyzed pre-post differences in caregiver-reported measures of behavioral health after RC participation. Eligibility criteria included children aged 0 - 5, referred by primary care providers following positive ACE screening; siblings were excluded. Eligible participants were allowed to join the intervention without joining the study.

Study measures included the Child Behavior Checklist (CBCL) for ages 1.5 to 5 years [7] to assess child behavioral challenges, Generalized Anxiety Disorder (GAD-7) [8] for caregiver anxiety, Patient Health Questionnaire (PHQ-8) [9] for caregiver depression, and Perceived Stress Scale (PSS-4) [10] for caregiver stress. Caregivers completed measurements at baseline and 3 months after intervention completion.

To estimate intervention effect sizes, we used Cohen *d* or (standardized mean difference), for paired samples. Cohen *d* value cutoffs of 0.2, 0.5, and 0.8 are considered as small, medium, and large effect sizes, respectively. *P* values were constructed from the Wilcoxon signed-rank test since the variables were not normally distributed, with significance set at $P<.05$.

This study was approved by the host institution's Institutional Review Board (22 - 37781) as minimal risk research. Signed informed consent was obtained from all participating caregivers. Data was stored on secure institutional servers and deidentified prior to analysis. Participants could receive up to $190 for completing all study activities.

Results

A total of 28 caregiver/child dyads were recruited; of these, 79% (n=22) preferred Spanish and 14% (n=4) preferred English. Median child age was 4.5 years (IQR 1.66) and 50% (n=14)

XSL•FO
RenderX

were male. Participants who completed both pre and post data collection were included in this analysis.

Three months post-intervention, caregivers reported large reductions in anxiety and perceived stress compared to baseline (Table 1).

Table . Pre-post changes in caregiver behavioral health measures.

Construct	Measures	Participants, n[a] (N=28)	Baseline scores median, (IQR)	Post intervention scores, median (IQR)	Cohen *d* (SMD)[b]	*P* value
Caregiver anxiety	GAD-7[c]	16	5.5 (1.75-9.25)	1.0 (0-4.25)	0.86	.01
Caregiver depression	PHQ-8[d]	4	8.0 (6.5-9.25)	5.5 (3.75-7.25)	0.63	.42
Caregiver-perceived stress	PSS)- 4[e]	18	7.0 (6-8)	4.0 (3-6)	0.92	.02

[a]Number of participants who completed both pre and postdata collection for that measure.

[b]SMD: Standardized mean difference.

[c]GAD-7: Generalized Anxiety Disorder-7-item.

[d]PHQ-8: Patient Health Questionnaire-8-item.

[e]PSS-4: Perceived Stress Scale-4-item.

Notably, the decrease in caregiver anxiety (GAD-7: d=0.86, P=.01) and caregiver-perceived stress (PSS-4: d=0.92, P=.02) suggested large and statistically significant intervention effect sizes for parental anxiety and perceived stress among RC participants. The PHQ-8 responses were limited as the full instrument was administered only if the PHQ-2 score exceeded 4, making it difficult to draw conclusions.

Similarly, moderate reductions were seen in postintervention measures of multiple child behavior challenges, including attention problems, aggression, externalizing problems, stress, and overall problems. The decrease in attention problems (d=0.72, P=.05) approached significance. Selected child behavior domains showing moderate postintervention score reduction are listed in Table 2.

All other CBCL domains showed small effect sizes (d<0.5), including emotionally reactive (0.27), anxious depressed (0.12), somatic complaints (0.46), withdrawn (0.36), sleep problems (0.16), internalizing problems (0.32), anxiety problems (0.02), autism spectrum problems (0.48), and oppositional defiant problems (0.40).

Table . Pre-post changes in the Child Behavior Checklist (CBCL).

Child behavior domain	Number of participants, n[a] (N=28)	Baseline scores, median (IQR)	Post-intervention scores, median (IQR)	Cohen *d* (SMD)[b]	*P* value
Attention problems	11	62 (57.5-67)	53 (51.5-62)	0.72	.05
Aggressive behaviors	11	64 (51.5-70)	56 (51-61)	0.53	.20
Externalizing problems	11	64 (53-70)	56 (48.5-60)	0.70	.11
Overall problems	11	68 (53.5-72)	58 (49.5-66.5)	0.50	.07
Stress	11	70 (53-72)	53 (52-62.5)	0.74	.09
Depression	11	63 (53-69.5)	56 (50-61.5)	0.52	.09
ADHD[c]	11	64 (59-71)	57 (52-65.5)	0.72	.08

[a]Number of participants who completed both pre and postdata collection for that measure.

[b]SMD: Standardized mean difference.

[c]ADHD: Attention deficit hyperactivity disorder

Discussion

Three months post-intervention, caregivers reported significant reductions in anxiety and perceived stress and moderate reductions in their children's attention problems, aggressive behaviors, externalizing problems, total problems, and stress and depressive problems. The decrease in caregivers' anxiety and perceived stress was significant (P<.05), and the reduction in child attention problems approached significance (P=.05). These findings suggest that participation in this group resilience intervention may help improve caregiver stress and anxiety and child behavior.

Study limitations include the small sample size and lack of a control group, which make the findings preliminary. Given these promising results, a randomized controlled trial is needed to confirm these intervention effects.

XSL•FO
RenderX

Given the age of these children, when mental health diagnoses are rare, most children would not otherwise be receiving mental health services. This pilot study indicates that similar primary care-based, preventative group interventions may offer meaningful improvements in caregiver and child behavioral health in the context of childhood adversity.

Acknowledgments

This intervention pilot study and evaluation were funded by a University of California ACES Aware Network (UCAAN) PRACTICE grant sponsored by the State of California-Department of Health Care Services (CA-DHCS) and the California Office of the Surgeon General (CA-OSG). The Stupski Foundation also funded program re-designing and implementation at the study's host institution, which preceded the community pilot reported in this manuscript. This publication was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through UCSF-CTSI Grant Number UL1 TR001872. The study authors would also like to thank the following colleagues from the University of California San Francisco (UCSF) School of Medicine, whose work on a companion study informed the design of this one: Neeta Thakur, MD, Associate Professor, Medicine; Dayna Long, MD, Professor, Pediatrics; Nicki Bush, PhD, Professor, Psychiatry; and Danielle Hessler Jones, PhD, Professor, Family and Community Medicine.

Conflicts of Interest

None declared.

References

1. Shonkoff JP, Garner AS, Committee on Psychosocial Aspects of Child and Family Health, Committee on Early Childhood, Adoption, and Dependent Care, Section on Developmental and Behavioral Pediatrics. The lifelong effects of early childhood adversity and toxic stress. Pediatrics 2012 Jan;129(1):e232-e246. [doi: 10.1542/peds.2011-2663] [Medline: 22201156]
2. Felitti VJ, Anda RF, Nordenberg D, et al. Relationship of childhood abuse and household dysfunction to many of the leading causes of death in adults. The adverse childhood experiences (ACE) Study. Am J Prev Med 1998 May;14(4):245-258. [doi: 10.1016/s0749-3797(98)00017-8] [Medline: 9635069]
3. Garner A, Yogman M, Committee on Psychosocial Aspects of Child and Family Health, Section on Developmental and Behavioral Pediatrics, Council on Early Childhood. Preventing childhood toxic stress: partnering with families and communities to promote relational health. Pediatrics 2021 Aug;148(2):e2021052582. [doi: 10.1542/peds.2021-052582] [Medline: 34312296]
4. Jeung J, Hessler Jones D, Frame L, et al. A caregiver-child intervention for mitigating toxic stress ("The Resiliency Clinic"): a pilot study. Matern Child Health J 2022 Oct;26(10):1959-1966. [doi: 10.1007/s10995-022-03485-4] [Medline: 35947275]
5. Yaholkoski A, Hurl K, Theule J. Efficacy of the circle of security intervention: a meta-analysis. J Infant Child Adolesc Psychother 2016 Apr 2;15(2):95-103. [doi: 10.1080/15289168.2016.1163161]
6. Dovetail Learning - We Are ResilientTM practical skills for coping with stress. URL: https://dovetaillearning.org/ [accessed 2024-09-25]
7. Achenbach TM, Rescorla LA. Manual for the ASEBA Preschool Forms and Profiles: University of Vermonth, Research Center for Children, Youth and Families; 2001. URL: https://store.aseba.org/MANUAL-FOR-ASEBA-PRESCHOOL-FORMS-PROFILES/productinfo/605/ [accessed 2025-01-22]
8. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006 May 22;166(10):1092-1097. [doi: 10.1001/archinte.166.10.1092] [Medline: 16717171]
9. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001 Sep;16(9):606-613. [doi: 10.1046/j.1525-1497.2001.016009606.x] [Medline: 11556941]
10. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. J Health Soc Behav 1983 Dec;24(4):385-396. [doi: 10.2307/2136404] [Medline: 6668417]

Abbreviations

ACE: adverse childhood experiences
CBCL : Child Behavior Checklist
GAD-7: Generalized Anxiety Disorder -7 item (screening tool for anxiety)
PHQ-8: Patient Health Questionnaire (PHQ)-8 item (screening tool for depression)
PSS: Perceived Stress Scale
RC: Resilience Clinic

XSL•FO
RenderX

Edited by S Badawy; submitted 16.10.24; peer-reviewed by F Loureiro, OL Gbètoho Atigossou; revised version received 30.12.24; accepted 02.01.25; published 10.02.25.

Please cite as:
Jeung J, Nguyen A, Martinez J, Zhang L
A Primary Care Group Resilience Intervention Promotes Child and Caregiver Behavioral Health
JMIR Pediatr Parent 2025;8:e67638
URL: https://pediatrics.jmir.org/2025/1/e67638
doi:10.2196/67638

© Joan Jeung, Andrew Nguyen, Jennifer Martinez, Li Zhang. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 10.2.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Research Letter

Importance of Engaging Partners in Digital Postpartum Depression Prevention: Qualitative Study

Adam Korrick Lewkowitz[1,2], MD, MPHS; Liana Lum[3], BA; Katrina Ursino[1], BA; Melissa Guillen[4], BA; Gabriela Garcia[3], BA; Sarai K Sales[5], BS; Saloni Taneja[6], BS; Crystal F Ware[1], BSN, CCRP; William A Grobman[1], MD, MPH; Caron Zlotnick[1,7], MD; Kate M Guthrie[4,7], PhD; Emily S Miller[1,7,8], MD, MPH

[1]Department of Obstetrics & Gynecology, Warren Alpert School of Medicine, Brown University, Providence, RI, United States
[2]Center for Digital Health, School of Public Health, Brown University, Providence, RI, United States
[3]Warren Alpert School of Medicine, Brown University, Providence, RI, United States
[4]Center for Behavioral and Preventive Medicine, Brown University Health, Providence, RI, United States
[5]Department of Epidemiology, School of Public Health, Brown University, Providence, RI, United States
[6]Division of Biology and Medicine, Brown University, Providence, RI, United States
[7]Department of Psychiatry and Human Behavior, Warren Alpert School of Medicine, Brown University, Providence, RI, United States
[8]Department of Health Services Policy & Practice, School of Public Health, Brown University, Providence, RI, United States

Corresponding Author:
Adam Korrick Lewkowitz, MD, MPHS
Department of Obstetrics & Gynecology
Warren Alpert School of Medicine
Brown University
101 Plain Street, 7th floor
Providence, RI, 02903
United States
Phone: 1 401 274 1122
Email: alewkowitz@kentri.org

Abstract

Participants in qualitative interviews designed to optimize the adaptation of a maternal postpartum depression intervention into a novel smartphone app noted that the app could be more useful if were delivered simultaneously to both parents; this calls for additional research on the feasibility and effectiveness of digital dyadic or stand-alone partner interventions to prevent postpartum depression.

(JMIR Pediatr Parent 2025;8:e71764) doi:10.2196/71764

KEYWORDS

digital perinatal mental health; postpartum depression prevention; nonbirthing partner; qualitative research

Introduction

Approximately 15% of women in the United States develop postpartum depression (PPD) [1]. The United States Preventive Services Task Force (USPSTF) recommends that women at risk for PPD participate in a program such as Mothers and Babies (MB), an in-person cognitive behavioral therapy (CBT)–based curriculum that prevents PPD [2]. Because smartphone app–provided CBT can reduce PPD symptoms and expand the reach of CBT programs [3], we used individual in-depth interviews with perinatal women to develop a novel app, MBapp, that adapts MB to a digital format [4].

During the interviews that guided app development, study participants noted that MBapp would be useful for their partner or would benefit their relationship with their partner. To explore MBapp's potential utility as a dyadic intervention, we conducted a qualitative analysis of emergent data obtained during thematic analysis from interviews that guided MB's adaptation into MBapp.

Methods

Overview

English- or Spanish-speaking women who were between 32 weeks' gestation and 6 months postpartum were eligible.

XSL•FO
RenderX

Consenting participants completed a virtual, individual, semistructured interview exploring their perspectives on perinatal mental health and pregnancy- or childbirth-related education and support [5]. They were also asked to provide feedback on draft versions of MBapp [4]. The interview agenda was not designed to elicit discussion on partners; therefore, partner data were emergent. As has been described previously [4,5], each interview was recorded, transcribed, and, after interrater reliability was confirmed, coded by 2 authors for consensus. Coded data were inputted into NVivo and interpreted using a thematic analytic approach. This paper includes only the emergent themes pertaining to participant-initiated perspectives of MBapp's utility for their partner or relationship with their partner.

Ethical Considerations

The study was approved by Women & Infant's Hospital of Rhode Island's institutional review board (1737296). Participants signed informed consent forms prior to participation and could opt out at any time. All data collected were deidentified, and participants received a US $50 gift card for completing the qualitative interview.

Results

As previously reported [4,5], the 25 interviewees were racially and ethnically diverse, with half primiparous, (n=13, 52%), half Spanish-speaking, (n=12, 48%), and half pregnant (n=13, 52%) (Table 1). Of the 25 women, 5 independently expressed, without any explicit prompting, that they saw value in providing MBapp to their partner. In this subgroup, 3 of 5 were Spanish-speaking, 2 of 5 were primiparous, and 3 of 5 were post partum.

Each of these 5 participants mentioned their interest in sharing MBapp with their partner when prompted to suggest ways to enhance the app's usefulness for perinatal women. The 5 women stated that providing MBapp to a partner would make it more effective as both a perinatal psychoeducational tool and a CBT-based program (Table 2). Some endorsed that MBapp could teach their partners how to improve communication and provide infant care, helping them be a more supportive partner. Others noted that MBapp could help their partners recognize the interplay between relationship dynamics, maternal isolation, and PPD symptoms. Each of these 5 participants was surprised that MBapp was planned to be delivered exclusively to the pregnant person.

Table 1. Sociodemographic and obstetric characteristics of study participants (N=25).

Characteristics	Values
Age (years)	
Median (IQR)	29 (24-35)
Range	20-43
Advanced maternal age (35 years or older at time of delivery), n (%)	6 (24)
Race, n (%)	
Black	5 (20)
American Indian or Alaska Native	3 (12)
Asian	2 (8)
White	6 (24)
Other[a]	9 (36)
Ethnicity, n (%)	
Hispanic	13 (52)
Language of interview[b], n (%)	
English	13 (52)
Spanish	12 (48)
Primiparous (pregnant with first child or recently delivered first child)	13 (52)
Pregnancy status, n (%)	
Pregnant	13 (52)
Postpartum	12 (48)

[a]Other: multiracial (White and Black): n=4; multiracial (White and American Indian or Alaska Native): n=3; multiracial (Black and American Indian or Alaska Native): n=2.

[b]Four participants spoke a combination of English and Spanish. Their interview language was categorized as the language that most of the interview was conducted in.

XSL•FO
RenderX

Table 2. Participant-elicited reasons that MBapp would be useful for their partner.

Themes	Quotes
Improve dyadic communication	"Maybe they're not knowing [how to] explain to the other partner how they're acting, like they're not being assertive enough, or they're being too aggressive. They can open [the app] up and show them, 'This is what is going on with us. This is how I feel like you're treating me,' so they can get more of a better understanding of how you feel." (English-speaking postpartum person with multiple children)
Increase partner's knowledge on infant care	"There is nothing like this for men. How is it possible that we are in the 21st century, and men don't know how to do things for their baby? My brother is like that. He will say, 'No, a woman does that.' And I say, 'No it's for men and women.'... There are a lot of men like him, who can't change a stupid diaper and don't fulfill their role fifty/fifty. The world could change when things like this [program] are mixed, for men and women." (Spanish-speaking pregnant person who is a first-time parent)
Effect of perceived partner support and maternal stress and isolation	"The emotional state you're in after giving birth, well. If you don't get support from your partner, you get stressed out.... Sometimes the baby starts crying and...many partners don't support you with that. That's when you get stressed. There comes a time when the woman starts crying because so many things build up that she explodes, and she feels alone." (Spanish-speaking pregnant person with a prior child)
Interplay between partner stress and maternal mental health symptoms	"People that are dealing with their spouses, like if they're stressed with each other, it's taking a toll on both of the parents, like on their mental health. Like, the mom will be dealing with postpartum [depression].... Fathers [must] understand how you have to do well with them to be doing well with yourself and with your baby" (English-speaking postpartum person with multiple children)

Discussion

This study presents emergent qualitative data from diverse perinatal women whose feedback was used to optimize MBapp, a novel app-based CBT program. Without prompting, 5 of 25 participants noted that MBapp would be more useful for them if it were also provided to their partners. Had the interview specifically queried about perceptions of partner use and involvement, the proportion of participants who reported MBapp would be more useful as a dyadic than a stand-alone intervention may have been higher. These emergent data align with the well-known bidirectional association between maternal and paternal perinatal mental health symptoms [6,7]. Though a small study has proven the feasibility of delivering in-person MB to both parents simultaneously [8], the feasibility and effectiveness of delivering MBapp—or other USPSTF-recommended psychotherapy [2]—as a digital dyadic intervention to prevent PPD has yet to be explored. Study strengths include a diverse study population and interviews conducted in English or Spanish. Furthermore, the study population can be considered sufficiently sampled per qualitative methodology principles [9]. Study limitations include exclusive recruitment at one obstetric clinic. Expanding data collection can assess whether these findings resonate in other populations. In addition, because the interviews were not intended to discuss partner status—much less partner support—the proportion of participants with partners (and supportive or unsupportive partners) is unknown. Lastly, emergent themes on partners were not identified until the data were analyzed; thus, thematic saturation was not achieved. In summary, this qualitative analysis demonstrates that an evidence-based maternal PPD-prevention intervention may be more useful if delivered simultaneously to both parents, potentially by being an upstream mediator of maternal PPD, as per dyadic coping theory [10]. Our results call for additional research examining not just the feasibility and effectiveness but the mechanisms of effectiveness of digital dyadic or stand-alone partner PPD prevention interventions.

Acknowledgments

The authors acknowledge the Qualitative Science and Methods Training Program (QSMTP), Department of Psychiatry and Human Behavior, Alpert Medical School of Brown University, through which the lead author (AKL) received training in qualitative research. Pertinent to this publication, the first author was trained via QSMTP in the conceptualization and design, preparation, implementation, and analyses of the data presented here. AKL is supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) (K23HD103961 and R01HD116695). ESM is supported by the NICHD (R01HD105499), National Institute of Nursing Research (R01NR021126), and National Institute of Mental Health (NIMH; R34 MH130969). CZ is supported by the NICHD (R01HD094801) and NIMH (R01MH130948). These funding sources had no role in study design, collection, analysis, or interpretation of the data, or in the decision to submit the article for publication.

Conflicts of Interest

None declared.

References

1. Ko JY, Rockhill KM, Tong VT, Morrow B, Farr SL. Trends in postpartum depressive symptoms - 27 states, 2004, 2008, and 2012. MMWR Morb Mortal Wkly Rep 2017 Feb 17;66(6):153-158 [FREE Full text] [doi: 10.15585/mmwr.mm6606a1] [Medline: 28207685]

XSL•FO
RenderX

2. US Preventive Services Task Force, Curry SJ, Krist AH, Owens DK, Barry MJ, Caughey AB, et al. Interventions to prevent perinatal depression: US Preventive Services Task Force recommendation statement. JAMA 2019 Feb 12;321(6):580-587. [doi: 10.1001/jama.2019.0007] [Medline: 30747971]
3. Lewkowitz AK, Whelan AR, Ayala NK, Hardi A, Stoll C, Battle CL, et al. The effect of digital health interventions on postpartum depression or anxiety: a systematic review and meta-analysis of randomized controlled trials. Am J Obstet Gynecol 2024 Jan;230(1):12-43. [doi: 10.1016/j.ajog.2023.06.028] [Medline: 37330123]
4. Lewkowitz AK, Guillen M, Ursino K, Baker R, Lum L, Battle CL, et al. Optimizing a novel smartphone app to prevent postpartum depression adapted from an evidence-based cognitive behavioral therapy program: qualitative study. JMIR Hum Factors 2024 Dec 09;11:e63143 [FREE Full text] [doi: 10.2196/63143] [Medline: 39652879]
5. Lum L, Ursinobared K, Guillen M, Ware CF, Ayala NK, Russo ML, et al. Preference on sources of obstetric and mental health education among perinatal people with Medicaid insurance: a qualitative study. Am J Obstet Gynecol MFM 2025 May;7(5):101640. [doi: 10.1016/j.ajogmf.2025.101640] [Medline: 39956477]
6. Paulson JF, Bazemore SD. Prenatal and postpartum depression in fathers and its association with maternal depression: a meta-analysis. JAMA 2010 May 19;303(19):1961-1969. [doi: 10.1001/jama.2010.605] [Medline: 20483973]
7. Goodman JH. Paternal postpartum depression, its relationship to maternal postpartum depression, and implications for family health. J Adv Nurs 2004 Jan;45(1):26-35. [doi: 10.1046/j.1365-2648.2003.02857.x] [Medline: 14675298]
8. Tandon SD, Hamil J, Gier EE, Garfield CF. Examining the effectiveness of the fathers and babies intervention: a pilot study. Front Psychol 2021;12:668284 [FREE Full text] [doi: 10.3389/fpsyg.2021.668284] [Medline: 34335380]
9. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. Field Methods 2006 Feb 01;18(1):59-82. [doi: 10.1177/1525822x05279903]
10. Falconier MK, Wojda-Burlij AK, Conway CA, Kim J. The role of emotion regulation in couples' stress communication and dyadic coping responses. Stress Health 2023 Apr;39(2):309-322. [doi: 10.1002/smi.3186] [Medline: 35938781]

Abbreviations

CBT: cognitive behavioral therapy
MB: Mothers and Babies
PPD: postpartum depression
USPSTF: United States Preventive Services Task Force

Edited by S Badawy; submitted 25.01.25; peer-reviewed by L Walekr, E Kemp, LL Leng; comments to author 10.09.25; revised version received 24.10.25; accepted 27.11.25; published 08.12.25.

Please cite as:
Lewkowitz AK, Lum L, Ursino K, Guillen M, Garcia G, Sales SK, Taneja S, Ware CF, Grobman WA, Zlotnick C, Guthrie KM, Miller ES
Importance of Engaging Partners in Digital Postpartum Depression Prevention: Qualitative Study
JMIR Pediatr Parent 2025;8:e71764
URL: https://pediatrics.jmir.org/2025/1/e71764
doi:10.2196/71764
PMID:

©Adam Korrick Lewkowitz, Liana Lum, Katrina Ursino, Melissa Guillen, Gabriela Garcia, Sarai K Sales, Saloni Taneja, Crystal F Ware, William A Grobman, Caron Zlotnick, Kate M Guthrie, Emily S Miller. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 08.12.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Effects of Exergames on Motor Skills, Psychological Well-Being, and Cognitive Abilities in Schoolchildren and Adolescents: Scoping Review

Eleonora Rosi, MSc; Valentina Bianchi, MSc; Ilaria Baù, MSc; Rebecca Nuzzo, MSc; Stefania Valsecchi, MSc; Massimo Molteni, MD; Paola Colombo, MSc, PhD

Child Psychopathology Unit-Smart Lab, IRCCS Eugenio Medea, Via Don Luigi Monza, 20, Bosisio Parini, Italy

Corresponding Author:
Eleonora Rosi, MSc
Child Psychopathology Unit-Smart Lab, IRCCS Eugenio Medea, Via Don Luigi Monza, 20, Bosisio Parini, Italy

Abstract

Background: In a world where children are increasingly sedentary, the need for innovative solutions to promote physical activity is felt more than ever. Exergames—interactive video games combining physical activity with gaming—are an attractive way to engage children in exercise while having fun. Although exergames have demonstrated several benefits for the health and physical activity of children and young people, the impact of these devices is poorly explored, especially in the school context.

Objective: This scoping review was aimed at analyzing the effects of exergames on motor skills, psychological well-being, and cognitive abilities in children and adolescents during physical education hours and play-based activities. Our specific goal was to explore and describe the effects of exergames in school programs and their potential to improve physical and mental health in educational settings.

Methods: We carried out our review in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines. We searched 3 bibliographic databases from 2019 to June 2024 and included all scientific studies involving children and adolescents interacting with exergames during physical education lessons at school.

Results: Our database search produced 1694 articles. After performing 3 levels of screening (title, abstract, and full text), 25 articles were left. The majority of the studies confirmed that the use of exergames during physical education and playful sport activities is associated with a number of improvements. More specifically, these devices can provide motor benefits as well as psychological or cognitive benefits, such as cognitive flexibility and attentional functions, overall well-being, and a greater sense of self-efficacy, self-confidence, and mood.

Conclusions: These results may have significant implications for public health or education: exergames may become accessible and useful devices for promoting physical activity in young people, potentially benefiting motor skills but also psychological and cognitive functions, increasing children's participation in physical activities, and leading to a general improvement in their sense of self-efficacy and well-being. Exergames can improve children's physical and cognitive skills, thus becoming a complementary and additional device to traditional physical education exercises and helpful tools to increase physical movement in extracurricular activities.

(JMIR Pediatr Parent 2025;8:e71416) doi:10.2196/71416

KEYWORDS

exergames; active video games; physical education; physical activity; school; children; adolescents

Introduction

The World Health Organization (WHO) has underlined the importance of physical activity, which is beneficial to health and mental and physical well-being, for the prevention of noncommunicable diseases [1]. Insufficient levels of physical exercise or physical inactivity may contribute to the development of diseases, such as obesity and overweight, cardiovascular disease, and motor development–related disorders [2,3]. Especially in children and adolescents, sedentary behavior increased adiposity and led to poorer cardiometabolic health, fitness, and behavioral conduct or prosocial behavior, as well as reduced sleep duration [1]. According to data from the Italian Institute of Statistics for the 2017 - 2018 period, Italian children and adolescents did not engage in sufficient levels of physical activity [4] as recommended by the WHO, whereby they should practice at least 60 minutes of moderate to vigorous physical activity for 3 days in a week [5,6]. In addition, Italian Institute of Statistics data (2021) highlighted that continuous sporting activity in children and young people aged 3 - 17 years has

XSL•FO
RenderX

decreased significantly, from 51.3% to 36.2%, while sedentariness has increased (from 22.3% to 27.2%) [7]. This trend is in line with other countries [8-10].

In accordance with the above-mentioned data, schools are considered the main educational context for the promotion of physical activity. There are multiple opportunities for exercise in the context of school, such as during recess, sports, physical education (PE) lessons, and active movement to and from school [11]. Several studies have shown that school-based focused interventions have been effective in increasing children's physical activity levels, achieving up to 50% of the weekly requirement identified by the WHO [1,12].

PE lessons aim to promote motivation and physical exercise in students [12]. However, the role of PE in the school system has led to some criticism concerning the methods and tools that are currently being used during classes, which generate very low interest among pupils and students [13]. With specific reference to educational processes connected to physical and sporting activity, the scientific community is now investigating the effects of incorporating devices into traditional teaching in order to increase student motivation and participation [14].

Among the technological tools available today, there are exergames. Their introduction in everyday life contexts not only helps children and young people to achieve the recommended levels of physical activity but also has a positive effect on their lives, as exergames foster the acquisition and development of motor skills and abilities, increasing participation in sporting activity [15].

Exergames—also known as active video games—are an activity combining video games and motor exercise and requiring physical effort on the part of the child [16]. They are characterized by the use of audio or visual feedback on performance compared to traditional physical activity, thus making it more enjoyable [16]. These digital motor activities aim to stimulate motor and motivational skills [12].

Exergames are based on the conversion of real movements within a virtual environment, allowing players to be more active by practicing virtual sports, fitness exercises, and other playful physical activities [15].

In addition to making health-promoting behavior more attractive and desirable, exergames also offer numerous advantages, such as increased motivation and engagement and a greater possibility for fun and challenge [17]. Their pros are also evident when they are compared with traditional exercises [18]. Exergames are more engaging, increasing motivation to train and consequently improving both motor skills, such as balance and mobility [17], and cognitive skills [18,19]. Moreover, they allow players to focus more on the impact of their own movements during the game and less on movements for their own sake [20]. Finally, they are easily adaptable to various contexts—they require a console and screen or projector—and can be carried out either alone or in small groups, encouraging collaboration and cooperation [18].

As claimed by previous reviews, exergames are able to promote a physically active lifestyle in children and young people [21,22]. However, most of the previous reviews have focused on exergame use in specific contexts and situations, such as nutrition and obesity [23-25], chronic diseases [26,27], and physical activity in general [15,28-30]. Specifically, Lamas and colleagues [21] have evaluated the effectiveness of using exergames to promote nutrition education and physical activity in children and adolescents. Their review points out the effectiveness of using exergames to promote health and prevent obesity by interventions aimed at increasing children's and adolescents' nutritional knowledge and introducing healthier and more balanced diets [21]. Other meta-analyses have focused on the benefits of exergames in school settings, specifically regarding PE learning. In particular, they have shown that exergames can improve performance in PE education and suggest using exergames in small classes, limiting the implementation cycle to 1 - 2 months, and selecting games according to different age groups [31].

Although exergames have demonstrated various benefits concerning the health and physical activity of children and young people, no review has been carried out so far on their potential use and benefits in the school setting, exploring not only motor or physical effects but also psychological and cognitive effects.

Therefore, the aim of this study was to expand and update knowledge on the potential effects of exergames within the school context, considering the past 5 years. A scoping review was conducted to illustrate and analyze the effectiveness of the use of exergames in schools (children aged 6 - 18 years) during PE lessons and play or sports activities, to understand their benefits and advantages, and their future application as inclusive tools.

Methods

This review was conducted according to the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines [32]. Four authors (IB, RN, ER, and SV) searched 3 bibliographic databases from 2019 to June 30, 2024: PubMed, Web of Science, and Scopus. The definitive search strategy is the following string: ("physical exercise" OR "physical education") AND ("exergaming" OR "active video games" OR "exergames" OR "interactive videogame" OR "technology") AND ("children" OR "adolescent") AND ("school" OR "school education" OR "education") NOT (meta-analysis OR review). For complete details of the search strings, refer to Multimedia Appendix 1. The search was manually completed, following the PCC (population, concept, and context) format (Table 1). We included all scientific studies involving children and adolescents, aged between 6 and 18 years, interacting with exergames during PE hours. We excluded papers not written in English, reviews and meta-analyses, and articles on adult participants or animals. We also excluded studies that used other types of technologies during PE hours or technologies with an evaluative purpose of sports performance and studies not related to the school setting.

XSL•FO
RenderX

Table . PCC (population, concept, and context) format.

Components	Description
Population (P)	• Children and adolescents aged 6-18 years
Concept (C)	• Experimental study with random or nonrandomized assignment, quasi-experimental study, cross-sectional study, natural experiment, and uncontrolled trial within exergames to assess motor, psychological, and cognitive skills • Exergames—devices using a digital game-based exercise system (eg, consoles such as Xbox 360 Kinect, HOPSports Brain Breaks, and Nintendo Wii Fit)
Context (C)	• Exergames during physical education lessons and other physical activity hours at school

All record titles and abstracts retrieved from the database search were screened by 4 blinded reviewers (IB, RN, ER, and SV), who excluded studies that did not meet the eligibility criteria. The same authors proceeded with the full-text screening of retained papers according to the inclusion criteria. In case of discordant opinions, the 4 authors voted to reach a decision. Interrater agreement was evaluated with the Fleiss kappa statistic (κ) [33,34]. Data from the articles were extracted into an extraction table, which includes columns for authors and year of publication; sample size, age, experimental groups, and country; methodology and duration of the sessions; outcome measures; and results.

Results

Our search from 3 databases produced 1694 articles. After screening titles and abstracts and removing duplicates, there were 57 articles. A total of 25 articles were included in this review. The PRISMA-ScR flowchart is shown in Figure 1. The interrater reliability for full-text screening was substantial across authors, with κ=0.65, κ=0.72, κ=0.68, and κ=0.71 [33,34].

XSL•FO
RenderX

Figure 1. PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) flow diagram. PA: physical activity; PE: physical education.

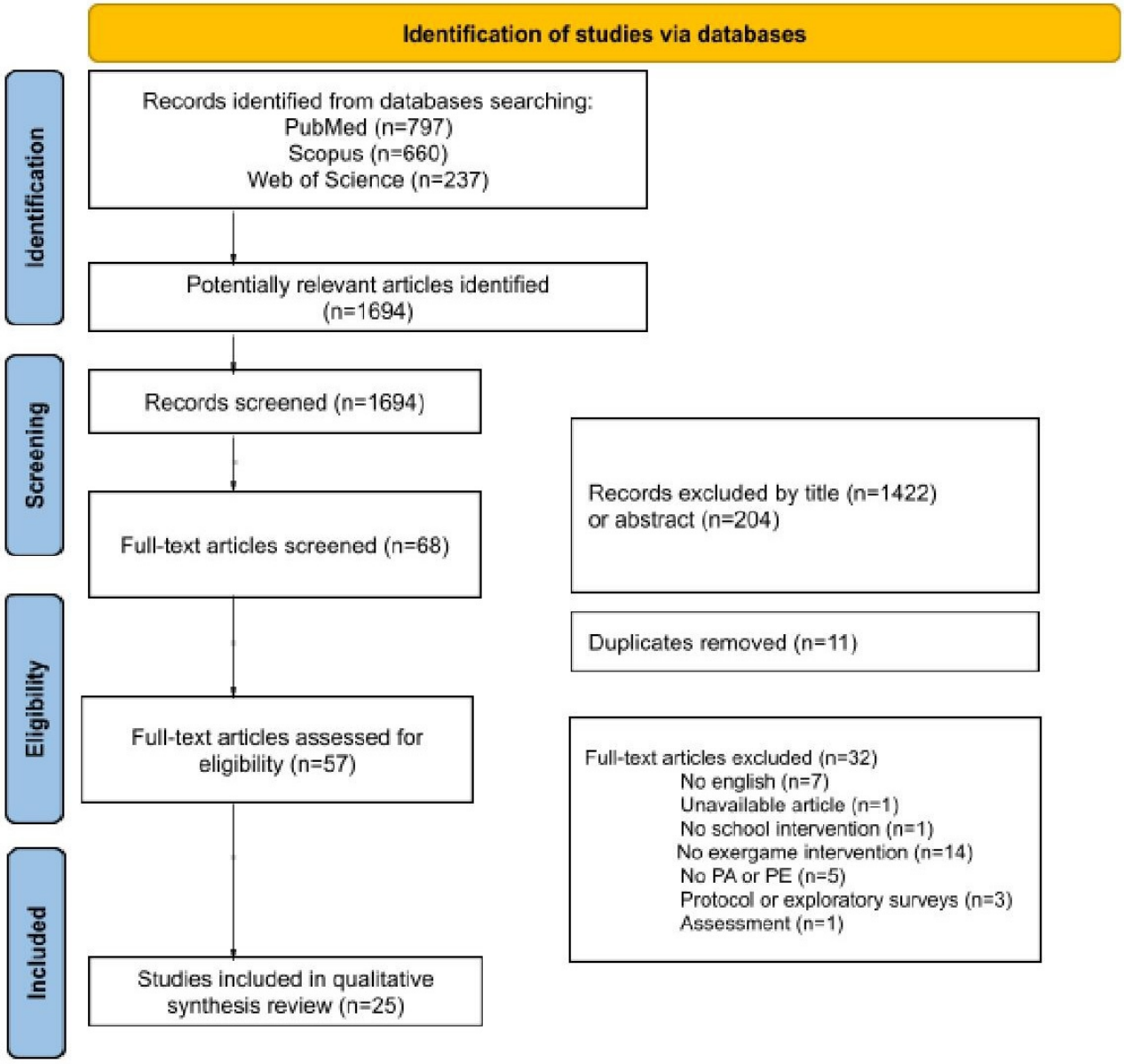


Table 2 summarizes the 25 studies included in this review, that is, research that used exergames within PE school hours. In two cases, the sample of study is the same but with different statistical analyses and research objectives. They are indicated by footnotes in the table.

XSL•FO
RenderX

Table . Studies comprising the use of exergames in physical education during school hours.

Reference	Sample, age, country, and groups	Methodology and durations	Outcome measures	Results
Andrade et al (2019)[a] [35]	• 140 participants (59 males) • Age range: 7 - 11 years (mean 9.41, SD 0.68 years) • Country: Brazil • EG[b]: 68 students (mean age 8.85, SD 0.44 years) • CG[c]: 72 students (mean age 9.96, SD 0.31 years)	• Nonrandomized controlled study • 1 week • EG intervention: three 40-minute sessions with Just Dance 2015 exergame, Xbox 360 Kinect console • CG intervention: 3 regular PE[d] classes	• Anthropometric measures: weight (kg) and height (m), BMI (kg/m^2) • BRUMS[e] to assess mood in 6 dimensions: 3 psychological states (feeling of depression, anger, and mental confusion) and 3 psychosomatic states (fatigue, tension, and vigor)	• Posttest, EG tension and mental confusion reduced, vigor increased • Significant time effect on mental confusion and tension for all participants • Significant group difference on vigor (higher EG than CG) • Significant time-group effect on fatigue
Andrade et al (2020)[a] [36]	• 140 participants (59 males) • Age range: 7 - 11 years (mean 9.41, SD 0.48 years) • Country: Brazil • EG: 68 students (male: mean age 8.77, SD 0.58 years; female: mean age 8.88, SD 0.39 years) • CG: 72 students (male: mean age 9.46, SD 0.77 years; female: mean age 9.38, SD 0.62 years)	• Cluster-randomized natural experiment • 1 week • EG intervention: three 40-minute sessions with Just Dance 2015 exergame, Xbox 360 Kinect console • CG intervention: 3 regular PE classes	• Anthropometric measures: weight (kg) and height (m), BMI (kg/m^2) • BRUMS to assess mood in 6 dimensions: 3 psychological states (feeling of depression, anger, and mental confusion) and 3 psychosomatic states (fatigue, tension, and vigor) • Rosenberg Self-Esteem Scale	• Posttest, higher tension in EG boys than in CG boys; vigor is higher among girls from the EG compared to the CG • EG boys had higher levels of anger than girls • CG boys had lower scores for mental confusion than girls • CG boys have lower anger, mental confusion, and higher self-esteem than EG boys • EG girls have moderate magnitudes, higher vigor, and lower mental confusion vs CG
Balasekaran et al (2021) [37]	• 113 participants (47 males) • Age range: 8 - 11 years (mean 9.68, SD 0.95 years) • Country: Singapore • EG: 48 students (mean age 9.71, SD 0.99 years) • CG: 65 students (mean age 9.66, SD 0.94 years)	• Quasi-experimental study • 10 weeks • EG intervention: 3 - 5 minutes daily during class time 5 days per week with HOPSports Brain Breaks, Physical Activity Solutions' videos • Use of video projectors • CG intervention: usual academic activity	APAS[f] to assess beliefs, attitudes, and self-efficacy PA[g] (test pre-post)	• Significant increase in the mean APAS scores for both groups • Significant group effect on importance, learning, self-efficacy, fun, and fitness • Significant time-group interaction effects for all APAS scores • Increase APAS scores in EG at posttest vs CG • Significant gender difference (males have higher self-efficacy) in post-F3 for EG

XSL•FO
RenderX

Reference	Sample, age, country, and groups	Methodology and durations	Outcome measures	Results
Bonnema et al (2022) [38]	• 122 participants (42 males) • Age range: 11 - 12 years (mean 11.92, SD 0.36 years) • Country: South Africa • EG: 73 students (mean age 11.85, SD 0.38 years) • CG: 49 students (mean age 12.02, SD 0.31 years)	• Nonrandomized intervention study • Daily PE intervention for 12 weeks • EG intervention: HOP-Sports Brain Breaks + standard PE • CG intervention: no video program, standard PE	• Eurofit test to assess physical fitness • 20 m SRT[h] for cardiovascular endurance • 10 × 5 m shuttle test for running speed, agility • Plate tapping test for speed of limb movement • Stork balance test for balance • Sit-and-reach test for hamstring flexibility • Standing long jump test for abdominal strength • Anthropometric measures: body mass, stature, skinfolds, and BMI	• EG improve in all the physical fitness components • Significant differences between the EG and CG groups in body fat, stork balance, plate tapping, sit-and-reach, standing jump, sit-ups, 10 × 5 m shuttle run, and 20 m shuttle run
Chae et al (2022) [39]	• 109 participants (50 males) • Age range: 15 - 17 years (male: mean 16, SD 0.71 years; female: mean 15.7, SD 0.61 years) • Country: Republic of Korea • EG: 50 students • CG: 59 students	• Nonequivalent control group with a nonsynchronized pretest-posttest design • 12 weeks • EG intervention: 30 minutes, 5 times a week (3 during lunch break and 2 during PE class) • Exergame: Wii Fit • Console: Nintendo Wii Sports (bowling, boxing, tennis, cycling, table tennis, and basketball) • CG intervention: usual activity, no intervention	• Sociodemographic questionnaire self-reported • Anthropometric measures: BMI (InBody J10); waist circumference (Tanita retractable ruler) • Physiological factor: Cholestech LDX • Analyzer Blood test: lipids, HDL[i], LDL[j], total cholesterol, triglyceride, and glucose level • Pedometer: Fitbit Zip (daily steps) in school • Weekday sitting time • Program satisfaction using 5 open-ended questions	• Significant differences between the groups in skeletal muscle mass, waist circumference, HDL-cholesterol, LDL-cholesterol, and weekend sitting time • Significant group and time interactions were found for skeletal muscle mass and waist circumference • HDL-cholesterol increased • EG decreased in CG, with a significant between-group difference • LDL levels increased in CG, with a significant between-group difference • Weekend daily sitting time significantly decreased in EG compared with CG
Dantas et al (2022) [40]	• 32 participants (males not specified) • Age range: 8 - 10 years • Country: Brazil • EG: 22 students (mean age 8.73, SD 0.76 years) • CG: 10 students (mean age 8.30, SD 0.67 years)	• Quasi-experimental research • Randomized groups • Evaluation before and after 16 weeks • Duration of the intervention is not specified • EG intervention: Just Dance 2015 exergame (20 minutes); Microsoft Xbox One console; Kinect accessory • CG intervention: routine activities planned	• Sit-and-reach test (Wells and Dillon) to assess flexibility • Arm flexion and abdominal tests to assess strength and resistance • Body weight	• Significant changes in flexibility for EG • EG presented significant adaptation for the upper limb strength • There were no significant changes in the variable abdominal strength
García-Massó et al (2023) [41]				

XSL•FO
RenderX

Reference	Sample, age, country, and groups	Methodology and durations	Outcome measures	Results
	• 30 participants (16 male) • Age range: 12 - 14 years Country: Spain • EHCLG[k]: 10 students (mean age 13, SD 1 year) • ELCLG[l]: 10 students (mean age 13, SD 1 year) • CG: 10 students (mean age 13, SD 1 year)	• Quasi-experimental study • 2 weeks • EHCLG intervention: two 45-minute sessions per week • Exergame: Feline Runner, Hungry Monster, Whack-a-Slime Wii Balance Board, LabVIEW, and 15 laptop • ELCLG intervention: two 45-minute sessions per week • Exergame: Feline Runner, Hungry Monster, Whack-a-Slime Wii Balance Board, LabVIEW, and 15 laptop • CG intervention: traditional PE	• Five tests (quiet standing with eyes open and eyes closed, forward limit of stability, pattern tracking in an anterior-posterior direction, and pattern tracking in medial-lateral direction) to assess postural control and stability on the Wii Balance Board	• Significant differences between groups after the intervention • "Forward limit of stability" was significantly higher in the group who trained with high-cognitive-load exergames compared with the group who trained with traditional physical education exercises • Significant intragroup differences between the initial and final assessments for the training groups assigned to both high- and low-cognitive-load exergames • Significant difference between pre- and postassessments after training in low-cognitive-load exergames, only in the anterior-posterior axis
Goncalves et al (2024) [42]	• 79 children (34 girls and 45 boys) • Age range: 7 - 11 years (mean 8.91, SD 1.21 years) • Country: France • EG: 79 children	• Pilot interventional study • Pre-post design • 3 weeks • Habituation phase: 4 sessions of 30 minutes, 1 week apart • Intervention: 30-minute DPA[m] sessions using Play LÜ Exergame platform combined with a motor skills circuit	• PLAYself tool to assess physical literacy • Academic performance measured using standardized math and French tests from the French Ministry of Education • Soft skills (motivation, self-efficacy, and concentration) evaluated through adapted, brief questions on a visual analog scale completed by students, and through short interviews with teachers who rated observed changes in their classrooms on a 1 to 10 scale	• Increased scores for physical literacy • Increased motivation in mathematics • General improvement in concentration in class • Higher academic achievement, concentration, and self-efficacy in French • No significant changes observed in academic performance or self-efficacy in mathematics
Irandoust et al (2021) [43]	• 59 participants with obesity (59 males) • Age range: not specified • Country: Iran • VGG[n]: 21 students (mean age 8.91, SD 1.21 years) • AEG[o]: 18 students (mean age 9.30, SD 1.30 years) • CG: 20 students (mean age 8.95, SD 1.15 years)			

XSL•FO
RenderX

Reference	Sample, age, country, and groups	Methodology and durations	Outcome measures	Results
		• Randomized, controlled, single-blinded study • 12 weeks • VGG intervention: 3 sessions of 60 minutes per week • Exergame: Wii Sports, Kinect Ultimate Sports, Wii Fit, and Just Dance using the Xbox Kinect game • AEG intervention: 3 sessions of 60 - 70 minutes per week • CG intervention: usual PA	• Anthropometrics measures: height (cm), weight (kg), body fat (%), WHR[p], and BMI (kg/m^2) • Cardiovascular fitness variables: SBP[q] (mm Hg) and DBP[r] (mm Hg) • A portable spirometer to measure FVC[s] and FEV1[t] • The Borg RPE[u] scale was used to determine the exercise intensity	• Lower weight and BMI in VGG and AEG in postintervention and follow-up compared to preintervention • Improvements in FVC and FEV1 in VGG and AEG in postintervention and follow-up compared to preintervention • CG has higher weight and BMI, and worse FVC and FEV1 in postintervention and follow-up vs VGG and AEG
Ji et al (2023) [44]	• 30 participants with mild to moderate ADHD[v] (26 males) • Age range: 8 - 12 years • Country: Republic of Korea • EG: 16 students (mean age 9, SD 1.46 years) • CG: 14 students (mean age 8.85, SD 1.63 years)	• Randomized controlled trial • 4 weeks • EG intervention: 50 min/day, 3 days per week • Exergame: Alchemist's Treasure (D&J Humancare) • CG intervention: 50 min/day, 3 days per week using a stationary bike	• Anthropometric measures: height (cm), weight (kg), BMI (kg/m^2) • Go/No-go task and EEG[w] to measure the capacity to sustain attention and response control • FAIR[x] test to assess attention and concentration	• Both the EG and CG had significantly increased selective attention, continuous attention, and self-control on the FAIR test • Both the EG and CG had significantly reduced response time on the Go/No-go test; for the Go response, the N2 amplitude was increased in Fz in EG but not in CG
Ketelhut et al (2022) [45]	• 34 students (17 males) • Age range: not specified (mean 10.5, SD 0.7 years) • Country: Germany • EG: 18 students (mean age 10.5, SD 0.7 years) • CG: 16 students (mean age 10.5, SD 0.6 years)	• 2-armed randomized controlled trial • 12 weeks • EG intervention: 15 - 20 min/day, 2 times per week, and normal PE class, 2 times per week • Exergame: "Sphery Racer" in Exercube • CG intervention: normal PE class, 2 times per week	• Anthropometric measures: BMI (kg/m^2), WHtR[y] • Physical fitness: 20-meter sprint test, using portable electronic timing gates (kettlebell sport); CMJ[z] using Optojump photocell system, a validated tool for assessing jump height • Aerobic fitness: SRT	• A significant group-time interaction in CMJ performance, with a significant increase in jumping height in the EG and a significant decrease in the CG • Sprint test performance significantly improved in the EG but not in the CG, revealing significant interaction effects and a large effect size • Significant group-time interactions and a large effect size were observed for the SRT, with a significant increase in distance covered in the EG
Kolovelonis et al (2023) [46]				

XSL•FO
RenderX

Reference	Sample, age, country, and groups	Methodology and durations	Outcome measures	Results
	• 122 participants (63 males) • Age: not specified (mean 9.98, SD 0.59 years); 4th- to 5th-grade elementary school • Country: Greece • 1st sample study: 74 participants (36 male) with no exergame experience • EG: 38 students • CG (waitlist-CG): 36 students • 2nd sample study: 48 participants (27 males) with exergame experience	• 1st study: a 2-group, repeated measures, cross-over quasi-experimental design • Single session • EG intervention: single exergames PE session • Exergame: Just Dance 2015 • Console: Xbox One Kinect • CG intervention: exergame session after posttest • 2nd study: a repeated measures, within-subjects design • Single session • Single exergame PE session • 2 months after a 4-week cognitive intervention with stimulating physical activity games • Exergame: Just Dance 2015 • Console: Xbox One Kinect	• DF[aa] to assess executive functions according to three conditions: (1) measuring design fluency, (2) measuring inhibition, and (3) measuring cognitive flexibility • Situational Interest Scale to assess students' situational interest according to 4 dimensions (total interest, instant enjoyment, exploration, and novelty)	1st study Exergame effect on EG • Significant time-group interaction in the 3 test condition scores (in particular, significant interaction for conditions 1 and 3, no significant interaction for condition 2) and in the total DF score • Both groups showed higher scores at time 2 (significant higher improvement for EG) Exergame effect on CG: • Significant improvement in total DF score in CG after receiving exergames • Significant effect for time (time 2 and time 3 measures) on the 3 conditions' scores • Significant improvement in all 3 test conditions • Students' situational interest: • High scores in all dimensions • 2nd study: • Significant effect in total DF scores from pretest to posttest
Lau et al (2020) [47]	• 203 participants with intellectual disability (86 males) • Age range: 8 - 18 years (mean 12.8, SD 2.8 years) • Country: Hong Kong • EG: 125 students • CG: 78 students	• Standard 2-arm parallel, single-blinded study • 12 weeks • EG intervention: two 30-minute sessions per week • Exergame: Xbox Sport Season 1 and Sport Season 2 • Console: Xbox 360 Kinect • CG intervention: usual PA	• Anthropometric measures: height (cm), weight (kg), BMI (kg/m^2), and body fat (%) • ActiGraph GT3X accelerometers to assess PA • BOT-2 short form to assess motor proficiency	• Significant increases in BMI, % body fat, and motor proficiency within both groups at posttest BOT-2[ab]: • Significant increase in EG and CG at posttest • No significant group differences in BMI, PA levels, or motor proficiency
Liang et al (2020) [48]	• 87 participants (54 males) • Age range: 9 - 12 years • Country: Hong Kong • EG: 30 students (mean age 10.5, SD 0.7 years) • CG: 57 students (mean age 10.4, SD 0.8 years)	• Quasi-experimental study • 8 weeks • EG intervention: two 1-hour sessions per week • Exergame: Kinect Adventures • Console: Xbox 360 Kinect CG intervention: usual PA		

XSL•FO
RenderX

Reference	Sample, age, country, and groups	Methodology and durations	Outcome measures	Results
			• Anthropometric measures: height (cm), weight (kg), BMI (kg/m^2), percentage body fat (%) • ActiGraph GT3X-GT3X+ accelerometers to assess PA and sedentary time (min/day) • Questionnaires measuring PA-related psychosocial factors (enjoyment, self-efficacy, and social support)	• No significant group differences in BMI or body Accelerometers: • No significant group differences in daily sedentary time • Significant treatment effect on after-school sedentary time • Significant group differences on LPA[ac] • Significant treatment effect on LPA and CPM[ad] • No significant group differences between MPA[ae] and VPA[af] • No significant group differences in PA-related psychosocial factors
McDonough et al (2021) [49]	• 47 participants (22 males) • Age range: not specified (mean 11.8, SD 1.3 years) • Country: United States • EG: 47 students • CG: not used	• Cross-sectional study • Duration not specified • EG intervention: 2 separate 15-minute exergaming sessions first in small groups (n=3 to 4), then in full class (n=23 to 24) • Exergame: Xbox One Kinect, Just Dance • CG intervention: not used	• Anthropometric measures: height (cm), weight (kg), body fat (%) • ActiGraph GT3X+accelerometers to measure participants' duration in SB[ag], LPA, MVPA[ah], and steps • PA-enjoyment and PA-self-efficacy were evaluated using a 5-point Likert scale	• Participants spent more time in SB during the full-class session vs the small-groups session, and more time in MVPA during the small-groups session vs the full-class session • Participants had greater enjoyment during the small-groups session vs the full-class session • No differences between exergaming sessions for time in LPA and self-efficacy
McGann et al (2020) [50]	• 40 participants (21 males) • Age range: 5 - 7 years • Country: Republic of Ireland • EG: 20 students (mean age 6.3 years) • CG: 20 students (mean age 6.4 years)	• Randomized trial • 8 weeks • EG intervention: purpose-built exergames + standard PE (1 hour, once a week, 8 lessons) • Four purpose-built exergames developed through Scratch Editor and Kinect 3D sensors: Hop Ball, Jump Ball, Slide Ball, and Alien Attack • CG intervention: commercial exergames + standard PE (1 hour, once a week, 8 lessons)	• TGMD-2[ai] to assess locomotor skills	• No significant differences between groups at pretest • Both groups improved in some locomotor skills at posttest • Purpose-built exergames had a significantly stronger effect on all user locomotor outcomes compared to commercial exergames (one locomotor skill)
Medeiros et al (2020) [51]			• TGMD-2 to assess motor skills	

XSL•FO
RenderX

Reference	Sample, age, country, and groups	Methodology and durations	Outcome measures	Results
	• 64 participants (30 males) • Age range: 8 - 10 years (mean 9.09, SD 0.75 years) • Country: Brazil • EG: 32 students • CG: 32 students	• Blind randomized trial • 9 weeks • EG intervention: two 45-minute sessions per week • Exergame: Kinect Sports 1 and 2 and Kinect Adventures • Console: Xbox 360 Kinect • CG intervention: regular PE classes		• Significant improvements in both groups in different motor skills (EG 10/12 motor skills) • No significant differences related to the intervention effect between EG vs CG
Mok et al (2020) [52]	• 3036 participants (1496 males) • Age range: 8 - 11 years • Countries: Croatia, Lithuania, Macedonia, Poland, Romania, Serbia, South Africa, and Turkey • EG: 1914 students • CG: 1122 students	• Quasi-experimental design • 10 weeks • EG intervention: 3 - 5 minute video, twice a day, 5 days per week during class time • HOPSports Brain Breaks Physical Activity Solutions' videos • Use of video projectors • CG intervention: usual academic activity	• Anthropometric measures: BMI (kg/m^2) • APAS to assess PA beliefs, attitudes, and self-efficacy	• Significant time-group effect for BMI and all APAS variables except fitness • Significant increase in EG attitudes toward PA for self-efficacy and learning when compared to CG
Quintas et al (2020)[aj] [53]	• 417 participants (195 males) • Age range: 10 - 12 years (mean 11.2, SD 1.7 years) • Country: Spain • EG: 226 students • CG: 191 students	• Natural experiment with a nonrandomized controlled design • 12 sessions for 4 weeks • EG intervention: corporal language session + Just Dance Now exergame + productive dance • Virtual platform: ClassDojo • CG intervention: corporal language session + dancing different dance styles without exergame + productive dance	• Perceived Locus of Causality Scale to assess motivation • Dispositional Flow Scale 2 to assess flow state • Basic Psychological Needs in Exercise Scale (competence, autonomy, and relatedness) • Qualitative evaluation of the teacher for Rhythmic Motor Skills (1 - 5 points) • Qualitative evaluation of the teacher for Commitment and Behavior Learning (1 - 5 points)	• Better positive gamified exergaming effects on basic psychological needs, commitment to and behavior toward learning and 2 flow dimensions (autotelic experience and time transformation) • No interaction effects (time-treatment) in intrinsic motivation, external regulation, and decreased motivation for EG
Quintas-Hijós et al[aj] (2020) [12]	• 417 participants (195 males) • Age range: 10 - 12 years (mean 11.1, SD 1.7 years) • Country: Spain • EG: 226 students • CG: 191 students, 8 teachers (6 males; mean age 37.5, SD 6.12 years)	• Natural experiment, nonrandomized controlled design • 4 or 6 weeks • EG intervention: 135 minutes/week (9 hours total) • MDA[ak] architecture • Exergame: Just Dance Now • Virtual platform: ClassDojo • CG intervention: traditional didactic teaching of dance in Spanish PE	• Qualitative measures: field notes and OQQ[al] • Focus groups (n=56 students) • Individual semistructured interviews (4 students; 8 teachers) • Thematic analysis and COREQ-32[am] for results analysis	• Greatest difficulty expressed: working in groups, complexity of dances, body expression, adapting to the song and the choreography, and making group decisions • Frequently shared feelings or opinions: enjoyment, embarrassment, positivity, motivation, fun, creativity, motor learning
Regaïeg et al (2021) [54]			• TGMD-2 to assess FMS[an]	

XSL•FO
RenderX

Reference	Sample, age, country, and groups	Methodology and durations	Outcome measures	Results
	• 24 participants with intellectual disability (13 males) • Age range: 7 - 10 years • Country: France • EG: 12 students (mean age 9.42, SD 1.65 years) • CG: 12 students (mean age 8.42, SD 1.08 years)	• Quasi-experimental study • 10 weeks • EG intervention: two 60-minute sessions per week • Hybrid program (30-minute virtual game and 30-minute real game) • Exergames: Kinect Adventures • Consoles: Wii Nintendo and Xbox 360 Kinect • CG intervention: adapted football and long jump in PE classes		• Significant intervention effect and time-group effect on the LS[ao], OCS[ap], and GMQS[aq] • No significant group factor effect on the LS, OCS, and GMQS • In the posttest, LS is significantly higher in both groups; in addition, OCS and GMQS are significantly higher only in EG compared to CG
Röglin et al (2023) [55]	• 27 participants (13 males) • Age range: not specified (mean 10.5, SD 0.7 years) • Country: Germany • EG: 27 students • CG: not used	• Experimental cross-sectional study • 12 weeks • EG intervention: two 15 - to 20-minute sessions per week + regular PE classes twice a week (total 135 minutes) • Exergame: “Sphery Racer” in the ExerCube CG intervention: not used	• Anthropometric measures: height (cm), weight (kg), waist circumference (cm), BMI (kg/m^2), WHtR, and VO_2max[ar] • Modified version of the PACES[as] to measure perceived enjoyment during the ES[at] and PE class • Structured interviews to evaluate staff and teachers’ perceptions of students’ interest, engagement, and motivation during the ES	• The mean PACES score during the ES in week 2 was significantly higher than during the PE class in the same week; no significant differences in perceived enjoyment after 2 and 12 weeks of intervention • The teachers and study staff reported high levels of interest, motivation, and engagement of most students throughout the ES
San Blas et al (2024) [56]	• 21 participants (males not specified) • Age range: 11 - 12 years (mean and SD not specified) • Country: Spain • EG: 21 students • CG: not used	• Case study • 1 month • 6 sessions of 1 hour • Each session has 3 parts: anticipated learning (10 minutes), comprehension guide (20 minutes), comprehension consolidation (30 minutes) • Exergame: Multiagent Platform	• Qualitative data: teachers’ observations about signs of amusement, gestures, or frustration • Quantitative data: tool score about the games, Technology Acceptance Model, questionnaire about students’ satisfaction and motivation	• Students obtained a slightly lower grade than that obtained from the tool; the tool is able to gain knowledge and reinforcement of the lessons • Students agree that the tool is useful in their learning process, and they want to use it in the future • Teachers observed that the students attended with greater effort and retained the information more easily, knowing that they would be playing games with the tool
van Biljon et al (2021) [57]				

XSL•FO
RenderX

Reference	Sample, age, country, and groups	Methodology and durations	Outcome measures	Results
	• 31 participants with overweight or obese (males not specified) • Age range: 9 - 12 years (mean 11.40, SD 0.86 years) • Country: South Africa • EG: 11 students • VGG: 10 students • CG: 10 students	• Experimental randomized study • 6 weeks • EG intervention: 15 minutes, 3 days a week • Exergame: Boxing and Hula Hooping • Console: Wii Nintendo • VGG intervention: 30 minutes, 3 days a week • Videogames: Madden NFL 10 and Knockout Kings • Console: PlayStation 2 • CG intervention: usual activities	• Body composition variables: body mass, BMI (kg/cm^2), and WHR • Cardiovascular fitness variables: RHR[au] (bpm), SBP (mm Hg), DBP (mm Hg), and VO_2peak[av] (mL/kg/min)	• No significant BMI percentile improvements within the 3 groups • Significant WHR decrease in EG, not in VGG and CG • Significant RHR improvement in EG, vs VGG and CG • Significant VO_2peak change in the 3 groups • No significant SBP and DBP change within the 3 groups
Yamamoto et al (2023) [58]	• 8 participants (2 males) with FASD[aw] and ADHD • Age range: 9 - 13 years (mean 11.4, SD 1.4 years) • Country: United States • EG: 8 students • CG: not used	• Uncontrolled trial • 6 weeks • EG intervention: 50 minutes per session for a total of 12, twice weekly • Exergame: Obie exergaming platform (EyeClick Ltd) • CG intervention: not used	• Anthropometric measures: weight (kg), height (m) • 6MWT[ax] to evaluate walking distance covered in meters after 6 minutes and estimate VO_2max	• 6MWT improved from baseline to week 6, which is a 31% improvement in estimated VO_2max

[a]Same sample of subjects.
[b]EG: experimental group.
[c]CG: control group.
[d]PE: physical education.
[e]BRUMS: Brunel Mood Scale.
[f]APAS: Attitudes Toward Physical Activity Scale.
[g]PA: physical activity.
[h]SRT: shuttle run test.
[i]HDL: high-density lipoprotein cholesterol.
[j]LDL: low-density lipoprotein cholesterol.
[k]EHCLG: exergames with high cognitive load group.
[l]ELCLG: exergames with low cognitive load group.
[m]DPA: daily physical activity.
[n]VGG: video game group.
[o]AEG: aquatic exercise group.
[p]WHR: waist-to-hip ratio.
[q]SBP: systolic blood pressure.
[r]DBP: diastolic blood pressure.
[s]FVC: forced vital capacity.
[t]FEV1: forced expiratory volume in the first second.
[u]RPE: rating of perceived exertion.
[v]ADHD: attention-deficit/hyperactivity disorder.
[w]EEG: electroencephalogram.
[x]FAIR: Frankfurter Aufmerksamkeits-Inventar.
[y]WHtR: waist-to-height ratio.
[z]CMJ: countermovement jump test.
[aa]DF: design fluency.
[ab]BOT-2: Bruininks-Oseretsky Test of Motor Proficiency—Second Edition.
[ac]LPA: light physical activity.

XSL•FO
RenderX

[ad]CPM: counts per minute.
[ae]MPA: moderate physical activity.
[af]VPA: vigorous physical activity.
[ag]SB: sedentary behavior.
[ah]MVPA: moderate to vigorous physical activity.
[ai]TGMD-2: Test of Gross Motor Development—Second Edition.
[aj]Same sample of subjects.
[ak]MDA: Mechanics-Dynamics-Aesthetics.
[al]OQQ: open-question questionnaire.
[am]COREQ-32: Consolidated Criteria for Reporting Qualitative Research.
[an]FMS: fundamental movement skills.
[ao]LS: locomotor scores.
[ap]OCS: object control scores.
[aq]GMQS: gross motor quotient scores.
[ar]VO_2max: maximum oxygen uptake.
[as]PACES: Physical Activity Enjoyment Scale.
[at]ES: exergaming session.
[au]RHR: resting heart rate.
[av]VO2peak: peak oxygen uptake.
[aw]FASD: fetal alcohol spectrum disorder.
[ax]6MWT: 6-minute walk test.

All studies involve children and adolescents: 23 studies include elementary or middle school children, 1 study includes high school students [39], and another one includes the 8‐ to 18-year-old age group [47]. Most of the articles are fairly balanced between males and females, but sex difference is often not measured in statistical analyses. For 3 studies [40,56,57], the male-female distribution is not known. Most studies include the general population, while 2 studies include children with overweight or obesity [43,57]; 1 study includes children with attention deficit/hyperactivity disorder [44] and another study includes both children with attention deficit/hyperactivity disorder and fetal alcohol spectrum disorder; lastly, 2 studies include children diagnosed with intellectual disability [47,54]. Studies differ in research methodology: there were 6 randomized controlled trials [43-45,50,51,57], 8 nonrandomized controlled studies [12,35,36,38,39,47,53,58], 7 quasi-experimental studies [37,40,41,46,48,52,54], 2 cross-sectional studies [49,55], 1 case study [59], and 1 pilot interventional study [42].

The studies come from different countries, in particular, 2 from North America [49,58], 2 from South Africa [38,57], 4 from South America [35,36,40,51], 6 from Asia [37,39,43,44,47,48], 10 from Europe [12,41,42,45,46,50,53-56], and only one study includes different populations [52].

Thus, their length varied, too, from a minimum of a single session to a maximum of 3 months. In 2 studies, the trial or training duration is not given [40,49]. Regarding the type of exergame used, 7 studies used dance-based exergames, such as Just Dance 2015 on Microsoft Xbox consoles [35,36,40,43,46,49] or Just Dance Now [12,53]. Three studies used videos from the HOPSports Brain Breaks package, which includes different sports such as baseball, basketball, soccer, volleyball, swimming, golf, football, and rowing [37,38,52]. Five studies used exergames based on specific sports such as Nintendo Wii Sports (bowling, boxing, tennis, cycling, table tennis, and basketball) or Wii Fit (yoga, muscle exercises, aerobic exercises, and balance games) or Xbox Sports Season 1 and 2 (including soccer, beach volleyball, bowling, table tennis, track and field, boxing, American football, baseball, darts, golf, skiing, and tennis) [39,43,47,51] or boxing and hula hooping on the Wii Nintendo console [57]. Eight studies used various games involving movement using the Wii balance board (eg, Feline Runner, Hungry Monster, and Whack-a-Slime) [41,54] or Xbox (eg, Kinect Adventures) [48,51] or still other platforms, such as D&J Humancare's Alchemist's Treasure [44], Obie [58], or Exercube's Sphery Racer [45,55]. Three studies developed specific exergames, building on existing ones [42,50,56].

All exergames could be played in a multiplayer mode, for example, by the whole class in some instances or small groups of 3‐4 in others.

The 25 studies were divided into three broad categories according to research objective and outcome measurement:

1. Research studying the effects on psychological or cognitive dimensions. There are 9 papers. The variables under investigation are psychological states or psychosomatic states [35,36]; self-esteem [36]; beliefs and attitudes and self-efficacy with respect to physical activity [37]; attention, concentration and response control, or executive function [44,46]; interest, enjoyment, commitment, flow state, and motivation [46,53,55]. All studies, except for two, found significant effects of exergames on the psychological variables under study. The two studies without significant effects or differences versus the control group specifically addressed intrinsic motivation, external regulation, decreasing amotivation, and perceived enjoyment [53,55].
2. Research studying direct effects on motor and anthropometric aspects or motor skills. There are 12 papers in total. The variables under investigation are physical fitness [38,43,45,57], anthropometric measures

XSL•FO
RenderX

[38-40,43,45,47,57,58], physiological factors [39], daily steps [39], and various motor skills [40,41,47,50,51,54,58]. Significant effects of the application of exergames on anthropometric variables were found in 11 papers [38], including papers on children with obesity [43,57], on various motor or locomotor components [40,41,50,51,54,58], on various physiological components [39], and on physical fitness variables [38,45]. In some of these cases [43,51,54], the significant increase in some or all motor skills or anthropometric variables pretest versus posttest did not differ from that of the control group. Only one study on children with intellectual disabilities did not find any effects [47], so exergames were rated as ineffective.

3. Research on the simultaneous effects on motor or physical aspects and psychological variables. There are 4 articles. The variables under investigation include both anthropometric variables [48,49,52], motor skills [48], physical literacy [42], or psychosocial factors such as enjoyment, self-efficacy, and social support [48,49], as well as beliefs and attitudes toward physical activity [52], and improvements in performance and concentration in other school subjects [42]. Significant effects of exergames were found on some anthropometric or motor variables [42,48,49,52], as well as on psychological variables such as attitude toward physical activity, self-efficacy, and learning [52], or motivation, engagement, and concentration in other school subjects [42]. In two studies [48,49], no effects were found on self-efficacy and psychosocial factors.

Discussion

Discussion of Included Studies

This scoping review focused on the effect of the use of exergames at school in different countries, during PE lessons and play or sports activities, in order to understand their benefits and advantages and their future applications. For these purposes, 25 articles were included.

Considering the majority of the studies, use of exergames during PE hours and playful sports activities is associated with a number of improvements; more specifically, these devices can provide psychological or cognitive as well as motor benefits for children and adolescents with a median age of 10 years. The studies presented use different types of games and vary in frequency, with an overall average duration of 7 weeks, in line with findings from a recent meta-analysis [31]. Below, the specific effects observed are discussed.

Discussion on Psychological or Cognitive Effects

We found 4 studies investigating the psychological effects of exergames. Based on them, we reached the conclusion that exergames played during PE hours or during didactic hours can help increase the students' sense of self-efficacy, vigor, learning, fun, and decrease tension, mental confusion, and perceived anxiety. In addition, they can improve the beliefs and attitudes that children and adolescents have toward sports and physical activities, leading to a general increase in exercise and physical activity [35-37,52]. Also, a review by Joronen and colleagues [59] aimed to observe nonphysical effects of exergames and found that exergames can increase situational interest and enjoyment during physical activity because they are perceived as being more enjoyable. For this reason, children are more likely to carry on playing exergames instead of traditional games. Despite some conflicting results, these researchers reported that successful experiences with exergames could increase perceived self-confidence and consequently the probability of future participation in motor activities [59]. An improvement in self-efficacy and self-confidence was also observed in a previous review and meta-analysis by Andrade and colleagues [60] investigating the effects of exergames in obese children. This could be related to the fact that exergames provide immediate feedback on the student's actions. The ability to see the outcome of their actions in real time may engage and motivate students to continue the activity.

As far as cognitive abilities are concerned, based on two studies taken into account, it can be concluded that an exergame-based intervention can improve executive-attentive functions, specifically selective attention, self-control, sustained attention, cognitive flexibility, and also the students' situational interest for the activity [44,46]. Additionally, some exercises with exergames can have positive effects on motivation and concentration in other school subjects, such as mathematics [42].

These improvements can also be observed at a physiological level, with alterations in event-related potential component N2 waves and cortical cingulate area activity, which are visible just after a single intervention [44]. Exergames would appear to better stimulate visual perception thanks to a virtual environment, which may be experienced by students as more dynamic and engaging. This thus suggests that exergames have attractive and interesting features for children, such as the nature of the game played, interactivity, and involvement through sounds and images. These features may increase participation in physical activity.

Although backed by only a few studies, these results were also confirmed in a previous review by Ramírez-Granizo and colleagues [61]: independently of the exergame used, cognitive performance significantly benefited from the sports or physical activity carried out using them. In particular, the use of electronic devices associated with motor activity seems to bring a general improvement in concentration, attention, and reaction speed.

Discussion on Effects of Motor Abilities

Most of the reviewed studies investigated the influence of exergames on various anthropometric parameters and physical performance. When compared to traditional physical activity interventions, exergames can demonstrably improve motor performance (such as jumping, running, shooting, football, and object control), flexibility and postural stability, and the students' physical fitness at a general level [40,41,45,51,54]. In addition, exergames can improve muscle mass, decreasing waist circumference and body fat [38,43,47], but they can also lead to a significant reduction in sitting time at weekends [39].

Exergames are effective tools for assisting in the acquisition of motor skills, thanks to the immediate feedback that children receive on their performance. In line with our findings, recent

XSL•FO
RenderX

reviews or meta-analyses found that interventions using exergames are effective in developing and improving several components of PE learning or physical fitness, such as agility, balance, and postural stability, while also benefiting the ability to control objects and locomotor skills [31,62]. It must be noted, however, that the authors concluded that their findings were not definitive due to the conflicting outcomes of the studies included in their review.

Despite this variability, most studies support the idea of integrating exergames into traditional PE lessons or using them during teaching hours. This approach can make physical activity more engaging for students while providing variety within the curriculum.

In summary, while current evidence points toward numerous benefits of exergames for improving motor skills and physical fitness among children and adolescents, ongoing research is essential to optimize their application and maximize their potential within educational settings. Further investigations can focus on which games are most effective and establish guidelines for their use to maximize the effectiveness and inclusivity of these tools (such as duration of use, single-player, or group gameplay).

Strengths and Limitations

As far as we are aware, this is the first scoping review aimed at investigating the motor, psychological, and cognitive benefits of exergame-based interventions in school settings and specifically during PE lessons and play activities.

While the primary strength of our study is its attempt to provide an up-to-date review—considering the last 5 years as a timeframe—of the effects of exergames on motor, psychological, and cognitive abilities, this study is not free of limitations, and, consequently, caution is required when interpreting its results.

First, we only included publications in English, which may have led to the exclusion of further available studies that explored this topic in other languages. Although the studies come from different continents, there is no complete heterogeneity. Second, no systematic review and meta-analysis were conducted to assess the effectiveness of exergames and the generalizability of the results.

Third, the studies considered in the review were highly heterogeneous and had several methodological biases. They used different types of exergames; the length was different as were outcomes and variables. For example, some studies used a single exergaming session [46,49], while other studies included several exergaming sessions, up to 3 months. Also, video games and devices were different across studies, and not all studies had a sufficient sample size or used sample randomization. All this could complicate the interpretation of findings and limit their generalizability.

Thus, more studies, such as systematic reviews and meta-analyses, are encouraged to reinforce the validity of the present findings.

Conclusions

In our scoping review of the effects of exergames on motor, psychological, and cognitive abilities during PE lessons and playful sports activities, we focused on the school context, given the central and important role that schools currently have in promoting physical activity in children and adolescents [11].

Our findings show that exergames can have a beneficial effect on children's motor skills, cognitive flexibility and attentional functions, and overall well-being, improving the sense of self-efficacy, self-confidence, and mood during PE lessons.

This may have significant implications for public health or education: exergames may become accessible and useful devices for promoting physical activity in young people, potentially bringing benefits not only on a motor skill level but also on a psychological and cognitive level, increasing children's participation in physical activities and leading to a general improvement in their sense of self-efficacy and well-being.

However, lack of knowledge of their potentials and benefits hinders their wider application. Furthermore, despite their effectiveness, their use is not yet common in the educational and school context.

For this reason, a more systematic application of digital technology in the school setting would contribute to improving and designing new immersive, effective, and inclusive interventions aimed at increasing the physical activity and well-being of children and adolescents. Exergames can improve children's physical and cognitive skills, enjoyment, and involvement in exercise and general well-being, thus becoming a complementary and additional device to traditional PE exercises and helpful tools to increase motor activity during extracurricular activities.

Acknowledgments

The authors acknowledge all partners and collaborators of the project ActivE3. For this paper, ChatGPT AI was used to assist with language revision. This work has been supported by the Italian Ministry of Health (Ricerca Corrente 2025) and by Fondazione Cariplo, grant 2021-0612-ActivE3 – Everyone, Everywhere, Everyday.

Data Availability

Data sharing is not applicable to this article as no datasets were generated or analyzed during this study.

XSL•FO
RenderX

Authors' Contributions

ER, VB, PC, and MM conceptualized the study. ER, IB, RN, and SV conducted the methodology of the study: literature searches and screening the eligibility. ER, VB, IB, RN, and SV wrote the first original draft of the manuscript. MM and PC critically reviewed and edited the manuscript. All authors have approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategies.
[DOCX File, 17 KB - pediatrics_v8i1e71416_app1.docx]

Checklist 1
PRISMA-ScR checklist.
[DOCX File, 23 KB - pediatrics_v8i1e71416_app2.docx]

References

1. Physical activity. World Health Organization. 2024 Jun 26. URL: https://www.who.int/news-room/fact-sheets/detail/physical-activity [accessed 2025-08-25]
2. Wu XY, Han LH, Zhang JH, Luo S, Hu JW, Sun K. The influence of physical activity, sedentary behavior on health-related quality of life among the general population of children and adolescents: a systematic review. PLOS One 2017;12(11):e0187668. [doi: 10.1371/journal.pone.0187668] [Medline: 29121640]
3. Moller AC, Sousa CV, Lee KJ, Alon D, Lu AS. Active video game interventions targeting physical activity behaviors: systematic review and meta-analysis. J Med Internet Res 2023 May 16;25(25):e45243. [doi: 10.2196/45243] [Medline: 37191992]
4. Stili di vita di bambini e ragazzi, anni 2017-2018 [Web page in Italian]. ISTAT. 2019 Oct. URL: https://www.istat.it/comunicato-stampa/stili-di-vita-di-bambini-e-ragazzi-anni-2017-2018 [accessed 2025-08-25]
5. WHO guidelines on physical activity and sedentary behaviour. World Health Organization. 2020. URL: https://iris.who.int/bitstream/handle/10665/336656/9789240015128-eng.pdf?sequence=1 [accessed 2025-08-25]
6. Navarra GA, Thomas E, Scardina A, et al. Effective strategies for promoting physical activity through the use of digital media among school-age children: a systematic review. Sustainability 2021;13(20):11270. [doi: 10.3390/su132011270]
7. Sport, attività fisica, sedentarietà - anno 2021 [Web page in Italian]. ISTAT. 2022 Dec. URL: https://www.istat.it/comunicato-stampa/sport-attivita-fisica-sedentarieta [accessed 2025-08-25]
8. Guthold R, Stevens GA, Riley LM, Bull FC. Global trends in insufficient physical activity among adolescents: a pooled analysis of 298 population-based surveys with 1·6 million participants. Lancet Child Adolesc Health 2020 Jan;4(1):23-35. [doi: 10.1016/S2352-4642(19)30323-2] [Medline: 31761562]
9. Merlo CL, Jones SE, Michael SL, et al. Dietary and physical activity behaviors among high school students – Youth Risk Behavior Survey, United States, 2019. MMWR Suppl 2020 Aug 21;69(1):64-76. [doi: 10.15585/mmwr.su6901a8] [Medline: 32817612]
10. Physical activity facts. CDC Healthy Schools. 2022 Jul 26. URL: https://archive.cdc.gov/#/details?url=https://www.cdc.gov/healthyschools/physicalactivity/facts.htm [accessed 2025-08-25]
11. Watson A, Timperio A, Brown H, Best K, Hesketh KD. Effect of classroom-based physical activity interventions on academic and physical activity outcomes: a systematic review and meta-analysis. Int J Behav Nutr Phys Act 2017 Aug 25;14(1):114. [doi: 10.1186/s12966-017-0569-9] [Medline: 28841890]
12. Quintas-Hijós A, Peñarrubia-Lozano C, Bustamante JC. Analysis of the applicability and utility of a gamified didactics with exergames at primary schools: qualitative findings from a natural experiment. PLOS One 2020;15(4):e0231269. [doi: 10.1371/journal.pone.0231269] [Medline: 32275688]
13. Appropriate use of instructional technology in physical education [position statement]. National Association for Sport and Physical Education. 2009. URL: http://getfitarkansas.pbworks.com/w/file/fetch/62316594/Appropriate-Use-of-Instructional-Technology-in-PE-2009-2.pdf [accessed 2025-08-25]
14. Monacis D, Colella D. The contribution of technologies for learning and development of motor skills in early age. Ital J Educ Res 2019;12(22):31-52 [FREE Full text]
15. de Medeiros P, Capistrano R, Zequinão MA, da Silva SA, Beltrame TS, Cardoso FL. Exergames as a tool for the acquisition and development of motor skills and abilities: a systematic review. Rev Paul Pediatr 2017;35(4):464-471. [doi: 10.1590/1984-0462/;2017;35;4;00013] [Medline: 28977134]
16. Li J, Theng YL, Foo S. Effect of exergames on depression: a systematic review and meta-analysis. Cyberpsychol Behav Soc Netw 2016 Jan;19(1):34-42. [doi: 10.1089/cyber.2015.0366] [Medline: 26716638]

XSL•FO
RenderX

17. Marques LM, Uchida PM, Barbosa SP. The impact of exergames on emotional experience: a systematic review. Front Public Health 2023;11:1209520. [doi: 10.3389/fpubh.2023.1209520] [Medline: 37744509]
18. Choi SD, Guo L, Kang D, Xiong S. Exergame technology and interactive interventions for elderly fall prevention: a systematic literature review. Appl Ergon 2017 Nov;65:570-581. [doi: 10.1016/j.apergo.2016.10.013] [Medline: 27825723]
19. Skjæret N, Nawaz A, Morat T, Schoene D, Helbostad JL, Vereijken B. Exercise and rehabilitation delivered through exergames in older adults: an integrative review of technologies, safety and efficacy. Int J Med Inform 2016 Jan;85(1):1-16. [doi: 10.1016/j.ijmedinf.2015.10.008] [Medline: 26559887]
20. Proffitt R, Lange B, Chen C, Winstein C. A comparison of older adults' subjective experiences with virtual and real environments during dynamic balance activities. J Aging Phys Act 2015 Jan;23(1):24-33. [doi: 10.1123/japa.2013-0126] [Medline: 24334299]
21. Lamas S, Rebelo S, da Costa S, Sousa H, Zagalo N, Pinto E. The influence of serious games in the promotion of healthy diet and physical activity health: a systematic review. Nutrients 2023 Mar 14;15(6):1399. [doi: 10.3390/nu15061399] [Medline: 36986129]
22. Sardi L, Idri A, Fernández-Alemán JL. A systematic review of gamification in e-Health. J Biomed Inform 2017 Jul;71:31-48. [doi: 10.1016/j.jbi.2017.05.011] [Medline: 28536062]
23. Baranowski T, Ryan C, Hoyos-Cespedes A, Lu AS. Nutrition education and dietary behavior change games: a scoping review. Games Health J 2019 Jun;8(3):153-176. [doi: 10.1089/g4h.2018.0070] [Medline: 30339086]
24. Guy S, Ratzki-Leewing A, Gwadry-Sridhar F. Moving beyond the stigma: systematic review of video games and their potential to combat obesity. Int J Hypertens 2011;2011:179124. [doi: 10.4061/2011/179124] [Medline: 21629863]
25. Mack I, Bayer C, Schäffeler N, et al. Chances and limitations of video games in the fight against childhood obesity – a systematic review. Eur Eat Disord Rev 2017 Jul;25(4):237-267. [doi: 10.1002/erv.2514] [Medline: 28467004]
26. Charlier N, Zupancic N, Fieuws S, Denhaerynck K, Zaman B, Moons P. Serious games for improving knowledge and self-management in young people with chronic conditions: a systematic review and meta-analysis. J Am Med Inform Assoc 2016 Jan;23(1):230-239. [doi: 10.1093/jamia/ocv100] [Medline: 26186934]
27. Huang H, Huang M, Chen Q, Hayter M, Watson R. Effects of serious games for patients with chronic obstructive pulmonary disease: systematic literature review. JMIR Serious Games 2023 Sep 25;11:e46358. [doi: 10.2196/46358] [Medline: 37747768]
28. Baranowski T, Abdelsamad D, Baranowski J, et al. Impact of an active video game on healthy children's physical activity. Pediatrics 2012 Mar;129(3):e636-e642. [doi: 10.1542/peds.2011-2050] [Medline: 22371457]
29. Biddiss E, Irwin J. Active video games to promote physical activity in children and youth: a systematic review. Arch Pediatr Adolesc Med 2010 Jul;164(7):664-672. [doi: 10.1001/archpediatrics.2010.104] [Medline: 20603468]
30. Parisod H, Pakarinen A, Kauhanen L, et al. Promoting children's health with digital games: a review of reviews. Games Health J 2014 Jun;3(3):145-156. [doi: 10.1089/g4h.2013.0086] [Medline: 26196173]
31. Zhao M, Lu X, Zhang Q, et al. Effects of exergames on student physical education learning in the context of the artificial intelligence era: a meta-analysis. Sci Rep 2024;14(1):7115. [doi: 10.1038/s41598-024-57357-8]
32. Tricco AC, Lillie E, Zarin W, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med 2018 Oct 2;169(7):467-473. [doi: 10.7326/M18-0850] [Medline: 30178033]
33. Fleiss JL. Measuring nominal scale agreement among many raters. Psychol Bull 1971;76(5):378-382. [doi: 10.1037/h0031619]
34. Landis JR, Koch GG. An application of hierarchical kappa-type statistics in the assessment of majority agreement among multiple observers. Biometrics 1977 Jun;33(2):363-374. [doi: 10.2307/2529786] [Medline: 884196]
35. Andrade A, Correia CK, da Cruz WM, Bevilacqua GG. Acute effect of exergames on children's mood states during physical education classes. Games Health J 2019 Aug;8(4):250-256. [doi: 10.1089/g4h.2018.0083] [Medline: 30730230]
36. Andrade A, da Cruz W, Correia CK, Santos ALG, Bevilacqua GG. Effect of practice exergames on the mood states and self-esteem of elementary school boys and girls during physical education classes: a cluster-randomized controlled natural experiment. PLOS One 2020;15(6):e0232392. [doi: 10.1371/journal.pone.0232392] [Medline: 32502164]
37. Balasekaran G, Ibrahim AAB, Cheo NY, et al. Using Brain-Breaks® as a technology tool to increase attitude towards physical activity among students in Singapore. Brain Sci 2021 Jun 14;11(6):784. [doi: 10.3390/brainsci11060784] [Medline: 34198480]
38. Bonnema J, Coetzee D, Lennox A. Effect of a three-month HOPSports Brain Breaks® intervention program on the physical fitness levels of grade 6-learners in South Africa. Int J Environ Res Public Health 2022 Sep 7;19(18):11236. [doi: 10.3390/ijerph191811236] [Medline: 36141508]
39. Chae SM, Yeo JY, Hwang JH, Kang HS. Effects of school-based "We Fit" weight control programme in adolescents. Nurs Open 2022 Jan;9(1):721-732. [doi: 10.1002/nop2.1125] [Medline: 34792283]
40. Dantas EHM, Andrade KB, Bezerra MRS, et al. Neuromotor and functional adaptations in schoolchildren practicing exergames. In: 2022 International Conference on Technology Innovations for Healthcare (ICTIH): IEEE; 2022:42-46. [doi: 10.1109/ICTIH57289.2022.10111946]
41. García-Massó X, Salvador-Fuertes Á, Sánchez-Santacreu M, Borrego A, Llorens R. Effectiveness of customized exergames to improve postural control in high school physical education. IEEE Trans Learning Technol 2023;16(5):759-768. [doi: 10.1109/TLT.2023.3264517]

XSL•FO
RenderX

42. Goncalves A, Lespiau F, Briet G, et al. Exploring the use of a learning-based exergame to enhance physical literacy, soft skills, and academic learning in school-age children: pilot interventional study. JMIR Serious Games 2024 Feb 23;12:e53072. [doi: 10.2196/53072] [Medline: 38393767]
43. Irandoust K, Taheri M, H'mida C, et al. Exergaming and aquatic exercises affect lung function and weight loss in obese children. Int J Sports Med 2021 Jun;42(6):566-572. [doi: 10.1055/a-1289-9307] [Medline: 33176381]
44. Ji H, Wu S, Won J, et al. The effects of exergaming on attention in children with attention deficit/hyperactivity disorder: randomized controlled trial. JMIR Serious Games 2023 May 9;11(1):e40438. [doi: 10.2196/40438] [Medline: 37159253]
45. Ketelhut S, Röglin L, Martin-Niedecken AL, Nigg CR, Ketelhut K. Integrating regular exergaming sessions in the ExerCube into a school setting increases physical fitness in elementary school children: a randomized controlled trial. J Clin Med 2022 Mar 12;11(6):1570. [doi: 10.3390/jcm11061570] [Medline: 35329896]
46. Kolovelonis A, Papastergiou M, Samara E, Goudas M. Acute effects of exergaming on students' executive functions and situational interest in elementary physical education. Int J Environ Res Public Health 2023;20(3):1902. [doi: 10.3390/ijerph20031902]
47. Lau PWC, Wang G, Wang JJ. Effectiveness of active video game usage on body composition, physical activity level and motor proficiency in children with intellectual disability. J Appl Res Intellect Disabil 2020 Nov;33(6):1465-1477. [doi: 10.1111/jar.12774] [Medline: 32881305]
48. Liang Y, Lau PWC, Jiang Y, Maddison R. Getting active with active video games: a quasi-experimental study. Int J Environ Res Public Health 2020 Oct 30;17(21):7984. [doi: 10.3390/ijerph17217984] [Medline: 33143064]
49. McDonough DJ, Liu W, Su X, Gao Z. Small-groups versus full-class exergaming on urban minority adolescents' physical activity, enjoyment, and self-efficacy. J Phys Act Health 2021 Feb 1;18(2):192-198. [doi: 10.1123/jpah.2020-0348] [Medline: 33440345]
50. McGann J, Issartel J, Hederman L, Conlan O. Hop.Skip.Jump.Games: the effect of "principled" exergameplay on children's locomotor skill acquisition. Brit J Educational Tech 2020 May;51(3):798-816. [doi: 10.1111/bjet.12886]
51. Medeiros P, Felden É, Zequinão MA, et al. Positive effect of a motor intervention program with exergames. Int J Game Based Learn 2020 Oct;10(4):55-64. [doi: 10.4018/IJGBL.2020100104]
52. Mok MMC, Chin MK, Korcz A, et al. Brain Breaks® physical activity solutions in the classroom and on attitudes toward physical activity: a randomized controlled trial among primary students from eight countries. Int J Environ Res Public Health 2020 Mar 4;17(5):1666. [doi: 10.3390/ijerph17051666] [Medline: 32143392]
53. Quintas A, Bustamante JC, Pradas F, Castellar C. Psychological effects of gamified didactics with exergames in physical education at primary schools: results from a natural experiment. Comput Educ 2020 Jul;152:103874. [doi: 10.1016/j.compedu.2020.103874]
54. Regaieg G, Sahli S, Kermarrec G. Hybrid program based on virtual and real games increases fundamental movement skills in children with intellectual disability: a quasi-experimental study. Adapt Phys Activ Q 2021 Oct 1;38(4):626-642. [doi: 10.1123/apaq.2020-0180] [Medline: 34453015]
55. Röglin L, Stoll O, Ketelhut K, Martin-Niedecken AL, Ketelhut S. Evaluating changes in perceived enjoyment throughout a 12-week school-based exergaming intervention. Children (Basel) 2023 Jan 11;10(1):144. [doi: 10.3390/children10010144] [Medline: 36670694]
56. Blas HSS, Mendes AS, Iglesia DHDL, Silva LA, González GV. A multiagent platform for promoting physical activity and learning through interactive educational games using the depth camera recognition system. Entertain Comput 2024 Mar;49:100629. [doi: 10.1016/j.entcom.2023.100629]
57. van Biljon A, Longhurst G, Shaw I, Shaw BS. Role of exergame play on cardiorespiratory fitness and body composition in overweight and obese children. Asian J Sports Med 2021;12(1):e106782. [doi: 10.5812/asjsm.106782]
58. Yamamoto T, Pandit B, Viggiano M, et al. Efficacy of a 6-week novel exergaming intervention guided by heart rate zones on aerobic performance in children with fetal alcohol spectrum disorder and attention-deficit/hyperactivity disorder: a feasibility study. Int J Exerc Sci 2023;16(3):710-720. [doi: 10.70252/JNJV1440] [Medline: 37649462]
59. Joronen K, Aikasalo A, Suvitie A. Nonphysical effects of exergames on child and adolescent well-being: a comprehensive systematic review. Scand J Caring Sci 2017 Sep;31(3):449-461. [doi: 10.1111/scs.12393] [Medline: 27862145]
60. Andrade A, Correia CK, Coimbra DR. The psychological effects of exergames for children and adolescents with obesity: a systematic review and meta-analysis. Cyberpsychol Behav Soc Netw 2019 Nov 1;22(11):724-735. [doi: 10.1089/cyber.2019.0341]
61. Ramírez-Granizo IA, Ubago-Jiménez JL, González-Valero G, Puertas-Molero P, San Román-Mata S. The effect of physical activity and the use of active video games: exergames in children and adolescents: a systematic review. Int J Environ Res Public Health 2020 Jun 14;17(12):4243. [doi: 10.3390/ijerph17124243] [Medline: 32545877]
62. Liu W, Zeng N, McDonough DJ, Gao Z. Effect of active video games on healthy children's fundamental motor skills and physical fitness: a systematic review. Int J Environ Res Public Health 2020 Nov 9;17(21):8264. [doi: 10.3390/ijerph17218264] [Medline: 33182327]

XSL•FO
RenderX

Abbreviations

PCC: population, concept, and context
PE: physical education
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
WHO: World Health Organization

Edited by S Badawy; submitted 17.01.25; peer-reviewed by F Noveletto, T Baranowski; revised version received 25.06.25; accepted 18.07.25; published 17.09.25.

Please cite as:
Rosi E, Bianchi V, Baù I, Nuzzo R, Valsecchi S, Molteni M, Colombo P
Effects of Exergames on Motor Skills, Psychological Well-Being, and Cognitive Abilities in Schoolchildren and Adolescents: Scoping Review
JMIR Pediatr Parent 2025;8:e71416
URL: https://pediatrics.jmir.org/2025/1/e71416
doi:10.2196/71416

© Eleonora Rosi, Valentina Bianchi, Ilaria Baù, Rebecca Nuzzo, Stefania Valsecchi, Massimo Molteni, Paola Colombo. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 17.9.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Early Digital Engagement Among Younger Children and the Transformation of Parenting in the Digital Age From an mHealth Perspective: Scoping Review

Nafisa Anjum[1], MS; Md Mehedi Hasan[1], MS; Nursat Jahan[1], BS; Sheikh Iqbal Ahamed[2], PhD; Allison Garefino[3], PhD; Nazmus Sakib[1], PhD

[1]College of Computing and Software Engineering, Kennesaw State University, 1100 South Marietta Parkway, Kennesaw, GA, United States

[2]Department of Computer Science, Marquette University, Milwaukee, WI, United States

[3]Department of Psychology, Kennesaw State University, Kennesaw, GA, United States

Corresponding Author:
Nazmus Sakib, PhD
College of Computing and Software Engineering, Kennesaw State University, 1100 South Marietta Parkway, Kennesaw, GA, United States

Abstract

Background: Evidence identifies that excessive screen time consumption during the crucial stage of life (0 - 3 years) significantly affects children's holistic development over time. In today's intricate socioeconomic setting, parents, especially working parents, face challenges in constantly supervising their children's activities, often turning to digital devices as a suitable substitute to keep them occupied. To address these issues, a mobile health (mHealth) app can emerge as a feasible solution to help parents manage digital habits for their infants while minimizing the harmful effects.

Objective: The aim of this scoping review from an mHealth viewpoint is to raise awareness among parents about the detrimental effects of unwarranted screen exposure in children younger than 3 years and recommend effective strategies for redirecting them to alternative developmental activities, promoting balanced digital engagement for their infants and toddlers within their domestic landscape.

Methods: A systematic search of academic databases, including Google Scholar, PubMed, IEEE Xplore, and Elsevier, was conducted. To discover existing child screen monitoring apps, searches were conducted in the Google Play Store and Apple App Store through specific keywords across regional marketplaces. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines were followed to organize the literature search process. Data collected from the studies were organized into a predeveloped Excel spreadsheet to facilitate analysis. Synthesized data were scrutinized to detect patterns, variances, and reasonable recommendations.

Results: While parents acknowledge the negative impacts of young children's excessive screen time, their dependence on digital devices survives due to today's modern lifestyle commands. In total, parents' insights were clustered into 9 separate categories, highlighting that parents often believe smart devices are beneficial for their children. A total of 6 intervention approaches for parents and 3 for pediatricians were summarized. A significant finding was parents' unawareness of the association between their own screen time and their toddlers' interactions with screen media. Additionally, parents also perceived existing intervention strategies positively and acknowledged them as helpful solutions. However, they also recognized that inadequate tools and insufficient time for execution caused the gap in these approaches.

Conclusions: The findings of this study underline the need for an empathetic tool to help parents manage their children's screen time efficiently. The development of a holistic mHealth app is presented that considers awareness, practical guidance, and personalized interventions to balance children's digital device use. The proposed solution could incorporate four essential features: (1) screen time tracking and monitoring, (2) a reservoir for parental training and guidelines, (3) an alternative activity advocator, and finally (4) an interactive artificial intelligence assistant. This study provides valuable insights into improving obedience to healthy screen use and fostering a digital ecosystem where technology itself functions as an advocate of child progress, instead of an obligation.

(JMIR Pediatr Parent 2025;8:e60355) doi:10.2196/60355

KEYWORDS

infants and toddlers; screen time; cognitive development; parental ignorance; intervention strategies; mHealth; digital addiction; children; developmental challenge; parents; engagement; decision-making

XSL•FO
RenderX

Introduction

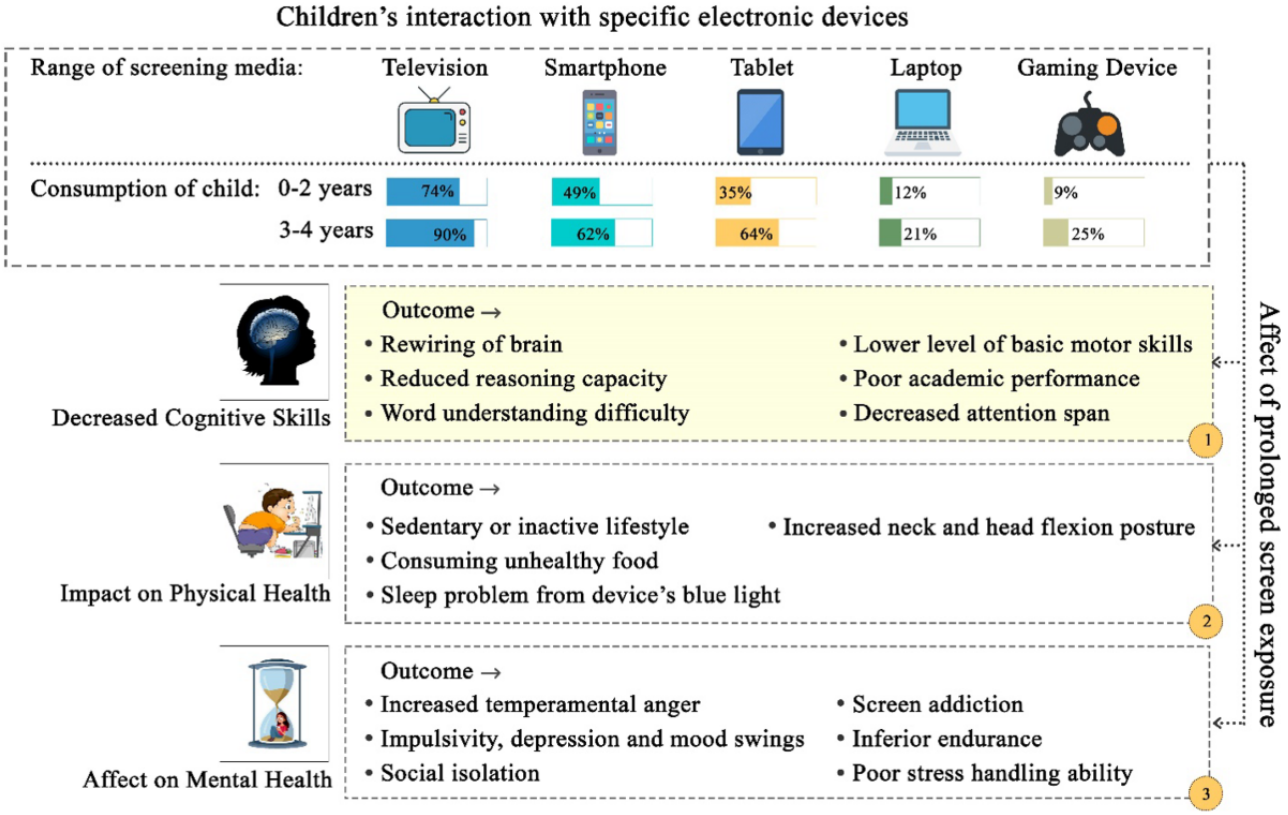
The escalating inclination towards extreme screen time use among children has become a universal problem recently, with evidence pointing to imposing severe impacts on children's early childhood development, for instance, lower academic achievements, increased anxiety, difficulties in language acquisition, and other developmental setbacks [1-4]. The American Academy of Pediatrics (AAP), a leading authority dedicated to safeguarding children's welfare, restricts any form of screen media exposure for children younger than 2 years [5]. Nevertheless, studies have uncovered that almost 68% of children younger than this age bracket often surpass this threshold, spending around 2.05 hours of screen time each day, which is overwhelming [6,7]. In addition, watching television, one of the most conventional modes of screen media, for more than 2 hours per day was observed to be 83% in the United States, 78% in Australia, and 82% in Canada among toddlers aged 2 to 5 years, contributing to a sedentary lifestyle within approximately 34% to 94% of children, which are equally alarming [7,8].

The complex socioeconomic landscape further intensifies this issue, as modern parents face an array of obstructions in constantly monitoring their children's activities. Parents play a central role in influencing their young children's screen time habits, as their screen observation levels and behavior are greatly related to those of their children. Their positive attitudes toward screen time can unconsciously increase screen exposure to their young children, leading to behavioral imitation and delays in developmental outcomes [9]. Contrariwise, research indicates that reduced parental screen time is associated with reduced screen exposure in children younger than 3 years, increasing parent-child interactions that are crucial for early cognitive and emotional development [10]. With the limited scope of supervision, screen devices have emerged as a convenient child supervision tool, performing as a companion for struggling parents, leading to approximately 70% of parents ignoring the AAP recommendations, unintentionally contributing to the challenge of screen time management [11,12]. These observations highlight a disconnect between existing guidelines for limiting screen time in infants and the practical challenges parents encounter in limiting digital device use, which implies the need for a detailed reassessment of prevailing strategies to promote a balanced lifestyle that is practical for parents and protective of children's optimal growth and developmental needs.

The foundations for effective intellectual and analytical skill advancement are embedded in early childhood, which offspring usually adopt and develop within the initial 3 years of life [13]. However, throughout this critical stage, infants and younger toddlers are also enormously vulnerable to the harmful consequences triggered by long-lasting screen exposure [14]. Evidence implies that consuming a higher rate of screen time negatively impacts children's cognitive growth with a downstream influence on their physical, academic, and psychological outcomes, as illustrated in Figure 1 [15-17]. A psychological study from Korea involving kids between 24 and 30 months of age displayed a proportionate relationship between prolonged screen time and delays in language development and challenge-solving skills [6]. Similarly, higher television exposure at only 29 months of age was correlated with minimum vocabulary acquisition levels at a later age [18]. On the contrary, research has exhibited that watching high-quality programs under parental supervision has advantages, including attention span and vocabulary improvements, compared with children who do not watch such content at all. Such quality content often uses tactics including findable object labeling, proper formatting, the interaction between the child and characters, and a structured program outline, which can help in their developmental benefits [19]. Nonetheless, many of these affirmative statements targeting children younger than 2 years remain unproven, as stated in the 1999 AAP policy announcements [2,20,21]. These opposing outcomes infer a huge gap in our understanding and the need for an adapted rather than a one-size-fits-all answer.

XSL•FO
RenderX

Figure 1. Influence of excessive screen time on early childhood developmental spheres.



Previous studies regarding the potential consequences of screen time have largely targeted the age range of children between 5 and 7 years; nonetheless, limited attention has been given to children between 0 and 36 months. This study argues that instead of completely discarding the abundant presence of screen devices, it is crucial to adopt a parent-centric, rational strategy that aligns with today's contemporary lifestyles. This paper proposes that the development of a mobile health (mHealth) app can enable parents to manage their children's screen time and maintain a balance between technology consumption and mindful parenting. This study aims to acknowledge the research gaps, emphasize the existing blind spots, and offer appropriate solutions. To accomplish this, the paper addresses the following fundamental research questions:

RQ1: How does the absence of knowledge regarding the prospective threats of excessive screen use influence parental decision-making procedures?

RQ2: What alternative approaches have been identified that parents can successfully use to divert their children from unnecessary screen time while reinforcing their intellectual, physical, and emotional expertise in a home-based surrounding?

RQ3: How can these alternate strategies be seamlessly integrated into a holistic approach that mitigates the adverse effects of excessive screen exposure on young children's overall development?

We start by representing a systematic approach to reviewing existing and appropriate literature in the designated field, analyzing their insights, and revealing critical knowledge gaps in parental understanding regarding screen time management. Building on these insights, we present some actionable suggestions and explore the capability of developing a mHealth app as a rational tool for parents to help them create a better and healthier digital balance for their children younger than 3 years.

Methods

Overview

Through a structured methodology, broad topics can be investigated and blind spots in the existing literature can be identified [22]. We conducted this research using the methodological framework for scoping reviews proposed by Arksey and O'Malley [23], ensuring a meticulous and transparent approach. The methodological framework of this research is designed to provide a comprehensive understanding of the central research questions by identifying primary studies through different sources. Our framework is divided into 3 distinct phases, covering a thorough scoping criteria, a systematic literature search, and a data synthesis process, which are rigorously carried out to ensure alignment with our research objectives.

Scoping Criteria

In phase 1, we identified studies inspecting the reasoning behind parents' dependence on smart devices, their impact on children's early development, and the viability of alternative intervention activities. The study, furthermore, accounts for parents' misunderstandings regarding the positive effects of screen media consumption on their children's health development, alongside how their own digital habits influence their children's media use patterns. In this research, all contributory studies related to the critical research questions offering insights into the

XSL•FO
RenderX

behavioral and developmental implications of excessive screen use received preliminary approval. This phase was performed to encourage parents' early involvement in using effective solutions, preceding a more thorough investigation of the problem.

Systematic Literature Search

In phase 2, we used a systematic literature search to identify studies that complemented the work done in phase 1 and focused on suggesting, describing, evaluating, and implementing novel insights into mitigating screen dependency on children younger than 3 years. The literature review contained journal papers, peer-reviewed articles, and official reports obtained from academic databases such as JMIR, Google Scholar, IEEE Xplore, Elsevier, and PubMed. Advanced search features, such as MeSH terms in PubMed, along with targeted searches including Pediatrics and Parenting, mHealth and uHealth within JMIR were used to recognize the role of child- and parent-centered approaches using mobile apps, information technologies, engineering solutions, and expand the scope of infants and toddlers' health outcomes. We then formulated a series of specified keywords stemming from the research questions to group papers across the abovementioned databases, as detailed in Table 1. Additionally, to gather information on publicly available parental child monitoring mobile apps for smartphones, we conducted searches of the Google Play Store and Apple App Store using keywords like "Family," "Child," and "Safety" across regional marketplaces.

Table . Search strategy.

Search approach	Field	Context	Motivation
Primary search term	Screen use and child development	Early childhood screen use	Parental monitoring solutions
Synonyms	"infants," "young toddlers," and "early childhood"	"cognitive growth," "psychological development," "sedentary lifestyle," "screen time," "factors and dominance of screen viewing," "risks of extreme screen media," and "alternate solutions"	"mHealth," "software system," "software application," and "safety"

Publications were eligible for inclusion if they were written in English, issued in interdisciplinary conference proceedings, satisfactory journals, or as official reports formed by a government constitution. Broad eligibility criteria were used to maximize the possibility of finding appropriate information, such as the studies that demonstrated expertise in child health science and child psychology, explored alternative strategies to reduce screen dependency such as outdoor activity or mHealth apps, and involved in a discussion related to the detection of effects, connections, and solutions for children younger than 36 months. Researchers applied exclusion criteria to ensure consistency in screening and to maximize the possibility of excluding unsatisfactory literature. The exclusion process involved 2 stages of screening, an initial removal of duplicate and irrelevant articles based on titles and abstracts followed by an exclusion of studies that were not peer-reviewed, published in gray literature, and unrelated especially to child cognitive or behavioral growth, resulting in the elimination of approximately 48% publications of the primary pool.

Data Synthesis Procedure

The data synthesis was performed to categorize the selected papers for evidence synthesis and address the research questions briefly. Data collected from the studies included were organized into a predeveloped Excel spreadsheet to facilitate analysis. The extracted data encompassed bibliographical data (eg, author, title, year of publication, DOI), study characteristics (eg, type of study and sample demographics), contextual information (eg, screen media type, parental decision-making factors, perceived developmental impacts), and evaluation criteria (eg, parental behaviors, child performance, intervention strategies, and outcomes such as cognitive, behavioral, physical, and social development). Classification formats were developed to organize the efficacy of interventions (eg, screen time reduction, improved parental engagement, and coviewing) and their relevance to developmental outcomes. Data charting involved systematically populating the metadata from each study into predefined categories. Key findings were reviewed to ensure accuracy. The synthesized data underlined crucial insights: parental fallacies regarding screen time, gaps in existing policies, and the necessity for accessible, technology-motivated solutions. This phase highlighted the similarities and discrepancies across selected literature, offering recommendations that address the research questions and confirming that this study's conclusions achieve optimal reliability and scalability in diverse childcare settings.

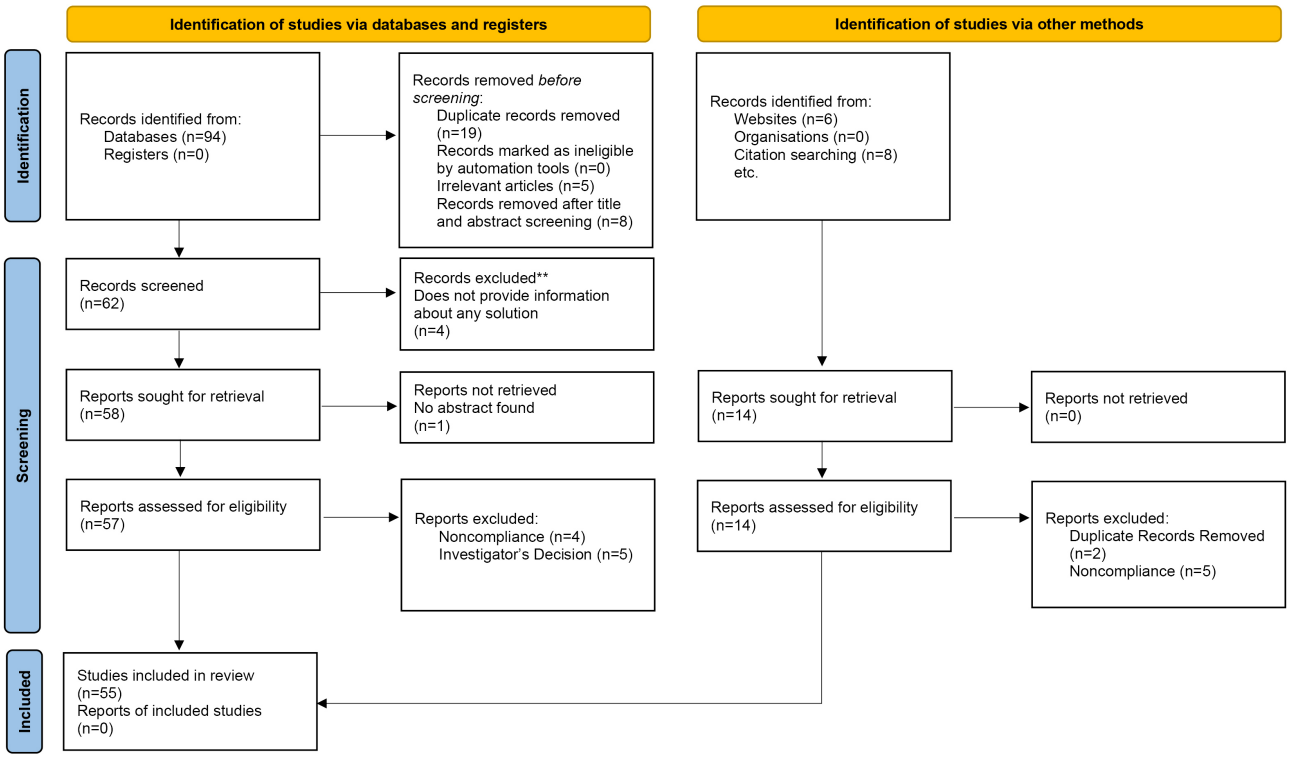
Results

Overview

This scoping review tries to answer research questions presenting the significance of parental attitudes, perspectives, and practices related to screen use that influence the screen time pattern of their infants and toddlers. This study reveals that parents' lack of awareness regarding their own habits of screen use directly affects their toddlers' relationship with smart devices, impeding their healthy development. Hence, these outcomes highlight the necessity to educate parents on the implications of screen use to promote well-informed decision-making that can draw the odds out of screen device use. The results also highlight the importance of balanced use of screen time by children due to the modern parenting environment. The study selection process is illustrated in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart, as shown in Figure 2, which outlines the records identified, screened, and included in the final analysis.

XSL•FO
RenderX

Figure 2. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart displaying systematic literature search.



Significance of Consciousness in Parental Decision-Making (RQ1)

The findings from reviewed studies reveal the outcomes related to early childhood screen exposure, highlighting that the majority of parents remain unaware of how their own screen use directly influences the screen time behavior adopted by their infants and young toddlers [11,24]. As the principal guardians and decision makers, parents uphold a momentous role in shaping their children's early interaction with smart devices, who are tremendously susceptible to the potential consequences of excessive screen exposure during this critical development stage [13]. Thus, to construct more rational and informed guidelines regarding screen time limitations, it is essential to further investigate parental decision-making procedures, incorporating their values and theories in today's modern settings. In Table 2, we categorized parents' perceptions towards their positive beliefs in smart devices for their children. The results of children's screen viewing depend heavily on wrong impressions of their parents' decisions regarding the age inappropriateness of content, exposure to background media, allowing screens during mealtimes, and so forth. For example, studies have identified that regularly exposing a toddler to noise made from television or other digital content playing in the background while a child is engaged in another activity can disrupt their focus, reduce verbal interactions, and delay vocabulary growth [15,20,25,26]. Similarly, dependence on any mode of screen device during sleep time often results in reduced parent-child bonds and a disrupted sleep pattern.

XSL•FO
RenderX

Table . Observations of parents as opposed to their actual impact.

Parents observations	Decision-making factors	Effects on cognitive development	Additional impacts	Reference
Protected from external world	Parents from unsafe neighborhoods prefer providing screen time to keep their toddlers indoors.	• Higher screen dependence at school age • Less attention span	• Higher risk of obesity • Aggressive behavior	[2,27]
Screen media as an educational tool	Confidence that programs that target younger toddlers are educational and enhance child development.	• Decreased child vocalizations. • No considerable linguistic abilities • Reduced school-connectedness	• Inverse impact on self-esteem.	[2,6,15,28]
Background media use	Children exposed to adult contents (termed as background noise) while being engaged in other activities.	• Delayed vocabulary development because of less “talk time”. • Reduced focus on intellectual tasks.	• Distraction of children from current activities. • Reduced exposure to meaningful family interaction.	[15,20,25,26]
Media as a peacekeeper	Parents use screen devices to escape tension and concentrate on tasks such as food preparation, doing office work, or household duties.	• Decreased focus and attention span. • Both short and long-term speech delay	• Decreased parent-child interaction. • Less time for creative activities. • Weakened psychological outcome.	[11,24,26]
Bedtime media use	Parents comprehending that screen time helps in calming children to sleep.	• Adverse outcome on speech delivery.	• Resistance to sleep • Condensed sleep length	[20]
Touchscreen benefits for motor development in infants	Belief that early touch screen interaction boosts fine motor skill advancement.	• Experiencing “video deficit”— difficulties while transitioning from 2D to 3D objects • Troubled motor skills.	• Disrupted mental flexibility. • Higher Body Mass Index (BMI)	[11,14,26]
Use of smart devices as an indication of status	Societal pressure to endlessly purchase latest screen gadgets to children for status.	• Delayed cognitive, and verbal advancement.	• Limited outdoor play opportunities. • Tendency towards a sedentary lifestyle	[2]
Underestimation of media consumption	Parents underestimating their own children’s screen viewing length.	• Physical changes to brain structure • Challenges in information processing.	• Agitated behavioral change. • Higher obesity risk • Reduced sleep duration	[24]
Lack of consciousness of existing recommendations	Confusion or ignorance of existing standards, with a focus only on benefits of physical activity.	• Disproportionate attainment of cognitive indicators. • Possibilities of hyperactivity and inattention	• Health hazards later in life • Disrupted sleep and eating routine	[5]

Table 2 demonstrates that a significant number of parents allow screen time for their children due to an array of familial and societal reasons. Many parents who have newborns and younger toddlers use screen devices as a mode of distraction or a means to prevent conflict, manage household chores, or even put children to sleep. Some of them give their child the latest smart gadgets as a means of maintaining social status because of the perception of these devices as standing symbols. Some parents just view these devices as a convenient educational tool, believing screen media literacy will prevent their offspring from falling behind other children in an academic setting, while others are protective against the outside world and would choose for their children to stay indoors and be secure. Moreover, some parents underestimate their children’s screen time entirely, and others are merely oblivious to the recommendations. Such dependence on screen devices has normalized their presence in regular life, advocating to parents that screen use is an innocent and required aspect of advanced upbringing, often obscuring the potential harms associated with screen use which can be serious such as mood fluctuations, sleep difficulties, psychological and physical changes, reduced attention spans, and other health problems. Studies also highlight the influence

XSL•FO
RenderX

of convincing marketing campaigns that portray screen time as absolutely imperative for educational and entertainment purposes, further concealing the challenges associated with them [28]. These findings highlight the need to promote parental awareness and mindful digital engagement during early childhood. It is therefore crucial to present parents with evidence-based tools that can balance their child's screen use with developmental requirements.

Strategies for Moderating Screen Time in Younger Children (RQ2)

The studies indicate that the continuous presence of smartphones and other smart gadgets within households has become an inherent component in the lives of infants and toddlers [29]. Among this significant population, roughly 72% of children aged 0 - 8 years and 38% of children younger than 2 years have access to some mode of smart devices such as smartphones, iPads, or tablet devices [30,31]. Despite a plethora of studies emphasizing the short-term difficulties during infancy and continuing long-term complications in the subsequent growing phases, such smart devices remain an inevitable part of current parenting due to their ability to attract the minds of children successfully [13]. After acknowledging the consequences, authorities such as the AAP, the US Department of Health and Human Services, the Australian Department of Health and Ageing, and the Canadian Pediatric Society strongly instruct plummeting screen time as one of the significant urgent issues by entirely restraining media use on children younger than 2 years, and instigating rigorous boundaries for those between 2 and 18 years [20]. Figure 3 demonstrates the recommended duration of screen time and other developmentally supportive activities for children stated by AAP to enable healthy behaviors, such as including enough sleep, outdoor activities, and constant physical play that can successfully counterbalance screen exposure.

Figure 3. The advised total amount of screen time, physical/outside activity, and sleep for discrete age groups of children [13,17-20]. AAP: American Academy of Pediatrics.

AAP'S COMPREHENSIVE GUIDELINES FOR SCREEN USE, SLEEP, AND PHYSICAL ACTIVITY ACROSS ALL AGE GROUPS

- Address what type of media and how much screen time is appropriate for each child.
- Promote a child's cognitive, physical and mental health
- Cultivate healthy lifestyle

AGE GROUP	RECOMMENDED SCREEN TIME	DURATION FOR OUTDOOR ACTIVITY	TOTAL AMOUNT OF SLEEP
0-12 Months	No Screen Media	Not Satisfactory	12-16 h/day
12-24 Months	Minimum screen participation in the presence of a parent	Not Satisfactory	11-15 h/day
2-5 years	At most 1h/day, consumption of high-quality content only	0.5-1 h/day	10-14 h/day
6-12 years	No more than 1h/day and always closely supervise	1h/day	9-12 h/day
13-18 years	Maximum 2h/day with limitations on content	1h/day	8-10 h/day

The results depicted that extreme screen use in a family is strongly associated with a toddler's own screen viewing practices. Given that children younger than 2 years have very limited power over their adjacent surroundings and their actions are merely a replication of what their parents do around them, their screen habits are formed by what they perceive. For instance, studies highlight that if parents engage in more than 4 hours a day watching TV, their toddlers will be 3 times more likely to exceed the same duration [32]. Thus, parents need to regulate their own screen use and model positive examples as they are the chief contributors to their infants' long-term well-being. Childcare providers, more specifically pediatricians, play a fundamental role in supporting well-adjusted screen habits by educating parents and continually supervising parental adherence to the guidelines during scheduled appointments, assuring their proper implementation within households [20,33]. Therefore, intervention strategies should largely entail actions taken by parents as well as childcare providers, as each of them has a unique role in the infant's long-term betterment [33]. Given the increasing impact of modernization within home environments, the following intervention strategies demonstrated in Table 3 provide ideal directions for distinct family perspectives, and it is imperative to implement such principles as references for forthcoming actions. Considering the outcomes of various studies, 6 types of intervention approaches for parents and 3 for pediatricians have been distinguished, along with their expected outcomes as summarized in Table 3.

XSL•FO
RenderX

Table . Intervention strategies and their anticipated outcome.

Target contributor and recommended intervention strategies	Description	Expected outcome	Reference
Parents			
Restriction on child's screen time	Consistently control screen time throughout the day, avert using any screen device during meals or sleep, and turn off devices while not in use.	• Promote healthy eating behaviors. • Enhance language acquisition • Better quality of life	[13,15]
Limit parental screen time	Formulate home-based regulations on screen media specifically for parents.	• Reduces screen time of children through modeling. • Increased parent-child connectivity	[17,34]
Coviewing contents	Parents encourage co-watching high quality content, supervising what their children see and hear.	• Enhances cognitive development. • Encourages parent-child interaction • Significantly expands vocabulary during infancy	[6,13,24]
Focus on quality over quantity	Promote educational content which uses schemes to assist language training, contains naive story structures and allows child interaction scopes.	• Higher communication skills • Increases prosocial behavior. • Expands concentration. • Encourages positive racial outlook	[6,13,15,26]
Promote child-directed and age-appropriate media content	Recommend contents for younger children that contains longer displays, provides narration hints, labeling, and structured storytelling.	• Facilitates cognitive understanding. • Overcomes "video deficit". • Higher school readiness	[11,17]
Promote a healthy lifestyle.	Include outdoor activity, imaginative play, a regular sleep cycle, and a nutritious diet.	• Promotes locomotive skills, reduces childhood obesity, and improves metabolic health. • Influence adaptive health.	[35]
Pediatricians			
Set age-appropriate "media limits"	Discuss and enforce screen media restrictions for children younger than 2 years during scheduled visits.	• Fosters balanced screen behaviors at an initial stage	[20]
Encourage supervised independent play	Inform parents about independent play when they are unavailable but able to supervise their child.	• Builds perseverance and problem-solving expertise while remaining under surveillance	[20,33]
Explain the value of "unplugged play"	Encourage parents to engage children in hands-on, imaginative, and performing activities that interest them.	• Encourages creative thinking • Expands problem solving skills.	[3]

XSL•FO
RenderX

Developing a Holistic Strategy: A Pathway to Expand Children's Cognitive Advancement

Studies indicate that engaged, collaborative, and informed parenting can successfully reverse the detrimental impacts of excessive screen use while fostering complete development [36]. For instance, research has confirmed that the presence of a parent who actively gives statements or explanations on the content their child watches, starting from as early as 6 months, can have a positive impact on the infant's intellectual engagement and attention span [26]. However, modern life often restricts the scope and time for quality parent-child communications, as time-restrained parents face tight spots to implement these policies. Therefore, a balanced solution is needed that moderates the negative impacts of screen time while leveraging the advantages of using several digital tools [37]. As the research team reviewed some existing strategies to help parents balance screen time for their infants and toddlers, studies revealed some parental control mobile apps, such as Google Family Link, Apple Family Sharing, and Microsoft Family Safety, which primarily focus on screen time management for older children. However, these apps provide inadequate guidance for children younger than 3 years, which needs to be addressed through age-appropriate solutions to guarantee healthy early development.

Discussion

Principal Results

This study underlines that excessive screen exposure has extensive consequences on the overall well-being of infants and younger toddlers, putting this phenomenon into a different perspective. The consequences are far more serious, and they are not simply a result of screen exposure but are greatly interconnected with parental personal screen media use, attitudes, behaviors towards technology, and ignorance of the risks posed by digital devices. Parents' reliance on screens—whether as an opportunity of defense against the outside world, a means of distraction, a perceived educational tool, or even a status symbol—plays a critical role in offering their children a smart device. It is undeniable that the presence of smart devices will further reinforce with time, augmenting the urgent necessity for appropriate and practical interventions that encourage mindful digital engagement, particularly in the case of infants and toddlers.

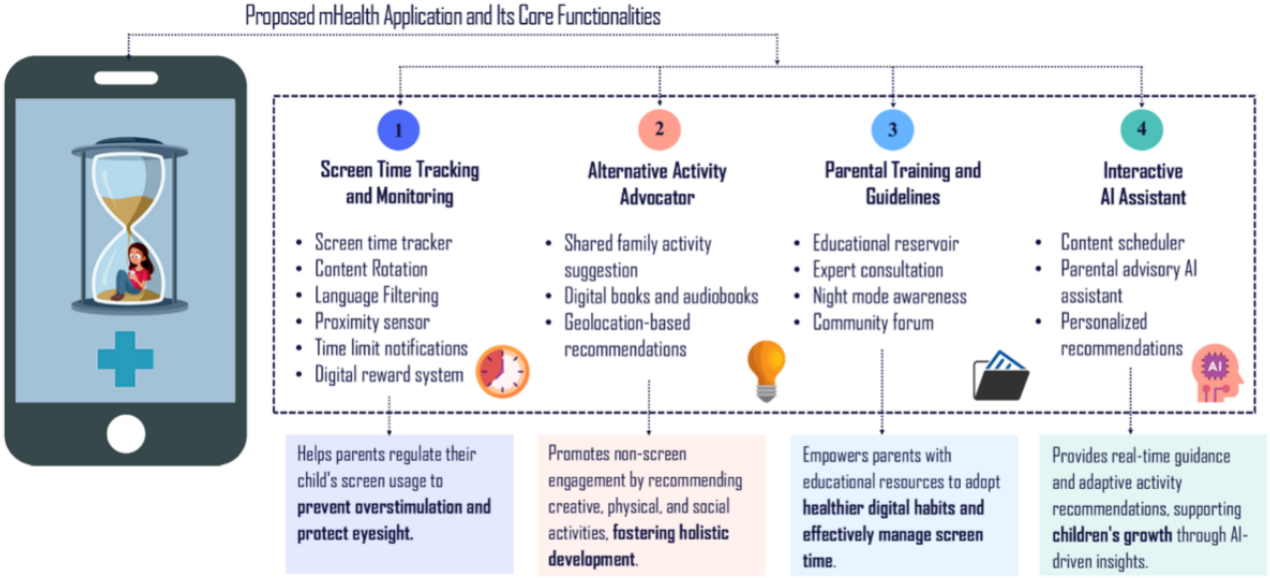
Major intervention strategies identified in this paper include restricting screen time for both parents and their offspring, coviewing age-appropriate programs, and prioritizing nonscreen activities as they promote healthier behavior and increase parent-child connection [13,15,17,34]. More hands-on strategies, such as quality regulation of content, are also essential as younger children often lack the decision-making capabilities of which programs to watch. Therefore, the prevailing guidelines are necessary for a constructive learning experience for the younger generation [14,26]. Pediatricians also play an essential role as part of their responsibility is to advise parents on the best actions required for their children, for instance, inspire parents to establish age-appropriate time limits and suggest both supervised and independent play according to the child's interest. Such pursuits can cultivate a recognition of persistence and broaden their thoughts of the outside world beyond just screens [20,33].

Given the presence of technology in this modern world, it is evident that addressing the challenges related to screen time consumption requires leveraging technology itself. Studies suggest an urgent need for solutions that balance regulatory guidance with sustainable and parent-centric approaches tailored to today's sociocultural and socioeconomic realities [38,39]. Therefore, building on the understanding of the research assembled from an examination of RQ1 and RQ2, we recommend that a mHealth app can be an empathetic, practical, and scalable tool that will make supervising children's screen time easier for today's busy parents. The justification for this app is plain and simple; since digital devices have become an inseparable part of our daily lives and high-tech devices are already accessible to every parent, it would be a logical and feasible decision to leverage them to tackle this issue. Additionally, it would enable parents to oversee the digital ecosystem precisely and cautiously within a household.

The app could be built using the Scrum Agile software development methodology to ensure the progress of the app development process in an incremental and iterative way. Each sprint could drive the systematic execution of planning, design, coding, testing, and review, facilitating efficiency and high-quality outcomes. Backend development could be implemented using the Swift programming language within the Xcode IDE (Apple Inc) to facilitate development, organize events, and enhance data flow. User interface (UI) could be designed by leveraging UIKit and SwiftUI frameworks. Additionally, Swift Package Manager could be leveraged to ensure efficient dependency management, Git for version controlling of the codebase, and Firebase Software Development Kits for documentation and cross-platform app development of the scalable prototype. In delineating the direction for the development of this app, we believe four core components with their prominent features as absolutely principal for creating a holistic framework: (1) screen time tracking and monitoring (could allow parents to monitor screen use across multiple devices and set goals), (2) provision of parental training and guidelines (could provide resources to educate parents, boosting parental self-confidence in their capability for successful screen management), (3) alternative activity advocator (could propose nonscreen pursuits tailored to each child's preferences), and finally (4) interactive artificial intelligence (AI) (could present personalized suggestions to parents, assisting them to address the challenges proactively and reducing screen dependency) (Figure 4).

XSL•FO
RenderX

Figure 4. Prototype of a mHealth app along with the supervising features. AI: artificial intelligence.



Outline of the Key Features

Screen Time Tracking and Monitoring

While it is not realistic for parents to completely eliminate providing their children with screen devices, they can guarantee controlled use [40]. A screen time tracking and monitoring feature can allow parents to track their toddlers' daily screen use by showing detailed data insights across multiple devices [41]. This functionality can be accomplished by applying parental control application programming interfaces (APIs) that supervise and log screen time, along with frameworks like Xamarin or React Native, which can be used for combined codebases. To prevent cognitive fatigue and avoid overstimulation in children from repeated use of the same content, the app can periodically suggest changes in media content after a predefined duration. Younger children can struggle with multilingual content, often overwhelming their learning abilities [42-44]. Recognizing the challenges, the app could offer a language-filtering option that enables parents to streamline content into a single language, supporting early language development, supporting early language development—particularly for children with special requirements. To help parents manage screen exposure effectively, the screen time goals and alerts feature can inform parents with alerts when time limits come closer or are exceeded. Furthermore, a digital reward system can be incorporated to persuade adherence to screen time limits, applied through a gamification reward framework linked to databases to track the improvement. It is well known that prolonged screen exposure at close distances could be extremely detrimental to children's eyesight [45]. A proximity sensor feature could use smartphone infrared sensors to alert parents if devices are held too close to infants' and toddlers' eyes, reducing the risk of eye strain. Both Screen Time API and the UsageStatsManager API can be operated for iOS and Android, respectively, and all the segments can be seamlessly synchronized across various devices using cloud-based services such as Firebase or AWS, confirming convenience and ease of use for parents.

Parental Training and Guidelines

The parental training and guideline feature could perform as an all-inclusive educational resource for parents, so that parents do not feel ignorant. The function can offer reasonable resources such as videos, articles, or infographics to delineate the outcomes of excessive screen time and suggest effective strategies for regulating it, attained using a content management system that handles the content dynamically. To make the app more reachable and user-friendly for parents with varying levels of digital literacy and access to technology, the app could incorporate a LangChain model to provide concise summaries of critical research findings as Daily Educational Push notifications, guiding them to take their next actions. This approach would guarantee that parents have easy access to an ample number of resources, removing the need for independent research and allowing them to make informed decisions regarding their child's screen time. After clicking on the popper notification, parents could be seamlessly redirected to the detailed materials. Real-time updates can be acquired using services, for example, Contentful or Strapi. The platform can connect parents with certified child psychologists or pediatricians through audio or video calls for adapted guidance and strategies on screen time administration, using a booking system and secure calling features such as Twilio API. The blue lights emitted during screen time can significantly disrupt sleep time and sleep quality of infants and toddlers [46]. It is feasible to create collaborative tutorials using libraries such as Intro.js and connect them to the device API to design a scheduled Night mode module that offers step-by-step directions on lowering blue light emission during nighttime gadget use. Finally, a community forum module can facilitate parents in sharing tips, their experiences, hardships, and success stories on monitoring their child's screen time so that they always feel supported in their journey. Both the front and back end of this segment can be developed by using React.js and Node.js, ensuring appropriate authentication, fundamental for this facility to operate.

XSL•FO
RenderX

Alternative Activity Advocator

Nonscreen activities play a vital role in the holistic development of children aged 0 - 3 years, as this period determines future behavioral and health outcomes [47]. While outdoor play promotes physical health and improves motor skills, shared family activities and social interactions improve communication skills [48]. It can be challenging for parents to come up with ideas to lure their kids away from screens. The alternative activity advocator feature can be instrumental in promoting nonscreen engagement for children. Subsections falling within this section can incorporate (1) Shared Family Activities, which could offer constructive, age-appropriate family activities. Existing parental control techniques, such as Google Family Link, Apple Family Sharing, and Microsoft Family Safety, emphasize screen time tracking but do not offer any guidance for alternative activities. The proposed feature could include diverse activity categories based on a child's creative, active, social, and educational interests and recommend tasks accordingly. For instance, interactive activities like listening to nursery rhymes to nurture creativity, baby yoga to encourage physical activity, or a scavenger hunt to build an adventurous mindset [49,50]. Such activities can significantly help children meet milestones, establish a foundation for parent-child bonding, and build their motor, sensory, and communication skills. (2) The next subfeature could suggest the Provision of Digital and Audiobooks, delivering an assorted library of books suitable for a child's age and intensity of reading. The level of engagement will be higher if the picture books include colorful visuals, simple language, and interactive storytelling options to capture the attention of children, particularly infants or younger toddlers [51]. (3) Finally, the app could further incorporate Geolocation-Based Recommendations to identify nearby parks, playgrounds, or family activity centers where parents can arrange playdates with other families [52]. This way, parents can discover safe and engaging environments for their children to socialize with same-age children and develop their social interaction skills at an early age. A decision tree algorithm could be used, driven by data collected through in-app surveys and stored in a NoSQL database like MongoDB for flexibility to attain such distinctive offerings. Activity recommendation algorithms can be used using Python's scikit-learn or comparable libraries. These features would reduce reliance on screens while fostering creativity, physical activity, and real-world interaction in an organized manner.

Interactive AI

The mHealth app can incorporate another innovative attribute by channeling the power of AI to present parents with adapted guidance. An AI-based Content Scheduler can be developed to offer busy parents flexible options for planning their child's activities during mealtimes, play hours, and bedtime, offering real-time support. Automatic AI scheduling could leverage collaborative filtering, content-based recommendations, and context awareness to generate developmentally appropriate schedules. A Parental Advisory AI assistant can be established, using natural language processing libraries such as NLTK or spaCy in Python, incorporated with an AI chatbot framework, for instance, Rasa or Microsoft Bot Framework. Additionally, an AI-assisted Personalized Activity Advocator, leveraging the LangChain framework and advanced large language model capabilities, could deliver tailored recommendations for nonscreen activities and developmentally appropriate digital educational content [53-55]. Drawing from user survey data, collaboration history, and professional input, this feature could support the fundamental cognitive development goals for infants and toddlers. Additionally, A/B testing could be used to continuously improve the algorithms based on user feedback, ensuring relevance and accuracy.

To ensure strategic scalability, the app could primarily launch a freemium model, proposing a basic version tailored for home-based ecosystem to allow widespread adoption. Simultaneously, a premium model, available through subscription or payment, could be introduced for daycare or childcare environments, generating sustainable revenue. The basic version can be upgraded to a premium version with a subscription at any time, ensuring accessibility and long-term market success. We believe that by integrating this innovative solution along with all the recommended features, the app will promote healthy cognitive and emotional development, establish positive media habits, and adapt seamlessly to busy family dynamics.

All in all, by leveraging the revolutionary principles of information technology, machine learning, and AI, the proposed mHealth app could become a one-stop solution for confronting the challenges modern parents face in managing screen time for their children younger than 3 years. This novel app can act as an exclusive knowledge hub for screen time management, parenting guidelines, tips, and expert advice. A comprehensive framework, easy-to-understand UI, and integration of advanced functionalities are future ways to maintain the digital lifestyles of toddlers and infants.

Limitations

The outcomes of this research contribute to a deeper understanding of the significant correlation between screen time consumption, parental behaviors, and early childhood development. However, it is compulsory to address specific limitations. Existing studies often fail to consider individual variability among children and different family dynamics, such as socioeconomic factors, parenting styles, and cultural influences. Consequently, this oversight restricts the relevance or applicability of findings across discrete socioeconomic populations. Our research concentrated on general patterns about the effects of screen time without considering different family structures, but recognizes the necessity for future research to further examine these nuances.

The complex and continuously evolving character of the digital landscape presents difficulties in effectively managing screen time. Therefore, the proposed mHealth app, including the existing guidelines, must be pliable and capable of addressing emerging challenges presented to it. Leveraging AI and machine learning to offer continuous updates would provide parents with more control over the watched contents, guaranteeing continual efficacy.

Ensuring user engagement is another challenging procedure. Integrating AI with diverse user input data may demand model

XSL•FO
RenderX

training data adjustments. Future studies could use iterative refinement cycles and investigate additional algorithms to ensure optimal performance. Furthermore, the usability evaluation may reveal unexpected UI challenges. Executing iterative usability testing cycles with small groups could enable mitigating this challenge, allowing for design refinement.

Conclusions

A significant proportion of children begin engaging with smartphones and other screen devices at an earlier stage and for a longer period than childcare authorities advocate. The clear effects of the digital landscape and smart device availability highlighted in this study uncover critical research questions about program content, parental behavior, and the possible direct effects on infants and toddlers; highlighting that there is a pressing need for holistic, evidence-based approaches to address the developmental challenges associated with excessive screen time consumption among children aged 0 - 3 years. In response to this issue, the paper proposes integrating technology into the solution through a mHealth app constructed to balance the developing requirements of children with the pressures of modern parenting. The novel solution, along with its innovative features, could become a valuable partner in helping parents face repercussions, offering massive support from early childhood. The beneficiaries of this solution are the children themselves, who would obtain immense enrichment in their overall cognitive and emotional advancement through reasonable and practical screen use. The findings should also inspire parents and pediatricians to discuss children's screen habits, warn researchers to unpack the contradictions in the existing literature, and discover potential prospects for defensive interventions. Finally, the paper underlines the importance of further research so that the solutions can appear to be readily applicable and adaptable across all naturalistic home-based settings. With strong potential for commercialization and industry impact, the proposed mHealth app is poised to transform child well-being and promote lasting benefits for families and communities.

Conflicts of Interest

None declared.

Checklist 1
PRISMA checklist.
[DOCX File, 544 KB - pediatrics_v8i1e60355_app1.docx]

References

1. Kaur N, Gupta M, Malhi P, Grover S. A multicomponent intervention to reduce screen time among children aged 2-5 years in Chandigarh, North India: protocol for a randomized controlled trial. JMIR Res Protoc 2021 Feb 11;10(2):e24106. [doi: 10.2196/24106] [Medline: 33570499]
2. Lauricella AR, Wartella E, Rideout VJ. Young children's screen time: the complex role of parent and child factors. J Appl Dev Psychol 2015 Jan;36:11-17. [doi: 10.1016/j.appdev.2014.12.001]
3. Linebarger DL, Vaala SE. Screen media and language development in infants and toddlers: an ecological perspective. Dev Rev 2010 Jun;30(2):176-202. [doi: 10.1016/j.dr.2010.03.006]
4. Jago R, Fox KR, Page AS, Brockman R, Thompson JL. Parent and child physical activity and sedentary time: do active parents foster active children? BMC Public Health 2010 Apr 15;10:194. [doi: 10.1186/1471-2458-10-194] [Medline: 20398306]
5. Domingues - Montanari S. Clinical and psychological effects of excessive screen time on children. J Paediatrics Child Health 2017 Apr;53(4):333-338 [FREE Full text] [doi: 10.1111/jpc.13462]
6. Kaur N, Gupta M, Malhi P, Grover S. Screen time in under-five children. Indian Pediatr 2019 Sep 15;56(9):773-788. [doi: 10.1007/s13312-019-1638-8] [Medline: 31638012]
7. Anjum N, Hasan M, Salma SU, Zhao L, de Clemente MV, Sakib N. ScreenSafeFuture: a parent-empathetic and pragmatic mhealth application for toddlers' brain development addressing screen-addiction challenges. SoftwareX 2025 Feb;29:101996. [doi: 10.1016/j.softx.2024.101996]
8. Anjum N, Hasan M, Karim E, Ahamed SI, Garefino A, Sakib N. Unpacking early digital addiction and developmental challenges in young children: a scoping review towards rethinking digital habits (preprint). J Med Internet Res. Preprint posted online on May 8, 2024. [doi: 10.2196/preprints.60355]
9. Brauchli V, Sticca F, Edelsbrunner P, von Wyl A, Lannen P. Are screen media the new pacifiers? the role of parenting stress and parental attitudes for children's screen time in early childhood. Comput Human Behav 2024 Mar;152:108057. [doi: 10.1016/j.chb.2023.108057]
10. Xu H, Wen LM, Rissel C. Associations of parental influences with physical activity and screen time among young children: a systematic review. J Obes 2015;2015:546925. [doi: 10.1155/2015/546925] [Medline: 25874123]
11. Hetherington E, McDonald S, Racine N, Tough S. Longitudinal predictors of self-regulation at school entry: findings from the all our families cohort. Children (Basel) 2020 Oct 16;7(10):186. [doi: 10.3390/children7100186] [Medline: 33081229]

XSL•FO
RenderX

12. Whiting S, Buoncristiano M, Gelius P, et al. Physical Activity, Screen Time, and Sleep Duration of Children Aged 6-9 Years in 25 Countries: An Analysis within the WHO European Childhood Obesity Surveillance Initiative (COSI) 2015-2017. Obes Facts 2021;14(1):32-44. [doi: 10.1159/000511263] [Medline: 33352575]
13. Tandon PS, Zhou C, Lozano P, Christakis DA. Preschoolers' total daily screen time at home and by type of child care. J Pediatr 2011 Feb;158(2):297-300. [doi: 10.1016/j.jpeds.2010.08.005] [Medline: 20980020]
14. Foreman J, Salim AT, Praveen A, et al. Association between digital smart device use and myopia: a systematic review and meta-analysis. Lancet Digit Health 2021 Dec;3(12):e806-e818. [doi: 10.1016/S2589-7500(21)00135-7] [Medline: 34625399]
15. Byeon H, Hong S. Relationship between television viewing and language delay in toddlers: evidence from a Korea national cross-sectional survey. PLoS One 2015;10(3):e0120663. [doi: 10.1371/journal.pone.0120663] [Medline: 25785449]
16. Zimmerman FJ, Christakis DA. Associations between content types of early media exposure and subsequent attentional problems. Pediatrics 2007 Nov;120(5):986-992. [doi: 10.1542/peds.2006-3322] [Medline: 17974735]
17. Panjeti-Madan VN, Ranganathan P. Impact of screen time on children's development: cognitive, language, physical, and social and emotional domains. MTI 2023;7(5):52. [doi: 10.3390/mti7050052]
18. Pagani LS, Fitzpatrick C, Barnett TA. Early childhood television viewing and kindergarten entry readiness. Pediatr Res 2013 Sep;74(3):350-355. [doi: 10.1038/pr.2013.105] [Medline: 23788060]
19. Madigan S, Browne D, Racine N, Mori C, Tough S. Association between screen time and children's performance on a developmental screening test. JAMA Pediatr 2019 Mar 1;173(3):244-250. [doi: 10.1001/jamapediatrics.2018.5056] [Medline: 30688984]
20. Brown A, Council on Communications and Media. Media use by children younger than 2 years. Pediatrics 2011 Nov;128(5):1040-1045. [doi: 10.1542/peds.2011-1753] [Medline: 22007002]
21. Wilkinson C, Low DF, Gluckman SP. Screen time: the effects on children's emotional, social, and cognitive development. Koi Tū Centre for Informed Futures. URL: https://informedfutures.org/screen-time/ [accessed 2025-01-12]
22. Weirauch V, Soehnchen C, Burmann A, Meister S. Methods, indicators, and end-user involvement in the evaluation of digital health interventions for the public: scoping review. J Med Internet Res 2024 May 31;26:e55714. [doi: 10.2196/55714] [Medline: 38819891]
23. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005 Feb;8(1):19-32. [doi: 10.1080/1364557032000119616]
24. Zimmerman FJ, Christakis DA, Meltzoff AN. Television and DVD/video viewing in children younger than 2 years. Arch Pediatr Adolesc Med 2007 May;161(5):473-479. [doi: 10.1001/archpedi.161.5.473] [Medline: 17485624]
25. Duch H, Fisher EM, Ensari I, Harrington A. Screen time use in children under 3 years old: a systematic review of correlates. Int J Behav Nutr Phys Act 2013 Aug 23;10(1):102. [doi: 10.1186/1479-5868-10-102] [Medline: 23967799]
26. Gingold JA, Simon AE, Schoendorf KC. Excess screen time in US children: association with family rules and alternative activities. Clin Pediatr (Phila) 2014 Jan;53(1):41-50. [doi: 10.1177/0009922813498152] [Medline: 23922251]
27. Certain LK, Kahn RS. Prevalence, correlates, and trajectory of television viewing among infants and toddlers. Pediatrics 2002 Apr;109(4):634-642. [doi: 10.1542/peds.109.4.634] [Medline: 11927708]
28. Lammers SM, Woods RJ, Brotherson SE, Deal JE, Platt CA. Explaining adherence to American academy of pediatrics screen time recommendations with caregiver awareness and parental motivation factors: mixed methods study. JMIR Pediatr Parent 2022 Apr 5;5(2):e29102. [doi: 10.2196/29102] [Medline: 35380541]
29. Auxier B, Anderson M, Perrin A, Turner E. Parenting children in the age of screens. Pew Research Center. 2020. URL: https://www.pewresearch.org/internet/2020/07/28/parenting-children-in-the-age-of-screens/ [accessed 2025-01-12]
30. Harrison E, McTavish M. 'i'Babies: infants' and toddlers' emergent language and literacy in a digital culture of iDevices. Journal of Early Childhood Literacy 2018 Jun;18(2):163-188. [doi: 10.1177/1468798416653175]
31. Lillard AS, Peterson J. The immediate impact of different types of television on young children's executive function. Pediatrics 2011 Oct;128(4):644-649. [doi: 10.1542/peds.2010-1919] [Medline: 21911349]
32. Visier-Alfonso ME, Sánchez-López M, Rodríguez-Martín B, et al. Parents' perceptions of children's and adolescents' use of electronic devices to promote physical activity: systematic review of qualitative evidence. JMIR Mhealth Uhealth 2023 Jul 20;11:e44753. [doi: 10.2196/44753] [Medline: 37471127]
33. Guellai B, Somogyi E, Esseily R, Chopin A. Effects of screen exposure on young children's cognitive development: a review. Front Psychol 2022;13:923370. [doi: 10.3389/fpsyg.2022.923370] [Medline: 36059724]
34. Papadakis S, Zaranis N, Kalogiannakis M. Parental involvement and attitudes towards young Greek children's mobile usage. Int J Child Comput Interact 2019 Dec;22:100144. [doi: 10.1016/j.ijcci.2019.100144]
35. Guram S, Heinz P. Media use in children: American academy of pediatrics recommendations 2016. Arch Dis Child Educ Pract Ed 2018 Apr;103(2):99-101. [doi: 10.1136/archdischild-2017-312969] [Medline: 29223974]
36. Ponti M, Bélanger S, Grimes R. Screen time and young children: promoting health and development in a digital world. Paediatr Child Health 2017 Nov;22(8):461-477. [doi: 10.1093/pch/pxx123] [Medline: 29601064]
37. Ponti M. Screen time and preschool children: promoting health and development in a digital world. Paediatr Child Health 2023 Jun;28(3):184-202. [doi: 10.1093/pch/pxac125] [Medline: 37205134]
38. Schmidt ME, Haines J, O'Brien A, et al. Systematic review of effective strategies for reducing screen time among young children. Obesity (Silver Spring) 2012 Jul;20(7):1338-1354. [doi: 10.1038/oby.2011.348] [Medline: 22222926]

XSL•FO
RenderX

39. Alkalash SH, Alshamrani FA, Alharthi SA, et al. Parents' knowledge on, attitude toward, and practice of screen time exposure regulation of their children under six years of age in Western Region, Saudi Arabia. Cureus 2023 Nov;15(11):e49464. [doi: 10.7759/cureus.49464] [Medline: 38152829]
40. Hiniker A, Suh H, Cao S, Kientz JA. Screen time tantrums: how families manage screen media experiences for toddlers and preschoolers. 2016 May Presented at: Conference on Human Factors in Computing Systems - Proceedings, Association for Computing Machinery; California, San Jose, USA p. 648-660. [doi: 10.1145/2858036.2858278]
41. Gentile DA, Reimer RA, Nathanson AI, Walsh DA, Eisenmann JC. Protective effects of parental monitoring of children's media use: a prospective study. JAMA Pediatr 2014 May;168(5):479-484. [doi: 10.1001/jamapediatrics.2014.146] [Medline: 24686493]
42. Dewaele JM, van Oudenhoven JP. The effect of multilingualism/multiculturalism on personality: no gain without pain for third culture kids? Int J Multiling 2009 Nov;6(4):443-459. [doi: 10.1080/14790710903039906]
43. Dumetz J, Vichnyakova A. Unexpected disadvantages of a simultaneous quadrilingual upbringing, a case study citation. Int J Teach Educ 2021 [FREE Full text]
44. Ren W. The difficulties and challenges of learning English in a multilingual environment. Lect Notes Lang Lit 2024;7(3):3. [doi: 10.23977/langl.2024.070324]
45. Priftis N, Panagiotakos D. Screen time and its health consequences in children and adolescents. Children (Basel) 2023 Oct 8;10(10):1665. [doi: 10.3390/children10101665] [Medline: 37892328]
46. Emond JA, O'Malley AJ, Neelon B, Kravitz RM, Ostbye T, Benjamin-Neelon SE. Associations between daily screen time and sleep in a racially and socioeconomically diverse sample of US infants: a prospective cohort study. BMJ Open 2021 Jun 24;11(6):e044525. [doi: 10.1136/bmjopen-2020-044525] [Medline: 34168024]
47. Craig D, Trina NA, Monsur M, et al. Effective nature-based outdoor play and learning environments for below-3 children: a literature-based summary. Int J Environ Res Public Health 2024 Sep 20;21(9):1247. [doi: 10.3390/ijerph21091247] [Medline: 39338130]
48. Sugiyama M, Tsuchiya KJ, Okubo Y, et al. Outdoor play as a mitigating factor in the association between screen time for young children and neurodevelopmental outcomes. JAMA Pediatr 2023 Mar 1;177(3):303-310. [doi: 10.1001/jamapediatrics.2022.5356] [Medline: 36689245]
49. Activities for baby using everyday household items. Pathways. URL: https://pathways.org/activities-for-baby-using-everyday-household-items/?gad_source=1 [accessed 2025-01-12]
50. Markham D. Your age-by-age guide to screen-free activities your child can do with minimal supervision. Peaceful Parent Happy Kids. URL: https://www.peacefulparenthappykids.com/read/screen-free-activities-kids [accessed 2025-01-12]
51. Lawless Z. How engaged are infants and toddlers while picture book? Undergraduate Honors Theses.: University of Arkansas URL: https://scholarworks.uark.edu/rhrcuht/85/ [accessed 2025-06-16]
52. Putnick DL, Trinh MH, Sundaram R, et al. Displacement of peer play by screen time: associations with toddler development. Pediatr Res 2023 Apr;93(5):1425-1431. [doi: 10.1038/s41390-022-02261-y] [Medline: 35986149]
53. Mattern D, Lopez FM, Ernst MR, Aubret A, Triesch J. MIMo: a multi-modal infant model for studying cognitive development in humans and ais. 2022 Presented at: 2022 IEEE International Conference on Development and Learning (ICDL); London, United Kingdom p. 23-29. [doi: 10.1109/ICDL53763.2022.9962192]
54. Sung IY, Jeon JY, Yun KJ, et al. Development of tablet personal computer-based cognitive training programs for children with developmental disabilities whose cognitive age is less than 4 years. Medicine (Baltimore) 2020 Jan;99(2):e18674. [doi: 10.1097/MD.0000000000018674] [Medline: 31914058]
55. Lu P, Feng X. Personalized recommendation algorithm in AI-assisted learning system. 2024 Sep Presented at: 2024 6th International Conference on Communications, Information System and Computer Engineering (CISCE); Guangzhou, China p. 1289-1294. [doi: 10.1109/CISCE62493.2024.10653402]

Abbreviations

AAP: American Academy of Pediatrics
AI: artificial intelligence
API: application programming interface
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
UI: user interface

XSL•FO
RenderX

Edited by S Badawy; submitted 08.05.24; peer-reviewed by C Aloba, RP Singh Kaurav, S Mehta, T Ogunmola; revised version received 08.02.25; accepted 18.03.25; published 03.07.25.

Please cite as:
Anjum N, Hasan MM, Jahan N, Ahamed SI, Garefino A, Sakib N
Early Digital Engagement Among Younger Children and the Transformation of Parenting in the Digital Age From an mHealth Perspective: Scoping Review
JMIR Pediatr Parent 2025;8:e60355
URL: https://pediatrics.jmir.org/2025/1/e60355
doi:10.2196/60355

© Nafisa Anjum, Md Mehedi Hasan, Nursat Jahan, Sheikh Iqbal Ahamed, Allison Garefino, Nazmus Sakib. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 3.7.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Review

Assessing and Enhancing Nutrition and Physical Activity Environments in Early Childhood Education and Care Centers: Scoping Review of eHealth Tools

Joyce Hayek[1*], PhD; Kelsi Dickson[1]; Lynne M Z Lafave[1*], PhD

Department of Health and Physical Education, Mount Royal University, Calgary, AB, Canada

[*]these authors contributed equally

Corresponding Author:
Lynne M Z Lafave, PhD
Department of Health and Physical Education
Mount Royal University
4825 Mount Royal Gate SW
Calgary, AB, T3E 6K6
Canada
Phone: 1 403 440 5967
Email: llafave@mtroyal.ca

Abstract

Background: Early childhood is a critical period for shaping lifelong health behaviors, making early childhood education and care (ECEC) environments ideal for implementing nutrition and physical activity interventions. eHealth tools are increasingly utilized in ECEC settings due to their accessibility, scalability, and cost-effectiveness, demonstrating promise in enhancing educators' practices. Despite the potential effectiveness of these eHealth approaches, a comprehensive collection of available evidence on eHealth tools designed to assess or support best practices for nutrition or physical activity in ECECs is currently lacking.

Objective: The primary objective of this scoping review is to map the range of available eHealth tools designed to assess or deliver interventions aimed at improving nutrition or physical activity in ECEC settings, while evaluating their components, theoretical foundations, and effectiveness.

Methods: This scoping review adhered to the Joanna Briggs Institute methodology, in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) checklist. The objectives, inclusion criteria, and methods for this review were predefined and specified. Eligibility criteria were (1) early childhood educators (population); (2) eHealth (digital) technologies, such as websites, smartphone apps, emails, and social media; and (3) tools designed to assess or deliver interventions aimed at improving best practices for nutrition, physical activity, or both within ECEC settings (context). A search was conducted across 5 electronic databases (PubMed, Scopus, CINAHL Plus, ERIC, and Embase) to identify white literature, and 3 electronic databases (ProQuest, Google Scholar, and targeted Google search), along with hand-searching of reference lists, were used to identify gray literature. All literature was reported in English or French, with the search extending until May 2024. Separate data charting tools were used for white and gray literature.

Results: The search strategy identified 3064 results for white literature, yielding 2653 unique citations after duplicates were removed. Full texts for 65 citations were retrieved and screened for inclusion, resulting in 30 studies eligible for data extraction and analysis. The most common study design was a randomized controlled trial, comprising 16 studies (53%). The largest proportion of studies were conducted in the United States (11 studies, 37%). In total, 19 eHealth tools were identified, targeting nutrition (8 tools, 42%), physical activity (5 tools, 26%), or both nutrition and physical activity (6 tools, 32%). All tools were web based (19 tools, 100%). The gray literature search yielded 1054 results, of which 17 were moved to full-text screening, and 7 met the eligibility criteria for data extraction and analysis. The tools identified in the gray literature originated in Canada (4 tools, 57%) and the United States (3 tools, 43%). The majority targeted nutrition (4 tools, 57%) and were primarily web based (6 tools, 86%), with 1 mobile app (1 tool, 14%).

Conclusions: This scoping review mapped the available eHealth tools designed to improve nutrition or physical activity environments in ECEC settings, highlighting the growing emphasis on web-based tools and the need for psychometric testing.

XSL•FO
RenderX

Future research should systematically evaluate the effectiveness of these tools, particularly those addressing both nutrition and physical activity, to identify the key factors that contribute to long-term behavior change.

Trial Registration: Open Science Framework XTRNZ; https://osf.io/xtrnz

International Registered Report Identifier (IRRID): RR2-10.2196/52252

(JMIR Pediatr Parent 2025;8:e68372) doi:10.2196/68372

KEYWORDS

eHealth; early childhood educators; ECE; early childhood education and care; ECEC; knowledge synthesis; digital technology; health technology; digital public health; eating; diet

Introduction

Background

Unhealthy lifestyle factors, such as physical inactivity and unhealthy diets, are primary contributors to the rising incidence of chronic diseases [1-5]. These conditions are recognized as growing global public health problems, leading to significant treatment costs and imposing an economic burden on health systems, individuals, and society as a whole [6,7]. Health behaviors often originate in early childhood and can persist into young adulthood [8]. Research indicates that health behaviors, such as eating habits and physical activity levels, are modifiable risk factors for obesity and chronic diseases [9]. These behaviors often co-occur or cluster together [10,11]. An integrated approach to health promotion, addressing both dietary intake and physical activity simultaneously [10], is therefore essential during early childhood to improve population health across the lifespan.

The early years are a critical period for shaping health behaviors and outcomes [12], with early interventions regarded as an essential component of preventive health [13]. Early childhood education and care (ECEC) settings provide a unique opportunity to reach a large number of children during this pivotal developmental period, making them an ideal setting for behavioral interventions [12,14]. Moreover, early childhood educators, as part of the ECEC environment, are well-positioned to successfully implement nutrition and physical activity behavior interventions [15,16]. Evidence from prior research shows that professional training of early childhood educators in best practices for nutrition and physical activity is associated with improved dietary intake and increased physical activity levels in young children [17-20].

With the widespread use of the internet, online or eHealth interventions have experienced significant growth. eHealth refers to the use of digital technologies, such as the internet, digital gaming, virtual reality, and robotics, for promoting, preventing, treating, and maintaining health [21]. Examples of eHealth technologies include smartphone apps, websites, computer programs, SMS text messaging, and social media platforms [22]. Digital technologies offer several advantages, including lower costs, reduced participant burden, enhanced accessibility, and increased scalability, thereby extending the reach of behavioral interventions [23,24]. Prior research indicates that eHealth interventions within ECEC settings are highly acceptable and effective in improving early childhood educators' knowledge and practices related to nutrition and physical activity [25-27].

Behavior change theories can guide the selection of intrapersonal constructs to target in intervention development, as well as the choice of behavior change techniques to achieve desired behavioral outcomes [28]. Evidence suggests that behavior change interventions, whether internet-based or not, are more effective when guided by a theoretical framework [29]. A meta-analysis [29] found that interventions extensively informed by theory demonstrated larger effects compared with those lacking theoretical underpinnings. The use of theory not only enhances the efficacy of interventions but also facilitates their replication and future development [30]. Consequently, it is crucial to determine whether theory has been applied in the development of eHealth tools.

Recognizing the importance of early learning settings and educators in fostering healthy behavior development in children, researchers have developed, implemented, and evaluated health promotion interventions within childcare settings [31-33]. A preliminary search of PROSPERO, PubMed, the Cochrane Database of Systematic Reviews, and JBI Evidence Synthesis identified several relevant reviews. However, these reviews primarily focused on evaluating the effectiveness of in-person nutrition and physical activity interventions [34,35], interventions conducted in family-based centers [36,37], or those targeting older children and adolescents [33]. No current or in-progress systematic or scoping reviews address eHealth tools for promoting the best nutrition and physical activity practices in ECEC settings.

Objectives

To address this gap in the literature, we conducted a scoping review. This method is used to identify the types of available evidence in a field, explore key characteristics related to a concept, and analyze knowledge gaps [38]. This review aimed to achieve the following objectives: (1) identify existing eHealth tools used to assess or deliver interventions that improve nutrition or physical activity environments in ECEC centers; (2) describe the components of the eHealth tools, including technology type (eg, websites, smartphone apps, social media) and health purposes (eg, nutrition evaluation, physical activity promotion); (3) outline the psychometric properties of the eHealth tools, when applicable; (4) report the theoretical foundations used in developing the eHealth tools; and (5) identify any evidence gaps. The purpose of this study was to map the available evidence on eHealth tools currently used to

XSL•FO
RenderX

assess and support best practices for nutrition or physical activity in ECEC centers.

Methods

Overview

This scoping review followed established methods for such studies [39] and adhered to the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines [40]. Methodological quality or risk of bias was not assessed, as the goal of this review was to provide a broad overview of existing evidence, regardless of methodological approach, to map the available evidence. This is consistent with guidance on scoping review methods [39]. Full details of the methods can be found in our published protocol [41]. The PRISMA-ScR checklist is included in Multimedia Appendix 1 [40].

Selection Criteria

Participants

This review considered studies involving early childhood educators within licensed ECEC programs, whether public or privately operated, providing full-day care for children aged 0-5 years. Studies focusing on educators in family-based settings, preschool programs where children attend for less than 4 hours per day, or before- and after-school care were excluded.

Concept

This review considered studies that explored eHealth tools designed to support nutrition or physical activity environments in the ECEC setting. eHealth tools were defined as digital technologies that (1) assessed or (2) delivered interventions to improve nutrition or physical activity environments and practices. eHealth tools that assessed the ECEC environment were included only if they provided feedback to the ECECs. Additionally, we included only studies where the eHealth tool was the primary component for assessment or intervention.

Context

This review focused on nutrition and physical activity environments in the ECEC setting, considering both the physical and social environments.

Types of Sources

For this scoping review, we considered all study designs, including quantitative, qualitative, mixed methods, protocols, experimental, quasi-experimental, and cross-sectional studies. Systematic reviews and meta-analyses were also included if relevant to the topic, with a primary focus on ECEC settings. Unpublished studies and gray literature were also considered as sources of information.

Search Strategy

Overview

The search strategy was developed in collaboration with 2 research librarians and aimed to capture both white and gray literature to encompass the full range of available eHealth tools.

White Literature

A preliminary limited search of PubMed and Scopus was conducted to identify articles on the topic. The text words in the title and abstract, along with the index terms used to describe the articles, were analyzed to develop a full search strategy for PubMed. This search strategy, incorporating all identified keywords and index terms, was then adapted for each included information source (see Multimedia Appendix 2). The databases searched included PubMed, Scopus, CINAHL Plus (EBSCOhost), ERIC (EBSCOhost), and Embase (OVID). The reference lists of all included sources of evidence were screened for additional white literature. The final search was conducted on October 4, 2023. For each database, a search alert was set up using its alert functions to track any new relevant publications for potential inclusion in the review. The final search alert was reviewed on May 5, 2024, and only 1 additional study was identified. All retrieved white literature was exported into Covidence software (Veritas Health Innovation) for screening and data extraction.

Gray Literature

Following the guidelines outlined by Godin et al [100], we conducted a thorough search of the gray literature to identify nonindexed sources such as dissertation abstracts, government documents, conference proceedings, educational materials, and reports. This was done through searches in (1) the ProQuest Database, (2) Google Scholar, (3) targeted web-based Google searches, and (4) hand searches of the reference lists of all included gray literature to identify additional relevant sources. The final gray literature search was conducted on April 30, 2024. All retrieved documents were exported into Microsoft Excel and assigned a unique identifier for screening and data extraction. Because of the potential volume of gray literature, we limited our review to the first 10 pages from Google Scholar and targeted web-based Google searches, based on title. Additionally, eHealth tools that required payment for access were excluded.

This review included studies and records published in English or French, with no date limitations.

Study Selection

Following the search, all identified records were uploaded into Covidence (for white literature) or Microsoft Excel (for gray literature). Title and abstract screening, full-text screening, and data extraction were performed by 2 independent reviewers (JH and LMZL) according to the inclusion criteria. Reasons for excluding full texts that did not meet the inclusion criteria were recorded and reported in the scoping review. Any disagreements between the 2 reviewers were resolved through discussion, and if consensus could not be reached, a third reviewer (KD) was consulted. The results of the search are reported and presented in a PRISMA-ScR flow diagram (Figure 1 in Results section).

Data Extraction

Separate data extraction charting tools for white and gray literature were developed by the reviewers (Multimedia Appendix 3), as outlined in our published protocol [41]. The extraction tools, used to capture relevant study and eHealth tool characteristics, were piloted before the review to ensure

XSL•FO
RenderX

consistency in information collection. Any disagreements between reviewers were resolved through discussion.

Data Analysis and Presentation

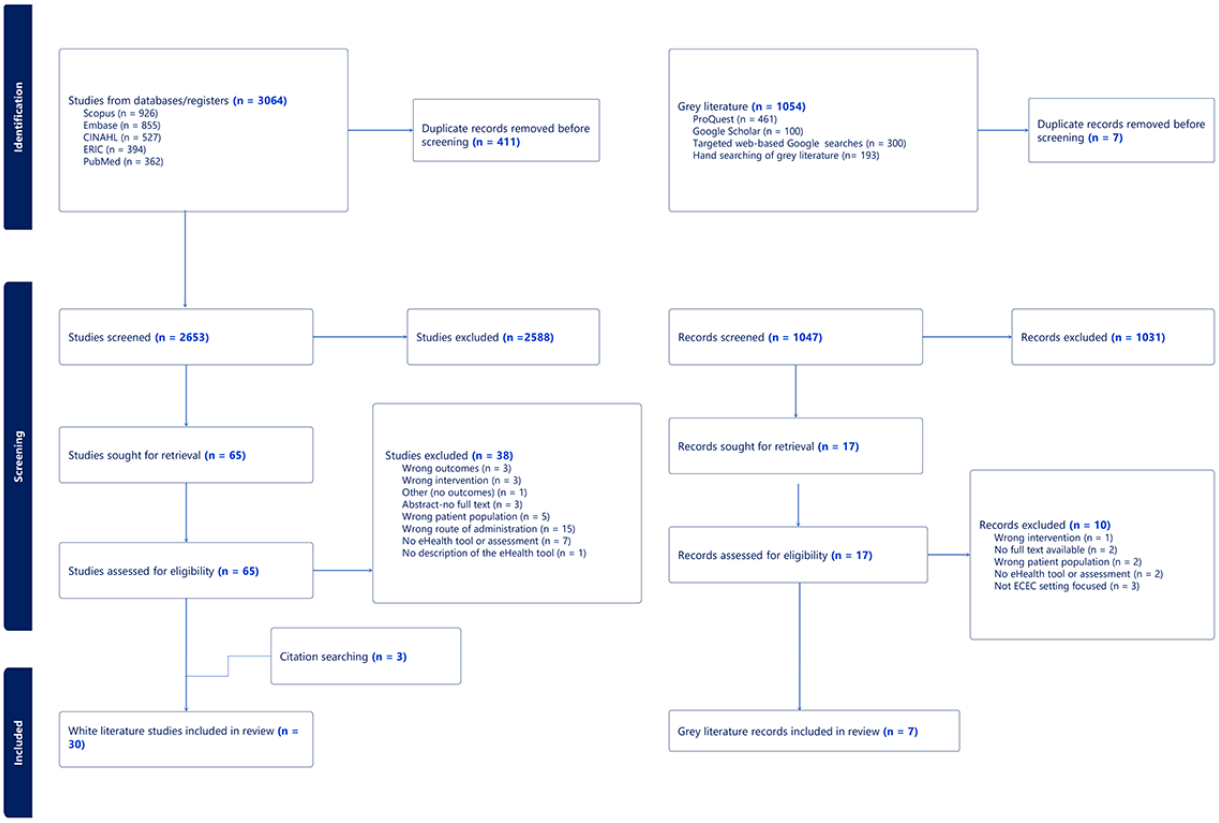
The extracted data were summarized using descriptive statistics (ie, frequency counts). The results were organized by each review question, highlighting study characteristics, eHealth tool characteristics, and the use of a theoretical framework. The findings are presented in a narrative summary, complemented by tables, charts, and illustrations.

Results

Literature Search and Selection Process

The white literature search yielded 3064 results, of which 411 were removed as duplicates. Titles and abstracts for 2653 records were screened for eligibility, and 2588 were excluded. Of the remaining records, 65 full-text articles were reviewed against the eligibility criteria. A total of 30 articles were included for data extraction (Figure 1). The gray literature search yielded 1054 results, of which 7 were removed as duplicates. Titles and abstracts of 1047 records were assessed against the eligibility criteria, and 17 were moved to full-text screening. Of these, 7 met the inclusion criteria and were included in the analysis. The PRISMA flowchart shows the selection process.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart.



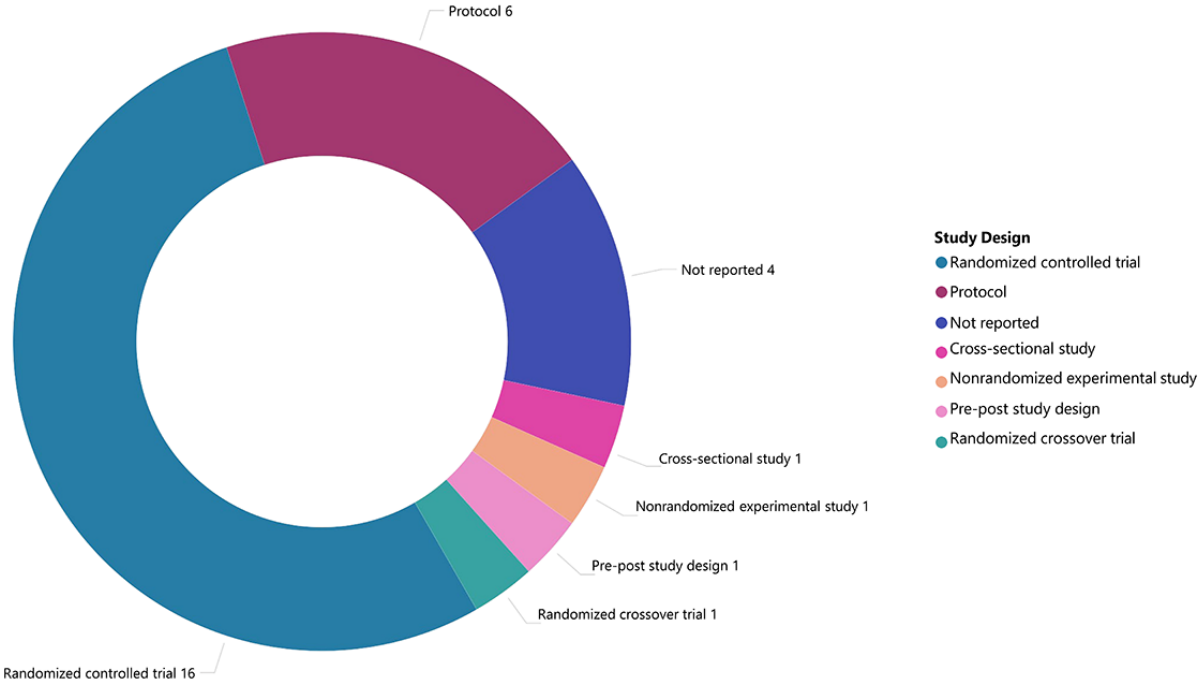
Included Records

A total of 30 research studies identified in the white literature were included in this review (Figure 1). Of these, 16 were randomized controlled trials, 6 were protocol studies, 1 was a cross-sectional study, 1 was a nonrandomized experimental study, and 1 was a randomized crossover control trial (Figure 2). Specific characteristics of the included studies are presented in Table 1, which reflects the study design, setting, and outcome measures. The study aims along with additional study details are provided in Multimedia Appendix 4. The largest proportion of studies were conducted in the United States (n=11, 37%) and Australia (n=11, 37%), followed by Canada (n=6, 20%) and Norway (n=2, 7%; Figure 3). The studies were conducted between 2016 and 2022. The baseline sample size ranged from n=13 to 2932. Of the 10 studies reporting participant sex, females comprised the largest proportion of participants ranging from 85% to 100%, with an average of 96% (Table 1). The mean age of participants ranged from 37.1 to 49.6 years.

A total of 7 records were identified in the gray literature and included in this review (Figure 1). These records represented community-based eHealth outreach initiatives related to nutrition or physical activity support for the ECEC community. Four of these initiatives originated from Canada and 3 from the United States.

XSL•FO
RenderX

Figure 2. Study designs of research articles identified in the white literature.



XSL•FO
RenderX

Table 1. Characteristics of included studies from the white literature.

Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Barnes et al [42]: Australia	RCT[b]	Childcare centers	NR[c]	NR	NR	•Improving implementation of targeted healthy eating practices. •Child dietary intake of fruit and vegetable servings in care. •Child dietary intake of sodium, saturated fat, and added sugar in care. •Mean servings of fruits and vegetables packed within lunch boxes.
Barnes et al [27]: Australia	RCT	Childcare centers	Total: 22 (intervention: 11; control: 11)	NR	Intervention group: supervisors 37.68 (5.92) and center champions 44.17 (6.40); control group: supervisors: 43.91 (10.57)	• Implementation of targeted healthy eating practices. • Supporting families to provide healthier foods consistent with dietary guidelines. •Provision of intentional healthy eating learning experiences. •Using feeding practices that support children's healthy eating. •Staff participating in professional development targeting healthy eating. •Having a comprehensive written nutrition policy that outlines key healthy eating practices.
Blomkvist et al [43]: Norway	Protocol for RCT	Kindergarten	Total: 46 kindergartens (intervention: 31; control: 15)	NR	NR	• Primary outcomes: (1) child vegetable intake; (2) children's level of food neophobia; and (3) child dietary habits and food variety. • Secondary outcomes: (1) self-reported weight and height; (2) parental and kindergarten staff feeding practices.
Blomkvist et al [44]: Norway	RCT	Kindergarten	Total: 46 kindergartens (intervention: 31; control: 15)	NR	NR	•Child intake of intervention vegetables and all vegetables combined. •Level of child food neophobia.
Bruijns[d,e] et al [45]: Canada	Pre-post study design	Center-based childcare, kindergarten, and preschool	Total: 110 early childhood educators	99.2%	37.1 (9.5)	•Knowledge of PA, outdoor/risky play, and sedentary behavior concepts. •PA, outdoor/risky play, and sedentary behavior self-efficacy. •Behavioral intention and perceived behavioral control.

XSL•FO
RenderX

Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Brussoni et al [46]: Canada	Protocol for RCT	ELCC[f]	Total: 324 ECEs[g] and ELCC administrators	NR	NR	•The primary outcome is increased tolerance of risk in children's play, as measured by the Teacher Tolerance of Risk in Play Scale. •The secondary outcome is self-reported attainment of a self-developed behavior change goal.
Brussoni et al [47]: Canada	RCT	ELCC	Total: 563 educators and administrators (intervention: 281; control: 282)	96.6%	NR	•Primary outcome: change in the total score on the T-TRiPS[h]. •Secondary outcome: participants' goal attainment at either follow-up time point (self-reported behavior change, measured by participants' self-reported progress in attaining the goal they set for themselves).
Chuang et al [48]: United States	RCT	ECE centers	Total: 111 ECE providers (intervention: 56; control: 55)	97.3%	43.55 (11.87)	• Psychosocial and behavioral measures: (1) nutrition knowledge, (2) mindful eating, (3) perceived barriers to eating fruits and vegetables, and (4) perceived barriers to promote healthy eating in classroom. • Environmental factors: (1) nutrition-related policy and practices at their ECE facilities and (2) number of healthy eating–related activities organized for the staff in the ECE center. • Individuals behavior: (1) dietary intake and (2) communication of nutrition information with ECE children and parents.
Clark et al [49]: United States	NR	Licensed childcare	Total: 38 childcare providers (intervention: 23; control: 15)	100%	NR	• Knowledge of and attitudes and behaviors toward feeding breast milk, formula, and solid food to the infants in their care.
Clarke et al [50]: United States	Protocol	ECE programs	Total: 2932 ECE providers	N/A[i]	N/A	• Uptake and perceived usefulness of on-demand online nutrition training.
Grady et al [51]: Australia	Nonrandomized experimental study	Long day care services	Total: 46 childcare services (intervention: 27; control: 19)	NR	Intervention group: 48.44 (10.36); control group: 43.74 (10.48)	• Uptake and use of the menu program: proportion of services adopting the program and proportion of services using the program as intended.

XSL•FO
RenderX

Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Grady et al [52]: Australia	RCT	Long day care services	Total: 54 childcare services (intervention: 27; control: 27)	NR	Intervention group: 48.4 (10.4); control group 44.9 (10.5)	• Primary outcome: the mean number of food groups compliant with dietary guidelines •Secondary outcomes: (1) compliance with dietary guidelines for all food groups, (2) individual food group compliance with dietary guidelines, and (3) mean servings of individual food groups.
Green et al [53]: Australia	NR	Long day care, preschool, and occasional care	NR	NR	NR	• Nutrition practice achievements such as (1) lunch boxes monitored daily and (2) fruits and vegetables on menu. •PA practice achievements such as (1) tummy time for babies and (2) active playtime for at least 25% of opening hours.
Hazard et al [54][e]: United States	RCT	Licensed childcare centers	Total: 20 childcare providers	98%	NR	• Evaluation of accessibility, acceptability, and satisfaction of nutrition and online education courses.
Hoffman et al [55]: United States	RCT	Preschools	Total: 11 teachers and 2 site supervisors	NR	NR	• Implementation fidelity, acceptability, and feasibility of WE PLAY[j].
Hoffman et al [19]: United States	RCT	Preschools	Total: 25 teachers (intervention: 11; control: 14)	100%	Intervention group 40.7 (9.0); control group 45.9 (13.2)	• Children's MVPA[k] (MVPA accelerometer). •Teachers' changes in PA knowledge and attitudes toward PA promotion.
Kempler et al [56]: Australia	Cross-sectional study	Childcare services	Total: 64 participants	NR	NR	• Qualitative outcomes explored use and experience with the menu tool.
Kennedy et al [57]: United States	NR	Preschools	Total: 41 teachers	NR	NR	•The percentage of the 60-minute daily goal reached in each classroom. •The proportion of students actively participating in MVPA. •The percentage of time spent in MVPA. •Teachers' involvement with children during PA opportunities. •Child enjoyment (students having fun during the PA opportunities).
Lafave [58]: Canada	Randomized crossover trial design	ECEC[l] centers	Total: 72 educators	100%	NR	• Psychometric evaluation of nutrition and PA assessment—online inter- and intrarater reliability.

XSL•FO
RenderX

Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Lafave et al [59]: Canada	Protocol for quasi-experimental study	ECEC centers	Total: 208 educators (intervention: 138; control: 50)	96.2%	40.05 (11.67)	•Food served in the center self-audit, eating environment/mealtime practices self-audit, nutrition education programming self-audit. •Mindful eating of educators. •Nutrition knowledge, attitude, and behaviors of educators. •Observation of nutrition environment in childcare. •Qualitative experiences of the nutrition environment. •PA environment self-audit. •Physical literacy knowledge, attitude, self-efficacy, and behaviors of educator and professional practices. •Objectively measured child PA levels. •Qualitative experiences of PA environment.
Lee et al [60][e]: United States	RCT	Licensed childcare centers	Total: 30 ECE or services (intervention: 19; control: 11)	NR	Intervention group 47.7 (10.8); control group 49.6 (12.	• Knowledge and awareness of and adherence to California's 2010 Healthy Beverages in Child Care Act.
Peden et al [61]: Australia	RCT	ECEC centers	Total: 104 educators	85%	NR	• Qualitative educator comments on the experience of the HOPPEL[m] program.
Peden et al [62]: Australia	RCT	ECEC centers	Total: 112 educators	85%	NR	•Changes in center-level healthy eating practices assessed using the EPAO[n] tool. •Changes in children's PA assessed using ActiGraph GT1M and GT3X + accelerometers.
Reilly et al [63]: Australia	RCT	ECEC services	Total: 1024 ECEC services (intervention: 684; control: 342)	NR	NR	•Intentions to adopt the guidelines. •Awareness and reach of the guidelines. •Knowledge of the guidelines. •Implementation of the guidelines. •Barriers to implementing the guidelines.
Saunders et al [64]: United States	NR	Preschools	Total: 818 teachers	NR	NR	• Classroom implementation completeness (ie, provision of 300 minutes of PA opportunities) and fidelity (ie, achieving PA fidelity and social environment fidelity).

XSL•FO
RenderX

Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Ward et al [65]: United States	RCT	Full-time and part-time childcare center programs	Total: 33 ECE centers (intervention: 18; control: 15)	NR	NR	• Change in centers' nutrition environments: (1) foods provided, (2) beverages provided, (3) feeding environment, (4) feeding practices, (5) menus, (6) education and professional development, and (7) nutrition policy.
Ward et al [25][o]: Canada	RCT	Early childcare centers	Total: 191 (intervention: 102; control: 89)	NR	NR	•Healthy eating practices. •Perceived knowledge about fundamental movement skills. •PA practices.
Willis et al [66]: United States	Protocol for RCT	ECE centers	Total: 168 teachers	N/A	N/A	•Children's dietary intakes and Healthy Eating Index scores. •Teachers' dietary intakes and Healthy Eating Index scores. •Anthropometrics measurements (children and teachers). •ECE center nutrition environment. •PA (children and teachers using accelerometers). •ECE center PA environment.
Yoong et al [67]: Australia	Protocol for RCT	Childcare services	Total: 54 long-day-care services	N/A	N/A	•Mean number of food groups on childcare service menus that comply with dietary guidelines. •Proportion of services that comply with dietary guidelines for each of the 6 food groups. •Proportion of services that meet the recommended number of serves for all of the 6 Australian Guide to Healthy Eating food groups. •Child dietary intake. •Child BMI. •Child health-related quality of life.

XSL•FO
RenderX

Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Yoong et al [68]: Australia	RCT	Childcare centers	Total: 35 childcare centers	NR	NR	•Number of servings of the 5 core and discretionary food groups defined by the Australian Guide to Healthy Eating consumed in care. •Childcare educator–reported child diet quality. •Child BMI *z*-scores. •Child health-related quality of life. •Child diet outside of care.

[a]PA: physical activity.

[b]RCT: randomized control trial.

[c]NR: not reported.

[d]In Bruijns et al [45], participants included both preservice and in-service ECEs. Only data from in-service ECEs were reported, which aligns with our target population of educators in childcare centers.

[e]In Bruijns et al [45], Hazard et al [54], and Lee et al [60], participants included both center- and family-based childcare. For our purposes, we only included data from center-based childcare (eg, sample size). Gender and age are reported for all participants, as specific breakdowns were not provided.

[f]ELCC: early learning childcare center.

[g]ECE: early care and education.

[h]TRiPS: Teacher Tolerance of Risk in Play Scale.

[i]N/A: not applicable.

[j]WE PLAY: Wellness Enhancing Physical Activity for Young Children.

[k]MVPA: moderate-to-vigorous physical activity.

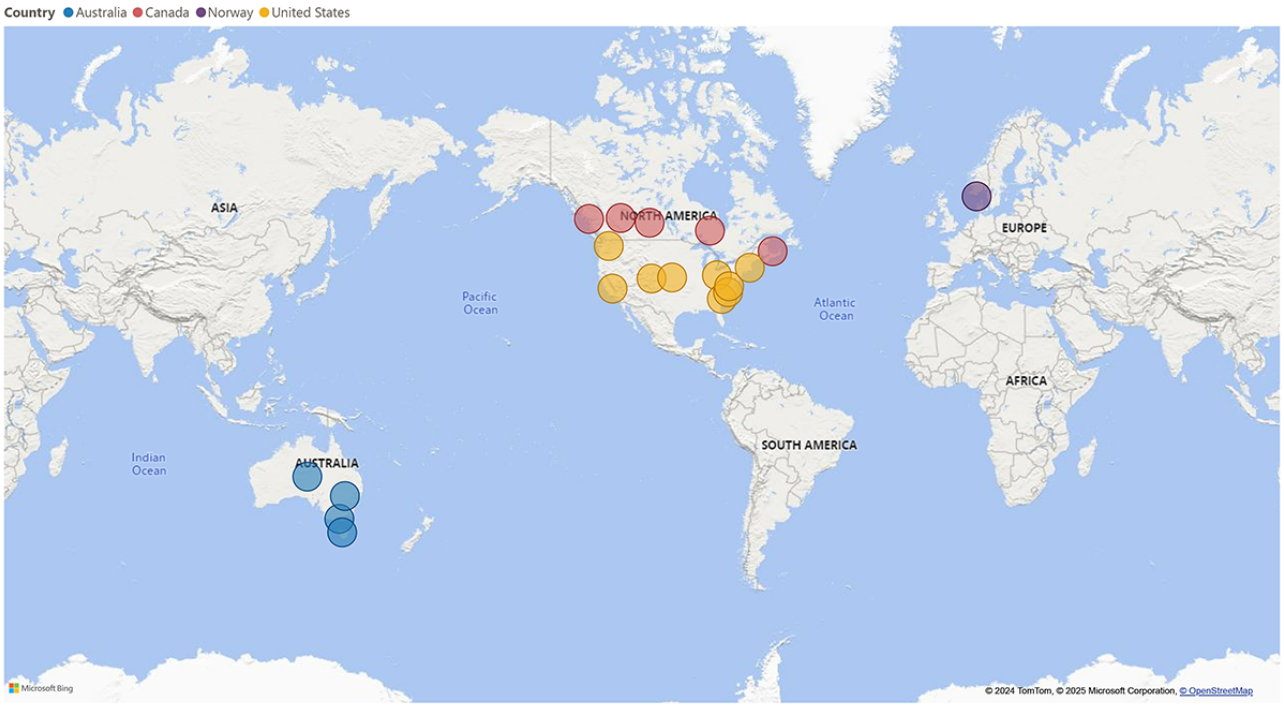
[l]ECEC: early childhood education and care.

[m]HOPPEL: Healthy Online Professional Program for Early Learners.

[n]EPAO: Environmental Policy Assessment and Observation.

[o]In Ward et al [25], the study included both in-person and online intervention groups. Our review focused only on extracting data from the online intervention group.

Figure 3. Country of study from eHealth research identified in the white literature and gray literature.



XSL•FO
RenderX

eHealth Tool Characteristics

The 30 research articles included in the review identified 19 unique eHealth tools, with 12 categorized as intervention-based and 7 as both assessment and intervention tools. The characteristics of these eHealth tools identified in the white literature are summarized in Table 2, with additional details available in Multimedia Appendix 4. Among the 7 eHealth tools incorporating an assessment component, only 1 underwent evaluation of its psychometric properties. All eHealth tools were delivered via a web-based modality (7/7, 100%).

The characteristics of the eHealth tools identified in the gray literature are summarized in Table 3, with additional details provided in Multimedia Appendix 5. Of the 7 eHealth tools identified, all were intervention-only tools (7/7, 100%). Of these, 6 (86%) were delivered via a web-based modality, while 1 (14%) was delivered as a mobile phone app.

XSL•FO
RenderX

Table 2. Characteristics of eHealth tools from included studies identified in the white literature.

eHealth tool	Country: References	Type of eHealth tool	eHealth modality[a]	Target of eHealth tool	eHealth tool component	eHealth tool description	Length of the intervention	Theoretical underpinning
Create Healthy Futures Program	United States: [48]	Intervention	Web based	Nutrition	Healthy eating practices	Self-paced web-based intervention on promoting healthy eating behaviors for ECE[b] providers	6 weeks	•Social Cognitive Theory •Social Ecological Model
CHEERS[c]	Canada: [58,59]	Assessment and intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices	Online educational modules and communities of practice to improve the nutrition and physical activity environment in ECECs[d]	10 months	•Social Cognitive Theory
EATS[e]	Australia: [27,42]	Assessment and intervention	Web based	Nutrition	Healthy eating practices	The web-based program supports center implementation of targeted healthy eating practices through self-assessment, feedback, and the development of an action plan	6 months	•Social Ecological Framework •Behavioral Change Wheel
FoodChecker	Australia: Kempler et al [56]	Assessment and intervention	Web based	Nutrition	Online menu planning	Web-based menu planning tool to support childcare services in planning healthy menus	NR[f]	NR
feedAustralia	Australia: [51,52,67,68]	Assessment and intervention	Web based	Nutrition	Online menu planning	Web-based menu planning program offering automated real-time assessment of childcare menu with feedback to support the planning of healthier menus	12 months	•Technology Acceptance Model •Theoretical Domains Framework
GO NAP-SACC[g]	United States: [50,65]	Assessment and intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices	Suite of online tools to guide ECE programs through a 5-step process to improve their nutrition and physical activity-related practices, including (1) self-assessment, (2) goal setting and action planning, (3) implementation, (4) education and training, and (5) reassessment	4 months	•Social Cognitive Theory •DESIGN[h] Procedure Framework •Theories of adult learning in public health practice •Behavior change techniques

XSL•FO
RenderX

eHealth tool	Country: References	Type of eHealth tool	eHealth modality[a]	Target of eHealth tool	eHealth tool component	eHealth tool description	Length of the intervention	Theoretical underpinning
GO NAPSACC Cares	United States: [66]	Assessment and intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices (center level) + educator's personal diet and physical activity	The traditional GO NAPSACC program and embedded Staff Wellness website that focus on ECE personal healthy behavior change strategies including healthy eating, increased physical activity, and weight management	6 months	•Social Cognitive Theory •The Social Ecological Model
HOPPEL[i]	Australia: [61,62]	Intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices	Synchronous and asynchronous online professional development to promote physical activity and healthy eating	12 weeks	•Community of Practice •The Guskey model of teacher change
Healthy Start-Départ Santé	Canada: [25]	Intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices	Online modules to improve healthy eating and physical activity practices	4 hours	NR
InfaNET	United States: [49]	Intervention	Web based	Nutrition	Infant feeding practices	Bilingual (English and Spanish) website with childcare-specific infant feeding information	3 months	•Social Learning Theory
Munch & Move	Australia: [53]	Intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices	Professional development training for early childhood educators to support healthy eating and physical activity habits in young children	NR	•The Monitoring Framework
OutsidePlay-ECE risk-reframing intervention	Canada: [46,47]	Intervention	Web based	Physical activity	Outdoor/risky play	Fully automated web-based intervention to reframe ECEs' perception of the importance of outdoor play and its inherent risks and promote a change in their practice in supporting children's outdoor play in ELCC[j] settings	Up to 100 minutes	•Intervention mapping process •Social Cognitive Theory
Online training on healthy beverage best practices	United States: [54]	Intervention	Web based	Nutrition	Healthy beverage practices	Self-paced online modules (English and Spanish) on healthy beverage best practices for childcare providers	English (29-minutes); Spanish (37-minutes)	NR

XSL•FO
RenderX

eHealth tool	Country: References	Type of eHealth tool	eHealth modality[a]	Target of eHealth tool	eHealth tool component	eHealth tool description	Length of the intervention	Theoretical underpinning
Online training on healthy beverage policy	United States: [60]	Intervention	Web based	Nutrition	Healthy beverage practices	Bilingual (English or Spanish) self-paced on-demand online training to increase knowledge and adherence of childcare providers to healthy beverage practices	30-minutes for the online training (+ with or without 6 months of online technical assistance)	•Implementation Science Framework •Humanistic Learning Theories
Online training to disseminate outdoor free-play information in relation to COVID-19 guidelines	Australia: [63]	Intervention	Web based	Physical activity	Outdoor/risky play	e-newsletter or animated video to increase ECEC service intentions to adopt an indoor-outdoor program for the full day and offer more time outdoors	e-newsletter (3 minutes); video (3.5 minutes)	•Model for Dissemination of Research •Interactive System Framework
SHAPES-D[k]	United States: [57,64]	Assessment and intervention	Web based	Physical activity	Physical activity practices	Self-assessment and online training modules to improve instructional physical activity practices and classroom social environment	12 weeks	NR
Tool to increase children's vegetable intake and reduce food neophobia	Norway: [43,44]	Intervention	Web based	Nutrition	Online menu planning and feeding practices	Access to online menu recipes to include vegetables each week, with or without pedagogical tools (sensory lessons, meal practice, and feeding practices recommendations)	3 months	NR
TEACH[l] e - learning course	Canada: [45]	Intervention	Web based	Physical activity	Physical activity and sedentary behavior	e-Learning course in physical activity and sedentary behavior comprising 4 modules	2 weeks	•Social Cognitive Theory •The Theory of Planned Behavior
WE PLAY[m]	United States: [19,55]	Intervention	Web based	Physical activity	Physical activity practices	Online asynchronous modules to promote physical activity	4 weeks	Social Cognitive Theory The Theory of Planned Behavior Quality Implementation Framework

XSL•FO
RenderX

eHealth tool	Country: References	Type of eHealth tool	eHealth modality[a]	Target of eHealth tool	eHealth tool component	eHealth tool description	Length of the intervention	Theoretical underpinning
Online training on healthy beverage policy	United States: [60]	Intervention	Web based	Nutrition	Healthy beverage practices	Bilingual (English or Spanish) self-paced on-demand online training to increase knowledge and adherence of childcare providers to healthy beverage practices	30 minutes for the online training (+ with or without 6 months of online technical assistance)	Implementation Science Framework Humanistic Learning Theories

[a]eHealth modality (eg, web, app, or SMS text messages).

[b]ECE: Early Care and Education.

[c]CHEERS: Creating Healthy Eating and Active Environments Survey.

[d]ECEC: early childhood education and care.

[e]EATS: Child Care Electronic Assessment Tool and Support.

[f]NR: not reported.

[g]NAPSACC: Nutrition and Physical Activity Self-Assessment for Child Care.

[h]DESIGN: decide target behavior, explore determinants, select theory-based model, indicate objectives, generate education plans, and nail down the evaluation.

[i]HOPPEL: Healthy Online Professional Program for Early Learner.

[j]ELCC: early learning childcare center.

[k]SHAPES-Dissemination: Study of Health and Activity in Preschool Environments.

[l]TEACH: Training Pre - Service Early Childhood Educators in Physical Activity.

[m]WE PLAY: Wellness Enhancing Physical Activity in Young Children.

XSL•FO
RenderX

Table 3. Characteristics of eHealth tools from included studies identified in the gray literature.

eHealth tool	Author/organization	Country: year	Participant information	Type of eHealth tool	eHealth modality[a]	Target of eHealth tool	eHealth tool description	Length of intervention
A Balanced Day: Tips and Guideline for Child Care Providers	Hastings Prince Edward Public Health	Canada: NR[b]	Childcare providers	Intervention	Web based	Physical activity	Online interactive modules (videos) on physical activity, sedentary behavior, sleep, and health messages for caregivers.	15 minutes
Boston Healthy Childcare Initiative	The Boston Public Health Commission	United States: NR	Early childhood educators	Intervention	Web based	Nutrition and physical Activity	Online training on evidence-based nutrition and physical activity best practices in early learning environments.	NR
Child Care Healthy Eating and Active Living Guidelines Training	Ottawa Public Health	Canada: 2015	Supervisors, childcare providers, and municipal cooks	Intervention	Web based	Nutrition and physical activity	Online training modules on healthy eating practices, environments, and physical literacy.	Part 1: Nutrition: 60 minutes; part 2: Active living: 30 minutes
Fostering Healthy Eating Habits	BC Provincial Health Services Authority—Interior Health	Canada: 2016	Childcare providers	Intervention	Web based	Nutrition	e-Learning course on healthy practices and environment.	1 hour
MyPlate on Alexa	United States Department of Agriculture	United States: 2020-2025	Everyone from parents and caregivers of babies starting at 4 months old through older adults (includes early learning professionals)	Intervention	App	Nutrition	An app that provides food and nutrition tips based on the Dietary Guidelines for Americans.	N/A[c]
Nourished and Active in Early Learning	University of Washington's Center for Public Health Nutrition and Washington State Department of Health	United States: NR	Early learning professionals	Intervention	Web based	Nutrition	Online course on healthy eating and beverages comprising 6 modules, strategies to support healthy eating, and common challenges.	NR
Nourishing Beginnings	Dairy Farmers of Canada	Canada: NR	ELCC[d] educators and directors as well as ELCC professors or program directors at colleges or universities.	Intervention	Web based	Nutrition	Online modules on healthy feeding practices	Module 1: 80 minutes; module 2: 70 minutes

[a]eHealth modality (eg, web, app, or SMS text messages).

[b]NR: not reported.

[c]N/A: not applicable.

[d]ELCC: early learning in childcare.

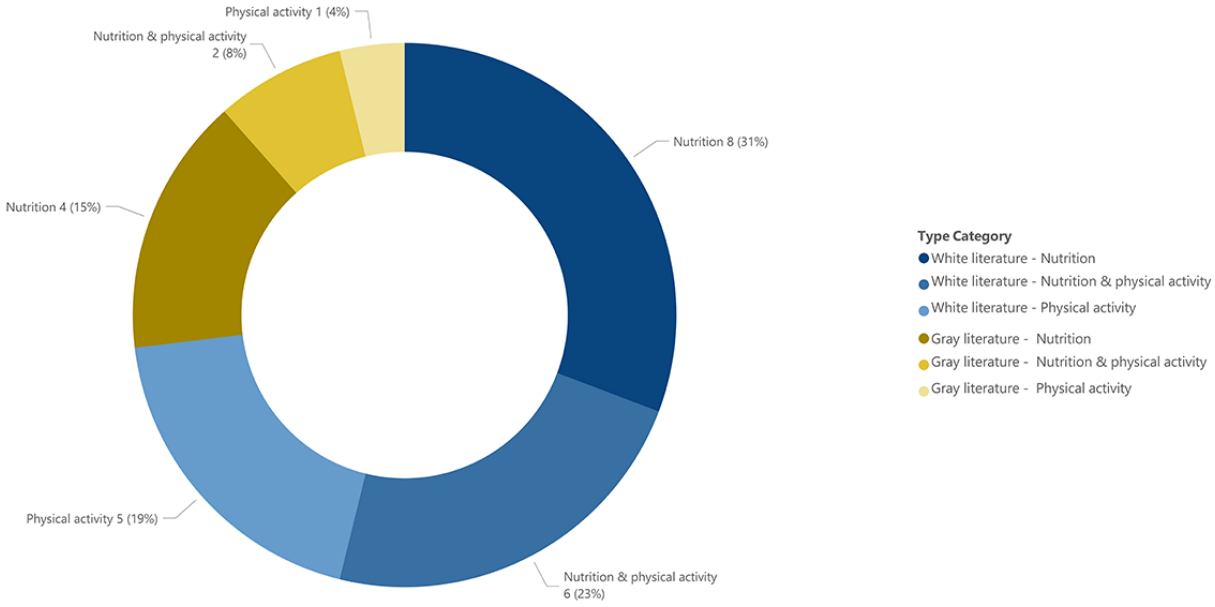
Practices Targeted

The majority of eHealth tools identified in the white literature (8/19, 42%) targeted nutrition practices, 6 of 19 (32%) targeted both nutrition and physical activity, and 5 of 19 (26%) exclusively addressed physical activity (Figure 4). The duration of intervention implementation ranged from 3 minutes to 12 months. The majority of eHealth tools identified in the gray

XSL•FO
RenderX

literature targeted nutrition (4/7, 57%), followed by tools targeting both nutrition and physical activity (2/7, 29%), and 1 focused solely on physical activity (Figure 4). For both the white (Table 2) and gray literature (Table 3), eHealth intervention tools targeting nutrition primarily addressed best nutrition and feeding practices, healthy eating or beverage practices, and menu planning. eHealth tools targeting physical activity mainly focused on best physical activity practices, outdoor play, and the reduction of sedentary behaviors.

Figure 4. Target of eHealth tool for white and grey literature.

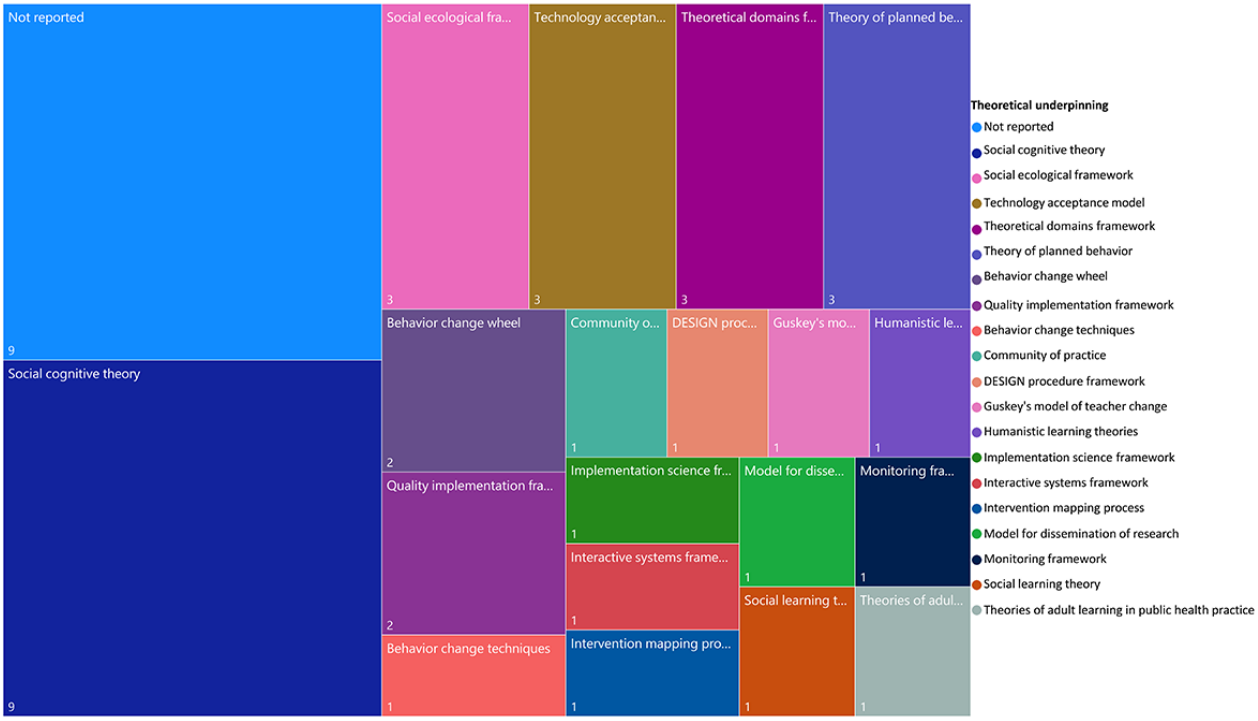


Theoretical Framework of the eHealth Tools

Of the 30 research studies identified in the white literature, 21 reported the use of theoretical models (Multimedia Appendix 4). The most commonly cited theories include Social Cognitive Theory, Social Ecological Model, Theoretical Domain Framework, Theory of Planned Behavior, Behavior Change Wheel, and Quality Implementation Framework (Figure 5). None of the eHealth tools identified in the gray literature reported a theoretical underpinning (see Multimedia Appendix 5).

XSL•FO
RenderX

Figure 5. Theoretical underpinning from studies identified in the white literature search. DESIGN: decide target behavior, explore determinants, select theory-based model, indicate objectives, generate education plans, and nail down the evaluation.



Discussion

Principal Findings

The purpose of this scoping review was to explore the available eHealth tools developed to assess or deliver interventions aimed at improving the nutrition or physical activity environments in ECEC settings. The results of this review provide insights into the digital tools available, outlining their methodological approach and characteristics.

Mapping the included white and gray literature identified 26 eHealth tools, highlighting a growing interest in leveraging digital tools to enhance nutrition and physical environments in early learning settings. Notably, all tools were web based except for 1 delivered via a smart device application. This finding is striking, given the widespread adoption of mobile health apps in health promotion interventions [69,70]. A likely explanation is that the nature and timing of the intervention may influence the choice of eHealth modality. Mobile apps are typically utilized in interventions requiring rapidly changing data and real-time feedback, such as step tracking or patient self-care and symptom management [71,72]. By contrast, interventions targeting nutrition and physical activity practices in educational settings often focus on gradual changes implemented over extended periods. Additionally, mobile apps are generally more expensive to develop and maintain than web-based tools and require regular updates [73]. Furthermore, most educational settings rely on web-based systems and have access to computers and the internet, making web-based platforms a more convenient option for educators while facilitating the implementation of interventions. Lastly, mobile-based interventions are often more prevalent among youth populations (children and adolescents) due to their capacity to incorporate gamification—a popular and engaging approach for health promotion interventions within this demographic [74].

The identified eHealth tools employed diverse approaches and strategies to enhance nutrition and physical activity practices. Most tools focused on professional development, offering online modules and self-paced training with both synchronous and asynchronous components to improve educators' knowledge and behaviors related to best practices in nutrition and physical activity. Most of these tools (21/26, 81%) included educational videos to create engaging and interactive content, while just over half (15/26, 58%) incorporated quizzes or evaluation questions to reinforce learning and assess understanding. Additionally, a smaller proportion (10/26, 38%) provided technical support from experts or facilitators to offer guidance and enhance educator engagement. Research suggests that such human support can improve compliance and foster the adoption of new behaviors [75,76]. However, relying on human support may not be a sustainable approach due to the significant resources required and the challenges it poses for scalability [77]. A smaller proportion of tools (3/26, 12%) emphasized menu planning and provided tailored support to aid in the creation of healthier menus. Tools targeting physical activity primarily addressed best practices, highlighted the importance of outdoor and risky play, and aimed to reduce sedentary behaviors. Nutrition-focused tools concentrated on promoting best practices for nutrition and feeding while optimizing eating environments.

Less than one-third (8/26, 31%) of the identified eHealth tools addressed both nutrition and physical activity together. Evidence suggests that multibehavior interventions, which target multiple health behaviors simultaneously, are often more effective in driving meaningful change compared with interventions focused

XSL•FO
RenderX

on a single behavior [78]. Given the interconnected nature of nutrition and physical activity, these behaviors play a crucial role in health and well-being [79,80] and are recognized as leading modifiable factors in the prevention of major chronic diseases [1,2]. Knowing that nutrition and physical activity tend to cluster together, addressing these behaviors collectively might enhance the effectiveness of interventions [11,81-84]. It has also been found that targeting both nutrition and physical activity behaviors can lead to synergistic effects on health outcomes [85-87]. Therefore, tools aimed at improving educators' nutrition and physical activity practices or the nutrition and physical activity environments in early learning centers should target determinants of both behaviors simultaneously.

Another key finding is that, among the 7 eHealth tools incorporating an assessment component, only 1 reported psychometric properties testing. Psychometric evaluations, such as reliability and validity testing, are crucial as they indicate the quality of the tools, ensure their effectiveness for the intended purpose, and support their reproducibility and replicability [88]. The lack of reported psychometric testing may be due to some tools originally being developed in a pen-and-paper format before being adapted to an online format. In the original articles describing the pen-and-paper versions, psychometric testing was reported [89]. However, it is important to recognize that tool validity and reliability are not static characteristics; rather, they are assessments of the tool's instrument scores within the context in which they have been evaluated [90]. It is therefore recommended to conduct and report updated psychometric testing when tools are adapted into digital formats to ensure that the validity and reliability of the results are maintained [91,92].

Among the 30 studies identified in the white literature, the majority (21/30, 70%) incorporated a theoretical framework in their design. The most frequently cited theory was the Social Cognitive Theory, which is commonly used in behavior change interventions, aligning with findings from other reviews [93-95]. A theoretical underpinning is a critical consideration when developing health promotion interventions. It serves as a blueprint for the study, structuring and guiding the intervention planning process, and also helps in understanding the factors that might influence behavior change and need to be targeted [96,97]. Previous reviews have indicated that health interventions grounded in theory are more effective [28] and are associated with positive significant outcomes, larger effect sizes [23,94,98], and the maintenance of behavior change [99]. Hence, future research designing eHealth tools should prioritize the use of theoretical underpinnings to increase effectiveness and ensure replicability. Regarding the gray literature findings, no reports on the theoretical underpinnings or reliability were identified for any of these tools. A possible reason for this could be that the gray literature often targets a general population audience, where the focus is on practical application, whereas in peer-reviewed literature, researchers look for evidence of theoretical grounding to evaluate and further refine or replicate these tools.

Implications/Recommendations

Future research involving the development and implementation of eHealth tools in ECEC settings should emphasize the integration of theoretical frameworks, consider comprehensive multibehavior intervention approaches, incorporate community perspectives in the development process, and prioritize long-term sustainability and scalability, with a focus on implementation and efficacy assessment. Theoretical frameworks provide essential guidance in identifying key determinants of behavior and mechanisms for promoting change. Incorporating theory can enhance the effectiveness of eHealth tools, ensure consistent implementation, and facilitate replicability across different contexts. Multipronged eHealth tools designed to target both nutrition and physical activity can lead to more beneficial outcomes, as these domains are interconnected. To enhance implementation and adoption, it is essential to involve a diverse range of stakeholders, such as educators, parents, and health professionals, in the development process. This ensures that the unique needs and cultural context of the targeted eHealth tool users are addressed. Additionally, researchers should prioritize long-term sustainability and scalability when designing these tools, ensuring that interventions can be maintained and expanded across various settings over time. Finally, the resulting eHealth tools should undergo rigorous testing, including pilot trials, to assess their usability, feasibility, and effectiveness in achieving the intended outcomes. This integrated approach provides a holistic strategy for fostering healthier environments in ECEC settings.

Strengths and Limitations

This review is the first to map and summarize the scope of available evidence on eHealth tools designed to assess or improve nutrition and physical activity environments in early learning settings. The findings from this review can guide future research on the use of eHealth technologies to promote healthy practices in childcare, ultimately contributing to improved children's health behaviors and outcomes. Two librarians with expertise in scoping and systematic reviews assisted in developing and refining the search strategy. The methodology employed facilitated a systematic search of both white and gray literature, ensuring a comprehensive review of available evidence. However, there are some limitations to this scoping review that should be considered. We only considered studies published in English or French, which may have led to the exclusion of relevant research in other languages. Additionally, this scoping review focused solely on full-time day care centers, excluding family-based day care and after-school programs. The primary reason for excluding family-based day cares was the lack of formalized data, and after-school programs were not included as they typically do not cater to children aged 0-5 years. Another limitation encountered during the search for gray literature was the presence of paywalls and restricted access to certain tools, which hindered our ability to fully explore available resources.

Conclusions

This scoping review explored the breadth of evidence on eHealth tools aimed at improving nutrition and physical activity environments in ECEC settings. Future research should conduct

XSL•FO
RenderX

a systematic review to assess the effectiveness of these tools and identify the specific elements that contribute to a greater impact and sustained behavior change.

Acknowledgments

This study was funded by the Government of Alberta, Children Services (ACS565189). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the paper. The authors acknowledge and thank the research librarians at the University of Calgary and Erik Christiansen at Mount Royal University for their expert advice in developing and refining the search strategy.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews checklist.
[PDF File (Adobe PDF File), 258 KB - pediatrics_v8i1e68372_app1.pdf]

Multimedia Appendix 2
Search strategy for the databases (PubMed, Scopus, CINHAL Plus [EBSCOhost], ERIC [EBSCOhost], Embase [OVID]).
[PDF File (Adobe PDF File), 94 KB - pediatrics_v8i1e68372_app2.pdf]

Multimedia Appendix 3
Data extraction forms for white and gray literature.
[PDF File (Adobe PDF File), 73 KB - pediatrics_v8i1e68372_app3.pdf]

Multimedia Appendix 4
Extraction sheet results for white literature.
[XLSX File (Microsoft Excel File), 66 KB - pediatrics_v8i1e68372_app4.xlsx]

Multimedia Appendix 5
Extraction sheet results for gray literature.
[XLSX File (Microsoft Excel File), 32 KB - pediatrics_v8i1e68372_app5.xlsx]

References

1. Jayedi A, Soltani S, Abdolshahi A, Shab-Bidar S. Healthy and unhealthy dietary patterns and the risk of chronic disease: an umbrella review of meta-analyses of prospective cohort studies. Br J Nutr 2020 Dec 14;124(11):1133-1144. [doi: 10.1017/S0007114520002330] [Medline: 32600500]
2. Brawner CA, Churilla JR, Keteyian SJ. Prevalence of physical activity is lower among individuals with chronic disease. Med Sci Sports Exerc 2016 Jun;48(6):1062-1067. [doi: 10.1249/MSS.0000000000000861] [Medline: 26741117]
3. Kesäniemi A, Riddoch CJ, Reeder B, Blair SN, Sørensen TI. Advancing the future of physical activity guidelines in Canada: an independent expert panel interpretation of the evidence. Int J Behav Nutr Phys Act 2010 May 11;7:41 [FREE Full text] [doi: 10.1186/1479-5868-7-41] [Medline: 20459785]
4. Swinburn BA, Caterson I, Seidell JC, James WPT. Diet, nutrition and the prevention of excess weight gain and obesity. Public Health Nutr 2004 Feb;7(1A):123-146 [FREE Full text] [doi: 10.1079/phn2003585] [Medline: 14972057]
5. Lee A, Cardel M, Donahoo WT. Social and environmental factors influencing obesity. In: Feingold KR, Anawalt B, Blackman MR, editors. Endotext. South Dartmouth, MA: MDText.com, Inc; 2000.
6. Hajat C, Stein E. The global burden of multiple chronic conditions: a narrative review. Prev Med Rep 2018 Dec;12:284-293 [FREE Full text] [doi: 10.1016/j.pmedr.2018.10.008] [Medline: 30406006]
7. Hadian M, Mozafari MR, Mazaheri E, Jabbari A. Challenges of the health system in preventing non-communicable diseases; systematized review. Int J Prev Med 2021;12:71 [FREE Full text] [doi: 10.4103/ijpvm.IJPVM_487_20] [Medline: 34447513]
8. Olsen A, Møller P, Hausner H. Early origins of overeating: early habit formation and implications for obesity in later life. Curr Obes Rep 2013 Jan 13;2(2):157-164. [doi: 10.1007/s13679-012-0046-3]
9. Budreviciute A, Damiati S, Sabir DK, Onder K, Schuller-Goetzburg P, Plakys G, et al. Management and prevention strategies for non-communicable diseases (NCDs) and their risk factors. Front Public Health 2020;8:574111 [FREE Full text] [doi: 10.3389/fpubh.2020.574111] [Medline: 33324597]

XSL•FO
RenderX

10. Gubbels JS, Kremers SP, Stafleu A, Dagnelie PC, de Vries SI, de Vries NK, et al. Clustering of dietary intake and sedentary behavior in 2-year-old children. J Pediatr 2009 Aug;155(2):194-198. [doi: 10.1016/j.jpeds.2009.02.027] [Medline: 19394036]
11. Alosaimi N, Sherar LB, Griffiths P, Pearson N. Clustering of diet, physical activity and sedentary behaviour and related physical and mental health outcomes: a systematic review. BMC Public Health 2023 Aug 18;23(1):1572 [FREE Full text] [doi: 10.1186/s12889-023-16372-6] [Medline: 37596591]
12. Larson N, Ward DS, Neelon SB, Story M. What role can child-care settings play in obesity prevention? A review of the evidence and call for research efforts. J Am Diet Assoc 2011 Sep;111(9):1343-1362. [doi: 10.1016/j.jada.2011.06.007] [Medline: 21872698]
13. Halfon N, Hochstein M. Life course health development: an integrated framework for developing health, policy, and research. Milbank Q 2002;80(3):433-79, iii [FREE Full text] [doi: 10.1111/1468-0009.00019] [Medline: 12233246]
14. Mazarello Paes V, Ong KK, Lakshman R. Factors influencing obesogenic dietary intake in young children (0-6 years): systematic review of qualitative evidence. BMJ Open 2015 Sep 16;5(9):e007396 [FREE Full text] [doi: 10.1136/bmjopen-2014-007396] [Medline: 26377503]
15. Nicklas TA, Baranowski T, Baranowski JC, Cullen K, Rittenberry L, Olvera N. Family and child-care provider influences on preschool children's fruit, juice, and vegetable consumption. Nutr Rev 2001 Jul;59(7):224-235. [doi: 10.1111/j.1753-4887.2001.tb07014.x] [Medline: 11475448]
16. Brown WH, Googe HS, McIver KL, Rathel JM. Effects of teacher-encouraged physical activity on preschool playgrounds. Journal of Early Intervention 2009 Feb 09;31(2):126-145. [doi: 10.1177/1053815109331858]
17. Bell LK, Golley RK. Interventions for improving young children's dietary intake through early childhood settings: a systematic review. Int J Child Health Nutr 2015 Feb 27;4(1):14-32. [doi: 10.6000/1929-4247.2015.04.01.2]
18. Hendy H, Raudenbush B. Effectiveness of teacher modeling to encourage food acceptance in preschool children. Appetite 2000 Feb;34(1):61-76. [doi: 10.1006/appe.1999.0286] [Medline: 10744893]
19. Hoffman J, Schmidt E, Arguello D, Eyllon M, Castaneda-Sceppa C, Cloutier G, et al. Online preschool teacher training to promote physical activity in young children: a pilot cluster randomized controlled trial. Sch Psychol 2020 Mar;35(2):118-127. [doi: 10.1037/spq0000349] [Medline: 31916788]
20. Pate RR, Brown WH, Pfeiffer KA, Howie EK, Saunders RP, Addy CL, et al. An intervention to increase physical activity in children: a randomized controlled trial with 4-year-olds in preschools. Am J Prev Med 2016 Jul;51(1):12-22 [FREE Full text] [doi: 10.1016/j.amepre.2015.12.003] [Medline: 26803357]
21. Borrelli B, Ritterband LM. Special issue on eHealth and mHealth: challenges and future directions for assessment, treatment, and dissemination. Health Psychol 2015 Dec;34S:1205-1208. [doi: 10.1037/hea0000323] [Medline: 26651461]
22. da Fonseca MH, Kovaleski F, Picinin CT, Pedroso B, Rubbo P. E-health practices and technologies: a systematic review from 2014 to 2019. Healthcare (Basel) 2021 Sep 10;9(9):1192 [FREE Full text] [doi: 10.3390/healthcare9091192] [Medline: 34574966]
23. Vandelanotte C, Müller AM, Short CE, Hingle M, Nathan N, Williams SL, et al. Past, present, and future of eHealth and mHealth research to improve physical activity and dietary behaviors. J Nutr Educ Behav 2016 Mar;48(3):219-228.e1. [doi: 10.1016/j.jneb.2015.12.006] [Medline: 26965100]
24. Oenema A, Brug J, Lechner L. Web-based tailored nutrition education: results of a randomized controlled trial. Health Educ Res 2001 Dec;16(6):647-660. [doi: 10.1093/her/16.6.647] [Medline: 11780705]
25. Ward S, Bélanger M, Leis A. Comparison between the Healthy Start-Départ Santé online and in-person training of childcare educators to improve healthy eating and physical activity practices and knowledge of physical activity and fundamental movement skills: a controlled trial. Prev Med Rep 2020 Dec;20:101264 [FREE Full text] [doi: 10.1016/j.pmedr.2020.101264] [Medline: 33354492]
26. West M, Dooyema C, Smith FT, Willis EA, Clarke E, Shira Starr A, et al. Multi-state implementation of Go NAPSACC to support healthy practices in the early care and education setting. Health Promot Pract 2023 May;24(1_suppl):145S-151S [FREE Full text] [doi: 10.1177/15248399221118890] [Medline: 36999493]
27. Barnes C, Yoong SL, Nathan N, Wolfenden L, Wedesweiler T, Kerr J, et al. Feasibility of a web-based implementation intervention to improve child dietary intake in early childhood education and care: pilot randomized controlled trial. J Med Internet Res 2021 Dec 15;23(12):e25902 [FREE Full text] [doi: 10.2196/25902] [Medline: 34914617]
28. Glanz K, Bishop DB. The role of behavioral science theory in development and implementation of public health interventions. Annu Rev Public Health 2010 Mar;31:399-418. [doi: 10.1146/annurev.publhealth.012809.103604] [Medline: 20070207]
29. Webb TL, Joseph J, Yardley L, Michie S. Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. J Med Internet Res 2010 Feb 17;12(1):e4 [FREE Full text] [doi: 10.2196/jmir.1376] [Medline: 20164043]
30. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013 Aug;46(1):81-95 [FREE Full text] [doi: 10.1007/s12160-013-9486-6] [Medline: 23512568]

XSL•FO
RenderX

31. Alkon A, Crowley AA, Neelon SEB, Hill S, Pan Y, Nguyen V, et al. Nutrition and physical activity randomized control trial in child care centers improves knowledge, policies, and children's body mass index. BMC Public Health 2014 Mar 01;14(1):215 [FREE Full text] [doi: 10.1186/1471-2458-14-215] [Medline: 24580983]
32. Jones J, Wolfenden L, Wyse R, Finch M, Yoong SL, Dodds P, et al. A randomised controlled trial of an intervention to facilitate the implementation of healthy eating and physical activity policies and practices in childcare services. BMJ Open 2014 Apr 17;4(4):e005312 [FREE Full text] [doi: 10.1136/bmjopen-2014-005312] [Medline: 24742978]
33. Kracht CL, Hutchesson M, Ahmed M, Müller AM, Ashton LM, Brown HM, et al. Obes Rev 2021 Dec;22(12):e13331 [FREE Full text] [doi: 10.1111/obr.13331] [Medline: 34476890]
34. Luybli M, Schmillen H, Sotos-Prieto M. School-based interventions in low socioeconomic settings to reduce obesity outcomes among preschoolers: a scoping review. Nutrients 2019 Jul 04;11(7):1518 [FREE Full text] [doi: 10.3390/nu11071518] [Medline: 31277426]
35. van de Kolk I, Verjans-Janssen SRB, Gubbels JS, Kremers SPJ, Gerards SMPL. Systematic review of interventions in the childcare setting with direct parental involvement: effectiveness on child weight status and energy balance-related behaviours. Int J Behav Nutr Phys Act 2019 Nov 21;16(1):110 [FREE Full text] [doi: 10.1186/s12966-019-0874-6] [Medline: 31752917]
36. Vorage L, Vincze L, Tudehope L, Harris N. Effectiveness of interventions promoting dietary intake, physical activity, and healthy weight status of children in family child care: a systematic review. J Nutr Educ Behav 2024 Apr;56(4):242-255 [FREE Full text] [doi: 10.1016/j.jneb.2023.12.011] [Medline: 38340129]
37. Yoong SL, Lum M, Jones J, Kerr E, Falkiner M, Delaney T, et al. A systematic review of interventions to improve the dietary intake, physical activity and weight status of children attending family day care services. Public Health Nutr 2020 Aug;23(12):2211-2220 [FREE Full text] [doi: 10.1017/S1368980019005275] [Medline: 32383429]
38. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. BMC Med Res Methodol 2018 Nov 19;18(1):143 [FREE Full text] [doi: 10.1186/s12874-018-0611-x] [Medline: 30453902]
39. Peters MDJ, Godfrey CM, Khalil H, McInerney P, Parker D, Soares CB. Guidance for conducting systematic scoping reviews. Int J Evid Based Healthc 2015 Sep;13(3):141-146. [doi: 10.1097/XEB.0000000000000050] [Medline: 26134548]
40. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med 2018 Oct 02;169(7):467-473. [doi: 10.7326/M18-0850] [Medline: 30178033]
41. Hayek J, Elliot K, Vermette M, Lafave L. eHealth tools supporting early childhood education and care centers to assess and enhance nutrition and physical activity environments: a scoping review protocol. OSF Registries. 2023 May 05. URL: https://osf.io/xtrnz [accessed 2023-08-19]
42. Barnes C, Grady A, Nathan N, Wolfenden L, Pond N, McFayden T, et al. A pilot randomised controlled trial of a web-based implementation intervention to increase child intake of fruit and vegetables within childcare centres. Pilot Feasibility Stud 2020 Oct 29;6(1):163 [FREE Full text] [doi: 10.1186/s40814-020-00707-w] [Medline: 33292720]
43. Blomkvist EAM, Helland SH, Hillesund ER, Øverby NC. A cluster randomized web-based intervention trial to reduce food neophobia and promote healthy diets among one-year-old children in kindergarten: study protocol. BMC Pediatr 2018 Jul 14;18(1):232 [FREE Full text] [doi: 10.1186/s12887-018-1206-8] [Medline: 30007401]
44. Blomkvist EAM, Wills AK, Helland SH, Hillesund ER, Øverby NC. Effectiveness of a kindergarten-based intervention to increase vegetable intake and reduce food neophobia amongst 1-year-old children: a cluster randomised controlled trial. Food Nutr Res 2021;65 [FREE Full text] [doi: 10.29219/fnr.v65.7679] [Medline: 34776826]
45. Bruijns BA, Vanderloo LM, Johnson AM, Adamo KB, Burke SM, Carson V, et al. Change in pre- and in-service early childhood educators' knowledge, self-efficacy, and intentions following an e-learning course in physical activity and sedentary behaviour: a pilot study. BMC Public Health 2022 Feb 07;22(1):244 [FREE Full text] [doi: 10.1186/s12889-022-12591-5] [Medline: 35125100]
46. Brussoni M, Han CS, Jacob J, Munday F, Zeni M, Walters M, et al. A web-based risk-reframing intervention to influence early childhood educators' attitudes and supportive behaviors toward outdoor play: protocol for the OutsidePlay study randomized controlled trial. JMIR Res Protoc 2021 Nov 18;10(11):e31041 [FREE Full text] [doi: 10.2196/31041] [Medline: 34792479]
47. Brussoni M, Han CS, Lin Y, Jacob J, Munday F, Zeni M, et al. Evaluation of the web-based OutsidePlay-ECE intervention to influence early childhood educators' attitudes and supportive behaviors toward outdoor play: randomized controlled trial. J Med Internet Res 2022 Jun 10;24(6):e36826 [FREE Full text] [doi: 10.2196/36826] [Medline: 35687394]
48. Chuang RJ, Cox JN, Mincemoyer CC, Sharma SV. A pilot randomized controlled trial of a nutrition and dietary intervention for early care and education providers. J Sch Health 2020 Nov;90(11):859-868. [doi: 10.1111/josh.12951] [Medline: 32959370]
49. Clark A, Anderson J, Adams E, Baker S, Barrett K. Assessing an infant feeding web site as a nutrition education tool for child care providers. J Nutr Educ Behav 2009 Jan;41(1):41-46. [doi: 10.1016/j.jneb.2007.12.007] [Medline: 19161919]
50. Clarke E, Smith FT, Willis EA, Herr M, Ward DS. Go NAPSACC on-demand trainings for early care and education providers: development and dissemination. J Nutr Educ Behav 2023 Jan;55(1):48-54. [doi: 10.1016/j.jneb.2022.07.001] [Medline: 36195540]

XSL•FO
RenderX

51. Grady A, Wolfenden L, Rissel C, Green S, Reilly K, Yoong SL. Effectiveness of a dissemination strategy on the uptake of an online menu planning program: a controlled trial. Health Promot J Austr 2019 Dec;30 Suppl 1:20-25. [doi: 10.1002/hpja.220] [Medline: 30417473]
52. Grady A, Wolfenden L, Wiggers J, Rissel C, Finch M, Flood V, et al. Effectiveness of a web-based menu-planning intervention to improve childcare service compliance with dietary guidelines: randomized controlled trial. J Med Internet Res 2020 Feb 04;22(2):e13401 [FREE Full text] [doi: 10.2196/13401] [Medline: 32014843]
53. Green AM, Mihrshahi S, Innes-Hughes C, O'Hara BJ, McGill B, Rissel C. Implementation of an early childhood healthy eating and physical activity program in New South Wales, Australia. Front Public Health 2020;8:34 [FREE Full text] [doi: 10.3389/fpubh.2020.00034] [Medline: 32154206]
54. Hazard K, Lee D, Ritchie L, Rose R, Rios LKD, Plank K, et al. Development of an online curriculum for California early care and education providers on healthy beverages. BMC Public Health 2021 Jul 13;21(1):1387 [FREE Full text] [doi: 10.1186/s12889-021-11428-x] [Medline: 34256720]
55. Hoffman JA, Schmidt EM, Castaneda-Sceppa C, Hillman CH. The theoretical foundation, fidelity, feasibility, and acceptability of a teacher training to promote physical activity among preschoolers in child care: a pilot study. Prev Med Rep 2019 Mar;13:214-217 [FREE Full text] [doi: 10.1016/j.pmedr.2019.01.003] [Medline: 30705808]
56. Kempler JV, Love P, Bolton KA, Rozman M, Spence AC. Exploring the use of a web-based menu planning tool in childcare services: qualitative cross-sectional survey study. JMIR Form Res 2022 Jul 18;6(7):e35553 [FREE Full text] [doi: 10.2196/35553] [Medline: 35849438]
57. Kennedy AB, Schenkelberg M, Moyer C, Pate R, Saunders RP. Process evaluation of a preschool physical activity intervention using web-based delivery. Eval Program Plann 2017 Feb;60:24-36. [doi: 10.1016/j.evalprogplan.2016.08.022] [Medline: 27669393]
58. Lafave LMZ. Is the online 'creating healthy eating and active environments survey' (CHEERS) tool reliable for early childhood educators in Alberta, Canada: a randomized crossover trial. Arch Public Health 2023 Feb 13;81(1):22 [FREE Full text] [doi: 10.1186/s13690-023-01036-z] [Medline: 36782334]
59. Lafave L, Hayek J, Webster A, McConnell C. Creating healthy eating and active environments in early learning settings: protocol of the CHEERS eHealth intervention study. Front Nutr 2024;11:1337873 [FREE Full text] [doi: 10.3389/fnut.2024.1337873] [Medline: 38481971]
60. Lee DL, Alkon A, Plank K, Neelon M, Díaz Rios LK, Hecht CE, et al. Self-paced online training on healthy beverage policy for child care providers. J Nutr Educ Behav 2021 Jun;53(6):457-470. [doi: 10.1016/j.jneb.2021.02.007] [Medline: 34116741]
61. Peden M, Eady M, Okely A, Jones R. Thinking beyond the norm: using alternate theories in early childhood education and care physical activity interventions. Journal of Research in Childhood Education 2020 Sep 06;35(4):642-650. [doi: 10.1080/02568543.2020.1810835]
62. Me P, Mj E, Ad O, Ra J. A blended professional learning intervention for early childhood educators to target the promotion of physical activity and healthy eating: the HOPPEL cluster randomized stepped-wedge trial. BMC Public Health 2022 Jul 15;22(1):1353 [FREE Full text] [doi: 10.1186/s12889-022-13542-w] [Medline: 35841084]
63. Reilly K, Jackson J, Lum M, Pearson N, Lecathelinais C, Wolfenden L, et al. The impact of an e-newsletter or animated video to disseminate outdoor free-play information in relation to COVID-19 guidelines in New South Wales early childhood education and care services: a randomised controlled trial. BMC Public Health 2023 Jul 07;23(1):1306 [FREE Full text] [doi: 10.1186/s12889-023-16177-7] [Medline: 37420179]
64. Saunders R, Schenkelberg M, Moyer C, Howie E, Brown W, Pate R. The translation of an evidence-based preschool physical activity intervention from in-person to online delivery of professional development to preschool teachers. Transl Behav Med 2019 Nov 25;9(6):1186-1196 [FREE Full text] [doi: 10.1093/tbm/ibz076] [Medline: 31116392]
65. Ward DS, Vaughn AE, Mazzucca S, Burney R. Translating a child care based intervention for online delivery: development and randomized pilot study of Go NAPSACC. BMC Public Health 2017 Nov 21;17(1):891 [FREE Full text] [doi: 10.1186/s12889-017-4898-z] [Medline: 29162057]
66. Willis E, Burney R, Hales D, Ilugbusi L, Tate D, Nezami B, et al. "My wellbeing-their wellbeing" - an eHealth intervention for managing obesity in early care and education: protocol for the Go NAPSACC Cares cluster randomized control trial. PLoS One 2023;18(7):e0286912 [FREE Full text] [doi: 10.1371/journal.pone.0286912] [Medline: 37418363]
67. Yoong SL, Grady A, Wiggers J, Flood V, Rissel C, Finch M, et al. A randomised controlled trial of an online menu planning intervention to improve childcare service adherence to dietary guidelines: a study protocol. BMJ Open 2017 Sep 11;7(9):e017498 [FREE Full text] [doi: 10.1136/bmjopen-2017-017498] [Medline: 28893755]
68. Yoong SL, Grady A, Wiggers JH, Stacey FG, Rissel C, Flood V, et al. Child-level evaluation of a web-based intervention to improve dietary guideline implementation in childcare centers: a cluster-randomized controlled trial. Am J Clin Nutr 2020 Apr 01;111(4):854-863 [FREE Full text] [doi: 10.1093/ajcn/nqaa025] [Medline: 32091593]
69. Tonkin E, Brimblecombe J, Wycherley TP. Characteristics of smartphone applications for nutrition improvement in community settings: a scoping review. Adv Nutr 2017 Mar;8(2):308-322 [FREE Full text] [doi: 10.3945/an.116.013748] [Medline: 28298274]

XSL•FO
RenderX

70. Aromatario O, Van Hoye A, Vuillemin A, Foucaut AM, Crozet C, Pommier J, et al. How do mobile health applications support behaviour changes? A scoping review of mobile health applications relating to physical activity and eating behaviours. Public Health 2019 Oct;175:8-18 [FREE Full text] [doi: 10.1016/j.puhe.2019.06.011] [Medline: 31374453]
71. Lee M, Lee H, Kim Y, Kim J, Cho M, Jang J, et al. Mobile app-based health promotion programs: a systematic review of the literature. Int J Environ Res Public Health 2018 Dec 13;15(12):2838 [FREE Full text] [doi: 10.3390/ijerph15122838] [Medline: 30551555]
72. Al-Nawaiseh HK, McIntosh WA, McKyer LJ. An-m-health intervention using smartphone app to improve physical activity in college students: a randomized controlled trial. Int J Environ Res Public Health 2022 Jun 13;19(12):7228 [FREE Full text] [doi: 10.3390/ijerph19127228] [Medline: 35742477]
73. Holzer A, Ondrus J. Mobile application market: A developer's perspective. Telematics and Informatics 2011 Feb;28(1):22-31. [doi: 10.1016/j.tele.2010.05.006]
74. Gkintoni E, Vantaraki F, Skoulidi C, Anastassopoulos P, Vantarakis A. Promoting physical and mental health among children and adolescents via gamification—a conceptual systematic review. Behav Sci (Basel) 2024 Jan 29;14(2):102 [FREE Full text] [doi: 10.3390/bs14020102] [Medline: 38392455]
75. Mohr DC, Cuijpers P, Lehman K. Supportive accountability: a model for providing human support to enhance adherence to eHealth interventions. J Med Internet Res 2011 Mar 10;13(1):e30 [FREE Full text] [doi: 10.2196/jmir.1602] [Medline: 21393123]
76. Fortuna KL, Brooks JM, Umucu E, Walker R, Chow PI. Peer support: a human factor to enhance engagement in digital health behavior change interventions. J Technol Behav Sci 2019 Jun 15;4(2):152-161 [FREE Full text] [doi: 10.1007/s41347-019-00105-x] [Medline: 34337145]
77. Mohr DC, Burns MN, Schueller SM, Clarke G, Klinkman M. Behavioral intervention technologies: evidence review and recommendations for future research in mental health. Gen Hosp Psychiatry 2013 Jul;35(4):332-338 [FREE Full text] [doi: 10.1016/j.genhosppsych.2013.03.008] [Medline: 23664503]
78. Prochaska JJ, Prochaska JO. A review of multiple health behavior change interventions for primary prevention. Am J Lifestyle Med 2011 May;5(3):10.1177/1559827610391883 [FREE Full text] [doi: 10.1177/1559827610391883] [Medline: 24358034]
79. Gillman MW, Pinto BM, Tennstedt S, Glanz K, Marcus B, Friedman RH. Relationships of physical activity with dietary behaviors among adults. Prev Med 2001 Mar;32(3):295-301. [doi: 10.1006/pmed.2000.0812] [Medline: 11277687]
80. Jakicic JM, Wing RR, Winters-Hart C. Relationship of physical activity to eating behaviors and weight loss in women. Med Sci Sports Exerc 2002 Oct;34(10):1653-1659. [doi: 10.1097/00005768-200210000-00018] [Medline: 12370568]
81. Mello GTD, Lopes MVV, Minatto G, Costa RMD, Matias TS, Guerra PH, et al. Clustering of physical activity, diet and sedentary behavior among youth from low-, middle-, and high-income countries: a scoping review. Int J Environ Res Public Health 2021 Oct 17;18(20):10924 [FREE Full text] [doi: 10.3390/ijerph182010924] [Medline: 34682670]
82. Leech RM, McNaughton SA, Timperio A. The clustering of diet, physical activity and sedentary behavior in children and adolescents: a review. Int J Behav Nutr Phys Act 2014 Jan 22;11:4 [FREE Full text] [doi: 10.1186/1479-5868-11-4] [Medline: 24450617]
83. Evers KE, Quintiliani LM. Advances in multiple health behavior change research. Transl Behav Med 2013 Mar;3(1):59-61 [FREE Full text] [doi: 10.1007/s13142-013-0198-z] [Medline: 24073161]
84. Laska MN, Lytle LA, Nanney MS, Moe SG, Linde JA, Hannan PJ. Results of a 2-year randomized, controlled obesity prevention trial: effects on diet, activity and sleep behaviors in an at-risk young adult population. Prev Med 2016 Aug;89:230-236 [FREE Full text] [doi: 10.1016/j.ypmed.2016.06.001] [Medline: 27283096]
85. Kim J, Hong Y, Baek S, Lee KP, Ahn S. The synergistic effect of physical activity and nutrition to improve the quality of life in breast cancer patients: a systemic review. Phys Act Nutr 2022 Dec;26(4):22-31 [FREE Full text] [doi: 10.20463/pan.2022.0021] [Medline: 36775648]
86. Elliot CA, Hamlin MJ. Combined diet and physical activity is better than diet or physical activity alone at improving health outcomes for patients in New Zealand's primary care intervention. BMC Public Health 2018 Feb 08;18(1):230 [FREE Full text] [doi: 10.1186/s12889-018-5152-z] [Medline: 29422040]
87. Södlerlund A, Fischer A, Johansson T. Physical activity, diet and behaviour modification in the treatment of overweight and obese adults: a systematic review. Perspect Public Health 2009 May;129(3):132-142. [doi: 10.1177/1757913908094805] [Medline: 19514637]
88. Souza ACD, Alexandre NMC, Guirardello EDB. Psychometric properties in instruments evaluation of reliability and validity. Epidemiol Serv Saude 2017;26(3):649-659 [FREE Full text] [doi: 10.5123/S1679-49742017000300022] [Medline: 28977189]
89. Benjamin SE, Neelon B, Ball SC, Bangdiwala SI, Ammerman AS, Ward DS. Reliability and validity of a nutrition and physical activity environmental self-assessment for child care. Int J Behav Nutr Phys Act 2007 Jul 05;4:29 [FREE Full text] [doi: 10.1186/1479-5868-4-29] [Medline: 17615078]
90. Zumbo BD, Chan EKH. Chapter 1: Setting the stage for validity and validation in social, behavioral, and health sciences: trends in validation practices. In: Zumbo BD, Chan EKH, editors. Validity and Validation in Social, Behavioral, and Health Sciences. Cham, Switzerland: Springer International Publishing AG; 2014:3-8.

XSL•FO
RenderX

91. Dima A. Scale validation in applied health research: tutorial for a 6-step R-based psychometrics protocol. Health Psychol Behav Med 2018 May 10;6(1):136-161 [FREE Full text] [doi: 10.1080/21642850.2018.1472602] [Medline: 34040826]
92. Du Y. A streamlined approach to scale adaptation: enhancing validity and feasibility in educational measurement. Journal of Language Teaching 2024 Sep 13;4(3):18-22. [doi: 10.54475/jlt.2024.017]
93. Rodriguez Rocha NP, Kim H. eHealth interventions for fruit and vegetable intake: a meta-analysis of effectiveness. Health Educ Behav 2019 Dec;46(6):947-959. [doi: 10.1177/1090198119859396] [Medline: 31347403]
94. Prowse R, Carsley S. Digital interventions to promote healthy eating in children: umbrella review. JMIR Pediatr Parent 2021 Nov 25;4(4):e30160 [FREE Full text] [doi: 10.2196/30160] [Medline: 34842561]
95. Painter J, Borba C, Hynes M, Mays D, Glanz K. The use of theory in health behavior research from 2000 to 2005: a systematic review. Ann Behav Med 2008 Jun;35(3):358-362. [doi: 10.1007/s12160-008-9042-y] [Medline: 18633685]
96. Davis R, Campbell R, Hildon Z, Hobbs L, Michie S. Theories of behaviour and behaviour change across the social and behavioural sciences: a scoping review. Health Psychol Rev 2015;9(3):323-344 [FREE Full text] [doi: 10.1080/17437199.2014.941722] [Medline: 25104107]
97. Bartholomew LK, Parcel GS, Kok G. Intervention mapping: a process for developing theory- and evidence-based health education programs. Health Educ Behav 1998 Oct;25(5):545-563. [doi: 10.1177/109019819802500502] [Medline: 9768376]
98. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, Medical Research Council Guidance. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008 Sep 29;337(sep29 1):a1655-a1655 [FREE Full text] [doi: 10.1136/bmj.a1655] [Medline: 18824488]
99. Joseph RP, Daniel CL, Thind H, Benitez TJ, Pekmezi D. Applying psychological theories to promote long-term maintenance of health behaviors. Am J Lifestyle Med 2016 Nov;10(6):356-368 [FREE Full text] [doi: 10.1177/1559827614554594] [Medline: 28217036]
100. Godin K, Stapleton J, Kirkpatrick SI, Hanning RM, Leatherdale ST. Applying systematic review search methods to the grey literature: a case study examining guidelines for school-based breakfast programs in Canada. Syst Rev 2015 Oct 22;4:138 [FREE Full text] [doi: 10.1186/s13643-015-0125-0] [Medline: 26494010]

Abbreviations

ECEC: early childhood education and care
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews

Edited by S Badawy; submitted 05.11.24; peer-reviewed by P Love; comments to author 04.12.24; revised version received 16.12.24; accepted 23.12.24; published 22.01.25.

Please cite as:
Hayek J, Dickson K, Lafave LMZ
Assessing and Enhancing Nutrition and Physical Activity Environments in Early Childhood Education and Care Centers: Scoping Review of eHealth Tools
JMIR Pediatr Parent 2025;8:e68372
URL: https://pediatrics.jmir.org/2025/1/e68372
doi:10.2196/68372
PMID:

©Joyce Hayek, Kelsi Dickson, Lynne M Z Lafave. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 22.01.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Review

Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review

Neda Barbazi[1], MArch; Ji Youn Shin[1], PhD; Gurumurthy Hiremath[2], MD; Carlye Anne Lauff[1], PhD

[1]Department of Design Innovation, College of Design, University of Minnesota, Twin Cities, Minneapolis, MN, United States

[2]Division of Pediatric Cardiology, Department of Pediatrics, Medical School, University of Minnesota, Twin Cities, Minneapolis, MN, United States

Corresponding Author:
Carlye Anne Lauff, PhD
Department of Design Innovation, College of Design
University of Minnesota, Twin Cities
13 Rapson Hall, 89 Church Street SE
Minneapolis, MN, 55455
United States
Phone: 1 724 889 5511
Fax: 1 612 625 7525
Email: carlye@umn.edu

Abstract

Background: Congenital heart disease (CHD) is the most common birth defect, affecting 40,000 births annually in the United States. Despite advances in medical care, CHD is often a chronic condition requiring continuous management and education. Effective care management depends on children's understanding of their condition. This highlights the need for targeted health educational interventions to enhance health literacy among children with CHD.

Objective: This scoping review aims to map and explore existing health educational interventions for children with CHD. The review identifies the types of interventions, target populations, delivery methods, and assessed outcomes. The goal is to consolidate fragmented research, identify gaps, and establish future research agendas.

Methods: Comprehensive searches were conducted in February 2024 using the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) framework across multiple databases: APA PsycINFO, MedlinePlus via Ovid, Web of Science, ACM Digital Library, Scopus, and EBSCOhost (CINAHL Complete, CINAHL Ultimate, Health Source: Nursing/Academic Edition, and ERIC). The search covered health care, design, and human-computer interaction disciplines to capture the interdisciplinary nature of CHD health educational interventions. There was no predefined time limit due to the limited number of relevant studies. Eligible studies were in English, published in peer-reviewed journals, and focused on primary data about educational health interventions for children with CHD. We extracted and synthesized data using thematic analysis.

Results: The review identified 11 studies: 9 randomized controlled trials and 2 observational studies. These used 6 educational strategies: 3D patient-specific models (n=3), habit formation interventions (n=2), empowerment-based health education programs (n=2), rehabilitation interventions (n=2), web-based portals (n=1), and videotape presentations (n=1). Interventions ranged from brief outpatient sessions to 1.5-year programs, with follow-up from none to 24 months. Studies aimed to improve coping, self-management, and knowledge for children with CHD and their families. The most frequently used assessment method was the independent samples *t* test (n=4) for pre- and postassessments, and all 11 studies used questionnaires, 8 of which incorporated qualitative feedback. The target participants for these interventions were children aged 13 years and older (n=3), parents (n=2), and children of various ages and their parents (n=6). Outcomes included improved children's health literacy, reduced parental burden, and increased health care provider efficiency.

Conclusions: This review underscores the critical need for tailored educational interventions for children with CHD. Current research mainly focuses on adolescents and relies heavily on parental involvement, possibly overlooking the specific needs of younger children younger than 13 years of age. It is essential to develop engaging, age-appropriate interventions that actively involve children with CHD in their health care journey. Effective health educational interventions are crucial in empowering these young patients and improving their long-term health outcomes.

(JMIR Pediatr Parent 2025;8:e64814) doi:10.2196/64814

XSL•FO
RenderX

KEYWORDS

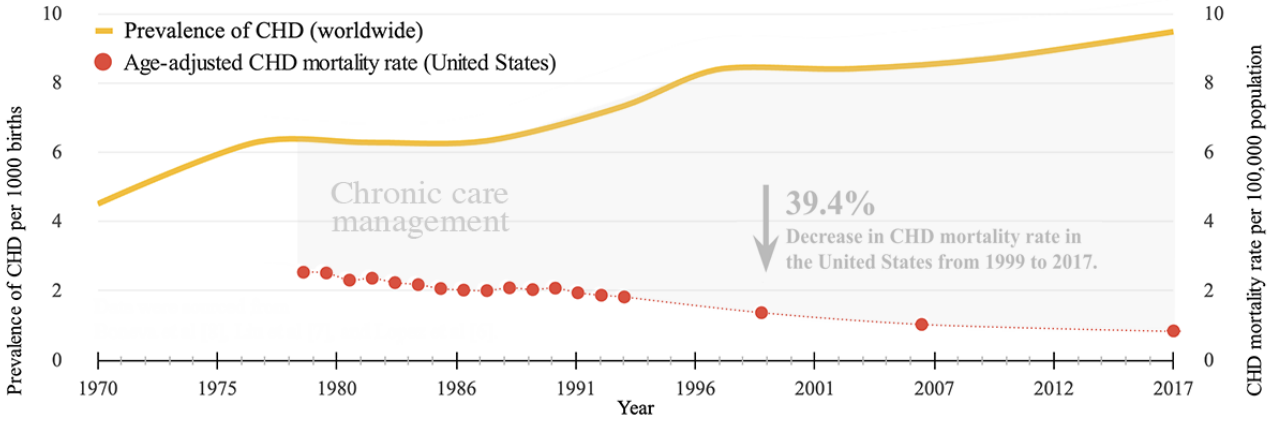
congenital heart disease; children health literacy; health education; health education interventions; patient-centered care; design; pediatric; PRISMA

Introduction

Background

Congenital heart disease (CHD) is a structural abnormality in the heart present at birth. It is the most common birth defect, affecting 1.35 million newborns worldwide and around 40,000 births annually in the United States. CHD often leads to other health complications and poses lifelong challenges to affected children, families, and health care systems [1-3]. Improved medical and surgical care have substantially increased survival rates, with up to 90% of children with CHD now surviving through to adulthood [4,5]. Despite improved medical care, CHD is more like a chronic condition that requires early diagnosis, timely treatment, and ongoing management. Figure 1 shows the worldwide prevalence of CHD from 1970 to 2017 and how survival rates in the United States since 1999 impact the need for continuing care [2,5-8]. Effective long-term care requires a comprehensive understanding of the condition by both pediatric patients and caregivers. Traditionally, health care providers have relied on parents to educate their children about their condition, assuming effective transmission of information. This approach often falls short, with parents struggling to comprehend and recall the information provided. Insufficient knowledge leads to extensive education during appointments, causing confusion and anxiety for children with CHD and their families [9-12]. Without proper education, the ability to proactively manage the condition diminishes, potentially leading to worse health outcomes, greater difficulty transitioning to adult care, and increased hospitalizations [4,13]. Accessible health information and organized educational support systems are crucial for improving health education, self-management skills, and health literacy (HL) among pediatric patients and caregivers [2,14].

Figure 1. Worldwide CHD prevalence and the effect of US survival rates on care management. Data were sourced from Boneva et al [8], Liu et al [7], Lopez et al [6]. CHD: congenital heart disease.



Prior Work

HL is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" [9]. However, there are uncertainties about the best educational and support approaches for improving HL in pediatric patients with CHD. Learning about this complex subject at a young age presents significant challenges. Limited learning opportunities hinder adequate information delivery and understanding [10]. Moreover, current educational materials (eg, pamphlets and postvisit summaries) are often inappropriate for young children and are primarily intended for their caregivers or parents [10,12]. To tackle these challenges, health educational interventions are designed to enhance individuals' knowledge, attitudes, skills, and behaviors to manage their condition [15]. These interventions are crucial for empowering children with CHD to understand their condition, adhere to treatment plans, and navigate the health care system effectively.

Recent focus has highlighted the importance of involving children with CHD and their caregivers in developing and executing their care plans through health educational interventions [10,12]. Despite this, the literature on educational interventions for children with CHD remains limited. To our knowledge, no systematic or scoping reviews have been conducted on this topic. Only a few scoping and systematic studies have attempted to understand the experiences of children with CHD, their families, and health care providers in managing CHD [2,16-18]. Furthermore, some studies focus on the coping mechanisms of parents and families of children with CHD rather than on the children themselves [19-21]. Therefore, a scoping review is necessary to consolidate fragmented research, identify existing gaps, and establish a future research agenda [22].

Purpose and Objectives

This scoping review systematically maps and explores existing educational interventions for children with CHD to identify intervention types, target populations, delivery methods, and assessed outcomes. Textbox 1 presents the PICOTS (population, intervention, comparator, outcome, timing, and setting) framework for educational interventions for children with CHD. PICOTS helps clarify and organize research questions. The key questions (KQs) addressed are:

XSL•FO
RenderX

KQ1: What types of educational interventions are available for children with CHD?

KQ2: What are the study designs, target populations, and the roles of various stakeholders in these educational interventions?

KQ3: What outcomes are assessed, and what approaches are used for assessment?

KQ4: What gaps exist in the current literature regarding educational interventions for children with CHD, and what areas require further exploration?

Figure 2 presents the analytical framework for the scoping review. It outlines a structured approach to address KQs concerning CHD and educational interventions for pediatric patients. The review covers intermediate outcomes, including intervention details, study design, stakeholder involvement, and assessed outcomes. The primary outcomes are improved children's HL, reduced parental burden, and enhanced efficiency of health care providers. Suboutcomes related to children's HL enhancement include understanding CHD, self-management or habits, coping or quality of life, empowerment, health care use, and health outcomes. The review also focuses on providing educational, emotional, caregiving, and financial support to reduce parental burden. Additionally, it considers suboutcomes related to saving time or effort, treatment adherence, care coordination, shared decision-making, and patient or family satisfaction to enhance the efficiency of health care providers.

Textbox 1. PICOTS (population, intervention, comparator, outcome, timing, and setting) framework for key questions on health educational interventions for children with congenital heart disease (CHD).

Population

- Children diagnosed with CHD <18 years.

Intervention

- Educational interventions targeting health literacy improvement among children with CHD.

Comparators

- Any comparator (as this is a scoping review).

Outcomes

- Engagement (use and satisfaction).
- Improved health literacy in children with CHD (understanding of CHD, self-management or habits, coping or quality of life, empowerment, health care use, and health outcome).
- Reduced parental burden through effective educational support (educational support, emotional support, and financial support).
- Enhanced health care efficiency by minimizing education needs during medical appointments (saving time or effort, treatment adherence, care coordination, shared decision-making, and patient or family satisfaction).

Timing

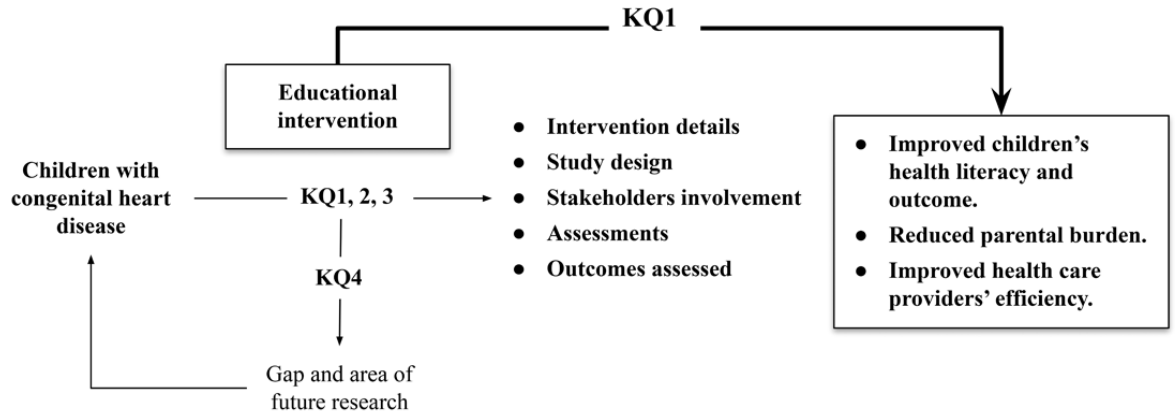
- No restrictions.

Setting

- All types of studies (as this is a scoping review), including various health care (eg, hospitals and clinics), nonhealth care (eg, school and support community), and home settings.

XSL•FO
RenderX

Figure 2. Logic model for the PICOTS (population, intervention, comparator, outcome, timing, and setting) framework and 4 key questions (KQs).



Methods

Literature Search Strategy

This study used a scoping approach guided by the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) framework [23]. Scoping reviews provide an overview of emerging evidence without aiming to appraise and synthesize results for a specific question. They are useful when it is still unclear what specific research questions a systematic review can address. Additionally, scoping reviews help inform and identify current research practices and methodologies in emerging research fields [22-25]. This research process was structured using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) framework, including four stages: (1) identification of relevant literature searches on various databases using specific keywords, (2) screening the title and abstract of the identified studies, (3) eligibility—full-text review of screened results to eliminate studies outside our intended scope, and (4) inclusion, helped extract relevant data that met the defined criteria [26]. The PRISMA-ScR checklist is available in Multimedia Appendix 1.

Eligibility Criteria

To be included in the review, studies must be written in English and published in a peer-reviewed journal to ensure accessibility and credibility. We only considered studies with a methods section, focusing on primary data and analyses rather than studies like systematic reviews. Our focus was on CHD in pediatric patients younger than 18 years of age, and the studies addressed educational interventions for this demographic, not just HL. We excluded studies that solely targeted parents or caregivers, focused only on health care providers, or related to transition care from pediatric to adult health care, as these areas fall outside our specific review scope. However, we included studies involving parents only when their participation aimed to improve the child's health outcomes, focusing on enhancing the children's educational experience rather than the parents. This selection process ensured that the included studies were directly relevant to pediatric CHD and educational health interventions.

Information Sources and Search

We conducted comprehensive searches across the following bibliographic databases during February 2024 to identify potentially relevant studies without a predefined time limit. Given the initial research indicating a scarcity of relevant studies, we maintained an open search time frame. We gathered relevant studies from APA PsycINFO and MedlinePlus via Ovid, Web of Science, ACM Digital Library, Scopus, and EBSCOhost, including CINAHL Complete, CINAHL Ultimate, Health Source: Nursing/Academic Edition, and ERIC. These databases cover health care, psychology, education, design, and human-computer interaction disciplines. They were selected to reflect the interdisciplinary nature of CHD health educational interventions.

Three main concepts were identified based on the research questions: HL, pediatric, and CHD. Synonyms and related concepts were incorporated to ensure a comprehensive search for related terminologies used in the literature. For example, synonyms of "pediatric" included "child," "children," "toddler," and "preschool," while related concepts like "boy" and "girl" were also included. Given the cross-disciplinary database search, listing each concept's relevant ideas and terms was important. MeSH terms and keywords were tailored to each database's specifications, as detailed in Multimedia Appendix 2. Boolean search strings were formulated using the OR operator for synonyms of the main concepts (ie, "children" OR "child" OR "pediatric") and the AND operator to combine the 3 main concepts (ie, "health literacy" AND "congenital heart disease" AND "pediatric"). The terms were refined through multiple iterations by adding new terms and synonyms or adjusting specificity to enhance the quality of results. For instance, recognizing that the term "health literacy" may be omitted in studies involving health education interventions, alternative terms such as "healthcare knowledge," "health awareness," and "health education" were included. Additionally, we intentionally avoided using "intervention" as a synonym for "health literacy" to ensure that studies focusing on clinical and surgical interventions in CHD were not included (Table 1).

XSL•FO
RenderX

Table 1. Boolean search strings in categories.

Categories	AND or NOT	Boolean search string
Health literacy	AND	("Health Literacy" OR "Healthcare Literacy" OR "Medical Literacy" OR "Health Understanding" OR "Health Education" OR "Healthcare Education" OR "Health Information Literacy" OR "Medical Comprehension" OR "Healthcare Knowledge" OR "Health Knowledge" OR "Health Proficiency" OR "Health Awareness" OR "Medical Awareness" OR "Health Competency" OR "Health Communication" OR "Information Literacy" OR "Patient Education" OR "Health Promotion" OR "Health Teaching")
Pediatric	AND	(Children OR Child* OR Kid OR Kids OR Girl* OR Boy OR Boys* OR Toddler* OR Childhood OR Preschool* OR Pre-school* OR Kindergarten* OR School OR Minors OR Pediatric* OR Paediatric*)
Congenital heart disease	AND	("Congenital Heart Defects" OR "Child Heart Disease" OR "Heart Defects" OR "Congenital Heart Disease" OR "Pediatric Cardiology" OR "Paediatric Cardiology" OR "Cardiac Defect*")

The first author (NB) and a collaborator independently screened the titles and abstracts using the PICO Portal, reaching a consensus on selections for full-text screening and consulting the health librarian for final decisions in disagreements. Before and during the screening process, the first (NB), second (JYS), and last authors (CAL) held weekly meetings to clarify the selection of databases, concepts, and criteria as well as to draft an internal guideline. For example, following our discussions, we added the ACM Digital Library database to broaden our search to include technology-mediated solutions. These meetings continued during data charting and thematic analysis. We also sought guidance from a medical expert, a public health expert, and 2 librarians throughout the review. We used Zotero (Corporation for Digital Scholarship) for reference management and Google Sheets and Microsoft Excel for data abstraction. We established decision rules to guide the coding process and ensure consistency in cases requiring subjective interpretation.

The research team abstracted data on study characteristics: (1) study identification (ie, ID, author or year, country, title, study design, date of study, setting, and objective or purpose), (2) participant details (ie, target population, intervention tested on, sample size, demographic, inclusion or exclusion criteria, and CHD severity), (3) intervention specification (ie, intervention, format, description, comparison, stakeholders' roles, duration, and follow-up), and (4) outcome specification (ie, outcome measures, results, and statistical analysis). Abstraction tables are shown in Tables S1-S5 in Multimedia Appendix 3 [27-37].

Data Synthesis

Due to the heterogeneous nature of the data, the research team used a qualitative approach using affinity diagramming and thematic analysis [38,39]. This approach enabled us to explore the data without predetermined frames and uncover emerging themes to answer our scoping review questions and objectives. We began by categorizing the studies based on the types of interventions they covered. We then performed open coding on all 11 papers to identify the specifications of educational interventions (ie, objectives, strategies, stakeholder involvement, and outcomes) for children with CHD. Through constant comparison and iterative coding, thematic categories emerged. Initially, open coding of studies yielded 43 discrete codes. Subsequently, these codes were iteratively aggregated based on commonalities, resulting in 15 representative codes. Next, affinity diagramming was used to cluster these 15 codes according to similarity, difference, and hierarchy relationships.

This process allowed us to establish high-level themes, refined through constant comparison and iterative coding. The key themes that emerged from the data include (1) types of educational interventions, (2) study design and stakeholder involvement, and (3) evaluation methods and outcome objectives. Each main theme was further divided into 2 subthemes (Textbox 2). This thematic synthesis provided a clear and structured understanding of the educational interventions for children with CHD, covering their implementation and evaluation.

Textbox 2. Identified themes and subthemes.

Types of educational interventions

- Educational strategies and objectives (eg, engaging sessions and disease education)
- Intervention duration (eg, duration and frequency of educational interventions)

Study design and stakeholder involvement

- Study design (eg, observational and randomized controlled trial)
- Target age groups and stakeholder involvement (eg, children and parents)

Evaluation methods and outcome objectives

- Assessed outcomes (eg, health literacy and health outcome)
- Data collection and analysis techniques (eg, questionnaires and interviews)

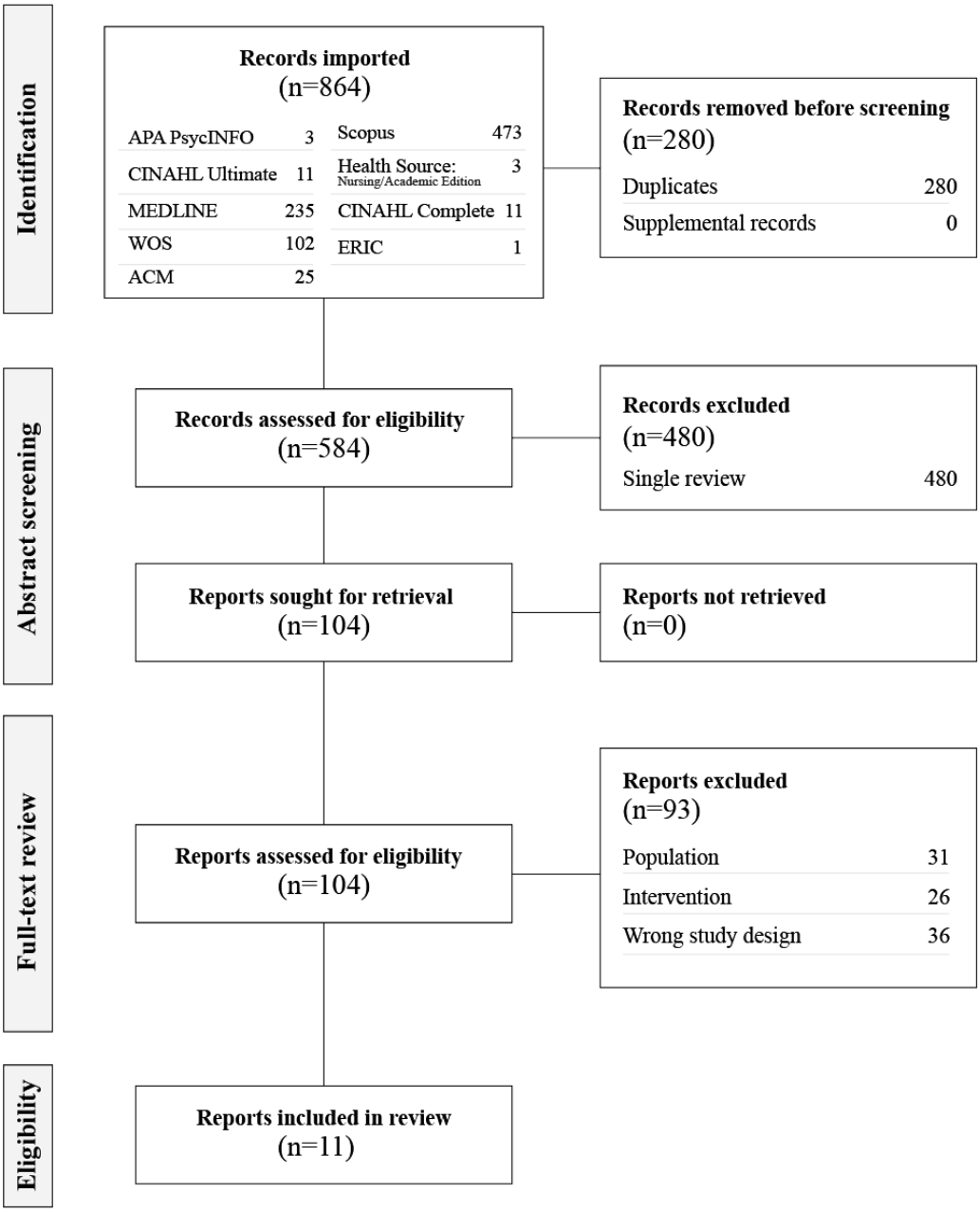
XSL•FO
RenderX

Results

Selection of Sources of Evidence

The literature search identified 864 records across 5 databases: APA PsycINFO (n=3), MEDLINE (n=235), Web of Science (n=102), ACM Digital Library (n=25), Scopus (n=473), CINAHL Complete (n=11), CINAHL Ultimate (n=11), Health Source: Nursing/Academic Edition (n=3), and ERIC (n=1). After removing 280 duplicates and supplemental materials, 584 records remained for abstract screening. Following abstract and title screening by the research team, 480 records were excluded for not meeting the review criteria. The full texts of the remaining 104 reports were assessed for eligibility. Of these, 93 reports were excluded for various reasons: 31 due to the population mismatch (ie, focusing on parents or caregivers or health care providers, participants aged >18 years, or studying general heart disease), 26 because the intervention was not relevant (ie, no interventions implemented, assessments used as interventions, or noneducational interventions), and 36 were excluded based on the wrong study design (ie, focusing on transitions to adulthood or objectives aimed at parents or health care providers). Finally, 11 reports met all the inclusion criteria and were selected for inclusion in the scoping review. Figure 3 illustrates the results of the literature search and screening. We used the PICO Portal review software to support the screening process. The reasons for exclusion at each stage were clearly documented, ensuring transparency and adherence to the PRISMA guidelines. References for papers excluded in the full-text review can be found in Multimedia Appendix 4.

Figure 3. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram of the literature review process.



XSL•FO
RenderX

Characteristics of Sources Evidence

From 1982 to 2023, 11 studies were reviewed, focusing on educational interventions for pediatric patients with CHD [27-37] (Figure 4). There was a gap in the selected studies from 1982 to 2015. After that, 1 study was published every year until 2023, except for 2016, which had 2 studies [31,34]. Two studies were from the Netherlands in 2017 and 2018 [29,36], while 3 were from the United States in 1982, 2021, and 2022 [33,35,37]. Among these studies were 9 randomized controlled trials (RCTs) [27-32,34-36], with 1 covering both a pilot and RCT [29]. Additionally, 2 were observational studies [33,37]. Even though we searched design, human-computer interaction, and health databases, the studies were published in 9 medical and health-related journals. Two of the reviewed studies were published in the *International Journal of Cardiology* [27,31].

Figure 4. Characteristics of included studies [27-37]. RCT: randomized controlled trial.

Author (year)	Study design	Canada	China	Denmark	England	Finland	France	Netherlands	United States
Uzark et al (1982)	RCT								*Pediatric Cardiology*
Biglino et al (2015)	RCT				*BMJ Open*				
Ni et al (2016)	RCT		*Journal of Child Health Care*						
Klausen et al (2016)	RCT			*International Journal of Cardiology*					
Etnel et al (2017)	Pilot + RCT							*Frontiers in Cardiovascular Medicine*	
van der Mheen et al. (2018)	RCT							*BMC Pediatrics*	
Amedro et al (2019)	RCT						*International Journal of Cardiology*		
Lemire et al (2020)	RCT	*Contemporary Clinical Trials*							
Zablah et al (2021)	Observational								*Progress in Pediatric Cardiology*
Liddle et al (2022)	Observational								*Cardiology in the Young*
Karikoski et al (2023)	RCT					*Caries Research*			

Results of Individual Sources of Evidence

Overview

In exploring educational interventions for children with CHD, the first emergent theme is "types of educational interventions," with subthemes of "educational strategies and objectives" and "intervention duration." Educational strategies and objectives refer to the strategies used to support children with CHD and how these interventions address specific objectives, like disease education. Duration presents the timing and duration of these interventions, whether they are 1-time sessions, have follow-ups, or are repeated over time. This theme and its subthemes address KQ1: What types of educational interventions are available for children with CHD?

Educational Strategies and Objectives

Across the reviewed studies, 6 educational strategies were used to support children with CHD and their families (Figure 5). These strategies include the use of 3D patient-specific models, habit formation interventions, empowerment-based health education programs, rehabilitation interventions, a web-based portal, and videotape presentations.

3D patient-specific models are anatomical models created from medical imaging data like computed tomography or magnetic resonance imaging scans, providing a detailed representation of a child's heart. They help visualize and understand complex cardiac structures and treatment plans. Three studies used these models to educate about cardiac anatomy and treatment plans. These models were accompanied by engaging discussions and supplemented with diagrams or images, clarifying complex anatomical structures and treatment options. One of these studies specifically targeted adolescent patients, combining 3D models with tele-education. These interventions offered a visual understanding of the heart's structure and treatment procedures, including cardiac catheterization [28,33,37]. Habit formation interventions aim to instill healthy habits in children with CHD through structured programs. These interventions often involve multiple components, such as printed materials, toolkits, websites, and counseling sessions, to encourage and support the development of these beneficial habits. Two studies focused on these interventions. One aimed at promoting physical activity through a multifaceted intervention, including printed materials, a physical activity toolkit, and a website. The other focused on oral health promotion through counseling, distributing oral hygiene products, and providing written information [30,32].

XSL•FO
RenderX

Figure 5. Educational strategies, objectives, and intervention durations [27-37]. CHD: congenital heart disease; NR: not reported.

Studies	Strategies	Objectives	Purpose	Duration	Follow-up
Biglino et al (2015) Zablah et al (2021) Liddle et al (2022)	3D patient-specific models	- Disease education	Provide a visual understanding of cardiac anatomy and treatment procedures, such as cardiac catheterization.	- Routine outpatient visits - Routine outpatient visits - 30-minute tele-education	- NR - NR - NR
Lemire et al (2020) Karikoski et al (2023)	Habit formation interventions	- Self-management skills	Promote physical activity and oral health—2 important habits—among children with CHD.	- 6 months (3-day workshop, conference call each month) - 1.5 years (sessions at 6, 12, 18 months)	- 6 months - 24 months
Ni et al (2016) van der Mheen et al (2018)	Empowerment-based health education programs	- Coping strategies - Disease education	Improve caregiving knowledge, caring behaviors, and self-efficacy of parents caring for children with CHD.	- 40 minutes + 3 monthly each 10 minutes - One-day workshop	- 1 month + 3 months after surgery - 6 months
Amedro et al (2019) Klausen et al (2016)	Rehabilitation interventions	- Self-management skills - Coping strategies	Enhance the quality of life, physical fitness, and health-related quality of life in adolescents and young adults with CHD.	- 12 weeks - 52 weeks	- 12 months - 12 months
Etnel et al (2017)	Web-based portal	- Disease education - Physician-patient communication	Improve patient knowledge and involvement and support physician-patient communication in the management of CHD.	- No limit	- 1 month
Uzark et al (1982)	Videotape presentation	- Coping strategies - Disease education	Enhance children's knowledge and coping during hospitalization for cardiac catheterization through visual education.	- 16 min	- 4 to 6 weeks after hospital discharge

Empowerment-based health education programs empower parents and family members by enhancing their knowledge, caregiving behaviors, and self-efficacy in managing a child's CHD. They typically include face-to-face education sessions, workshops, and follow-up support such as telephone calls, helping caregivers feel more confident and competent in their roles. Two studies implemented these programs to improve the caregiving knowledge, caring behaviors, and self-efficacy of parents or family members caring for children with CHD. One offered face-to-face education sessions and follow-up telephone calls, while the other conducted workshops [34,36]. Rehabilitation interventions aim to enhance the physical and psychological well-being of children and adolescents with CHD. These include structured cardiac rehabilitation programs (center or home-based) and eHealth interventions that use technology to improve physical fitness, activity levels, and overall health-related quality of life over an extended period. Two studies explored these interventions. One evaluated the impact of a combined center- and home-based cardiac rehabilitation program on the quality of life of adolescents and young adults with CHD. The other assessed the effects of a 52-week eHealth intervention on physical fitness and health-related quality of life in adolescents with CHD [27,31].

Web-based portals are digital platforms that enhance patient education, engagement, and communication. They provide accessible information about CHD, treatment options, and self-management strategies. These portals also facilitate communication between patients, families, and health care providers, ensuring continuous support and information exchange. Only 1 study assessed the effectiveness of these interventions in improving adolescent patient knowledge and involvement and supporting physicians in communicating with their patients [29]. Videotape presentations prepare children and their families for medical procedures and hospital stays. The videos use engaging, playful, and child-friendly formats, such as fictional or animated characters and stories, to simplify complex medical concepts and make them less intimidating. In 1982, a study evaluated the impact of a 16-minute videotape presentation on children's knowledge and coping skills during cardiac catheterization. The study featured a fictional lion who presented the videotape to guide hospitalized children through the events, sights, sounds, and sensations associated with the cardiac catheterization procedure [35].

Of the 11 studies reviewed, 7 offered disease education using the following methods: 3D patient-specific models, empowerment-based health education programs, web-based portals, and videotape presentations [28,29,33-37]. Four studies

XSL•FO
RenderX

focused on improving self-management skills using 2 strategies: habit formation interventions and rehabilitation interventions [27,30-32]. Five studies aimed to teach coping strategies using 3 approaches: empowerment-based health education programs, rehabilitation interventions, and videotape presentations [27,31,34-36] (Figure 5). It is important to note that some studies addressed more than 1 aspect, which is why the numbers overlap across different categories.

Intervention Duration

The duration of educational interventions varied across the studies, as shown in Figure 5. Some interventions were brief sessions within routine visits, while others lasted up to 1.5 years. Follow-ups also differed. Some interventions had no follow-ups, while others included assessments at intervals of 1 month, 6 months, 1 year, or 2 years.

In total, 2 of 3 studies using 3D patient-specific models were integrated into routine outpatient visits without a specified duration. Another study used digital 3D heart models during a 30-minute tele-education session instead of in person. After the session, patients received a USB drive containing a video of their 3D heart and digital files for potential self-learning, with no follow-up mentioned [28,33,37]. In contrast, habit formation interventions, such as the oral health promotion intervention and a multifaceted physical activity intervention, spanned extended periods. Oral health promotion intervention lasted 1.5 years with sessions at baseline, 6, 12, and 18 months, followed by a 24-month follow-up. The multifaceted physical activity intervention spanned 6 months, including a 3-day workshop and monthly conference calls, with a follow-up period of 6 months [30,32].

As part of the empowerment-based health education program, 1 study included a 40-minute face-to-face education session with individualized instructions on the second day after surgery. There were also 2 monthly 10-minute telephone calls after the discharge to discuss the child's care and modify action plans. Subsequent assessments were conducted at 1 month and 3 months after surgery. Another study, the Congenital Heart Disease Intervention Program-Family intervention, involved a 1-day workshop and a 6-month follow-up session and assessment [34,36]. Using the rehabilitation interventions strategy, 1 study implemented the QUALI-REHAB cardiac rehabilitation program, consisting of a 12-week program with 5 days of hospitalization at the rehabilitation center and home-based training. Recall sessions were held every 3 weeks at the center, with a final evaluation at the end of week 12 and a 12-month follow-up period for outcome measurements. Another program, the Paediatric Rehabilitation for Vanguard in Lifeskills (PReVaiL), lasted 52 weeks, with a follow-up assessment conducted after 1 year. Patients received group-based health education sessions lasting 45 minutes and individual counseling sessions lasting 15 minutes [27,31].

Additionally, 1 study introduced a web-based portal during outpatient visits that could be used anytime, with follow-up assessments conducted 1 month after the visit [29]. Finally, 1 study conducted a 16-minute videotape presentation session 1 day before procedures, with a follow-up undertaken 4 to 6 weeks after discharge from the hospital [35]. In total, 3 studies had a 1-month follow-up timeline, while 2 had 6 months and 2 had 1 year.

Study Design and Stakeholder Involvement

Overview

The second emergent theme is "study design and stakeholder involvement," with subthemes of "study design" and "target age groups and stakeholder involvement." Study design focuses on the methodologies used in the studies and the size of participant samples. Target age groups and stakeholder involvement examines the target population's age range and impact on stakeholder roles. It analyzes whether parents, caregivers, or health care providers are involved in delivering or evaluating the intervention and identifies the target population. Together, these address KQ2: What are the study designs, target populations, and the roles of various stakeholders in these educational interventions?

Study Design

In total, 8 of the 11 studies used an RCT design, while 1 study included a pilot phase followed by an RCT [27-32,34-36]. The sample sizes in these RCTs ranged from 53 to 250, with a mean of 126.11 (SD 43.95). The intervention group size ranged from 31 to 125, with a mean of 63 (SD 25.20), and the control group size ranged from 22 to 125, with a mean of 62.78 (SD 24.60).

These RCTs varied in their approach, including prospective randomized clinical trials; questionnaire-based feasibility and acceptability studies; prospective clinical trials; single-center, single-blinded, randomized controlled trials; prospective, multicenter, randomized, controlled, parallel-arm studies; cluster randomized controlled trials; and multicenter stepped-wedge implementation trials. Additionally, 2 studies adopted observational study designs [33,37]. The observational studies explored a single-center cross-sectional study and a prospective pre-post study, with sample sizes of 46 and 22, respectively.

Reviewed studies used diverse settings for their interventions. Three studies implemented interventions across home settings, cardiac clinics, and digital or telehealth platforms [29,32,33]. Another 3 studies implemented interventions at home and children's hospitals [30,34,36]. One study used interventions in home settings, cardiac clinics, and rehabilitation centers [27]. Additionally, 1 study used home settings, rehabilitation centers, and digital or telehealth platforms [31]. In total, 2 studies were conducted at cardiac centers [28,37], while 1 was conducted exclusively at a hospital [35]. The study designs and settings are summarized in Figure 6.

XSL•FO
RenderX

Figure 6. Study design and population characteristics [27-37]. N/A: not applicable; NR: not reported; RCT: randomized controlled trial.

Authors and date		Biglino et al (2015)	Zablah et al (2021)	Liddle et al (2022)	Lemire et al (2020)	Karikoski et al (2023)	Ni et al (2016)	van der Mheen et al (2018)	Amedro et al (2019)	Klausen et al (2016)	Etnel et al (2017)	Uzark et al (1982)
Strategy		3D patient-specific models			Habit formation		Empowerment health education		Rehabilitation		Web portal	Videotape
Intervention tested on		Parent	Children Parent	Children	Children Parent	Children Parent	Parent	Children Parent	Children	Children	Children Parent	Children Parent
Study design	**RCT studies**											
	Prospective randomized clinical trial											✔
	Questionnaire-based feasibility study	✔										
	Prospective clinical trial						✔					
	Randomized clinical trial									✔		
	Single-center, single-blinded, RCT							✔				
	Prospective, multicenter, RCT, parallel-arm study								✔			
	Cluster RCT				✔							
	RCT					✔						
	Pilot + RCT											
	Multicenter stepped-wedge implementation trial										✔	
	Observational studies											
	Single-center cross-sectional study		✔									
	Prospective pre-post study			✔								
Setting	Home			✔	✔	✔	✔	✔	✔	✔	✔	
	Children hospital					✔	✔	✔				✔
	Cardiac clinic or center	✔	✔	✔	✔				✔		✔	
	Rehabilitation centers								✔	✔		
	Digital or telehealth			✔	✔					✔	✔	
Population	**Stakeholders involvement**											
	Pediatric patients (children)		✔	✔	✔	✔		✔	✔	✔	✔	✔
	Parents or caregivers or family	✔	✔		✔	✔	✔	✔	✔	✔	✔	✔
	Health care providers	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
	Age range											
	Pediatric patients (children)	6-18 y	1 mo-21 y	13-18 y	5-17 y	0-24 mo	1 mo-5 y	4-7 y	13-25 y	13-16 y	Adolescent	3-12 y
	Parents or caregivers or family	35-51 y	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Sample size											
	Total	103	46	22	200	72	86	90	130	158	250	53
	Intervention group size	45	N/A	N/A	100	35	44	45	65	77	125	31
	Control group size	52	N/A	N/A	100	37	42	45	65	77	125	22

Target Age Groups and Stakeholder Involvement

In the reviewed studies focusing on educational interventions for children with CHD, stakeholder involvement varied depending on the participants' age range. This variation influenced the roles played by different stakeholders, such as parents or caregivers and health care providers, within these interventions.

The primary emphasis of this review was on educational interventions tailored for children with CHD, although not all studies exclusively targeted children as participants. Several studies also included parents of children with CHD within specific age groups to enhance the overall health outcomes for these children. Among the 11 studies examined, 2 exclusively focused on parents [28,34], while 6 involved both parents and children [29,30,32,35-37]. Additionally, 3 studies specifically targeted children aged 13 to 18, 13 to 25, and 13 to 16 years [27,31,33]. The youngest participants in the studies targeting just children with CHD were aged 13 years.

In a study conducted by Uzark et al [35], the researchers assessed the impact of a videotape presentation on the knowledge and coping of children with CHD aged 3 to 12 years during hospitalization for cardiac catheterization. The study also targeted the parents of these younger children to improve outcomes for both children and parents. Another study by Biglino et al [28] investigated the effectiveness of 3D patient-specific models of CHD as a communication tool during cardiology consultations for pediatric patients aged 6 to 18 years and their parents. The age range of parents included in this study was 35 to 51 years.

Lemire et al [32] studied children with CHD aged 5 to 17 years and their parents. The intervention aimed to assess whether providing resources and protocols would enable clinicians to counsel about physical activity during every pediatric cardiology appointment. In another study, Karikoski et al [30] targeted children with CHD up to 24 months old and their parents to investigate the effectiveness of repeated counseling provided by a dental hygienist in improving oral health behavior during the first 1000 days of life. They aimed to improve parental hygiene habits with the expectation that it would also enhance young children's hygiene habits.

XSL•FO
RenderX

Ni et al [34] evaluated the effectiveness of an empowerment-based health education program for parents caring for children aged 1 month to 5 years who had undergone corrective surgery for CHD. Their goal was to improve the health outcomes for the children and not the parents. Van der Mheen et al [36] assessed the effects of a program on parental mental health and the psychosocial well-being of children with CHD aged 4 to 7 years. This program also involved siblings to help normalize the child's CHD position within their family dynamic.

In all 11 studies, key stakeholders—children, parents or caregivers, and health care providers—actively participated in the interventions. In total, 8 studies involved all these stakeholders [27,29-32,35-37], while 2 involved parents and health care providers [28,34], and 1 included children and health care providers [33]. The age ranges in these studies varied widely, from birth to 25 years. However, the age range for parents was not consistently provided across the studies. Only 1 study specified the age range for parents as 35 to 51 years, with children aged 6 to 18 years [28]. Figure 6 provides details of population specification, including stakeholder involvement, age ranges, and sample sizes across the reviewed studies.

Evaluation Methods and Outcome Objectives

Overview

Theme 3, "evaluation methods and outcome objectives," includes 2 subthemes: "assessed outcome" and "data collection and analysis techniques." Assessed outcomes discusses the specific objectives and goals the interventions aimed to achieve. Data collection and analysis techniques examines the methods and approaches used to gather and analyze data. Together, these subthemes address KQ3: What outcomes are assessed, and what approaches are used for assessment?

Assessed Outcomes

The outcomes assessed represent the specific objectives the reviewed studies measure to evaluate the effectiveness of their interventions. This scoping review categorized assessed outcomes into three main categories: (1) improved children's HL and outcome, (2) reduced parental burden, and (3) improved efficiency of health care providers. Figure 7 summarizes these categories, demonstrating the varied impacts of interventions on children with CHD, their parents or caregivers, and health care providers.

Improving children's HL involves various suboutcomes. These include understanding CHD, self-management and habits, coping and quality of life, empowerment, health care use, and health outcomes. Two studies evaluated the understanding of CHD, and both reported increased knowledge following the intervention [33,35]. Meanwhile, 3 other studies are still under investigation [29,32,36]. Three studies were conducted on self-management and habits. In total, 2 showed positive impacts [30,35], while 1 showed no change or impact [31]. Furthermore, 1 study found a relationship between the intervention and self-management and habits, indicating a need for further investigation in future studies [33]. Ongoing research is being conducted in 3 more studies under investigation [27,32,36].

Two other studies assessed coping and quality of life, one showing no change after intervention [31], and one showing improvement [35], while ongoing investigations continue in 4 studies [27,29,32,36]. Regarding empowerment, 2 studies showed improvement [33,35], with ongoing investigations in 2 more studies [29,36]. Health care use was evaluated once, with no observed difference [30]. Health outcomes were assessed in 2 studies, one indicating improvement [34] and the other showing no change [31]. Additionally, 2 studies without assessments reported a relationship between health outcomes and the intervention [30,35], while ongoing investigations are underway in 2 studies [27,36].

Reducing parental burden focused on various suboutcomes, including educational, emotional, caregiving, and financial support. In total, 4 studies assessed educational support, with 3 showing improvement [30,34,37] and 1 showing no change [28]. Two studies evaluated emotional support, both indicating improvement [34,35]. One study identified a relationship between intervention and emotional support without formal assessments [28], while 2 studies are under investigation [29,36]. Three studies assessed caregiver support, all of which showed improvement [30,34,37]. Similarly, 3 studies identified a relationship that needs further assessment [28,33,35], and 2 are still under investigation [29,36]. Financial support was not assessed in any of the reviewed studies.

Furthermore, regarding enhancing the efficiency of health care providers, one study assessed saving time and effort but found no significant time savings [28], while another study on this topic is still ongoing [32]. Treatment adherence was not directly assessed in any reviewed study, although 1 study noted a relationship without formal assessment [37]. Two studies evaluated care coordination, one indicating improvement [37] and another showing no change [30]. In total, 3 studies identified a relationship between the intervention and care coordination but did not conduct formal assessments [28,33,34], and 1 study is currently under investigation [32]. Shared decision-making and patient or family satisfaction were each assessed in 1 study, both showing improvement [33]. However, another study still investigates shared decision-making [29]. Additionally, 3 studies found a relationship between the intervention and shared decision-making [28,34,37], while 1 reported a relationship with patient or family satisfaction [28]. These findings suggest avenues for future research to assess these relationships more deeply.

XSL•FO
RenderX

Figure 7. Evaluation methods and outcomes objectives [27-37]. ANCOVA: analysis of covariance; CHD: congenital heart disease.

⬆denotes positive outcome, ⬇denotes negative outcome, – denotes no change, ○ indicates a relationship is present but not assessed, **NR** indicates the statistic is under study and not reported yet, ✔ indicates the statistic was used in the study and the method.

	Authors and date	Biglino et al (2015)	Zablah et al (2021)	Liddle et al (2022)	Lemire et al (2020)	Karikoski et al (2023)	Ni et al (2016)	van der Mheen et al (2018)	Amedro et al (2019)	Klausen et al (2016)	Etnel et al (2017)	Uzark et al (1982)
	Strategy	3D patient-specific models			Habit formation		Empowerment health education		Rehabilitation		Web portal	Videotape
	Intervention tested on	Parent	Children Parent	Children	Children Parent	Children Parent	Parent	Children Parent	Children	Children	Children Parent	Children Parent
Outcome	**Improved children's health literacy and outcome**											
	Understanding of CHD			⬆	NR			NR			NR	⬆
	Self-management or habits			○	NR	⬆		NR	NR	–		⬆
	Coping or quality of life				NR			NR	NR	–	NR	⬆
	Empowerment			⬆				NR			NR	⬆
	Health care use					–						
	Health outcome					○	⬆	NR	NR	–		○
	Reduced parental burden											
	Educational support	–	⬆	○		⬆	⬆	NR			NR	○
	Emotional support	○					⬆	NR			NR	⬆
	Caregiving support	○	⬆	○		⬆	⬆	NR			NR	○
	Improved health care providers' efficiency											
	Save time or effort	⬇			NR							
	Treatment adherence		○									
	Care coordination	○	⬆	○	NR	–	○					
	Shared decision-making	○	○	⬆			○				NR	
	Patient or family satisfaction	○		⬆								
Statistic	Repeated measures ANOVA				✔		✔	✔				
	ANCOVA analysis				✔					✔		✔
	Post hoc *t* test						✔					
	Independent samples t test	✔				✔	✔					✔
	Wilcoxon signed-rank test		✔	✔								
	Mann-Whitney *U* test		✔		✔	✔						
	Chi-square analysis (χ^2)	✔					✔					✔
	Fisher exact test					✔						
	Post hoc power analysis	✔										
	Cohen *d*							✔				
	Regression analysis							✔				
	Stepwise regression											✔
	Simple logistic regression					✔						
	Multiple logistic regression					✔						
	Logistic regression				✔					✔		
	Correlation analysis (*r*)											✔
	Cluster analysis											✔
	Weighted Cohen κ			✔								
Method	Software: STATA (ST), SPSS (SP)	(ST)	(SP)		(SP)	(SP)	(SP)			(ST, SP)		
	Quantitative questionnaire (ie, pre or post)	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
	Medical record or device				✔		✔		✔			
	Qualitative feedback (ie, in-person digital interview, call, focus group)			✔		✔	✔	✔		✔	✔	

Data Collection and Analysis Techniques

Across the 11 reviewed studies, various assessment methods and statistical analyses were used to evaluate the effectiveness of interventions for children with CHD. These methods and analyses provided comprehensive insights into the outcomes measured and the statistical rigor applied.

As a statistical software, SPSS (IBM Corp) was predominantly used in 5 studies [30-32,34,37], reflecting its widespread utility for quantitative data analysis in health care research. Data collection methods varied, with all studies using questionnaires, often administered before and after the intervention. In total, 3 studies relied solely on questionnaires and quantitative methods [28,35,37], while 5 studies integrated questionnaire data with qualitative feedback from in-person or digital interviews, calls, or focus groups [29-31,33,36]. Two studies incorporated medical records or devices alongside questionnaires [27,32], and 1 used all 3 methods, including questionnaires, qualitative feedback, and medical records or devices [34].

Statistical analyses used in the reviewed studies to analyze the data included a wide range of methods. The most frequently used statistical analysis method was the independent samples *t* test, used in 4 studies primarily as pre- and postassessments [28,30,34,35]. Other common analyses included repeated measures ANOVA [32,34,36], analysis of covariance analysis [31,32,35], Mann-Whitney *U* test [30,32,37], and chi-square analysis [28,34,35], each used 3 times to assess various outcomes. Several studies have also applied regression analysis techniques such as stepwise regression [35], simple logistic regression [30], multiple logistic regression [30], and logistic regression [31,32].

Among the 11 studies, 2 statistical approaches were used in 3 studies [31,33,37]. Notably, 1 study in 1982 used 6 statistical

XSL•FO
RenderX

techniques, including analysis of covariance analysis, independent samples *t* test, chi-square analysis, stepwise regression, correlation analysis (*r*), and cluster analysis [35]. Figure 7 provides an overview of the statistical approaches used across the studies, highlighting a range from 2 to 6 approaches per study.

The reviewed studies used various methods and statistical techniques, indicating no single approach to achieving their objectives. The frequent use of quantitative methods, primarily involving stakeholders other than children with CHD, suggests the need for tailored methods and techniques for this patient demographic.

Discussion

Principal Findings

Overview

This scoping review identified 11 studies conducted between 1982 and 2023, focusing on educational interventions for children with CHD. The studies included 9 RCTs and 2 observational studies. These studies used various intervention strategies, durations, study designs, and evaluation methods, offering a comprehensive overview of current research in this field. Six primary types of educational strategies were identified: 3D patient-specific models (n=3), habit formation interventions (n=2), empowerment-based health education programs (n=2), rehabilitation interventions (n=2), web-based portals (n=1), and videotape presentations (n=1). These interventions varied in duration, ranging from brief sessions during outpatient visits to programs lasting up to 1.5 years. Follow-up periods also varied, with 3 interventions having no follow-up, 2 having a 6-month follow-up period, 3 having follow-ups ranging from 4 to 6 weeks, and 1 study having a follow-up period of 24 months. The primary goals of these interventions were to improve the quality of life and coping strategies, self-management skills, and knowledge of children with CHD and their families. Among these studies, 3 interventions specifically targeted children above 13 years of age, 2 focused on parents, and 6 involved both children and parents. The primary statistical method used was the independent samples *t* test, used in 4 studies for pre- and postassessments. Outcome assessments focused on children's HL, reducing parental burden, and improving the efficiency of health care providers. These findings reveal the potential and the limitations of current health educational interventions, highlighting the need for more child-centric approaches to engage younger patients with CHD.

Limited Interventions for Children With CHD

This scoping review highlights the potential of educational interventions to significantly improve chronic care management for children with CHD and their families, aligning with previous findings [10-13,40-45]. Existing research indicates that well-informed pediatric patients can delay or prevent secondary illnesses, enhance their quality of life, and reduce health care costs [46-50]. However, many children with chronic conditions lack sufficient understanding of their illnesses, leading to confusion, anxiety, and other complications [51-54]. One contributing factor is the reliance on parents by health care providers to educate their children, assuming effective transmission of information [55,56]. Additionally, the development of interventions has mostly neglected children's perspectives, focusing primarily on feedback from health care providers and parents. Younger children face barriers to participation due to limited attention spans, difficulty understanding abstract concepts, and challenges in expressing their needs [57,58]. As a result, interventions typically depend on parental feedback as a proxy for testing and design insights [59].

The review also found that educational materials were predominantly designed for teenagers or parental caregivers, lacking age-appropriate and engaging solutions for children younger than 13 years of age. Among the 11 studies reviewed, only 3 [27,31,33] exclusively targeted children, focusing on those aged 13 years and older, likely due to usability challenges for younger children [58,60-62]. This is the case despite the review's specific focus on educational interventions for children with CHD. The concept that "children are not small adults" is widely acknowledged in pediatric care. It emphasizes that children represent a unique population with their own culture, norms, and complexities [63-65]. This understanding underscores the necessity for developing more inclusive and age-appropriate educational interventions for younger children with CHD.

Limited Engaging Strategies

Among the reviewed studies, 3D modeling emerged as a prominent strategy for educating pediatric patients and their families about CHD [28,33,37]. This approach offers engaging learning and improves communication between families and health care providers. However, despite its interactivity, 3D modeling and the other 5 strategies examined in this review lack engaging, playful interactions. Earlier educational tools, such as videotape presentations featuring friendly and playful characters like a fictional lion, effectively engaged young patients by making complex medical procedures more understandable and less intimidating through storytelling [35].

Playful strategies naturally engage children and facilitate learning through play. By communicating complex health information in an age-appropriate and engaging manner, they make a painful and tedious subject more approachable. In the 1920s, nurses Nightingale and Erikson first recognized the importance of systematizing play sessions to improve children's hospitalization experience and adherence to medical procedures [66-73]. Since then, strategies like pretend play [74,75] and serious games [76,77] have been used for chronic care management, educating children about their conditions, and helping them manage their fears. However, these strategies are rarely used for children with CHD. The evolution of educational interventions from videotape presentations in 1982 to patient-specific 3D printing indicates significant technological advancements. Integrating engaging and playful approaches into current interventions could substantially boost their effectiveness by involving children directly in their health care journey through their own language: play.

XSL•FO
RenderX

Enhancing Methodological Approaches

The majority of the reviewed studies used RCTs [27-32,34-36], reflecting robust methodologies for evaluating educational interventions for children with CHD. However, except for 1 [33], many studies primarily assessed parental outcomes as proxies without adequately evaluating specific outcomes for pediatric patients themselves [28-30,32,34-37]. This highlights a gap in HL measures tailored for children with CHD. While parental involvement is essential, directly assessing children's HL, coping mechanisms, and overall well-being is equally vital.

One notable strength of these studies was the involvement of various stakeholders in intervention delivery, including pediatric patients, parents or caregivers, and health care providers. Eight studies involved all stakeholders, ensuring a comprehensive approach [27,29-32,35-37]. Nevertheless, there is a need for more extensive engagement, particularly with pediatric patients, throughout the intervention's ideation, design, and implementation phases. Early involvement of stakeholders, including children as design partners, enhances the integration of interventions into routine care, ensuring practicality, feasibility, and alignment with clinical needs [58,78-82].

While most studies used questionnaires supplemented by qualitative feedback, there is a major focus on quantitative approaches. Incorporating more qualitative studies in the initial stages could help identify challenges, barriers, and desires more effectively. Unlike quantitative methods, qualitative methods aim to explore, narrate, and explain phenomena, making sense of complex realities. Health interventions could develop as an outcome of qualitative research [83,84]. Statistical analyses were diverse, with the independent samples *t* test being the most commonly used method, typically involving defined objectives and pre- and postassessment measures. Despite the rigorous methodologies, there was a lack of long-term longitudinal studies to assess the sustained effectiveness of the interventions [85]. Most studies had follow-up periods ranging from 1 month to 1 year, with only 1 study extending to 24 months [30]. This highlights the need for future research to include extended follow-up periods to understand the long-term impact of educational interventions on children with CHD and their families.

By addressing these methodological gaps and expanding stakeholder engagement, particularly with pediatric patients, we can enhance the effectiveness of health educational interventions. Designers, health care providers, and policymakers should prioritize developing and implementing solutions with all stakeholders, not just for them. This collaborative approach can enhance care quality, coordination, and outcomes for children, families, and health care providers.

One effective strategy is to integrate engaging learning tools—both digital and physical—through play. For example, a playful, educational toy similar to Rufus the Bear with Diabetes (Empath Labs), used in diabetes education, can help children manage their health. A comparable toy featuring a simplified heart model allows children to explore their anatomy and medical routines through hands-on play, making complex concepts more accessible. Designed to meet developmental needs, these tools can reduce anxiety, foster independence, and help children manage fears through pretend play. By prioritizing children's needs rather than relying on parents to convey information, we ensure that health information remains relatable and engaging. Ultimately, these child-led strategies empower families to build the knowledge and resilience necessary for effectively managing CHD. Such efforts could improve health outcomes during the transition to adulthood, enhance autonomy in managing CHD, and streamline education and health care delivery.

Limitations

This scoping review has offered valuable insights but has limitations. First, the search was limited to English-language publications, which may have excluded relevant studies published in other languages. Second, despite efforts to conduct a comprehensive search, it is possible that some relevant studies were missed, thus introducing selection bias. Finally, the inclusion criteria were restricted to published peer-reviewed studies, which means that relevant gray literature and unpublished studies were excluded, introducing publication bias. It is essential to consider these limitations while interpreting the findings of this scoping review. Additionally, the limited number of studies meeting the inclusion criteria highlights the scarcity of research that focuses specifically on educational interventions for children with CHD. Moreover, the variability in study designs, intervention types, outcome measures, and follow-up periods across the included studies has limited the ability to conduct a meta-analysis and draw definitive conclusions about the effectiveness of educational interventions for children with CHD.

Research Directions

Educational interventions have shown promise in enhancing the quality of life, self-management skills, and knowledge of children with CHD and their families. However, there is a pressing need for further research to develop and evaluate HL-focused pediatric care interventions tailored specifically for patients with CHD younger than 13 years of age. Drawing from successful interventions in this review, such as the approach by Uzark et al [35] that engaged both pediatric patients and parents to enhance understanding and coping during hospitalization, offers a promising framework for younger children with CHD. This playful approach significantly improved HL, empowerment, and self-management skills. While this study focused exclusively on children with CHD and health educational interventions, future research could draw insights from playful interventions designed for other pediatric conditions like cystic fibrosis and diabetes. As part of our multiphase research project, this comparative approach will inform the iterative development of our health education intervention for younger children with CHD and their families.

Additionally, since no studies included in this review used qualitative approaches such as co-design, our research would prioritize integrating such methodologies to involve all stakeholders, including children, early on. This would enhance the relevance and effectiveness of the interventions. Acknowledging challenges and working with all stakeholders toward finding solutions is essential, as simply ignoring the problem will not lead to progress. Involving children as design

XSL•FO
RenderX

partners, despite all the barriers, can ensure that the interventions are engaging, relevant, and effective in meeting the unique needs of children with CHD.

Conclusions

Educational interventions promise to enhance the quality of life, self-management skills, and knowledge of children with CHD and their families. However, insufficient evidence to support educational interventions for this pediatric population highlights a significant gap in the literature. While this scoping review aimed to identify these gaps, the scarcity of evidence highlights the need for further research. Advocating for such research is crucial to guide designers, health care providers, and policymakers in delivering effective interventions tailored to the specific needs of children with CHD. There is a clear need for more research explicitly addressing pediatric care interventions for children with CHD, focusing on developing age-appropriate, engaging, and engaging educational interventions. Improving HL in pediatric patients can reduce parental educational burden and increase health care provider efficiency by improving communication and patient empowerment.

Acknowledgments

The authors gratefully acknowledge the funding provided by the Kusske Design Initiative and Dr Gwenyth Fischer, MD. The authors sincerely appreciate Dr Mary Butler from the Department of Public Health at the University of Minnesota, Twin Cities, for the thoughtful insights and feedback.

Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) checklist.
[DOCX File , 109 KB - pediatrics_v8i1e64814_app1.docx]

Multimedia Appendix 2
Search strategy.
[DOCX File , 23 KB - pediatrics_v8i1e64814_app2.docx]

Multimedia Appendix 3
Study characteristics.
[DOCX File , 354 KB - pediatrics_v8i1e64814_app3.docx]

Multimedia Appendix 4
Excluded full-text studies.
[DOCX File , 34 KB - pediatrics_v8i1e64814_app4.docx]

References

1. Data and statistics on congenital heart defects. Centers for Disease Control and Prevention. URL: https://www.cdc.gov/heart-defects/data/index.html [accessed 2023-09-22]
2. Chong LSH, Fitzgerald DA, Craig JC, Manera KE, Hanson CS, Celermajer D, et al. Children's experiences of congenital heart disease: a systematic review of qualitative studies. Eur J Pediatr 2018;177(3):319-336. [doi: 10.1007/s00431-017-3081-y] [Medline: 29327140]
3. Liu C, Wang D, Liu C, Jiang J, Wang X, Chen H, et al. What is the meaning of health literacy? A systematic review and qualitative synthesis. Fam Med Community Health 2020;8(2):e000351 [FREE Full text] [doi: 10.1136/fmch-2020-000351] [Medline: 32414834]
4. Lee A, Bailey B, Cullen-Dean G, Aiello S, Morin J, Oechslin E. Transition of care in congenital heart disease: ensuring the proper handoff. Curr Cardiol Rep 2017;19(6):55. [doi: 10.1007/s11886-017-0859-5] [Medline: 28477319]
5. van der Linde D, Konings EEM, Slager MA, Witsenburg M, Helbing WA, Takkenberg JJM, et al. Birth prevalence of congenital heart disease worldwide: a systematic review and meta-analysis. J Am Coll Cardiol 2011;58(21):2241-2247 [FREE Full text] [doi: 10.1016/j.jacc.2011.08.025] [Medline: 22078432]
6. Lopez KN, Morris SA, Sexson Tejtel SK, Espaillat A, Salemi JL. US mortality attributable to congenital heart disease across the lifespan from 1999 through 2017 exposes persistent racial/ethnic disparities. Circulation 2020;142(12):1132-1147 [FREE Full text] [doi: 10.1161/CIRCULATIONAHA.120.046822] [Medline: 32795094]

XSL•FO
RenderX

7. Liu Y, Chen S, Zühlke L, Black GC, Choy M, Li N, et al. Global birth prevalence of congenital heart defects 1970-2017: updated systematic review and meta-analysis of 260 studies. Int J Epidemiol 2019;48(2):455-463 [FREE Full text] [doi: 10.1093/ije/dyz009] [Medline: 30783674]
8. Boneva RS, Botto LD, Moore CA, Yang Q, Correa A, Erickson JD. Mortality associated with congenital heart defects in the United States: trends and racial disparities, 1979-1997. Circulation 2001;103(19):2376-2381. [doi: 10.1161/01.cir.103.19.2376] [Medline: 11352887]
9. Lawrence PR, Feinberg I, Spratling R. The relationship of parental health literacy to health outcomes of children with medical complexity. J Pediatr Nurs 2021;60:65-70. [doi: 10.1016/j.pedn.2021.02.014] [Medline: 33621896]
10. Burns J, Higgins C, Ganigara M, Kalivas B, Basken A. Health literacy in CHD. Cardiol Young 2022:1-4. [doi: 10.1017/S1047951122001020] [Medline: 35611812]
11. Veldtman GR, Matley SL, Kendall L, Quirk J, Gibbs JL, Parsons JM, et al. Illness understanding in children and adolescents with heart disease. Heart 2000;84(4):395-397 [FREE Full text] [doi: 10.1136/heart.84.4.395] [Medline: 10995408]
12. Rodts ME, Unaka NI, Statile CJ, Madsen NL. Health literacy and caregiver understanding in the CHD population. Cardiol Young 2020;30(10):1439-1444. [doi: 10.1017/S1047951120002243] [Medline: 32746956]
13. Goossens E, Fieuws S, Van Deyk K, Luyckx K, Gewillig M, Budts W, et al. Effectiveness of structured education on knowledge and health behaviors in patients with congenital heart disease. J Pediatr 2015;166(6):1370-1376.e1. [doi: 10.1016/j.jpeds.2015.02.041] [Medline: 25841537]
14. Moons P, De Volder E, Budts W, De Geest S, Elen J, Waeytens K, et al. What do adult patients with congenital heart disease know about their disease, treatment, and prevention of complications? A call for structured patient education. Heart 2001;86(1):74-80 [FREE Full text] [doi: 10.1136/heart.86.1.74] [Medline: 11410567]
15. Steckler A, Allegrante JP, Altman D, Brown R, Burdine JN, Goodman RM, et al. Health education intervention strategies: recommendations for future research. Health Educ Q 1995;22(3):307-328. [doi: 10.1177/109019819402200305] [Medline: 7591787]
16. Watkins S, Isichei O, Gentles TL, Brown R, Percival T, Sadler L, et al. What is known about critical congenital heart disease diagnosis and management experiences from the perspectives of family and healthcare providers? A systematic integrative literature review. Pediatr Cardiol 2023;44(2):280-296 [FREE Full text] [doi: 10.1007/s00246-022-03006-8] [Medline: 36125507]
17. Wei H, Roscigno CI, Hanson CC, Swanson KM. Families of children with congenital heart disease: a literature review. Heart Lung 2015;44(6):494-511. [doi: 10.1016/j.hrtlng.2015.08.005] [Medline: 26404115]
18. Cocomello L, Dimagli A, Biglino G, Cornish R, Caputo M, Lawlor DA. Educational attainment in patients with congenital heart disease: a comprehensive systematic review and meta-analysis. BMC Cardiovasc Disord 2021;21(1):549 [FREE Full text] [doi: 10.1186/s12872-021-02349-z] [Medline: 34798837]
19. Jackson AC, Frydenberg E, Liang RPT, Higgins RO, Murphy BM. Familial impact and coping with child heart disease: a systematic review. Pediatr Cardiol 2015;36(4):695-712. [doi: 10.1007/s00246-015-1121-9] [Medline: 25618163]
20. Lumsden MR, Smith DM, Wittkowski A. Coping in parents of children with congenital heart disease: a systematic review and meta-synthesis. J Child Fam Stud 2019;28(7):1736-1753. [doi: 10.1007/s10826-019-01406-8]
21. Eagleson KJ, McCombs D, Gerlich TM, Justo RN, Kasparian NA, Bora S. Systematic review of instruments assessing psychosocial adaptation and outcomes among families of children with congenital heart disease. J Pediatr Psychol 2023;48(6):537-552 [FREE Full text] [doi: 10.1093/jpepsy/jsad015] [Medline: 37221700]
22. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. BMC Med Res Methodol 2018;18(1):143. [doi: 10.1186/s12874-018-0611-x] [Medline: 30453902]
23. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med 2018;169(7):467-473 [FREE Full text] [doi: 10.7326/M18-0850] [Medline: 30178033]
24. Levac D, Colquhoun H, O'Brien KK. Scoping studies: advancing the methodology. Implement Sci 2010;5:69 [FREE Full text] [doi: 10.1186/1748-5908-5-69] [Medline: 20854677]
25. PRISMA for Scoping Reviews (PRISMA-ScR). PRISMA Statement. URL: https://www.prisma-statement.org/scoping [accessed 2024-04-28]
26. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009;6(7):e1000097 [FREE Full text] [doi: 10.1371/journal.pmed.1000097] [Medline: 19621072]
27. Amedro P, Gavotto A, Legendre A, Lavastre K, Bredy C, De La Villeon G, et al. Impact of a centre and home-based cardiac rehabilitation program on the quality of life of teenagers and young adults with congenital heart disease: the QUALI-REHAB study rationale, design and methods. Int J Cardiol 2019;283:112-118. [doi: 10.1016/j.ijcard.2018.12.050] [Medline: 30616811]
28. Biglino G, Capelli C, Wray J, Schievano S, Leaver LK, Khambadkone S, et al. 3D-manufactured patient-specific models of congenital heart defects for communication in clinical practice: feasibility and acceptability. BMJ Open 2015;5(4):e007165 [FREE Full text] [doi: 10.1136/bmjopen-2014-007165] [Medline: 25933810]

XSL•FO
RenderX

29. Etnel JRG, van Dijk APJ, Kluin J, Bertels RA, Utens EMWJ, van Galen E, et al. Development of an online, evidence-based patient information portal for congenital heart disease: a pilot study. Front Cardiovasc Med 2017;4:1-7 [FREE Full text] [doi: 10.3389/fcvm.2017.00025]
30. Karikoski E, Sarkola T, Blomqvist M. Early counseling to improve oral health behavior in children with major congenital heart defects: a randomized controlled trial. Caries Res 2023;57(5-6):563-574. [doi: 10.1159/000531817] [Medline: 37442113]
31. Klausen SH, Andersen LL, Søndergaard L, Jakobsen JC, Zoffmann V, Dideriksen K, et al. Effects of eHealth physical activity encouragement in adolescents with complex congenital heart disease: the PReVaiL randomized clinical trial. Int J Cardiol 2016;221:1100-1106. [doi: 10.1016/j.ijcard.2016.07.092] [Medline: 27448540]
32. Lemire O, Yaraskavitch J, Lougheed J, Mackie AS, Norozi K, Graham J, et al. Impacting child health outcomes in congenital heart disease: cluster randomized controlled trial protocol of in-clinic physical activity counselling. Contemp Clin Trials 2020;91:105994. [doi: 10.1016/j.cct.2020.105994] [Medline: 32222326]
33. Liddle D, Balsara S, Hamann K, Christopher A, Olivieri L, Loke YH. Combining patient-specific, digital 3D models with tele-education for adolescents with CHD. Cardiol Young 2022;32(6):912-917. [doi: 10.1017/S1047951121003243] [Medline: 34392874]
34. Ni Z, Chao Y, Xue X. An empowerment health education program for children undergoing surgery for congenital heart diseases. J Child Health Care 2016;20(3):354-364. [doi: 10.1177/1367493515587057] [Medline: 26105060]
35. Uzark K, Klos D, Davis W, Rosenthal A. Use of videotape in the preparation of children for cardiac catheterization. Pediatr Cardiol 1982;3(4):287-291. [doi: 10.1007/BF02427029] [Medline: 7163015]
36. van der Mheen M, van Beynum IM, Dulfer K, van der Ende J, van Galen E, Duvekot J, et al. The CHIP-Family study to improve the psychosocial wellbeing of young children with congenital heart disease and their families: design of a randomized controlled trial. BMC Pediatr 2018;18(1):230 [FREE Full text] [doi: 10.1186/s12887-018-1183-y] [Medline: 30001701]
37. Zablah JE, Rodriguez SA, Lorenz A, Morgan GJ. Cardiac catheterization laboratory and the role in effective patient education: a model approach. Prog Pediatr Cardiol 2021;63:101396. [doi: 10.1016/j.ppedcard.2021.101396]
38. Braun V, Clarke V. Thematic analysis. In: Cooper H, Camic PM, Long DL, Panter AT, Rindskopf D, Sher KJ, editors. APA Handbook of Research Methods in Psychology, Vol. 2. Research Designs: Quantitative, Qualitative, Neuropsychological, and Biological. Washington, DC: American Psychological Association; 2012.
39. Creswell JW, Poth CN. Qualitative Inquiry and Research Design: Choosing Among Five Approaches. Washington, DC: SAGE Publications; 2016.
40. Levert EM, Helbing WA, Dulfer K, van Domburg RT, Utens EMWJ. Psychosocial needs of children undergoing an invasive procedure for a CHD and their parents. Cardiol Young 2017;27(2):243-254. [doi: 10.1017/S1047951116000391] [Medline: 27055357]
41. Shin JY, Kedroske J, Vue R, Sankaran R, Chaar D, Churay T, et al. Design considerations for family-centered health management: preliminary findings with pediatric BMT patients. 2018 Presented at: Proceedings of the 17th ACM Conference on Interaction Design and Children; June 19-22, 2018; Trondheim, Norway p. 593-598 URL: https://dl.acm.org/doi/10.1145/3202185.3210781
42. Shin JY, Choi SW. Online interventions geared toward increasing resilience and reducing distress in family caregivers. Curr Opin Support Palliat Care 2020;14(1):60-66 [FREE Full text] [doi: 10.1097/SPC.0000000000000481] [Medline: 31842019]
43. Shin JY, Holtz BE. Towards better transitions for children with diabetes: user experiences on a mobile health app. 2019 Presented at: Proceedings of the 18th ACM International Conference on Interaction Design and Children; June 12-15, 2019; Boise, ID, United States p. 623-628 URL: https://dl.acm.org/doi/10.1145/3311927.3325319
44. Su Z. Caring for children's health and wellbeing through understanding and designing for health data literacy. 2023 Presented at: Proceedings of the 22nd Annual ACM Interaction Design and Children Conference; June 19-23, 2023; Chicago, IL, United States p. 785-788 URL: https://dl.acm.org/doi/10.1145/3585088.3593922
45. Soltero EG, Lopez C, Hernandez E, O'Connor TM, Thompson D. Technology-based obesity prevention interventions among Hispanic adolescents in the United States: scoping review. JMIR Pediatr Parent 2022;5(4):e39261 [FREE Full text] [doi: 10.2196/39261] [Medline: 36331547]
46. Chomutare T, Johansen SG, Hartvigsen G, Årsand E. Serious game co-design for children with type 1 diabetes. Stud Health Technol Inform 2016;226:83-86. [Medline: 27350472]
47. Kulandaivelu Y, Hamilton J, Banerjee A, Gruzd A, Patel B, Stinson J. Social media interventions for nutrition education among adolescents: scoping review. JMIR Pediatr Parent 2023;6:e36132 [FREE Full text] [doi: 10.2196/36132] [Medline: 37471119]
48. Milne-Ives M, Lam C, Meinert E. Digital technologies for monitoring and improving treatment adherence in children and adolescents with asthma: scoping review of randomized controlled trials. JMIR Pediatr Parent 2021;4(3):e27999 [FREE Full text] [doi: 10.2196/27999] [Medline: 34533463]
49. Bird M, Li L, Ouellette C, Hopkins K, McGillion MH, Carter N. Use of synchronous digital health technologies for the care of children with special health care needs and their families: scoping review. JMIR Pediatr Parent 2019;2(2):e15106 [FREE Full text] [doi: 10.2196/15106] [Medline: 31750840]

XSL•FO
RenderX

50. Novak D. A serious game (MyDiabetic) to support children's education in type 1 diabetes mellitus: iterative participatory co-design and feasibility study. JMIR Serious Games 2024;12:e49478 [FREE Full text] [doi: 10.2196/49478] [Medline: 38713496]
51. Eiser C, Patterson D, Tripp JH. Illness experience and children's concepts of health and illness. Child Care Health Dev 1984;10(3):157-162. [doi: 10.1111/j.1365-2214.1984.tb00174.x] [Medline: 6478544]
52. Eiser C, Town C, Tripp JH. Illness experience and related knowledge amongst children with asthma. Child Care Health Dev 1988;14(1):11-24. [doi: 10.1111/j.1365-2214.1988.tb00560.x] [Medline: 3359563]
53. Wang Q, Hay M, Clarke D, Menahem S. Associations between knowledge of disease, depression and anxiety, social support, sense of coherence and optimism with health-related quality of life in an ambulatory sample of adolescents with heart disease. Cardiol Young 2014;24(1):126-133. [doi: 10.1017/S1047951113000012] [Medline: 23402427]
54. Bray L, Sharpe A, Gichuru P, Fortune P, Blake L, Appleton V. The acceptability and impact of the Xploro digital therapeutic platform to inform and prepare children for planned procedures in a hospital: before and after evaluation study. J Med Internet Res 2020;22(8):e17367 [FREE Full text] [doi: 10.2196/17367] [Medline: 32780025]
55. Hölgyesi Á, Luczay A, Tóth-Heyn P, Muzslay E, Világos E, Szabó AJ, et al. The impact of parental electronic health literacy on disease management and outcomes in pediatric type 1 diabetes mellitus: cross-sectional clinical study. JMIR Pediatr Parent 2024;7:e54807 [FREE Full text] [doi: 10.2196/54807] [Medline: 38506893]
56. Sakamoto M, Ishikawa H, Suzuki A. Evaluation of parents' use of a child health care information app and their health literacy: cross-sectional study. JMIR Pediatr Parent 2024;7:e48478 [FREE Full text] [doi: 10.2196/48478] [Medline: 38623727]
57. Vang PC, Lauff CA. Reflections on data collection during toy prototype development in a design studio course. 2024 Presented at: Proceedings of the 23rd Annual ACM Interaction Design and Children Conference; June 17-20, 2024; Delft, Netherlands p. 940-944 URL: https://dl.acm.org/doi/10.1145/3628516.3659422
58. Banker A, Lauff C. Usability testing with children: History of best practices, comparison of methods and gaps in literature. 2022 Presented at: DRS Biennal Conference Series 2022; June 25-July 3, 2022; Bilbao, Spain URL: https://doi.org/10.21606/drs.2022.646
59. Koutná V, Blatný M, Jelínek M. Concordance of child self-reported and parent proxy-reported posttraumatic growth in childhood cancer survivors. Cancers (Basel) 2021;13(16):4230 [FREE Full text] [doi: 10.3390/cancers13164230] [Medline: 34439384]
60. Bradbury-Jones C, Taylor J. Engaging with children as co-researchers: challenges, counter-challenges and solutions. Int J Soc Res Methodol 2013;18(2):161-173. [doi: 10.1080/13645579.2013.864589]
61. Committee on the Science of Children Birth to Age 8: Deepening and Broadening the Foundation for Success, Board on Children, Youth, and Families, Institute of Medicine; National Research Council. In: Allen L, Kelly BB, editors. Transforming the Workforce for Children Birth Through Age 8: A Unifying Foundation. Washington, DC: National Academies Press; 2015.
62. Shepard L, Kagan S, Wurtz E. Principles and recommendations for early childhood assessments. National Education Goals Panel. 1998. URL: https://eric.ed.gov/?id=ED416033 [accessed 2024-03-16]
63. Gillis J, Loughlan P. Not just small adults: the metaphors of paediatrics. Arch Dis Child 2007;92(11):946-947 [FREE Full text] [doi: 10.1136/adc.2007.121087] [Medline: 17954476]
64. Larcher V. Children are not small adults: significance of biological and cognitive development in medical practice. In: Schramme T, Edwards S, editors. Handbook of the Philosophy of Medicine. Dordrecht: Springer Netherlands; 2015:23-94.
65. Druin A. The role of children in the design of new technology. Behav Inf Technol 2001;21(1):1-35 [FREE Full text] [doi: 10.1080/01449290110108659]
66. Gjærde LK, Hybschmann J, Dybdal D, Topperzer MK, Schrøder MA, Gibson JL, et al. Play interventions for paediatric patients in hospital: a scoping review. BMJ Open 2021;11(7):e051957 [FREE Full text] [doi: 10.1136/bmjopen-2021-051957] [Medline: 34312210]
67. Carrington L, Hale L, Freeman C, Smith D, Perry M. The effectiveness of play as an intervention using International Classification of Functioning outcome measures for children with disabilities—a systematic review and meta-synthesis. Disabil Rehabil 2024;46(17):3827-3848. [doi: 10.1080/09638288.2023.2259305] [Medline: 37750218]
68. Díaz-Rodríguez M, Alcántara-Rubio L, Aguilar-García D, Pérez-Muñoz C, Carretero-Bravo J, Puertas-Cristóbal E. The effect of play on pain and anxiety in children in the field of nursing: a systematic review. J Pediatr Nurs 2021;61:15-22. [doi: 10.1016/j.pedn.2021.02.022] [Medline: 33711642]
69. Gibson JL, Pritchard E, de Lemos C. Play-based interventions to support social and communication development in autistic children aged 2-8 years: a scoping review. Autism Dev Lang Impair 2021;6:23969415211015840 [FREE Full text] [doi: 10.1177/23969415211015840] [Medline: 36381525]
70. Li WHC, Chung JOK, Ho KY, Kwok BMC. Play interventions to reduce anxiety and negative emotions in hospitalized children. BMC Pediatr 2016;16:36 [FREE Full text] [doi: 10.1186/s12887-016-0570-5] [Medline: 26969158]
71. Nijhof SL, Vinkers CH, van Geelen SM, Duijff SN, Achterberg EJM, van der Net J, et al. Healthy play, better coping: the importance of play for the development of children in health and disease. Neurosci Biobehav Rev 2018;95:421-429 [FREE Full text] [doi: 10.1016/j.neubiorev.2018.09.024] [Medline: 30273634]

XSL•FO
RenderX

72. Perasso G, Camurati G, Morrin E, Dill C, Dolidze K, Clegg T, et al. Five reasons why pediatric settings should integrate the play specialist and five issues in practice. Front Psychol 2021;12:687292 [FREE Full text] [doi: 10.3389/fpsyg.2021.687292] [Medline: 34267710]
73. de Jong NB, Elzinga-Plomp A, Hulzebos EH, Poppe R, Nijhof SL, van Geelen S. Coping with paediatric illness: child's play? Exploring the effectiveness of a play- and sports-based cognitive behavioural programme for children with chronic health conditions. Clin Child Psychol Psychiatry 2020;25(3):565-578 [FREE Full text] [doi: 10.1177/1359104520918327] [Medline: 32508158]
74. Moore M, Russ SW. Pretend play as a resource for children: implications for pediatricians and health professionals. J Dev Behav Pediatr 2006;27(3):237-248. [doi: 10.1097/00004703-200606000-00011] [Medline: 16775523]
75. Di Riso D, Cambrisi E, Bertini S, Miscioscia M. Associations between pretend play, psychological functioning and coping strategies in pediatric chronic diseases: a cross-illness study. Int J Environ Res Public Health 2020;17(12):4364 [FREE Full text] [doi: 10.3390/ijerph17124364] [Medline: 32570747]
76. Holtz BE, Murray K, Park T. Serious games for children with chronic diseases: a systematic review. Games Health J 2018;7(5):291-301. [doi: 10.1089/g4h.2018.0024] [Medline: 29957082]
77. Wang Y, Wang Z, Liu G, Wang Z, Wang Q, Yan Y, et al. Application of serious games in health care: scoping review and bibliometric analysis. Front Public Health 2022;10:896974 [FREE Full text] [doi: 10.3389/fpubh.2022.896974] [Medline: 35757619]
78. Litwin S, Clarke L, Copeland J, Tyrrell J, Tait C, Mohabir V, et al. Designing a child-, family-, and healthcare provider-centered procedure room in a tertiary care children's hospital. HERD 2023;16(3):195-209 [FREE Full text] [doi: 10.1177/19375867231161097] [Medline: 37021379]
79. Bird M, McGillion M, Chambers EM, Dix J, Fajardo CJ, Gilmour M, et al. A generative co-design framework for healthcare innovation: development and application of an end-user engagement framework. Res Involv Engagem 2021;7(1):12 [FREE Full text] [doi: 10.1186/s40900-021-00252-7] [Medline: 33648588]
80. Saiger MJ. How do we engage children and young people in the design and development of mental health games. 2023 Presented at: Proceedings of the 22nd Annual ACM Interaction Design and Children Conference; June 19-23, 2023; Chicago, IL, United States p. 756-759 URL: https://dl.acm.org/doi/10.1145/3585088.3593921
81. Weightman A, Preston N, Holt R, Allsop M, Levesley M, Bhakta B. Engaging children in healthcare technology design: developing rehabilitation technology for children with cerebral palsy. J Eng Des 2009;21(5):579-600. [doi: 10.1080/09544820802441092]
82. Thabrew H, Fleming T, Hetrick S, Merry S. Co-design of eHealth interventions with children and young people. Front Psychiatry 2018;9:481 [FREE Full text] [doi: 10.3389/fpsyt.2018.00481] [Medline: 30405450]
83. Verhoef MJ, Casebeer AL. Broadening horizons: integrating quantitative and qualitative research. Can J Infect Dis 1997;8(2):65-66 [FREE Full text] [doi: 10.1155/1997/349145] [Medline: 22514478]
84. Renjith V, Yesodharan R, Noronha JA, Ladd E, George A. Qualitative methods in health care research. Int J Prev Med 2021;12:20 [FREE Full text] [doi: 10.4103/ijpvm.IJPVM_321_19] [Medline: 34084317]
85. Caruana EJ, Roman M, Hernández-Sánchez J, Solli P. Longitudinal studies. J Thorac Dis 2015;7(11):E537-E540 [FREE Full text] [doi: 10.3978/j.issn.2072-1439.2015.10.63] [Medline: 26716051]

Abbreviations

CHD: congenital heart disease
HL: health literacy
KQ: key question
PICOTS: population, intervention, comparator, outcome, timing, and setting
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
RCT: randomized controlled trial

Edited by S Badawy; submitted 26.07.24; peer-reviewed by Y Yang; comments to author 20.09.24; revised version received 04.11.24; accepted 28.11.24; published 24.01.25.

Please cite as:
Barbazi N, Shin JY, Hiremath G, Lauff CA
Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review
JMIR Pediatr Parent 2025;8:e64814
URL: https://pediatrics.jmir.org/2025/1/e64814
doi:10.2196/64814
PMID:

XSL•FO
RenderX

©Neda Barbazi, Ji Youn Shin, Gurumurthy Hiremath, Carlye Anne Lauff. Originally published in JMIR Pediatrics and Parenting (https://pediatrics.jmir.org), 24.01.2025. This is an open-access article distributed under the terms of the Creative Commons Attribution License (https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR Pediatrics and Parenting, is properly cited. The complete bibliographic information, a link to the original publication on https://pediatrics.jmir.org, as well as this copyright and license information must be included.

XSL•FO
RenderX

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org

XSL•FO
RenderX