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Original Paper

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

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Abstract

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

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

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

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

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

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KEYWORDS

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

Introduction

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

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

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

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

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

Methods

Study Context- Use of the My Baby Now App

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

Study Design

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

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Recruitment

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

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

Data Collection

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

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

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

Data Analysis

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

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

Researcher Reflexivity and Credibility

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

Ethical Considerations

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

Results

Participants

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

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

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

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

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

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

[a]Technical and further education.

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

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

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

Theme 1: Previous Information Seeking

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

Theme 2: Functionality of the My Baby Now App

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

Theme 3: Engagement With the My Baby Now App

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

Theme 4: Aesthetics of the My Baby Now App

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

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

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

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

Discussion

Principal Findings

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

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

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

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

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

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

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

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

Strengths and Limitations

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

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

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

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

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Data Availability

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

Authors' Contributions

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

Conflicts of Interest

None declared.

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

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Abbreviations

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

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Implementing Diabetes Distress Screening in a Pediatric Endocrinology Clinic Using a Digital Health Platform: Quantitative Secondary Data Analysis

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Abstract

Background: Type 1 diabetes (T1D) management requires following a complex and constant regimen relying on child or caregiver behaviors, skills, and knowledge. Psychological factors such as diabetes distress (DD), depression, and burnout are pertinent considerations in the treatment of pediatric T1D. Approximately 40% of youth and 61% of caregivers experience DD. Implementation of DD screening as part of clinical best practice is recommended and may facilitate treatment referral, perhaps leading to improved health or well-being for youth with T1D and their caregivers. By building on existing institutional infrastructure when available, screening via digital health platforms (applications, or "apps") may allow for timely screening of, and response to, DD.

Objective: This work details the creation, implementation, and refinement of a process to screen for DD in youth and their caregivers in the context of routine T1D care using a digital health platform.

Methods: DD screening was implemented in an outpatient endocrinology clinic over 1 year as part of a larger screen-to-treat trial for children aged 8 - 12.99 years and their caregivers. Validated measures were sent via digital health platform to be completed prior to the clinic visit. Results were initially reviewed manually, but a digital best practice alert (BPA) was later built to notify staff of elevated scores. Families experiencing DD received resources sent via the digital health platform. For this secondary analysis, child demographics and glycated hemoglobin A_{1c} (HbA_{1c}) were collected.

Results: During the screening period, absolute completion rates were 36.78% and 38.83%, with adjusted screening rates at 52.02% and 54.48%, for children and caregivers, respectively. A total of 21 children (mean HbA_{1c} 8.04%, SD 1.39%) and 26 caregivers (child mean HbA_{1c} 8.04%, SD 1.72%) reported elevated DD. Prior to BPA development, resources were sent to all but 1 family. After BPA implementation, all families were sent resources.

Conclusions: Early findings indicate that DD education, screening, and response can be integrated via digital platforms in a freestanding outpatient endocrinology clinic, thereby facilitating timely treatment referral and provision of resources for those identified with distress. Notably, in the observed 1-year screening period, screening rates were low, and barriers to implementation were identified. While some implementation challenges were iteratively addressed, there is a need for future quality improvement initiatives to improve screening rates and the identification of, or response to, DD in our pediatric patients and their families.

Trial Registration: ClinicalTrials.gov NCT05268250; https://clinicaltrials.gov/study/NCT05268250

(JMIR Pediatr Parent 2025;8:e65107) doi:10.2196/65107

KEYWORDS

type 1 diabetes; diabetes mellitus, type 1; pediatric; child; children; youth; parents; diabetes distress; eHealth; screening; digital health; diabetes; diabetic; type 1; DM; T1D; endocrinology; alert; best practice alert; BPA; patient education

Introduction

Rates of type 1 diabetes (T1D) in youth aged 19 years or younger have been increasing in recent years, from approximately 1.48 per 1000 youth in 2001 to 2.15 per 1000 youth in 2017 [1]. Rates increased at the highest levels in non-Hispanic White and non-Hispanic Black children [1]. Health-promoting management of T1D requires following a complex and constant treatment regimen with tasks relying on child and caregiver behaviors, skills, and knowledge [2]. Given the complexity and constancy of diabetes management, it is not surprising that psychological factors such as distress, depression, anxiety, and burnout are highlighted as pertinent to consider in the management of pediatric T1D [2-4].

Diabetes distress (DD) is the "emotional distress that results from living with diabetes and the burden of relentless daily

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self-management" that can be seen across the life span, as well as in caregivers of those with diabetes [5]. It occurs at rates of approximately 25% in adults with T1D [6]. In children aged 8 - 12 years, as many as 40% of youth and 61% of their parents or caregivers experience at least some DD [7]. Notably, DD is occurring at higher rates, on average, than depression in pediatric populations with diabetes [8,9]. Increased levels of DD relate to deficits in diabetes self-management behaviors, increased glycated hemoglobin A_{1c} (HbA_{1c}), and negative impacts on mental health and well-being [4,6]. DD differs from burnout, defined as the physical or emotional exhaustion associated with continuous DD and management needs, and depression, although these can co-occur [10,11]. Implementation of DD screening (and subsequently, treatment of DD) as part of clinical best practice may facilitate treatment referral and could lead to improved health and well-being for youth and their caregivers [6].

The American Diabetes Association (ADA) Standards of Care in Diabetes recommends DD screening starting at 8 years of age, with the parent, child, and adolescent versions of the Problem Areas in Diabetes (PAID) highlighted as validated assessment tools in this domain [2]. Similarly, the International Society for Pediatric and Adolescent Diabetes (ISPAD) recommends that age-appropriate and validated assessment tools be used routinely to monitor and guide conversations specific to the psychosocial well-being of all youth with diabetes as well as their caregivers [4]. Despite these recommendations, 1 recent publication reported that less than half of surveyed pediatric diabetes clinics screened for mental health problems of any kind using a validated tool [12]. In contrast, another survey of T1D exchange participants reported that 96% of pediatric centers included use at least 1 standardized measure of patient reported symptoms or needs. However, measures included in this study were more broadly inclusive of mental health, transition readiness, and structural determinants of health, among other domains, with <30% of centers reporting screening for DD [13].

In line with best practice recommendations, we sought to implement standardized DD screening for youth aged 8 - 12 years and their caregivers in an outpatient endocrinology clinic in a large, freestanding, pediatric medical center. Screening was completed using validated surveys sent prior to children's clinical visit via digital health platform. Thus, by building on existing infrastructure, it was possible to conduct DD screening and deliver a response to elevated scores using the institutional app, which we anticipated would be a highly scalable process.

Methods

Participants

This project occurred in the pediatric endocrinology clinic at Nemours Children's Health-Jacksonville, which serves more than 1000 children with T1D. The reported results focus on screening procedures initiated and tested from April 1, 2022, through March 31, 2023. Children eligible for screening were aged between 8 and 12.99 years, with any diagnosis of diabetes (broadly identified by visit type, because at the time of implementation, the system could not differentiate between T1D, type 2 diabetes, or another diabetes), and able to read and understand English. Adolescents aged 13 years and older were excluded from DD screening because they were already participating in another screening initiative at our institution (depression screening). Eligible parents or caregivers had a child who met the eligibility criteria, were signed up to use the Nemours app for health care management, and were able to read and understand English. The Nemours app is a stand-alone app created by the larger Nemours Children's Health system. Families were encouraged to sign up for this app beginning in August 2019 to access child health records, manage appointments, message providers, complete paperwork and payments, receive resources, and participate in telehealth visits. At the start of the screening period (April 2022), approximately 68% of families followed in the endocrinology clinic were signed up for the Nemours app, although this increased to 78% by month 12 (Table 1). Of note, 30.7% of families on average who started previsit questionnaires in the app (the "GetReady" process) did not complete their questionnaires and were able to attend clinic visits despite outstanding paperwork.

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Table . Application use data and completion of pre–check-in paperwork over 1-year implementation period.

	Month of screening implementation											
	1	2	3	4	5	6	7	8	9	10	11	12
Percentage of patients seen with active app accounts (enterprise-wide)	51.5	52.4	53.3	54.2	55.2	56.0	56.8	57.6	58.4	59.1	59.7	60.5
Percentage of patients seen with active app accounts (division/location-specific)	68.0	69.1	70.6	71.5	73.0	73.3	74.4	75.3	75.9	76.6	77.5	78.0
Percentage of appointments where GetReady was started but not completed (division/location-specific)	34.9	29.3	24.7	31.6	26.1	30.6	33.9	30.5	30.3	32.1	33.6	30.9

Ethical Considerations

Given the use of retrospective chart reviews for data collection, the authors obtained institutional review board approval (2057003) for secondary (exempt) research prior to the collection of data. The institutional review board determined based on the methods, proposed analyses, and the researcher's ability to work with deidentified data that informed consent or assent was not required for this project. Compensation was not provided as part of this secondary research.

Procedure

In line with standard of care recommendations from the ADA and ISPAD [2,4], and as part of a larger screen-to-treat trial, the pediatric endocrinology clinic at Nemours Children's Health-Jacksonville, implemented a screening program to detect symptoms of DD in school-aged children and their parents. The clinic used automated processes, a digital health platform, and validated screening tools to minimize any negative impact on clinic flow and to capitalize on the existing system for paperwork completion via the Nemours app. Per the screening protocol, the automated system assigned the DD screening tools to children, aged at least 8 years and younger than 13 years, with a visit type "Diabetes NP (new patient) w/Care Team" or "Diabetes FP (follow up patient) w/Care Team" and the clinic location in Jacksonville, Florida. Children and parents received the DD screeners every 6 months via the Nemours app "GetReady" feature along with other clinic surveys (eg, intake form) up to 10 days before their scheduled clinic visit. Regular reminders to complete paperwork were provided prior to the visit through an automated messaging system. Once completed, the Nemours app automatically scored the DD screeners and uploaded the screener results into the child's electronic health record (EHR). Initially, each week, a diabetes psychologist would manually review the completed DD screeners and send messages in the EHR to the visit provider when a child or parent had an elevated DD screen. Furthermore, for each elevated DD screen, the psychologist manually sent families a message via the EHR, which (1) thanked the family for completing screening; (2) defined and normalized DD; and (3) listed local resources including community diabetes groups and camps, web-based resources, relevant web pages, ways to access mental health services (including within their institution from psychology and social work providers), and information about the larger

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screen-to-treat DD trial so that families could reach out to learn more if interested. This resource list was created collaboratively between endocrinology physicians, psychologists, and a licensed clinical social worker assigned part-time to the endocrinology clinic. Eventually, to automate the process more fully, the clinic technology team built a best practice alert (BPA) into the EHR so that clinical providers associated with an upcoming visit and the diabetes psychologist would receive an automated alert flag for elevated DD scores. This feature made it possible for providers to engage in standard of care practices to address elevated DD screening results with families directly during the clinic visit and to include a resource list in their electronic after-visit summary. The psychologist also continued to review screening BPAs and send families a local resource list via an EHR message.

Measures

We selected 2 validated DD screening tools, the Problem Areas in Diabetes-Child (PAID-C) and the Parent Problem Areas in Diabetes-Child (P-PAID-C) to screen for child and parent symptoms of DD, respectively. The PAID-C is an 11-item survey of DD symptoms specifically designed and validated for children aged 8 - 12 years [7]. The PAID-C yields a total score that ranges from 11 to 66, with higher scores reflecting more distress. The P-PAID-C is a 16-item survey of DD symptoms specifically designed and validated for parents of school-aged children [7]. Like the child form, the P-PAID-C yields a single total score. The P-PAID-C total score can range from 16 to 96, and higher scores reflect more distress.

We collected child demographics (eg, age, biological sex, race, and ethnicity) and examined these within the larger eligible clinic population; the subpopulation who participated in the screening program; and the group who had elevated DD screening results. We also collected child HbA_{1c} levels from the visit associated with DD screening captured between April 1, 2022, and March 31, 2023. For children's HbA_{1c}, the clinic uses instruments certified by the National Glycohemoglobin Standardization Program and traceable to reference methods from the Diabetes Control and Complications Trial.

Data Analyses

We used approved tools to retrieve all EHR data. We report the percentage of eligible families screened for DD out of all eligible families in the clinic population (absolute percentage screened) and the percentage of eligible families screened for DD out of all eligible families with a completed clinic visit between April 1, 2022, and March 31, 2023 (adjusted percentage screened). To analyze these data, we examined the screening rate by each month and the average across the year. We also examined the rate of EHR documentation of follow-up resources being sent to families with elevated screening results. To identify elevated DD, the clinic applied a clinical cut point of ≥41 for children and a cut point of ≥64 for parents or caregivers [7]. Descriptive statistics and HbA_{1c} were examined for both the population who completed DD screening and the families who had elevated screening results. Given that the screening period took place over a 12-month period, some families received and completed the screening measures on more than 1 occasion. If a child or a caregiver was identified as having elevated DD on multiple screenings, he or she was sent resources each time; however, for the purposes of data analysis, only the first elevated screen that also had a clinic visit with an associated HbA_{1c} was included for analyses.

Results

Participants

Children who completed any DD screening (eg, child and parent or caregiver completed, child-only completed, and parent or caregiver-only completed) were 55.2% female, 44.8% male, and had a mean age of 10.22 (SD 1.36) years. With respect to their self-reported race, 1.8% were Asian American and Pacific Islander, 0.75% were American Indian or Alaskan Native, 0.8% were Asian Indian, 19.6% were Black or African American, 64.16% were White, 5.0% reported more than 1 race, 8.0% reported other/unspecified, and 1.0% reported "prefer not to say." For their self-reported ethnicity, 12.1% identified Hispanic/Latinx, 86.4% identified not Hispanic/Latinx, and 1.5% reported "prefer not to say" (Table 2).

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Table . Demographic information.

	Participants, n (%)
Ethnicity	
Hispanic/Latinx	49 (12.1)
Not Hispanic/Latinx	349 (86.4)
Prefer not to answer	6 (1.5)
Race	
AAPI[a]	7 (1.8)
American Indian or Alaskan Native	3 (0.8)
Asian Indian	3 (0.8)
Black or African American	78 (19.6)
White	256 (64.2)
More than 1 race	20 (5.0)
Other/unspecified	32 (8.0)
Prefer not to say	4 (1.0)
Age (years)	
8	70 (14.3)
9	77 (16.4)
10	102 (21.8)
11	117 (25.0)
12	103 (22.0)
Sex	
Female	223 (55.2)
Male	181 (44.8)

[a]AAPI: Asian American and Pacific Islander.

Primary Outcomes

Screening Completion Rates

During the 1-year screening period, the institutional app system automatically assigned a total of 590 PAID-C questionnaires and 649 P-PAID-C questionnaires to children aged 8 - 12.99 years and their caregivers, respectively. A higher number of caregiver questionnaires than pediatric questionnaires were assigned, as some pediatric patients had multiple caregivers associated with their account in the institutional app. Of those, 396 PAID-C and 435 P-PAID-C questionnaires assigned were associated with attended clinic visits. Absolute percentage screened (questionnaire completion out of all assigned) were 36.78% (217/590) and 38.83% (252/649), respectively. Screening rates (questionnaire completion) for those who attended their clinic visits (adjusted percentage screened) for children or caregivers were 52.02% (206/396) and 54.48% (237/435), respectively. Completion rates were relatively stable over the 12 months of DD screening.

DD Rates and Resource Provision

In total, 10.2% (21/206) PAID-C and 11.0% (26/237) P-PAID-C surveys scored as elevated during the 1-year screening period, with 1 child and 3 caregivers completing the measure with an elevated score at multiple clinic visits. During this period, 11 child and caregiver dyads scored as elevated on both measures of DD, with 4 of these dyads including a child with a diagnosis of type 2 diabetes or prediabetes, and the remaining dyads with a child diagnosed with T1D. All other elevated screens were present in only a caregiver or a child, who was not part of a parent and child dyad. Of those who were identified as having DD, resources were sent in the app to families in response to 91.7% of elevated PAID-C scores and 100% of elevated P-PAID-C scores; only 1 patient who screened as elevated was not flagged by manual processes and did not receive resources. This occurred before the automated BPA system was put in place. After the BPA was established, all families with elevated parent or child DD scores were sent resources electronically.

DD, Demographics, and HbA_{1c}

Mean HbA_{1c} was calculated for youth with T1D who also attended the clinic visit associated with the date of elevated DD screening (15 PAID-C and 17 P-PAID-C scores were included). Youth with type 2 diabetes or prediabetes were not included in this subsample. For this subsample including all youth with DD, mean HbA_{1c} was 8.04% (SD 1.39%) and mean child HbA_{1c} for those with caregivers screening elevated for DD was 8.04% (SD 1.72%). This subsample of youth was 68% female (17/25),

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32% male (8/25), and had a mean age of 10.4 (SD 1.44) years. With respect to their self-reported race, 8.3% were Black or African American (2/24), 70.8% were White (17/24), 8.3% reported more than 1 race (2/24), and 12.5% reported other/unspecified (3/24). For their self-reported ethnicity, 12.5% identified as Hispanic/Latinx (3/24) and 87.5% identified as not Hispanic/Latinx (21/24).

Discussion

Principal Findings

This study details the creation, implementation, and refinement of a process to routinely screen for DD in youth with T1D and their caregivers using a digital health platform. Furthermore, we present descriptive information for those who completed screening. During the 1-year screening period, screening rates for DD were relatively stable, and lower than our initial goals. Approximately 10% of youth and 11% of caregivers who completed screening were identified as having elevated DD. Most of these families were appropriately sent resources via EHR when DD was identified, with 1 patient not flagged prior to an automated BPA being placed. Iterative processes allowed for improvements to be made in the way families with DD were screened and identified using our institutional app, and for resources to be appropriately shared in the families through the digital health platform. Additional suggestions for quality improvement (QI) processes to increase DD screening as well as relevant clinical implications can now be trialed based on findings and lessons learned during this initial 1-year screening period.

Challenges with Screening Implementation

We identified several challenges to screening families using our institutional app, some that were corrected and others that inform future QI initiatives and clinical research. First, while the automated system was coded to assign the DD screening tools to children aged at least 8 years and those younger than 13 years, for a brief period the questionnaires were incorrectly sent to all pediatric patients or parents seen for diabetes associated visit types in endocrinology. Once identified, this error was corrected. However, the error reoccurred following a later system update and because the system assigns questionnaires at the time an appointment is scheduled (sometimes 6 or more months in advance), the clinic experienced a backlog of incorrectly assigned questionnaires intermittently throughout the first 9 months of the screening period. For the current analyses, children and parent or caregivers who incorrectly received the questionnaires due to age were not included. Nevertheless, the error had clinical implications in that some children and parents or caregivers who were outside of the PAID-C normative age range were identified as distressed and sent electronic resources in line with our procedures.

Second, with our institutional app and its supporting automated system, we could only assign the DD screening tools to children aged 8 - 12.99 years (and their caregiver) with a visit type “Diabetes NP w/Care Team” or “Diabetes FP w/Care Team”. These visit types are not coded to differentiate between different diabetes diagnoses. Although DD is also observed in persons with type 2 diabetes, the screening tools we used are not validated for families of youth with type 2 diabetes. In the 1-year screening period, there were 4 elevated PAID-C surveys and 4 elevated P-PAID-C surveys associated with youth with type 2 diabetes or prediabetes. These could represent false-positive results. Thus, if using an automated system to assign a clinical screening tool, it may be important to identify a solution for assigning screeners with greater specificity.

Third, while the initial system for manually reviewing screening results and sending electronic resources to families who had an elevated screen was generally effective, 1 child was not immediately identified and therefore did not receive resources in response to his or her elevated score in a timely manner. Although this represented <5% of total population that screened as elevated, it highlighted the need for an automated BPA process in the EHR to promote greater accuracy and improve response time when sending resources to families. Unfortunately, upon implementing the automated BPA, we identified a new problem, as clinical providers had the ability to close the BPAs without sending families electronic resources. Thus, the lesson learned was also the value of providing ongoing provider education about screening processes in clinic so that these alerts could be appropriately responded to.

Fourth, while 73.6% of families in the endocrinology division were signed up for the Nemours app during the screening year, 30.6% of families who started the “GetReady” paperwork did not complete it before their appointment, thus limiting the number of families screened for DD. While specific reasons for incomplete paperwork were not collected, it can be hypothesized that the length of time to complete “GetReady” paperwork, which included our DD screeners, as well as other standardized paperwork, may have exceeded family availability. Also, as part of the “GetReady” system, we learned that new surveys added to the system are placed at the end of the queue and the order cannot by adjusted. Thus, it is likely that the DD screeners were at the end or near the end of the package of surveys assigned to families. It may be more effective to use an institutional app for routine DD screening if it is possible to toggle the order of surveys so that the clinic can ensure that families receive the screeners earlier in their web-based paperwork.

Notably, the number of families signed up for our institutional app has increased in 3 years since becoming available (from about 25% of families enrolled to current rates). In part, the Covid-19 pandemic and related concerns [14] spurred enrollment, as telehealth functionality is built directly into the app; and many divisions at this institution, including endocrinology, have set annual goals to increase app enrollment. However, it warrants comment that to create and support a process to routinely screen for DD in youth with T1D and their caregivers using a digital health platform, it is important to select a digital health platform that families are willing to use.

Future Directions

We plan to (1) implement a series of QI cycles to increase DD screening rates (these QI cycles will focus on current screening processes in the institutional app, as well as processes that are not app reliant if feasible, for example, integrating screening during clinic appointments); (2) expand screening to other

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endocrinology clinic locations within our multisite medical system; (3) create and implement a system to track follow-through on resources or recommendations sent to those with elevated DD; and (4) include options for Spanish-language speakers to receive and complete DD screening, with the eventual goal for this to be integrated into the institutional app when the app is available in Spanish. Our third goal is of particular importance given the increasing rates of T1D among Hispanic/Latinx children [1], and Hispanic youth have been identified as having the highest rates of mental health needs per Youth Risk Behavior Surveillance data [15]. The Problem Areas in Diabetes Survey—Pediatric Version (PAID-Peds) was recently normed for Spanish speakers [16], with the Spanish version of the Problem Areas in Diabetes Survey—Parent Revised (PAID-PR) also validated [17]. Improving distress screening in Spanish-speaking youth and families may assist in decreasing disparities in treatment access for mental health needs.

Relatively low rates of elevated DD were observed for the children or the caregivers in the current report. In the future, a less stringent cutoff for DD may be needed to better identify families and direct provision of referrals and resources; cut point studies may be warranted. Furthermore, given challenges previously noted specific to completion rates, it is possible that those families experiencing higher levels of distress were less likely or able to complete GetReady paperwork. Alternative methods to screen families who do not complete previsit paperwork may be necessary to improve completion rates and to identify or respond to DD. It will be important to increase buy-in at the institutional and provider level to increase opportunities to complete screening during clinical visits.

Conclusions

DD screening is recommended by the ISPAD and the ADA as part of standards of care [2]; however, it is not consistently applied across institutions (currently, the US News & World Report review of pediatric health systems tracks only the inclusion of depression screening in youth aged 13‑18 years [18]). Given that depression is identified at lower rates than DD in populations with T1D, especially for preadolescent age groups [8,9], that DD and depression screening are not interchangeable, and that DD may play a stronger role in predicting HbA_{1c}, many pediatric endocrinology clinics are missing valuable screening opportunities to direct patient care and impact health outcomes if they are screening only for depression. Our findings indicate that DD education, screening, and response can be integrated via digital platforms in a pediatric endocrinology clinic, facilitating timely treatment referral and provision of resources for those identified with distress. Of note, mean child HbA_{1c} for those with elevated DD in our sample (mean 8.04%, SD 1.72%) was higher than the mean HbA_{1c} for the larger sample of youth aged 8‑12.99 years with T1D seen in the endocrinology clinic (mean 7.75%, SD 1.46%), and higher than the clinical target of <7.0% recommended by the ADA [2]. This further emphasizes the importance of evaluating DD and providing appropriate resources and interventions in pediatric endocrinology settings.

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Authors' Contributions

NAK collected and analyzed data and wrote the first draft of the manuscript. NAK and SRP collaboratively reviewed and edited the manuscript. LAF and MB contributed to discussions and manuscript review.

Conflicts of Interest

LAF receives material research support from Dexcom unrelated to this protocol. LAF is an advisory board member for Ki Health and receives honoraria and stock options. MB is a consultant for Arbor and Tolmar Pharmaceuticals. He receives salary and stock options as an advisory board member of Ki Health and receives research support from Novo-Nordisk, Sanofi/Provention-Bio, Beta Bionics, and Diurnal. The remaining authors report no conflicts of interest.

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Abbreviations

ADA: American Diabetes Association
BPA: best practice alert
DD: diabetes distress
EHR: electronic health record
HbA_{1c}: glycated hemoglobin A_{1c}
ISPAD: International Society for Pediatric and Adolescent Diabetes
P-PAID-C: Parent Problem Areas in Diabetes-Child
PAID: Problem Areas in Diabetes
PAID-C: Problem Areas in Diabetes-Child
PAID-Peds: Problem Areas in Diabetes Survey—Pediatric Version
PAID-PR: Problem Areas in Diabetes Survey—Parent Revised
QI: quality improvement
T1D: type 1 diabetes

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Exploring Stress and Stress-Reduction With Caregivers and Clinicians in the Neonatal Intensive Care Unit to Inform Intervention Development: Qualitative Interview Study

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Abstract

Background: Parents and caregivers with preterm babies in the neonatal intensive care unit (NICU) experience high levels of distress and are at an increased risk of anxiety, depression, and acute stress disorders. Effective interventions to reduce this distress are well described in the literature, but this research has been conducted primarily in Europe and North America. To our knowledge, few interventions of this sort have been developed in Australasia, and none have been developed or tested in Aotearoa New Zealand.

Objective: The primary aims of this study were to explore sources of stress with caregivers and clinicians in a NICU in Aotearoa New Zealand and gather participant ideas on ways to reduce caregiver stress to inform intervention development.

Methods: This qualitative design used an essentialist and realist methodology to generate findings aimed at future intervention development. Overall, 10 NICU clinicians (neonatologists, nurses, and mental health clinicians) and 13 caregivers (mothers, fathers, and extended family members) of preterm babies, either currently admitted or discharged from the NICU within the last 12 months, were recruited to participate in interviews exploring stress and stress-reduction in the NICU.

Results: The 23 participants included 10 clinicians (all female, with an average of 15 years of experience in the NICU) and 13 parents and caregivers (majority of them were female; 10/13, 77%) of preterm babies. We identified 6 themes relevant to intervention development. Three themes focused on caregiver stress: the emotional "rollercoaster" of NICU; lack of support, both culturally and emotionally; and caregivers feeling "left out" and confused. Three themes focused on participant-proposed solutions to reduce stress: caregiver empowerment, improving emotional support, and communication on "my" terms (ie, digitally).

Conclusions: Participants reported high levels of caregiver stress in the NICU, and they proposed a range of stress-reducing solutions, including increasing caregiver empowerment and improving emotional and cultural support. Clinicians and caregivers also strongly agreed on providing more information for caregivers in digital, mobile-friendly formats.

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KEYWORDS

neonatal intensive care unit; NICU; parents; preterm infants; stress; stress reduction; intervention development; digital; neonatology; pediatric; infants; babies; neonatal; toddler; children; caregiver; telemedicine; telehealth; virtual care; virtual health; virtual medicine; remote consultation; qualitative study

Introduction

Parents with babies in the neonatal intensive care unit (NICU) have described the NICU experience as "terrifying" and "traumatic" [1], and they frequently experience high rates of stress, anxiety, depression, and acute stress disorders [2,3]. These effects can last well after discharge, with long-term negative effects including problems with parent-child bonding and attachment [4].

The most common cause of admission to the NICU is preterm birth (born at less than 37 weeks gestational age). Preterm birth affects an estimated 1 in 10 births annually around the world and is the leading cause of death for children under 5 years of age [5]. In Aotearoa New Zealand, a diverse, bicultural country,

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preterm birth is estimated to occur in 8.9% of annual births [6]. New Zealand Europeans experience fewer preterm births, perinatal deaths, and maternal deaths than Māori, the Indigenous people of Aotearoa New Zealand who make up 17.3% of the population [7]. They also experience fewer adverse perinatal outcomes than Pacific Peoples and Indian minority groups in Aotearoa New Zealand [8]. Additionally, New Zealand European babies are less likely to be admitted to NICU than these 3 groups [9].

Effective interventions to reduce the distress of parents with babies in the NICU are well described in the literature, but this research has been conducted primarily in Europe and North America, and mostly with Caucasian mothers [10,11]. To our knowledge, few interventions of this sort have been developed in Australasia, and none have been developed or tested in Aotearoa New Zealand. As a recent study of services showed, psychosocial support for caregivers in the NICUs in Aotearoa New Zealand is highly limited, with no formalized support programs, limited cultural support services, and fewer staff members available to provide support to parents with babies in the NICU [12]. Given the limited resources available to support this highly distressed population, clinically feasible and culturally appropriate interventions for use in the NICU should be developed for the Aotearoa New Zealand context.

A few qualitative studies have explored the experiences of families in Aotearoa New Zealand NICUs [13,14], including for Māori whānau (families) [15]. However, no intervention research focused on reducing distress has been conducted with caregivers in the NICUs of Aotearoa New Zealand.

Therefore, the main objectives of this study were to gather feedback from caregivers and clinicians in the NICU on sources of caregiver stress and ways to reduce that stress to inform future intervention development.

Methods

Study Design

We conducted a qualitative study using semistructured interviews with caregivers and clinicians from September 2022 to April 2023 in a level 3 NICU in Auckland, Aotearoa New Zealand. We analyzed the data using thematic analysis (framework method).

Ethical Considerations

The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist was followed to report the qualitative study findings. The Auckland Health Research Committee provided ethical consent (#AH24458). Informed written consent was provided by participants in advance of their participation in this study. Individuals were provided with a NZ $50 (US $28) gift voucher to a local store as thanks for their participation. To ensure confidentiality, all identifying details were removed from the data, and participant transcripts were issued numeric codes.

Setting

This study was conducted at Te Toka Tumai Auckland Starship Child Health NICU, a level 3 NICU and one of Aotearoa New Zealand's largest NICUs. Most rooms are shared, with 40 cots in the unit and an average of 900 infant admissions per year. The unit is a regional specialty center with a diverse patient population. In 2023, 29% of babies in the unit were New Zealand European, 19% were Other Asian, 17% were Indian, 17% were Pacific Peoples, and 16% were Māori. Common causes of admission were preterm birth (42%), respiratory distress (25%), and congenital abnormalities (14%) [16].

All participants in our study had admissions in the NICU during the COVID-19 pandemic. COVID-19–related visitor restrictions in the unit varied during this study's time period, with parents recruited earlier in the study experiencing more restrictive conditions than those recruited later in the study. NICU visitor restrictions included limiting visitors in the NICU to one parent at a time, not allowing extended family visitors without special permission, and requiring all visitors to wear facial masks in the unit.

Participants and Recruitment

We sought to collect a range of perspectives on caregiver stress and support in the NICU, so we recruited both currently admitted and discharged parents and legal guardians of preterm babies in the NICU. We also aimed to include other types of caregivers in this study, such as extended family members who had spent significant time in the NICU. This is important in the Aotearoa New Zealand cultural context, as grandparents and other extended family members (such as aunts and uncles) often play important caregiver roles in many cultures, including Māori [15].

Caregivers were eligible for the study if their baby was currently admitted to the NICU or discharged within the previous 12 months and had an admission lasting at least 2 weeks. Participants also had to be 18 years of age or older and be able to read and speak English.

Clinicians were eligible for the NICU clinician group if they were currently employed by Te Toka Tumai Auckland Starship Hospital and interacted closely with caregivers in the NICU as a standard part of their job. Eligible roles included nurses, neonatologists or pediatricians, and mental health clinicians, including social workers and psychotherapists.

An experienced research nurse in the NICU recruited parents with babies currently admitted in the unit. Parents of discharged babies were introduced to the study by clinicians using convenience sampling in an outpatient follow-up clinic for NICU graduates. Parent participants were encouraged to invite their extended family members to participate if they had spent significant time in the NICU.

Clinicians in the NICU were recruited via voluntary response sampling. Study promotion flyers for clinicians were displayed in the unit staff room and distributed by email.

Recruitment for this study was closed after data saturation was reached in both groups. Data saturation was defined as the point at which little or no relevant new categories were found in the data [17]. The final study sample size (N=23) also met the recommended sample size guidelines for achieving rigor in qualitative research of this type [18].

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Interview Schedule

The open-ended interview questions (Multimedia Appendix 1), with a caregiver version and a clinician version, were developed by the research team and based on existing literature about the sources of stress and support for parents with babies in the NICU. In the caregiver interview, part 1 included open-ended questions about sources of stress (ie, "What situations did you find most stressful in the NICU?") and support (ie, "What helped you manage your stress most in the NICU?"). In part 2, caregivers were shown examples (websites, apps, and printed materials) of NICU education materials and evidence-based stress-reduction activities from a range of sources (both local and international) and asked for their feedback on usefulness and feasibility. Questions were a mixture of open and closed questions in part 2 (ie, "Would you have used this type of intervention in the NICU? Why or why not?").

In the clinician interview, in part 1, clinicians were asked questions about their work with caregivers and what was most stressful and supportive from their perspective (ie, "In your experience, what types of support, education, or staff roles are most helpful in reducing stress for parents and family members?"). In part 2, clinicians were asked about their ideas on stress reduction tools and what they would like to see included (ie, "What are some features of a stress-reduction intervention that you would like to see for parents in the NICU?"). They were also asked about potential challenges involved in the implementation and feasibility of a new stress-reduction intervention.

The interview schedules were piloted with a researcher with lived NICU experience and a NICU clinician uninvolved in this study. Based on that feedback, the order of questions was changed to improve the interview flow, and some questions were simplified.

Procedure

After expressing interest in the study, participants were contacted by a researcher who introduced them to the study and sent them a link to study enrollment materials. Participants provided informed consent and completed a demographic survey through the web-based research tool REDCap (Research Electronic Data Capture; Vanderbilt University).

Participants chose their preferred interview method (in-person or on Zoom), and families were invited to participate in interviews either individually or as a group. Each participant was given a voucher as a gift of thanks at the start of the interview.

Interviews lasted an average of 45 minutes for clinicians and 60 minutes for caregivers. Interviews were audio-recorded (if in-person) or via Zoom's recording feature.

Two researchers conducted interviews and had no prior relationship with any of the participants. One interviewer (JR) was an experienced female Māori nurse and qualitative researcher who holds leadership roles in equity and Māori engagement. She is a mother of 5 children and grandmother of 7. The other interviewer (KHG) was a European, female, health psychology PhD candidate, licensed mental health clinician who specializes in perinatal mood disorders, and mother of 2 children.

Participants who self-identified as Māori were offered the choice of being interviewed by the non-Māori or Māori researcher. The Māori researcher conducted interviews in alignment with tikanga Māori (Māori protocols).

Interviews were transcribed using automatic speech recognition tools (Zoom and Whisper.AI [19]) and checked and corrected for accuracy using audio or video recordings. To ensure confidentiality, all identifying details were removed, and participant transcripts were issued numeric codes. Participants could review transcripts if they wished within 2 weeks after completing an interview.

Qualitative Methodology

This study's methodology was grounded in an essentialist and realist epistemology (that a reality exists independently of researcher beliefs or interpretations) [20] and informed by existing stress theory, including the situational stress model [21], on which the validated PSS:NICU (Parental Stress Scale: Neonatal Intensive Care Unit) was developed [22]. We used the framework method of thematic analysis, a qualitative method commonly used in applied health research [23]. The framework method allows for both a deductive approach, led by existing theory and predetermined concepts organized into a "framework," and an inductive approach, exploring new concepts based on the data [17].

Data Analysis

Anonymized interview transcripts were imported into the qualitative data analysis software NVivo (release 1.3, Lumivero). Data were then analyzed using the five-step process of the framework method: (1) familiarization with the data, (2) creating a coding framework, (3) indexing (coding), (4) charting (sorting and grouping of coded data), and (5) mapping and interpreting (creating themes) [23].

The initial coding framework for the caregiver dataset was developed a priori from the interview schedule and existing research on NICU parental stress using a deductive approach. It was piloted on 3 transcripts by KHG and PR. During that process, codes were also added as needed in an inductive, data-driven fashion in accordance with the framework method, which allows for both inductive and deductive approaches [17]. The same method was used to create the clinician framework. All investigators discussed and agreed on the final codes and frameworks.

Working independently and using the frameworks, 2 researchers (KHG and PR) coded transcripts, charted (grouped) the data into categories, and developed initial minor and major themes. Then, they used a collaborative approach to create the final themes, working together to compare theme ideas against transcripts and reevaluate when needed.

Initially, themes were created separately for the caregiver and clinician groups. However, after both researchers identified nearly identical themes in the 2 groups independently and shared the results with the investigative team, the decision was made to merge the datasets together. This agreement between datasets

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also provided triangulation, which helps ensure data rigor and credibility in qualitative research [24].

The Māori researcher (JR) also reviewed themes and example quotes for cultural understanding for the Māori participant transcripts. The final themes were reviewed and refined by all coinvestigators.

Results

Participant Characteristics

We interviewed 23 participants, conducting 13 interviews on Zoom (including 2 with couples) and 8 in-person: at a university (n=5), in the NICU (n=1), and, for caregivers, at participants' homes (n=2). Three babies were present during these interviews.

Thirteen caregivers (12 parents and 1 grandparent) completed interviews and experienced NICU stays with 10 infants (8 singletons and 1 set of twins). Although we aimed to recruit multiple types of caregivers (ie, parents, grandparents, aunts, and uncles) in this study, only 1 nonparent caregiver was successfully recruited. This was likely due to COVID-19–related restrictions in the unit that ran throughout the study period and only allowed nonparent or legal guardian family members into the unit with special permission (such as to support a single mother) and did not allow children (siblings). All study families had infants admitted to the NICU due to preterm birth, and the majority of babies (6/10, 60%) had stays of 8 weeks or more.

We also interviewed 10 clinicians, who were all female and who had an average of 15 years of experience in the NICU (Table 1). Seven parents completed enrollment paperwork but did not schedule interviews and were removed from the study.

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Table . Participant characteristics.

Variables	Values, n (%)
Parents or family members (n=13)	
Female	10 (77)
Ethnicity	
European	9 (69)
Māori	2 (15)
Other[a]	3 (23)
Age (years)	
21 - 30	3 (23)
31 - 40	7 (54)
41 - 50	2 (15)
51 - 60	1 (8)
Education	
Completed high school	2 (15)
Completed tertiary education	11 (85)
Employment status	
Unemployed	2 (15)
Employed part-time	4 (31)
Employed full-time	2 (15)
On parental leave	5 (38)
Baby admission details (n=10)	
Reason for admission	
Premature birth	10 (100)
Admission status	
Currently admitted	4 (40)
Discharged to home	6 (60)
Discharged: total length of stay	
6-8 weeks	2 (20)
More than 8 weeks	4 (40)
Currently admitted: length of stay	
2 to less than 4 weeks	2 (20)
More than 8 weeks	2 (20)
Clinicians (n=10)	
Female	10 (100)
Ethnicity	
European	8 (80)
Māori	1 (10)
Other[a]	1 (10)
NICU[b] role	
Registered nurse	4 (40)
Nurse specialist or practitioner	3 (30)
Mental health clinician	2 (20)

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Variables	Values, n (%)
Neonatologist or pediatrician	1 (10)
Years of experience in the NICU	
1 - 10	4 (40)
11 - 20	2 (20)
21 - 30	4 (40)

[a]Chinese, Indian, Korean, Samoan; participants could select multiple ethnicities, so totals may add up to more than 100%.

[b]NICU: neonatal intensive care unit.

Themes

Stress and Support Themes

We identified 6 themes centered on stress and stress-reduction that we considered relevant to future intervention development. Three themes focused on caregiver stress: (1) the emotional "rollercoaster" caused by the NICU experience, (2) insufficient emotional and cultural support, and (3) caregivers feeling "left out" and confused. Participant-proposed solutions to reduce stress were to (1) empower caregivers through education, (2) improve emotional support, and (3) communicate on "my" terms (ie, digitally) (Textbox 1).

Textbox 1. Themes.

Sources of stress*Emotional "rollercoaster"*

- Fear and anxiety
- Overwhelmed and helpless
- Grief and loss

Left out and confused

- Mixed messages
- Not informed about medical care
- Lack of information

Unsupported

- Forgotten fathers
- Limited emotional and cultural support
- Lack of empathy

Participant-proposed solutions

Empower caregivers

- Provide basics about premature birth, the neonatal intensive care unit, and common medical procedures
- Educate on how to care for premature babies

Communicate on "my terms"

- Deliver information digitally
- Make mobile phone-compatible
- Simplify information

Improve emotional support

- Peer support, including father- and cultural-specific support
- Foster online forums and support groups
- Teach stress-reduction skills

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Theme 1: Emotional "Rollercoaster" of the NICU

Nearly all the parent participants in our study described their time in the NICU as significantly stressful and highly distressing.

> *It's an emotional rollercoaster, with lots of crying.* [Mother #9]

Multiple participants described it as the most stressful event of their lives.

> *It's a massive test of your emotional resources, certainly the biggest of my life, and I felt like I was having an existential crisis.* [Mother #1]

Many parents reported ongoing episodes of fear in the NICU, related to the highly medicalized NICU environment and concerns about their babies' survival.

> *It's terrifying to be in NICU. It's terrifying because of so many things…seeing my baby in pain and needing so much life support to keep him alive.* [Mother #13]

Consistently, parent participants also reported feeling overwhelmed and helpless in the NICU because of the intensity of the environment and their inability to help their babies. Fathers also shared explicit feelings of helplessness.

> *My partner gave birth and can express [milk] and do all that stuff, and I can't do any of that.* [Father #10]

Participants also reported feelings of grief and loss throughout the NICU experience. While parents whose babies died in the unit were not part of our study, 4 participants reported sharing rooms with or befriending other families whose babies died in the unit.

> *I feel like being in NICU, you not only have your own experiences, which can be quite scary, but you are also forced to take on other family's difficult experiences too.* [Mother #1]

Some participants also felt cultural traditions were not considered after a baby's death.

> *We felt quite unstable after a baby had passed [in the same room], and another baby just turned up. For us, it's very tapu [sacred, with complex spiritual restrictions] when someone's passed away. So spiritually... we felt unsafe.* [Mother #5]

Theme 2: Insufficient Cultural and Emotional Support

While some parents stated they felt emotionally supported by staff in the NICU, most reported that they felt their needs were secondary.

> *If you weren't dying, you weren't a priority.* [Mother #1]

Clinicians agreed that they often do not spend much time talking to parents about their well-being.

> *We don't finish a visit by saying [to parents], "How are you feeling? Are you doing ok?" We just don't have time.* [Clinician #8]

Multiple parents also felt that some medical staff did not respond to their emotional needs in helpful ways.

> *Something had gone wrong and the doctor told me about it. And then he went on to talk about other things that could go wrong [in the future]. And I was like, that was information I needed to know, but it wasn't information I needed to know right then. Eventually, I was like, "I want you to leave because I want to get upset in private."* [Mother #12]

Additionally, 3 fathers participated in our study, and most reported they felt "forgotten" and treated differently than mothers.

> *I felt like [some staff] didn't expect the dad to ask questions or be involved. Gender expectations were quite out of date.* [Father #2]

A few mothers also commented on this, expressing frustration on behalf of their babies' fathers about a lack of consideration for them.

> *I used to joke to [baby's dad], "you're at the bottom, no one really cares about you." It's terrible, actually, I mean, talk about the gender disparity.* [Mother #1]

All the Māori and minority participants in this study reported mixed levels of cultural support in the NICU. Three parents reported speaking their first or Indigenous language to their babies in the NICU and all expressed concerns that they were making English-speaking staff uncomfortable by doing so. The Māori participants in our study also reported concerns that staff did not understand cultural practices that were important to them.

> *Because I'm brown, I felt like people were thinking, "Oh, is she capable?" I also wondered if they were treating me differently because of my skin color.* [Mother #1]

One clinician (#5) commented on unconscious bias as a barrier to appropriate Māori cultural support, which she noted is a requirement of the Te Tiriti o Waitangi (Treaty of Waitangi), New Zealand's founding document signed by Māori and the British Crown in 1840.

> *I'm always reminding staff that we work within Te Tiriti, and that's the place we need to start from, particularly for Māori.* [Clinician #5]

Some participants also detailed gaps in cultural support for Asian families, including limited translation services and a lack of understanding about some cultural practices.

> *So we have this cultural thing that for the first 30 days after delivery we are not supposed to go out of the house, but immediately I'm traveling between NICU and home, so that's gone out of the window. And on the days when I wasn't going, the nurses were ringing me like, "Are you coming today?" And I was like, "I will come tomorrow." You have this pressure on you.* [Mother #8]

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Theme 3: Caregivers "Left Out" and Confused

Caregivers reported significant confusion and uncertainty in the NICU due to a lack of information, which they reported increased their stress. Many reported having unanswered questions about day-to-day procedures in the NICU, who the staff were that cared for their babies, and what they could expect in the future.

> *When I went into labour, I didn't know how early you could have a baby, or what the survival rate was. I didn't know what NICU was! I wish someone had explained it all to me more clearly.* [Mother #6]

A few caregivers also noted that it was difficult for them to take in information early in their baby's admission due to the suddenness of their baby's birth and the feelings of fear and overwhelm they were experiencing.

> *We're almost three months into our admission, and I'm probably only now just getting to a point where I can mentally understand everything that happens in NICU and communicate about it clearly. It was just a real shit show for a long time, and of course I had to recover from birth. It probably took me eight weeks to feel like myself.* [Mother #12]

Some mothers also reported feeling nervous about asking questions of the medical team.

> *I know at the start, I remember sitting there and wanting to say things [to the doctors]. But even just asking something was nerve-wracking and overwhelming.* [Mother #8]

Similarly, a few clinicians expressed the concern that the information they were providing was not always understood by caregivers, and they attributed this to both a lack of time they had available to talk to families and potential power differentials between medical providers and caregivers.

> *The [medical] hierarchy is sometimes an issue for people to speak up and ask more questions. They may come back later and say, "Look, I actually didn't understand a word." Or they may come back and ask a nurse but not the doctor.* [Clinician #4]

Participants also mentioned feeling more stressed when they received conflicting information from different staff members.

> *[My baby] couldn't latch properly, and the machine would start beeping [about his oxygen], and I had different messages from the nurses. So some nurses say "it's totally fine," and then some nurses will say, "If he drops then you need to stop breastfeeding and let him breathe." The mixed messages gave me a lot of anxiety.* [Mother #8]

Concerningly, many parents also reported stressful situations in which they were not informed about their babies' medical care. One mother (#6) reported a "really scary" incident when she was not told that her baby had stopped breathing, which she reported "made me lose my mind." Additionally, 2 participants reported being told "at the last minute" or without their knowledge that their babies were moved to a different section of the unit.

> *So before we moved from Level 3 to Level 2, we were told, "It's not going to happen for a while." But then we're told over the phone that now she's in Level 2. That was very stressful for us. The doctor had given us clear plans, yet the transition happened without us.* [Mother #5]

Clinicians also reported stressful situations when parents were "left out of the conversation," attributing this to time constraints and frequent staff changes.

> *If we had more staff, that would give me more time to talk to parents, rather than thinking, "Oh, but I've got these 3 other babies to think about." If the staff is not stressed, then everybody can be less stressed.* [Clinician #3]

Theme 4: Empower Parents

Overwhelmingly, participants expressed an interest in learning more about the NICU and learning how to better care for and respond to their preterm babies in the NICU. Generally, caregivers wanted information that would help them feel more confident and empowered in the NICU.

> *The things at the top of my education wish-list would be on breastfeeding and pumping, which was so stressful; how to hold your baby; the importance of skin-to-skin and any other developmental tools I could use; and understanding your baby's behaviour.* [Mother #9]

Clinicians echoed this idea and felt it important to emphasize the importance of caregiver involvement and partnership with the medical team in the NICU.

> *I think an intervention that would include solid medical information and highlight ways for parents to be involved in NICU would be really helpful. It needs to have a big focus on what parents can do, because there's so much already taken away from them. And focus much more on the message, 'this is your baby,' and emphasize that they are part of the medical team.* [Clinician #4]

Participants also had many specific ideas about the types of NICU information that would be helpful to them, as well as a desire to receive personalized information about their babies.

> *I wanted to know more about everything. How long does my baby need to be on the incubator, how long for the overall stay, the timing of things. Also, their growth, their weight, are they on track?* [Mother #8]

Some participants had specific information requests, from standard medical procedure timelines to developmental week-by-week guides.

> *It would be nice to have a brief timeline of when babies will get the brain scans, when they'll get their first eye checks. It would be good to know when things are going to happen before, instead of after, so you can ask if you should be there and know to ask about the results.* [Mother #11]

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Some parent participants also commented on the lack of information available to them about their babies' medical care through the hospital's electronic health record system, and one suggested an "integrated" web-based approach to include both NICU education and updates about their babies' medical care.

> *It'd be great to have education about NICU in an app form that also includes the doctor's notes from the day. I'd like to have more information that keeps you updated when you aren't there.* [Mother #11]

Theme 5: Provide More Emotional Support

Most participants stated they wanted more emotional support, including more empathy from staff and more ways to destress. Participants also mentioned a desire to connect with other caregivers "like me," such as fathers or caregivers from the same cultural group.

> *It would have been nice to chat with a few more dads. If there was some way that brought people together in a casual format, that'd interest me.* [Father #10]

Some participants expressed a desire to connect both in-person and via online support groups with caregivers from the same NICU.

> *It'd be great if there was an online forum or group for parents from this NICU. I found connecting to other NICU parents helped online, even if their baby is no longer in NICU or was in another city. Also, if they can invite some ex-NICU parents [to the unit], I think that would be really good too.* [Mother #8]

Clinicians also commented on the strength of support parents could provide to each other.

> *It's all very well for us as professionals to say "I've been here for years, and this is what 25-week-old babies do." But that doesn't make a parent feel better sometimes. But if another parent who had a 25-week-old maybe two years ago can say, "Look, now I have a healthy child," that's hugely helpful.* [Clinician #1]

In addition to peer-support as a source of stress reduction, many caregivers also expressed an interest in learning specific stress-reduction skills that they could use while in the NICU.

> *It would be quite nice to put on headphones and do some breathing exercises or to listen to a guided meditation.* [Caregiver #7]

Clinicians expressed an interest in having more ways to help parents reduce stress.

> *We know parents are really stressed, and it'd be great to be able to say, "Here are some tools to reduce your stress."* [Clinician #2]

A few participants also noted that there is a lot of downtime in the NICU, and having stress-reducing activities to try would be more helpful than "doom scrolling" on a phone.

> *Based on my experience, I spent a lot of time in NICU just sitting there not doing anything, especially in my baby's early days. So I would have tried some stress-reduction activities if someone had given them to me, because hopefully they'd help me feel better, but also to give me something to do.* [Mother #9]

One mother stated that she and her partner had a session with a psychotherapist during their baby's admission, which she reported helped reduce her stress. However, she noted that scheduling these sessions was challenging and privacy was limited within the unit. (Clinicians also noted similar challenges in this regard.) She recommended complementing this type of in-person therapy with resources and activities that could be done at home.

> *The therapist gave us self-reflective questions to think about, and those were really helpful for us to talk about later. Like, what was most important to us as parents in NICU? It's hard to get perspective when you are in the midst of it, and those reflective questions really helped us do that. I think a list of those types of questions could be really useful for other parents, too.* [Mother #12]

Participants also recommended ways to improve cultural support, including more diverse staffing and staff training on cultural traditions.

> *I think it'd be helpful to have really good information in different languages and then basic info for staff [on cultural traditions], like this is something a family might want to do, and here's how to support them.* [Clinician #1]

Two Māori participants also recommended specific cultural practices around stress reduction.

> *I'm always interested in karakia (Māori ritual chants/incantations) and ones to do with breathing. For me, it's really helpful in stressful situations and really important that I keep doing it in the NICU.* [Mother #13]

Theme 6: Communicate on "My" Terms (ie, Digitally)

Many caregivers and clinicians expressed an interest in authoritative, reliable web-based resources for information about the NICU and premature baby development, and they commented that the printed resources currently provided in the unit were "not helpful."

> *I've spent more than a decade dedicated to the NICU, and I wouldn't read our pamphlets. Also, we're all on our phones. That's how we communicate. So I think digital is way better.* [Clinician #6]

Another clinician agreed, observing that younger parents in particular prefer digital information.

> *Digital is the way to go. The younger parents never read a printed pamphlet. They take out their phone, and they find their answers, good or bad. I think content needs to be short, sharp, and ideally, more video rather than lots of text. I think it should also be easy to navigate so that when they are hopefully sitting at the bedside or expressing milk, they can look at it when they have a few minutes.* [Clinician #4]

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While 2 caregivers preferred printed materials over web-based, the majority of caregivers wanted information delivered in digital formats and specifically mobile-friendly.

> *I never open my laptop. I'm always on my phone. You want it to be easy to read and less words and more videos. But you do want to find the right information that's accurate for your baby.* [Mother #12]

Three participants brought specific app and blog ideas they had brainstormed to their study interviews because they felt "so frustrated" by the lack of information they felt they received about the NICU and premature babies. They also noted they wanted to be able to access information regardless of the time of day.

> *I want more information about my baby and NICU, and I want to be able to work things out in my own time, online, even if it's at 2 am.* [Father #2]

Discussion

Principal Findings

Our study explored caregiver stress in the NICU and solicited participant ideas on ways to reduce stress to inform future intervention development. Broadly, our stress themes highlight how the majority of caregivers felt devalued in the NICU and that their emotional needs were not a priority. They expressed a desire to be treated as partners in their babies' medical care and seen as individuals, with unique values and strengths that were vital to their babies' health and well-being.

These findings align with stress theory, which posits that stress occurs in response to specific components of a situation as well as an individual's perceptions of that environment and their ability to cope within it [21]. The PSS:NICU [22], which was developed based on this theory, measures parental perceptions' of stress in response to four specific components of the NICU environment: (1) "sights and sounds of the NICU," (2) "infant behavior and appearance," (3) "parental role alteration" (with examples such as "not being able to hold my baby" and "feeling helpless"), and (4) "staff communication and behaviors."

Our study data contain examples of all of the categories measured by the PSS:NICU. Importantly, the majority of our data about parental stress can be organized within the category of "parental role alteration." In particular, our themes around parents feeling left out of decisions about their babies' medical care, uniformed, and unsupported emotionally highlight how parents felt disempowered in the NICU. This is important, as a meta-analysis of studies from around the world using the PSS:NICU found that "parental role alteration" is the most significant factor in parental stress in the NICU, with higher perceptions of changes in the parental role leading to higher rates of parental stress [25].

The stress themes in our study highlight problematic gaps in emotional and cultural support for families that led to feelings of parental isolation and disempowerment. While some parents stated they were supported in the NICU, the majority reported stressful interactions that made them feel devalued, confused, or judged as parents. Fathers, in particular, reported feeling "less important" than mothers in the NICU. Fathers' needs have long been understudied in the NICU, with many studies focusing exclusively on mothers [5]. However, recent studies have demonstrated that fathers can experience high levels of distress in the NICU, including elevated rates of depression and posttraumatic stress disorder compared to non-NICU fathers, and specialized interventions in the NICU can help [26].

In total, 30% (7/23) of our study participants self-identified from Māori and other minority cultures. These participants all reported mixed experiences of cultural safety (such as feeling judged by speaking a non-English language to their baby in front of medical staff), which are similar to findings reported in previous studies internationally with minority families [27] and in Aotearoa New Zealand with Māori families in the NICU [15].

Cultural support is a critical area for improvement and should be considered an important component of parental empowerment in the NICU [28] and an avenue for future intervention development. As a systematic review of Indigenous populations' birth outcomes in New Zealand, Australia, Canada, and the United States found, Indigenous groups experience significantly higher rates of preterm birth and neonatal death than non-Indigenous populations [29], and a growing body of international research has also documented a strong dose-dependent relationship between experiences of discrimination and health outcomes [30]. Few studies have explored experiences of discrimination and health outcomes within the NICU [31] or how cultural support can affect outcomes, and these are much-needed avenues of future research.

All participants shared ideas on ways to reduce parental stress in the NICU and what they felt would be helpful in a future intervention. Participants overwhelmingly agreed on the need for caregivers to feel more confident and empowered in the NICU. This idea has significant support in the literature, with decades of evidence documenting the benefits for parents and babies of increased parental involvement and engagement in the NICU [32]. As our study highlights, however, this knowledge can be difficult to translate into practice. Formalized "empowerment" interventions in the NICU have been designed to address this challenge, and most involve multimodal intervention programs that include hands-on caregiver education and changes in clinical practices. These have been found effective in reducing parental stress and depression [32].

Caregiver participants were interested in learning about education topics in 2 categories: how to care for their baby in the NICU and understanding the NICU environment, which was new and unfamiliar to all the families in our study. This desire is backed by research: educational interventions for parents with babies in the NICU have been shown to improve parenting confidence and decrease parental anxiety [33]. Clinicians echoed this need, and most participants wanted information to be provided in "short and sharp," easy-to-understand text and video. Participants also overwhelmingly agreed on the need for digital, mobile-friendly delivery of information (both for education and about their babies).

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Digital interventions are a worthwhile avenue for future exploration, as evidence has demonstrated the effectiveness of digital interventions with pregnant and postnatal women. A 2024 meta-analysis examined 31 randomized controlled trials testing digital intervention effects on postpartum anxiety and depression and found significant reductions in symptoms compared to treatment as usual, particularly for interventions that incorporated psychotherapy such as cognitive behavioral therapy or mindfulness [34]. Despite this evidence base, to our knowledge, no digital mental health interventions have been evaluated for parents with babies in the NICU.

Participants also proposed a range of strategies to improve emotional support, including through parent-to-parent support (both in-person and through online support groups). Participants also wanted improved cultural support, including increased staff training on diverse cultural traditions, hiring more Māori and minority staff, and creating more ways for parents to connect with other parents from similar cultures. This personal connection aligns with the Māori concept of whakawhanaungatanga, which emphasizes building meaningful, trusting relationships.

Strengths, Limitations, and Future Research

To inform future intervention development, this study explored sources of stress and solicited ideas about ways to reduce stress with caregivers and clinicians in a level 3 NICU in Aotearoa New Zealand. Soliciting participants' ideas on caregiver stress reduction in the NICU is an uncommon approach in the literature and a strength of the study.

This study is qualitative, and therefore its findings are not generalizable but may be transferable to similar populations. Our results are reflective of one participant group, in which the majority of participants were female, self-identified as European in ethnicity, and most were tertiary-level educated and employed. The study interviews were also conducted during the COVID-19 pandemic, which may have influenced participants' perceptions of stress and contributed to their ideas about stress reduction (such as more interest in digital sources of information).

In the recruitment process, 7 parent participants completed enrollment paperwork but did not schedule interviews. We do not know the reasons for this change in participation interest; however, we were aware of possible barriers, including parental hospitalization, a transfer out of the unit, and a lack of access to a mobile phone, limiting interview scheduling.

Future studies should strive to reduce barriers to participation in research for all caregivers with babies in the NICU, and they should aim to recruit more fathers and minority participants, who are underrepresented in the literature [5]. Caregivers and clinicians in the NICU are also valuable, knowledgeable resources for intervention development and design. Involving stakeholders such as parents, extended family members, and clinicians in intervention development is likely to improve patient-centered care, improve engagement in interventions, reduce inefficiencies in research, and improve research outcomes [35].

Conclusions

This study explored sources of parental stress in the NICU with caregivers and clinicians, and gathered participants' ideas and feedback on ways to reduce stress to inform future intervention development. Proposed solutions by participants focused on increasing parental empowerment, improving emotional and cultural support, and providing information in digital, mobile-friendly formats. This formative study was essential in identifying the unique needs and views of both caregivers and clinicians working in the NICU. It has since informed the development of a digitally delivered psychoeducational program that we are currently evaluating in a randomized controlled trial [36].

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Conflicts of Interest

Coauthor AS is Associate Editor of *JMIR Pediatrics and Parenting*.

Multimedia Appendix 1
Semistructured interview outlines.
[DOCX File, 19 KB - pediatrics_v8i1e66401_app1.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
NICU: neonatal intensive care unit
PSS:NICU: Parental Stress Scale: Neonatal Intensive Care Unit
REDCap: Research Electronic Data Capture

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Impact of a 6-Week Postpartum Text Messaging Program (Essential Coaching for Every Mother) at 6 Months: Follow-Up Study to a Randomized Controlled Trial

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Abstract

Background: Essential Coaching for Every Mother is an SMS text messaging program that positively improved parenting self-efficacy and reduced postpartum anxiety when measured immediately after intervention at 6 weeks postpartum. However, the impact of a short-term postpartum intervention over time is unknown.

Objective: This study aims to compare parenting self-efficacy, postpartum anxiety symptoms, postpartum depression symptoms, and perceived social support at 6 months postpartum for mothers in the Essential Coaching for Every Mother trial.

Methods: Participants (n=150) were randomized to Essential Coaching for Every Mother or control (usual care). Data were collected on parenting self-efficacy (primary outcome, Karitane Parenting Confidence Scale), postpartum anxiety symptoms (Postpartum Specific Anxiety Scale), postpartum depressive symptoms (Edinburgh Postnatal Depression Scale), and perceived social support (Multidimensional Scale of Perceived Social Support) at enrollment and 6-months postpartum. Data were analyzed using analyses of covariance and chi-square analysis.

Results: A total of 139 women completed the primary outcome at 6 months and 136 completed secondary outcomes. At 6 months, there were no statistically significant differences between mothers in the intervention group and mothers in the control group on any of the outcomes. More mothers in the intervention group had higher postpartum anxiety scores (31/68, 45.6%) than mothers in the control group (16/68, 23.5%; *P*=.007).

Conclusions: At 6 months postpartum, all mothers had similar scores on parenting self-efficacy, postpartum anxiety symptoms, postpartum depression symptoms, and social support. Thus, Essential Coaching for Every Mother improved parenting self-efficacy and reduced postpartum anxiety at 6 weeks, with all mothers having similar scores at 6 months postpartum.

Trial Registration: ClincialTrials.gov NCT04730570; https://clinicaltrials.gov/study/NCT04730570

International Registered Report Identifier (IRRID): RR2-10.2196/27138

(JMIR Pediatr Parent 2025;8:e62841) doi:10.2196/62841

KEYWORDS

mHealth; mobile health; SMS text message; text messages; messaging; self-efficacy; postpartum depression; postpartum anxiety; social support; intervention; postpartum; postnatal; mental health; parenting; mother; depression; anxiety; RCT; randomized controlled trial

Introduction

Background

The growth of digital health interventions to address mental health and maternal health outcomes has grown significantly over the past decades [1,2]. Despite this growth, the extent to which preventative digital health interventions improve or maintain outcomes after the intervention has concluded is unclear. This is known as the maintenance effect, which is essential to behavior change interventions and measures the impact of the intervention on outcomes after the treatment has taken place [3]. To date, evidence is mixed as to whether the positive effects of digital health interventions are maintained over time for a variety of health areas including obesity or weight loss [4], smoking [5], and increasing physical activity

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[6]. However, a meta-analysis on the maintenance effect of SMS text messaging–based interventions found that even after the intervention ends, there is a significant maintenance effect [4]. Furthermore, in the postpartum period, there have been mixed findings as to which type of interventions can maintain behavior change in maternal physical and mental health outcomes [7,8]. Thus, there is a need for reporting follow-up periods of digital health interventions to determine the effectiveness of maintenance postintervention [9] to facilitate the understanding of potential factors that lead to greater maintenance effects and whether ongoing follow-up is needed to maintain effects.

This study reports on the postimplementation outcomes of a 6-week postpartum SMS text messaging program called Essential Coaching for Every Mother. This program was designed to send daily SMS text messages to birthing people during the first 6-weeks postpartum who are living in Nova Scotia to improve parenting self-efficacy and perceived social support and to reduce postpartum anxiety and depression symptoms. Essential Coaching for Every Mother was developed through iterative testing with mothers/birthing people (eg, individuals who are physically capable of giving birth) and postpartum health care providers as an evidence-based, SMS text messaging program [10]. In the published results of this randomized controlled trial (RCT), it was found that primiparous women who received the Essential Coaching for Every Mother program had higher parenting self-efficacy at 6 weeks postbirth than those who did not receive the intervention [11]. Additionally, all mothers (regardless of parity) who received the intervention had lower postpartum anxiety symptoms than mothers who did not receive the intervention [11]. This success highlights the effectiveness of the Essential Coaching for Every Mother program to improve immediate parenting self-efficacy and reduce postpartum anxiety symptoms. However, outcomes were measured immediately after completing the intervention at 6 weeks postpartum, and thus, exploration of whether the study effects were maintained is needed to determine whether a short-term intervention has longer-term effectiveness and to determine whether ongoing follow-up is required to maintain positive outcomes.

Aim

This study aimed to compare parenting self-efficacy, postpartum anxiety symptoms, postpartum depression symptoms, and perceived social support at 6 months postpartum for mothers in the Essential Coaching for Every Mother trial.

Hypotheses

The following were our hypotheses:

1. Mothers who received Essential Coaching for Every Mother would have higher parenting self-efficacy and lower postpartum anxiety mean scores at 6 months compared with the control group.
2. Mothers who received Essential Coaching for Every Mother would be more likely to have clinically high parenting self-efficacy scores and clinically low postpartum anxiety scores at 6 months, compared with the control group.
3. Given that no significant differences were found in the original trial on postpartum depression symptoms and perceived social support, no differences at 6 months are hypothesized.

Methods

Participants

Birthing persons from Nova Scotia, Canada, were recruited remotely through SMS text messages between January 5, 2021, and August 1, 2021. Additional details are available in the study by Dol et al [11].

Ethical Considerations

This study was approved by the IWK Health Research Ethics Board (#1024984) and Nova Scotia Health Research Ethics Board (#1026534) and is registered with the ClinicalTrials.gov Protocol Registration System (NCT04730570). All participants provided informed consent and were able to opt out at any time.

Design

This is a follow-up evaluation of a 2-group, stratified, parallel arm RCT which followed a predefined protocol [12]. Participants were recruited from Nova Scotia, Canada via social media advertisements and research study posters at local hospitals and family practice clinics. Participants initiated contact by texting a study phone number to complete a preprogrammed eligibility screening process. All recruitment and onboarding occurred through standardized SMS text messages.

Upon enrollment, participants were first stratified by parity (primiparous and multiparous) and then using a 1:1 allocation, participants were randomized into the intervention or control group. Participants were not blind to their allocation, but hospital staff were. Researchers were aware of allocation but due to the nature of the randomization and remote data collection process, this did not increase any risk of bias.

Intervention

The Essential Coaching for Every Mother program includes standardized evidence-based SMS text messages that provide information related to newborn care and maternal mental health in the first 6-weeks postpartum [10]. Participants allocated to the intervention are sent messages from birth to 6 weeks postpartum based on the age of their newborn, with 2 messages sent per day in the first 2 weeks (one at 10 AM and one at 5 PM) and a daily message (at 10 AM) for weeks 3 through 6. Participants allocated to the control group did not receive any SMS text messages aside from recruitment and survey requests. No changes to regular care were implemented and no study contact occurred between the 6-week and 6-month surveys.

Outcome Measures

Participants were invited to complete a survey hosted on Research Electronic Data Capture (REDCap) [13] via SMS text message at enrollment/baseline (preintervention), 6 weeks postpartum (postintervention), and 6 months postpartum (follow-up). For the purposes of this study, only the baseline and 6-month data were used. The primary outcome was parenting self-efficacy measured using the Karitane Parenting Confidence Scale [14]. This 15-item scale assesses the perceived

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self-efficacy of mothers with newborns from birth to 12 months of age. Scores can range between 0 and 45 and a score of 39 or less is considered to be clinically low perceived parenting self-efficacy [14]. Secondary outcomes included postpartum anxiety symptoms (Postpartum Specific Anxiety Scale [PSAS] [15]), postpartum depression symptoms (Edinburgh Postnatal Depression Scale [EPDS] [16]), and perceived social support (Multidimensional Scale of Perceived Social Support [17]). For the PSAS, the clinical cut-off for postpartum anxiety symptoms is 112 out of a possible 201 [15] and for the EPDS, a score of 9 or above indicates depressive symptoms in a community sample and 13 or greater indicates probable clinical depression [16,18]. Therefore, higher scores in both the PSAS and EPDS indicate higher symptomology of postpartum anxiety and depression, respectively. No clinical cut-off scores are available for the Multidimensional Scale of Perceived Social Support.

Data Analysis

Data were analyzed on a per-protocol analysis, excluding women who requested to stop receiving the messages or did not return the 6-month follow-up survey. A series of analyses of covariances were conducted to examine the effects of the intervention on the outcomes of interest at 6 months postpartum considering allocation. In all analyses of covariances, parity, maternal age, and scores on the respective outcomes at baseline were entered as co-variates (ie, when analyzing parenting self-efficacy, parity, maternal age, baseline parenting self-efficacy scores were included as co-variates).

Chi-square analysis was conducted to compare whether participants scored above or below the clinical cut-off that identifies low parenting self-efficacy or high postpartum anxiety and depression symptoms. For the chi-square analysis, all participants who completed the outcome survey at 6 months were included. A *P* value of .05 was considered significant for all outcomes. SPSS (version 29.0; IBM SPSS Statistics) was used for analysis.

Results

Overview

Of the 171 participants randomized, 150 participants completed the baseline survey and were enrolled in the study. Of those enrolled, 139 (81.2%) participants completed the 6-month follow-up survey and were included in this analysis (Figure 1). All participants identified as cis-gendered females and as mothers; thus, the term “mother” will be used in describing the sample. Mothers were predominantly married, White, and had an undergraduate degree or higher. At 6 months, the groups were similar in all demographics, except for race, with mothers in the control group being more likely to identify as White compared with mothers in the intervention group. This differed from baseline, as there was no difference in race but mothers in the control group were significantly older than mothers in the intervention group (*P*=.053) [11]. At baseline, there were no differences between the groups on any of the primary outcomes [11]. Additional demographic details are available in Table 1 and Dol et al [11].

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Figure 1. Consolidated Standards of Reporting Trails (CONSORT) flowchart.

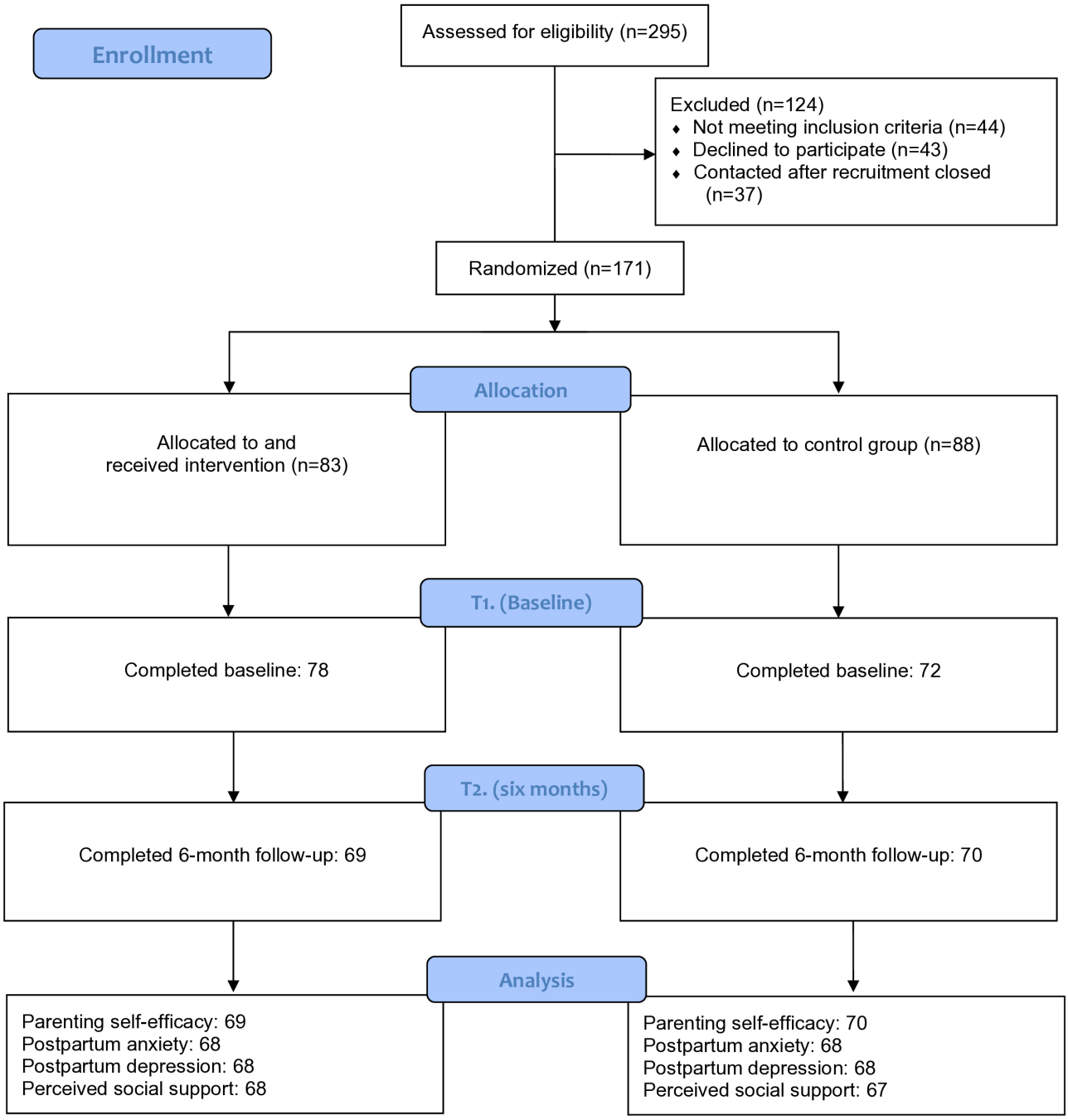

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Table . Baseline characteristics for the intervention and control groups.

Demographics	Intervention (n=69)	Control (n=70)	*P* value
Maternal age (years), mean (SD)	30.7 (4.8)	32.1 (4.1)	.07[a]
History of depression or anxiety, n (%)	24 (34.8)	18 (25.7)	.27[b]
Marital status, n (%)			.71[b]
Single or not living with partner	3 (4.3)	4 (5.7)	
Married, common-law, or living with partner	66 (95.7)	66 (94.3)	
Household income in CAD[c], n (%)			.06[b]
Less than 74,999 (US $ 52,286)	26 (37.7)	16 (22.9)	
75,000-149,999 (US $52,287-US $104,573)	31 (44.9)	34 (48.6)	
Over 150,000 (US $104,574)	8 (11.6)	17 (24.3)	
Prefer not to answer	4 (7.2)	3 (4.3)	
Education n (%)			.31[b]
High school or incomplete college or university	4 (5.8)	9 (12.9)	
College diploma	16 (23.2)	10 (14.3)	
Undergraduate degree (BA, BSc)	31 (44.9)	35 (50.0)	
Graduate degree (MSc, PhD)	17 (24.6)	16 (22.9)	
Prefer not to answer	1 (1.5)	__[d]	
Race, n (%)			.02[b]
White	58 (84.1)	67 (95.7)	
Non-White (included Black, Chinese, Filipino, Latin American, Greek, and Indigenous)	11 (15.9)	3 (4.3)	

[a]Conducted using independent *t* test.

[b]conducted using Pearson chi-square analysis.

[c]Conversion CAD to USD estimated at 1 CAD=US $0.70.

[d]Not applicable.

Parenting Self-Efficacy

Based on the 139 mothers who completed parenting self-efficacy measures at 6 months, there was no statistically significant difference in parenting self-efficacy at 6 months postpartum based on allocation ($F_{1,134}$=0.112, *P*=.74, partial η^2=0.001) (Table 2). A chi-square analysis was conducted to determine whether the proportion of mothers who had high (≥40) or low parenting self-efficacy scores (≤39) at 6 months were different based on group allocation. There were no differences in the proportion of mothers with high or low parenting self-efficacy scores based on allocation at 6 months postpartum (χ^2_1=0.091, *P*=.76) (Table 3).

Table . Adjusted means scores based on allocation at 6 months postpartum.

Outcome	Intervention, mean (SD)	Control, mean (SD)	*P* value
Parenting self-efficacy (n=139)	40.14 (3.73)	40.11 (3.94)	.74
Postpartum anxiety scores (n=136)	106.71 (20.97)	99.35 (19.13)	.30
Postpartum depression scores (n=136)	10.01 (4.66)	8.19 (4.94)	.20
Social support (n=135)	5.82 (0.95)	5.82 (1.12)	.79

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Table . Comparison of high and low scores at 6 months postpartum by allocation.

Outcome	Intervention, n (%)	Control, n (%)	*P* value
Parenting self-efficacy[a]			.76
High (40 or above)	47 (68.1)	46 (65.7)	
Low (39 or below)	22 (31.9)	24 (34.3)	
Postpartum anxiety[b]			.007
High (112 or above)	31 (45.6)	16 (23.5)	
Low (111 or below)	37 (54.4)	52 (76.5)	
Postpartum depression[b]			.12
High (9 or above)	42 (61.8)	33 (48.5)	
Low (8 or below)	26 (38.2)	35 (51.5)	
Postpartum depression[b]			.08
High (13 or above)	17 (25)	9 (13.2)	
Low (12 or below)	51 (75)	59 (86.8)	

[a]Intervention (n=69) and control (n=70).

[b]Intervention (n=68) and control (n=68).

Postpartum Anxiety Symptoms

Based on 136 mothers who completed the postpartum anxiety measure at 6 months postpartum, there was no statistically significant difference in postpartum anxiety scores at 6 months postpartum ($F_{1,131}$=1.077, P=.30, partial η^2=0.00) (Table 2). These findings differed in the chi-square analysis, where mothers in the intervention group were more likely to have clinically high (≥112) postpartum anxiety scores (31/68, 45.6%) compared with those in the control group (16/68, 23.5%) (χ^2_1=7.315, P=.007) (Table 3).

Postpartum Depression Symptoms

Based on the 136 mothers who completed the postpartum depression measure at 6 months, there was no statistically significant difference in postpartum depression mean scores at 6 months postpartum based on allocation ($F_{1,131}$=1.680, P=.20, partial η^2=0.013) (Table 2). In the chi-square analysis comparing mothers with scores ≥9 to ≤8, there were no differences in the proportion of mothers with high or low postpartum depression symptoms at 6 months postpartum (χ^2_1=2.408, P=.12). Additionally, comparing participants who scored ≥13 or ≤12, there were no differences in the proportion of mothers with high or low postpartum depression symptoms (χ^2_1=3.043, P=.08).

Perceived Social Support

Based on the 135 mothers who completed the perceived social support measure, there was no statistically significant difference in perceived social support scores at 6 months postpartum based on allocation ($F_{1,130}$=0.071, P=.79, partial η^2=0.001) (Table 2).

Discussion

Principal Results

This study sought to explore mothers' parenting self-efficacy, postpartum anxiety symptoms, postpartum depression symptoms, and perceived social support at 6 months postpartum, after receiving Essential Coaching for Every Mother, a 6-week postpartum SMS text messaging intervention immediately after birth. At 6 months, all mothers, regardless of their allocation, had similar scores on all outcomes. Mothers in the intervention group were slightly more likely to have high postpartum anxiety symptoms compared with mothers in the control group. The implications of these findings are discussed below.

For the primary outcome of parenting self-efficacy, the hypotheses were not supported in the analysis. The hypotheses were that mothers who received Essential Coaching for Every Mother would have higher mean parenting self-efficacy scores compared with mothers in the control group and would be more likely to have parenting self-efficacy scores that would be considered high (≥40). While there were no significant differences in scores or differences in high scores, both the intervention and control groups had mean scores that would be considered "high" parenting self-efficacy. In the RCT measuring immediate intervention effectiveness [11], primiparous women who received the Essential Coaching for Every Mother program had a greater increase in parenting self-efficacy than those who did not receive the program. This may suggest that Essential Coaching for Every Mother was able to improve parenting self-efficacy during the earlier postpartum period, particularly for primiparous women, showing potential to improve immediate parenting self-efficacy during an early critical period. Given the relatively high parenting self-efficacy scores at 6 months postpartum, it is clear that parenting self-efficacy increases over time in the first 6 months as mothers become more comfortable and confident in their parenting role [19].

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Early interventions for primiparous mothers may be helpful in bridging the gap to achieve earlier parenting self-efficacy.

In relation to postpartum anxiety symptoms, the original RCT found that postpartum anxiety symptoms decreased at 6 weeks for women who received the Essential Coaching for Every Mother program, regardless of parity, compared with the control group [11]. Thus, the hypothesis was that mothers who received Essential Coaching for Every Mother would have lower mean postpartum anxiety scores at 6 months as well as more mothers would have clinically low postpartum anxiety scores compared with the control group. Like parenting self-efficacy, there were no significant differences at 6 months between the groups on average postpartum anxiety scores. However, mothers in the intervention group were more likely to have a clinically high postpartum anxiety score compared with mothers in the control group. Postpartum anxiety symptoms have been found to be higher in mothers with an infant 4 - 6 months than mothers with an infant 0 - 3 months [20], suggesting that perhaps there may be factors that influence a later emergence of anxiety symptoms during the postpartum period. Additionally, it has been suggested that postpartum anxiety may have a u-shaped relationship, with mothers who have higher anxiety levels during pregnancy experiencing a dip when their infant is born and then continue to increase back up to pregnancy levels up to 24 months postpartum whereas mothers with low anxiety levels during pregnancy tend to stay low across the postpartum period [21]. In this study, anxiety scores at baseline were higher for the intervention group, so there may be an influence of self-referral bias whereby mothers who were more anxious were interested in enrolling in the study. Particularly since the COVID-19 pandemic, the loss of support and ability to consult with health care providers or friends has also been associated with higher levels of mental health concerns [22]. Combined with normal fluctuation that occurs in the postpartum period along with decreased social support and potentially being predisposed to higher anxiety, there may be factors other than the Essential Coaching for Every Mother program that resulted in increased anxiety symptoms for intervention mothers. Despite the higher levels in the Essential Coaching for Every Mother group, both groups had a mean below the clinical cut-off for high levels of postpartum anxiety. At the individual level, it is important to ensure that birthing people have access to ongoing mental health support throughout the postpartum period.

Last, no differences in postpartum depression symptoms and perceived social support at 6 months were hypothesized since there were no significant differences found in the original trial at 6 weeks postpartum. This was found in both analyses, with no differences in postpartum depression symptoms and social support at 6 months. Despite the lack of significant findings, mothers in the intervention group did have higher postpartum depression mean scores, and more mothers were in the >9 group than mothers in the control group. During the recruitment for the RCT, participants were not excluded if they were currently experiencing mental health concerns or had a history of mental health concerns. While randomization is expected to equalize this between groups by design, this may not have been sufficient to balance this across groups as the intervention group had higher, yet not significant, postpartum depression symptoms at baseline as well [11]. Additionally, the intervention group had a higher, although again not significant, difference in having a history of mental health concerns (24/69, 34.8% vs 18/70, 25.7%) which may have influenced their postpartum depression symptoms at 6 months postpartum.

Limitations

This follow-up analysis is limited by the small sample size and loss of follow-up, which may have impacted the ability to be sufficiently powered in the analyses. While the original study was sufficiently powered, this follow-up study lost some power as participants who did not complete the 6-month timepoint were removed. This study was carried out in Canada in English, and findings may be different in other populations. We were unable to explore other variables that influenced mothers' psychosocial and mental health scores across the postpartum period. Mothers who participated in the study may not be fully representative of the population, as they were predominately White, highly educated, and high-income earners. Additionally, our sample may have been influenced by self-referral bias, as participants were remotely recruited and signed themselves up for participation and there was a greater number of participants in the control group who dropped out before completing the baseline questionnaire [11]. Given these limitations, the findings should be interpreted in this light.

Comparison With Prior Work

Questions remain about the appropriate dose and engagement of postpartum SMS text messaging interventions to improve psychosocial and mental health outcomes. The first year after an infant is born is associated with significant changes in physical and emotional outcomes for mothers. Risk factors for postpartum depression and anxiety are wide-ranging and include, but are not limited to, having depression during pregnancy [23-25], having a history of depression [23,26], or experiencing abuse or marital conflict [24,25]. Additionally, evidence shows that postpartum anxiety varies across the first 6 months of the postpartum period, ranging from 14.8% to 17.8% [27]. In addition, well established is the comorbidity between anxiety, depression, social support, and parenting self-efficacy in the postpartum period [19,28], suggesting that postpartum adjustment is multifaceted and interdependent. More research is needed to understand whether ongoing support throughout the postpartum period may be able to alter mental health outcomes as well as other interventions that may address additional risk factors. Given that Essential Coaching for Every Mother was designed primarily to improve parenting self-efficacy, it is important that other supports are available to mothers that target mental health outcomes beyond the initial 6-weeks.

There is a challenge with designing interventions that improve mental health outcomes in the postpartum period, particularly in regard to universal support to women considered low risk [29]. In a recent scoping review analyzing 70 unique evidence-based universal interventions to support parents between conception and 12 months postpartum, only half reported evidence of effectiveness against their reported outcome measures, suggesting a need for a multifaceted approach to support parent well-being across the perinatal period [30].

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Another review examining digital health interventions for postpartum anxiety and depression found that digital health interventions significantly reduced postpartum depression and postpartum anxiety symptoms [31]. It is also important to consider what might make an intervention effective beyond the treatment period. In analyzing the maintenance effectiveness of physical activity and dietary interventions for adults, Fjeldsoe et al [32] found that intervention characteristics that were associated with maintenance effects were those of longer duration (>24 weeks), face-to-face contact, the use of a variety of intervention strategies, and the use of follow-up prompts. Examining parent training more broadly, providing booster sessions or intermittent contact postintervention, have been suggested as potentially effective strategies to maintain intervention effects over time [33].

While digital health interventions are desired and accepted by postpartum mothers [34], interventions designed for implementation during the postpartum period should take into consideration how interventions can maintain positive impacts over time. In a meta-synthesis of what women want in the postpartum period, Finlayson et al [35] clearly summarize: "To cope with this period of adjustment women express the need for practical, emotional and psychological support from family members, peer groups and online sources, as well as from health providers. Women also want information and reassurance from health providers delivered in a consistent manner by authentic, familiar providers who recognise the mother's as well as baby's needs, within a well-resourced and flexible healthcare system that respects their cultural context". Given the multiple challenges that emerge for mothers during the postpartum period, both in-person and digital support from reliable sources of information that respond to mothers' needs and infant development is needed. Engaging patients in the development of perinatal digital health solutions is important to improve health outcomes but is not yet common practice [36-38].

Future Directions

Future work should explore the potential to expand the timeline of the Essential Coaching for Every Mother program beyond the immediate 6-week period, as there are clearly challenges parents experience beyond this time frame that are impacting their psychosocial and mental health. Additionally, future work should consider the population that may be in most need of such an intervention, such as primiparous mothers or those with higher postpartum anxiety and depression scores at baseline. Future work should identify at-risk groups and determine whether any differences between low-risk and high-risk groups can be improved with the Essential Coaching for Every Mother program.

Conclusions

In conclusion, mothers, regardless of whether they received Essential Coaching for Every Mother, a 6-week postpartum intervention, had similar scores on parenting self-efficacy, postpartum anxiety symptoms, postpartum depression symptoms, and social support at 6 months. This suggests that the Essential Coaching for Every Mother program was able to improve parenting self-efficacy for primiparous mothers and reduce postpartum anxiety symptoms in the immediate postpartum period. At 6 months, both groups were similar, indicating that support during the immediate 6-week postpartum period is critical to ensure early intervention.

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Authors' Contributions

JD and MCY researched the literature and conceived the study with input from MA and DM. JD led protocol development, gained ethical approval, patient recruitment, and data analysis. AKG provided statistical guidance on the analysis. JD wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Checklist 1
CONSORT-eHEALTH checklist.
[PDF File, 1092 KB - pediatrics_v8i1e62841_app1.pdf]

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Abbreviations

EPDS: Edinburgh Postnatal Depression Scale
PSAS: Postpartum Specific Anxiety Scale
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture

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Fetal Birth Weight Prediction in the Third Trimester: Retrospective Cohort Study and Development of an Ensemble Model

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Abstract

Background: Accurate third-trimester birth weight prediction is vital for reducing adverse outcomes, and machine learning (ML) offers superior precision over traditional ultrasound methods.

Objective: This study aims to develop an ML model on the basis of clinical big data for accurate prediction of birth weight in the third trimester of pregnancy, which can help reduce adverse maternal and fetal outcomes.

Methods: From January 1, 2018 to December 31, 2019, a retrospective cohort study involving 16,655 singleton live births without congenital anomalies (>28 weeks of gestation) was conducted in a tertiary first-class hospital in Shanghai. The initial set of data was divided into a train set for algorithm development and a test set on which the algorithm was divided in a ratio of 4:1. We extracted maternal and neonatal delivery outcomes, as well as parental demographics, obstetric clinical data, and sonographic fetal biometry, from electronic medical records. A total of 5 basic ML algorithms, including Ridge, SVM, Random Forest, extreme gradient boosting (XGBoost), and Multi-Layer Perceptron, were used to develop the prediction model, which was then averaged into an ensemble learning model. The models were compared using accuracy, mean squared error, root mean squared error, and mean absolute error. International Peace Maternity and Child Health Hospital's Research Ethics Committee granted ethical approval for the usage of patient information (GKLW2021-20).

Results: Train and test sets contained a total of 13,324 and 3331 cases, respectively. From a total of 59 variables, we selected 17 variables that were readily available for the "few feature model," which achieved high predictive power with an accuracy of 81% and significantly exceeded ultrasound formula methods. In addition, our model maintained superior performance for low birth weight and macrosomic fetal populations.

Conclusions: Our research investigated an innovative artificial intelligence model for predicting fetal birth weight and maximizing health care resource use. In the era of big data, our model improves maternal and fetal outcomes and promotes precision medicine.

(JMIR Pediatr Parent 2025;8:e59377) doi:10.2196/59377

KEYWORDS

fetal birthweight; ensemble learning model; machine learning; prediction model; ultrasonography; macrosomia; low birth weight; birth weight; fetal; AI; artificial intelligence; prenatal; prenatal care; Shanghai; neonatal; maternal; parental

Introduction

The assessment of fetal birth weight for the purpose of fetal growth monitoring is essential in contemporary prenatal care, as anomalies in growth are linked with negative consequences for both the mother and the fetus [1,2]. For instance, the birth of a macrosomic fetus is associated to unfavorable delivery outcomes (operative vaginal, caesarean delivery, or shoulder dystocia), trauma (maternal severe birth canal laceration and postpartum hemorrhage, fetal clavicular fracture, brachial plexus injury, neonatal hypoglycemia, and birth asphyxia) [3]. Infants with low birth weight may present a greater risk of acute or chronic hypoxia, acidemia, fetal demise, neonatal death, neonatal morbidity, and abnormal neurodevelopmental outcome, which are more likely to be admitted to a neonatal intensive care unit (NICU) and to have lifelong illnesses [4]. Consequently, precise fetal birthweight prediction helps clinical decision-making, such as appropriate prenatal treatments and acceptable mode of delivery selection, which might assist to enhance pregnancy outcomes [5].

Ultrasonographic evaluation based on biometric measurements and regression equations is the method of choice in obstetrics

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due to its objectivity and convenience. However, the majority of ultrasonic formulae are based on western populations, and there are biases when applied to Chinese as fetal birth weight after 20 weeks varies significantly by race [6]. Predictions of macrosomia and low birth weight infants based on estimated fetal weight are significantly less accurate [7,8]. A meta-analysis of 29 studies reveals that the pooled sensitivity of the Hadlock formula for fetal weight estimation was only 0.56. (95% CI 0.49 - 0.62) [9]. Inaccurate estimations may result in inappropriate interventions, so alternative approaches to precision estimation are urgently required.

With more ability than traditional statistical methods of handling complex, nonlinear, and multidimensional clinical data, machine learning (ML) has been explored successfully in several obstetrics domains, including gestational diabetes mellitus (GDM) [10], preterm birth [11], and postpartum hemorrhage [12]. Currently, there are only a few of published models using ML to estimate fetal birth weight before delivery, such as Wang et al [13]. used a Random Forest Algorithm to predict macrosomia and Gao et al [14] proposed a fetal weight prediction model based on genetic algorithm to improve back propagation (GA-BP) neural network. However, their simple size was too small and the feature parameters were insufficient; consequently, the performance of published models was unreliable and differentially robust.

In this study, we aimed to analyze the vast clinical data of a large cohort of pregnant women and create predictive models for the prediction of fetal birth weight using a variety of ML algorithms. Compared to the preexisting ultrasound formula, our novel ML models are anticipated to achieve an advanced result with a high degree of accuracy and offer convenient service to both medical staff and families of pregnant women in the future.

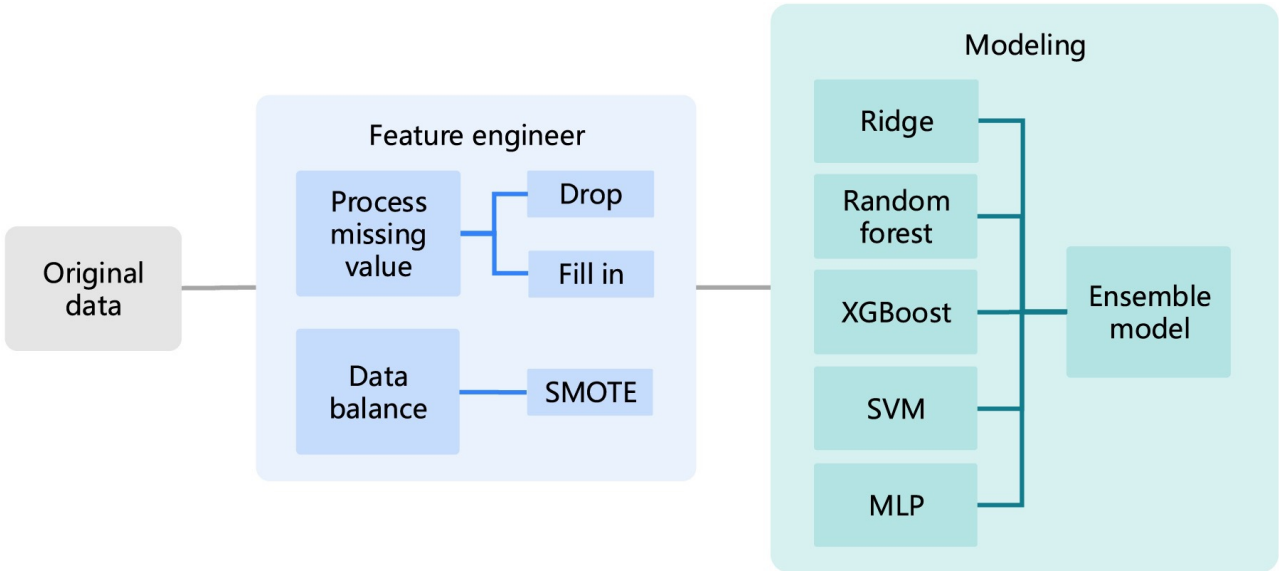
Methods

Study Design

This is a retrospective observational study using ML algorithms to increase the accuracy of fetal birth weight prediction based on real-world data. The process included feature engineering and modeling, as depicted in Figure 1 and described in detail in this section. This project established a simplified model suitable for maternal self-testing or clinical staff rapid prediction and transformed this model into a mobile application for use in clinical practice. Previously, there existed a model suitable for medical electronic record system with more detailed features, and the results will be improved.

This research was reported in accordance with the Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD) statement. The official TRIPOD checklist is shown in Table S1 (Multimedia Appendix 1).

Figure 1. The whole process of fetal birth weight prediction. SMOTE: Synthetic Minority Over-sampling Technique; SVM: support vector machine; MLP: multilayer perceptron.



Study Population and Data Source

International Peace Maternity and Child Health Hospital (IPMCH), a tertiary first-class hospital in China, is the source of the data. The following were the criteria for inclusion: (1) gestational weeks of less than 28, (2) a singleton pregnancy, and (3) a normal pregnancy outcome (no or severe fetal malformations, stillbirths, or neonatal deaths). We searched for predictors of fetal birth weight that were repeatedly reported in studies or systematic reviews, can be easily ascertained in different settings with various clinical experiences, and are part of the routine examination during pregnancy. It includes samples of 18,837 pregnant women who gave birth between January 1, 2018 and December 31, 2019, including parental demographics, clinical characteristics, ultrasound information, and laboratory tests. Concerning the height and weight of the husband were oral reported by pregnant women, both the reliability and filling rate were extremely low, so we only included the age and education level information of the husband. A total of 59 characteristics, was shown in Table S2 in Multimedia Appendix

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1. The measurement data's extreme and error values were eliminated, and the categorical data were standardized and coded.

At the first prenatal visit, between 9 and 13 weeks of gestation, we gathered parental data on the demographics, reproductive history, and medical history. Parental age was calculated through the date of birth and double checked by interviews. Face-to-face interviews were used to record maternal weight, height, parity, gravity, parental educational level, and baseline blood pressure (diastolic blood pressure [DBP] and systolic blood pressure [SBP]). Gestational weight gain (GWG) throughout pregnancy was measured by subtracting prepregnancy weight from the woman's weight at her final prenatal checkup. Gestational age was derived from sonographic measurement of the fetal crown-rump length or biparietal diameter. In the first trimester, between 9 and 14 weeks of pregnancy, samples of the mother's fasting lipid serum were collected in vacutainer tubes of 10 mL and centrifuged. Triglycerides (TG), high-density lipoprotein (HDL), low-density lipoprotein (LDL), and total cholesterol (TC), were among the laboratory indices. The glucose index was derived from a 75-g oral glucose tolerance test (OGTT) between pregnancy weeks 24 and 28—including fasting plasma glucose (FPG), 1-hour glucose (GLU-1H), 2-hour glucose (GLU-2H), and hemoglobin (HGB). Attending physicians with more than 5 years of obstetric ultrasound experience performed routine sonographic evaluations of the fetal abdominal circumference (AC), head circumference (HC), biparietal diameter (BPD), humerus length (HL), transverse trunk diameter (TTD), femur length (FL), amniotic fluid index (AFI), and anteroposterior trunk diameter (APTD). Only ultrasound data within 2 weeks before delivery were collected. Each neonate's birthweight (in gram) was measured routinely by registered midwives using an electronic weighing scale within half an hour of delivery. Those newborns with birth weights <2500 g or ≥4000 g were defined as low birth weight or macrosomia, separately. Shinozuka's formula [15] was used to estimate fetal weight since it has been shown to be most suitable for weighing Asian fetuses.

$$(1) y=1.07*BPD3+3.42*APTD*TTD*FL$$

During the modeling process, four-fifths of the sample is picked at random as train data, and one-fifth is used as test data. Each model is trained on the same dataset partition.

Model Training and Validation

The Model Training and Validation process involved feature engineering steps, including handling missing values, filtering outliers, creating new features, selecting important features, and balancing the dataset. Pearson correlation coefficient, Ridge, and XGBoost methods were used for feature selection. The dataset imbalance was addressed by dividing the samples into categories and performing up-sampling using the SMOTE algorithm. Ensemble learning with bagging was used, averaging results from benchmark models, which included Ridge, Random Forest, support vector machine (SVM), k-nearest neighbor (KNN), and Multilayer Perceptron (MLP). Evaluation metrics such as relative error (RE), absolute error (AE), mean squared error (MSE), root mean squared error (RMSE), and mean absolute error (MAE) were used. The process aimed to optimize the model's accuracy in predicting fetal birth weight.

Statistical Analyses

The classification index expressed in numbers and percentages (%). The continuous data were shown as mean (SD). Kolmogorov-Smirnov (KS) divergence were used to measure whether there is a significant difference between 2 sets of data distributions, a P value less than .05 was deemed significant.

Ethical Considerations

International Peace Maternity and Child Health Hospital's Research Ethics Committee granted ethical approval for the usage of patient information (GKLW2021-20). We ascertained that the International Peace Maternity and Child Health Hospital's Ethics Committee waived informed consent since the research was reviewed.

Results

Sample Size and Clinical Features

A total of 16,655 individuals were enrolled in our study after application of inclusion criteria and data cleaning; 13,324 cases were included in the train dataset, and 3331 cases were included in the test dataset (Figure 2).

Table 1 provides an outline of clinical characteristics. The incidence of low birth weight and macrosomia did not differ statistically between the train dataset and the test dataset (low birth weight 1.79% vs 1.92%; P=.24; macrosomia 5.87% vs 5.88%; P=.98). There is generally good data consistency between the training dataset and the testing dataset (Table 1).

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Figure 2. Chart illustrating patient flow in this study. SMOTE:Synthetic Minority Over-sampling Technique .

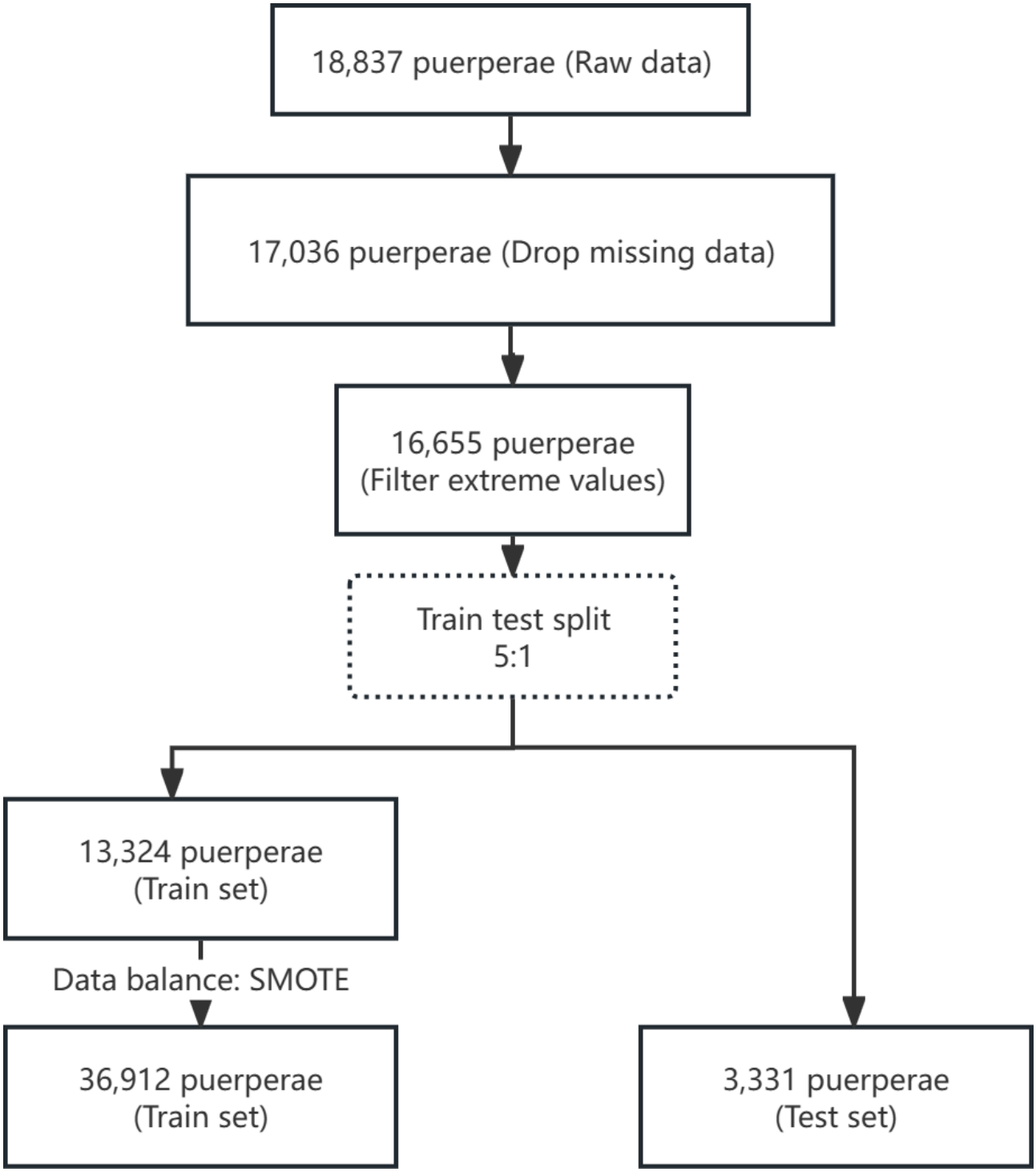

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Table . Clinical characteristics of the train group and test group.

Characteristics		Train set (N=13,324)	Test set (N=3331)	*P* value
Fetal birth weight categories, n (%)				
	Low birth weight	238 (1.79)	64 (1.92)	.24
	Normal weight	12304 (92.34)	3071 (92.2)	.24
	Macrosomia	782 (5.87)	196 (5.88)	.98
Sociodemographic characteristics, mean (SD)				
	Preg_Days[a]	274.5 (8.1)	274.7 (8)	.82
	Gravida	1.9 (1.1)	1.9 (1.1)	.98
	Parity	1.3 (0.5)	1.3 (0.5)	≥.99
	pre_weight[b]	55.8 (7.9)	55.9 (8.2)	.98
	maternal_weight_last[c]	70.5 (9)	70.6 (9.1)	.99
	GA_last[d]	269.8 (8.9)	270 (9)	.68
	GWG[e]	14.7 (4.5)	14.7 (4.5)	.72
	height	161.9 (5)	161.9 (5)	.91
	pre_BMI[f]	21.3 (2.8)	21.3 (2.8)	.75
	SBP_first	111.3 (12.5)	111.2 (12.5)	.84
	DBP_first	69.4 (9.8)	69.4 (9.6)	.85
	GDM[g]	0.1 (0.3)	0.2 (0.4)	.7
	HDP[h]	0.1 (0.2)	0.1 (0.2)	≥.99
Ultrasound measurements, mean (SD)				
	BPD[i]	92.9 (4.1)	93 (4.1)	.47
	HC[j]	317.9 (13.2)	318.3 (13.4)	.34
	FL[k]	68.2 (3.3)	68.3 (3.3)	.36
	HL[l]	59.8 (3.2)	59.9 (3.3)	.07
	AC[m]	315.9 (20.2)	316.8 (19.8)	.16
	TTD[n]	99.8 (7.2)	100.2 (7.1)	.06
	APTD[o]	101.7 (7.4)	101.9 (7.5)	.42
	days_last_ul_to_delivery[p]	11.4 (8.8)	11.1 (8.6)	.22
	AFI[q]	126.3 (31.5)	125.6 (30.9)	.2
Laboratory indices, mean (SD)				
	FPG[r]	4.2 (0.4)	4.2 (0.4)	.87
	GLU-1H[s]	7.8 (1.5)	7.8 (1.6)	.32
	GLU-2H[t]	6.6 (1.4)	6.6 (1.4)	.73
	HBA_{1C}	5 (0.3)	5 (0.3)	.98
	HDL[u]	2 (0.4)	1.9 (0.4)	.29
	LDL[v]	2.5 (0.7)	2.6 (0.7)	.61
	TG[w]	1.4 (0.5)	1.4 (0.5)	.51
	TC[x]	4.5 (0.7)	4.5 (0.7)	.67

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Characteristics	Train set (N=13,324)	Test set (N=3331)	*P* value
HGB[y]	118.7 (11.4)	118.8 (11.6)	.67

[a]Gestational age.
[b]Prepregnancy weight.
[c]Maternal weight at the last antenatal examination.
[d]Gestational age at the last antenatal examination.
[e]GWG: gestational weight gain.
[f]Prepregnancy body mass index.
[g]GDM: gestational diabetes mellitus.
[h]HDP: hypertensive disorders of pregnancy.
[i]BPD: biparietal diameter.
[j]HC:head circumference.
[k]FL: femur length.
[l]HL: humerus length.
[m]AC: abdominal circumference.
[n]TTD: transverse trunk diameter.
[o]ATD: anteroposterior trunk diameter.
[p]The number of days from the last antenatal ultrasound measurement to delivery.
[q]Sum of Amniotic Fluid Indices.
[r]Fasting plasma glucose.
[s]1-hour glucose.
[t]2-hour glucose.
[u]HDL: high-density lipoprotein.
[v]LDL: low-density lipoprotein.
[w]TG: triglycerides.
[x]TC: total cholesterol.
[y]HGB: hemoglobin

Variable Setting

Table S2 (Multimedia Appendix 1) displays 59 alternative variables, including sociodemographic characteristics, ultrasound measurements, and laboratory indices. In order to facilitate fetal birthweight prediction in the real world, a number of feature selection models were used to evaluate feature significance, as depicted in Figure 3. Due to the significance of features and the difficulty of obtaining them in the real world, few variables were eliminated before engineering implementation. A total of 17 variables were selected into our "few feather model," including "Parity," "pre_weight," "maternal_weight_last," "days_last_ul_to_delivery," "BMI," "GWG," "GA," "GWG_Inspect_Preg_Days," "GDM," "BPD," "HC," "FL," "HL," "AC," "TTD," "APTD," and "AFI" (Table 2). Those variables can be verbally responded to by pregnant women or extracted through an ultrasound report, instead of the blood test report requiring careful checking, which is convenient for clinical use and saves time.

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Figure 3. Feature importance on different models.

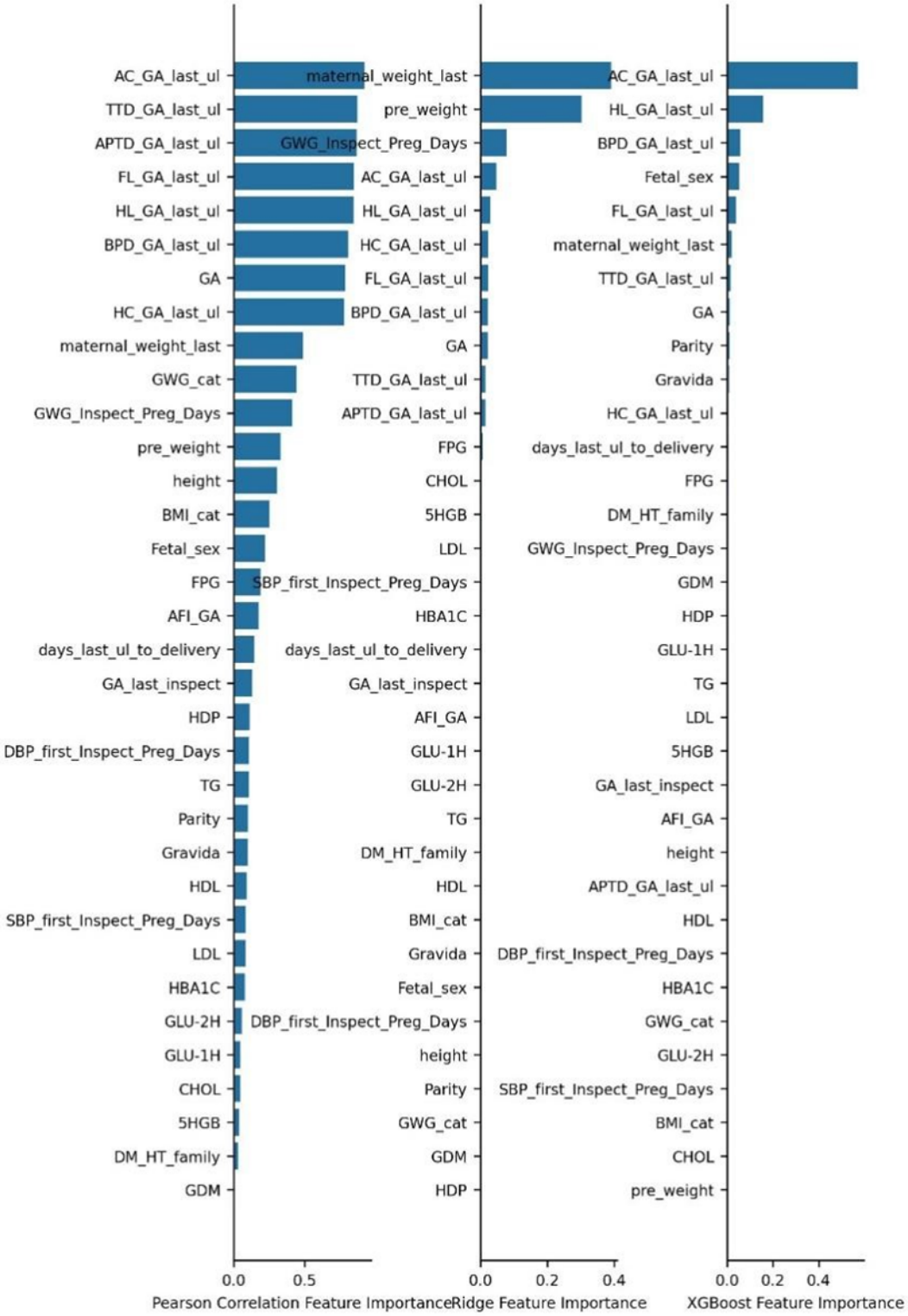

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Table . Meaning and value range of 17 features.

Variable	Variable meaning	Minimum	Maximum	Unit
Preg_Days	Gestational age	239	295	days
Parity	Parity	1	4	__[a]
pre_weight	Prepregnancy weight	40	125	kg
maternal_weight_last	Maternal weight at the last antenatal examination	43.6	129.3	kg
GA_last	Gestational age at the last antenatal examination	86	290	days
GWG	Gestational weight gain	−45.4	45.2	kg
pre_BMI	Prepregnancy body mass index	14.5	39.6	kg/m^2
GDM	Gestational diabetes mellitus	0	1	—
BPD	Biparietal diameter	53	109	mm
HC	Head circumference	197	367	mm
FL	Femur length	37	78	mm
HL	Humerus length	4	71	mm
AC	Abdominal circumference	158	381	mm
TTD	Transverse trunk diameter	45	130	mm
APTD	Anteroposterior trunk diameter	55	128	mm
days_last_ul_to_delivery	The number of days from the last antenatal ultrasound measurement to delivery	0	113	days
AFI	Sum of Amniotic Fluid Indices	12	333	mm

[a]Not available.

The Development and Performance of Prediction Model

The basic models, with the exception of KNN, were substantially superior to the ultrasound formula. Therefore, KNN was omitted from the ensemble model, which was a bagging ensemble model based on the results of the remaining 5 models. Using a variety of models, including basic models and an ensemble model, to predict fetal birthweight, and comparing the results of these models to those calculated by the original ultrasound formula, while keeping only a few essential and easily-obtained variables. The ensemble model with 17 variables predicted fantasy performance displayed in Table 3 with an accuracy of 81.84% (RE≤10%) and 66.98% (AE≤250 g) , and the MSE, RMSE, and MAE were the lowest when compared with other methods. (Table S3 in Multimedia Appendix 1, and Figures 4 and 5). The results demonstrated that the effect of the final ensemble learning is greater than that of the ultrasound formula and other single models.

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Table . Evaluation on different models based on 17 features.

Model		Accuracy		MSE[c]	RMSE[d]	MAE[e] (g)
		RE[a] (≤10%)	AE[b] (≤250 g)			
Ultrasound formula methods						
	Shinozuka's formula	0.71	0.59	125,65	354	266
Machine learning methods						
	Ridge	0.79	0.64	76,14	276	220
	XGBoost[f]	0.79	0.65	75,97	276	218
	Random Forest	0.81	0.66	72,05	268	212
	SVM[g]	0.79	0.64	75,99	276	220
	KNN[h]	0.73	0.57	10,53	325	257
	MLP[i]	0.80	0.67	77,08	278	212
	Ensemble model	0.82	0.67	68,47	262	208

[a]RE: relative error.
[b]AE: absolute error.
[c]MSE: mean squared error.
[d]RMSE: root mean squared error.
[e]MAE: mean absolute error.
[f]XGBoost: extreme gradient boosting.
[g]SVM: support vector machine.
[h]KNN: k-nearest neighbor.
[i]MLP: Multilayer Perceptron.

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Figure 4. Prediction scatter diagram based on 17 features (RE≤10%). SVM: support vector machine; KNN: k-nearest neighbor.

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Figure 5. Prediction scatter diagram based on 17 features (AE≤250 g). SVM: support vector machine; KNN: k-nearest neighbor.

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In addition, a segmented evaluation of the final prediction results was conducted, with division values of 2500 g and 4000 g for the 3 segments. Displaying the range of 10 percent metrics was selected. It demonstrates that the prediction effects of various models in various weight intervals were quite distinct. Some models performed better in the low weight interval, such as XGBoost and Random Forest, while others performed better in the high weight interval, such as Ridge and SVM. In addition, the MLP performed better in the normal weight range. The Ensemble Model combines the benefits and drawbacks of these distinct algorithm models, which has no serious shortcomings. The predictive effect of our established ensemble learning method significantly outweighs that of ultrasound. The accuracy for low birth weight can reach 70.30% (RE≤10%) and 73.44% (AE≤250 g). With 81.12% (RE≤10%) and 61.22% (AE≤250 g), the accuracy of macrosomia has also increased significantly (Figures 4 and 5). Besides, during the training process, trying to use more features (31 features) did not bring much improvement to the results with an accuracy of 83.49% (RE 10%) and 69.71% (AE≤250 g; Table S2, and Figure S1a and S1b in Multimedia Appendix 1). This group of controlled experiments shows that the 17 features are considered to be able to maintain good results, and to select easy obtain variables is of great significance for practical use.

Discussion

Principal Findings

As a key parameter for monitoring fetal development in utero, fetal birth weight can be used to evaluate fetal growth trends and screen for abnormal growth. Predicting the fetal birth weight in late gestation can effectively guide clinical decisions and reduce adverse pregnancy outcomes, such as increasing the survival of infants with intrauterine growth restriction and decreasing maternal-fetal complications in macrosomia delivery. Consequently, an accurate estimation of the fetal birth weight is crucial. Unfortunately, it is not possible to measure the fetal birth weight directly. Clinicians lack confidence in the estimation of the formula fetal birth weight at present due to the large variation in the accuracy of estimation results obtained through abdominal palpation or ultrasound measurement.

ML is based on clinical data, and the ML method is used to optimize health care resource use. The established ML algorithm model has high accuracy and is straightforward to implement; it is a win-win project that benefits patients, hospitals, and society; and it will have a major impact on the future of reproductive health.

In this study, data on pregnant women, including outpatient prenatal visits and hospital deliveries, was subjected to necessary feature processing and imbalanced data handling. A total of 5 ML methods were used as basic models for modeling through ensemble learning, which effectively balances the prediction effects of all models on fetuses in different weight ranges, achieving promising performance in predicting the different birth weights of newborns (low weight infants, normal weight infants, and macrosomia infants). The defining characteristic of ensemble learning is “Learn from the best.” First, it prevents underfitting by combining all the weaker learners and obtaining superior models through collective intelligence (in this case, like expert consultation, more complex learning models are obtained from advice from experts in different fields). Second, the integrated model prevents over-fitting: by combining all the results, it is simple to develop a more moderate model, thus avoiding some extreme case. Although it is not the best in all weight estimation ranges, the overall effect is the best, reducing the likelihood of large errors in a particular weight range.

In this study, the maternal sociodemographic characteristics and sonomicrometry data were inputs, and the predicted fetal birthweights were outputs of machine learning algorithms. Age, parity, mode of conception, education, prepregnancy weight and BMI, weight gain during pregnancy, gestational age, and GDM were the sociodemographic variables of the mothers. These variables are readily accessible in clinical practice and do not involve specific, difficult-to-obtain clinical indicators such as blood glucose, lipids, and protein levels, etc. In published prediction models, the input indicators usually include data such as uterine height [16] and pelvic measurements [13], which are subjective and prone to risk of bias.

Ultrasound as a direct method for measuring fetal size contributes significantly to the estimated fetal weight. Sonography is a time-saving, non-painful, and radiation-free tool that is widely used in obstetrics. In the third trimester, term-pregnant women in Shanghai undergo more than 2 or 3 ultrasound examinations. In our model, all ultrasonographic input data come from a reliable and accurate ultrasound report. In our model, we accounted for the time between the acquisition of ultrasound data and maternal delivery outcomes, which may have contributed to the model’s accuracy. However, Lu et al [16] and Shigemi et al [17] abandoned ultrasound data to benefit pregnant women in clinical practice, considering limited medical resources, whereas, at the expense of lower accuracy (the accuracy of Lu’s model is only 64.3%). Ultrasonography has become the most common auxiliary examination in obstetrics because of its security. In the vast majority of patient populations, ultrasound data need not be discarded. Our predictive model maximizes the clinical use of ultrasound and has significant implications for antenatal monitoring, antenatal assessment, intrapartum decision-making, and postpartum care. On the contrary, Ye et al [18] established an ensemble model, only used ultrasonographic measurements based on 26 different empirical ultrasonographic formulas. The risk factors associated with macrosomia were not collected thoroughly; therefore, the model did not provide the greatest benefits.

Compared with previously published predicted models, our model predicts fetal birth weight ranges with greater precision. Gao et al [14] adopted back propagation neural network model with the accuracy rate of 76.3%. Another previously published model reveals that the genetic algorithm-optimized neural network model’s accuracy is 74.9% [19]. In addition, 1 study found that the accuracy of prediction was only around 80% among GDM pregnant women [20]. Both low birth weight (2500 grams) and macrosomia (≥4000grams) are major public health concerns. In contrast to ultrasound’s poor performance in estimating extreme fetal weight, our model not only has excellent predictive performance in normal weight, but also in estimating extreme fetal weight. Although numerous studies

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have been conducted in the field of predicting extreme body weight, many prediction models consist only of simple binary variables ("Yes or No") and do not provide quantitative results [13,21-23]. In our model, the evaluation metrics for accuracy were based on predicting birth weight within ±10% or ±250g, which are two of the most commonly used metrics in the existing literature. For larger birth weights, the ±250g metric may better reflect the accuracy of the model, while for smaller birth weights, the ±10% metric is more appropriate for assessing the model's precision. In our study results, the ensemble learning model demonstrated satisfactory predictive performance in both the <250 g and >4000 g subgroups. In contrast, other models exhibited better predictive ability in only one of the extreme weight categories. Our model's accurate estimation of fetal birth weight values will improve clinical decision-making and have significant clinical application value.

In order to turning our ML model into practice, we transformed the simple optimization model into a mobile application with a visual page to provide pregnant women, obstetricians, and midwives with a real-time, efficient method for fetal birthweight estimation (Figure S2 in Multimedia Appendix 1). In the future, with the purpose of improving the accuracy of fetal weight estimation, we will embed the original model into the doctor's medical record workstation so that it can cover more variables and retrieve the relevant data automatically.

Limitations

This model is primarily designed for monitoring the fetal growth trend in the third trimester, not the second. The subsequent research can further expand the data set (including the first and second trimesters) in order to optimize the ML algorithm for estimating the fetal weight at various gestational ages.

Fetal birthweight is also closely associated with genetic predisposition. In our study, we lack the husband or partner's more relevant information, such as weight, height, and weight gain during pregnancy. Provided it is possible, we can also obtain the parental birth weight. For further study, we can invite the husband or partner to join our first interview for more details.

Conclusions

Assessment of the fetal birth weight in late-pregnant women before delivery presents numerous challenges, but also presents an opportunity for the advancement of ML in the obstetric field. In our study, 5 fundamental algorithms (Ridge, SVM, Random Forest, XGBoost, and Multi-Layer Perceptron) and an ensemble learning model were investigated to determine the algorithm with the best performance in fetal birth weight prediction. As anticipated, ensemble learning performed the best and was chosen to create a mobile application for pregnant women and obstetric staff. We believe our model will promote precision medicine and improve the quality and efficiency of maternal and fetal health care, despite the need for additional experiments.

Acknowledgments

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Data Availability

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

Authors' Contributions

WC, XJ, JG, and JX designed the study. JG and RC were responsible for writing the manuscript. LC and JC collected and sorted out the data. YY and JX performed the statistical analysis. WC and XJ reviewed and edited the manuscripts. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary material.
[DOCX File, 722 KB - pediatrics_v8i1e59377_app1.docx]

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Abbreviations

AC: abdominal circumference
AE: absolute error
AFI: amniotic fluid index
APTD: anteroposterior trunk diameter
BMI: body mass index
BPD: biparietal diameter

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DBP: diastolic blood pressure
FL: femur length
FPG: fasting plasma glucose
GA-BP: genetic algorithm to improve back propagation
GDM: gestational diabetes mellitus
GLU-1H: 1-hour glucose
GLU-2H: 2-hour glucose
GWG: gestational weight gain
HBG: hemoglobin
HC: head circumference
HDL: high-density lipoprotein
HL: humerus length
IMPCH: International Peace Maternity and Child Health Hospital
KNN: k-nearest neighbor
KS: Kolmogorov-Smirnov
LDL: low-density lipoprotein
MAE: mean absolute error
ML: machine learning
MLP: Multilayer Perceptron
MSE: mean squared error
NICU: neonatal intensive care unit
OGTT: oral glucose tolerance test
PCC: Pearson correlation coefficient
RE: relative error
RMSE: root mean squared error
SBP: systolic blood pressure
SVM: support vector machine
TC: total cholesterol
TG: triglycerides
TRIPOD: Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis
TTD: transverse trunk diameter
XGBoost: extreme gradient boosting

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Preoperative Anxiety Management Practices in Pediatric Anesthesia: Comparative Analysis of an Online Survey Presented to Experts and Social Media Users

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Abstract

Background: Managing preoperative anxiety in pediatric anesthesia is challenging, as it impacts patient cooperation and postoperative outcomes. Both pharmacological and nonpharmacological interventions are used to reduce children's anxiety levels. However, the optimal approach remains debated, with evidence-based guidelines still lacking. Health care professionals using social media as a source of medical expertise may offer insights into their management approaches.

Objective: A public survey targeting health care professionals was disseminated via social media platforms to evaluate current practices in anxiety management in children. The same questions were posed during an annual meeting of pediatric anesthesiologists with their responses serving as reference. The primary objective was to compare pediatric anesthesia expertise between the groups, while secondary objectives focused on identifying similarities and differences in preoperative anxiety management strategies hypothesizing expertise differences between the groups.

Methods: Two surveys were conducted. The first survey targeted 100 attendees of the German Scientific Working Group on Pediatric Anesthesia in June 2023 forming the "Expert Group" (EG). The second open survey was disseminated on social media using a snowball sampling approach, targeting followers of a pediatric anesthesia platform to form the "Social Media Group" (SG). The answers to the 24 questions were compared and statistically analyzed. Questions were grouped into 5 categories (pediatric anesthesia expertise, representativity, structural conditions, practices of pharmacological management, and practices in nonpharmacological management).

Results: A total of 194 responses were analyzed (82 in EG and 112 in SG). The EG cohort exhibited significantly greater professional experience in pediatric anesthesia than the SG cohort (median 19 vs 10 y, $P<.001$), higher specialist status (97.6% vs 64.6%, $P<.001$), and a greater pediatric anesthesia volume (43.9% vs 12% with more than 500 cases per year, $P<.001$). Regarding the representativity, 2 items out of 4 were statistically significant (level of care of institution, annual caseload of institution). Regarding the overall anxiety management practices used, there is a heterogeneous response pattern within both groups.

Conclusions: Despite heterogeneous approaches, health care professionals using social media demonstrated less expertise in pediatric anesthesia but showed minimal differences in the daily management of preoperative anxiety compared with pediatric anesthesia experts. Our study highlights the potential for meaningful use of social media but future studies should explore the impact of social media health care professionals' knowledge in other specific topics. Additionally, regarding preoperative anxiety, further recommendations are needed that could help to standardize and improve anxiety levels in children.

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KEYWORDS

pediatric anesthesia; pharmacological interventions; nonpharmacological interventions; preoperative; anxiety; anxiety management; practices; anesthesia; comparative analysis; online survey; preoperative anxiety; challenges; postoperative outcome; pediatric; infant; baby; neonatal; toddler; child; social media; survey; anesthesia provider

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Introduction

Although “no fear” is the first of the “10-N quality criteria” in pediatric anesthesia, preoperative anxiety remains prevalent [1,2]. It is evident that high levels of anxiety are associated with decreased cooperativeness during induction of anesthesia, increased postoperative analgesic requirements, increased rates of postoperative delirium, and maladaptive behavioral problems [3,4]. Therefore, it is crucial to keep anxiety levels low.

Established options for preoperative anxiolysis in children include pharmacological and nonpharmacological interventions. Midazolam, clonidine, and dexmedetomidine as well as (s-)ketamine are frequently used for pharmacological premedication [5,6]. However, the general use of these drugs is subject to controversial debate [6,7]. Nonpharmacological interventions include parental presence at induction of anesthesia, educational approaches (eg, informational mediation and prior inspection of the operating room), complementary medical procedures (such as acupuncture, music therapy, hypnosis), and cognitive-behavioral therapeutic measures (such as strengthening coping strategies, distraction, breathing exercises, model learning) [8-14]. Nonpharmacological interventions have been shown to be at least as effective as the administration of midazolam [15]. Although many different options are available, there are currently no evidence-based recommendations and guidelines on which intervention is best for which situation. Recently, we conducted a survey on the current practice of preoperative anxiety management in pediatric anesthesia among German-speaking participants [16]. It was conducted during an expert meeting of the Scientific Working Group for Pediatric Anesthesia of the German Society of Anesthesiology and Intensive Care Medicine and revealed relevant differences in the structural conditions, management of pharmacologic premedication, and the use of nonpharmacologic measures [16].

However, participants in expert meetings may not accurately reflect the realities of daily anxiety management practices. Social media, defined as “any form of electronic communication [...] to share information” [17], offers the potential to enhance these insights by leveraging swarm intelligence and engaging a broader and more diverse group of health care professionals involved in preoperative anxiety management. Web-based surveys disseminated through social media targeting pediatric anesthesia health care professionals could thus capture a larger, geographically diverse sample, enhancing overall insight. While web-based surveys are efficient and cost-effective, they have limitations, such as open participation, low response rates (≈10%), and uncertain respondent identity [18]. In contrast, closed-group surveys, such as those conducted among expert meeting participants, provide more defined and reliable profiles, potentially serving as a reference for comparison.

Thus, a web-based survey on preoperative anxiety was sent to social media users involved in pediatric anesthesia, and their responses were compared with those from a pediatric anesthesia Expert Group (EG). The study aimed to test the hypothesis that expertise and preoperative anxiety management practice differ between a broad, randomly selected social media population and a dedicated EG.

Methods

Overview

The web-based survey was aimed at anesthesiologists who are active on social media. Currently, there are approximately 27,000 anesthesiologists in Germany, around 3300 in Austria, and 1600 in Switzerland [19-21]. It is estimated that approximately 70% - 90% of all physicians actively use social media, meaning that around 25,000 anesthesiologists were eligible to participate in the web-based questionnaire [22,23]. As this was an open survey, the participation of nonanesthesiologists could not be excluded. The survey related to the scientific conference was directed at the scientific working group on pediatric anesthesia in German-speaking countries. It consists of physicians with predominantly high expertise in the field of pediatric anesthesia, with approximately 100 participants attending the conference each year.

Ethical Considerations

This analysis did not require approval by an institutional review board or entry into a clinical trial register since it did not include data from patients or medical records according to the Helsinki Declaration. Participation was voluntary, and privacy was ensured through the anonymous collection of study data. No personal information, cookies, or IP addresses that could enable identification were stored. Participants did not receive any compensation.

Survey Development

We adhered to the items of the “Good practice in the conduct and reporting of survey research” and the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [24,25]. Technical tests were carried out before the surveys were conducted to enhance comprehensibility and rule out possible errors. The completion rate (ratio of users who finished the survey/users who answered the first question) was calculated for both groups and the participant rate (ratio of unique visitors who agreed to participate/unique first survey page visitors) for EG. For completeness checking, incomplete data were marked as “not applicable” to indicate the extent of survey completion. The processed data consisted of 2 surveys, each conducted independently. There were no follow-up validation attempts to verify if the respondents were truly qualified.

Data Sources

The first survey was conducted among participants of the annual meeting of the Scientific Working Group on Pediatric Anesthesia of the German Society for Anesthesiology and Intensive Care medicine (DGAI), which took place in Hamburg, Germany, on June 16 - 17, 2023. During the event, access to a web-based survey, using Microsoft Forms (Office 365), was given via a QR code. The survey contained 25 questions targeting the daily practice of preoperative anxiety management in children (Multimedia Appendix 1). Those respondents formed the EG, serving as a reference to the second survey. The results of this survey were formerly published [16].

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The second open survey was announced among followers of a German-language podcast on pediatric anesthesia [26]. This podcast is broadcast on platforms such as Spotify and Apple Podcast (in total 44 platforms) and has achieved approximately 130k downloads and streams with its 34 episodes (data retrieved on July 01, 2024). Users were given access to this survey from October 01 to 31, 2023. The first call for participation was made on October 01, 2023, via short posts on the social media platforms X, Bluesky, and Instagram, as well as posts on the corresponding social media accounts in the field of anesthesiology following the random snowball sampling method. The invitation included an image with a QR code and a link to the web-based survey (Multimedia Appendix 2) along with a request for reposts. Several reposts were made and a short podcast episode on October 19, 2023, was broadcast to recall for participation (1117 downloads in the survey period). The episode was available on major podcast platforms, including Podigee, Spotify, Apple Podcasts, Amazon Podcasts, and Google Podcasts [27]. In comparison to the first survey, this one was expanded to cover the broad spectrum of social media users with 4 more questions (marked with asterisk (*) in Multimedia Appendix 1). Respondents formed the "Social Media Group" (SG).

All items were displayed on a website and were only interrupted by adaptive questions. Completeness checks before submission were not integrated, and respondents were able to modify their answers before submission. For both surveys, multiple participation could not be technically excluded but respondents of the second survey were asked to refuse participation in case of prior participation to the first survey. Multiple selections were possible for some questions.

Data Processing

Both survey data were checked for incomplete data and then matched using Microsoft Excel (Office 2019, Microsoft). The questions were clustered into five categories: (1) pediatric anesthesia expertise (3 items), (2) representativity (5 items for both surveys and 4 additional items in SG), (3) structural conditions (9 items), (4) practices of pharmacological routine (6 items), and (5) practices of nonpharmacological routine (2 items). The item "zip codes" and the 4 additional questions were excluded from the comparison between the 2 groups, resulting in a total of 24 items being compared.

Objectives

The primary objective was to assess the pediatric anesthesia expertise of the SG compared with the EG, given by significant differences in professional expertise (defined by years of professional experience), expert status (defined as being a board-certified anesthesiologist with passed professional examination), and a number of personal annual pediatric anesthesia case volume. The secondary objectives were the differences in the clustered categories of general characteristics and practices in managing preoperative anxiety, capturing structural conditions and practices in both pharmacological and nonpharmacological interventions.

Statistical Analysis

In the descriptive analysis, we presented the absolute and relative frequencies for the respective groups for categorical variables and the medians, IQRs, and total ranges for the respective groups for continuous variables. We applied a significance level of 0.05 for all statistical tests. The Kolmogorov-Smirnov test was used to assess the normality of the distribution. *P* values for the comparison of both groups were calculated using Fisher exact test or chi-square test for categorical variables, and the Wilcoxon rank sum test for continuous variables. Analysis and illustrations were performed using GraphPad Prism (GraphPad Software) and Microsoft Excel (Office 2019, Microsoft).

Results

Overview

A total of 198 respondents participated in both surveys, 82 respondents in the EG and 116 respondents in the SG, respectively. Two responses from the SG were excluded due to prior participation in the EG survey, and another 2 responses were excluded due to missing data, leaving 194 responses for the final analysis in both groups (Figure 1). Unless stated otherwise, the full analysis set consisted of 82 respondents in the EG and 112 in the SG, with nonrespondents excluded from all calculations.

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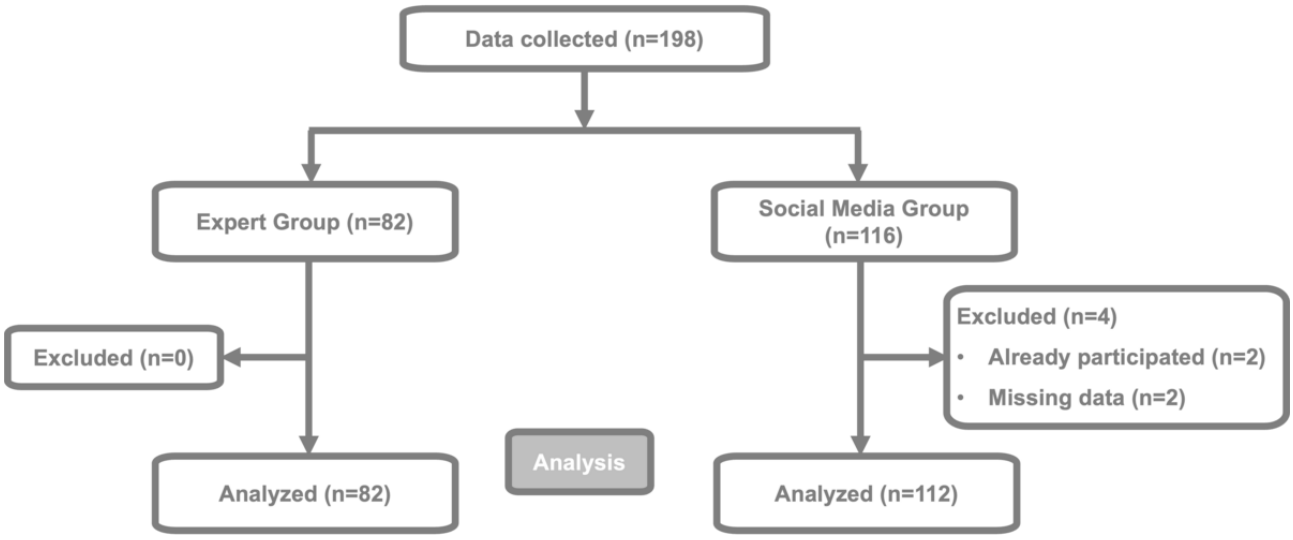
Figure 1. Flow chart of data collection and analysis.



The participation rate in EG was 82% as 82 participants out of 100 joined the survey during the annual meeting. Since no IP addresses were recorded, the participation rate for the SG could not be calculated. The completion rate of analyzed data was 100% in both groups.

In the 5 clustered categories, we found 10 out of 24 items to be significantly different in the response behavior between the 2 groups (see Table 1, corresponding questions in Multimedia Appendix 1).

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Table . Survey items in clustered categories with differences between the Expert Group (EG) and the Social Media Group (SG). Detailed evaluation in the text.

Category and item		*P* value
Pediatric anesthesia expertise		
	Years of professional experience	<.001
	Specialist (board-certified anesthesiologist)	<.001
	Personal pediatric anesthesia case volume annually	<.001
Representativity		
	Gender	.51
	Country of respondents' institution	.65
	Level of care of the institution	<.001
	Institutional pediatric anesthesia case volume annually	<.001
Structural conditions		
	Written protocols for managing preoperative anxiety	.47
	Existing preoperative preparation programs	.76
	Used preoperative preparation programs	.90
	Feasibility (local conditions) of parental presence during induction of anesthesia	.01
	Standard of parental presence during induction of anesthesia	.69
	Place of separation of the children from their caregivers	.84
	Routine in anxiety measurement	.16
	Used anxiety measurement tools	__[a]
	Known anxiety measurement tools	<.001
Practices of pharmacological management		
	Regular use of preoperative medication	.99
	Indication-based prescription of premedication, avoiding routine use	.04
	Criteria for deciding on premedication use	.24
	Most commonly used substance	.23
	1st choice for premedication	.999
	Minimum age for administering premedication	<.001
Practices of nonpharmacological management		
	Standard practice of nonpharmacological interventions	.63
	Use of nonpharmacological interventions	<.001

[a]Not applicable (only 4 responses in the EG and only 1 response in the SG, no statistical analysis was carried out).

Pediatric Anesthesia Expertise

The level of pediatric anesthesia expertise demonstrated by the SG was significantly lower than that reported in the EG. This was given by a lower number of professional experience in the SG with a median of 10 years (IQR 6 - 18; total range 1 - 45) compared with a median of 19 years (14-25; 5-35) in the EG (*P*<.001), a lower share of respondents in the SG group of specialists, with 64.6% (64/99, with 13 nonrespondents), compared to 97.6% (80/82) in the EG group (*P*<.001), a lower share of respondents in the SG group reported performing more than 500 pediatric anesthesia cases per year, with 12% (13/108, with 4 nonrespondents), compared to 43.9% (36/82) in the EG group (*P*<0.001; details in Table 2).

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Table . Distribution of performed anesthesia case volume per year.

Personal pediatric anesthesia case volume annually	EG[a] (n=82), n (%)	SG[b] (n=108)[c], n (%)
0 - 49	4 (4.9)	50 (46.3)
50 - 99	1 (1.2)	17 (15.7)
100 - 199	13 (15.9)	15 (13.9)
200 - 299	11 (13.4)	7 (6.5)
300 - 399	11 (13.4)	5 (4.6)
400 - 499	6 (7.3)	1 (0.9)
>500	36 (43.9)	13 (12)

[a]EG: Expert Group.

[b]SG: Social Media Group.

[c]4 nonrespondents; total n=112.

Representativity

Both groups showed a similar gender distribution, with 56.6% (45/81, 1 nonrespondent) female respondents in EG compared to 50% (56/112) in SG (*P*=.51) and the same percentage of respondents from Germany (93.8% each; 76/81, with 1 nonrespondent, in EG and 105/112 in SG). In the EG, respondents originated from 3 more countries (Switzerland, Austria, and Italy), whereas in the SG, respondents came from 5 more countries (Switzerland, Austria, Serbia, United Kingdom, and Hungary).

Differences in the level of care across respondents' workplaces were statistically significant (*P*<.001, Table 3). Most respondents came from university hospitals (28/81, 1 nonrespondent, 34.6% in EG vs 33/112, 29.5% in SG) while more respondents came from standard care hospitals in the SG (27/112, 24.1%) than in the EG (6/81, 1 nonrespondent, 7.4%).

Table . Level of care across respondents' workplaces.

	EG[a] (n=81)[b], n (%)	SG[c] (n=112), n (%)
Ambulatory	6 (7.4)	10 (8.9)
Standard care hospital	6 (7.4)	27 (24.1)
Children's hospital	18 (22.2)	11 (9.8)
High care hospital	17 (21)	27 (24.1)
University hospital	28 (34.6)	33 (29.5)
Others	6 (7.4)	4 (3.6)

[a]EG: Expert Group.

[b]1 nonrespondent; total n=82.

[c]SG: Social Media Group.

The annual pediatric anesthesia caseloads varied between groups. In the EG group, most 71.3% (n=57) reported over 1000 cases annually, with smaller proportions handling 500-999 (n=11, 13.8%), 250-499 (n=10, 12.5%), or fewer than 250 cases (n=2, 2.5%). In the SG group, 34.6% (n=36) managed over 1000 cases, 22.1% (n=23) reported 500-999, 18.3% (n=19) had 250-499, and 25% (n=26) handled fewer than 250 cases. Some respondents in both groups did not answer (n=2 in EG and n=8 in SG).

Structural Conditions

In EG, 36 (43.9%) respondents reported having a written standard operating procedure for managing preoperative anxiety, compared with 43 (38.4%) respondents in SG (*P*=.46). A preoperative preparation for children and their caregivers was included as part of anesthesia information by 28 (34.1%) respondents in EG and by 35 (31.3%) respondents in SG (*P*=.76). Among those who reported using specific material, there was no difference in the choice of measures (*P*=.90). The most frequently used materials were "pediatric-specific informed consent", information flyers, and comics (Table 4).

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Table . Materials used to help prepare children and their caregivers preoperatively.

	EG[a] (n=28), n (%)	SG[b] (n=35), n (%)
Pediatric-specific informed consent	19 (25.5)	23 (20.5)
Information flyer	16 (21.5)	15 (13.4)
Comics	8 (10.7)	10 (8.9)
A designed mascot	7 (9.4)	8 (7.1)
Videos	4 (5.4)	2 (1.8)
Other[c]	2 (2.7)	3 (2.7)
Hypnosis	1 (1.3)	0 (0)
Guidance through the operating room	2 (2.7)	1 (0.9)

[a]EG: Expert Group.

[b]SG: Social Media Group.

[c]Other used materials mentioned: instruction on how to use topical anesthesia patches, offering website information, the use of soap bubbles, and a virtual operating theater tour.

When asked whether the local structural conditions would generally allow the parents to be present until the children are anesthetized, 52 (63.4%) respondents in the EG and 50 (45%) respondents in the SG answered in the affirmative (*P*=.01). Among those, 38 (46.3%) respondents in the EG and 57 (50.9%) respondents in the SG reported not offering parents to be present during the induction of anesthesia. In EG, 26 (31.7%) respondents reported enabling parental presence while 29 in SG (25,9%). Another 18 (22%) respondents in the EG stated that parental presence depends on the individual workplace within their institution, while 26 (23.2%) respondents in the SG reported the same. The place where the children were separated from their parents or parental substitutes did not differ significantly between the groups.

Separation locations for children from parents did not significantly differ between groups (*P*=.84). Most commonly, separation occurred during transfer to the operating room (EG: 44 out of 80 respondents, 55%; SG: 67 out of 109 respondents, 61.5%). Separation in the induction room was less frequent (EG: 13 out of 80 respondents, 16.3%; SG: 13 out of 109 respondents, 11.9%) and in the holding area similarly rare (EG: 12 out of 80 respondents, 15%; SG: 13 out of 109 respondents, 11.9%). Separation in the operating room itself was reported even less often (EG: 9 out of 80 respondents, 11.3%; SG: 12 out of 109 respondents, 11%), while on the ward it was rarest of all (EG: 2 out of 80 respondents, 2.5%; SG: 4 out of 109 respondents, 3.7%). A small number of respondents did not provide an answer (EG: 2 respondents; SG: 3 respondents).

A total of 95.1% (78/82) of respondents in EG and 99.1% (111/112) in SG reported that children's anxiety is not routinely measured. Regarding anxiety scales, 31.7% (n=33) of EG respondents and 55.8% (n=67) of SG respondents stated that they were not familiar with any. The Yale Preoperative Anxiety Scale was the most recognized scale in the EG, with 25% (n=26) of respondents indicating familiarity with it. In contrast, only 8.3% (n=10) of respondents in the SG reported familiarity with the Yale Preoperative Anxiety Scale. The visual analog scale (VAS) was the most recognized scale in the SG, with 30% (n=36) of respondents indicating familiarity with it. In contrast, only 24% (n=25) of respondents in the EG reported familiarity with the VAS.

Practices of Pharmacological Interventions

The use of pharmacological premedication in daily practice was reported by 80.5% of respondents (66/82) in EG and 79.5% (89/112) in SG, with no statistically significant difference between the 2 groups (*P*>.99), indicating that both groups have a similarly high rate of routine use of premedication.

When it comes to actively avoiding premedication, there was a significant difference between the 2 groups (*P*=.04). In EG, 50% (41/82) tried to avoid premedication, whereas only 34.4% (39/112) in the SG did so.

Both groups showed similar responses (*P*=.24) regarding their decision-making process for administering pharmacologic premedication (refer to Table 5). Individual responses included consulting children or their parents about the need for premedication, with some also specifying the placement of an intravenous line before anesthesia induction.

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Table . Criteria for deciding on premedication use. Multiple answers were possible.

	EG[a] (n=82), n (%)	SG[b] (n=112), n (%)
The children are generally premedicated with medication	28 (34.1)	55 (49.1)
According to the child's anxiety	52 (63.4)	52 (46.4)
According to the parents' anxiety	18 (22)	18 (16.1)
According to the child's wishes	38 (46.3	35 (31.3)
According to the parents' wishes	22 (26.8)	25 (22.3)
According to medical history	46 (56.1)	52 (46.4
According to experience/gut feeling	31 (37.8)	46 (41.1)
Individual answer	12 (14.6)	10 (8.9)

[a]EG: Expert Group.

[b]SG: Social Media Group.

In both groups, midazolam was reported as the most frequently used premedication drug (EG: 81/82, 98.8% and SG: 112/112, 100%). In EG, (es-)ketamine (41/82, 50%), clonidine (18/82, 22%), and dexmedetomidine (6/82, 7.3%) were used as well as in SG (42/112, 37.5%; 19/112, 17%; and 11/112, 9.8%, respectively) without significant difference (*P*=.23). Overall, midazolam was the drug of first choice in both groups (76/80, 2 nonrespondents, 95% in EG vs 105/111, 1 nonrespondent, 94.6% in SG).

The median minimum age for administering premedication was 6 months (6-8; 0-48) in EG and 9.5 months (6-12; 0-36) in SG (*P*<.001).

Practices of Nonpharmacological Interventions

Nonpharmacological interventions were routinely used by 60 (73.2%) respondents in EG and by 78 (69.6%) respondents in SG (*P*=.63). There was a significant difference (*P*<.001) in the selection of which nonpharmacological interventions were used (Table 6). While in the EG parental presence was the most reported intervention (43/60, 71.7%), it was the use of videos in the SG (62/78, 79.5%).

Table . Practices of nonpharmacological interventions. Multiple answers were possible.

	EG[a] (n=60), n (%)	SG[b] (n=78), n (%)
Parental presence	43 (71.7)	38 (48.7)
Videos (tablet, smartphone, etc)	42 (70)	62 (79.5)
Reading or showing books	21 (35)	29 (37.2)
Games	17 (28.3)	14 (17.9)
Other activities[c]	12 (20)	12 (15.4)
Audio books	8 (13.3)	5 (6.4)
Music distraction	7 (11.7)	14 (17.9)
Hypnosis	7 (11.7)	2 (2.6)
Behavioral exercises	7 (11.7)	0 (0)
Clowns	5 (8.3)	4 (5.1)
Virtual reality glasses	2 (3.3)	4 (5.1)

[a]EG: Expert Group.

[b]SG: Social Media Group.

[c]Other activities mentioned in both groups were the use of a floating bird, the integration of cuddly toys, the use of a glitter wand, interactive storytelling, a starry sky projection, and the use of soap bubbles.

Discussion

Principal Results

The respondents to the publicly announced survey on social media demonstrated significantly less pediatric anesthesia expertise than the respondents to the survey among experts. This was evidenced by fewer years of professional experience, fewer board-certified specialists, and a lower pediatric anesthesia caseload. However, when looking at the items related to the practice of pediatric anxiety management, significant differences were found in less than a third. Regardless of the survey group,

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our results showed very heterogeneous approaches to the management of preoperative anxiety in pediatric patients.

Our study presents 2 principal findings. First, it remains debatable whether web-based surveys are an effective method for reaching the target group of pediatric anesthesia providers. On the one hand, the respondents to the web-based survey rated their level of expertise lower than those who were involved in a scientific meeting survey. However, specific parameters that best identify an expert in the field of pediatric anesthesia remain undefined. It seems clear that increased experience in this field correlates with a lower rate of complications in children [28]. A high volume of pediatric anesthesia cases likely contributes to a higher level of expertise. Being classified as a specialist (board-certified anesthesiologist) further indicates that a minimum standard of experience in pediatric anesthesia has been met [29]. However having many years of professional experience does not necessarily equate to extensive pediatric anesthesia practice, as hospital structure, hospital focus, and patient demographics may limit exposure to pediatric cases [30,31]. In addition, the higher share of institutions with a higher level of care and a higher number of children's hospitals among experts might indicate pediatric anesthesia expertise due to a higher pediatric caseload. But there may be also anesthesia providers with a high individual pediatric caseload in standard care hospitals. On the other hand, when responses from an EG exhibit significant heterogeneity [16], it is not unexpected that similar heterogeneity would persist when querying a larger (or another) sample. This leads to the conclusion that it is not that obvious as our results may indicate which of the 2 groups can more accurately reflect the actual reality of pediatric anesthesia care.

Further, the dissemination of a web-based survey through social media is debatable. The methodology of web-based surveys offers significant advantages, particularly due to their rapid deployment and extensive reach, which facilitate the swift collection and distribution of data. Similarly, social media, which has become increasingly popular in the medical field, enables the rapid dissemination of insightful opinions and information and underscores the value of web-based surveys [23,32]. Drawbacks of web-based surveys are the inadequate representation of the sample population due to insufficient coverage, the absence of a sampling frame to guide sample selection, nonselection bias, and a low participation rate, which is estimated at approximately 11% [33-35]. Of course, it is difficult to verify data quality with anonymous questions, and there is ongoing research into how to implement attention checks or other means of detecting poor-quality data in web-based surveys [36]. The presence of selection bias within the SG is also possible. This could skew the data, as operating within a "bubble" may predominantly reach individuals already familiar with the topic, potentially also limiting a full representation of reality. An interesting direction for future research could involve comparing groups with similar characteristics to examine whether the survey access method (social media vs conference or "classic") introduces a selection effect related to expertise. With a participation rate of more than 80%, the EG directly addressed at the conference meeting demonstrated a high willingness to participate. Overall, slightly more responses were collected in the SG, even though access was open for an extended period and potentially a higher amount of respondents, indicating a low response rate in this "digital" SG. This suggests that if a survey on a specific topic, such as anxiety in pediatric anesthesia, is announced via social media, it is likely that only a specific subset of individuals, those with a particular interest or relevance to the topic, will actively engage and participate.

The second point, apart from the discussion about whom to ask for pediatric anesthesia surveys, is what both groups have in common: There is a large heterogeneity in applied anxiety management practices. This includes the debated issue of parental presence during anesthesia induction. Although it does not reduce children's anxiety, children have the right to be accompanied by their parents or substitutes. Surprisingly, parental presence during induction remains uncommon [37,38]. Local conditions appear to inhibit parental presence, and even if it was possible in principle, it is often not implemented. Potential reasons for this could include the need for additional staff or carefully coordinated arrangements to manage the logistics of parental involvement, as well as considerations pertaining to hygiene.

The same heterogeneity exists in the question of when which child should receive premedication. This is shown by the many varying approaches regardless of the 2 survey groups. Medication is currently made in a highly inconsistent manner, largely based on individual clinical judgment. When it comes to the application of medication, midazolam holds a high relevance in both groups. However, it has been proven to significantly reduce preoperative anxiety, it also has evident disadvantages including a long recovery time, respiratory adverse effects, and amnestic effects [6,7]. That may explain why all respondents reported using alternative premedication agents such as (es-)ketamine, clonidine, and dexmedetomidine frequently [5]. In addition, the application of nonpharmacological interventions is heterogeneous [15]. But if applied, one of the most favored options is video distraction. This does not seem surprising since video distraction is easy to implement, widely available, and requires no training or infrastructure (unlike, for example, clowns).

With regard to anxiety scales, it is noteworthy that 30% of the experts were unfamiliar with any scales for measuring anxiety. Awareness of specialized scales, such as the modified Yale Preoperative Anxiety Score, was higher among the EG, likely due to its frequent use in studies and the fact that many experts are affiliated with university settings [39]. In contrast, participants in the SG reported slightly greater familiarity with the VAS, a tool widely recognized for its application in pain management [40]. Despite the availability of these tools, their limited use remains puzzling. Broader implementation could enhance the identification of preoperative anxiety and increase awareness of its importance in clinical practice.

Limitations

The study faced several limitations. First, it is prone to bias as there likely was a potential overrepresentation of more tech-savvy individuals in the SG, leading to a demographic discrepancy compared with the EG with a potential risk for self-selection bias. Second, the reach of the web-based survey

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could not be sufficiently quantified, and attention checks were omitted, compromising information about the response rate and its quality. The survey was disseminated through a variety of social media platforms, but without considering social media use statistics, which may have biased the sample. Additionally, the anonymity of the survey precluded verification of respondent accuracy.

Conclusion

The respondents from a scientific working group on pediatric anesthesia had more professional experience in this medical subspecialty and also more specific knowledge than survey participants from social media. However, when it comes to the use of strategies that reflect daily practice, the groups differed little and only in general terms. A diverse range of pharmacological and nonpharmacological interventions are used in daily practice and their use seems to be based more on individual preferences. Consequently, there is a need for evidence-based recommendations regarding the appropriate use of these interventions, including indications for their use. Web-based surveys via social media can have the potential to gain insights into daily practice on specific topics like managing preoperative anxiety in pediatric patients. Further studies should investigate whether surveys disseminated through social media yield similar results in other specific subject areas.

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Authors' Contributions

AS contributed to the conceptualization, methodology, validation, formal analysis, investigation, resources, data curation, visualization, and writing the original draft. CE was responsible for reviewing and editing the draft and validation. MN contributed to conceptualization, methodology, validation, data curation, writing the original draft, and reviewing and editing the draft. CM was involved in conceptualization; methodology; validation; data curation; and writing, reviewing, and editing the draft.

Conflicts of Interest

AS is the host of a German-language podcast on pediatric anesthesia (“Kinderanästhesie-Talk”). The other authors do not have any conflicts of interest to declare.

Multimedia Appendix 1
Survey to “Preoperative Anxiety Management Practices in Pediatric Anesthesia: A Comparative Analysis of an Online Survey presented to Experts and Social Media Users.”
[DOCX File, 27 KB - pediatrics_v8i1e64561_app1.docx]

Multimedia Appendix 2
Image that was posted for invitation to participate to the online survey for the social media group.
[PNG File, 741 KB - pediatrics_v8i1e64561_app2.png]

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Abbreviations

CHERRIES: Checklist for Reporting Results of Internet E-Surveys
EG: Expert Group
SG: Social Media Group
VAS: visual analog scale

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A Noninvasive Approach to Assess the Prevalence of and Factors Associated With Anemia Risk in Malaysian Children Under Three Years of Age: Cross-Sectional Study

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Abstract

Background: Anemia remains a significant public health concern with adverse effects among children. Noninvasive screening assessments enable the early detection and prompt treatment of anemia. However, there is limited literature on the use of such screening assessments.

Objective: The study aimed to assess the prevalence of and factors associated with being at risk of anemia among Malaysian children aged ≥6 months to ≤36 months by using a noninvasive hemoglobin assessment.

Methods: This was a cross-sectional study (from July to December 2022) of outpatient Malaysian children, aged ≥6 months to ≤36 months, who were selected from five maternal-and-child health clinics by convenience sampling. At risk of anemia was defined as a total hemoglobin level of <12 g/dL, measured using the Masimo Rad-67, a noninvasive screening device for total hemoglobin levels. The χ^2 and multiple logistic regression analyses were used to assess the prevalence and factors associated with being at risk of anemia, using R-Studio (version 4.0.0).

Results: The study included 1201 participants, of whom 30% (95% CI 28 - 33) were at risk of anemia. Children aged 6 - 12 months (210/364, 57.7%, *P*<.001), those of Asian Malay race (238/364, 65.4%, *P*<.05), those residing in the Klang district (123/371, 33.9%, *P*<.05), those born via a normal vaginal delivery (275/364, 75.5%, *P*<.05), those without a family history of thalassemia (284/364, 78.0%, *P*<.05), and those with lower weight-for-age Z scores (*P*<.05) were associated with being at risk of anemia. Children aged 6 - 12 months (adjusted odds ratio=1.73; 95% CI 1.34 - 2.24) had higher odds of being at risk of anemia compared to children aged >12 - 36 months. However, weight-for-age (adjusted odds ratio=0.88; 95% CI 0.80 - 0.98) was associated with lower odds of being at risk of anemia.

Conclusions: The current study revealed a substantial prevalence of Malaysian children being at risk of developing anemia. The study results therefore imply a need for more community education and awareness on anemia, including nutrition education, as well as targeted community screening to enable the early detection and prompt treatment of anemia cases. Anemia reduction strategies in Malaysia should consider the highlighted factors indicative of higher risk of anemia.

Trial Registration: Clinicaltrials.gov NCT05181436, https://clinicaltrials.gov/study/NCT05181436

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KEYWORDS

anemia; iron deficiency; children; Masimo Rad-67; noninvasive assessment; Malaysia

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Introduction

Anemia is a specific condition where the body does not have enough normal or healthy red blood cells or hemoglobin (Hb) to provide adequate oxygen to the body tissues. It is usually caused by iron deficiency, which is the most common micronutrient deficiency in both low-income and high-income countries [1,2]. Generally, it takes at least several weeks after the depletion of iron stores before anemia develops. When iron deficiency occurs, Hb concentrations are reduced to below-optimal levels, a condition known as iron deficiency anemia (IDA) [2], which is the most common type of anemia found in children. Among children, the most common causes of IDA include insufficient iron intake along with rapid growth, low birth weight, and gastrointestinal losses, among others [3,4].

Generally, the prevalence of anemia and IDA in low-income countries is three to four times higher than that in high-income countries [1]. The global prevalence of anemia in 2019 was 39.8% in children aged 6 - 59 months, with 269 million children having anemia, while in Malaysia, the prevalence of anemia was 24.6% in children of the same age [5]. In Malaysia, the current prevalence of anemia is approximately 46.5% among children, and 1 in 3 children (<5 years of age) has iron deficiency [6,7].

Iron deficiency can occur without anemia; this occurs when the iron store is depleted while the individual is still having normal Hb levels. IDA is a situation where the iron store and Hb levels are both below normal levels. Iron deficiency and IDA are typically diagnosed through an invasive blood test, with one of the diagnostic criteria for anemia being a Hb level below 11 g/dL [2]. The American Academy of Pediatrics recommends that all infants be tested for anemia starting between ages 9 months and 12 months [8], and that for those who have risk factors for iron deficiency, additional screenings will be required at later ages between 1 and 5 years [9].

Iron deficiency in childhood is associated with adverse outcomes such as impaired neurocognitive function and brain development, as well as compromised immune function [10,11]. In Malaysia, recent evidence shows that anemia is associated with cognitive and motor delays among infants aged 6 - 12 months [12]. This implies that prompt diagnosis and anemia prevention are essential through early screening during infancy and early childhood.

The conventional diagnosis of anemia and IDA in infants is difficult, as blood sampling and obtaining sufficient blood volume are often difficult for typical laboratory detection. Moreover, these tests can be painful for the participant, expose the staff to human blood, and require training and quality control to ensure appropriate utilization and adherence to standards [3,11]. In this regard, an alternative device can be preferable, such as noninvasive Hb screening using a sensor that shines multiwavelengths of light through the finger of the patient [13]. Such noninvasive device options include the Masimo Pronto (Masimo Corporation) and Masimo Rad-67™ Pulse CO-Oximeters (Masimo Corporation). These devices were cleared by the US Food and Drug Authority for use in clinical and nonclinical settings to measure oxygen saturation [14] and have been used as a noninvasive measurement method for determining the Hb levels in children [15]. The Masimo Pronto and Masimo Rad-67™ Pulse CO-Oximeters have good accuracy and validity compared to Hemocue (HemoCue); however, the Hb levels were underreported for the devices compared to the levels determined in venous blood samples [16-18]. This study used the Masimo Rad-67™ Pulse CO-Oximeter for anemia screening.

This study aimed to assess the prevalence and factors associated with being at risk of anemia (defined as total Hb levels <12 g/dL) among Malaysian children aged ≥6 to ≤36 months by using noninvasive Hb assessment (the Masimo Rad-67 Pulse CO-Oximeter). We used a noninvasive approach for anemia screening and compared the prevalence rates with those obtained in previous studies. Using a noninvasive screening approach offers the potential for the early detection and prompt treatment before worsening of the child's condition to severe anemia-related complications.

Materials and Methods

Study Design

This was a cross-sectional study among children aged ≥6 months to ≤36 months conducted in five maternal-and-child health clinics and Ministry of Health primary care clinic settings in urban and rural areas of Malaysia from July to December 2022. The clinics were chosen and the study participants were enrolled based on the need to include major ethnic groups in Malaysia in the study via convenience sampling.

Participants and Sample Size Planning

The study participants were outpatient children aged ≥6 months to ≤36 months at maternal-and-child health clinics accompanied by their primary caretakers (ie, parents, grandparents, or relatives) who were aged ≥18 years and could speak English, Bahasa Malaysia, or Chinese (Mandarin). Children who came to the clinics for routine vaccinations or routine health examinations were enrolled if the study requirements were met. The plan was to have 50% of participants aged 6 - 12 months and 50% aged >12 - 36 months, with the following ethnicity distribution: 69.8% Malay and Bumiputera, 22.4% Chinese, 6.8% Indian, and 1% others to ensure good representation of data from each site.

The study excluded children with any medical conditions for which interventions to increase nutritional intake might not be effective, per the investigator, in improving weight gain and the nutritional status. In addition, children participating in other studies involving iron-fortified foods or supplementation and those whose caretakers were not able to communicate effectively with the interviewers were excluded. The enrolment at the clinic was stopped when the participant number for specific sexes, age groups, and ethnicities, determined at the start of the study, was achieved. The World Health Organization and World Bank estimated the prevalence of anemia (ie, Hb level <11 g/dL) at 25% in 2019 among Malaysian children under 5 years of age [19]. In this study, we estimated that 30% of children aged ≥6 to ≤36 months will be at risk of anemia (ie, Hb level <12 g/dL), and considering a precision of ±3% and 95% confidence level,

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a sample size of 1200 subjects was required after accounting for 10% each of screen failures and dropouts. Any withdrawn subjects and screen failures were replaced until the sample size was obtained.

Data Collection

The study was conducted in five maternal-and-child health clinics that were conveniently selected based on the research need: three from urban areas and two from rural areas of Malaysia. From each of the clinics, approximately 240 participants were selected. Interviewers were trained on the protocol. The trained interviewers identified and approached potential participants and asked the parents or guardians to participate in the survey. Those who were willing to participate were screened for eligibility, and written consent was obtained after they were briefed about the study objectives, procedures, and other details. Respondents were reminded of their right to quit the study at any time without any consequences, and anonymity was guaranteed.

During the assessment, a clip with a sensor attached to the Masimo Rad-67 Pulse CO-Oximeter was placed on the child's finger or toe, and the reading took approximately 30 seconds. Children found to be at risk of anemia were referred to healthcare professionals for further clinical assessment. In addition, the child's weight (kg) and length or height (cm) were measured and input into the Iron Strong app (Groupe Danone).

Data were collected via the Iron Strong app device, a data collection tool with an optical character recognition model that allows the user (by taking a picture) to accurately predict all units and digits on the Masimo Rad-67 Pulse CO-Oximeter and stores the data within the app or server during face-to-face interviews in English, Bahasa Malaysia, or Chinese (Mandarin). The interview and data collection took about 30 - 40 minutes to complete.

Measurements

Development of the Questionnaire

The questionnaire was developed by a panel of three public health researchers. Bilingual researchers translated the English version of the questionnaire into Bahasa Malaysia and Chinese (Mandarin). The agreed versions were back-translated into English by independent bilingual researchers to ensure linguistic equivalence. The questionnaire was not pretested because it mainly asked about respondents' sociodemographic characteristics, anthropometric measurements, and 24-hour dietary recall.

Sociodemographic Characteristics

Participants reported their sociodemographic characteristics, such as the child's sex, age, race, residence location, physical activity, as well as caregiver's education level and household income. Birth history key indicators were asked, including mode of delivery, gestational age at birth, birth order, and the number of siblings. In addition, key indicators of family history such as thalassemia diagnosis and family history of anemia were asked.

Hb Level and Other Rad-67 Measurements

Anemia was assessed on the basis of the continuous total Hb level, with a cutoff value determined at <12 g/dL; this value was indicative of at risk of anemia, after considering the underestimation of the Hb concentration reported for Masimo devices [16-18]. This was measured using the Masimo Rad-67 Pulse CO-Oximeter, which is a noninvasive device for screening the total Hb levels. The reliability of the Masimo Rad-67 Pulse CO-Oximeter was reported to be ±1 g/dL versus the laboratory reference device in adults who had no motion, children, and infants. These findings have been validated by a group of researchers from Thailand [20].

Growth Parameters

Growth parameters were taken from the documentation available in the infant and child health record book. These parameters were taken by trained clinic nurses using standard methods.

Statistical Analysis

Categorical variables were summarized as the frequency and percentages, while continuous variables were summarized as the mean and standard deviation. Being at risk of anemia was the dependent variable. The χ^2 test was used to test for the differences in background and predictor variables between children at risk of anemia and those not at risk. Bivariable and multivariable logistic regression models were fitted to explore the association between independent variables and the dependent variable (at risk of anemia). The multivariable regression models included significant factors on bivariable analysis as well as other factors known to be associated with being at risk of anemia from previous studies, regardless of their significance on bivariable analysis. We presented the respective crude odds ratios, adjusted odds ratios, 95% CI, and *P* values. All the analyses were performed using R-Studio (Posit, PBC), version 4.0.0, with a *P* value <.05 being the level of statistical significance.

Ethical Considerations

The study was approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia (Ref: 21 - 02114-PV7(2)) and the Medical Research Ethics Committee, University of Malaya Medical Centre (Ref: 20211014 - 10694). Study data were anonymized to ensure the privacy of all participants and were accessed only by authorized personnel. Informed consent was obtained from all participants prior to their involvement in the study. Participants were provided with detailed information about the study and were informed that participation was voluntary and that they could withdraw at any time without penalty. For secondary analyses of previously collected data, the original informed consent covered subsequent research uses, as confirmed by the ethics committee. Participants in the study received RM 20 (US $4.50) as monetary payment that was approved by the ethics board for their time and effort involved in participation.

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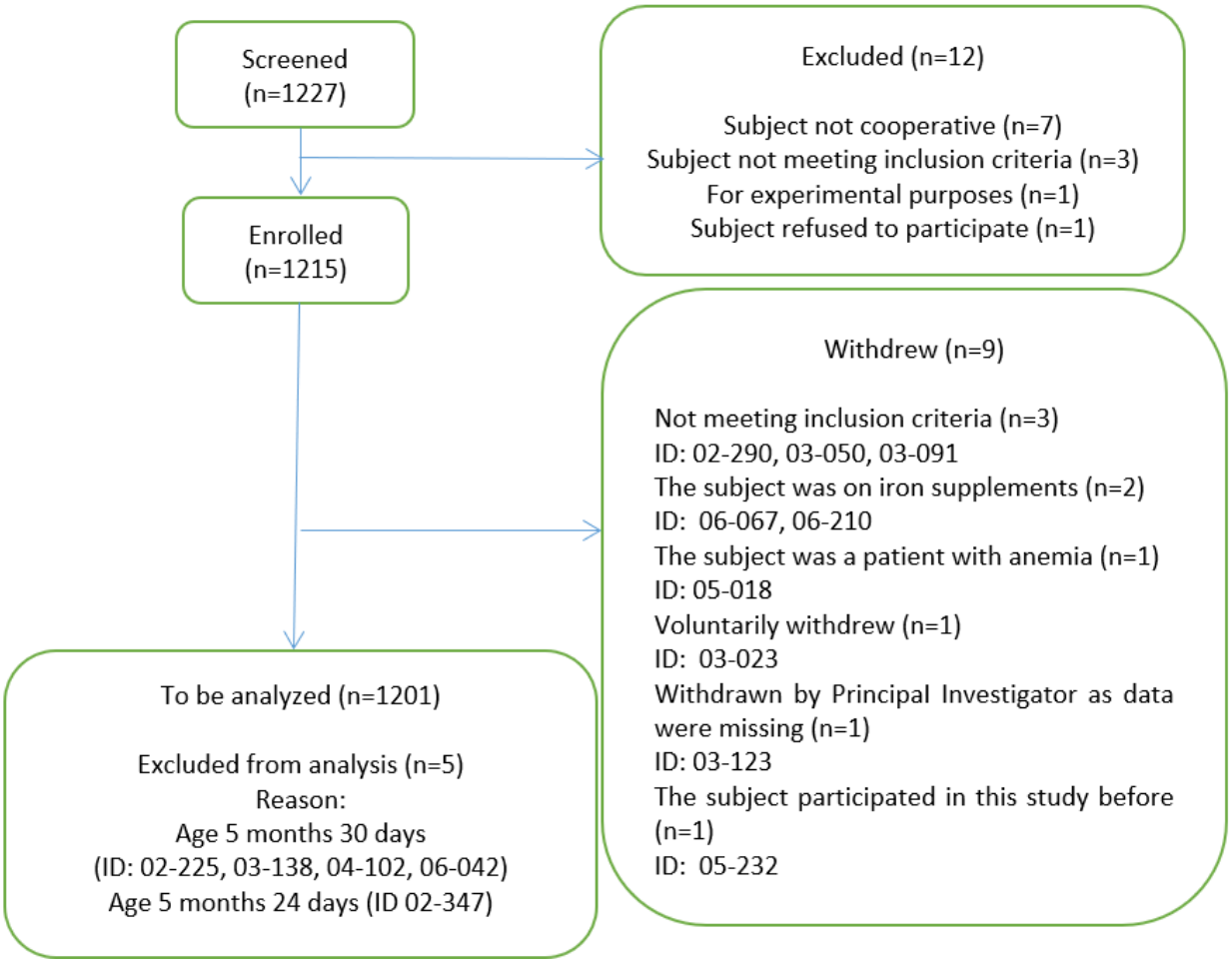
Results

A total of 1227 potential respondents were reached, of whom 27 declined to participate due to various reasons, yielding a response rate of 97.9% (Figure 1).

Figure 1. Flowchart depicting the selection of study participants for a cross-sectional study on the prevalence and risk factors of anemia among Malaysian children aged 6 - 36 months. The study was conducted across five maternal-and-child health clinics in Malaysia between July and December 2022.



Characteristics of Participants

A total of 1,201 participants were included in this study (Table 1). Slightly more than half were male (631/1201, 52.5%) and aged >12 - 36 months (610/1201, 51%); the majority were Asian Malay (727/1201, 60.5%) and from urban areas (687/1201, 57.2%). The majority had mothers with no university degree (898/1201, 74.8%), were born full-term (916/1201, 76%), via normal vaginal delivery (860/1201, 72%), and were of second or higher birth order (767/1201, 63.9%). Moreover, a very small number reported a family history of thalassemia (6/1201, 0.5%) with a quarter not knowing their thalassemia status (316/1201, 26.3%), while a majority had no family history of anemia (1078/1201, 89.8%) and reported moderate or vigorous physical activity (862/1201, 71.8%).

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Table . Baseline characteristics of the study participants (N=1201).

Characteristics	Frequency, n (%)
Sex	
Female	570 (47.5)
Male	631 (52.5)
Age	
>12 - 36 months	610 (51)
6 - 12 months	591 (49)
Race	
Asian, Chinese	270 (22.5)
Asian, Bumiputera	119 (9.9)
Asian, Indian	85 (7.1)
Asian, Malay	727 (60.5)
Town or District	
Alor Setar	205 (17.1)
Klang	369 (30.8)
Endau	240 (20.0)
Kota Kinabalu	133 (11.1)
Tumpat	253 (21.1)
Residence location	
Rural	514 (42.8)
Urban	687 (57.2)
Mother's education	
Bachelor's degree or higher	303 (25.2)
Secondary education and below	898 (74.8)
Household income	
Low	585 (48.7)
Middle or high	616 (51.3)
Physical activity level	
Sedentary or lightly active	177 (14.7)
Moderately active or vigorously active	862 (71.8)
No activity recorded	162 (13.5)
Gestational age at birth	
Term	916 (76)
Preterm	285 (24)
Mode of delivery	
Vaginal	860 (72)
Cesarean	341 (28)
Birth order	
First	434 (36.1)
Second or more	767 (63.9)
Family history of thalassemia	
Yes	6 (0.5)
No	879 (73.2)

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Characteristics	Frequency, n (%)
Not known	316 (26.3)
Family history of anemia	
Yes	123 (10.2)
Not known	1078 (89.8)

Population at Risk of Anemia and Other Masimo Rad-67 Pulse CO-OximeterParameters

Of the 1,201 participants, 364 (30%, 95% CI 28‑33) were identified as being at risk of anemia on the Masimo Rad-67 Pulse CO-Oximeter (Table 2). Additionally, participants had a mean (SD) weight-for-age Z score of −0.67 (1.29), length-for-age Z score of −0.65 (1.72), and weight-for-length Z score of −0.41 (1.29).

Table . Population at risk of anemia and other Rad-67 measurements (N=1201).

Study site	Frequency of subjects at risk of anemia, n/N (%)
Alor Setar	39/205 (10.7)
Klang	123/371 (33.9)
Endau	60/240 (16.5)
Kota Kinabalu	43/133 (11.8)
Tumpat	98/252 (27.0)

Distribution of Being at Risk of Anemia by Study Variables

The distribution of being at risk of anemia across the study variables is shown in Table 3. Children aged 6‑12 months (n=210, 57.7%), those of Asian Malay race (n=238, 65.4%), those from Klang district (n=123, 33.9%), those birthed via normal vaginal delivery (n=275, 75.5%), and those without a history of thalassemia (n=284, 78.0%) were associated with being at risk of anemia. Additionally, children at risk of anemia had significantly lower weight-for-age Z scores (ie, a greater negative deviation from the normal weight) than those at no risk.

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Table . Distribution of being at risk of anemia across study variables among Malaysian children aged ≥6 months to ≤36 months.

Variable	Not at risk of anemia, N=837	At risk of anemia, N=364	*P* value
Sex, n (%)			.87
Female	396 (47.3)	174 (47.8)	
Male	441 (52.7)	190 (52.2)	
Age, n (%)			<.001
>12 - 36 months	456 (54.5)	154 (42.3)	
6 - 12 months	381 (45.5)	210 (57.7)	
Race, n (%)			.02
Asian, Chinese	201 (24.0)	69 (19.0)	
Asian, Bumiputera	79 (9.4)	40 (11.0)	
Asian, Indian	68 (8.1)	17 (4.7)	
Asian, Malay	489 (58.4)	238 (65.4)	
Residence location, n (%)			.19
Rural	348 (41.6)	166 (45.6)	
Urban	489 (58.4)	198 (54.4)	
Education, n (%)			.75
Bachelor's degree or higher	209 (25.0)	94 (25.8)	
Secondary education and below	628 (75.0)	270 (74.2)	
Household income, n (%)			.08
Low	394 (47.1)	191 (52.5)	
Middle or high	443 (52.9)	173 (47.5)	
Gestational age at birth, n (%)			.83
Term	637 (76.1)	279 (76.6)	
Preterm	200 (23.9)	85 (23.4)	
Mode of delivery, n (%)			.046
Vaginal	585 (69.9)	275 (75.5)	
Cesarean	252 (30.1)	89 (24.5)	
Birth order, n (%)			.17
First	313 (37.4)	121 (33.2)	
Second or more	524 (62.6)	243 (66.8)	
Siblings, n (%)			.37
No	289 (34.5)	116 (31.9)	
Yes	548 (65.5)	248 (68.1)	
Family history of thalassemia, n (%)			.03
Yes	4 (0.5)	2 (0.5)	
No	595 (71.1)	284 (78.0)	
Not known	238 (28.4)	78 (21.4)	
Family history of anemia, n (%)			.57
Yes	83 (9.9)	40 (11.0)	
Not known	754 (90.1)	324 (89.0)	
Weight-for-age Z score, mean (SD)	−0.62 (1.35)	−0.78 (1.15)	.03
Length-for-age Z score, mean (SD)	−0.60 (1.77)	−0.77 (1.57)	.10

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Variable	Not at risk of anemia, N=837	At risk of anemia, N=364	*P* value
Weight-for-length Z score, mean (SD)	−0.38 (1.36)	−0.47 (1.09)	.20

Factors Associated With Being at Risk of Anemia Among Malaysian Children Aged ≥6 Months to ≤36 Months

The results of bivariable and multivariable logistic regression are detailed in Table 4. In our logistic regression analysis examining being at risk of anemia in children, the primary independent variable, weight-for-age Z score, showed a statistically significant inverse association with being at risk of anemia both in univariable (crude odds ratio=0.91, 95% CI 0.82 - 1.00; *P*=.046) and multivariable models (adjusted odds ratio=0.88, 95% CI 0.80 - 0.98; *P*=.020), indicating that higher Z scores were associated with reduced odds of being at risk of anemia. Among the covariates, only age showed a significant association; specifically, children aged 6 - 12 months had 1.73 times higher odds of being at risk of anemia compared to those aged 12 - 36 months (adjusted odds ratio=1.73, 95% CI 1.34 - 2.24; *P*<.001). Other demographic and medical factors, such as sex, race, residence location, and socioeconomic status, did not significantly impact being at risk of anemia (Table 4). This study underscores the importance of weight monitoring and age-specific interventions in mitigating anemia risk in children.

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Table . Results from bivariable and multivariable logistic regression models examining predictors of being at risk of anemia among Malaysian children aged ≥6 months to ≤36 months.

Variable	Crude odds ratio (95% CI)	*P* value	Adjusted odds ratio (95% CI)	*P* value
Sex				
Female	1		1	
Male	0.98 (0.77 - 1.25)	.876	0.96 (0.75 - 1.23)	.74
Age				
>12 - 36 months	1		1	
6 - 12 months	1.63 (1.27 - 2.09)	<.001	1.73 (1.34 - 2.24)	<.001
Race				
Asian, Chinese	1		1	
Asian, Bumiputera	1.47 (0.92 - 2.35)	.104	1.34 (0.80 - 2.24)	.25
Asian, Indian	0.73 (0.39 - 1.30)	.298	0.72 (0.38 - 1.31)	.29
Asian, Malay	1.42 (1.04 - 1.95)	.029	1.23 (0.88 - 1.73)	.22
Residence location				
Rural	1		1	
Urban	0.85 (0.66 - 1.09)	.195	0.96 (0.72 - 1.27)	.76
Education				
Bachelor's degree or higher	1		1	
Secondary education and below	0.96 (0.72 - 1.27)	.754	0.84 (0.62 - 1.14)	.25
Household income				
Low	1		1	
Middle or high	0.81 (0.63 - 1.03)	.086	0.78 (0.59 - 1.02)	.07
Physical activity level				
Sedentary or lightly active	1		1	
Moderately active or vigorously active	1.04 (0.74 - 1.50)	.812	1.19 (0.80 - 1.79)	.39
Gestational age at birth				
Term	1		1	
Preterm	0.97 (0.72 - 1.29)	.839	0.98 (0.73 - 1.32)	.91
Mode of delivery				
Vaginal	1		1	
Cesarean	0.75 (0.57 - 0.99)	.046	0.78 (0.58 - 1.04)	.09
Birth order				
First	1		1	
Second or more	1.23 (0.93 - 1.63)	.144	1.11 (0.83 - 1.49)	.49
Family history of thalassemia				
No	1		1	
Yes	1.15 (0.16 - 5.92)	.872	1.26 (0.17 - 6.90)	.79
Family history of anemia				
Yes	1		1	
Not known	0.89 (0.60 - 1.34)	.573	0.95 (0.62 - 1.49)	.83

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Variable	Crude odds ratio (95% CI)	*P* value	Adjusted odds ratio (95% CI)	*P* value
Weight-for-age Z score	0.91 (0.82 - 1.00)	.046	0.88 (0.80 - 0.98)	.02
Length-for-age Z score	0.95 (0.88 - 1.03)	.206	0.74 (0.41 - 1.31)	.31
Weight-for-length Z score	0.95 (0.85 - 1.05)	.313	0.65 (0.28 - 1.47)	.30

Discussion

Principal Findings and Comparison with Previous Works

The study assessed the prevalence and profiles of Malaysian children aged ≥6 to ≤36 months being at risk of anemia using a noninvasive Hb approach (the Masimo Rad-67 Pulse CO-Oximeter). Unlike the conventional methods of assessing anemia, this noninvasive screening approach offers rapid, accurate, and reproducible results, favoring the implementation in maternal child health clinics for early detection and prompt treatment before the condition worsens to severe anemia-related complications. This study had a response rate of 97.9% and only 7 out of 1227 patients were not cooperative to be included in the study. A high response rate among participants to be part of the study indicates their receptiveness to a noninvasive approach. The lack of parental consent due to invasive approaches has been observed and highlighted as a limitation in a similar study [21]. Caregivers of children highly favor noninvasive disease screening methods that lead to better testing compliance compared to invasive techniques that can cause discomfort and pain [22]. Noninvasive methods also reduce the risk of infection and could potentially be more cost-effective due to less usage of consumables and reagents [23].

This study found that 30% of Malaysian children aged ≥6 to ≤36 months were at risk of anemia. The observed prevalence was slightly higher than the 25% national prevalence of anemia among children below 5 years [19]. Moreover, the observation was also higher than that observed in two previous studies, which reported prevalence rates of 21.2% [23] and 22.3% [24], respectively. However, the observed prevalence was lower than the prevalence rate of 42.4% reported by Sabri et al [12] and 46.5% reported by the 2022 National Health and Morbidity survey [7]. As a screening tool for anemia, the Masimo Rad-67 Pulse CO-Oximeter is less stringent, which may account for the slightly higher prevalence observed in this sample population. As this is as a screening tool, confirmatory laboratory tests will be required for a diagnosis after screening.

This study focused on looking at contributing factors of anemia, although it did not measure iron content to evaluate the prevalence of IDA. A retrospective study in Pulau Pinang showed that the rate of IDA was 24% among children [24]. However, the 24-hour dietary recall that was performed may give an idea of the children's iron intake. It will be interesting to see if the children's intake of iron and other nutrients has any association with anemia development in this study. In this study, parental interpretation was used to measure physical activity. No specific children's physical activity measurement tool was used.

Although several measures have been undertaken, the observed prevalence of being at risk of anemia in Malaysia is substantially high, implying a need for more focused interventions aimed at prevention, early screening, and detection as well as treatment. In this regard, the extensive use and adoption of noninvasive screening tools at maternal and health clinics, which are points of child vaccination and regular health checks, would be essential for the early detection and providing prompt treatment, thus curbing the adverse complications of anemia in children [25-27].

The study explored factors associated with anemia among Malaysian children, of which age and weight-for-age were significant. The study results indicate that a higher risk of anemia is more common among children aged 6 - 12 months and lower weight-for-age. As expected, our results partly agree with the existing literature that has also reported children 6 - 12 months to have a higher risk of anemia compared to older children, due to increased iron needs that, if not provided by weaning foods, put this age group at a higher risk of serious anemia [3,4,28]. This aligns with previous studies that have reported a similar trend in India [29], Ethiopia [30], Brazil [31], and Peru [32].

Notably, although nonsignificant on adjusted regression analysis, children of the Asian-Malay race showed higher proportions of being at risk of anemia (65%) than other races, a finding that aligns with previous studies that have reported racial disparities in the risk of anemia [33,34]. Khalil et al showed a vast difference in the prevalence of anemia between the Orang Asli tribes in Malaysia, which was attributed to differences in socioeconomic background and other risk factors of anemia [35]. Similar to another study, anemia prevalence differences observed among racial and ethnic groups in this study can also be due to different food practices and low dietary intake of iron [21].

We expected thalassemia, a genetic predisposing factor affecting one's Hb concentration, to be positively associated with the risk of anemia, which is in contrast to this study's finding. In our study, Thalassemia status is based on parental and carer's reporting and could be subjected to reporting error, since as high as 26.3% of the subjects were unaware of their thalassemia status. Similarly, cesarean section as a mode of delivery is reported to have a negative impact on child feeding practices compared to normal vaginal delivery [21]; thus, we expected a positive association with anemia risk, which also deviates from our finding. Nonetheless, the difference in sample size and composition in our study could explain the observed mismatch. Additionally, mothers with children born of cesarean section and with thalassemia may be more aware of the increased risk of anemia from clinical counseling and education [36]. Therefore, they may be more likely to take extra measures to

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prevent anemia in their children, unlike mothers with no such known risk, which may explain our finding of surprisingly increased risk of anemia among children born via normal vaginal delivery and with no family history of thalassemia.

Malnutrition has been previously recognized as a factor for anemia among underweight children [28,37]. Additionally, micronutrient deficiency, food insecurity, and poverty have been established as factors leading to underweight children [28,38]. A study in China found that malnutrition resulted from the caregiver's lack of knowledge of child feeding practices [37], which may also be a contributing factor to anemia among children in this study. In addition, although the current data revealed that children from lower-income families had a higher proportion of being at risk of anemia, the household income surprisingly showed no statistically significant association with being at risk of anemia in the previous study [37].

It is worth noting that the observed high prevalence of anemia risk among children, including Malaysian children, is driven by complex interlinked factors including socioeconomic status, access to healthcare, dietary patterns, and cultural practices, amongst others [21,28,37,38]. A few such factors have been re-echoed in this study. The socioeconomic status, for example, affects food access and dietary quality, which are primary causes of anemia [28,38]. The socioeconomic status also affects healthcare access, without which the impact of anemia among children may be worsened. This calls for a comprehensive and inclusive approach to designing anemia prevention programs, considering the interaction of various key drivers.

Implications of Study Findings

Our study findings have some practical implications for addressing the observed high risk of anemia among Malaysian children. There is a need for more efforts in strengthening prompt community screening of anemia nationwide to enable the early detection and, thus, appropriate intervention or treatment, and this could be achieved by the adoption and use of noninvasive screening tools like the Masimo Rad-67 Pulse CO-Oximeter. The study results also imply that the Masimo Rad-67 Pulse CO-Oximeter could be a useful tool in the clinical assessment of Malaysian children for anemia, which could be incorporated into regular child immunization and monitoring visits. These efforts and other anemia prevention strategies should focus on children aged 6 - 12 months of Asian Malay heritage or race, and underweight children because they have a higher risk of anemia. Moreover, more efforts are needed in community education and sensitization about anemia risk, its consequences and prevention, and this should focus on the mothers and caregivers of children under 5 years. Additionally, nutritional education should be incorporated in the discussions with parents and caregivers after the examination of infants and young children to reduce the incidence of being underweight among children and to ensure anemia prevention and reduction.

Limitations

The study has some limitations. Some of the data, especially background predictor variables, were based on self-reporting, risk recall, and misclassification biases. Moreover, given the cross-sectional design of the study, no causal inference can be drawn between anemia and the other factors considered, beyond mere associations. Despite the limitations, the study provides valuable information on the prevalence of the risk of anemia and associated factors among Malaysian children using a noninvasive assessment tool.

Conclusions

Using a noninvasive screening tool, the study found that 30% of Malaysian children aged ≥6 to ≤36 months are at risk of anemia. Moreover, children aged 6 - 12 months and of Asian-Malay heritage or race had high odds of anemia. Weight-for-age was also negatively associated with the risk of anemia. Therefore, there is a need for more efforts in targeted community screening to enable the early detection and prompt treatment of anemia. More community education and awareness about anemia, including nutrition education, is also needed to address the high levels of anemia in the country.

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Data Availability

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

Conflicts of Interest

None declared.

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Abbreviations

Hb: hemoglobin
IDA: iron deficiency anemia

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Parental Experiences of Administering Pediatric Tuina for Sleep and Appetite in Early School-Aged Children With Attention-Deficit/Hyperactivity Disorder: Qualitative Study in Hong Kong

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Abstract

Background: Previous research suggested that parent-administered pediatric *tuina* could improve symptoms of attention-deficit/hyperactivity disorder (ADHD), such as sleep quality and appetite.

Objective: This study aimed to explore the experiences and perceptions of parents administering pediatric *tuina* to school-aged children with ADHD in Hong Kong.

Methods: This qualitative study was embedded in a pilot randomized controlled trial on parent-administered pediatric *tuina* for improving sleep and appetite in school-aged children diagnosed with ADHD. Purposive sampling was used to invite 12 parents who attended a pediatric *tuina* training program and delivered the intervention to their children at home for at least 8 weeks. Data were collected through semistructured focus group interviews and individual interviews, which were audio-recorded, transcribed verbatim, and analyzed using thematic analysis.

Results: Two main themes emerged: (1) effects of parent-administered pediatric *tuina* and (2) parents' experience of administering pediatric *tuina*. Parents reported significant improvements in children's sleep quality, appetite, behavior, mental state, and academic performance. Facilitators provided professional guidance and applied a user-friendly course design. Challenges included difficulties in mastering techniques, locating acupuncture points, and time management. Participants suggested the need for more traditional Chinese medicine pattern diagnostic sessions, real-time supervision methods, and extended follow-up to better observe long-term effects.

Conclusions: Parent-administered pediatric *tuina* was perceived to improve children's sleep quality and appetite significantly, along with other aspects of well-being. Professional guidance and a structured training program facilitated implementation, and challenges highlighted the need for more frequent diagnostic sessions, real-time supervision, and extended follow-up.

Trial Registration: ClinicalTrials.gov NCT06007742; https://clinicaltrials.gov/study/NCT06007742

(JMIR Pediatr Parent 2025;8:e65471) doi:10.2196/65471

KEYWORDS

pediatric massage; child; traditional Chinese medicine; TCM; ADHD; qualitative study; complementary medicine; attention deficit; hyperactivity; massage; tuina; tui na; mental health; sleep; appetite; parent; parenting; interview; focus group; anmo; attention-deficit/hyperactivity disorder

Introduction

Attention-Deficit/Hyperactivity Disorder

Attention-deficit/hyperactivity disorder (ADHD) is a common neurodevelopmental disorder in children, affecting approximately 5% of the pediatric population [1]. It is characterized by 3 primary symptoms: inattention, hyperactivity, and impulsivity [2,3]. Children with ADHD often experience additional mental, emotional, or behavioral disorders, which can include learning disorders, sleep disorders, oppositional

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defiant disorders, anxiety, and conduct disorders [4]. Among the comorbidities, sleep problems and appetite disturbances are particularly prevalent among school-aged children with ADHD [5,6]. Sleep problems can include difficulty falling asleep, restless sleep, frequent awakenings, and difficulty waking up in the morning [7]. These sleep issues may be caused by the hyperactive and impulsive nature of ADHD, the side effects of medications, or coexisting emotional and behavioral issues [8]. Eating problems are common in children with ADHD, ranging from poor appetite and picky eating to overeating and cravings for unhealthy foods [9]. The causes of these eating problems can include the side effects of ADHD medications, which often suppress appetite, and the impulsivity associated with ADHD [10]. Notably, stimulant medications, which are commonly prescribed for ADHD, can lead to sleep disturbance and eating problems [11]. Sleeping and eating issues can affect the child's physical health, growth, and development, which could complicate the management of ADHD symptoms [5,6]. Strategies such as establishing consistent bedtime routines, creating a calming sleep environment, and encouraging balanced diets are crucial to specifically address sleep and appetite issues [5,6]. Parents and caregivers play a vital role in implementing these coping interventions to help manage symptoms and improve the quality of life for the child and the family [12].

Parent-Administered Pediatric *Tuina*

Pediatric *tuina*, also known as pediatric *anmo* or traditional Chinese medicine (TCM) pediatric massage, is a specialized form of massage therapy tailored for infants and children [13]. It is grounded in TCM principles, which emphasize the harmonious functioning of the body's systems [13]. In ancient Chinese medicine, the term "double *yang* person" was used to describe individuals exhibiting symptoms of ADHD [14]. By targeting specific acupoints, pediatric *tuina* aims to restore the *yin-yang* balance, thereby enhancing overall health and well-being. As an external, noninvasive therapy, it offers a complementary approach to conventional medical treatments, providing a holistic option for pediatric care [13]. This therapeutic technique has been extensively studied for its potential benefits in addressing various clinical conditions and diseases [15] such as diarrhea [16], anorexia [17], torticollis [18], constipation [19], enuresis [20], and functional dyspepsia [21]. Pediatric *tuina* is used to promote the growth and development of healthy children in China [22]. The practice of pediatric *tuina* involves the stimulation of specific areas or acupoints on the body through various manipulation techniques, including pushing, kneading, pressing, rotating, nipping, circular movements, and pounding [13]. These techniques generate different types of stimuli on the skin, which are detected by surface sensory receptors and transmitted to the central nervous system [23]. This sensory input is believed to induce a series of protective and adaptive homeostatic activities within the body. Research has demonstrated that in young children, the skin can rapidly regulate basic and adaptive homeostatic responses [24]. This regulation may be facilitated by a low compensatory basal level of stress-responsive enzymes, allowing for a broad range of physiological responses [25]. The mechanisms behind these responses suggest that pediatric *tuina* may substantially affect the autonomic nervous system, potentially leading to improved clinical outcomes for various pediatric conditions [26].

Research Gap

In recent years, several research studies have preliminarily demonstrated the effects of pediatric *tuina* in treating ADHD. For instance, a randomized controlled trial (RCT) on 120 children with ADHD comparing pediatric *tuina* with medication reported that the Conners scores in the pediatric *tuina* group were significantly lower than those in the control group (Cohen d=0.96, P<.05), as were the ADHD scores (Cohen d=.57, r=0.28, P<.05). The incidence of adverse events was lower in the pediatric *tuina* group (3.33%) than in the control group (16.67%, P=.015) [27]. A systematic review of 11 clinical trials suggested the potential benefits of pediatric *tuina* in improving concentration, mood, sleep, and social functioning in children and adolescents with ADHD [28]. However, the extant literature lacks robust qualitative insights into parents' understanding of using this intervention and the specific implementation as a complementary intervention. Therefore, limited information exists exploring the practicalities, challenges, and perceived benefits of parent-administered pediatric *tuina* for ADHD. The authors' team recently conducted a pilot RCT to further examine parent-administered pediatric *tuina* for improving sleep and appetite in school-aged children with ADHD in Hong Kong. This study is the qualitative part of the pilot RCT, aiming to further explore parents' experiences and perceptions of delivering pediatric *tuina* at home, particularly in parents' experiences on its effects on children's sleep and appetite and parents' experience of administering pediatric *tuina*. This project could provide valuable insights into the real-world application of pediatric *tuina* and offer guidance for parents and health care providers in optimizing this intervention's use in more contexts.

Methods

Ethical Considerations

Ethical approval for the study was granted by the Hong Kong Polytechnic University (HSEARS20230810005). A written informed consent to participate in this study was obtained from the participants. Each participant was assigned a randomly generated code to ensure confidentiality. Each participant received a cash incentive of HK $200 (approximately US $25.64 based on an exchange rate of HK $1=US $0.1282) to acknowledge their participation.

Study Design

This project was registered on ClinicalTrials.gov under the identifier NCT06007742. This study presents the qualitative findings from a pilot RCT investigating the effects of parent-administered pediatric *tuina* on sleep quality and appetite in school-aged children with ADHD in Hong Kong. In the RCT, parents received systematic training from TCM practitioners, including 2 face-to-face sessions (each lasting 2 hours). The first session focused on theoretical knowledge, and the second session covered TCM pattern identification and pediatric *tuina* techniques. Following the training sessions, parents administered pediatric *tuina* to their children at home over an 8-week period on the basis of individualized prescriptions formulated by TCM

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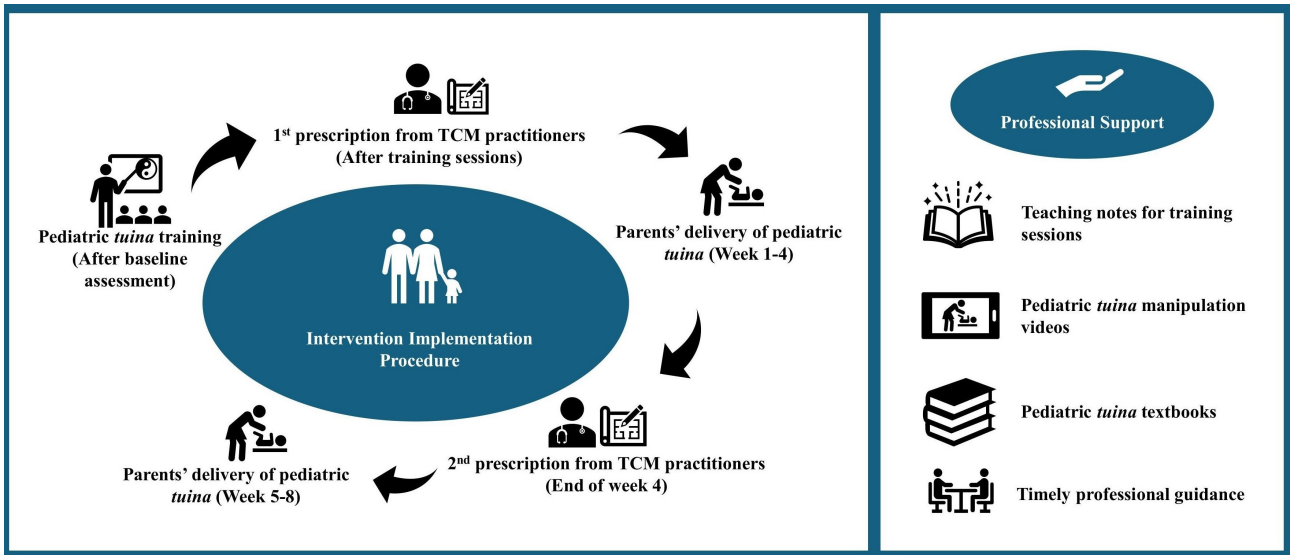
practitioners. Each participant in the pediatric *tuina* group received parent-administered pediatric *tuina* sessions every other day, totaling 24 sessions over an 8-week period (at least 3 sessions each week). Each session lasted approximately 25 - 30 minutes. The *tuina* protocol was developed from a 2021 feasibility RCT for ADHD involving 64 parent-child pairs, where 128 individualized pediatric *tuina* prescriptions were analyzed to identify commonly used and safe acupoints [29]. The resulting standardized basic prescription allows TCM practitioners to make individualized modifications based on syndrome differentiation. This TCM diagnosis guided the selection of specific acupoints and manipulation techniques tailored to each child's condition. Details regarding the implementation of the intervention are illustrated in Figure 1. The interviews commenced 1 week after the completion of treatment for the first wave of participants in the RCT, which was conducted in 3 sequential waves. Interviews were strategically scheduled at 3 distinct timepoints, following the conclusion of each treatment wave. This timing ensured that participants had sufficient experiences and perceptions for in-depth exploration and allowed for the prompt collection of data while their experiences were still vivid, ensuring accurate and immediate reflections on the treatment effects. The study's reporting adhered to the Consolidated Criteria for Reporting Qualitative Research's checklists [30].

Figure 1. The implementation of the parent-administered pediatric *tuina* program. TCM: traditional Chinese medicine.



Setting

This study used a qualitative approach with the use of semistructured focus group interviews and individual interviews. The research methodology allows for a great flexibility of the participants to join. The focus group interviews were conducted face-to-face in the campus of the Hong Kong Polytechnic University.

Participants

Participants were parents with children with ADHD. The participants for the interviews were invited from the participants in the pilot RCT who received the parent-administered pediatric *tuina* intervention [31]. Recruitment information was sent to potential participants by WhatsApp message at the end of February 2024, and purposive sampling was applied for recruitment. The children included in the pilot RCT (1) were aged 6 - 8 years; (2) possessed internationally recognized diagnostic information or certification for ADHD; and (3) had a score equal to or higher than 39 (borderline cutoff) of the Sleep Disturbance Scale for Children, which indicated sleep problems of children. The parents included in this study (1) participated in the project on using parent-administered pediatric *tuina* for improving sleep quality and appetite in children with ADHD who completed the 2-month treatment and follow-up assessment of the intervention during the treatment period, (2) were able to communicate in Cantonese fluently, and (3) agreed to participate and were willing to share their experience in applying this intervention. This study focused on children aged 6 - 8 years, representing the early school-age period. This study focused on children aged 6 - 8 years, representing the early school-age period. This focus is driven by the significance of early intervention in ADHD's developmental trajectory and the specific responsiveness of this age group to pediatric *tuina*. Research suggests that early school years are critical for implementing interventions that could substantially alter the course of ADHD, making timely and targeted intervention essential [32]. Furthermore, tactile therapies such as pediatric *tuina* are shown to be highly effective in younger children, who are generally more receptive to such treatments [33].

Data Collection

A semistructured interview guide was created and refined on the basis of previous relevant studies and comments from experts, including 2 TCM practitioners (KCL and PMW) and 2 qualitative researchers (WFY and SCC). The guide comprised 5 open-ended questions detailed in Textbox 1. The focus group interviews were moderated by the first author (SCC), with an assistant moderator (LYP) responsible for note-taking and operating the recording equipment. Both moderators received training from the corresponding author (WFY), a TCM practitioner with extensive research experience in TCM interventions and qualitative methodologies. At the beginning of each interview session, the moderator introduced herself,

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clarified the study's purpose and procedures, and emphasized the confidentiality rules. She also explained the questions and facilitated group interaction by providing prompts and pauses, ensuring that the discussion remained focused without imparting any value judgments. Participation in the study was voluntary, and no individuals other than the participants and researchers were present during the interviews. Participants were reassured that, although the sessions were audiotaped, their names would not be recorded.

Textbox 1. Questions for the semistructured interview.

Do you think pediatric *tuina* has changed or affected your child's eating habits?
Do you think pediatric *tuina* has changed or affected your child's sleep?
Besides diet and sleep, in what other aspects do you think pediatric *tuina* has changed or affected your child?
What difficulties did you encounter from learning to performing pediatric *tuina*?
How do you evaluate the content and process of the pediatric *tuina* treatment for attention-deficit/hyperactivity disorder? What are the advantages and areas for improvement?

Data Analysis

All interviews were audiotaped and transcribed verbatim in traditional Chinese before data analysis commenced. All study-related documents and transcripts were deidentified, and the audio files were destroyed once transcription was completed. The transcripts were analyzed using thematic analysis with hierarchical coding [34,35]. The template analysis applied the following steps: (1) an initial reading of the transcripts to identify a priori themes and perform preliminary coding; (2) development of an initial coding template; (3) systematic review of all datasets to refine the template by adding, removing, or merging codes as necessary; and (4) finalization of the template for application to the entire dataset [36]. The first author (SCC) conducted the transcription and initial coding, which were subsequently reviewed for accuracy and consistency by another researcher (HL). Any discrepancies in coding were resolved through consultation with the principal investigator (WFY). Microsoft Word software was used to manage the coding process [37,38]. Descriptive statistics were used to summarize the demographic characteristics of the sample. The Results section presented a summary of the main themes and subthemes, illustrated with participant quotes. For each quote, only the participant codes are provided.

Trustworthiness

This study adhered to the trustworthiness criteria for qualitative research as outlined by Lincoln and Guba [39,40]. For credibility, a semistructured interview guide was developed through 2 group discussions and subsequently pilot-tested during the initial interview session. Purposive sampling was used to select participants capable of providing diverse perspectives and experiences relevant to the intervention delivery. For transferability, the richness of the data was assessed using the saturation theory [41]. Data collection continued until the point of near exhaustion of new information, which was achieved by the third session [42]. Dependability was maintained through independent coding of the collected data by 2 researchers, complemented by regular debriefing sessions with WFY, an individual with substantial expertise in qualitative research. Finally, participants were provided with the findings, including the code tree and quotations, for their feedback and verification to ensure confirmability. This process aimed to minimize bias and ensure that the intervention reflected the true perspectives and experiences of the participants.

Results

General Characteristics of Data

In total, 4 group interviews and 3 individual interviews were conducted in Cantonese between February 2024 and April 2024. The group interviews averaged 86 minutes in duration, ranging from 77 to 96 minutes, and the individual interviews averaged 35.3 minutes, with durations ranging from 30 to 46 minutes. Of the 61 parents invited, 12 ultimately participated. Each interview session included between 1 and 3 participants, none of whom knew each other. Themes and subthemes were initially identified by the fourth interview session and further refined by the seventh session.

Sample Profile

Overall, 12 parents, comprising 10 females (83.3%) and 2 males (16.7%), whose children were diagnosed with ADHD participated in the interviews. The average age of the parents was 40.1 (SD 3.7) years, and the mean age of their children was 6.9 (SD 0.9) years. Detailed demographic information on the participants can be found in Table 1.

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Table . Demographic characteristics of participants interviewed (N=12).

Characteristics		Values
Age (years), mean (SD)		
	Parents	40.1 (3.7)
	Child	6.9 (0.9)
Gender (parent), n (%)		
	Male	2 (16.7)
	Female	10 (83.3)
Gender (child), n (%)		
	Male	10 (83.3)
	Female	2 (16.7)
Educational level (parent), n (%)		
	Senior high school	4 (33.3)
	College or above	8 (66.7)
Career (parent), n (%)		
	Professional/semiprofessional	4 (33.3)
	Unskilled worker	1 (8.3)
	Homemaker	5 (41.7)
	Others	2 (16.7)
Family members, mean (SD)		4.3 (1.1)
Family monthly income in HK$[a], n (%)		
	10,001 - 24,999	2 (16.7)
	25,000 - 49,999	7 (58.3)
	50,000 or above	3 (25)
BMI (child), mean (SD)		14.3 (1.8)
Past treatment for ADHD [b] (child), n (%)		
	Medication	0 (0)
	Cognitive behavioral therapy	3 (25)
	Others	1 (8.3)
Current treatment for ADHD (child), n (%)		
	Medication	3 (25)
	Cognitive behavioral therapy	3 (25)
	Others	1 (8.3)

[a]All income values are presented in Hong Kong dollars. For the purpose of this study, the conversion rate used is HK $1=US $0.1282 (as of February 2024).

[b]ADHD: attention-deficit/hyperactivity disorder.

Major Themes

Two themes regarding the participants' experience in applying the parent-administered pediatric *tuina* intervention and participating in the study were identified: (1) effects of parents performing pediatric *tuina* and (2) parents' experience of performing pediatric *tuina*. The specific subthemes under each theme were described. Table 2 presents the code structure.

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Table . Code structures.

Themes and subthemes		Code units
Effects of parent-administered pediatric *tuina*		
	Improvements in children's eating	• Increased appetite and food intake • Improved diet structure (less picky eating and trying new things) • Improved gastrointestinal function (indigestion, vomiting, and constipation)
	Improvements in children's sleep	• Improved sleep quality (restlessness, snoring, teeth grinding, sweating, and yelling) • Improved sleep habits (shorter time to fall asleep and able to sleep on their own)
	Improvements in other aspects of children	• Improved behavioral habits (milder behavior) • Improved mental state (relaxed and better emotions) • Improved attention (academic performance) • Improved interpersonal relationships (family and school) • Improved physical condition (bedwetting, rhinitis, weight, and height)
Parents' experience of performing pediatric *tuina*		
	Advantages of this intervention implementation	• User-friendly course design (appropriate difficulty and clear teaching materials) • Professional guidance from instructors • Noninvasive treatment method • Customized diagnosis and treatment • Satisfactory treatment effects (effective and quick results)
	Difficulties encountered during implementation	• Difficulty in operation (knowledge, locating acupuncture points, and techniques) • Difficulty in children's cooperation • Time management difficulties (parents and children)
	Parents' suggestions on improving the intervention	• Increasing guidance during practice and operation • Use of real-time supervision methods (such as electronic records or apps) • Increasing number of diagnostic sessions • Extending treatment and follow-up time

Effects of Parent-Administered Pediatric *Tuina*

This theme encompasses three subthemes: (1) improvements in children's eating, (2) improvements in children's sleep, and (3) improvements in other aspects of children.

Improvements in Children's Eating

Parents observed noticeable improvements in their children's eating habits following the administration of pediatric *tuina*. Many reported an increase in appetite and food intake, as illustrated by one parent who stated, "I think his appetite is better...at least he's willing to eat more, which is an achievement; the most important thing is that he's willing to eat" [Participant 12]. Another parent noted a reduction in the child's resistance to eating: "Normally, if we hurry him to eat, he immediately says he's full, but after doing *tuina*, he says he wants more, and his food intake has increased" [Participant 59]. Additionally, some parents observed an improvement in their children's diet structure, with children becoming less picky and more willing to try new foods. A parent shared, "After the pediatric *tuina*, I felt he started eating meat...he even ate fish that he previously didn't eat" [Participant 1]. Improvements in gastrointestinal function were reported, with one parent noting a remarkable change: "His stools have clearly improved, previously they were like small pellets, similar to Maltesers...during the massage period, his stools became much more normal" [Participant 50]. Another parent highlighted the benefits of stomach massages: "I think massaging his stomach helped with bowel movements...his stomach is more relaxed now, it used to be tight, and his belly was cold before, now it's warm" [Participant 40].

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Improvements in Children's Sleep

Parents also reported enhancements in their children's sleep quality and habits after pediatric *tuina*. Improved sleep quality was a common theme, with one parent describing their child's more stable sleep: "Before doing *tuina*, he used to sleep like a whirlwind, rolling from the head to the foot of the bed and back all night long, but now he's more stable and it's less frequent" [Participant 59]. Another parent mentioned a reduction in excessive sweating and sleep disturbances: "He usually sweats a lot while sleeping, even at 4 AM he still sweats, but after the *tuina*, he sweats less...also, he used to yell in his sleep, I had to wake him, about two or three times a week, but this has noticeably reduced now" [Participant 50]. Improved sleep habits, such as shortened time to fall asleep and the ability to sleep independently, were noted. A participant shared, "He sleeps more soundly now; previously, he had no sense of security and needed me to accompany him to sleep, but now, for example, after I massage him and turn off the lights, he is willing to sleep by himself, at least it's the first step" [Participant 40]. Another mom observed, "It takes him less time to fall asleep now; it used to take him two hours to fall asleep, but now it might only take half an hour" [Participant 59].

Improvements in Other Aspects of Children

Beyond eating and sleep, parents observed various other benefits of pediatric *tuina* on their children's behavior and overall well-being. Improvements in behavioral habits were frequently mentioned, with one parent noting a decrease in aggressive behavior: "I think he has fewer outbursts, and so do I...he used to hit people, very bad temper like a volcano...now I feel like he has fewer explosive moments" [Participant 12]. Enhancements in the children's mental state were reported, with one mom describing their child as more relaxed: "I think he's more relaxed, when I massage him, I ask if he likes it, if it hurts...he says he likes it, it's very comfortable...I think his emotions are more relaxed" [Participant 43]. Another parent noticed improved emotional expression: "Previously, he would get very angry if he didn't like what I said, but now he just says, 'Mom, I don't like it, I don't want you to say that,' expressing himself more gently" [Participant 13]. Improvements in attention and academic performance were highlighted by some parents, with one noting, "The homeroom teacher says he's doing okay, although he still gets easily distracted sometimes, but compared to last semester, he has made progress" [Participant 40]. Another parent observed remarkable academic improvements: "My son scored over 70 in listening in the first semester, but after doing *tuina*, he scored 95 in both Chinese and English exams at the end of March; I'm not sure if it had an effect, but I can see his attention has improved" [Participant 52]. Enhanced interpersonal relationships were reported, with one parent stating, "During the *tuina* process, the parent-child relationship improved, he likes to discuss math with his dad, using many methods to calculate, which helps his academics, he feels a sense of achievement, more confident, and even teaches friends how to calculate, and his relationship with classmates has improved" [Participant 15]. Physical conditions, such as bedwetting, rhinitis, weight, and height, were noted to have improved. One parent shared, "After the *tuina*, his nose is no longer as sensitive, it used to be really bad, I even thought about taking him to see a doctor" [Participant 52]. Another parent observed, "Her physical condition has really improved, he eats more, sleeps better, and her weight has increased...she gained a few pounds compared to last semester" [Participant 52]. Bedwetting was reported to have decreased, with one parent stating, "He used to wet the bed, but recently it has decreased" [Participant 43].

Parents' Experience of Performing Pediatric *Tuina*

Parents' experiences of administering pediatric *tuina* include three subthemes: (1) advantages of this intervention implementation, (2) difficulties encountered during implementation, and (3) parents' suggestions on improving the intervention.

Advantages of This Intervention Implementation

Parents highlighted several advantages of implementing pediatric *tuina* for their children. One notable advantage was the user-friendly course design, which many found to be appropriately challenging yet accessible. As one parent explained, "The Chinese medicine doctor starts by explaining things, we initially didn't know much about acupuncture points, but I think the course depth is suitable for us parents" [Participant 31]. Additionally, parents appreciated the professional guidance from instructors, with another parent noting, "I think they did a good job. A Chinese medicine PhD analyzed the problem, and then a *tuina* therapist taught the techniques and let me record videos. After filming, they explained the whole process, answered my questions directly, and didn't make it difficult to grasp. Later, they sent me the technique videos, which was great" [Participant 13]. The noninvasive nature of pediatric *tuina* was valued, with one parent stating that "(Pediatric *tuina*) is more natural and noninvasive, which is already very good" [Participant 1]. Furthermore, parents appreciated the customized diagnosis and treatment plans tailored to their children's specific needs. One parent shared, "The first time I came back to see the doctor, I described my child's situation, and the doctor added two acupuncture points, explaining that it was because of my child's current condition, which I found acceptable" [Participant 43]. Lastly, the satisfactory treatment effects were highlighted, with parents observing quick improvements in their children's overall well-being. As one parent noted, "I think pediatric *tuina* is effective for my child. At least his emotions improved, as well as his appetite, diet, growth, and digestion" [Participant 1]. Another parent remarked, "After two weeks, I noticed he slept better" [Participant 59], and another one observed, "In the first week, I felt he became more obedient and focused" [Participant 4].

Difficulties Encountered During Implementation

Despite the advantages, parents also encountered several difficulties during the implementation of pediatric *tuina*. One common challenge was the difficulty in operation, particularly in terms of knowledge, locating acupuncture points, and mastering techniques. As one parent expressed, "When actually performing the *tuina*, we were guessing. I felt uncertain about the position and pressure, and we were trying to imitate, so some areas were unclear, like using several fingers..." [Participant 43]. Another difficulty was gaining children's

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cooperation, with one parent noting, “He found repeating the same thing boring and asked if there was anything else to do” [Participant 40]. Time management posed a considerable challenge for parents and children. One parent mentioned: “I was very busy myself and didn’t have the determination to schedule a specific time for the *tuina*” [Participant 13]. Another parent added, “If I felt it was too late or he was tired that day, I would do one or two techniques and then sleep” [Participant 40].

Parents’ Suggestions on Improving the Intervention

Parents suggested several improvements to enhance the implementation of parent-administered pediatric *tuina*. Increased guidance during practice and operation was a common request. One parent suggested, “It would be better if the doctor could watch the whole process of how I execute it from start to finish. We are beginners and may not notice if we are making mistakes” [Participant 43]. Another parent proposed: “I hope the doctor can check our techniques after a few weeks” [Participant 24]. The use of real-time supervision methods, such as electronic records or applications, was suggested to facilitate the process. As one parent noted, “The paper (logbook) could be converted to phone input, as *tuina* requires using olive oil, and the paper gets oily after filling it out” [Participant 50]. Another parent mentioned, “Using an app would save parents some effort. Besides recording if the points were done, it could also record the time, duration, and timely track the child’s weight, eating, bowel movements, and sleep” [Participant 31]. Parents also expressed a desire for an increased number of diagnostic sessions. One parent stated, “More TCM pattern diagnostic sessions would give us more confidence. Now it’s once every four weeks; if it were every two weeks, we’d feel more assured. Sometimes we are just blindly following instructions” [Participant 59]. Lastly, extended treatment and follow-up time were deemed necessary by some parents to observe long-term effects. As one parent remarked, “I think it needs more follow-up, a few months would be best. I genuinely want to see the long-term effects” [Participant 52].

Discussion

Main Findings

This study explored the effects and parental experiences of administering pediatric *tuina* to improve sleep and appetite in school-aged children with ADHD. This study is the first qualitative investigation into parent-administered pediatric *tuina* for addressing specific issues in children in Hong Kong. Insights from 12 parents were gathered using semistructured focus group interviews and individual interviews. The findings revealed 2 key themes: the effects of pediatric *tuina* on children and parents’ experiences with the intervention. Parents reported significant improvements in their children’s eating habits, sleep quality, and other areas such as behavior, mental state, and academic performance. They also highlighted advantages such as the user-friendly course design and professional guidance but noted challenges in mastering techniques and managing time. Parents suggested more guidance, real-time supervision, frequent diagnostic sessions, and extended follow-up to improve the intervention.

Comparison With Previous Studies

The findings of this study align well with a previous RCT on the effects of pediatric *tuina* for improving children’s sleep quality and habits, eating habits, behavioral regulation, emotional well-being, and parent-child relationship [29]. Improvements on children’s sleep quality and habits are consistent with the results of several previous studies examining the effects of pediatric *tuina* on sleep disturbance [43,44] or sleep problems in populations with different conditions such as bronchitis [45] and pneumonia [46]. The enhancements in eating habits reported by parents are in line with findings from a systematic review of pediatric *tuina* for anorexia in children on 28 RCTs [17]. In this study, a meta-analysis based on 9 RCTs indicated that pediatric *tuina* was superior to Western medicine (mean difference: −0.88, 95% CI −1.27 to −0.5) and Chinese herbs (mean difference: −0.69, 95% CI −1 to −0.38) in terms of improving food intake, suggesting that pediatric *tuina* could be an effective intervention for children with eating difficulties. The improvements in behavioral regulation and emotional well-being noted in this study mirror those documented in research on other pediatric massage therapies. Previous studies have found that children receiving massage therapy exhibit lessened behavioral outbursts, improved self-regulation, enhanced emotional regulation, reduced anxiety, and improved mood [47,48]. Moreover, the findings regarding the enhancement of parent-child relationships resonate with previous research emphasizing the importance of parental involvement in therapeutic outcomes. Studies on parent-involved therapies, such as cognitive behavioral therapy for children with ADHD, have shown that active parental participation is crucial for achieving effective outcomes [49,50]. Parent-administered pediatric *tuina* increases quality time spent between parents and children, thus fostering closer bonds, enhanced communication, and a sense of security. This engagement is similar to the benefits seen in cognitive behavioral therapy, where parental involvement plays a critical role in the success of the intervention.

The findings reveal notable inconsistencies with previous research focused on the effects of parent-administered pediatric *tuina* on children’s attention. While a prior qualitative study on exploring the effects of parent-administered pediatric *tuina* on ADHD in preschool children conducted in Mainland China reported that almost all parents who participated reflected that pediatric *tuina* had minimal effect on improving attention in their children [51], this study reveals considerable improvements in children’s attention and academic performance based on the description from several parents. The possible explanation may be attributed to the context (eg, culture and intervention implementation) and population differences between the two studies. In this study, the participants are school-aged children who may be more responsive to physical touch due to their developmental stage [52] and the academic demands [53] they face, which could enhance the effect of improved attention on academic performance. Additionally, cultural factors in Hong Kong, such as parental involvement and parental warmth in education, may have contributed to the more pronounced effects observed in this study [54]. Besides, the face-to-face TCM pattern diagnosis and parent training of this study may be more

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accurate than the web-based intervention implementation mode of the previous study, thereby generating more satisfactory effects on children's attention. These inconsistencies underscore the need for further research to explore the contextual factors that influence the implementation of pediatric *tuina* across different populations and developmental stages.

One unanticipated finding was that pediatric *tuina* produced remarkably fast-acting benefits across various health outcomes, as reported by parents. For instance, one parent observed that their child's sleep quality improved noticeably after just 2 weeks of treatment. Another parent noted that their child's weight, which had been stagnant at 16 or 17 kg for a year, increased rapidly to 18 kg after 4 weeks of pediatric *tuina* therapy. Additionally, another parent observed considerable behavioral changes within the first week, noting that their child became more obedient and focused. Possible explanations for the fast-onset of pediatric *tuina* relate to the young age of participants and the underlying effect theory of pediatric *tuina*. According to the TCM theory, children, particularly those under 6 years of age, are more responsive to sensory stimuli due to their more sensitive organs [23], making them more receptive to external manipulations. This heightened sensitivity potentially allows the effects of pediatric *tuina* to activate the body's self-healing mechanisms quickly [55]. The concentration of pediatric *tuina* acupoints in areas rich in sensory receptors, such as the palms and head, enables effective stimulation of these receptors, thereby initiating quick physiological responses [56]. Furthermore, the specific manipulations used in pediatric *tuina*, such as pressing and rubbing, provide varied sensory stimuli that are rapidly processed by the nervous system, leading to swift improvements in the body [26]. While previous research has primarily focused on the targeted outcomes of pediatric *tuina*, the findings of this study offer new insights into the onset speed of these benefits, challenging the common perception that TCM interventions are primarily suited for chronic conditions and work slowly.

Implications

The findings have remarkable implications for several key stakeholders. For pediatricians, the integration of pediatric *tuina* into conventional ADHD treatment protocols is recommended, particularly for managing common comorbidities such as sleep and eating disorders in young children. For TCM practitioners, developing systematic training programs for parents to administer pediatric *tuina* effectively at home is meaningful for extending the benefits of this therapy beyond clinical settings and addressing a broader range of pediatric conditions. For researchers focusing on parent-administered pediatric *tuina*, future clinical trials should aim to enhance the guidance provided during practice, which can be achieved by developing real-time supervision methods, increasing the frequency of diagnostic sessions, and extending the treatment and follow-up periods. Besides, future research should consider triangulating qualitative findings with quantitative data to enhance the robustness and applicability of the study results.

Limitations

The limitations of this qualitative study should be acknowledged. First, the mixed-method approach, incorporating individual interviews and focus group interviews, was necessitated by time management barriers faced by participants. While this approach allowed great flexibility and participation, it may have introduced variations in the depth and breadth of data collected, potentially affecting the consistency and comparability of the findings. Second, the study was geographically limited to Hong Kong, which may have restricted the generalizability of the results to other populations and cultural contexts. The unique cultural and health care practices in Hong Kong could have influenced parents' perceptions and experiences, potentially differing considerably from those in other regions. Third, only participants who were willing to attend and had completed the intervention period were included, which may have excluded the perspectives of those who declined to participate in the interviews and may have expressed more negative views.

Conclusion

The findings reveal that parent-administered pediatric *tuina* considerably improved children's sleep quality, appetite, behavioral habits, mental state, and academic performance. Parents appreciated the professional guidance and user-friendly course design, which facilitated the intervention's implementation. However, challenges included difficulties in mastering techniques, locating acupuncture points, and managing time. Parents expressed the need for more frequent diagnostic sessions, real-time supervision, and extended follow-up to observe the long-term effects. Future research should address these challenges and consider integrating qualitative findings with quantitative data to enhance the robustness and applicability of the results.

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Authors' Contributions

Conceptualization: SCC
Data curation: KCL, HL
Formal analysis: KCL, HL, WFY
Methodology: WFY
Writing – original draft: SCC
Writing – review & editing: PMW, LYP, JQ, WFY

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Conflicts of Interest

None declared.

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
RCT: randomized controlled trial
TCM: traditional Chinese medicine

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Perspectives of Adolescents and Young Adults With Inflammatory Bowel Disease on a Biopsychosocial Transition Intervention: Qualitative Interview Study

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Abstract

Background: The transition from pediatric to adult health care marks a complex and pivotal process for adolescents and young adults with inflammatory bowel disease (IBD). This group requires support regarding disease self-management, skill development, and system navigation in preparation for transition. Evidence-based interventions are needed to promote optimal health and psychosocial outcomes for adolescents and young adults with IBD during this period.

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Objective: A qualitative study embedded within a randomized controlled trial was conducted to evaluate the perceived impact of a biopsychosocial transition intervention on the transition experiences of adolescents and young adults, their views on the intervention, and recommendations for future care.

Methods: This patient-oriented research study used a qualitative descriptive design. Virtual semistructured interviews were held with 21 adolescents and young adults with IBD (16 - 18 y) enrolled in the randomized controlled trial (intervention arm n=11 and control arm n=10). Interviews were audio-recorded, transcribed, and analyzed using an inductive approach to reflexive thematic analysis. Five members of a Youth Advisory Panel with lived experience of IBD collaborated throughout data analysis, interpretation, and the presentation of findings.

Results: We constructed three themes through our analysis: (1) making meaning of transitions in care; (2) perceptions and impact of the biopsychosocial transition intervention; and (3) considerations for future transition care, including the importance of individualized support.

Conclusions: Our findings illustrate the importance of relationships and the impact of a biopsychosocial intervention on adolescents' and young adults' confidence, knowledge, and self-management skills during transition. The results, which indicate the criticality of tailoring transition supports according to adolescents' and young adults' preferences and characteristics, will be used to refine the biopsychosocial intervention before it can be scaled and spread.

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KEYWORDS

gastroenterology; inflammatory bowel disease; biopsychosocial; patient-oriented research; transition to adult care; qualitative methods; young adults; qualitative; adolescents; patient perspectives; Crohn's disease

Introduction

The transition from the pediatric to the adult health care system can be a complex period for adolescents and young adults with inflammatory bowel disease (IBD) and their families [1]. In adult care, adolescents and young adults are expected to self-advocate, communicate with providers, understand their health history, and manage their health with greater independence [2,3]. However, service disruptions at the pediatric-adult juncture, shifts in parental involvement, a lack of readiness for transition, and differing treatment philosophies and models of care can complicate the transition process [1,4]. While the transition from pediatric to adult care for adolescents and young adults with IBD has been well studied and identified as a priority area for policy and program development [5-7], evidence-based transition interventions that account for the priorities of adolescents and young adults are needed.

Adolescents and young adults with IBD face a series of challenges around the transition from pediatric to adult care [1]. Psychosocial stressors are prominent at this stage of life, including the emergence or worsening of mental health conditions, changing roles within the family, and co-occurring transitions in the areas of employment, education, and living [8]. Termination of longstanding relationships with pediatric providers and expectations for autonomous management of one's health condition following a transfer out of pediatric care can exacerbate the challenges associated with this period [1,9]. Additionally, this group is susceptible to poor health outcomes and high health care costs should the transition from pediatric to adult care be disjointed [10-12]. Therefore, a purposeful, coordinated, and planned transition from the pediatric to the adult health care system is required to ensure adolescents and young adults with IBD can achieve the best possible health and psychosocial outcomes during a complex developmental period [13].

Transition interventions for adolescents and young adults with IBD to date have typically included joint pediatric-adult clinic visits, face-to-face education about disease processes and self-management, and meetings with allied health professionals focused on self-efficacy and goal setting [14]. However, transition intervention components are highly variable and limited research has focused on adolescents' and young adults' perspectives of the most valuable and well-received aspects of such interventions [14]. Further, there is no level-one evidence (eg, randomized controlled trials [RCTs]) for any intervention in transition in IBD [15]. To improve the standards for health care delivery and transition care across Canada for adolescents and young adults with IBD, a biopsychosocial transition intervention was developed and is currently being evaluated in a type 1 hybrid effectiveness-implementation trial (ClinicalTrials.gov NCT05221281) [16]. While various functional and implementation outcomes are being assessed within the RCT using standardized measures, qualitative research can elucidate adolescents' and young adults' needs and experiences of the intervention to support the translation of findings into practice [17]. Thus, the objectives of this study were to explore adolescents' and young adults' transition experiences, perceptions of the transition intervention, and recommendations for future transition care to inform the refinement of the intervention.

Methods

Study Design and Population

This patient-oriented research study [18] adopted a qualitative descriptive design [19] to understand the needs and experiences of adolescents and young adults with IBD during the transition while concurrently assessing the perceived impact and acceptability of the biopsychosocial transition intervention. It was embedded within an ongoing multicenter RCT evaluating the effectiveness of the transition intervention among

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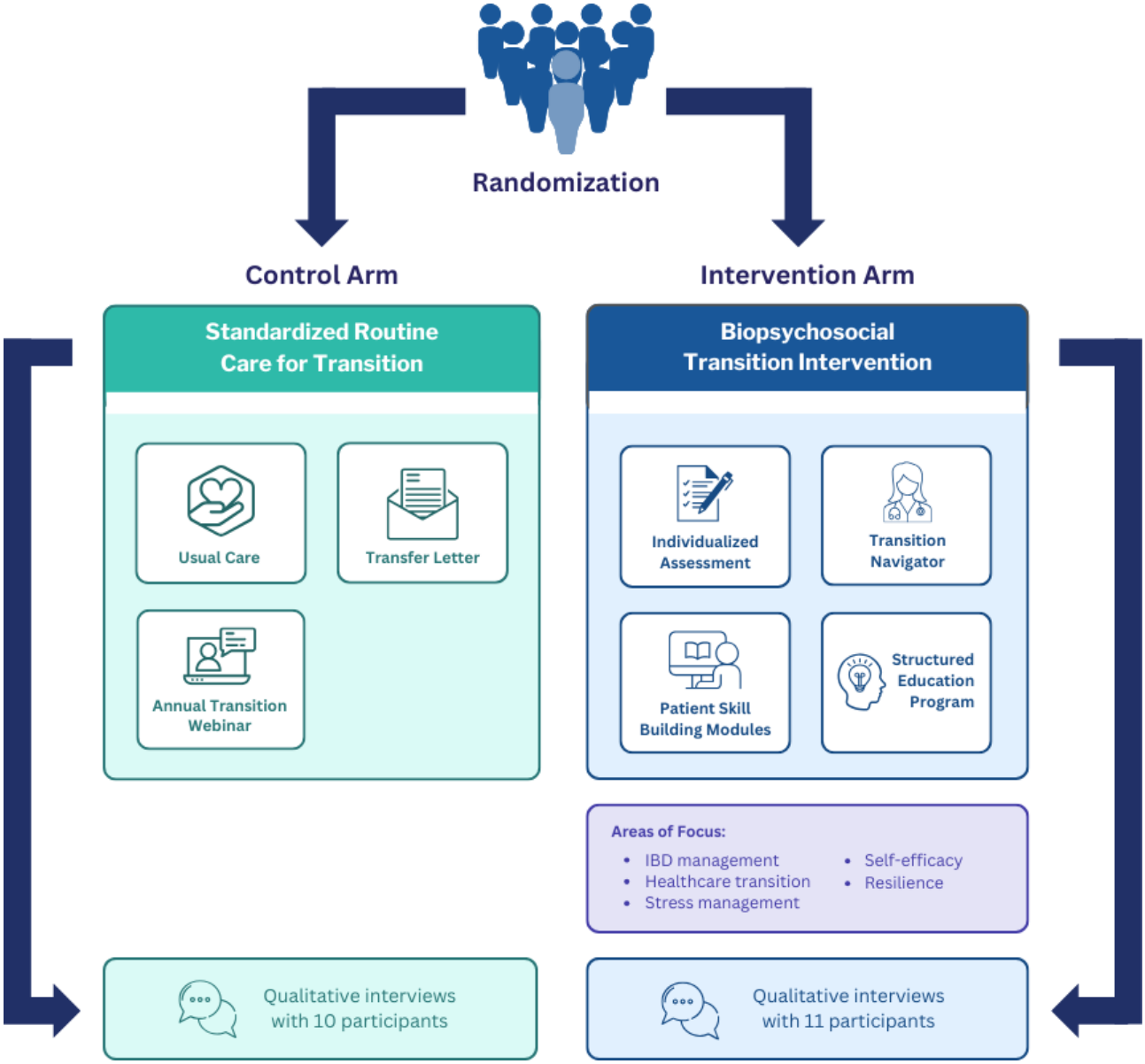
adolescents and young adults with IBD [16]. A qualitative descriptive design was used to explore the perspectives of adolescents and young adults in addition to the outcomes being assessed in the RCT [16,19]. The intervention consisted of (1) an individualized assessment, (2) a transition navigator, (3) patient skill-building delivered via online modules, and (4) a structured education program (see Figure 1 for an overview of the RCT design) [16]. Half of the RCT participants were randomized to the biopsychosocial intervention, and half received a standardized version of routine care for transition [16]. Adolescents and young adults in the intervention arm received support from a transition navigator. They had access to online skill-building activities and an online education program with topics focused on IBD management, resilience, health care transition, self-efficacy, and stress management for the duration of the study [16]. Though the RCT has 3 study sites at Canadian tertiary care centers, this study explored the perspectives of adolescents and young adults at the study site, which has the largest cohort of participants and has participants who had access to the intervention for the longest duration.

Figure 1. Overview of RCT design. IBD: inflammatory bowel disease; RCT: randomized controlled trial.



In embracing a patient-oriented research approach [18], the study investigators collaborated with a project-specific Youth Advisory Panel (YAP) consisting of 5 patient partners with diverse backgrounds, expertise, and lived experience with IBD. YAP members were recruited from an existing national IBD advisory council. The national IBD advisory council was involved in a previous qualitative study conducted by our team [20]. Subsequently, select advisory panel members expressed the desire to become involved in this study to further explore and contribute to the qualitative findings. The YAP consisted of 3 male and 2 female members aged 18 - 30 years from across Canada, thereby increasing the study's transferability with enhanced diversity of input and representation of health care experiences. The YAP members actively contributed to data analysis, interpretation, presentation of results, and preparing this article, helping align research findings with patient-identified priorities [18]. This collaborative partnership and bidirectional flow of knowledge helped cultivate a sense

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of ownership in members while capturing nuanced insights often overlooked in traditional research paradigms. YAP members were supported and mentored by 2 study team members (BA and AM) throughout the process. Study investigators and YAP members frequently corresponded via email. They held virtual weekly or biweekly progress meetings over 3 months (March-May 2024) with flexible agendas to promote clarity of purpose, efficient use of time, and active participation during meetings.

Eligibility and Sampling

Study procedures are available in a prior publication [20]. Briefly, eligible qualitative participants were the following: (1) aged 16 - 20 years, (2) English-speaking, (3) diagnosed with IBD, (4) enrolled in the RCT at the SickKids study site for at least six months, and (5) capable of providing informed consent. Purposive sampling [21] was used to select a clinically and demographically diverse sample of adolescents and young adults in the intervention and control arms, with varying levels of engagement with the intervention. We discontinued recruitment once we gleaned a breadth and depth of relevant information from participants to answer our study questions [22].

Data Collection

A female qualitative researcher with a social work background conducted individual interviews with adolescents and young adults using an institutional account of Microsoft Teams (Microsoft Corp). A semistructured interview guide, developed with YAP members and an interdisciplinary team of IBD clinicians and researchers, was used. Interview questions focused on adolescents' and young adults' experiences preparing for or undergoing health care transitions, perceptions of the biopsychosocial intervention, and recommendations for future transition care in IBD. Consent was obtained, and interviews were digitally recorded, transcribed, verified, and anonymized before analysis. Reflective memos were used during data analysis to highlight striking patterns and impressions of the interview data [23]. Participants received a US $20 electronic gift card and 1 volunteer hour for completing an interview.

Data Analysis

An inductive approach to reflexive thematic analysis [23,24] was used to analyze the data. Interview transcripts were reviewed by 2 coders (BA and M Browne) who reflected on their positionality, assumptions, and social locations in reference to the data. The coders then engaged in line-by-line coding inductively, designating codes to portions of interview text to categorize shared ideas [23,24]. They met consistently during the coding process to consider their perceptions of the data, important codes, and emerging patterns and to begin collectively making sense of the data [23]. Codes were grouped into themes to capture the meaning and key concepts within the data, and relationships between codes and themes were examined using mind maps. YAP members independently reviewed the list of codes and preliminary mind maps. YAP members shared their opinions on organizing concepts, developing themes and figures, and determining which ideas were most important to convey synchronously at online team meetings using the Microsoft Teams platform and asynchronously using collaborative documents. The preliminary themes, codeveloped with the YAP, were presented to the larger team for input, refined, and final themes were named and consolidated through discussion. Analysis was conducted using NVivo (version 14; Lumivero).

Ethical Considerations

Institutional approval for this study was obtained from The Hospital for Sick Children (SickKids) Research Ethics Board (REB #1000078476). Informed consent was obtained for each participant in the RCT and prior to enrollment in this substudy.

Results

Overview

A total of 21 adolescents and young adults were interviewed between May and September 2023 (intervention arm=11 and control arm=10). Participants were aged between 16 and 18 years, primarily female, and at different stages of health care transition. The demographic and clinical characteristics of the participants are presented in Table 1. Participant identifiers beginning with "C" denote control arm participants, and those beginning with "I" indicate intervention arm participants in the results. We constructed three themes through our analysis: (1) making meaning of transitions in care; (2) perceptions and impact of the biopsychosocial transition intervention; and (3) considerations for future transition care, including the importance of tailored supports.

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Table . Participant characteristics (N=21).

			Values, n (%)
Demographic characteristics			
	Gender		
		Female	13 (61.9)
		Male	7 (33.3)
		Nonbinary	1 (4.8)
	Age (years)		
		16	2 (9.5)
		17	15 (71.4)
		18	4 (19.1)
	Ethnicity		
		Black	4 (19)
		South Asian	6 (28.6)
		White	9 (42.9)
		Other or multiracial	2 (9.5)
	Immigration status (participant)		
		Born in Canada	19 (90.5)
		Immigrated to Canada	2 (9.5)
	Immigration status (parents)		
		Born in Canada	7 (33.3)
		Immigrated to Canada	14 (66.7)
	Sexual orientation[a]		
		Bisexual	2 (9.5)
		Gay or lesbian	2 (9.5)
		Heterosexual or straight	15 (71.5)
		Other	2 (9.5)
	Household income of family of origin (US $)		
		0 - 49,999	1 (4.8)
		50,000 - 99,999	1 (4.8)
		100,000 - 149,999	3 (14.3)
		150,000 - 199,000	3 (14.3)
		200,000+	3 (14.3)
		I do not know	10 (47.5)
	Study arm		
		Control arm	10 (47.6)
		Intervention arm	11 (52.4)
	Highest level of parental education		
		High school	1 (4.8)
		Some postsecondary	1 (4.8)
		Graduated postsecondary	19 (90.4)
	Vocational status[b]		
		Employed (full or part-time)	6 (28.6)

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				Values, n (%)
		High school student		18 (85.7)
		Postsecondary student		1 (4.8)
		Not currently in school or employed		0 (0)
Clinical characteristics				
	Diagnosis type			
		Crohn disease		15 (71.4)
		Inflammatory bowel disease type		
			IBDU[c]	2 (9.5)
			UC[d]	4 (19.1)
	Age at diagnosis (years)			
		≤5		2 (9.5)
		6 - 12		5 (23.8)
		13 - 17.9		14 (66.7)
	Family history of IBD[e]			
		Yes		7 (33.3)
		No		14 (66.7)
	Transferred to adult gastroenterologist at the time of interview?			
		Yes		4 (19.1)
		No		17 (80.9)

[a]Response categories based on participants' language.

[b]Multiple response options were possible.

[c]IBDU: inflammatory bowel disease type unclassified.

[d]UC: ulcerative colitis.

[e]IBD: inflammatory bowel disease.

Theme #1: Making Meaning of Transitions in Care

Overview

Adolescents and young adults expressed a range of reflections on the meaning of the transition from pediatric to adult health care. Their conceptualizations of this transition ranged from "switching doctors" to more existential thoughts about the health care transition, marking the loss of childhood. The meanings ascribed to health care transitions appeared to influence adolescents' and young adults' feelings about entering adult care and their overall readiness to engage in self-care tasks with greater autonomy.

On one end of the spectrum, adolescents and young adults described the transition to adult care as "an inevitability and a necessity" [C-036] once they were aged 18 years. Participants with this view seemed to understand transition as moving from one specialist to the next, with expectations that care would be delivered similarly. Those who conceptualized this change as primarily related to switching providers without ascribing a deeper philosophical meaning to transition tended to express minimal concerns or worries about entering the adult system. Many of these participants had well-managed IBD or family members (eg, parents or siblings) with IBD who were already receiving treatment in the adult system. As described by 1 participant, "For me, it's not a big deal, you're just switching doctors. And it'll just be the same thing over there anyway, so I'm not really stressed out about it." [C-001]. Importantly, however, those with this mindset had not yet transferred or been exposed to the adult care environment.

Others reflected that the transition to adult health care aligned with the launch from adolescence to young adulthood. Many adolescents and young adults viewed the health care transition as a signal that they were now "grownups" [I-039] who would be required to assume new roles and responsibilities within and outside their IBD management. Some adolescents and young adults felt the transition allowed them to reflect on their growth and development. There was an overarching sense of hope for the future, while, at times, this was coupled with feelings of sadness about the loss of relationships with familiar pediatric providers: "I mean, it's a sign of maturity and that I'm growing. It's kind of sad in that way, but you know, it's a part of life." [C-031]. Most participants accepted the transition and described it as a period in which they would take greater initiative, advocate for themselves, learn more about their health history, and plan their appointments. One participant shared:

> *I look at [transition] as me having to know a lot about myself, especially where I am with my health. At the end of the day, my mother has to stop bringing me to*

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> *the appointments, I can't bring her all the time, right? Because it's that independent thing that comes in. So I think it's just a learning experience about myself, learning about where I am with my health, knowing everything that I need to know for myself so I don't have to depend on anybody else to know it for me.* [I-021]

Most participants felt motivated, empowered to take ownership of their care, and even excited to enter a new environment, mainly due to the reputations of the adult IBD clinics or specialists and their confidence in their ability to self-advocate. However, a few adolescents and young adults expressed some hesitance about moving into adult care due to the perceived expectations of adult providers: "While new things are exciting, they're also unknown and unknown things are scary. [My adult team] will have expectations for grownups, but I don't really feel like a grownup" [I-039]. The following subtheme delves into the role of relationships between adolescents and young adults and their support networks.

Relationality and Transitions to Adult Care

Trusting relationships with health care providers, family members, and peers emerged as transition facilitators for adolescents and young adults. When participants had strong and supportive relationships with their pediatric health care providers, they expressed confidence in their adult IBD providers' ability to meet their needs: "I have lots of trust in my pediatric doctor, so if he recommended me to this one then this one must be pretty great." [C-014]. Adolescents and young adults outlined their hopes for developing trust with their new providers in adult care and shared examples of factors promoting engagement with clinicians. These included providers offering clear and detailed responses to adolescents' and young adults' questions, adopting a nonjudgmental stance, being transparent about treatment plans, offering adolescents and young adults choices, listening intently to their concerns, and asking for adolescents' and young adults' input on health-related decisions.

Adolescents and young adults receiving the biopsychosocial intervention described their relationship with the transition navigator as being one of the most beneficial aspects of this study. Many felt the navigator played a key role in preparing them for the transition by serving as a point of contact for any questions or concerns and "checking in" with adolescents and young adults, particularly between their final pediatric and first adult appointments. Adolescents and young adults described the transition navigator as demonstrating genuine care for their well-being, offering support with the transition to postsecondary education, encouraging the development of self-management skills, and providing anticipatory guidance about what to expect in adult care. "[My transition navigator] made that effort to make me feel like she's not just a transition navigator, she's a person that actually cares about me." [I-015]. The quality of their relationship with the transition navigator also prompted some adolescents and young adults to open up about their emotions and mental health. In one case, this led to a participant receiving a diagnosis for longstanding anxiety symptoms and subsequently accessing mental health supports:

> *Before I got diagnosed with generalized anxiety, I talked to my transition navigator about how I was feeling and how I didn't really know how to cope. She helped me make the decision to go see a doctor about it to see if [I] could get prescribed medication or get some sort of diagnosis. Even though I was kind of on edge about going to a doctor for something that sounded so silly in my brain, she helped me calm myself about it.* [I-016]

Lastly, adolescents' and young adults' relationships with family members and peers facilitated the acquisition of self-management skills and enhanced confidence in preparation for transition. They described the pivotal roles their parents played in helping them cope with IBD and how they are taking more responsibility for specific tasks over time:

> *My parents have always been supportive and on top of it, maybe even a little more than I have. Because at first, I was in denial, I was like, "no, my IBD's not that bad". But they were keeping me on top of my medication and stuff, especially when I was younger, my mom helped me a lot with that. I've become a little more independent now and I'm able to take medication on my own.* [I-020]

Many outlined the value of having parents, siblings, and extended family members offering emotional support (eg, listening, reassuring, or encouraging), instrumental support (eg, teaching how to refill prescriptions), and advice as they approach the transition to adult care. Parents often served as mentors to adolescents and young adults, coaching them to assume greater responsibility for their care and IBD management incrementally. Most participants were aware their roles would change in adult care and were working with parents to practice skills and negotiate what these new roles would be like posttransfer.

The transition experience appeared to be constructed in relation to others. Trusting relationships with health care providers, family members, and peers were found to promote confidence and readiness to engage in the tasks required to manage IBD care during transition. Adolescents' and young adults' ability to communicate their needs openly to others (and feel validated by them) was a priority for participants, and supportive relationships helped facilitate this.

Theme #2: "It Gets Me Ready to Start Doing Things on My Own": Perceptions and Impact of the Biopsychosocial Transition Intervention

Overview

A combination of adolescents' and young adults' communication preferences, personality characteristics (eg, curiosity, motivation, or social), learning styles, and sources of support influenced their uptake of and perspectives on the intervention. Participants' perceptions of the intervention's impact fell into three categories: (1) knowledge and preparedness, (2) emotional support and validation, and (3) confidence and independence. Additionally, barriers and facilitators to engagement with the intervention were described by adolescents and young adults (Figure 2).

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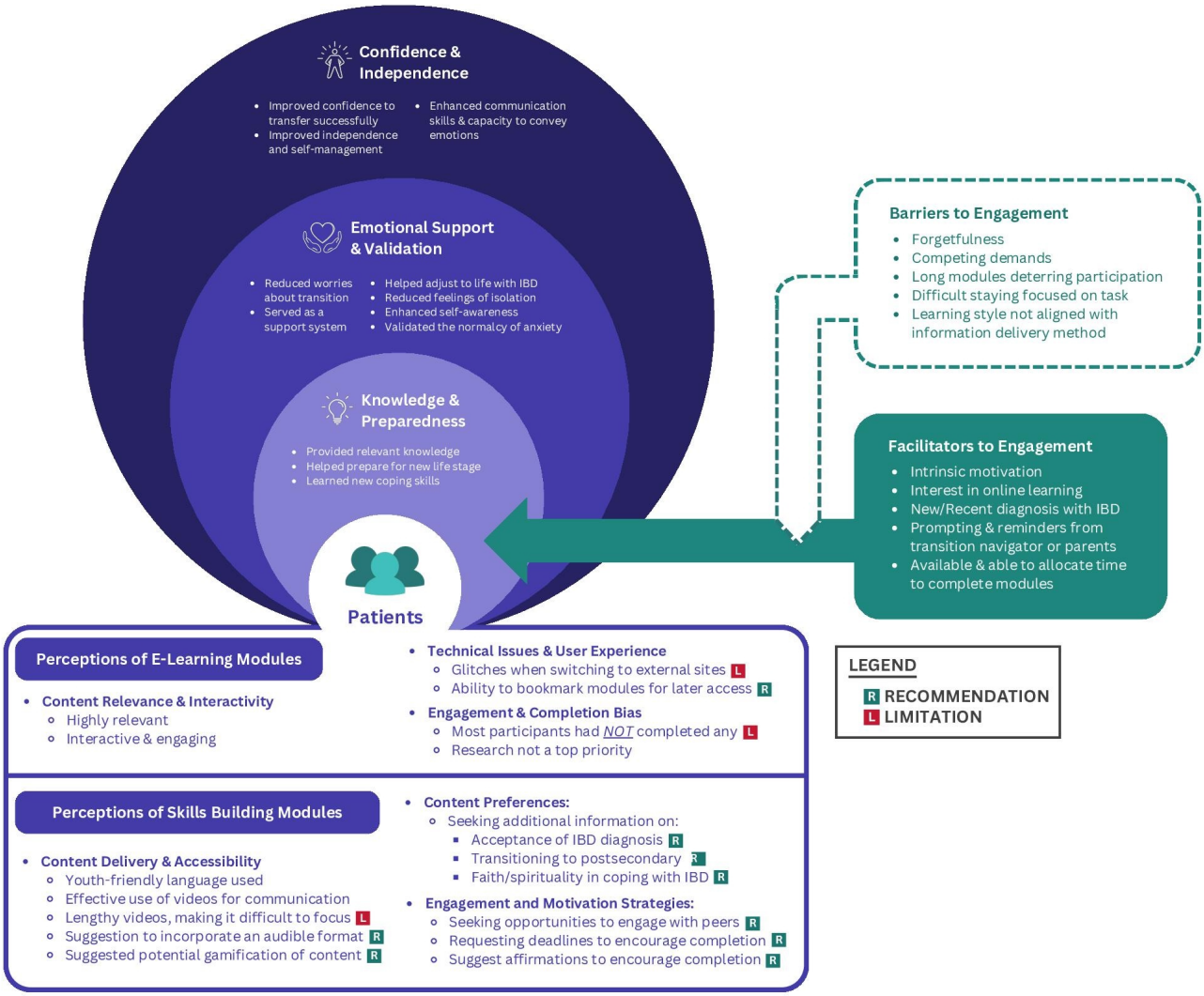
Figure 2. Impact and perceptions of the biopsychosocial transition intervention. IBD: inflammatory bowel disease.



Knowledge and Preparedness

Adolescents' and young adults' experiences of the intervention indicated that acquiring knowledge helped foster a sense of agency and supported their transition readiness. Core components of the transition intervention helped adolescents and young adults envision their transition journeys while arming them with the competencies required to succeed in adult care and life. Participants receiving the intervention expressed positive sentiments about their experiences in the trial, noting that it catalyzed personal growth and empowerment. Shifting from a mindset of passive acceptance to one of proactive engagement in navigating the complexities of transition, many participants, with curious mindsets, described applying newly acquired skills and knowledge in their daily lives to improve aspects of pain management, communication, and self-regulation:

> *The transition from pediatric care to adult healthcare is one that's not easy, [but] there are things that you can learn in order to be more successful during transition with respect to being an adult. I think it's really just using your skills, engaging in things like mindfulness, and building your confidence so that you can communicate with your healthcare team as best as you can.* [I-019]

A few participants even considered the newfound sense of agency to extend beyond health care transitions to encompass broader life transitions, such as education, career choices, and relationships:

> *Before I started this, I barely even knew what transition was! It was very foreign to me and it was almost scary because I didn't know what to expect. Especially in addition to going from high school to university, there was just a lot of stuff going on in relation to transition. So having these modules, having this information is something that has definitely helped me in that sense.* [I-007]

Emotional Support and Validation

Given the myriad of psychosocial stressors and challenges inherent in transitioning from pediatric to adult care, adolescents and young adults voiced that validation and emotional support were important. Participants in the intervention arm found these types of support in different intervention components based on their individual characteristics and relational factors (Figure 3).

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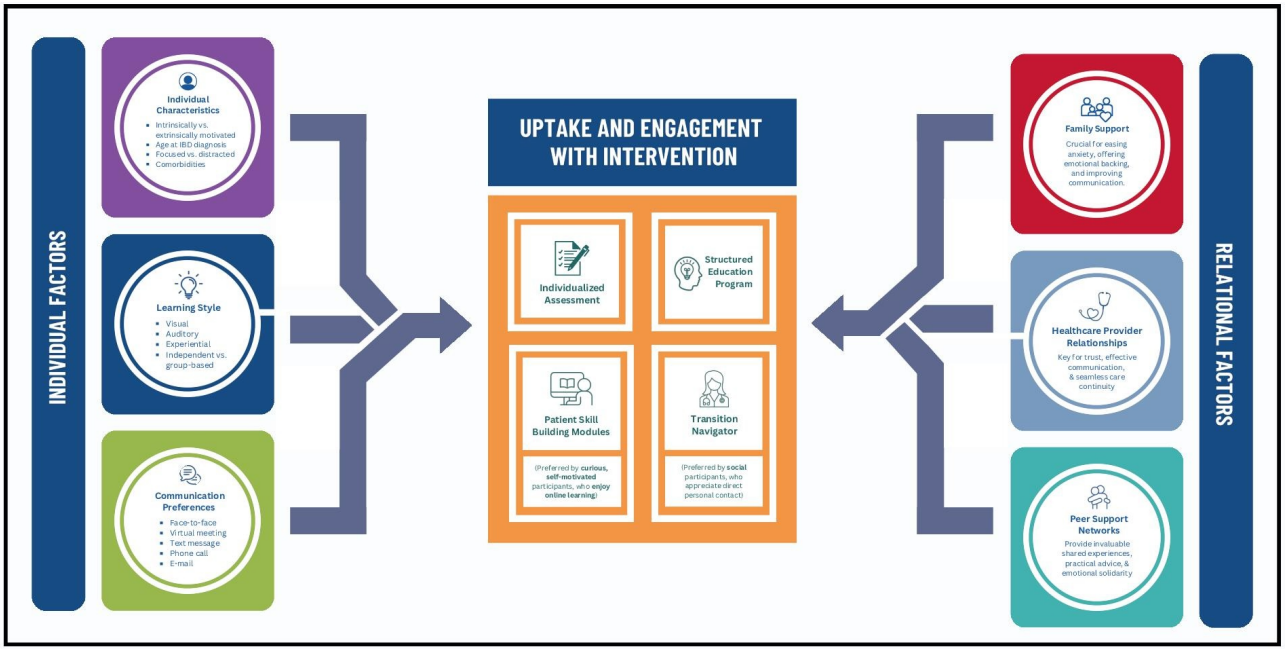
Figure 3. Factors influencing engagement with the intervention. IBD: inflammatory bowel disease.



Most adolescents and young adults who were social found that having direct access to a transition navigator (eg, via text or email) offered reassurance and interpersonal connection; one such adolescent or young adult shared: “100% talking to [my transition navigator is the most helpful component of the intervention] because I’m a people person, so talking to somebody is very helpful, whereas I just get bored doing the modules and stuff.” [I-016]. Other participants with similar personality characteristics felt that having a transition navigator helped foster a trusting relationship that extended beyond clinical interactions, providing them with an open outlet to voice their hopes, fears, and concerns regarding their transition to adult care. Many adolescents and young adults even felt immediately more prepared to transition, knowing that their transition navigators represented a dependable source of information that they could turn to and confide in during times of need: “I did get a person [transition navigator] who I can text about anything I’m struggling with. They’ve definitely helped me be open about how I’m feeling.” [I-007]

Other adolescents and young adults voiced that the variety of concepts covered in the skills-building modules validated their concerns and helped them feel less alone in coping with the challenges of living with IBD: “if they’re making modules like this, I’m not the only one that’s feeling like this.” [I-020]. Regardless of their personality traits, most adolescents and young adults described being well supported by their transition navigator in making informed decisions, whether that be related to accessing postsecondary accommodations or scholarships, obtaining referrals to relevant resources (eg, mental health services, volunteer opportunities, or support groups), or learning about the expectations of adult IBD providers.

Confidence and Independence

Adolescents and young adults outlined how the intervention promoted confidence in preparation for adult care. Some adolescents and young adults viewed the skills-building modules as the most relevant and beneficial aspect of the intervention because they gained independence through acquiring new strategies. Participants who were self-motivated and enjoyed online learning appreciated the wealth of information offered on a range of topics and the ability to access the modules at their own pace given their busy schedules at this stage of life (eg, planning for postsecondary education, participating in extracurricular activities, or working). Additionally, most adolescents and young adults felt that the skills and knowledge developed through the intervention could be applied to their illness and beyond: “I feel like the skills are the most applicable to your everyday life. You can use them with Crohn’s or without Crohn’s. They teach you how to deal with any obstacle you might have in that sense.” [I-019]

Many adolescents and young adults outlined the impact of the intervention in its entirety on their feelings of confidence and preparedness for a new care environment:

> *To have a navigator or to have modules, I just feel more comfortable now and more confident. Because even before I was like, “what’s going to happen when I turn 18? I don't want to leave [pediatric hospital] because I just feel like they know all about everything I've been going through and have helped me.”* [I-020]

While all participants receiving the intervention approved of its impact on their knowledge, skills, emotional well-being, confidence, and overall preparedness for transitioning to adult care, each adolescents’ and young adults’ preferences and personality traits impacted how and where they experienced the greatest benefit.

Barriers and Facilitators to Engagement

As outlined in Figure 3, a series of individual, intervention-specific, and familial characteristics supported or hindered adolescents’ and young adults’ engagement with the intervention and in their overall health care.

Individual characteristics that facilitated engagement included being newly diagnosed with IBD, having strong relationships

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with health care providers, and feeling well supported by family members and peers. Adolescents and young adults with recent diagnoses were motivated to complete the skills-building modules because they were interested in developing a higher-level understanding of their illness, including symptom management, self-care, and peer support. Adolescents and young adults who were intrinsically motivated and had learning styles conducive to online learning with visual aids, audio, and text-based materials favorably viewed the presentation of the modules. Consequently, these individuals did not require much prompting as they were driven to learn and expand their skill sets of their own accord.

The support systems adolescents and young adults had in place were critical to the uptake of the intervention, particularly for those who described themselves as forgetful. Most participants benefited from the navigator prompting or reminding them to complete the modules and appreciated the navigator's persistence in communicating with them. Adolescents and young adults with comorbidities (eg, diabetes, arthritis, or anxiety) seemed to require more encouragement from the transition navigator or family members to support module completion, given they were managing multiple illnesses, appointments, and medication regimens. Some adolescents and young adults described completing the modules alongside parents who were interested in learning and supporting their adolescents or young adults, aiding participants who may otherwise have lacked interest in engaging with the content: "My mom was super on top of it [skills-building modules], and she's like, 'come do the modules with me'" [I-020]. When these supports were available, adolescents and young adults seemed better able to complete the materials and solidify their learnings through conversation and questions.

Regarding barriers to engaging with the intervention and completing the skills-building modules, most adolescents and young adults cited competing demands (eg, examinations, work, family, or romantic relationships) and forgetfulness as factors influencing their ability to commit time toward modules, despite their interest in the content. Some participants felt it challenging to initiate contact with the navigator or begin a new module without prompting because the research was admittedly not their top priority:

> *Sometimes, it's hard for me to open the tablet and go on there [to do the modules] because it's not the first thing that comes to my mind. Every day, I wake up, and I'm like, "Okay, I have to do this and that today. I also have to message this person [transition navigator]," and I don't get around to doing it.* [I-021]

The length of the modules was described by several participants as a deterrent, especially for those with difficulty staying on task. Some adolescents and young adults struggled to remain engaged and interested in the skills being discussed, inadvertently leading them to become distracted:

> *With the modules, I get distracted very easily, so it's been very hard for me to stay on task. I've been struggling to remember since the end of grade 11 to do these modules. It's not that they're boring per se, it's that I'm not focused enough, ever.* [I-016]

Finally, adolescents and young adults whose learning preferences were at odds with how information was conveyed in the modules and educational curriculum faced barriers to retaining knowledge. For instance, participants who were visual learners expressed difficulties taking in the information and solidifying their learning, given that most of the content was delivered via a speaker on camera without visuals to illustrate concepts. This led to feelings of frustration and a lack of motivation to stay engaged for some:

> *I don't know if it's because I'm a visual person, but sometimes it's really hard for me to sit down and watch somebody talk for 20 minutes. Something about it disengages me. My ears are open, but I'm not really taking in everything.* [I-021]

In summary, each adolescent's or young adult's learning styles, needs, and preferences were important factors to consider when using and evaluating the intervention.

Theme #3: Considerations for Future Transition Care

Overview

Adolescents and young adults in both arms of the trial highlighted a "gentle transition," defined as a period of overlap between pediatric and adult IBD providers or a joint visit with pediatric and adult providers, as an approach that would help reduce stress and illustrate that "the first team trusts the second team fully" [C-006]. Most participants also felt the topic of transition should be raised, and the process started early (around being aged 16 years) to allow ample time for gradual skill acquisition:

> *I'd say [introduce transition] at about 16 because 18 is when transition starts and throughout the journey, you don't really realize how little time you have until it's right there and it's knocking on your doorstep. But if you start teaching what they need to learn at around 16, I think they'll be able to develop skills and become more mature and be able to deal with those things as time goes on.* [I-019]

Adolescents and young adults approved of the value of a clinician (eg, transition navigator) responsible for "guiding [youth] through the transition process" [C-006], offering advice, addressing transition-related concerns, and providing service navigation. They felt having a trusted person they could go to (as opposed to a website or app) would allow them to practice the communication and advocacy skills needed for adult care in real time:

> *If you can have someone that people can reach out to and talk to, actually face-to-face whether it's Zoom, texting, calling, or emailing, I feel like that would be beneficial just so they know they're actually talking to someone. And that would help with socializing and getting them used to adult responsibilities and communicating on their own.* [C-013]

Others suggested providing adolescents and young adults with case scenarios that commonly arise for transition-age youth

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with IBD to role play, followed by discussions about how to respond to different situations. They felt this approach would help them solidify experiential knowledge, build confidence, and prepare them for possible challenges:

> *I think it would be the most helpful to have [youth] actually do a fake phone call. Because if you're talking about something like a conversation, it's better to learn it in its application and learn to try to say things yourself rather than knowing that you have to do something like, "oh, I should say that, I should do this". Being forced to deal with some of the discomfort that might come along with the conversations and practicing that would be beneficial.* [C-036]

Finally, participants advocated for group-based education sessions (either in person or online) to support their learning. Those in the intervention arm felt that providing a method for adolescents and young adults with IBD to (optionally) interact with one another through the online platform would allow them to feel more connected and less alone.

Recommendations for Refinement of Biopsychosocial Intervention

Adolescents and young adults in the intervention arm highlighted the importance of keeping participants engaged in the intervention (and their care more broadly) around the time of transition when young people face competing priorities; thus, they suggested shortening the modules into "bite-sized" [I-007] pieces to improve their delivery. Several adolescents and young adults were interested in audio versions of the skills-building modules based on their learning styles and preferences. Many participants thought including games, knowledge tests, or offering awards for completion could help participants stay motivated and on task. Most participants were satisfied with the range of topics available regarding the module content. However, a few adolescents and young adults felt having materials focused on accepting IBD and adjusting to life with a chronic illness would be beneficial to them, especially for those newly diagnosed or experiencing challenges coping with IBD. Others suggested incorporating education focused on diversity within IBD, including the roles of faith, cultural traditions, and food customs in IBD management. Lastly, some adolescents and young adults felt the transition to postsecondary (education or employment) should be elaborated upon in the modules based on their experiences, especially advocating for themselves with teachers or employers and accessing accommodations.

Discussion

Principal Findings

Using qualitative methods, this study offered a detailed understanding of the experiences, priorities, and needs of adolescents and young adults with IBD during the pediatric-adult transition. Learning about the biopsychosocial intervention from adolescents' and young adults' perspectives contextualized the RCT results and provided insights about engagement, acceptability, and future directions. Our findings revealed the importance of making meaning during health care transition, the impact of the biopsychosocial transition intervention, and adolescents' and young adults' viewpoints on future transition care.

Regarding conceptualizations of the transition to adult care, adolescents and young adults with IBD expressed various ideas about its meaning. Hislop et al [25] outlined a similar range of views regarding the transition to adult care from youth with chronic conditions, from "laid back" to "anxious." Additionally, the youth in their study expressed the value of social interaction with family, peers, and professionals to assist with the transition from pediatric to adult care [25]; findings echoed in the present study. Of note, most participants in our study had not yet transferred to adult care at the time of data collection, possibly influencing their conceptualizations of transition. Understanding adolescents' and young adults' views on the meaning of transition and the quality of their interpersonal relationships could support the development of personalized transition plans in clinical settings that consider their readiness. It is also important to examine whether adolescents' and young adults' conceptualizations of transition before they enter adult care impact their capacity for self-management and experiences posttransfer.

This study validates the importance of relational support for adolescents and young adults with IBD, which helped facilitate engagement with the intervention and readiness for transition. Fostering positive relationships with health care providers, family members, peers, or community members may play an important role in promoting flourishing, a known predictor of physical and mental health [26,27]. Given adolescents and young adults are often experiencing multiple life transitions simultaneously, external support is critical [26]. Future research could explore the development and evaluation of companion modules or educational resources for family members supporting adolescents and young adults with IBD.

Tailoring educational resources and support to align with the needs of adolescents and young adults arose as a prominent concept in this study. This included considering adolescents' and young adults' communication preferences, learning styles, familial or community supports, and pre-existing traits, including age at IBD onset and personality characteristics, in designing and delivering patient education. Individualizing care according to genetic, social, and individual- and family-specific factors is a key tenet of precision child health, an emerging paradigm for pediatric quality and safety [28]. Precision child health focuses on the unique needs and characteristics of pediatric patients and their families to provide proactive, person-centered care [28]. Moreover, offering personalized support for adolescents and young adults with chronic conditions transitioning to adult care according to their level of preparedness has been endorsed in the literature. Charles et al [29] identified a typology of transition readiness for adolescents and young adults with congenital heart disease, suggesting that different groups require varying levels of support in preparation for the transition, from minimal intervention required to "follow-up needed" to "at-risk." A transition intervention that is customized based on the ethnocultural needs of adolescents and young adults with traumatic brain injury has also been described and reported [30]. Further, the IBD literature demonstrates the importance of

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delivering culturally sensitive care that recognizes the impact of health inequities, cultural values and beliefs, and the roles of implicit or explicit biases on patients' experiences navigating the health care system [31]. Our results provide evidence of the criticality of attending to adolescents-, young adults-, family-, and system-level factors in providing transition care to promote optimal experience, uptake, engagement, and outcomes.

Patient navigators have been identified as a promising intervention for adolescents and young adults with chronic conditions transitioning to adult care [32,33]. Our results confirmed the value and acceptability of the relational support offered by a transition navigator, with participants detailing the navigator's impact on their experiences and outcomes during the transition. This was especially apparent for adolescents and young adults with challenging diagnostic journeys, mental health concerns, and co-occurring conditions. This speaks to the potential usefulness of a transition navigator intervention for adolescents and young adults with chronic health conditions or mental health conditions more broadly. Given the logistical challenges of holding joint pediatric-adult clinic appointments in North America, cross-appointed navigators could be a favorable option for promoting continuity of care [34,35]. Further exploration of individual characteristics, including personality traits and existing supports, and how these relate to engagement during transition is warranted. Adolescents and young adults in our study expressed their interest in gamified transition resources to enhance motivation to engage with educational materials. Indeed, a recent scoping review identified that gamification improves patient engagement and biopsychosocial outcomes and could represent a valid approach to cancer patient education [36]. Future research could explore gamification within IBD care and its impact on patient experience, knowledge, and outcomes. Finally, given the complexity of factors (eg, communication preferences, personality, or learning styles) influencing adolescents' and young adults' transition needs, future iterations of the biopsychosocial transition intervention could consider the integration of artificial intelligence to support adolescents and young adults. This would enable tailored guidance when navigator support is unavailable (eg evenings or weekends) or when adolescents and young adults prefer more self-directed approaches.

Limitations and Future Directions

This study's results should be considered in light of some limitations. Sampling bias could be a concern given that the qualitative study participants were enrolled in an RCT and consisted of mostly female participants. Regarding transferability, our findings may not apply to all adolescents and young adults with IBD or those in different health care systems or regions. Additionally, only 1 participant had completed any education modules at the time of the interview, so we could not assess participants' perceptions of this aspect of the intervention. To enhance trustworthiness, we used member checking with the YAP. YAP members reviewed and confirmed the data and interpretations, which helped ensure our findings' accuracy. Following initial coding and analysis based on their lived experiences, they provided their insights and perspectives. Finally, they co-authored, reviewed, and offered feedback on this paper.

Future research in this field could examine the experiences of adolescents and young adults with IBD in various cultural and socioeconomic contexts. This would allow for a more complete understanding of the transition process and different groups' unique challenges given research has shown that access to resources, cultural values, health literacy, family roles, faith, and stigma play important roles in the daily realities of individuals with IBD [31,37]. Qualitative research involving data collection with adolescents and young adults at multiple time points (eg, pretransfer, during the transition, or posttransfer) could offer unique insights into how their care needs and priorities evolve to support the development of tailored interventions. Finally, the development and evaluation of resources targeting caregivers and parents of adolescents and young adults with IBD could be considered, given their critical roles in mentoring and coaching adolescents and young adults during transition.

Conclusions

Incorporating qualitative data within the RCT enabled a multifaceted exploration of the acceptability of a biopsychosocial transition intervention through different sources of information to support the translation of findings into practice. Our findings provide important insights into the needs and experiences of adolescents and young adults with IBD during the transition, including the criticality of considering individual, family, and system-level factors when implementing clinical interventions for this population. These results will contribute to developing youth-friendly resources and possibly refining the biopsychosocial transition intervention before scale and spread.

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Conflicts of Interest

LK is an equity owner and scientific advisor to Trellus Health, and a consultant to Pfizer and Coprata Health. EIB has acted as a consultant for McKesson Canada and the Dairy Farmers of Ontario for matters unrelated to medications used to treat inflammatory bowel disease. He has also acted as a consultant for the Canadian Drug Agency. SAK is a colicense owner of the iPeer2Peer Program. SL is a speaker or consultant for Abbvie, Janssen, Takeda, and Celltrion. KIK has received honoraria from Abbvie, Janssen, Celltrion, Pfizer, Takeda, and has acted as a consultant for the CADTH. KL has consulted for AbbVie Corp, Janssen, and Takeda.

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Abbreviations:

C: control arm participant
I: intervention arm participant
IBD: inflammatory bowel disease
RCT: randomized controlled trial
YAP: Youth Advisory Panel

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Original Paper

Perspectives on Swedish Regulations for Online Record Access Among Adolescents With Serious Health Issues and Their Parents: Mixed Methods Study

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Abstract

Background: With the increasing implementation of patient online record access (ORA), various approaches to access to minors' electronic health records have been adopted globally. In Sweden, the current regulatory framework restricts ORA for minors and their guardians when the minor is aged between 13 and 15 years. Families of adolescents with complex health care needs often desire health information to manage their child's care and involve them in their care. However, the perspectives of adolescents with serious health issues and their parents have not been studied.

Objective: This study aims to qualitatively and quantitatively investigate the perceived benefits and risks of ORA and the awareness of and views on ORA regulations among adolescents with serious health issues and their parents in Sweden.

Methods: We used a convergent mixed methods (qualitative and quantitative) design, consisting of a survey and semistructured individual interviews with adolescents with serious health issues (aged 13-18 y) and their parents. Participants were recruited via social media and in clinics. Quantitative data were presented descriptively. Interviews were audio recorded, transcribed, and analyzed using inductive thematic content analysis.

Results: The survey population included 88 individuals (adolescents: n=31, 35%; parents: n=57, 65%). Interviews were completed by 8 (26%) of the 31 adolescents and 17 (30%) of the 57 parents. The mean age of the surveyed adolescents was 16 (SD 1.458) years, and most of the parents (29/57, 51%) were aged 45 to 54 years. The surveys indicated that most of the parents (51/56, 91%) were critical of the access gap, and most of the adolescents (20/31, 65%) were unaware of the age at which they could gain access. In the interviews, adolescents and parents identified benefits related to ORA that were categorized into 6 themes (*empowering adolescents*, *improved emotional state*, *enhanced documentation accuracy*, *improved partnership and communication*, *supported parental care management*, and *better prepared for appointments*) and risks related to ORA that were categorized into 4 themes (*emotional distress and confusion*, *threatened confidentiality*, *increased burden*, and *low usability*). Adolescents' and parents' views on ORA regulations were categorized into 3 themes (*challenges of the access gap*, *balancing respect for autonomy and support*, and *suggested regulatory change*).

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Conclusions: In Sweden, ORA regulations and a lack of available information cause significant inconvenience for adolescents with serious health issues and their parents. Views on access age limits differed, with adolescents expressing their perceived need for independent access, while parents exhibited concerns about adolescents having ORA. The findings indicated the importance of increased education, dialogue, and flexibility to uphold confidential and consistent delivery of adolescent health care. Further exploration is needed to understand the experiences of adolescents and parents in diverse clinical and geographic contexts, as well as the perspectives of pediatric health care professionals on restrictive ORA regulations.

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KEYWORDS

health care professionals; adolescent health; patient-accessible electronic health record; electronic health record; patient portal; survey; eHealth; interviews

Introduction

Background

Worldwide, online record access (ORA) enables more patients and caregivers to read their health records via patient portals. Electronic health records (EHRs) often include clinical notes, laboratory test results, and medications. In the United States, the practice of sharing clinical notes with patients is referred to as "open notes" [1]. In the European Union, individuals have a right to access their health information in registries such as EHRs, under the General Data Protection Regulation. A proposed European Health Data Space will provide patients with access to their EHRs throughout Europe. A growing body of research [2] indicates that ORA benefits for adolescents and parents are similar to those for adults (eg, better recall, increased treatment adherence, and an increased sense of control [1,3,4]). Unique benefits for adolescents and parents may also include increased autonomy [5] and a supported transition from adolescent to adult health care [6,7].

Despite potential benefits, access to pediatric records is often restricted due to concerns about confidentiality, particularly during adolescence. While most young children benefit from parental proxy access, adolescents may be deterred from seeking help for sensitive health care issues if parental monitoring remains possible, leading to potential ethical concerns and a need to protect the developing autonomy of the young person [8]. As a result, 1 policy response has been to limit adolescents' and parents' access when the child becomes an adolescent. However, the implementation of patient-accessible EHRs (PAEHRs) for parents and adolescents differs globally [9-11]. A variety of access control practices attempting to balance parents' and adolescents' needs have been adopted, with approaches either based on set access limits or case-by-case assessment.

Sweden has an advanced ORA system, facilitated through the national PAEHR 1177 Journal. A regulatory framework implemented in 2017 grants parents default access to their child's PAEHR from birth until the child turns 13 years of age, after which the adolescent gains their own access at the age of 16 years. Parents' loss of access to their child's PAEHR when the child turns 13 years of age was due to concerns that teens may refrain from seeking care for sensitive issues, such as birth control, sexual health, or mental health, if they know that their parents have access to their records. In the first regulatory framework, adolescents themselves gained access to their records only at the age of 18 years, but this age limit was later lowered to 16 years, based on the argument that most teenagers are mature enough to make informed decisions about their health at this age. More than half (50.5%) of adolescents access their records from the age of 16 years [12]. The "access gap," when the child is aged between 13 and 15 years, a period during which neither the child nor the parent has access, has been criticized for hindering active participation and engagement in health care, especially by parents of children with serious illness [13,14]. There is an option for both guardians and minors to apply for extended access under special circumstances (such as chronic illness) when the child is aged between 13 and 15 years. The application process involves filling out and submitting a specific paper form to the health care provider, followed by a maturity assessment and approval by the health care provider's operations manager. To approve the application, health care professionals (HCPs) assess needs and risks, as well as the minor's level of maturity and wishes. The process must be repeated for each clinic where the minor is receiving care. However, few applications for extended access from either adolescents or parents have been observed [12]. Thus, although the restrictive policies are intended to ensure safety, their consequences for adolescents with serious health issues and their parent caregivers may be dire and have not been studied.

Several topic experts have noted the unique need for ORA among families where adolescents are undergoing treatment or have extensive contact with health care systems [15,16]. In previous research in Sweden, we found that adolescents with lower self-reported health may have less interest in being able to control who can access their records and to conceal information from relatives [17]. Indeed, many adolescents depend on their parents for health care management [6]. In addition, in an interview study, adolescents aged 13 to 17 years with cancer and blood disorders report that, after reading their records, they are better able to prepare for clinical consultations and are able to check accuracy; moreover, examining their test results makes it easier to talk to HCPs [7]. Parents of children who are critically ill report similar benefits: the ability to check accuracy [18], better understanding [18], improved recall of information [19,20], reduced anxiety [21], and an increased sense of control [21]. They also reported that ORA makes them better able to advocate for their child [18].

Parents offer complex home-based health care and provide emotional support in advocating for their child. Rather than communicating directly with HCPs, adolescents often prefer

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asking questions via their parents [6,7]. Furthermore, a framework developed by Ford et al [22] described how partnerships between adolescents, parents, and HCPs can improve the adolescent's health, stating that, for example, adolescents are more likely to seek support from their parents if they are well informed.

Study Aim

Views on policies regarding adolescents' and parents' ORA access are underresearched. Increasing our knowledge about adolescents who are ill and parents in caregiving roles is vital to enable the design of informed policies and education for HCPs and patient portal users, with the long-term purpose of improving adolescent health. This study aimed to investigate, both qualitatively and quantitatively, adolescents' and parents' views on the perceived benefits and risks of using the PAEHR, as well as their perspectives on the national ORA regulatory framework in Sweden. Our research questions (RQs) were as follows:

- RQ1: What benefits and risks do adolescents and parents perceive regarding access to adolescents' health records for both adolescents and parents?
- RQ2: What are adolescents' and parents' views on and awareness of the ORA regulations governing access to adolescents' health records?

Methods

Ethical Considerations

This study received ethics approval from the Regional Ethical Review Board in Uppsala, Sweden (EPN 2022/02160). Survey participants provided consent digitally, while participants recruited in the clinic provided consent in paper format. No financial incentive was offered to survey participants; however, interview participants received a gift card worth 200 SEK (approximately US $18). Data were deidentified.

Study Design

Data collection occurred from March 2022 to November 2023, after ethics approval was received. A convergent mixed methods (qualitative and quantitative) approach was adopted [23,24]. Mixed methods can be defined as the "concurrent collection of both quantitative and qualitative data" where data are integrated in the analysis [23]. The purpose of combining methods was to provide a breadth of data on an understudied topic, with interviews designed to facilitate a deeper understanding of the reasons underlying the quantitative results. The qualitative component is reported in accordance with the COREQ (Consolidated Criteria for Reporting Qualitative Research) [25] guidelines (Multimedia Appendix 1).

Participants and Setting

We recruited adolescents aged 13 to 18 years with serious health issues and parents of adolescents aged ≥13 years with serious health issues with experience in accessing their child's EHR, either having lost access or gained extended access. In this context, serious health issues refer to physical or mental health conditions that significantly affect an adolescent's well-being and require ongoing care or intervention. Study participants were recruited via social media advertisements by patient organizations and through collaboration with Uppsala University Hospital and other clinical partners (eg, during appointments, by sending surveys via mail to former patients, and by posting study information in waiting rooms). Although citizens gain access to the 1177 Journal at the age of 16 years, adolescents aged ≥13 years were eligible to participate because they can apply for early access, and the study aimed to explore views on ORA regulations. Both parents of a child were able to participate.

The national regulatory framework for patients' ORA was designed by Inera AB, the company managing the 1177 patient portal that houses the PAEHR 1177 Journal, and approved by the Swedish Association of Local Authorities and Regions. The record typically includes clinical notes, test results, and diagnoses, but information availability differs across Sweden's 21 regions and affiliated HCPs (those who have agreed to provide access). No data are concealed from parental view unless an HCP actively chooses to block information access, which can occur in cases where, for example, child abuse is suspected.

Data Collection

Survey

Two survey instruments were designed: one for adolescents and one for parents (refer to Multimedia Appendix 2 for the full surveys and Swedish translations). For this study, 9 (69%) of 13 questions were included from the adolescent survey and 13 (93%) of 14 questions from the parent survey, based on the study aim (Textbox 1). Parents' awareness of ORA was not examined. The value of including patients in research has been noted previously [26,27]. Therefore, adolescents and parents were consulted for input, which was used to revise the surveys. Questions were not mandatory, except for those on inclusion criteria and contact information (in case the participant marked interest in participating in an interview). In Sweden, study participants aged <15 years must provide written parental consent, as mandated by the Swedish Act (2003:460) concerning the ethical review of research involving humans [28]. Therefore, age was a mandatory question for adolescents, along with the provision of written parental consent for those aged 13 or 14 years. In the web-based survey, adolescents could provide parental consent digitally. For participants aged ≥15 years, consent was provided by submitting the survey. The web-based survey was conducted using REDCap (Research Electronic Data Capture; Vanderbilt University) software.

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Textbox 1. Survey questions for adolescents and parents.

ADOLESCENTS

Inclusion

1. How old are you?

a. How do you want to provide guardian consent? (if younger than 15 years old)

Experience with health care

2. What types of care have you received?

Views on and awareness of online record access (ORA)

3. At what age do you think you will have (or when you received) online access to your electronic health record (EHR)?

4. Do you want to be able to read your patient-accessible EHR?

5. To what extent do you agree with the following statements? (views on ORA age limits)

6. If you have thoughts or comments to add about the EHR, please write below.

Demographics

7. You identify as...? (gender)

8. Who do you live with? (select all that apply)

9. Would you participate in an interview about this?

a. E-mail

b. Phone number

c. How would you prefer to be contacted?

PARENTS

Inclusion

1. How old is the child for whom you base your answers?

2. Did you read your child's EHR online before your child turned 13?

Experience with health care

3. What types of care has your child received?

Views on ORA

4. To what extent do you agree with the following statements? (views on ORA age limits)

5. If you have thoughts or comments to add about the EHR, please write below.

Demographics

6. You identify as...? (gender)

7. How old are you?

8. Which region do you live in?

9. In what type of area do you live?

10. What is your level of knowledge in Swedish?

11. What is your highest completed education?

12. Approximately how much is your household income before tax in a normal month?

13. Would you participate in an interview about this?

a. E-mail

b. Phone number

c. How would you prefer to be contacted?

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Interviews

The first author (JH, a PhD student in health informatics with past experience of qualitative research and training) conducted the interviews with participants who registered their interest in the survey. Verbal consent for audio recording was provided before the interview. Interviews were conducted between February 2022 and November 2023 via telephone or videoconferencing software. Interview guides were created based on prior work on ORA for adolescents, children, and parents (Multimedia Appendix 3) and included similar themes as the surveys. At the start of each interview, JH introduced herself and the reasons for conducting the research. JH had no prior relationship with any of the study participants.

Data Analysis

Descriptive statistics were used to present quantitative survey data. Of the 25 interviews, 18 (72%) were transcribed by a professional company and 7 (28%) by JH. Interview analysis was conducted by JH and MH using NVivo (release 1.7.2; Lumivero). MH is a researcher in health informatics with experience of leading and conducting qualitative research. As views on ORA regulations were previously unexplored, we analyzed the interview data using thematic content analysis [29] with an inductive approach. First, JH read all transcripts to develop an understanding of participants' responses. Next, the data were categorized into codes that were grouped into categories and themes. Definitions were refined further through discussions during meetings. Discussions of the findings among all authors improved credibility. Analysis of perceived benefits and risks was inspired by previous work [7,30].

Results

Participant Demographic Characteristics

In total, 31 (74%) of 42 adolescents and 57 (81%) of 70 parents completed the survey and were included in the study. While most of the participants identified as woman in both groups, the proportion was larger among parents (47/57, 83%) than among adolescents (15/31, 48%; Table 1). Regarding gender, of the 31 adolescents, 3 (10%) selected *other* or did not want to state their gender. Of the 31 adolescents, 1 (3%) had recently turned 19 years of age.

Table 1. Survey and interview participants' demographic characteristics (n=88).

Characteristics	Adolescents (n=31)		Parents (n=57)	
	Interviewed (n=8), n (%)	Not interviewed (n=23), n (%)	Interviewed (n=17), n (%)	Not interviewed (n=40), n (%)
Gender				
Man	4 (50)	9 (39)	3 (18)	6 (15)
Woman	4 (50)	11 (48)	13 (76)	34 (85)
Other	0 (0)	1 (4)	0 (0)	0 (0)
Don't know or don't want to state	0 (0)	2 (9)	0 (0)	0 (0)
Missing	0 (0)	0 (0)	1 (6)	0 (0)
Child age (y)				
13	1 (13)	1 (4)	1 (6)	17 (42)
14	0 (0)	0 (0)	3 (18)	9 (22)
15	2 (25)	4 (17)	5 (29)	5 (12)
16	1 (13)	4 (17)	0 (0)	2 (5)
17	0 (0)	10 (44)	8 (47)	5 (12)
18	3 (38)	4 (17)	0 (0)	1 (2)
19-25	1 (13)	0 (0)	0 (0)	1 (2)
Child's diagnosis[a]				
Juvenile arthritis	2 (25)	7 (30)	4 (24)	17 (42)
Cancer	2 (25)	9 (39)	9 (53)	10 (25)
Gastrointestinal diseases (eg, irritable bowel syndrome)	2 (25)	3 (13)	0 (0)	5 (12)
Mental health issues	1 (13)	3 (13)	1 (6)	4 (10)
Diabetes	0 (0)	2 (9)	1 (6)	3 (7)
Other	3 (38)	1 (4)	3 (18)	8 (20)

[a]Participants could select all that applied; therefore, the total can exceed 100%.

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Of the 31 adolescents and 57 parents who responded to the survey, 11 (36%) adolescents and 28 (49%) parents agreed to participate in an individual interview. Ultimately, of those agreeing to take part in an interview, 8 (73%) of the 11 adolescents and 17 (61%) of the 28 parents completed an interview, while 3 (27%) adolescents and 11 (39%) parents did not participate in an interview despite registering interest in the survey due to scheduling difficulties or a lack of response. Interviews lasted for a mean of 28 (range 13-40) minutes for adolescents and a mean of 42 (range 21-70) minutes for parents. Of the 17 parents, 5 (29%) reported having a medical profession. Notably, 2 (12%) of the 17 interviewees were parents of the same child, and none was a parent of a participating adolescent. All participants reported having moderate or higher levels of digital literacy.

As shown in Table 2, of the 8 adolescents, 2 (25%; aged 13 and 15 years) preferred parental ORA, whereas the remaining adolescents (n=6, 75%; aged 15 to 19 years) wanted their own access and either did not want or were indifferent to parental access, perceiving no need for it but expressing no privacy concerns. Almost all parents (16/17, 94%) desired longer access than current regulations allow (Table 3). The exception was a parent whose access was lost when their child was diagnosed with a serious health issue after the age of 13 years. Most of the parents (10/17, 59%) did not have access to their child's EHR; 2 (20%) of these 10 parents reported accessing it via the child logging in on their behalf. Additional demographic characteristics can be found in Multimedia Appendix 4.

Table 2. Adolescent participants' characteristics as reported in the interviews (n=8).

ID	Age (y)	Gender[a]	Interview setting	Child's diagnosis (age at diagnosis [y])	Current ORA[b] preference				Current ORA situation
					Adolescent	Start age (y)	Parent	End age (y)	
A27	19	Female	Telephone	Juvenile arthritis (14)	Yes, in favor	14[c]-15[c]	Okay but no need	13	Access by default
A14	18	Female	Telephone	Inflammatory bowel disease (17)	Yes, in favor	16-17[d]	No, opposed	16[c]-18[c]	Access by default
A26	18	Male	Video	Inflammatory bowel disease (14)	Yes, in favor	13[c]-14[c]	No, opposed	13	Access by default
A19	18	Female	Telephone	Juvenile arthritis (1.5)	Yes, in favor	15[c]	Okay, but no need	15[c]	Access by default
A10	16	Male	Video	Cancer (7)	Yes, in favor	13[c]	Okay, but no need	18[c]	Access by default
A29	15	Female	Video	Asthma and allergies (0), mental health (13)	Yes, in favor	12[c]-13[c]	No, opposed	12[d]-13	No access by default
A23	15	Male	Telephone	Neurological disease (5)	No need	16	Yes, in favor	16[c]	No access by default
A4	13	Male	Telephone	Cancer (2)	No need	15[c]-16	Yes, in favor	15[c]	No access by default

[a]On the basis of survey responses.

[b]ORA: online record access.

[c]Less restrictive than current regulations.

[d]More restrictive than current regulations.

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Table 3. Parent participant characteristics as reported in the interviews (n=17).

ID	Age (y)	Gender[a]	Interview setting	Child's diagnosis (age at diagnosis [y])	Adolescent age (y)	Current ORA[b] preference				Current ORA situation
						Adolescent	Start age (y)	Parent	End age (y)	
P22	48	Female	Video	Cancer (13)	14	No, opposed	16	Yes, in favor	+[c]	Gained extended access
P48	50	Male	Video	Juvenile arthritis (10)	15	No, opposed	?[d]	Yes, in favor	+[c]	Gained extended access
P52	37	Female	Video	Skin disease (0)	15	Okay, but no need	13[c]	Yes, in favor	16[c] or 18[c]	Gained extended access
P8	44	Female	Video	Cancer (7)	14	Okay, but no need	15[c]	Yes, in favor	+[c]	Gained partial extended access
P15	55	Female	Video	Cancer (17)	17	Okay, but no need	18[e]	Yes, in favor	18[c]	Access to the child's EHR[f] via the child's account (with assent)
P31	48	Female	Telephone	Bone marrow disease (5)	17	Okay, but no need	16	Yes, in favor	+[c]	Access to the child's EHR via the child's account (with assent)
P1	41	Female	Video	Cancer (11)	14	Yes, in favor	14[c]-15[c]	Yes, in favor	14[c]-15[c]	Applied for but not gained extended access
P2	49	Female	Video	Cancer (4)	13	No need	16	Yes, in favor	16[c]	Applied for but not gained extended access
P54	52	Female	Video	Juvenile arthritis (3)	17	Okay, but no need	16	Yes, in favor	18[c]	Applied for but not gained extended access
P47	47	Female	Video	Juvenile arthritis (10)	15	Okay, but no need	16	Yes, in favor	+[c]	Extended access expired
P5	57	Male	Video	Cancer (2)	17	Okay, but no need	16/18[e]	Yes, in favor	18[c]	No access, unaware of extended access
P9	49	Female	Video	Cancer (4)	17	Okay, but no need	16	Yes, in favor	18[c]	No access, unaware of extended access
P12	52	Female	Telephone	Cancer (4)	17	Okay, but no need	16	Yes, in favor	?[d]	No access, unaware of extended access
P26	45	Female	Telephone	Dental surgery and orthopedic issues (7)	17	Yes, in favor	16-18[e]	No need	+[c]	No access, unaware of extended access
P38	47	Female	Video	Juvenile arthritis (10)	14	Yes, in favor	15[c]	Yes, in favor	18[c]	No access, unaware of extended access
P49	47	Female	Telephone	Juvenile arthritis (11)	15	Yes, in favor	16	Yes, in favor	16[c]	No access, unaware of extended access
P55	54	Male	Video	Diabetes (16)	17	Okay, but no need	16	No need	13	Aware of extended access

[a]On the basis of survey responses.

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[b]ORA: online record access.

[c]Less restrictive than current regulations.

[d]Unable to specify.

[e]More restrictive than current regulations.

[f]EHR: electronic health record.

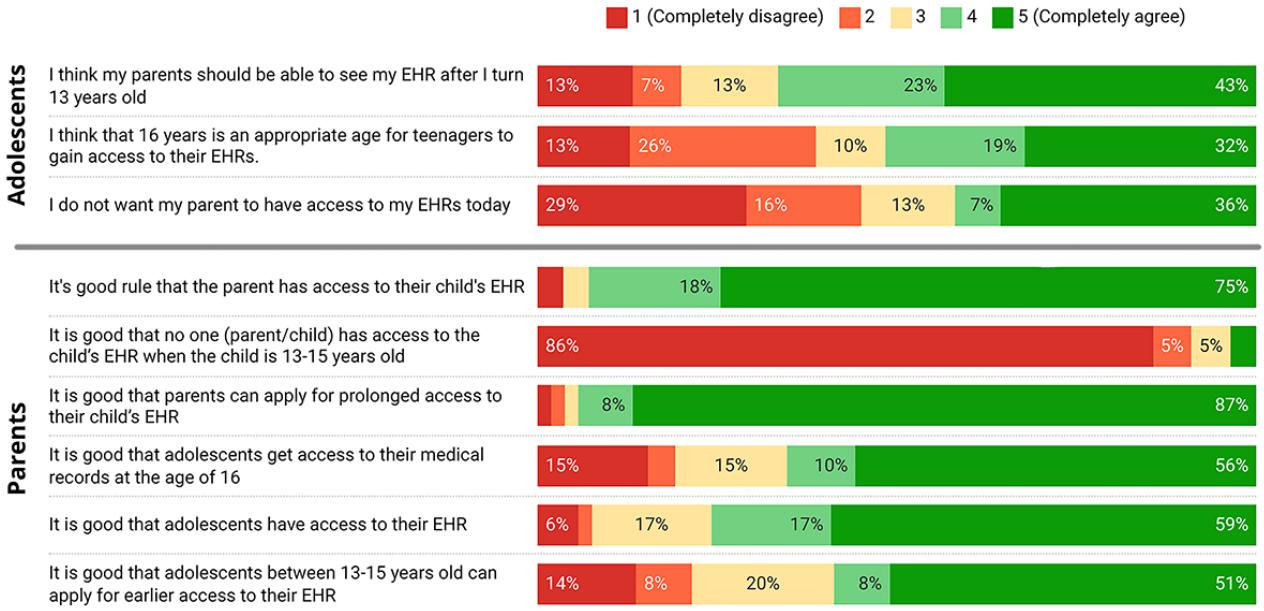
Quantitative Findings

Almost all adolescents (29/31, 94%) reported wanting access to their records. Low knowledge about the access age limit was observed: only a little more than a third (11/31, 36%) knew that the access age limit was 16 years of age, and almost as many (10/31, 32%) incorrectly guessed it to be 13 years of age. Of the respondents aged ≥16 years, 43% (10/23) claimed that they did not have current access to their records although this is the default.

Most of the adolescents (20/31, 65%) wanted their parents to be able to read their EHR after they had turned 13 years of age (Figure 1). A slight majority (16/31, 52%) agreed that 16 years of age is an appropriate age to gain access to one's health records. Most of the parents (51/55, 93%) were positive about parental ORA for children aged <13 years and negative about the gap in access from the ages of 13 to 15 years (51/56, 91%). Almost all parents (50/53, 94%) were positive about the option of applying for extended access for themselves, while more than half (30/51, 59%) were positive about adolescents applying for earlier access.

Most of the free-text comment data were reflected in the interviews. One parent responding to the survey noted that there should be a screening process for parents to access their children's records, while another referred to regulations regarding parents' rights to medication information as unclear, noting that the PAEHR is more restrictive than the information provided by pharmacies.

Figure 1. Adolescents' and parents' ratings for statements related to online record access and current regulations. EHR: electronic health record.



Qualitative Findings

Perceived Benefits of ORA

Adolescents and parents reported 6 perceived benefits of ORA: *empowering adolescents*, *improved emotional state*, *enhanced documentation accuracy*, *improved partnership and communication*, *supported parental care management*, and *better prepared for appointments* (Textbox 2).

Empowering adolescents referred to ORA helping adolescents to gradually become more involved in their care (eg, by helping them to remember appointments, track their illness, and understand their illness history). Adolescents shared that reading the notes from the beginning helped them gain a better understanding of what they had been through, providing information about events that they were too young to remember. Both adolescents and parents envisioned that this information would be helpful when meeting new HCPs. Parents were positive about their children being able to read the records "in the future," to understand their journey.

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Textbox 2. Themes identified in the interviews of the perceived benefits of adolescent and parental online record access.

Empowering adolescents

- "It could be good to learn how to do things when you get older. When they might not be there." [A4, aged 13 years, diagnosed with cancer]
- "If you're 16, I believe you have the right to receive the same information that's actually written in the record." [P47, mother of child aged 15 years diagnosed with juvenile arthritis]

Improved emotional state

- "It's quite nice, well...if something happens, that I can go...I have security in that I can go back and read exactly everything, and even show that 'this is how it was.'" [A19, aged 18 years, diagnosed with juvenile arthritis]
- "As a mother I have felt that it is a security to be able to go back and read, 'what did they do now,' and it has felt good." [P15, mother of child aged 17 years diagnosed with cancer)

Enhanced documentation accuracy

- "We always have a discussion at health care meetings and such. But...they won't write down word for word what we have said...and sometimes there are misunderstandings, and then it's always good to be able to go back and check." [A26, aged 18 years, diagnosed with inflammatory bowel disease]
- "At several occasions, doctors have said, 'oh my god, how lucky you spotted that,' and such." [P22, mother of child aged 14 years diagnosed with cancer]

Improved partnership and communication

- "I have learned a lot through my parents sitting at home and reading, we have read the records together." [A23, aged 15 years, diagnosed with neurological disease]
- "[My boyfriend] has also been allowed to read a bit from the record...So that he can gain a better understanding." [A19, aged 18 years, diagnosed with juvenile arthritis]
- "You can sit together and reflect. Because otherwise it's somewhat difficult to just 'yeah, so now we're going to talk about this' and...then they want to go on some social media or something else like that. Maybe you can have a little focus on this." [P54, mother of child aged 17 years diagnosed with juvenile arthritis]
- "He clams up when doctors come to talk, then he won't speak, he won't say anything...It may be better if we talk together in advance, and he gets to ask us his questions, and we can ask the doctor." [P22, mother of child aged 14 years diagnosed with cancer]

Supported parental care management

- "You have to remember to schedule appointments and make sure to attend those appointments you've booked, so it's very, very much to manage logistically when you're sick, and it's quite nice to get help from parents when you're young." [A26, aged 18 years, diagnosed with inflammatory bowel disease)
- "It has been good to track it, because then you can also tell [the child] that 'you have to eat this vitamin because there is a deficit.' It's not as though I give her medication because it is fun." [P1, mother of child aged 14 years diagnosed with cancer]
- "Just last week, we had a situation where [my child] had got a specific medication and has been taking it, but then test results came and I saw that the levels regulated by this medication were sky high, so if we had continued taking the medication it might not have been so good. Then I could contact the physician to ask 'should we keep giving this medication or not?' And they say, 'no, don't do that.'" [P22, mother of child aged 14 years diagnosed with cancer]

Better prepared for appointments

- "I can tell [my child] that 'on Wednesday, we will see the physician, and we will talk about how to move forwards, and it might be that we will, blah blah blah,' whatever it is. And then he knows, so then when we meet the physician it won't be as dramatic." [P22, mother of child aged 14 years diagnosed with cancer]
- "We have a younger brother and live in the countryside, we have animals, and I may have to call my work and inform them I will be gone all week, so it facilitated a lot for everyone's well-being in the family that we could see for example test results on beforehand." [P52, mother of child aged 15 years diagnosed with skin disease]

Improved emotional state referred to an increased control and a sense of safety. Adolescents and parents reported that these feelings often related to having quick access to test results and being able to go back and read information. One adolescent (A26) described reading notes from childhood as fun and nostalgic. Parents reported feeling a sense of control due to increased knowledge about the illness and its terminology. Some parents stated that access to information reduced their anxiety and worry. One parent (P52) mentioned that because physicians did not always indicate that they had seen new test results, seeing that they had been active from checking the log list provided a sense of relief. Some adolescents described feeling safe when reading the EHR with their parents or merely knowing that their parents had access. One adolescent (A23) speculated that ORA provided parents with a feeling of safety, but parents

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did not express this in relation to benefits of ORA for adolescents.

Enhanced documentation accuracy was reported as a benefit by both adolescents with ORA experience and parents; for example, it enabled them to ensure that HCPs had understood the information they shared during a consultation correctly and that there were no errors. Experiences of inaccuracies often involved HCPs misunderstanding details about symptoms, such as the degree of gravity or timing. One parent (P52) reported having once noted to an HCP that their child's records contained someone else's test results, apparent because the results were "too good." Another parent (P1) who had lost access to the EHR described a case involving their child where a referral had been sent for a sex change investigation because the HCP had misunderstood the adolescent's request to stop their period. The parent argued that if they had been able to review the EHR, they could have intervened earlier, preventing the adolescent's distress and avoiding unnecessary efforts.

Improved partnership and communication was reported as a benefit by both adolescents (with or without ORA experience) and parents. This referred to ORA enabling better communication among adolescents, parents, and HCPs in working together to manage the illness. Parents stated that ORA could help adolescents formulate questions beforehand, which the parents could then forward to HCPs. Many stated that parental ORA lessened the burden on the adolescent with health issues. The youngest adolescent (A4) expressed a substantial need for parental EHR access because they felt unable to manage everything alone. Older adolescents described that their perceived need for parental EHR access had decreased over time, partly because their ability to independently communicate with HCPs had increased. In addition, ORA facilitated reading the EHR together at home, allowing families to focus on the illness and providing an opportunity to ask questions in a safe environment, either in preparation for visits or as a way to debrief afterward.

Supported parental care management referred to ORA facilitating parents' provisioning of care in various ways; for example, both adolescents and parents reported that ORA facilitated parents' management of medications and appointments, improved recall of information, and enhanced parents' understanding of the child's health condition. Some parents stated that the EHRs contained more information than otherwise communicated, such as positive test results. Parents described that ORA facilitated dealing with insurance tasks and that access to test results enabled them to motivate the child to take their medications. Some parents noted that reading test results allowed them to anticipate being called to the hospital, enabling them to prepare their child mentally and emotionally in advance. Quick access to test results also enabled parents to speed up the care process and prevent unnecessary distress. One parent (P52) mentioned that test results revealed the child's actual condition, even when the adolescent claimed to feel well to avoid a hospital visit. The same parent stated that the only perceived benefit of their adolescent having ORA was that they could log in on their behalf.

Better prepared for appointments was reported as a benefit by both adolescents and parents, in that ORA facilitated the formulation of questions before appointments. Some parents described how ORA enabled preparations that were critical for their individual situation; for example, a parent (P52) living in the countryside could organize family life, animal care, and work in preparation for a hospital stay that might otherwise be sudden. Another parent (P22), whose adolescent had mild autism and struggled to process information during an appointment, described that ORA enabled her to use information from the EHR to prepare her child for what HCPs may bring up.

Perceived Risks of ORA

Participants identified 4 perceived risks of adolescent and parental ORA: *emotional distress and confusion*, *threatened confidentiality*, *increased burden*, and *low usability* (Textbox 3).

Emotional distress and confusion referred to the inability to understand information that was vague or written in clinical language, which could cause distress and lead to feelings of worry and frustration for both adolescents and parents. Confusion was also reported by an adolescent (A26) in relation to the unintuitive organization of information on the portal. Parents expressed concerns about adolescents reading concerning or negative test results while alone or learning about difficult medical events from their childhood, leading them to emphasize the importance (or necessity, for some) of having a parent present to answer questions and provide explanations. An adolescent aged 18 years diagnosed with juvenile arthritis (A26) recounted past experiences of feeling low after reading about traumatic experiences with health care in the EHR. Some adolescents and parents explained that their worry did not derive from accessing negative information in the record but from the progression of the illness itself. Two adolescents (A26 and A27) described that their close contact with HCPs reassured them that they would not receive bad news in the EHR without it being communicated in advance. Adolescents without experience of ORA did not anticipate emotional distress. While most desired an explanation from HCPs before receiving negative results, some reported prioritizing quick access to the information. Several parents recognized that other parents may worry; however, they themselves were not ones to worry.

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Textbox 3. Themes identified in the interviews of the perceived risks of adolescent and parental online record access.

Emotional distress and confusion

- "It's those difficult words that one doesn't understand...And you don't really know what kind of test results you're getting back or what it means, so there's been quite a lot of Googling, consulting with mom all the time." [A10, aged 16 years, diagnosed with cancer]
- "One day it may pop up and boom, she has cancer everywhere and they can't do anything. And if you find out in her EHR. And the doctor hasn't called and explained anything. Then you get a little frustrated about it." [P2, mother of child aged 13 years diagnosed with cancer]
- "Some [parents] might say 'no, I won't read because it makes me more worried.' But in our case, I felt that nothing can... I'm already worried anyway, it's part of having a very sick child, so to speak." [P12, mother of child aged 17 years diagnosed with cancer]
- "If I read something and suddenly just feel like...oh my god, I got heart palpitations because I read something very negative or something. Then I think, for him to sit alone without anyone beside him and read this, no, I think that would just harm him, honestly. He's too young." [P22, mother of child aged 14 years diagnosed with cancer]
- "Even I, who work as a medical secretary, don't understand these terms either. I haven't worked in oncology. I don't understand everything either, so it's a bit poor of the doctors then perhaps also to dictate so that one doesn't...or the staff actually, to write and dictate so one doesn't understand." [P15, mother of child aged 17 years diagnosed with cancer]

Threatened confidentiality

- "If there's something I don't want them to know or something, they'll be able to see it or they'll be able to see all the notes that you might just...'They don't need to see this note.'" [A14, aged 18 years, diagnosed with inflammatory bowel disease]
- "If parents perhaps pressure one to log in, or something like that." [A29; aged 15 years; diagnosed with asthma, allergies, and mental health issues]
- "With honor-related violence, among other things, if you see that your child perhaps has a sexual activity and you don't believe it and so...yes, then it can get very bad...And also transgender care." [P54, mother of child aged 17 years diagnosed with juvenile arthritis]

Increased burden

- "[The teen] might have to bear too much responsibility." [P48, father of child aged 15 years diagnosed with juvenile arthritis]
- "I can understand that it could also lead to a greater workload for [HCPs], because I think that...Now, I might be a quite reasonable parent who also understands that one shouldn't reach out unnecessarily and so on. But I can imagine that there might be others who read things and maybe don't quite understand, and then they call." [P22, mother of child aged 14 years diagnosed with cancer]

Low usability

- "The website or app itself, or how one chooses to read the records, well...I can't say that it has a really great layout, and it's a bit difficult to know how everything is sorted and to find things." [A26, aged 18 years, diagnosed with inflammatory bowel disease]

Threatened confidentiality referred to the risk of sensitive information about the adolescent becoming visible to parents or others. While several adolescents mentioned that "the parent might see something one wants to hide," parents commonly specified potentially sensitive topics, such as mental or sexual health. One adolescent (A26) and many parents recognized that privacy may be a problem in families where parents seek to exercise control and may not focus on the child's best interest. Both adolescents and parents also recognized the risk that some parents might attempt to access their child's records via their account or pressure them to log in. Some adolescents and parents mentioned the risk of young adolescents sharing information with peers or on social media.

Increased burden referred to a burden placed on both adolescents and HCPs. Adolescents (only those who had not had access) and parents reported that granting adolescents access could lead to excessive responsibility for adolescents, who, especially when ill, wanted to be able to depend on their parents. Some parents imagined a burden on HCPs, such as adolescents sending numerous messages through the portal. Moreover, HCPs may feel compelled to omit sensitive information from the EHR, which would be detrimental to the child's future care. Some parents stated that patients' ORA is not a priority for HCPs, who understandably focus on providing care.

Low usability was reported as a downside or risk by an adolescent (A26), who found it challenging to locate and identify specific types of notes, such as diagnoses, clinical notes, or other documentation, due to unclear categorization and sorting. As a result, they spent more time searching for the desired information.

Views on ORA Regulations

Three themes were identified with regard to views on ORA regulations: *challenges of the access gap*, *balancing respect for autonomy and support*, and *suggested regulatory change* (Table 4). Similarities and differences between adolescents' and parents' report of themes and subthemes are visualized in Figure 2.

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Table 4. Themes related to adolescents' and parents' views on online record access regulations.

Themes and subthemes	Representative quotes
Challenges of the access gap	
Lack of information	• "Being able to access it at all, I found out just a month ago from someone at a primary care clinic, that like, you have to order it and then you'll get it on paper...but, that you can get earlier access or so, I haven't heard anything about. And it's probably because even when you ask your physician at the clinic, they don't know either." [A29; aged 15 years; diagnosed with asthma, allergies, and mental health issues] • "We knew it would come, but we still thought that 'she is sick, maybe they understand that we should have access to the record anyways.' But it...it wasn't the case." [P2, mother of child aged 13 years diagnosed with cancer]
Losing access causes a loss of control and complicates care	• "I got really angry [when losing access], as I said, because it's my child that I'm responsible for. Then she shouldn't be able to do a bunch of things without my knowledge either." [P15, mother of child aged 17 years, diagnosed with cancer] • "I felt a confusion, not being able to read the test results, if she has inflammation in her body, where does she have it or does she not, how do the liver tests look? You couldn't follow her illness in the same way when you couldn't read the EHR [electronic health record]." [P38, mother of child aged 14 years diagnosed with juvenile arthritis] • "There is extra work, both for me and physicians...or the nurse I guess, because I have to call in. And I have to match their phone hours, and then I take their time and time from those who need it better." [P1, mother of child aged 14 years diagnosed with cancer]
Cumbersome to extend access	• "It feels like a very complicated process. Especially for 13- to 15-year-olds...like, we find it easy to do something on our mobile phones, fill it out there, but if we have to first find a paper, figure out how to print it, fill it out, send it in, get it signed, get it into the system...that probably takes a few months." (A29; aged 15 years; diagnosed with asthma, allergies, and mental health issues] • "You have a thousand other things that are higher priority when you have sick children...To then submit long paper forms, find the right nurse who also doesn't know what to do...and specifically write the exact clinic on them when you go to...they send referrals here and there, I barely know what all the clinics he has been to and is going to are called." [P52, mother of child aged 15 years diagnosed with a skin disease]
Balancing respect for autonomy and support	
Need for parental support	• "It can be good, because you're darn young, and maybe you don't know how to do everything yourself and might need help." [A4, aged 13 years, diagnosed with cancer] • "It's completely different from person to person. Some might develop faster than others. And if you haven't, it might be nice for parents to be able to help." [A27, aged 19 years, diagnosed with juvenile arthritis] • "I probably wouldn't have wanted [adolescents'] access that early. There is a conflict, I'm thinking, with the child's right to know and at the same time, whether a child is emotionally equipped to see serious illnesses or prognoses, and take in the information. I think that you're young when you are...below 16, you're still young to deal with these difficult things." [P48, father of child aged 15 years diagnosed with juvenile arthritis] • "Maybe they don't need access before they're 18...I feel at least that I'm glad he can access his EHR. Otherwise, we wouldn't have seen anything. Because it's mostly me who reads it." [P15, mother of child aged 17 years diagnosed with cancer]
Adolescent autonomy	• "I think maybe you can have access slightly earlier, so that you can like, understand a little bit." [A10, aged 16 years, diagnosed with cancer] • "I live in [region], where many live in rural areas and when you're 15-16, you can move away from home. Like, into the city, and then you become more or less an adult and a bit more, 'I can take care of my record myself.'" [A29; aged 15 years; diagnosed with asthma, allergies, and mental health issues] • "I would probably wish that [my daughter] had access to see her test results. It's still her life, you know." [P38, mother of child aged 14 years diagnosed with juvenile arthritis] • "This thing about medication and making your own decisions...it's something you have to phase in. For it to work, I think you need to phase it in over a few years. It's not something you just fix with a bang on your 18th birthday. So it's still good at 16 years old that they get access and...if they are mature and willing." [P54, mother of child aged 17 years diagnosed with juvenile arthritis] • "There are some children who are more mature than their parents, I think it provides an opportunity for the children who are interested and listen during their meetings like parents...I think the opportunity should be there for them to see the whole time." [P52, mother of child aged 15 years diagnosed with a skin disease]

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Themes and subthemes	Representative quotes
Need for privacy	• "It really depends, like some might start...like, if we say that one goes to BUP [child and youth mental health services] or some other place...I would say it begins at around 12-13, that one seeks help but doesn't want to tell." [A29; aged 15 years; diagnosed with asthma, allergies, and mental health issues] • "I don't think it's really about age, but more about what happens in the child's life. Because I think that there might be a difference...I'm thinking in terms of privacy. Now we have an ongoing illness process where I believe he also benefits from us being involved in and being able to help follow up. And as long as he's in that loop...I think it's very important that we have access. But after that, maybe not as much." [P22, mother of child aged 14 years diagnosed with cancer] • "There are far too many controlling guardians out there who want to control their children and all that. But I think that it must be more prevalent within certain areas, such as counseling support and youth clinics and so on. And I think we should never have access to those." [P8, mother of child aged 14 years diagnosed with cancer]
Suggested regulatory change	
Closing the access gap	• "I think maybe parents should have access until you are 13-14, and then I think it should be brought up that you can gain your own access to it." [A26, aged 18 years, diagnosed with inflammatory bowel disease] • "I think one should be able to read always, or maybe until they're 16, and from 16 they can perhaps log in themselves." [P52, mother of child aged 15 years diagnosed with skin disease]
Enhanced information on extended access	• "Could one consider sending information to the health care center, to youth...I mean, to health care centers, that parents can apply [for access extension]? Or maybe conduct some webinar?" [P49, mother of child aged 15 years diagnosed with juvenile arthritis] • "I think it should be very clear on 1177, that 'if you want to see your child's medical record, fill in here' or something like that." [P54, mother of child aged 17 years diagnosed with juvenile arthritis] • "For anything that isn't transient, like a cancer diagnosis that doesn't go away on its own, there should be a dialogue at least 6 months before the child turns 13 with the treating physician, and it should pop up in the EHR when the doctor opens it. Explaining to both children and parents, 'this is what will happen if we don't do anything, and how do you view it and what would you like access to?' and so on...Perhaps even that there can be some standard procedure, 'this is how we usually do it when it comes to cancer diseases, that you have access to blah, blah, blah...this and this.' But this you won't see. So that the wheel doesn't need to be reinvented every time." [P8, mother of child aged 14 years diagnosed with cancer]
Tailored access for privacy protection	• "Can't you block certain parts [from parents], like youth psychiatry, counseling, youth health, or something like that? I'm thinking that you could be allowed to read all the time but maybe block certain parts." [P52, mother of child aged 15 years with skin disease] • "Maybe [the adolescent] can make an agreement with the person writing in the record that 'no, but this can be kept hidden, I don't want anyone else to see this.' That there's like a toggle switch, like, private or not. You know, like when booking [setting up appointments] in Outlook, you can just be like, this is private." [P22, mother of child aged 14 years diagnosed with cancer] • "I think that if a child seeks care independently, the health care professional could perhaps ask the question 'do you not want your parent to be able to read this?' That it can be customized." [P47, mother of child aged 15 years diagnosed with juvenile arthritis]

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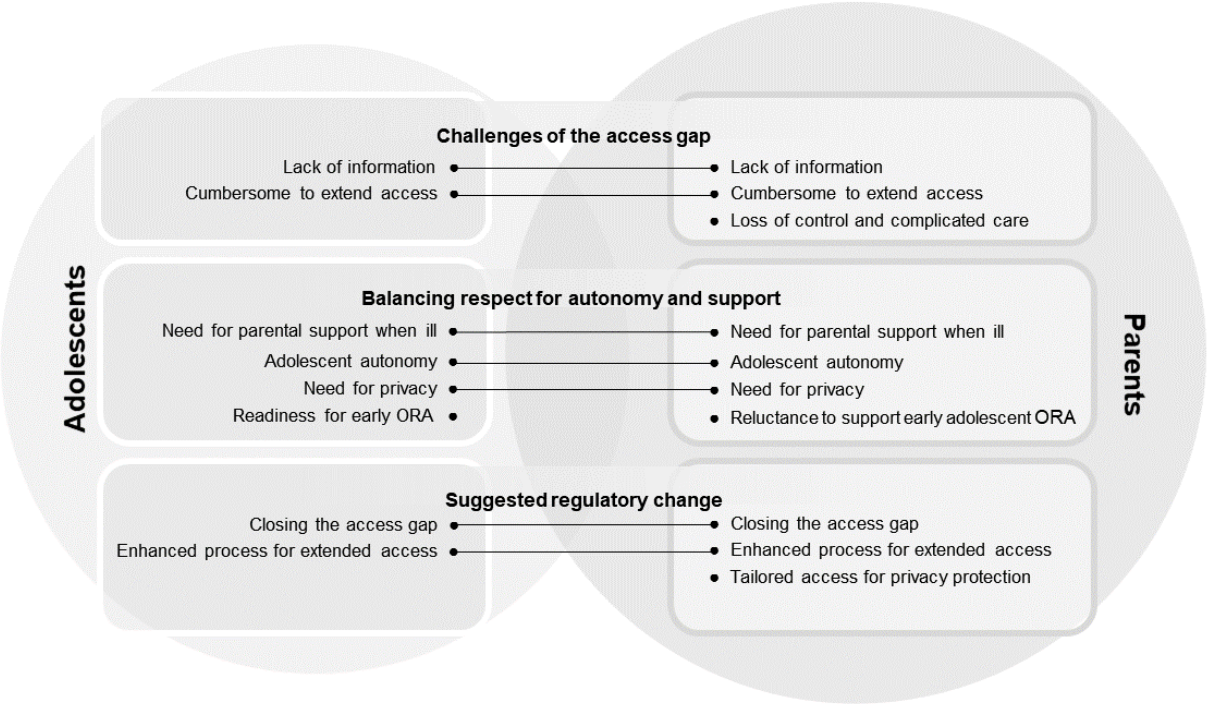
Figure 2. Themes related to adolescents' and parents' views on online record access (ORA) regulations.



Challenges of the access gap were mentioned by both adolescents and parents. Several parents expressed strong feelings of frustration and desperation over losing their access, citing the many benefits they had experienced. Despite receiving notifications, several parents had not fully understood that they would lose access when the child turned 13 years of age and were convinced that HCPs would ensure continued ORA due to their situation. Losing access made it difficult for parents to track their child's illness because they could no longer check test results, manage appointments, or monitor medications needing refills. Instead, they had to travel to the pharmacy for medications and contact HCPs to inquire about test results during designated hours, leading them to feel that they were burdening HCPs. Most adolescents and some parents were unaware of the option to apply for extended access, especially in the case of adolescents. Of those who had applied, a majority described the application process as cumbersome: identifying the right form; submitting separate applications for each desired unit; and parents needing to frequently raise the issue with HCPs, who often lacked the necessary knowledge or information. Difficulties with the application process were both anticipated and encountered. One adolescent (A26) and several parents had given up on their efforts to apply for access due to these challenges. A few parents who had applied for extended access immediately after losing access did not regain it until 6 months later, while 1 parent (P1) was still waiting for a signature, 2 years after applying.

Adolescents and parents were *balancing respect for autonomy and support* in their appraisal of appropriate access ages. Several participants perceived that the need for adolescent and parental ORA depended on factors other than age, such as the adolescents' maturity and interest, which may not correlate with age. Adolescents and parents who advocated access earlier than the age of 16 years focused on adolescents' rights to read their records, as well as the importance of involving interested adolescents with serious health issues in their care from an early age. By contrast, having a serious health issue was often perceived as a situation necessitating parental access beyond the age of 13 years, a view supported by 5 (62%) of the 8 adolescents and almost all parents (15/17, 88%). Parents stated that parental ORA should extend into adulthood for children with severe neurocognitive impairments. Some adolescents and most parents were positive about the idea of adolescents aged 16 years gaining access, citing that younger adolescents are often less capable of managing their care and require parental support. Still, most valued the opportunity for interested and mature adolescents to become involved in their own care before adulthood. Some parents were negative about early adolescent ORA, seeing it as a burden for the adolescent or perceiving illness-related information in the EHR as harmful. One parent (P48) stated that the age of 16 years is "too young to deal with such difficult matters," and several stated that adolescents should have a parent present when reading the records.

Another source of divergent opinion was adolescents' need for confidentiality. Privacy was a priority for adolescents and 1 parent (P55) who were positive about parents losing access when their child turned 13 years of age. Many referred to a difference in the timing of adolescents beginning to seek care for sensitive matters. While most parents were understanding of the need to conceal sensitive information, they still viewed their parental responsibility as critical. Most adolescents stated that they did not feel the need to conceal information from their parents, citing a relationship of openness and their parents' prior involvement in the treatment. Nevertheless, some expressed a desire to hide nontreatment information, such as alcohol use. The exception was an adolescent aged 15 years who had

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experience with mental health care and was not open to parental access, stating that any information could be sensitive for an individual. Adolescents' view of sensitive information was generally broader than that of the parents, with parents primarily focusing on mental and reproductive health. Furthermore, several parents and 1 adolescent (A26) discussed the importance of considering adolescents who may experience harm from parental ORA, such as children with controlling parents or in honor-based contexts. However, a few parents argued that such cases are rare and that the majority of adolescents benefit from parental access.

Suggested regulatory change was mentioned by both adolescents and parents. A common suggestion was to remove the existing access gap between the ages of 13 and 15 years, perhaps by finding a middle ground. Furthermore, participants proposed increasing education for adolescents, parents, and HCPs about the option of access extension and the application procedure. Parents suggested facilitating the procedure by digitizing the application to the patient portal and enabling a combined application for all units involved in treatment. Both adolescents and parents cited the need for HCPs to have more knowledge of the process. Some parents also stated that parental access should be tailored based on adolescents' preferences or technological tagging of diagnoses, allowing for the concealment of sensitive information from parental view.

Mixed Methods Comparison

Overall, the qualitative accounts of adolescents and parents largely reflected and elaborated on their ratings and views observed in the quantitative measurements. Consistent with survey findings, both adolescents and parents criticized the access gap between the ages of 13 and 15 years and expressed a desire for this gap to be closed. The qualitative findings provided insights into the perceived benefits and risks of ORA, which aided an understanding of various findings, such as parents' preference for parental ORA over that of adolescents. Moreover, extensive challenges related to access extension were revealed.

Discussion

Summary of Findings

This study found that adolescents and parents were negative about the current access gap in Sweden for adolescents aged 13 to 15 years. While adolescents were largely positive about longer parental access, parents strongly advocated it. By contrast, adolescents also preferred earlier own access, which most parents opposed. The current option to extend access beyond the default was considered complicated due to a cumbersome application process and a lack of information and HCP knowledge. Perceived benefits and risks of ORA differ, revealing tensions in the respective views, particularly concerning parents' worries about adolescents' access.

Comparison With Prior Work

While in alignment on many aspects related to ORA regulations, adolescents and parents differed mainly in their views on adolescents' access. Our findings suggest a tension between adolescents and parents similar to that between patients and HCPs [31]—adolescents appreciate having access, while parents worry about adolescents' lack of health literacy and the potential for harmful consequences. While adolescents in this study acknowledged the risk of not understanding medical terminology with ORA, they expressed minimal concern and described coping strategies to manage this challenge. However, many parents perceived a lack of interest among adolescents in reading their records, in addition to a high risk of potential harm. This is in line with previously identified parental concerns, including the possibility of adolescents misunderstanding information or reading negative test results independently [7]. These concerns are understandable, particularly during times of illness and vulnerability when parents want to ensure the best possible care for their child [32]. Nevertheless, a recent case study comparing Swedish and Finnish adolescents' ORA use indicates that earlier access may lead to increased uptake at earlier ages [12].

The tension emerging from parents' hesitance to support adolescent ORA may in part be a result of the perceived serious risks in the face of a lack of significant benefits. Notably, while several adolescents reported improved emotional states and 1 adolescent speculated that parents may feel safer with ORA, no parent envisioned that adolescents may experience more control or increased safety. Furthermore, parents reported many benefits that adolescents did not perceive, such as being able to prepare the child for medical appointments and explain medication needs. This is important because noncompliance with treatment in adolescents has been documented [33], where access to information is essential [32]. The difference in adolescents' and parents' perceived benefits indicates the difficulty in understanding another person's perspective and experiences. Given the importance of partnerships between the adolescent patient, parent, and HCPs, noted in earlier work [22], there is potential for ORA to serve as a tool for improving such partnerships; for example, we identified that the opportunity to read EHRs together at home contributed positively to adolescents' and parents' experiences. A better understanding of each other's perspectives might help mitigate concerns about harm related to a lack of health literacy and confidentiality. Both adolescents and parents recognized the benefit of adolescent access in empowering adolescents and supporting the transition into adulthood, supporting previous work [6,7].

Most of the adolescents in this study were positive about allowing parental access after the age of 13 years, recognizing that parental support lessened the burden on the child, particularly in the case of serious health issues. However, adolescents advocated a need for privacy regarding some types of information unrelated to treatment. The need for privacy regarding sensitive information was reported to increase with age and also varied depending on the type of care received. Notably, an adolescent aged 15 years with experience of mental health issues such as depression (A29) preferred restricted parental access from the age of 12 or 13 years, which was earlier than the preference expressed by adolescents with diseases such as cancer, inflammatory bowel disease, or juvenile arthritis. The adolescent also reported having moved away from home for school, which likely increased their level of independence. While most of the parents reported that they would accept not having access to sensitive information, they often referred to

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sensitive topics pertaining to sexual or mental health. Meanwhile, some adolescents cited allergies and experiences of bullying as potentially sensitive. Aligned with previous findings [17], adolescents stated that what is considered sensitive information can vary from person to person, indicating a need to allow adolescents to decide what should be visible to parents in the EHR. Parents suggested enabling customization of information availability, as has been recommended in earlier work [34]. An example of a system that allows customization is found in Finland, where HCPs assess each minor's decision-making capacity and then allow those found capable to decide whether parents should have access. While such case-by-case approaches lead to a risk of increased work burden for HCPs, more research is required to explore the feasibility of customized access.

Adolescents and parents reported low knowledge about access extension, the intended solution to aid families of children with serious illness during the access gap between the ages of 13 and 15 years. It was reported that HCPs often lacked knowledge about the application process and even the possibility of extending access. Our previous research shows that <1% of adolescents aged 13-15 and their parents access the Swedish patient portal [12]. Furthermore, adolescents lacked knowledge about regulations. Adolescents have reported receiving little encouragement from HCPs to access their records [35]. Possibly, the implementation of ORA in Sweden has failed to involve and educate HCPs about the new regulations. Furthermore, given that ORA and EHR documentation are known causes for HCP job dissatisfaction and burnout [36], some HCPs may be reluctant to encourage ORA use. To improve our understanding of HCPs' perspectives, the aim of a study conducted by the authors in parallel with this study was to examine the experiences and awareness of ORA regulations among oncology HCPs in Sweden.

Implications

On the basis of the findings, we have summarized a number of implications that concern adolescents with serious health issues and their parents (Textbox 4).

Textbox 4. Implications of the findings.

Implications

- Provide health care professionals (HCPs) with information on online record access (ORA) regulations related to extended access and guidance on how to facilitate the application procedure for adolescents and parents.
- Establish a plan for families with adolescents with serious illness to retain necessary ORA through a facilitated process of applying for extended access.
- Ensure clear communication to parents and adolescents about the management of sensitive information in records on the national patient portal.
- Provide comprehensive information to adolescents regarding the age limit for gaining access and the option to receive early access on the national patient portal.
- Provide comprehensive information to parents regarding ORA regulations, loss of access, and the option to extend access on the national patient portal.
- Foster dialogue between HCPs, adolescents, and parents regarding ORA and the concealment of sensitive information.
- Implement patient portal features that enable adolescents to customize the concealment of sensitive information according to their preferences.

Limitations

This study has a number of limitations. The sample size was relatively small due to persistent recruitment difficulties, particularly in engaging adolescent participants. Future research may explore alternative recruitment strategies, such as reaching adolescents through schools or other community channels. Moreover, half of the adolescents interviewed (4/8, 50%) were aged 18 or 19 years, which likely affected their views. Among the parent participants, the majority (47/56, 84%) were women, and approximately one-third of the interview participants (5/17, 29%) had a medical background or a partner working as an HCP. Notwithstanding this limitation, unequal sample sizes are a common occurrence in mixed methods research [23]. Furthermore, our sample included adolescents with a variety of conditions; however, the focus was not on comparing experiences across groups with specific illnesses but rather on exploring broader perspectives related to ORA use. While the parents varied in education, residential area, and income, most had Swedish as their primary language (53/56, 95%). Given the role of socioeconomic factors in driving disparities in pediatric ORA adoption [37,38], future work should include minors and parents from diverse language backgrounds to capture broader perspectives. Moreover, 1 survey item included a negation ("I do not want my parents to access..."), which could have been challenging for participants to interpret and therefore to accurately respond to on a scale ranging from 1 to 5. The surveys used were designed by the authors because there are no validated questionnaires available for examining views on ORA. Finally, both adolescents who had read their records and those who had not participated in the study. As a result, some shared their expectations rather than experiences. We strove to present the findings with due consideration to this limitation because there may be differences between expectations and experiences of ORA [2]. We did not provide a demonstration for adolescents without access, which may have impeded their ability to answer anticipatory questions. However, most of the interviews (5/8, 62%) with adolescents were conducted via telephone, precluding visual demonstrations. Regarding interviews conducted via videoconferencing software, it is possible that this format influenced participants due to the potential sensitivity of the topic. In addition, technical issues such as connectivity problems or the lack of a private and secure environment could have further impacted the conversation flow. However, video

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interviews offer advantages over telephone interviews by allowing for the conveyance of nonverbal cues, such as facial expressions and body language, which can help foster a sense of connection and empathy between the interviewer and participant. An interview guide was followed to improve trustworthiness, and the study was reported in accordance with the COREQ guidelines.

Conclusions

In Sweden, the regulatory framework on ORA (characterized by a default lack of access for adolescents aged 13-15 y and their parents) and a lack of available information on access extensions creates challenges for parents of adolescents with serious health issues. Both adolescents and parents desire consistent access to the EHR that considers adolescents' growing need for privacy. While there is parental reluctance to support adolescent ORA due to concerns about potential harm and low perceived need, adolescents experience benefits from ORA that parents are not aware of, and vice versa. Informing adolescents, parents, and HCPs about experienced benefits and access regulations could improve partnerships, reduce distress, and facilitate adolescent care.

Acknowledgments

The authors are grateful to all participating adolescents and parents who shared their views and experiences, making this study possible, and feel privileged to have received their insights. Furthermore, the authors would like to acknowledge Lillemor Berntsson and Linn Ullberg Anderson at Uppsala University Hospital as well as the patient organizations that helped in recruiting participants. The authors would also like to thank the young experts panel at Uppsala University Hospital and the adolescents and parents who provided their input on the study material.

Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File (Adobe PDF File), 105 KB - pediatrics_v8i1e63270_app1.pdf]

Multimedia Appendix 2
Surveys in English and Swedish.
[PDF File (Adobe PDF File), 145 KB - pediatrics_v8i1e63270_app2.pdf]

Multimedia Appendix 3
Interview guides in English and Swedish.
[PDF File (Adobe PDF File), 1318 KB - pediatrics_v8i1e63270_app3.pdf]

Multimedia Appendix 4
Demographics and detailed results.
[PDF File (Adobe PDF File), 76 KB - pediatrics_v8i1e63270_app4.pdf]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
EHR: electronic health record
HCP: health care professional
ORA: online record access
PAEHR: patient-accessible electronic health record
REDCap: Research Electronic Data Capture
RQ: research question

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Original Paper

Digital Health Program to Support Family Caregivers of Children Undergoing Growth Hormone Therapy: Qualitative Feasibility Study

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Abstract

Background: Caregivers of children with growth hormone deficiency often face emotional challenges (eg, stress) associated with their children's health conditions. This psychological burden might affect children's adherence to treatment and hinder their health-related quality of life (HrQoL). This assumption is leading to seriously considering multidimensional clinical approaches to pediatric health conditions where the emotional well-being of caregivers should be accounted for to optimize children's health outcomes. Novel mobile health (mHealth) solutions based on emotional and behavioral change techniques can play a promising role because they are increasingly used within different health areas to support adaptive psychological functioning. However, whether and how mHealth solutions of this type of emotional well-being support caregivers of children with growth-related problems is an issue that needs to be clarified.

Objective: This study aimed to gather qualitative information to better understand individualized experiences of caregiving of children undergoing growth hormone therapy (GHt) and perceived barriers or facilitators for the adoption of an mHealth solution called Adhera Caring Digital Program (ACDP).

Methods: A total of 10 family caregivers were recruited at Miguel Servet Children's Hospital, and they engaged with the ACDP for 1 month. The ACDP is a mobile-based digital intervention focused on promoting the overall well-being of family caregivers which provides access to personalized education, motivational mobile-based messages, and mental well-being exercises such as mindfulness or respiratory exercises. Subsequently, an individual semistructured interview was performed to gather qualitative user experience information.

Results: The digital intervention was well-received. The ACDP was found to be useful, easy to use, and understandable, addressing all the difficulties expressed by caregivers. It was also noted to be particularly helpful at the beginning of the treatment and, for some families, became a natural tool that strengthened the parent-child relationship.

Conclusions: The ACDP is a promising and well-accepted tool that enhances the experience of patients and caregivers. It improves the management of growth hormone deficiency and promotes the overall well-being of family caregivers.

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Trial Registration: ClinicalTrials NCT04812665; https://clinicaltrials.gov/study/NCT04812665
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KEYWORDS
growth hormone deficiency; mobile based solutions; caregivers; technology acceptance; digital health; children; therapy; feasibility study; health condition; psychological burden; quality of life; wellbeing; pediatric; mobile Health; mHealth; behavioral change; parent-child relationship

Introduction

Growth hormone deficiency (GHD) in infants is a treatable disease that causes short stature [1]. The most used growth hormone therapy (GHt) for the pediatric population is a daily injection of a recombinant human growth hormone (rhGH) [2]. The daily administration is performed out of the clinic and requires patients and caregivers to be active and engaged in the self-management of this health condition. This active self-management is of paramount importance because poor adherence to rhGH treatments can lead to reduced efficacy and increased health care costs [3]. However, as the rhGH treatment can last many years, self-management is challenging for patients and caregivers [4], and suboptimal adherence to the treatment has been constantly reported in the literature [5]. Several factors such as missed injections, poorer level of treatment understanding, discomfort with the injections, and misperceptions about the consequences of missed doses have been reported as potential causes of poor adherence [5].

Children with GHD often have to address other issues related to their short stature that impact negatively on their quality of life. As exemplified, Stephen et al [6] found that children with GHD had significantly worse quality of life and cognitive functions than children with normal stature. Varni et al [7] found that children with short stature, including those with GHD, reported statistically significantly worse fatigue than healthy children. Social withdrawal, shyness, anxiousness, and depression have also been reported as a consequence of GHD [8-15].

Caregivers play a key role in the management of the GHD. They are responsible for the treatment management and administration of GHt to children who are not autonomous enough. Furthermore, they have the responsibility of managing their children's health condition, including all children's quality of life issues. This role is not premeditated nor chosen, so caring could turn out to be burdensome and affect the caregiver both psychologically and physically [16]. For instance, stress was one of the reported consequences of caring for children living with GHD, presenting higher levels of stress among parents whose children were receiving GHt, but still had short stature [17]. This higher stress level may impact their environment, their health, and treatment adherence [16]. Therefore, caregivers are at risk of developing psychosocial problems, such as anxiety and depression, that could seriously impact the child's health management. As an example, parental stress has been associated with poorer adherence of children to medical treatment [18]. Therefore, some authors have recommended assessing routinely caregivers' stress and conducting psychosocial interventions aimed at promoting caregivers' adaptation outcomes [17].

Currently, the health care sector is being transformed to benefit from the use of information and communication technologies. Digital health enables more accessible and potentially cost-effective alternatives to deliver family-centered interventions. Few studies have reported promising results on the efficacy of mobile health (mHealth)–based interventions for caregivers of children with chronic conditions [19]. Digital solutions, especially mobile apps, supporting patients and caregivers in the management of their disease have experienced significant and rapid growth. In GHD, Fernandez-Luque et al [20] found and analyzed 76 mHealth apps related to growth monitoring and growth hormone treatment available in the Android app store (Google). Most of these apps were intended for patients and caregivers. Some of the functionalities included in these self-management apps were education about GHD, education about growth tracking, and supporting and tracking adherence. However, the quality of digital health solutions is often not high enough and issues, such as trustworthiness or data privacy, are not appropriately addressed. This fact may lead to reduced adoption and engagement rates and, therefore, impact the effectiveness of the health interventions. In addition, the acceptability of digital health solutions by targeted users (patients or caregivers) is a key factor that also impacts the effectiveness of these interventions. Patients or caregivers will be reluctant to use digital health solutions that they do not find appropriate for them. There is still a need for conducting research on understanding the factors impacting caregivers' adoption and acceptance of the use of mHealth apps supporting them in the management of pediatric diseases.

Several technology acceptance models and theories such as the Technology Acceptance Model (TAM) [21] or the Unified Theory of Acceptance and Use of Technology (UTAUT) [22] have been proposed in the literature. The UTAUT and its versions have been widely used in digital health [23-25]. The UTAUT proposes that 4 constructs play a significant role as direct determinants of user acceptance and usage behavior—performance expectancy, effort expectancy, social influence, and facilitating conditions. Performance expectancy is defined as "the degree to which an individual believes that using the system will help him or her to attain gains in job performance." This construct is related to concepts such as perceived usefulness, extrinsic motivation, and outcome expectations. Effort expectancy is defined as "the degree of ease associated with the use of the system." This construct is related to perceived ease of use. Social influence is defined as "the degree to which an individual perceives that important others

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believe he or she should use the new system." This construct is related to subjective norms. Finally, facilitating conditions are defined as "the degree to which an individual believes that an organizational and technical infrastructure exists to support the use of the system." In addition, the UTAUT defines 4 moderators (gender, age, voluntariness, and experience) that influence these determinants.

This research aims to gather qualitative information to better understand the psychological burdens experienced by caregivers of children undergoing growth hormone treatment, as well as the perceived barriers and facilitators related to accepting an mHealth solution that supports the self-management of GHD.

Methods

Recruitment

A total of 10 volunteer caregivers of children with GHD being treated by the physician AA from the Pediatric Endocrinology Unit at the Miguel Servet Children's University Hospital were invited to participate during face-to-face hospital visits. The sampling was selected by convenience from June to July 2021, and none of them refused to join the study. To be included in the study, all the described criteria had to be met (Textbox 1).

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Adherence to growth hormone therapy (GHt) monitored in the last month before enrollment indicates a ratio of less than 85% (since it has been considered as an index of relatively suboptimal adherence) [26,27].
- Legal guardian of children who receive GHt in accordance with approved indications in Spain.
- Explicit agreement on data sharing regarding adherence to GHt gathered through Easypod Connect (a digital platform that monitors GHt).
- Participants must not report any limitations in the use of smartphones and smartphone apps.
- Participants must accept the terms of use and agree to install the Adhera Caring Digital Program mobile-based intervention app.
- Participants must sign the specific informed consent form for the study.

Exclusion criteria

- Candidates without an Android or Apple smartphone because the solution only works through these 2 operating systems.
- Reporting any limitation in the use of smartphone apps.
- Only 1 legal guardian per child can participate in the study.

Procedures

At baseline, participants were requested to sign the informed consent and asked about demographic data and distress assessed by the Depression, Anxiety, and Stress Scale–21 (DASS-21) in its version in Spanish. After being introduced to the mHealth solution, they were guided to download, install, and configure the app on their own mobile phone. They were granted a free month of full access to the Adhera Caring Digital Program (ACDP).

After enrolling in the ACDP for 1 month, user experience was assessed with a semistructured interview. All the research was performed in Spanish.

Ethical Considerations

The current research was approved by the Ethical Committee CEICA (Comité de Ética de la Investigación de la Comunidad de Aragón; number CP-CI PI20/494). All procedures followed were in accordance with the Helsinki Declaration of 1975, as revised in 2000. Participation in the study was voluntary and anonymous; no compensation was given. All participants gave their informed consent. Audio recordings were deleted once transcribed. All personal information was deidentified.

Measures

DASS-21 Scale

The DASS-21 is a self-reported questionnaire divided into 3 scales that measure the emotional states of depression, anxiety, and stress. Each scale has 7 items, which are graded on a Likert scale from 0 to 3 (0: did not apply to me at all, 1: applied to me to some degree or some of the time, 2: applied to me to a considerable degree or a good part of the time, and 3: applied to me very much or most of the time). The scores are calculated by measuring the result of each scale multiplied by 2. The final result is classified as normal, mild, moderate, severe, or extremely severe [26,27].

Qualitative Interview

A semistructured interview was designed in order to gather the user experience after joining the ACDP for one month.

Adhera Caring Digital Program

The ACDP is a mobile-based digital intervention focused on promoting the overall well-being of family caregivers which provides access to personalized education, motivational messages, and mental well-being exercises such as mindfulness or respiratory exercises. In this study, participants were invited to participate in the program for 4 weeks [28].

Psychoeducational modules provide educational content for parents or guardians of children with GHD (refer to Figure 1

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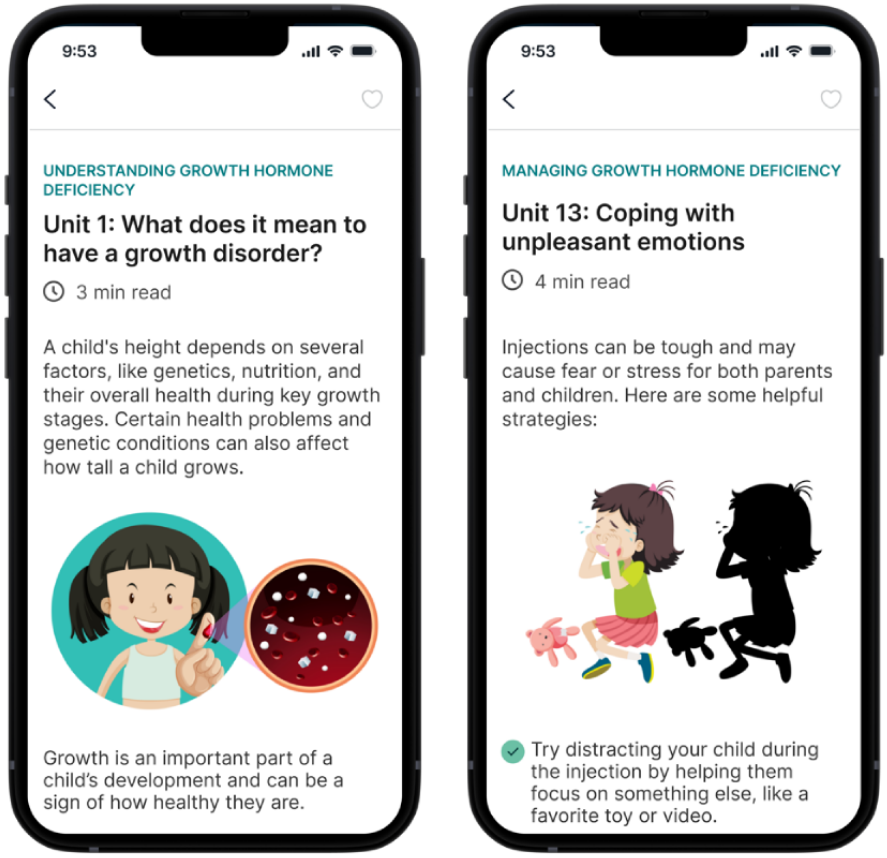
for some examples). The contents include 39 units, classified into four sections: (1) managing GHD, (2) health habits to improve dealing with GHD, (3) adjusting to living with GHD, and (4) taking care of yourself to be able to take care of your child.

The program also includes a behavioral change module which complements and strengthens the knowledge of the psychoeducational module and provides lifestyle suggestions and action planning. It is done by delivering brief messages created by a multidisciplinary team of experts, including doctors and psychologists. The artificial intelligence–driven Adhera Precision Digital Companion Platform will select the tailored mobile-based messages to be sent (so the message selected will be personalized according to the patient profile, interests, and other peculiarities) [29]. This program incorporates the principles of personalized health education into a mobile platform, achieved by applying the Integrated Model of Behavioral Change [30] which is further expanded using recommender systems.

The ACDP is part of the Adhera Health Precision Digital Companion Platform, which has been developed using the best practices regarding data protection and quality management in accordance with the guidelines of ISO (International Organization for Standardization) 27001 and ISO 13465.

Figure 1. An Educational Unit within the app.



Interview Data Collection and Analysis

Participants were individually interviewed by 2 trained doctors (physicians) from the hospital. The training was provided by the sponsor's principal investigator through a workshop. The interviews were performed at the hospital or by secured video calls with caregivers or family and researchers being involved only. The mean duration of each interview was approximately 15 minutes. Individual interviews were anonymous, audio-recorded, manually transcribed, and anonymized by MP. MP and AJ-D managed and analyzed the transcripts using ATLAS.ti (Lumivero) Scientific Software Development GmbH (ATLAS.ti version 7.5.4 1993-2012 Windows). They performed an independent parallel analysis and arrived at the same conclusions regarding the themes that emerged during the interviews. Some translations of the interview can be consulted in Multimedia Appendix 1.

A data-driven inductive strategy was generally followed. However, some UTAUT model concepts [31] were considered regarding some aspects of technology acceptance, following a deductive-like approach in this specific case. The study followed the consensual qualitative research methodology [31,32]. In this approach, core ideas are identified and organized into categories, which are embedded in broader domains. To do so, 2 reviewers (MP and AJ) independently extracted and organized the data. They then compared their findings in a series of feedback meetings to ensure objectivity and reach interrater consensus. A third reviewer (RH) was consulted in case of discrepancy.

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Results

Overview

The characteristics of the sample (n=10) are described in Table 1. The majority of participants were female (80%) with a mean age of 44.9 (SD 4.41) years. Most of the caregivers were married (70%). In terms of education, the majority held a university degree (70%). The children were primarily female (70%) with a mean age of 10.6 (SD 2.5) years. The average age at the start of was 5.9 (SD 1.66) years and had been under treatment for a mean of 60.3 (SD 23.59) months. The mean adherence rate was 73.44% (SD 28.6).

Table 1. Descriptive characteristics of the sample.

Characteristic	Statistical value (N=10)
Caregiver's sex, n (%)	
Male	2 (20)
Female	8 (80)
Caregiver's age, mean (SD)	44.9 (4.41)
Caregiver's marital status, n (%)	
Married	7 (70)
Divorced	3 (30)
Education, n (%)	
High school	2 (20)
Professional training	1 (10)
University degree	7 (70)
Child's sex, n (%)	
Male	3 (30)
Female	7 (70)
Child's age, mean (SD)	10.6 (2.5)
Child's age at the start of the treatment, mean (SD)	5.9 (1.66)
Time under treatment (months), mean (SD)	60.3 (23.59)
Adherence rate to growth hormone therapy (%), mean (SD)	73.44 (28.6)

DASS-21 Scale

At baseline, DASS-21 showed that the majority of participants had no symptoms of depression (70%), anxiety (90%), or stress (70%). However, some of the participants had mild (20%) or moderate (10%) depression, severe anxiety (10%), and mild (20%) or severe (10%) stress, as described in Table 2.

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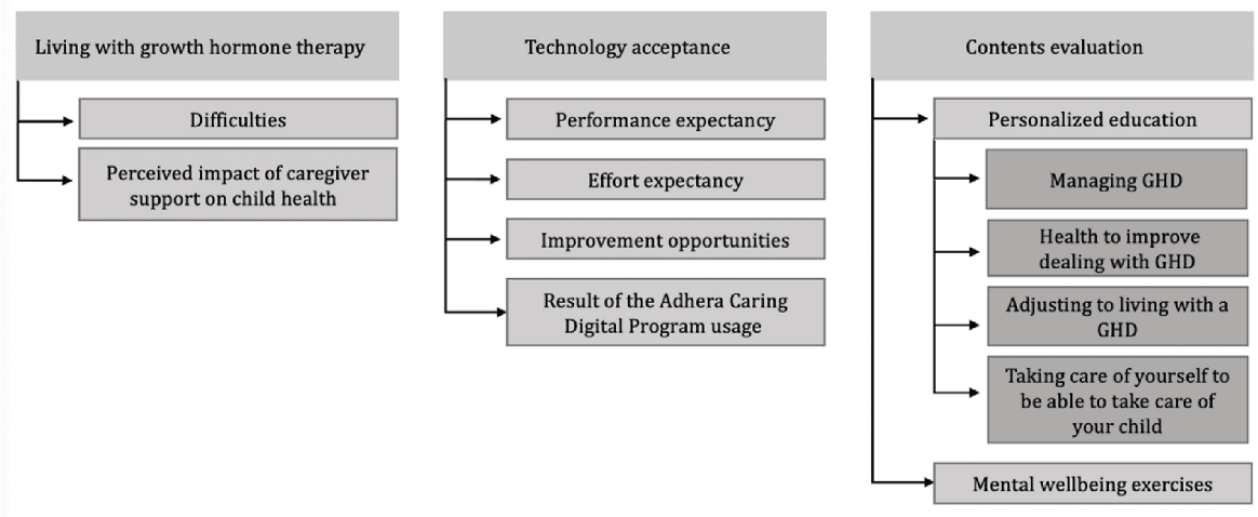
Table 2. Depression, Anxiety, and Stress Scale–21 results on baseline.

	Participants, n (%)
Depression	
Normal (0-4)	7 (70)
Mild (5-6)	2 (20)
Moderate (7-10)	1 (10)
Severe (11-13)	0 (0)
Extremely Severe (14+)	0 (0)
Anxiety	
Normal (0-3)	9 (90)
Mild (4-5)	0 (0)
Moderate (6-7)	0 (0)
Severe (8-9)	1 (10)
Extremely severe (10+)	0 (0)
Stress	
Normal (0-7)	7 (70)
Mild (8-9)	2 (20)
Moderate (10-12)	0 (0)
Severe (13-16)	1 (10)
Extremely severe (17+)	0 (0)

Interview Results

A total of 3 domains were identified as shown in Figure 2, that are living with GHt, technology acceptance, and contents evaluation, containing a total of 8 categories. Furthermore, 1 category comprehended 4 subcategories.

Figure 2. Categories or themes identified in the interviews. GHD: growth hormone deficiency.



Living With Growth Hormone Therapy

This domain encompasses the perceived impact of dealing with this condition on caregivers' everyday lives. In total, 2 categories were highlighted, difficulties and perceived impact of caregiver support on child health.

Difficulties

This category was not included as a specific question of the semistructured interview. However, caregivers expressed concern about common issues. Beyond the diagnosis, participants reported children's behavioral issues and individual characteristics that hinder the treatment administration. For instance, the child's difficulties in understanding the disease promoted their refusal of hormone treatment.

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> *She is a complicated child (…) that is my main problem. I do not know if it's something to do with my daughter's character or if I do not know how to deal with it.* [Caregiver 06]

> *The child said "why do I have to do this? I do not mind. I do not mind that people do not like it."* [Caregiver 09]

Daily injections were reported to be difficult for both, children and caregivers. Participants also expressed great concern about their children's lack of autonomy toward treatment. As children get older and socialize outside the nuclear family, the lack of autonomy in treatment becomes more evident, limiting children's independence and increasing caregivers' distress.

> *She will be thirteen this summer, fourteen next summer, and that has caused me a lot of problems. I can't let her sleep anywhere, if I let her, I have to go and perform the injection. Wherever she is. This means that I can't leave her with friends. She tells me, "I want to sleep over." Well, no. If you don't inject by yourself, you can't stay. It is impossible to go camping. It is a medication that has to be in a refrigerator... that she does not inject herself. How are you going to send her? My daughter has never been to camp.*" [Caregiver 02]

Caregivers' fear of hurting their children or mismanaging treatment was also raised.

> *I don't know if there are many children who inject themselves. Maybe there are a lot, but I haven't been able to. It's impossible for him; he has needle phobia.* [Caregiver 02]

> *My mouth went dry every time I had to inject her.* [Caregiver 02]

Perceived Impact of Caregiver Support on Child Health

Participants were asked whether they felt that being supported could influence their children's health. Many participants agreed that it was important to maintain a certain level of calmness and well-being as they could be perceived as role models by the children. Consequently, it is likely that if caregivers are angry or anxious these feelings would be transmitted to their children, increasing resistance to treatment.

> *If the parents feel bad, the children will feel awful (...). If I was stressed at the beginning, I transmitted the stress to the child, and it wasn't good. The children see us as... well, "if mom says that everything is going to be fine, then it will be fine." It is very important [to know] that if we are down, we transmit fear to the children. I think it is very important.* [Caregiver 04]

The importance of achieving personal well-being in order to effectively care for others was also emphasized.

> *It would be the main subject of the twenty-second century: taking care of yourself in order to take care of others.* [Caregiver 09]

Technology Acceptance

This domain highlights that, in general, caregivers expressed a positive attitude toward the use of technology as emotional and self-management support during the growth hormone treatment.

During the analysis, four categories concerning the usefulness of the digital solution were identified, of which the first 2 were directly related to the UTAUT model: (1) performance expectancy, (2) effort expectancy, (3) improvement opportunities, and (4) result of the ACDP usage.

Performance Expectancy

According to the authors, this construct refers to the user's perception of how effectively the technology will help them achieve improvement [31]. In this study, performance expectancy refers to the caregiver's perception of the ACDP's usefulness, regarding emotional support and management of the GHt. Overall, the participants agreed with the idea that digital solutions can be a useful and positive means of supporting the role of caregivers. They often mentioned that the wide variety of resources present in the ACDP allows very different types of families enjoy appropriate support for their specific needs. For instance, some caregivers stated how the ACDP helped them normalize the GHD and explain it openly to their children while paying attention to maintaining children's self-esteem.

> *Overall, I found it very useful, not only the theoretical part but the messages that appear on your cell phone. …. It is not that I see a part that is not useful and another that is more useful. I understand that for each person there may be a part that is more useful than others... But in general, I would give it a 9… (out of 10).* [Caregiver 01]

> *I really liked it because, of course, I didn't know how to encourage my girl and how to explain to her that this is something normal.* [Caregiver 04]

In addition, the ubiquity of the resources in the ACDP, available anywhere and anytime, was also appreciated. This, together with the fact that they perceived the contents of this digital solution to be highly reliable and clinically validated, made the caregivers feel reassured.

> *It is good to include explanations because sometimes in the consultation you feel overwhelmed and end up having doubts. Then the application reminds you everything again.* [Caregiver 03]

> *Well, what I have seen is that this is the information that should be there. ... In a consultation with the doctor, he will explain the medical issues. Then, on your own, you will go to Google and you will also search for medical issues. You will find good, bad, and irrelevant information. In addition, the information might be useful for you or not, and you might rely on information unrelated to your case. That is due to how Google works and how a low-skilled person might interpret the information. Regarding the emotional side, I do consider that it would be a very good path, a very good course or training, to have it at the beginning because it has*

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> *the information that needs to be there. For me, this is the starting point. From there, you can find more, but there's the information you need to have.* [Caregiver 09]

Nonetheless, one parent expressed that they preferred receiving face-to-face support rather than having a mobile app for this purpose. Also, they shared that their child did not have some of the behavioral issues mentioned in the program. Thus, the caregiver stated that they could not apply all the information received within the digital program to make the child understand the need for treatment, but they saw it as useful to support parents.

> *An application, no. A child psychologist, yes. A face-to-face, yes. I don't think the app would be useful [to make the child understand the need for treatment](...) Also, because of treatment insecurities, it would be useful for supporting parents, but through an app, I don't think it would work one hundred percent (...) I think that, apart from an application, a set [of activities] as well. A talk with parents...* [Caregiver 08]

Another person stated that one of the strategies proposed for managing the app was not suitable for their children because of their age. However, the caregiver expressed their will to continue trying other strategies suggested within the digital intervention.

> *And, in fact, I read it again and told her, "well, I'm going to try again and we're going to try to do it like this." Also, XXX is already 7 years old, so distracting her is complicated … no matter how much you form the habit: let's get her involved, let's play music, let's do it in some other way. She realizes it... You cannot fool her anymore. She knows that, in the end, [there is] an injection that she does not want. However, I will try these guidelines and ideas again.* [Caregiver 06]

Effort Expectancy

The effort expectancy concept refers to how easy the users perceive it will be to use a technology or system [31]. In this study, this construct is expressed in terms of the user experience and user interface, the structure of the information, and the degree of understandability.

The ACDP was described as easy to use by 8 participants. The adjectives "intuitive" and "beautiful" were also mentioned by some participants. It was stated that the user experience allows a peaceful state of mind which in turn facilitates the comprehension of its contents. The navigation flow was also appreciated.

> *I did not find it difficult. I found it, on the opposite side, very simple, very comfortable, very pleasant. Even the presentation of the application. Or I don't know what to call it, by folders and then more units. I find it very comfortable. I find it very nice. They are calm, it helps to make it more relaxed reading, which is what is needed for this type of information. It seems to me that you have taken great care of that.* [Caregiver 07]

However, 1 participant reported that she found the app neither pleasant nor unpleasant but contextualizing that was not important for her.

> *Neither particularly attractive nor obviously unpleasant [the application]. No, the design maybe... Because I pay little attention to those things and more to the information.* [Caregiver 01]

Most of the participants did not encounter technical issues while using the app. However, 3 users reported that they could not access a specific kind of notification related to motivational mobile-based messages. Another participant reported having issues accessing but it was smoothly solved through a password recovery process.

Regarding the understandability of the contents within the ACDP, most of the users described them as easily understandable, as the contents were described in a clear manner, using precise, direct, and natural language.

> *It seemed to me a very direct and very clear form of expression. It is very clear that anyone can understand it. That is very important. I found the information very clear. No difficult words or expressions that are difficult to understand. No, on the contrary, it seems to me that it is very well written. For easy understanding, yes. … They are like very short units that make you think. It doesn't make you read everything at once. It makes you think, and it is very good.* [Caregiver 07]

Nonetheless, a nonnative Spanish speaker reported that they would find some difficulties related to technical vocabulary related to the medical condition. These difficulties were solved by searching the words in a dictionary.

Finally, most of the users reported that the content was well-organized in diverse units, and provided brief pieces of information, with an interface similar to that of the social network platforms they are used to. This amount of information allowed for a better acquisition of knowledge and deeper reflections, compared with the relative overload of information that they felt during the diagnostic clinical visit.

> *The simplicity and clarity, the information come in very concise pills. It does not require a super long text that can make you feel tired, the information is very well dosed. … It is distributed in very chewable doses. In the open world we live in, we are more and more used to the Twitter context, with just a few characters. So, I think that this information and training is quite well dosed.* [Caregiver 01]

Improvement Opportunities

This category reflects that there is always room for improvement. The main limitation of the digital program was the moment in the patient journey when the digital program was introduced, which was mentioned by 7 participants. They declared that the digital intervention would have been especially useful right after the initial diagnosis, notwithstanding it still adds value to the GHD management at the present time.

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> *I think I told you that at the beginning. I think it is a very positive, very good application. I think it will help families who are just starting out a lot, it will clarify things for them. And for families that have been using it for a long time, if it is shared with them, it will also strengthen what we have been doing for years. For those who are just starting out, it will really help them a lot more. As I was reading it I was saying "I wish I had had this when I started with this."* [Caregiver 07]

The participants also commented on some desired additional content for the program. The parents mentioned that including techniques to involve the grandparents in the treatment (when possible) would be of interest. Also, a parent proposed including storytelling to reflect the reality of living with GHD. Thus, stories could be read before the treatment application, to help the child understand and normalize both the condition and its treatment.

> *I would look for more alternatives for the parents. It's very good to award prizes, it's very good to motivate them. But the motivation often also comes from the fact that there are alternatives for the children. I don't know [motivation] for them to start self-injecting. I don't know whether to look for other alternatives, other formulas, other... I don't know. Because I am looking for it, I told him, "be aware that if I inject you, you won't be able to stay anywhere. If I inject you, you won't be able to go camping." I don't know, look for some... some story motivating to [complete] a process, as ... the stories for children in the autism spectrum regarding how to go to a birthday, how to behave or socialize. I don't know if there is something uncomfortable like an injection, and there is some story or something that can be read to the children during nights that they can motivate themselves with. I don't know if there are any stories on the market. There surely will be.* [Caregiver 02]

Furthermore, some parents suggested that they would appreciate having a section with testimonials of other families living with GHD so that they could learn from others' experiences, or even get in touch with other families. Finally, a participant stressed the task of having a larger number of mindfulness and breathing exercises.

> *I don't think anything should be removed. Add what I was telling you, apart from those two small meditation and breathing practices. If there were any more, it would be good. I don't know if there could be some kind of sharing of experiences among people who are among parents, among children. Surely there are resources that we can use with each other... or situations how to handle them. I don't know if it is feasible in the application or not.* [Caregiver 06]

Result of the Adhera Caring Digital Program Usage

All the core ideas regarding the benefits of using the program fall within this category. Participants agreed with several benefits that the ACDP had provided them. On the one hand, it allows the normalization of their children's condition. This generates, for instance, increased self-esteem and decreased embarrassment in children. On the other hand, parents indicated that using the app leads to clarification of general concepts and knowledge about the disease, which empowers them. Finally, in the case of joint use with their children, the improvement in the relationship between caregivers and children was highlighted. The above-mentioned practical exercises have been described as "their moment together," which would be missed after the study was completed.

> *It's a perfectly normal thing, it's not like this happened to my daughter and she was born like this. It's normal. It's a disease like any other that can be cured. … she was a little embarrassed and [after] reading that with me... well, "look, I shouldn't be ashamed, that's the way it is. On the contrary, I have to say that I am brave, look. That I inject myself. And I'm going to grow up, and there's no problem." … I think I get along with her much better than before. It gives her more confidence, I don't know how to explain it. We accept it more.* [Caregiver 04]

Contents Evaluation

This domain encompasses the evaluation of the specific contents included in 2 components of the ACDP, personalized educational and mental well-being exercises.

Personalized Education

This category was organized in subcategories regarding the 4 sections of the personalized education section of the ACDP.

A. Managing GHD

In this section of the program, caregivers could obtain general information and advice on treatment management. Although it has been noted that this could be redundant as it is an explanation that the family receives when the patient is diagnosed, most participants agreed that receiving accurate and clear information resulted in a great benefit. Specifically, a sense of increased self-confidence and acceptance was highlighted in both patients and caregivers.

> *This information is missing at the beginning and creates uncertainty. Thinking about what we put in it and what effects it will have.* [Caregiver 08]

Among the most frequent core ideas were advice on how to mitigate the pain of the injection, or the reward system to promote treatment self-management.

> *(Talking about benefits of using the solution). Using ice or talking about something else... the typical advice given to mitigate the pain perception due to injections or the information given. For example, I read that sometimes it causes pain and other times it does not. It is something that we have experienced, and it is not known why. To me, it is something that catches my attention. I never knew if it was because the child was complaining because it really hurts, or because the needle is really very fine. So, I think having that knowledge regarding sometimes it hurts*

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but you don't know why and sometimes it doesn't hurt is really important. [Caregiver 07]

B. Health Habits to Improve Dealing With GHD

Some units of the personalized education section were aimed at promoting healthy habits and, more specifically, enhancing healthier eating and sleeping habits. Overall, these contents were labeled as "interesting" and "important." However, 3 participants reported that they were already aware of that information since it had been provided by schools and pediatric health care providers. To them, this information was not that necessary.

Well, less useful, but not because they are not useful. Perhaps, for example, the component focused on healthy eating. It is very general information, but remembering it is important because not all families have the same opinion regarding diet or the importance of healthy eating. But maybe that's the less useful part if I have to say one. [Caregiver 07]

C. Adjusting to Living With a GHD

Considering the emotional impact of the diagnosis on the children's mental health, the program proposed the necessity of providing clear information about emotions and advice on how to strengthen the bond with the caregivers. Participants evaluated positively this content, being a topic that is rarely addressed by medical staff at diagnosis.

In my case, the first section related to the disorder. I can remember things that perhaps would have been forgotten. [Caregiver 06]

D. Taking Care of Yourself to Be Able to Take Care of Your Child

In line with the aforementioned, it is also important to consider the circular process of caring for oneself in order to care for others. Therefore, more content concerning the emotional management of caregivers was also suggested. They acknowledged the importance of their own emotional issues in the development of their children's treatment.

Mental Well-Being Exercises

These exercises included visually guided mindfulness and breathing exercises. This category gathers the users' opinions regarding mental well-being exercises. A caregiver described that practicing these exercises before applying the treatment had strengthened their relationship.

... I think I get along with her much better than before ... "mom, look what I can do." It gives her more confidence, I don't know how to explain it. ... It's our moment. She even told me the day before yesterday "when I don't do the sessions anymore it will seem strange to me, mom. That was our moment" I think it affects a lot, we talk about many things, and since we read it together (talking about the educational content) ... we commented on it. [Caregiver 04]

Some caregivers expressed their curiosity toward these practical exercises and found them appealing and enjoyable. Only 1 caregiver reported that they did not receive any benefit from these exercises, which might be related to their specific preferences as stated.

I especially liked the meditation practice. And I would tell you, I would include a little bit more. Regarding caregivers, I liked all contents focused on working as a support, as a caregiver. [Caregiver 03]

Discussion

Principal Findings

Caregivers of children undergoing GHt have reported several factors such as difficulties in understanding the disease or fear of hurting their children that may significantly impact the disease management. The role of caregivers is crucial in the management of GHD, and they have reported their well-being as a very important factor in being able to care for their children. Indeed, our results show that some caregivers have symptoms of depression, anxiety, or stress. In these circumstances, digital health enables the provision of digital services and tools supporting them in the care of their well-being and in the management of their children's disease. In this study, caregivers have expressed a positive attitude toward the use of mHealth solutions for health and well-being management. This finding is in line with those reported by other authors [32]. The results of this study support the ACDP as a feasible and potentially effective tool for caregivers of children undergoing treatment for GHD.

Caregivers' empowerment plays a key role in the effective management of GHD. Unfortunately, during routine consultations, it is not always feasible to cover all the aspects and doubts related to chronic diseases [32], especially the mental well-being of the caregiver. Digital health allows the provision of educational materials that are available just in time. Educational content must be designed not only to cover any lack of knowledge but also to encourage, empower, and optimize the caregivers' role as a manager of the GHD. In this study, caregivers realized and expressed the importance of emotional well-being as well as healthy habits and adequate control of unpleasant situations related to their child's condition. Considering that treatment adherence and the patient's health can be influenced by the caregiver's mental health [17], the ACDP can be a valuable part of the caregiver and patient journey. It is especially relevant once some participants expressed that the subcategory "family adjusting to living with a GHD" is not a common subject addressed during the diagnosis consultations. In this sense, participants in this study considered important not only the educational content but also the dispensing time of the digital health solution. Caregivers consider that the digital program is so useful that should be offered right after the diagnosis of the disease. To maximize their usefulness, digital health programs focused on helping caregivers manage their mental well-being and the day-to-day of their children's disease should be offered at the right time. Furthermore, it was suggested to include a testimonials section or a virtual space where families in the same situation can be in touch. These social features may impact user's motivation resulting in an increased adoption rate. This finding reinforces the fact that digital health can offer effective and motivational

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services for caregivers' unmet needs that complement clinical practice [33,34].

Regarding the technology acceptance defined by the UTAUT theory [22-25], ACDP has been perceived positively by caregivers on performance expectancy and effort expectancy. The most important points of digital health solutions are that they can be used autonomously in the natural environment of the user, so usefulness, ease of use, and likeability are key [35,36]. The results indicate that the program seems to adjust to the core aspects of digital solutions as well as to cover all the needs and difficulties of participant caregivers of children and the user experience leads to a peaceful state of mind. Caregivers' stress levels can affect treatment adherence and the child's health [16], so giving them different tools to manage the disease seems to be a cardinal element in improving the quality of life of both. Therefore, understanding the factors that influence caregivers' adoption and acceptance of mHealth apps is essential for the development of effective digital health interventions [20]. Our study contributes to this understanding, addressing the barriers to acceptance, and adoption among caregivers managing pediatric diseases, including data security.

An interesting result is that the program has become a familiar intervention even though its target is caregivers. Some parents used mental well-being exercises together with their children, which has been reported as a great tool to improve the relationship between the caregiver and the child. Further research with higher samples will be conducted to explore deeply this promising result and analyze how this family intervention could impact caregivers' motivation, engagement, and well-being.

Limitations

This is a local study located in Zaragoza (Spain) with a small sample of 10 caregivers. Because of inclusion and exclusion criteria, people with low digital literacy were not able to participate. Interviewers were not experts but received training for the purpose of the study. Besides, although the general prevalence of GHD is higher in boys, most caregivers participating in this study were female with daughters affected with GHD, thus, parents with GHD sons might be underrepresented as well as male caregivers. Finally, the program needs further study to include recently diagnosed children.

Although there are quantitative questionnaires to measure the acceptability of digital solutions [37,38], we opted for a qualitative approach in order to get a more comprehensive understanding of the psychological burden experienced by caregivers of children undergoing growth hormone treatment, as well on the factors that influence the acceptability of the digital solution. Due to the post-positivist nature of the consensual qualitative research methodology, an interjudge reliability index is not calculated. However, trustworthiness in the qualitative analysis is guaranteed through iterative discussions between reviewers to share their independent interpretation of the qualitative data. Where consensus is not achieved, a deeper discussion is held until consensus is reached or a third independent reviewer is consulted.

Conclusions

In conclusion, the ACDP shows good acceptance results for family caregivers of children undergoing GHt. The interviews helped identify aspects for further refinement and improvement of the program, including a more intensive focus on the communication between parents and children. This study provides insights into how digital interventions can better support families of children undergoing growth hormone treatment.

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Data Availability

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

Authors' Contributions

LF-L contributed to conceptualization, funding acquisition, supervision, project administration, methodology, resources, writing-original draft, and writing-review and editing. AA contributed to conceptualization, supervision, investigation, methodology, data curation, project administration, resources, writing-original draft, and writing-review and editing. RCB contributed to funding acquisition, project administration, writing-original draft, and writing-review and editing. SQ-P contributed to formal analysis, visualization, writing-original draft, and writing-review and editing. AS-U and PMC contributed to investigation. RB, AJ-D, MP,

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and RH contributed to data curation, formal analysis, and visualization. OR-R contributed to validation, writing-original draft, and writing-review and edition. No artificial intelligence tools were used in any portion of the manuscript.

Conflicts of Interest

This study is about a digital solution developed and commercialized by Adhera Health. Adhera Health, AA, and OR-R have other collaborations with Merck Healthcare KGaA beyond this study.

Multimedia Appendix 1
Quotes from participants.
[DOCX File , 141 KB - pediatrics_v8i1e55023_app1.docx]

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Abbreviations

ACDP: Adhera Caring Digital Program
DASS-21: Depression, Anxiety and Stress Scale–21

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GHD: growth hormone deficiency
GHt: growth hormone therapy
HrQoL: health-related quality of life
ISO: International Organization for Standardization
mHealth: mobile health
rhGH: recombinant human growth hormone
TAM: Technology Acceptance Model
UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

Community Caregivers' Perspectives on Health IT Use for Children With Medical Complexity: Qualitative Interview Study

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Abstract

Background: Children with medical complexity represent a unique pediatric population requiring extensive health care needs and care coordination. Children with medical complexities have multiple significant chronic health problems that affect multiple organ systems and result in functional limitations and high health care needs or use. Often, there is a need for medical technology and total care for activities of daily living, much of which is provided at home by family and caregivers. Health IT (HIT) is a broad term that includes various technologies, such as patient portals, telemedicine, and mobile health apps. These tools can improve the care of children with medical complexity by enhancing communication, information exchange, medical safety, care coordination, and shared decision-making. In this study, we identified children with medical complexity as children aged <21 years who have >3 chronic health conditions. Community caregivers contribute to the care management of children with medical complexity, serving as advocates and coordinators, primary sources of information about children's needs, and facilitators of access to care. They are often the first point of contact for the families of children with medical complexity, particularly in vulnerable communities, including families in rural areas, low-income households, and non–English-speaking immigrant populations.

Objective: This study aims to introduce the HIT needs and preferences for children with medical complexity from the perspective of community caregivers. By including their perspective on HIT development, we can better appreciate the challenges they face, the insights they offer, and the ways in which they bridge gaps in care, support, and resources.

Methods: We conducted semistructured interviews (n=12) with formal community caregivers of children with medical complexity populations from a parent advocacy network on the US East Coast. Interviews were audio recorded via Zoom and then transcribed. An inductive thematic analysis was conducted to reveal HIT challenges and preferences for improving the care of children with medical complexity.

Results: We categorized the interview results into themes and subthemes. There are four main themes: (1) telehealth transforming care for children with medical complexity during the COVID-19 pandemic, (2) suggested tools and technologies for care for children with medical complexity, (3) HIT feature preferences, and (4) transition to adult care. Each theme had multiple subthemes capturing all details related to design features of needed technologies.

Conclusions: The study emphasizes the need to develop and enhance HIT for the care of children with medical complexity. The identified themes can serve as design guidelines for designers by establishing a foundation for user-centered HIT tools to effectively support children with medical complexity and their families. Telehealth and mobile health apps could improve care management and quality of life for children with medical complexity.

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KEYWORDS

pediatric care; children with medical complexity; family-centered care; health information technology; health care software solutions; mobile phone; artificial intelligence

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Introduction

Background

Children with medical complexity are a unique group within the pediatric population, characterized by diverse and significant medical needs. Though they represent <1% of children in the United States, children with medical complexities face chronic health conditions that are severe and enduring [1]. These children, all aged <21 years, often have congenital or acquired multisystem diseases or severe neurological conditions that lead to substantial functional impairments [2]. Although there is no universal definition, we used the most common criteria in our study for children with medical complexity as children aged <21 years who have >3 chronic health conditions [2].

Caring for children with medical complexity requires collaboration among stakeholders, including parents, health care providers in hospitals and clinics, school and home nurses, and community caregivers. Despite efforts, the challenges in coordinating care for these children persist, remaining largely unresolved [3]. These challenges include barriers to technology systems, inadequate access to health information, and a lack of partnership in care [4]. The burden of managing these complex medical needs falls heavily on parents, who often experience a significant caregiver burden [5].

Various technologies have been used in health care to improve the quality-of-care process. Health IT (HIT), including patient portals, telemedicine, and mobile health apps, has the potential to help with data management, sharing, and care coordination [6]. These HITs can positively impact medical outcomes, including physical, psychological, and continuity of care [7], minimize medication errors, and provide safer care [8]. For instance, telehealth emerged as a primary technology to provide safer care to children with medical complexity during the COVID-19 pandemic. Children with medical complexity is a vulnerable population that can benefit from technological interventions to improve care management, including information exchange, shared decision-making, and follow-up [9]. However, there is a need for studies to evaluate the effectiveness of HIT in caring for the children with medical complexity population and to identify the challenges and limitations associated with it. It is also critical to explore strategies for safely and effectively integrating HIT into the overall care management of children with medical complexity [10-12].

While parents are responsible for the day-to-day care of their children, community caregivers play a broader role by helping parents navigate complex health care systems. In addition, they ensure that children with medical complexities become fully participating and contributing members of their communities [13]. Community caregivers contribute to the care management of children with medical complexity, serving as advocates, coordinators, primary sources of information about children's needs, and facilitators of access to care [13]. In addition, they support families in vulnerable communities who have a child with a medical complexity, including families in rural areas, low-income households, and non–English-speaking immigrant populations [13,14]. Their experience navigating health care systems and HIT enables them to identify gaps in care and areas for improvement. Understanding their feedback and perspective on the use of technology in care for children with medical complexity is essential.

Objective

This study aimed to fill this gap by exploring how current tools and technologies are used and how they can be further optimized to meet the specific needs of children with medical complexity from the viewpoint of community caregivers. By gathering their insights, challenges, and recommendations, this study seeks to guide the development of technological solutions that enhance communication among stakeholders and improve the quality of life for children with medical complexity and their families. To our knowledge, this is the first study to specifically address technology suggestions from the perspective of formal community caregivers.

Methods

Study Design and Data Collection

We recruited formal community caregivers of children with medical complexity populations from the Parent Advocacy Network organization based in New Jersey in the United States, which was founded by the parents of children with special needs in 1987 to provide support to the families of patients with special needs [13]. The staff have supported >500 families of children with medical complexity in New Jersey for many years. We disseminated an informative recruitment email to all the staff members to participate in our study. Most of the staff are also parents of patients with special needs. We used a theoretical data saturation approach in recruitment. The saturation level was determined as the stage where adding more interviews would no longer enrich the conceptual depth of existing themes or reveal additional themes [15]. We ended up with 12 in-depth, semistructured interviews conducted from April 2023 to August 2023. Most (11/12, 92%) participants were female, and (1/12, 8%) participants were male. This study has an exploratory nature to identify various suggestions and needs in HIT design requirements for care for children with medical complexity. The exploratory nature of a qualitative approach generates very rich data and allows us to capture the caregivers' detailed experiences in the matter.

We conducted audio interviews over Zoom (Zoom Video Communications) and recorded all the interviews to be transcribed verbatim for the analysis. The interview guide included questions on the pros and cons of technologies used in care for children with medical complexity, user preferences and needs, suggestions for improving current technologies, telehealth experiences during the COVID-19 pandemic, and design recommendations for new technologies. We did ask probes when necessary to capture more details in unbiased ways. The audio interview was over Zoom per institutional review board requirement, so we did not record the video or observe any nonverbal cues. Each interview lasted from 45 to 60 minutes, and the participants' comfort level determined the duration in continuing to disclose their perceptions and share their experiences.

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Data Analysis

The interviews were recorded, transcribed, and analyzed using inductive thematic analysis. The raw data were initially labeled into themes to capture essential data. The themes emerged upon comparing experiences views, situations, and contexts from the same and different participants, and we gradually refined the coding schema. We emerged themes by comparing experiences, views, situations, and contexts from the same and different participants and gradually refined the coding schema. The first author (FE) coded the data and created the themes and a codebook, which the second researcher (OA) validated and refined. Both authors performed the coding using Excel (Microsoft Corp).

During the data analysis process, the authors used an inductive approach to identify themes and understand technological needs, preferences, available options, challenges, and suggestions for improvements. The inductive approach is characterized by a search for patterns [16]. We identified 4 primary themes with their codes. After coding the data, both authors collaborated to categorize the data within each theme into subthemes. Subthemes define common dimensions within the main theme [17]. The objective was to explore the data beyond identifying common or dominant themes to uncover unique insights [18].

Ethical Considerations

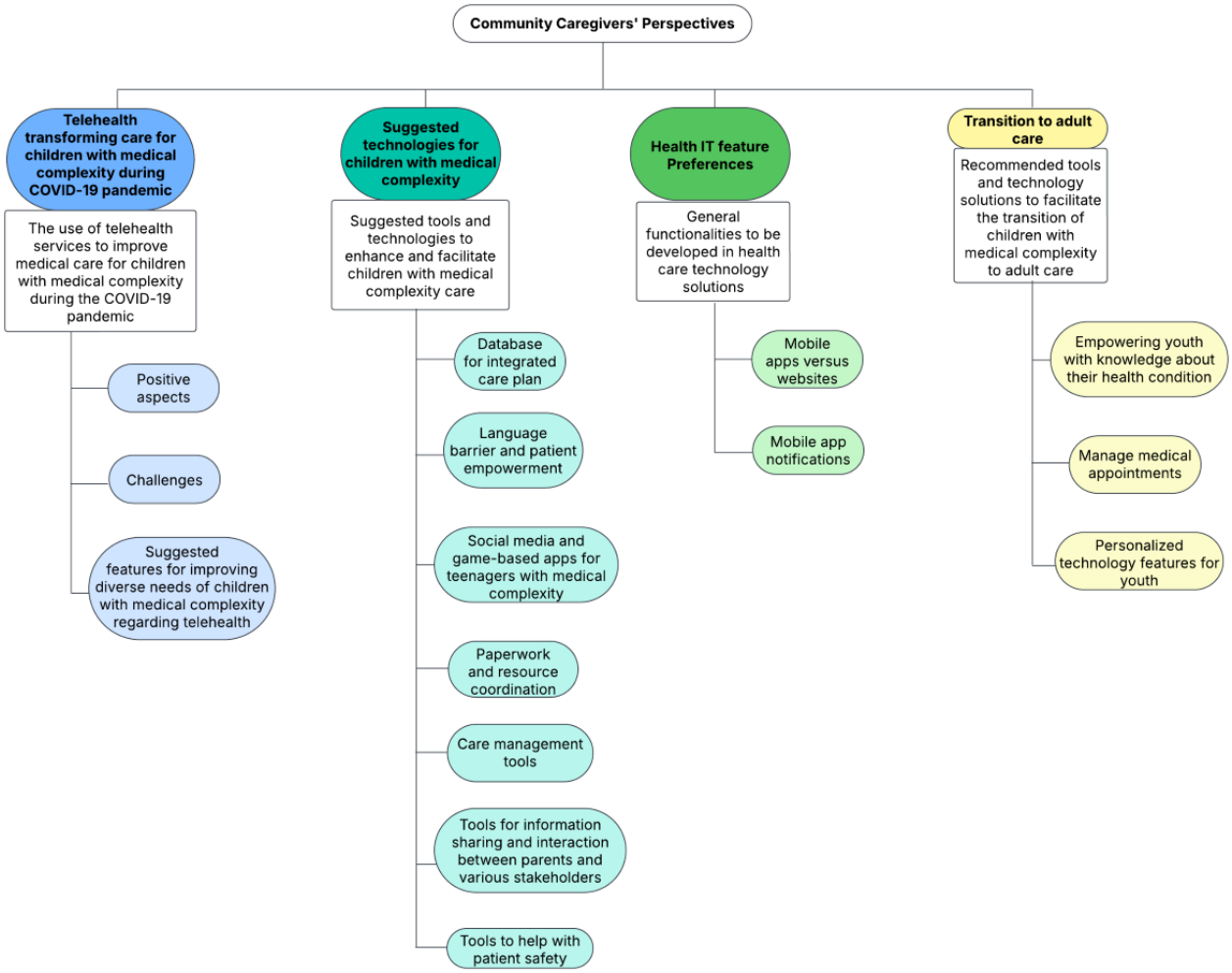
This qualitative study used semi-structured interviews to collect data after obtaining ethics approval (ID 2023-006 (N)) from the Stevens Institute of Technology. The data was de-identified and does not include any identifier. Participants were paid 30 dollars compensation upon completion of the interviews.

Results

Overview

The inductive analysis resulted in four major themes: (1) telehealth transforming care for children with medical complexity during the COVID-19 pandemic, (2) suggested tools and technologies for care for children with medical complexity, (3) HIT feature preferences, and (4) transition to adult care. Figure 1 shows the 4 major themes and associated subthemes.

Figure 1. Identified major themes and subthemes.



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Theme 1: Telehealth Transforming Care for Children With Medical Complexity During the COVID-19 Pandemic

The first primary theme identified from the thematic analysis was telehealth use, which is defined as using telehealth services to improve medical care for children with medical complexity health needs during the COVID-19 pandemic. We also developed several subthemes for positive and negative perceptions regarding telehealth use in care for children with medical complexity and suggestions to improve telehealth technologies for care for children with medical complexity from caregivers' perspectives.

The diverse needs of children with medical complexity result in varying health outcomes from telehealth services, depending on the child's medical condition during the COVID-19 pandemic. For example, participant 9 reported improvements in the child's health through telehealth visits, while participant 10 expressed dissatisfaction with the health outcomes achieved through telehealth therapy sessions:

> *They are all so different. I have one parent that I know when they went virtual, it worked beautifully with her daughter, who has limited speech. It helped so much because she was able to navigate everything. She had clear expectations. She is very visual. So it actually helped a lot.* [Participant 9]

> *Occupational therapy, or the physical therapy or speech therapy, even some of these therapy sessions cannot be offered for children who have very limited understanding or limited functional skills so having those virtual sessions were not beneficial for them, or meaningful for them. For example, if the child cannot follow a direction because of their cognitive ability, or because of that developmental status, then the virtual therapy is not meaningful for them. If the physical therapist is giving the child this direction but then the child cannot move, so the parent has to be right next to the child so that they can either assist the child or they can model that to the child. So then it is a barrier. If the parents are busy with their work, or if they have other commitments then the child is not getting the meaningful therapy sessions.* [Participant 10]

However, the participants who are the community caregivers shared common points regarding positive aspects, challenges they observed children with medical complexity parents experiencing, and ideas for improving telehealth services. Multimedia Appendix 1 presents subthemes of the positive aspects of telehealth as perceived by participants, alongside the challenges and limitations they experienced. It also includes suggestions for improving telehealth services to address the diverse needs of children with medical complexity. We reported at least 1 sample quote for each identified subtheme. Positive aspects include just-in-time access to care services (telehealth provides easier access to a variety of needed health care providers), facilitating physician-patient or parent interaction (telehealth facilitates interaction and communication between parents and providers during the COVID-19 pandemic), and overcoming geographical barriers (mitigating the barriers in health care services resulting from physical distance). However, participants also identified several challenges, including technical difficulties (the challenges and issues related to the technology used for telehealth appointments that impact the accessibility of services), a lack of communication while transitioning to telehealth during COVID-19 pandemic (the difficulties experienced due to unclear communication while shifting to telehealth services during the COVID-19 pandemic), and simplicity for non–tech-savvy parents (the need for technology that is easy to use and navigate, especially for parents who are not comfortable using various digital tools). In addition, participants suggested several features to improve telehealth for children with medical complexity, including visual graphics (using visual elements to enhance communication and engagement during the telehealth session), educational components (enhancing users' understanding of telehealth), video and audio support (the critical need for high-quality video and audio technology in telehealth to facilitate effective and accurate communication between health care providers and patients), questionnaire addition (the integration of questionnaires into telehealth services), and providing variety of ways to communicate (offering diverse methods to facilitate communication for patients who may find it challenging to express themselves).

Theme 2: Suggested Tools and Technologies for Care for Children With Medical Complexity

This theme covers suggestions for developing tools and technologies to enhance and facilitate care for children with medical complexity. Participants suggested developing various tools and technologies to support themselves or the parents of children with medical complexity, along with the features to be added to existing technology, as shown in Multimedia Appendix 2. One suggestion was the creation of a database for integrated care plans, a comprehensive system to help families manage and coordinate all aspects of their child's health care. This would serve as a centralized database to provide a clear and organized record of their child's information:

> *The parents need to keep records and, when anything changes, be ready and clear on what needs to happen. Even if a home nurse is coming to assist the parents, the parents are still, as I like to refer to them, the captain of the ship. They are the ones who need to know everything there is to know about their child's health.* [Participant 12]

Participants also recommended tools to address language barriers and empower patients, aiming to overcome communication challenges between parents and health care providers arising from differences in languages or communication styles:

> *It becomes even more complex for my underserved families. For example, if the nurse needs to talk to the child's doctors because the parent does not speak English, the parent should still be included in all of those conversations.* [Participant 5]

> *Some of the medical terminology is very difficult to translate into the parents' native language. Although we have the technology in place, certain medical*

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> *terms cannot be translated or interpreted in a way that parents can understand.* [Participant 7]

To enhance social development for teenagers with medical complexity, suggestions included social media and game-based apps designed to improve social skills and provide relevant health care information in engaging formats:

> *When things are developed in a very controlled setting, they work fabulously. However, as they trickle down into real life and society, and real people use them, often the system itself does not work as it should. For example, a system that allows communication without speech by exchanging pictures might help children, but instead of encouraging language development, it may lead to them becoming too comfortable using pictures. When applied in real time, this is very challenging for them, and they are not motivated to become verbal. I have heard many parents complain about this. These should be considered social skill lessons. If a game or solution could be developed and applied to real life, that would be great.* [Participant 11]

Paperwork and resource coordination tools were also highlighted to help families organize and track paperwork and resources associated with their child's care:

> *Sometimes families are not always that organized. One of the things we always advise families is to write down information when they go to the doctor's office, whether in person or virtually. We encourage them to learn how to communicate effectively with doctors and schools and to centralize their paperwork in one place. Managing all the documents, doctor's notes, and medication records can be overwhelming, so it is important to teach families how to keep everything organized.* [Participant 3]

Regarding care management tools, participants suggested tools to assist parents with scheduling, tracking appointments, and managing medications:

> *Medications themselves can be particularly difficult to manage. Understanding and managing prescriptions, including knowing when to refill medications. There are complex instructions like "do not give this one with that one," "take this one with food," "this one needs to be refrigerated," and "this one is an intramuscular injection." With so many different medications and dosages, it can be overwhelming. For example, the same medication might require two pills in the morning and only one at night, which can change on the same day.* [Participant 3]

In addition, suggestions were made for tools to facilitate the exchange of information between parents, medical providers, and other care providers. Effective communication is essential for informed care coordination and comprehensive childcare:

> *Text-like feature that allows parents to choose who they want to include in a conversation. Parents do not necessarily want the school involved when it comes to medical matters. But it could have that option where the parent can choose to include people. It should have easy access to sharing and being able to pick and choose what you share and with whom. Making sure that the parent has control and is aware of who is getting what information.* [Participant 9]

Finally, the participants suggested tools to minimize risks and prevent errors in the care of children with medical complexity:

> *I think there is a need for tools and features that support children with medical complexity care to minimize risks. Unfortunately, families are sometimes the care managers. So, for example, if a child needs a diet for a gastrointestinal condition, yet also has kidney disease. They would need to consult with the medical team before they could give that diet and often that does not happen. The family has to say that this child has this medical condition and has to coordinate care between different teams, and it should not be that way, particularly with the availability of electronic health records. But unfortunately, they do not necessarily read the charts, or they are so siloed that they are only focused on their specific specialty.* [Participant 5]

Theme 3: HIT Feature Preferences

The analysis showed another major theme around general recommendations preferred in HIT. This theme may assist system and software engineers in developing effective platforms that meet the needs of parents and supporters of children with medical complexity. Understanding these shared preferences is essential for designing technology that provides meaningful support and enhances engagement. The participants expressed their preferences for mobile apps and websites. They valued the convenience of mobile apps for quick access. In addition, mobile apps are beneficial for caregivers or patients with disabilities. However, they recognized that older adults caring for grandchildren with medical complexity prefer websites for their ability to display information on larger screens, such as laptops. The participants also emphasized the importance of mobile app notifications in coordinating care by providing timely reminders for caregivers. Table 1 presents the participants' perspectives on mobile apps and websites.

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Table 1. Perspectives on mobile apps and websites.

Subthemes and definitions	Quotes
Mobile apps versus websites (the comparison between mobile apps and websites in terms of preferences)	• "Mobile access provides much more freedom. You do not need to have your laptop with you; if you are outside, you can still access data through your mobile device. However, many grandparents who take care of their grandchildren might not be able to have or use mobile apps." [Participant 10] • "I think it is important to have something that is not so cumbersome, something they can pull out and use, which is a phone. The invention of the smartphone might have so many capabilities for individuals with disabilities." [Participant 12]
Mobile app notifications (the importance of mobile app notification feature for caregivers)	• "I would like an app to coordinate everything and also send reminders or share reminders of what is coming up next. For instance, in terms of care coordination, I am adding information to the app, perhaps that my child visited a specialist on this date, then maybe the app can add reminders in additional ways about an upcoming appointment. Or maybe, if I say in my notes that I met with this specialist and need to schedule a follow-up appointment with so and so. Maybe the app can understand the action items from those notes and say you mentioned this, and you need to schedule a follow-up appointment with this specialist." [Participant 1]

Theme 4: Transition to Adult Care

The last primary theme focuses on a sensitive period in the continuum of care of children with medical complexity. At the age of 21 years, children with medical complexity experience the transition or transfer of care from pediatric settings to an adult setting, findings showed suggestions for technologies specifically for this transition period. The community caregivers highlighted several features of these technologies, especially those related to enabling self-care and management for the patients. The theme emphasized the necessity of designing technology to empower the youth with the necessary knowledge during this transition to adulthood. In addition, given the shortage of resources and skillsets in adult settings compared to pediatric settings for the children with medical complexity population, they highlighted the various needs children with medical complexity teenagers or young adults with medical complexity might have during and after the transition; therefore, a personalized technology, specifically addressing their needs, would be beneficial. Table 2 presents the subthemes related to various suggestions for using technology to facilitate the transition to adult care.

Table 2. Suggested technology to support the transition to adult care.

Subthemes and definitions	Quotes
Empowering youth with knowledge about their health condition (providing youth with the necessary knowledge to understand and manage their own health issues)	"A youth app would be so important to support health care transition. It is supposed to start at 12 because our kids are going to grow up. Youth are going to go to college, and they are going to have a new provider who is a specialist. Mom is not going to be there with them. So, I believe it is important to provide them with resources about their disability, what it is, and their medications." [Participant 5]
Manage medical appointments (teaching youth with medical complexities how to schedule and organize their own health care visits)	"I think of an app that would help the child to make appointments such as a scheduler. As a mother of a child with medical complexity, we do everything. The truth is that they are going to grow up, and the first steps might even be just having your child sign their name when they come into a doctor's office or calling to make an appointment. The app should be integrated with text to talk for youth with medical complexity." [Participant 5]
Personalized technology features for youth (technology solutions that meet the unique needs and abilities of children with medical complexity)	"An app should be able to assess whether users can read well; based on this assessment, we would use either tenth or twelfth-grade English. If users have receptive issues or dyslexia, we will avoid using this font and instead use one without unusual markings. For example, consider a twelfth-grader who reads at a third-grade level but is transitioning to adulthood. Currently, there are no resources for this, so the child will often rely on information from his parents. This can be a real struggle because, although the content is intended for him, he does not have access to it." [Participant 10]

Discussion

Principal Findings

This qualitative study explores formal community caregivers' perspectives on integrating HIT in the care of children with medical complexity. Community caregivers are an essential part of the care model for children with medical complexity from underserved populations [13,14]. Our findings showed the critical benefits of telehealth for this population, especially during the COVID-19 pandemic, though some negative experiences and improvement suggestions are also noted. We also identified various specific needs that can promote future technology design to address the specific needs of children with medical complexity in care management as well as the interaction between the parents of children with medical complexity and care providers. Finally, our findings address the need for technologies that support the transition from pediatric to adult care for the children with medical complexity population. To our knowledge, this is the first study capturing children with medical complexity community caregivers' perception of the role and needs of HIT in an effective care for children with medical complexity model.

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Shifting From In-Person Visits to Telehealth

The COVID-19 pandemic has accelerated the adoption of telehealth into the American health care systems, providing safe access to medical care [19,20]. The data reveal that telehealth provided alternatives and safer options to the children with medical complexity population during the peak time of the COVID-19 pandemic as a cost-effective solution that can potentially improve health outcomes for children with medical complexity, facilitate physician-caregiver interaction, and increase caregiver satisfaction, as reported in other studies [21-23]. Community caregivers emphasize that telehealth eases the burden on parents, especially those from underserved populations, by reducing the time they need to take off work and travel long distances, as discussed by other studies [24,25]. During the COVID-19 pandemic, telehealth was the safest method to maintain physical distance while ensuring timely and affordable care [26]. Telehealth facilitated follow-up care, reducing the burden on care teams and decreasing exposure risks for both patients and health care providers [27]. However, the findings also showed that there are certain tasks, especially in inpatient settings, which cannot be done using telehealth. Clear communication between parents and health care providers is needed to ensure timely and reliable care [28]. Our study also revealed that community caregivers advocate for the continuity of telehealth services after the COVID-19 pandemic, driven by the factors mentioned earlier. Despite its advantages, our analysis also showed several challenges related to telehealth use in the care of children with medical complexity. These challenges include technical difficulties, connection issues, a user-unfriendly interface, and a lack of clear instructions for parents to connect to the system [29-31]. These challenges should be addressed and enhanced for better use of telehealth in care for children with medical complexity.

A previous study focused on providing recommendations to enhance telehealth functionalities and support diverse communication needs from the perspective of children, which aligns with our findings [32]. Our participants reported that children with medical complexity often struggle to sit still, listen, and engage throughout a long telehealth session. They suggested that for children with medical complexity, particularly those with developmental disabilities, integrating fun graphics with timers into telehealth can transform their experience. This approach allows families to create a structured environment that actively engages children and leads to more productive telehealth sessions. Moreover, our participants suggest accommodating diverse communication preferences during telehealth sessions, as some children might feel more comfortable expressing themselves through text. Integrating features such as fill-in-the-blank sentences, text-to-voice options, and voice-to-text options can significantly enhance accessibility. In addition, allowing children to choose their voice gender and use emojis to convey their pain levels or express agreement and disagreement can facilitate more effective communication. These adaptations can help create a more inclusive and supportive telehealth experience.

In addition, health care providers must listen to parents' concerns and answer their questions, as it will assist them in coping with difficult situations [33]. Our participants recommend that preappointment questionnaires may enhance communication between parents and health care providers. This approach will help parents in addressing their concerns in advance, which will be discussed during the session. In addition, integrating an educational component into telehealth will enhance parents' understanding of the medical information presented during the session.

Technologies for Improving Outcomes of Care for Children With Medical Complexity

Community caregivers suggested tools to address various needs of this population, including parent or patient empowerment, information management, care coordination, communication, and patient safety. Visiting the physician's office can be stressful for this vulnerable group due to the unfamiliar environment [34,35]. Our study revealed that games and social media platforms could improve the social skills of children with medical complexity, such as interacting with the health care staff. Participants suggested gamified learning apps that focus on teaching what is socially appropriate and inappropriate. In addition, social media platforms, such as TikTok, Snapchat, and Instagram, provide short videos that capture children's attention. This feature can help children with medical complexities learn how to interact in a physician's office and encourage them to participate actively in their health management.

Several subthemes emerged from the analysis, showing various management tools to help the parents of children with medical complexity at different levels of care for children with medical complexity, not only in hospitals but mostly in home settings. The data clearly show the increasing interest among caregivers in integrating various HIT tools into the care for children with medical complexity journey to improve the quality of care. As this interest expands, concerns arise regarding validating these technologies, as many lack regulatory approval. In addition, improving patient safety in complex pediatric health care requires providing families with tools that help them with decision-making and communication. Successful communication requires timely information exchange between primary care, specialty care, and families to enhance medical outcomes for children with medical complexity [36]. Our participants indicated that parents often felt responsible for sharing information, as they are the primary drivers of their children's care. Miscommunication and the use of multiple medications in complex medical conditions increase opportunities for error, particularly as children transition between health care settings and practitioners [37]. Communication barriers often prevent parents from properly filling prescriptions or adjusting dosages, resulting in frequent errors and increased risks to patient safety [38]. In addition, parents need to find the right channels and have a road map to assist in understanding and managing the complicated situations or challenges they will encounter in the future [39]. Therefore, community caregivers ask for effective technologies and tools to be developed to address these critical needs of the parents of children with medical complexity.

Another subtheme highlighted the need to address language barriers and empower parents and patients, especially those from underserved populations with low education levels. Parents

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with limited English proficiency encounter communication challenges that negatively affect access to and quality of health services for children with medical complexity [40]. Language barriers and health literacy limitations could be associated with parents' less understanding of diagnoses, treatment options, care plans, and follow-up recommendations [41]. In addition, language barriers include a limited understanding of medical terminology while explaining the child's diagnosis and treatment plan [42]. The parents want clear instructions, simplified medical terms, and concrete medication directions [43]. A well-designed tool can help these parents mitigate these barriers and become empowered in the care of their own children with medical complexity.

Preferences and Specifications for User-Centric Design

The data showed some discussions on preferences on the type of technology platforms discussed by community caregivers. The participants discussed their preferences for mobile apps and websites, focusing on how these platforms can meet diverse needs. Smartphones allow users to access information and services anytime and anywhere [44]. However, older adults caring for children or grandchildren with medical complexity might prefer using desktops and laptops, as larger screens provide a more accessible information display.

The participants also emphasized the importance of reminders and notifications in managing their caregiving responsibilities effectively. Reminders are an important feature in mobile apps, helping users manage medication, appointments, and adherence to medical conditions [45]. For instance, the participants in our study mentioned that writing notes is a common practice to keep track of important tasks and appointments; however, this can often lead to information overload and disorganization. It was suggested that an app could analyze these notes and identify action items. Then, the mobile app could send reminders on upcoming appointments and other important tasks. This could be achieved using an artificial intelligence (AI)–powered mobile app that uses natural language processing to analyze the text notes. AI-assisted mobile apps could be designed to provide personalized experiences for parents and offer insights that drive better decision-making [46]. In addition, AI-assisted apps could be extended to assist parents in enhancing medication adherence by recognizing medications and verifying their ingestion [47].

The Role of Technology in Supporting Transitions to Adult Health Care

Our data revealed an interesting theme focusing on the care transition or transfer of this vulnerable population from pediatrics to adult care and how to make this transition better by using various technologies and tools. These tools should educate youth about their complex medical conditions, medications, and overall health management [48]. Children with medical complexity will inevitably grow up, and they will need to navigate independent adult life and responsibilities. Managing multiple medical appointments and follow-ups becomes a significant skill while transitioning to adult care. Our participants suggested an app that includes features such as appointment scheduling and text-to-speech integration, which could help youth with medical complexity learn to navigate this aspect of their care independently. Furthermore, personalized technology solutions that adapt to individual reading levels and cognitive abilities are essential [49]. As suggested by Statewide Parent Advocacy Network participants, an app that provides content accommodating varying reading skills can ensure that children with medical complexity with different learning needs can equally engage with and access adult transition resources.

As shown in the literature, this transition period is risky, and adult settings are significantly less prepared compared to pediatric settings to care for this vulnerable population [50]. Transitioning from pediatric to adult health care is unique to each child and ideally occurs between the ages of 18 and 21 [51]. The negative impact of poorly managed care transition contributes to family burden and distress [52,53]. Families face significant challenges in motivating their children and often lack clarity about the steps needed for the adult care transition phase [53]. There is growing interest in leveraging HIT to facilitate the transition from pediatric to adult care [54,55]. Health care providers and parents support youth in developing autonomy, decision-making skills, and self-management by creating tailored plans that address their abilities and complexities [49]. This process can be further empowered by leveraging HIT, which can provide tools and resources to enhance personalized care and support this transitioning phase, as highlighted by the participants in our study.

Limitations

A limitation of this study is that the interviews were conducted with members of only one organization. In addition, we only collected gender as demographic information about participants. Our participants were predominantly female, so future studies could balance the insights by adding more male community caregivers.

Conclusions

This study explored and analyzed the needs of children with medical complexities and their caregivers throughout their care journey from community caregivers' perspectives. We identified several areas where HIT could enhance care for children with medical complexity conditions. There is a need for improvement in telehealth and the development of mobile health apps across various areas of care for children with medical complexity, such as data management, educational resources, care coordination, and transition to adult care. By addressing these areas, technology designers can contribute to more effective, coordinated, and personalized care for children with medical complexity. This improvement will potentially lead to better health outcomes and a higher quality of life for children with medical complexity.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Telehealth subthemes, definitions, and sample quotes.
[DOCX File , 20 KB - pediatrics_v8i1e67289_app1.docx]

Multimedia Appendix 2
Suggested tools and technologies to be developed for children with medical complexity care.
[DOCX File , 19 KB - pediatrics_v8i1e67289_app2.docx]

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Abbreviations

AI: artificial intelligence
HIT: health IT

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Using a Consumer Wearable Activity Monitoring Device to Study Physical Activity and Sleep Among Adolescents in Project Viva: Cohort Study

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Abstract

Background: The increasing prevalence of physical inactivity and insufficient sleep in adolescents likely contribute to worsening cardiometabolic and mental health. However, obtaining accurate behavioral measures is a challenge. Consumer wearable devices offer a user-friendly method to assess physical activity and sleep.

Objective: This study aimed to describe the process and the preliminary results of physical activity and sleep collected using a consumer wearable Fitbit device in an adolescent cohort.

Methods: We provided Fitbit Charge 2 or Charge 3 wrist-worn activity monitors to adolescent participants in Project Viva, a Boston, Massachusetts area cohort, from 2017 to 2022. We invited participants to wear the devices for ≥7 days for 24 hours a day to measure their physical activity, heart rate, and sleep, and allowed them to keep the device as a participation incentive.

Results: We collected over 7 million minutes of physical activity, heart rate, and sleep data from 677 participants, 53% (356/677) of whom were female. The mean (SD) age of participants was 17.7 (0.7) years. Among the 677 participants, 65% (n=439) were non-Hispanic White, 14% (n=947) were non-Hispanic Black, 10% (n=69) were Hispanic, 3.2% (n=22) were non-Hispanic Asian, and 7.8% (n=53) belonged to other races. Participants demonstrated a high adherence to the research protocol, with the mean (SD) wear duration of 7.5 (1.1) days, and 90% of participants (612/677) had 5 or more days wearing the device for >600 minutes/day. The mean (SD) number of steps was 8883 (3455) steps/day and the mean (SD) awake sedentary time was 564 (138) minutes/day. Male participants were more often engaged in very active (27 minutes/day) and moderately active physical activity (29 minutes/day) compared with female participants (15 and 17 minutes/day, respectively). Over 87% (588/677) of participants had sleep data available for 5 or more days, among whom the average nightly sleep duration was 7.9 (SD 0.9) hours.

Conclusions: This study demonstrated the feasibility of using consumer wearable devices to measure physical activity and sleep in a cohort of US adolescents. The high compliance rates provide valuable insights into adolescent behavior patterns and their influence on chronic disease development and mental health outcomes.

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KEYWORDS

wearable device; Fitbit; physical activity; sleep; adolescents; behavior risk; mobile phone

Introduction

The prevalence of physical inactivity and insufficient sleep in adolescents has become a major health concern worldwide. In the United States, approximately 76% of children aged 6 - 17 years engage in less than the recommended 60 minutes of moderate-to-vigorous physical activity per day [1]. Similarly, almost a quarter of US children aged 6 - 17 years have less than the recommended 8 hours of sleep per day [2]. Adolescence is a vulnerable period for the development of both psychiatric and chronic medical illnesses [3]. A lack of moderate-to-vigorous physical activity is linked to a higher risk of excessive calorie

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intake, obesity [4,5], and cardiometabolic diseases [6-8]; higher risk of depression and anxiety [9-11]; and lower cognitive and school performance [12,13]. In addition, insufficient sleep has been associated with unhealthy dietary behavior [14,15], being overweight [14,16,17], poor school performance, and depression [18-20]. Given the health concerns related to physical inactivity and insufficient sleep among adolescents, a better understanding of these health behaviors through accurate, large-scale data among representative populations is crucial.

Consumer-based wearable devices such as Fitbit (Google) have become popular for objectively measuring physical activity and sleep due to the advancements in microtechnology, wireless communication, battery capacity, and multidimension measurements. In addition, Fitbit devices use Bluetooth for easy data transfer to Fitbit servers through a smartphone or tablet, allowing for synchronization of real-time data. This helps avoid the burden of mailing devices back to researchers and potential data loss that may occur with actigraphs meant solely for research. Fitbits have been validated for collecting real-time behavior data on free-living subjects [21-25]. Although Fitbits have been used to collect real-time behavior data, researchers have not described real-world methods to operationalize consumer-based wearable devices to collect health behavior data in adolescent cohorts. Detailing the operational methods for these devices in real-world setting can enable researchers to examine this novel approach in depth and understand the measurement values.

In this study, we used commercially available Fitbit devices to gather physical activity and sleep data in adolescents. We describe our data collection and cleaning process, and present participants' wear-time results. The collected data will be used to study associations of physical activity and sleep with many aspects of adolescent and young adult health, including cardiometabolic, experiential, and mental health, in future research.

Methods

Project Viva Cohort

Project Viva is an ongoing prospective cohort focused on maternal and child health. We recruited pregnant women between 1999 and 2002 in eastern Massachusetts who received prenatal care at Atrius Harvard Vanguard Medical Associates. Detailed recruitment, eligibility, and cohort information have been previously reported [26]. We collected comprehensive information from mothers and their children at various life stages, and attempted to follow all willing participants after birth. Of the 2128 mother-child pairs enrolled at birth, 1576 pairs had not previously disenrolled and thus were eligible for the Mid-Teen visit.

Data Collection

We contacted participants from July 1, 2017, to August 30, 2021. We invited participants as mother-child pairs by mail or email to participate in the Mid-Teen visit when the child turned 16.5 years old. If the child had sibling(s) who were also enrolled in Project Viva, the sibling(s) also attended the visit regardless of the age.

We collected data on the demographic variables at several life stages. At recruitment, we collected data about the maternal education. We obtained the child sex at birth and birth date from hospital medical records. During the Mid-Teen visit, trained research assistants measured weight using a calibrated Tanita scale (model TBF-300A; Tanita Corporation of America) and weight using a calibrated stadiometer (Shorr Productions). We calculated the BMI using weight (kg)/ square of height (m^2). Race, ethnicity, and household income were collected through a questionnaire.

Wearable Device

We invited all adolescent participants to provide data on physical activity, heart rate, and sleep for 1 week to align with traditional actigraphy study and avoid over burdening participants. Participants had to consent to wear a Fitbit Charge 2 (before 2018) or Fitbit Charge 3 (after 2018) wearable device, depending on the year of the research visit. Both devices have the same core measurement technique, MEMS 3-axis accelerometer and optical heart-rate tracker and are able to track physical activity, heart rate, and sleep on free-living subjects [27,28]. Trained study staff instructed participants to download the Fitbit app on their smartphone and to register a Fitbit account. Study staff then linked their account ID to Fitabase [29], a data management platform to support research projects using Fitbit devices. Participants were asked to wear the device on the nondominant wrist and to synchronize their Fitbit with the app at least once daily. Once synced, study staff were able to access participant data through Fitabase. During the data collection period, research staff checked the platform 2 times a week. For those who did not provide the requested 5 days of data, we sent up to 10 reminders to participants to initiate or continue wearing the device and to sync their data on the app.

The Fitbit device measures physical activity, heart rate, and sleep stages. Physical activity is measured through miniaturized accelerometers. Fitbit uses a proprietary algorithm to calculate steps and categorizes activity intensity into 4 levels—very active, moderately active, lightly active, and sedentary, at the minute level [30,31]. The heart rate is measured through photoplethysmography, an optical technique that uses a light sensor to detect blood volume changes in the capillaries above the wrist [32]. Fitbit uses this measurement to run through a proprietary algorithm to get the beats per minute (bpm). Then, Fitbit combines the accelerometers and heart-rate pattern under a proprietary sleep algorithm to estimate sleep stages. Although some studies have implied that Fitbit may overestimate or underestimate the physical activity and sleep in certain situations, the algorithm has been validated in the contexts of measuring steps and 2-stage wake and sleep classification, with the accuracy mostly being between 80% and 90% when compared with research-grade devices [21-25,33-35].

Data Cleaning and Analysis

We downloaded minute-level Fitbit data on August 29, 2022. The data contained information on activity intensities, steps, heart rate, and sleep every minute. We used heart rate as a proxy to determine wear time. If participants did not have heart rate observed in a given minute, we considered it as nonwear time. We used 2 cutoffs to define participants' valid data, (1)

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participants with heart rate data for at least 600 minutes (10 h)/day for 5-9 days and (2) participants with heart rate data for at least 1200 minutes (20 h)/day for 5-9 days. The first cutoff is commonly used in actigraphy studies [36], while the second cutoff allows us to evaluate participants who had high compliance in a full 24-hour period [37].

We used the minute-level data to calculate the results at the daily and participant levels for valid participants. For the daily value of physical activity, we calculated the average steps/hour (during wear time), total steps per day, awake sedentary minutes, lightly active minutes, moderately active minutes, and very active minutes. The awake sedentary time was defined based on the Fitbit algorithm and excluded sleep. We then used the daily value to calculate the physical activity at the participant level.

For sleep data, we selected participants who had sleep data for 5-9 days from the 600 minutes/day cutoff described above. Fitbit assigns 3 values to indicate sleep stages for each minute during sleep periods, “1” indicates being asleep; “2” indicates being in a restless state, which may indicate restlessness during sleep or wakefulness; and “3” indicates being awake during the sleep period. Otherwise, sleep is categorized as “NA,” which indicates being fully awake (ie, not part of a sleep period) [38]. We defined a series of sleep metrics based on previous studies [39-41]. We defined sleep cycle as a series of distinct stages of sleep that a person can go through from being asleep to being awake. We defined sleep period as a specific time interval between sleep onset and the end of sleep, where multiple sleep cycles can occur in 1 sleep period. To determine the main sleep period, we manually examined participants’ sleep cycles and merged sleep cycles if multiple cycles occurred between 6 PM and 6 AM. If no sleep was found between 6 PM and 6 AM, we then examined the post 6 AM sleep onset time and manually identified the sleep period based on all available Fitbit sleep records for the participant. For the calculation of sleep duration, we focused on the main sleep period, excluding any nap times that occurred after the main sleep period.

Next, we classified the total time spent awake between the sleep onset time and sleep wake up time as wakefulness after sleep onset (WASO). We used the total asleep time between the sleep onset and wake up time divided by the total sleep duration to calculate sleep efficiency. We also calculated the sleep midpoint, which is the middle time between the sleep onset time and final wake up time. We then used the sleep midpoint to determine social jet lag, which measures the difference in sleep midpoint time between week nights (Sunday-Thursday) and weekend nights (Friday and Saturday).

We obtained the demographic characteristics for all participants who had Fitbit data available and for the subset of participants with adequate wear time based on 600 minutes/day and 1200 minutes/day cutoffs. We determined the mean (SD) for average wear days, daily wear time, total steps/hour, and total steps/day using each minimal cutoff. We then compared the wear time by sex into 4 physical activity categories: very active, moderately active, lightly active, and awake sedentary in participants who met our 600 minutes/day cutoff. Finally, we showed sleep results for all valid participants and classified participants who had average sleep onset times before and after midnight, respectively. All the data preparation and analyses were conducted using R (R Foundation for Statistical Computing).

Ethical Considerations

The Institutional Review Board at Harvard Pilgrim Health Care approved this study protocol (235301). All participants provided written informed consent (if aged over 18 years) and assent in combination with parent or guardian informed consent (if under the age of 18 years).

Results

Overall

Out of the 901 invited participants, 809 consented to the Mid-Teen visit and 702 agreed to participate in the Fitbit substudy (Figure 1 shows the participant eligibility flow chart). We ultimately obtained Fitbit data from 677/702 participants (96% of those who consented to the Fitbit substudy). We found similar demographic characteristics between participants who consented to the Mid-Teen visit but did not consent to the Fitbit substudy and those who consented to the Fitbit substudy (Table 1). The raw dataset comprised over 7 million minutes of physical activity and 6 million minutes of sleep data from 677 participants. After data cleaning, the percentage of valid participants remained high (612/677, 90%, using the 600 minutes/day for 5-9 days as the cutoff, and 538/677, 79%, using 1200 minutes/day for 5-9 days as the cutoff).

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Figure 1. Diagram of participant flowchart showing the number of participants at different stages of the Mid-Teen (MT) visit.

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Table . Demographic and socioeconomic characteristics of participants who consented to the Mid-Teen visit, participants who received a Fitbit device, and participants with valid data based on 600 minutes/day and 1200 minutes/day cutoffs.

Characteristic	Participants who consented to the Mid-Teen visit (n=809)	Participants who consented to the Mid-Teen visit but did not provide Fitbit data (n=132)	Participants who received the Fitbit device (n=677)	Participants with valid data considering the cutoff of 600 minutes/day for 5 - 9 days (n=612)	Participants with valid data considering the cutoff of 1200 minutes/day for 5 - 9 days (n=538)
Age (years), mean (SD)	17.4 (0.7)	18.3 (0.8)	17.7 (0.7)	17.7 (0.7)	17.7 (0.7)
Sex at birth, n (%)					
Female	423 (52)	67 (51)	356 (53)	332 (54)	295 (55)
Male	386 (48)	65 (49)	321 (47)	280 (46)	243 (45)
Race and ethnicity, n (%)					
Non-Hispanic White	528 (65)	89 (67)	439 (65)	395 (65)	346 (64)
Non-Hispanic Black	121 (15)	27 (20)	94 (14)	85 (14)	76 (14)
Hispanic	78 (9.6)	9 (6.8)	69 (10)	60 (9.8)	50 (9.3)
Non-Hispanic Asian	26 (3.2)	4 (3)	22 (3.2)	22 (3.6)	22 (4.1)
Other	56 (6.9)	3 (2.3)	53 (7.8)	50 (8.2)	44 (8.2)
BMI (kg/m^2), mean (SD)	23.96 (5.2)	22.65 (2.8)	24.01 (5.3)	23.94 (5.2)	24.03 (5.3)
Unknown, n (%)	114 (14.1)	104 (79)	10 (1.5)	9 (1.5)	9 (1.7)
Household income, n (%)					
<$40,000	51 (6.3)	10 (7.6)	41 (6.1)	34 (5.6)	33 (6.1)
$40,000-$70,000	79 (9.8)	15 (11)	64 (9.5)	54 (8.8)	45 (8.4)
>$70,000	597 (74)	72 (55)	525 (78)	482 (79)	423 (79)
Unknown	82 (10)	35 (27)	47 (6.9)	42 (6.9)	37 (6.9)
Maternal college education, n (%)	598 (74)	103 (78)	495 (73)	453 (74)	400 (75)

Participant Compliance

Among all participants with valid data considering the cutoff of at least 600 minutes/day (on every day worn), participants tended to wear the device for more than 10 hours per day and for more days than requested (Figure S1 in Multimedia Appendix 1). Furthermore, the pattern of wearing the device for more than 10 hours per day persisted when comparing the first recording day with the last recording day (Table S1 in Multimedia Appendix 1). When comparing the wear time between the two cutoffs, the average number of wear days and daily wear time were similar between the 600 minutes/day cutoff group and the 1200 minutes/day cutoff group (wear days: 7.5 days, SD 1.1 days vs 7.7 days, SD 0.9 days; wear time: 1323 minutes, SD 100 minutes vs 1350 minutes, SD 61 minutes). Similarly, the average values for steps/hour were similar between the groups defined by the two different cutoffs (Table 2).

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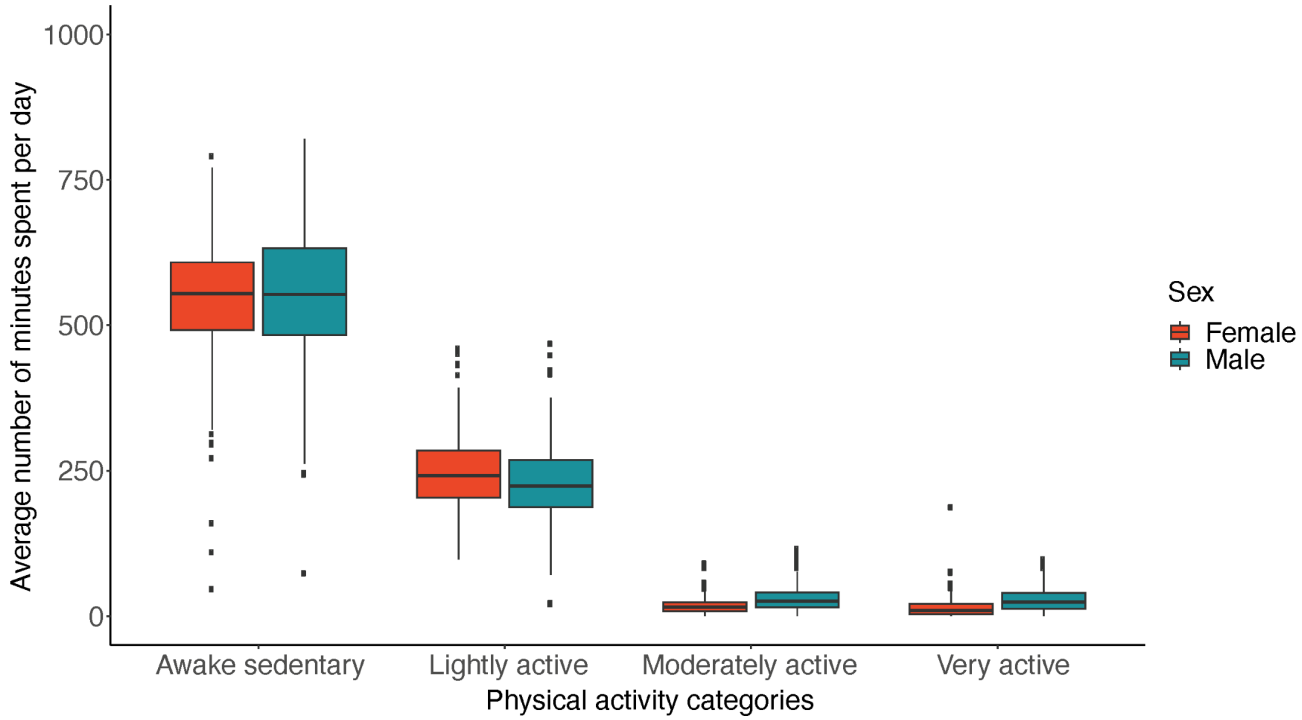
Table . Participants' physical activity results based on 600 minutes/day and 1200 minutes/day cutoffs.

Variable	Participants with valid data considering the cutoff of 600 min/d wear time for 5 - 9 days (n=612), mean (SD)	Participants with valid data considering the cutoff of 1200 min/d wear time for 5 - 9 days (n=538), mean (SD)
Total wear time (d)	7.5 (1.1)	7.7 (0.9)
Daily wear time (min)	1323 (100)	1350 (61)
Total steps per hour (steps/h)	399 (157)	400 (150)
Total steps per day (steps)	8883 (3455)	9041 (3414)
Physical activity level		
Very active (min/d)	20 (20)	21 (20)
Moderately active (min/d)	23 (18)	23 (18)
Lightly active (min/d)	235 (70)	239 (67)
Awake sedentary (min/d)	564 (138)	568 (121)

Physical Activity Results

Among the 4 physical activity categories (awake sedentary, lightly active, moderately active, and very active), we found that of the total awake wear time, the longest duration was spent in sedentary activity for both the 600 minutes/day cutoff group (mean 564 min/d, SD 138 min/d) and the 1200 min/d cutoff group (mean 568 min/d, SD 121 min/d; Table 2). The average wear time spent in the physical activity categories of very active and moderately active was less than 25 minutes per day for both cutoffs. Male participants spent a slightly higher wear time in the physical activity categories of very active and moderately active compared with female participants (very active: 27 min/d vs 15 min/d, moderately active: 29 min/d vs 17 min/d; Figure 2). On the other hand, female participants spent slightly more time in light activity compared with male participants (245 min/d vs 222 min/d).

Figure 2. Average time spent per day in each of the 4 activity levels: awake sedentary, lightly active, moderately active, and very active. Orange represents female participants and teal represents male participants. The vertical axis indicates the wearing time spent in each activity. Participants were selected using the minimal cutoff for wear time of at least 600 minutes/day for 5 - 9 days.



Sleep Results

Out of the 612 participants who wore the Fitbit for at least 600 minutes/day, 588 participants had sleep data available (Table 3). In these participants, the average number of days with sleep data available was 6.9 (SD 1.2) days with a mean sleep duration of 7.9 (SD 0.9) hours and average sleep onset time of 00:16 AM (SD 1.5 h). When stratified by weekends and weekdays, participants exhibited longer sleep duration during weekends compared with weekdays (mean 8.4 hours, SD 1.4 hours vs 7.8

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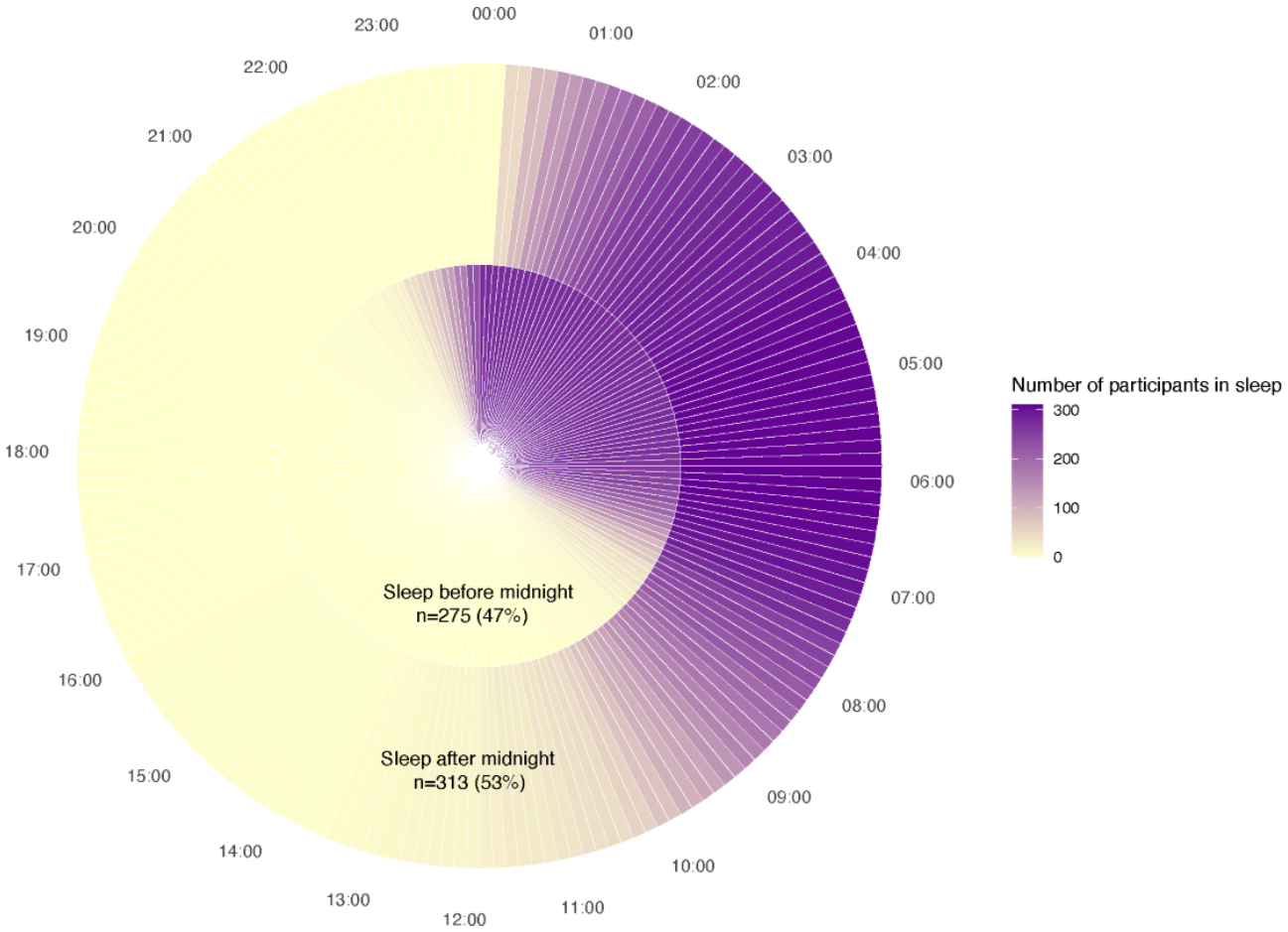
hours, SD 1.1 hours), while the sleep efficiency and WASO stayed consistent (Table S2 in Multimedia Appendix 1). In addition, we classified participants into 2 groups (average sleep onset time before midnight vs average sleep onset time after midnight). The sleep efficiency and WASO were minimally different between the two groups. However, the group with the average sleep onset time before midnight had a longer sleep duration, more social jet lag, and earlier wake up time compared with the second group (sleep duration: 8.1 hours, SD 0.8 hours vs 7.8 hours, SD 0.95 hours; social jet lag: 1.0 hour, SD 1.2 hours vs 0.6 hours, SD 1.9 hours; and wakeup time: 07:16 AM, SD 0.9 h vs 09:09 AM, SD 1.6 h). Furthermore, Figure 3 shows that participants with sleep onset after midnight have a wider wake window (a larger SD) compared with participants with sleep onset before midnight.

Table . Sleep results for participants who have valid data for 5 - 9 days of sleep considering 600 minutes/day, and separated by sleep onset before midnight and sleep onset after midnight.

Sleep measure	Overall participants (n=588), mean (SD)	Participants with average sleep onset before midnight (n=275), mean (SD)	Participants with average sleep onset after midnight (n=313), mean (SD)
Number of days with available data	6.9 (1.2)	6.9 (1.3)	6.9 (1.2)
Sleep duration (h)	7.9 (0.9)	8.1 (0.8)	7.8 (0.95)
Sleep efficiency (%)	93 (5)	93 (6)	93 (5)
Wakefulness after sleep onset (h)	0.6 (0.4)	0.6 (0.5)	0.6 (0.4)
Social jet lag (h)	0.8 (1.6)	1.0 (1.2)	0.6 (1.9)
Sleep onset time	00:16 AM (1.5 h)	23:11 PM (0.6 h)	01:17 AM (1.2 h)
Wake-up time	08:17 AM (1.6 h)	07:17 AM (0.9 h)	09:09 AM (1.6 h)

Figure 3. Sleep patterns for participants with average sleep onset before or after midnight (N=588). The inner circle includes participants whose average sleep onset time occurred before midnight (275/588, 47%) and the outer circle includes participants whose average sleep onset time occurred after midnight (313/588, 53%). The clock is based on 24-hour clock with 15 minute intervals. The gradient represents the number of participants in sleep in that given interval, where more purple color indicates more participants in sleep.



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Discussion

Principal Findings

Physical activity and sleep are major behavioral factors associated with various domains of health in adolescents. Consumer-based accelerometry devices, such as Fitbit, have enabled researchers to examine these behaviors efficiently at scale. For our Mid-Teen visit (aged ~17 years old), we invited Project Viva participants to use a Fitbit wearable device to collect physical activity and sleep data. We found participants were likely to consent and to wear the devices for the requested time. We observed that adolescents were spending the majority of their awake time in sedentary activities, with very little time participating in the physical activity categories of very active and moderately active. In the sleep data, we noticed that sleep onset time minimally impacted average sleep duration, sleep efficiency, and WASO; however, participants with a sleep onset after midnight tended to have much wider wakeup time window and less social jet lag.

The rising popularity of wearable devices has introduced a new method of data collection for assessing physical activity and sleep for epidemiology research [42]. This study illustrated the feasibility of using consumer-based wearable devices to collect human-behavior data, such as physical activity, sleep duration, and other sleep metrics, in free-living conditions. In addition, the high granularity of this data enabled us to examine physical activity and sleep at multiple levels: minute level, daily level, and the participant level. The objective data collection method avoided measurement errors resulting from recall or social desirability bias [43,44]. The device being used, unlike many research-based devices, does not need to be mailed back by participants, which avoided additional communication and shipping costs for the researchers, and participant burden of shipping back devices. We additionally avoided the potential of device and data loss during shipping. Furthermore, in the initial communications for the Mid-Teen visit, study staff informed participants that they could keep the device after the study period, and many participants felt it was a nice incentive to participate.

Project Viva has collected sleep and cardiometabolic health information across multiple visits in childhood and adolescence, and plans to continue health assessments in many domains in young adulthood. Our physical activity findings align with existing research, emphasizing the prevalence of sedentary lifestyle among adolescents [45,46]. Notably, we observed a delayed sleep onsite time and longer sleep duration on weekends, similar to previous studies [47,48]. For our future studies, we plan to examine associations of sleep and physical activity behaviors with cardiometabolic health data already collected at the midadolescence visit, such as weight, body composition, blood pressure, and blood biomarkers of cardiovascular health. Furthermore, we plan to use the Fitbit results as a calibration tool to enhance the accuracy and reliability of the self-reported physical activity and sleep data for participants who did not participate in the Fitbit substudy. These Fitbit data offer a unique way to examine health behavior and provide valuable insights into the relationship between behavioral factors and chronic disease development with opportunities for potential interventions. In addition, we have minute level and daily level dataset on objective health behaviors available for more detailed analyses.

Limitations and Challenges

While this study provides insights in using wearable devices to collect adolescent behavior data, there are some limitations to the inferences we can make. First, unlike other actigraphy studies that require participants to complete sleep diaries to self-report sleep onset and wake up times while wearing the device, our study did not request participants to fill out sleep diaries. This made it more difficult to clean the sleep data, especially for participants whose sleep period was less consistent, requiring us to make judgments based on their recorded sleep patterns and manually assign “sleep periods.” Second, despite instructing participants to wear the device on the nondominant wrist, we were unable to actively track the wearing status of the device. The wear habits might have influenced the accuracy of step counts and sleep stage recording [49-51]. The third limitation is the proprietary algorithm used by Fitbit. Although previous validation studies have shown 80% - 90% of accuracy for Fitbit devices in adolescents and adults when comparing both physical activity and sleep using research-grade accelerometry[21-25,50-52], the lack of accessibility to Fitbit’s underlying algorithms poses challenges in understanding the logic behind the algorithms for each device type and age populations. Finally, Project Viva is composed of adolescents from families with generally high median incomes and higher educational background, which could restrict the ability to generalize the findings to other populations. However, the high granularity data captures individual differences and can be used for comparative analyses as well as integrating with other cohort to extend the findings to a diverse population.

Conclusion

This study provided valuable insights into using consumer-based wearable devices to collect human behavior data. These data on physical activity and sleep characteristics are important for researchers seeking to understand their influence on chronic disease development and mental health outcomes. For future research, consumer wearable devices hold great potential for researchers to apply across different adolescent populations. Their use allows us to gain greater understanding of how lifestyle factors impact long-term health outcomes in diverse populations. These data may shed light on future policies or interventions aiming at increasing physical activity and improving sleep health, ultimately leading to improvements in physical and mental health.

Acknowledgments

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Data Availability

The datasets analyzed during this study are not publicly available due to Project Viva's data use and sharing policy but are available upon reasonable request at project_viva@hphci.harvard.edu.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Basic statistical results.
[DOCX File, 78 KB - pediatrics_v8i1e59159_app1.docx]

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Abbreviation

BPM: beats per minute
WASO: wakefulness after sleep onset

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Original Paper

Parental Perceptions of Priorities and Features for a Mobile App to Promote Healthy Lifestyle Behaviors in Preschool Children: Mixed Methods Evaluation

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Abstract

Background: Parents of preschool-aged children are a key focus for interventions to shape healthy lifestyle behaviors and support risk reduction for obesity from an early age. In light of limited existing evidence on the use of mobile technology to promote healthy lifestyle behaviors among young children, we sought to gather parental priorities regarding a mobile app focused on guided goal setting across the domains of diet, physical activity, media use, and sleep.

Objective: The purpose of this study was to explore the priorities and needs of parents of 2- to 5-year-old children to guide developing the content and features of a mobile app aimed at promoting healthy lifestyle behaviors using a novel convergent mixed methods approach.

Methods: From November to December 2021, we invited parents or guardians in Kentucky to complete a series of web-based concept mapping activities and semistructured interviews (total N=30). Using 2 lists of items focused on (1) parental priorities (content areas) and (2) application features, we asked participants to conduct concept mapping procedures for each list: a web-based sorting activity, where participants grouped items together into thematic piles that made sense to them, and a rating activity, where participants rated each item on a 5-point Likert-type scale. The qualitative interviews were transcribed verbatim, coded, and then analyzed by constant comparative analysis to identify themes. We used the quantitative findings from the concept mapping process to triangulate the resulting themes from the qualitative interviews and generate possible app content areas and features.

Results: The concept mapping results resulted in two 3-cluster concept maps. For parental priorities, participants identified the clusters Creating Healthy Eating Habits, Forming Boundaries, and Building Good Relationships; for app features, participant clusters included Eating Healthy, Using the App, and Setting Goals. The interview themes also represented those 2 domains. Overall, the participants indicated that the top priorities were general health and wellbeing, routine and setting boundaries, and food and healthy eating when it comes to building healthy behaviors among their preschool-aged children. Parents indicated that quick, easy, and child-friendly recipes, goal tracking, and the use of tips and notifications were the features they valued most.

Conclusions: This study contributes to the understanding of what parents or caregivers of young children want from mobile apps, in both content and features, to support building healthy behaviors and routines. The findings can inform future research

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on the development and evaluation of existing or new mobile apps. Specific app features identified to meet family needs should be designed closely with a diverse set of families and tested using rigorous designs to identify the mechanisms of action that mobile apps may use for efficacious healthy parenting outcomes.

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KEYWORDS

mHealth; childhood obesity; mixed methods; pediatric; healthy lifestyle behaviors; preschool children; mobile application; diet; physical activity; exercise; media use; sleep; development; semi-structured interviews; healthy eating; parents; caregivers

Introduction

Healthy lifestyle behaviors remain an essential focus for health care efforts in the United States. As of 2017-2020, the US obesity prevalence rate was 41.9%, with obesity being the leading cause of preventable death across major outcomes, such as heart disease, stroke, type II diabetes, and several forms of cancer [1]. Likewise, childhood obesity rates continue to be a concern in the United States, including a prevalence rate of 12.7% among 2- to 5-year-old children in 2017-2020, resulting in conditions such as high blood pressure, high cholesterol, asthma, sleep apnea, and joint problems at an early age [2]. Additionally, childhood obesity disproportionately affects children of lower socioeconomic status and minority groups [3-5], exacerbating and contributing to this vast array of secondary consequences [6,7]. The state of Kentucky currently ranks second in the nation for both adult and childhood obesity rates, with significantly high rates of obesity among rural Appalachian and urban minority residents [1,2,8]. Parents of preschool-aged children remain a key focus for interventions supporting communities with disproportionately high obesity rates in an attempt to curtail these rates from an early age [9].

Recent research on healthy lifestyle behaviors among preschool-aged children has identified relevant determinants and behaviors. For example, Townsend et al [10,11] describe 12 dietary and behavioral determinants for childhood obesity risk reduction: fat, dietary fiber, fruit or vegetables, calcium or dairy, sweetened beverages, restaurant-prepared food, breakfast, energy density of eaten foods, physical activity, TV-viewing, sleep duration, and parenting. A recent systematic review of family-based childhood obesity prevention interventions indicates that interventions tend to focus on the domains of diet, physical activity, media use, and sleep; however, less than half of the included studies targeted a behavioral domain beyond diet and physical activity, and only 16% targeted all 4 behavioral domains [12]. Likewise, few studies exist that focus on goal-setting interventions among children and adolescents [13], even though guided goal setting represents a feasible strategy for parents to improve health behaviors for obesity risk reduction among children [14]. Additionally, a recent meta-analysis indicated that obesity prevention interventions in youth with low socioeconomic status are more successful when several behavior change strategies are integrated, rather than relying solely on one strategy [15].

Thousands of mobile apps exist that focus on nutrition and physical exercise but are primarily geared toward adults [16]. In our recent review, we found only 3 preexisting reviews of multiple mobile health (mHealth) apps designed for children and parents between 2015 and 2022 [17]. Of the 3 reviews, only one provided a list of specific app names, focusing on nutrition as a behavioral intervention for child obesity [18]. The authors of this review concluded that most apps, although free or relatively inexpensive (making them highly attractive to parents), contained content of low quality, were poorly designed, or were not grounded in credible dietary guidelines due to a lack of involvement of nutrition or scientific professionals in the design process [18]. In this review, the most common nutrition features in such apps included promotion of energy balance and guidance on appropriate portion size, and the most common behavioral change feature involved goal setting. Our review identified only 9 apps that use goal setting to change the health behaviors of children.

In light of limited existing evidence, we sought to design a mobile app geared toward parents of preschool-aged (2- to 5-year-old) children, integrating guided goal setting across the domains of diet, physical activity, media use, and sleep. During the formative stage of app development, we sought to integrate feedback from parents with children in our target age range in order to assess major areas of interest and ways the app could best meet their needs. Using a novel mixed methods approach, we combined concept mapping activities and qualitative interviews to capture the perceptions of parents on app content and features. Concept mapping is a useful formative design research tool that uses a structured process to create a visual representation or cognitive map of ideas and concepts [19]. This method has been widely used in a range of formative research topics including mHealth app evaluation [20] and in the development of apps focused on reducing school absences [21]. To our knowledge, this is the first application of concept mapping combined with interviews in the formative design and development of a health-focused app for parents of preschool-aged children. Specifically, the purpose of this study was to use this novel convergent mixed methods approach to explore the needs and desires of parents of 2- to 5-year-old children for the content and features of a health-based mobile app designed to promote healthy behaviors to reduce future obesity risk.

Methods

Recruitment

Study inclusion criteria include the following: primary caregiver of a 2- to 5-year-old child, 18 years or older, and use a smartphone or mobile phone and smartphone apps. Participants were recruited via printed flyers placed at various community-based organizations and distributed via community outreach activities as well as email listservs and social media

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channels managed by the university. Recruitment advertisements invited parents to participate in a study to help design a smartphone app for families. Those interested in the study could connect with the study team via an internet link, email, or telephone. The study team employed eligibility prescreening via a REDCap (Research Electronic Data Capture; Vanderbilt University) survey [22]. Participants had the option to complete the eligibility survey online or over the phone.

Ethical Considerations

A waiver of documentation of consent was granted by the University of Kentucky Medical Institutional Review Board (61563). The survey included a web-based process with consent indicated by selecting the "submit" button. If administered by phone, the staff read the consent information and asked participants to consent verbally. Eligible participants were contacted by study staff to schedule an interview and sent a link and log-in information for concept mapping activities.

Study Procedures

From November to December 2021, we conducted 60-minute qualitative interviews (N=30). Interviews were facilitated by staff with a background in public health nutrition and qualitative methodology and conducted via Zoom (Zoom Video Communications) [23]. Interviews were recorded with participant permission. The interview protocol was developed based on a multilevel model of behavioral factors related to pediatric overweight (eg, dietary intake, physical activity, sedentary behavior, sleep, family meals, parenting styles, and feeding practices) [10,11] and research on the importance of goal setting in behavior change [24,25]. In addition, questions were informed by our formative research that demonstrated interest in health-focused apps designed among parents with preschool aged children [26,27] and a review of the content and features of existing apps for parents related to goal setting and tracking [17]. Based on this literature, we developed a semistructured discussion guide (Table S1 in Multimedia Appendix 1) in which we intentionally grouped questions in three logically progressing areas: (1) overall parenting routines and challenges, (2) health and wellness for their preschool-aged child with probes in specific domains from the literature (eg, mealtime, sleep, and active play), and (3) current mobile app use and desired features.

Using a convergent mixed methods design [28], interview participants were simultaneously asked to join in web-based concept mapping activities. Concept mapping is a participatory mixed method that incorporates quantitative elements with qualitative data collection to build consensus around a topic of interest [19,29]. To begin, the study team developed 2 sets of items based on formative research [26,27], which responded to two focal questions: (1) What are health and wellness priorities of your 2- to 5-year-old child? (23 items) and (2) What are the features you would like to have on an app on your phone that could help you set goals and work on goals for taking care of the health and wellness of your 2- to 5-year-old child (31 items)? The first question sought to gather perspectives on app content while the second served to capture desires for app features. We asked participants to complete 2 procedures: a virtual sorting activity, where participants grouped items into thematic piles that made sense to them, and a rating activity, where participants rated each item on a 5-point Likert-type scale. For the 23 health and wellness priority items, this rating question was as follows: How important is this item to you as a priority for your child's health (from not at all important [1] to extremely important [5])? For the 31 app feature items, we asked the following question: How often would you use this feature in an app on your phone (from never [1] to all the time [5])? In addition, we asked demographic questions, including race, ethnicity, marital status, number of children, employment status, education, income, and receipt of assistance programs. All concept mapping data were collected using Groupwisdom (Concept Systems, Inc), a web-based concept mapping software [30].

Analysis

The qualitative interviews were transcribed verbatim and analyzed through a combination of a deductive approach and grounded theory to identify themes [31,32] using the ATLAS.ti qualitative data analysis software (version 8.0) [33]. The initial identification of overarching thematic codes used a deductive strategy based on the interview questions, which was informed by previous research on behavioral determinants related to childhood obesity risk reduction, mealtime and child feeding practices, and guided goal setting among parents of preschool-aged children [10,11]. This initial deductive analysis also focused on overarching thematic codes related to potential app features and tools for families of preschool-aged children [17]. Additionally, we used a line-by-line analysis approach to generate a list of emergent, more granular subcodes within the larger coding schematic. In total, 3 coders with backgrounds in public health were trained to allocate codes to quotations. Interrater reliability was determined according to the procedures of Gough and Conner [34], which resulted in a high level of correspondence (93% agreement). The criteria of Lincoln and Guba [35] for trustworthiness of qualitative research were applied to ensure credibility of the findings.

We analyzed the sorting data from each set of concept mapping items in the Groupwisdom software. Specifically, we used similarity matrices and multi-dimensional scaling to generate 2-point maps, which reflect group consensus on the similarity of items. Next, we performed hierarchical cluster analysis for each set of sorting data to group the sets of items into common thematic clusters, resulting in 2 cluster maps. We combined the point and cluster maps for each focus area (parental priorities and app features) to depict items within their thematic areas. As a part of the recommended concept mapping methodology, we also analyzed average item ratings for the Likert-type rating scales to determine which items participants believed were the most important priorities for the health and wellness of their child and which app features were most likely to be used [19].

Finally, we used the interview themes to triangulate the concept mapping findings. Specifically, we synthesized the parental priorities and desired app features results to derive possible content and features of a novel mobile app to improve health behaviors among preschool-aged children.

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Results

Participant Characteristics

Table 1 shows the characteristics of those who participated in at least one activity (N=30): qualitative interviews only (n=2), concept mapping only (n=4), or both (n=24). Overall, the majority of participants identified as non-Hispanic White (93.3%), married (70.0%), having 1 or 2 children (80.0%; range 1 to ≥4), and being employed either part- or full-time (63.4%). A significant portion of the sample (36.6%) had a monthly income of US $2999 or less and 40.0% had not obtained a Bachelor's degree. For families using public assistance, most participated in a combination of WIC (Special Supplemental Nutrition Program for Women, Infants, and Children), SNAP (Supplemental Nutrition Assistance Program), and Medicare or Medicaid.

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Table 1. Characteristics for interview or concept mapping participants (N=30).

Demographic variables	Frequency, n (%)
Race or ethnicity	
Non-Hispanic White or Caucasian	28 (93.3)
Hispanic, Latino, or Spanish origin	2 (6.7)
Marital status	
Married	21 (70.0)
Single—divorced	2 (6.7)
Single—never married	6 (20.0)
Did not respond	1 (3.3)
Children	
1	14 (46.7)
2	10 (33.3)
3	3 (10.0)
4 or more	3 (10.0)
Employment	
Full-time	17 (56.7)
Part-time	2 (6.7)
Not employed	11 (36.7)
Education	
High school or GED (General Educational Development high school equivalency diploma)	3 (10.0)
Some college or technical degree	9 (30.0)
Bachelor's degree	5 (16.7)
Graduate degree	9 (30.0)
Did not respond	4 (13.3)
Monthly income	
<US $1000	4 (13.3)
US $1000-US $1999	3 (10.0)
US $2000-US $2999	4 (13.3)
US $3000-US $3999	1 (3.3)
US $4000-US $4999	5 (16.7)
US $5000+	7 (23.3)
Did not respond or don't know	6 (20.0)
Types of assistance	
WIC (Special Supplemental Nutrition Program for Women, Infants, and Children)	8 (26.7)
Head start	2 (6.7)
SNAP (Supplemental Nutrition Assistance Program)	7 (23.3)
TANF (Temporary Assistance for Needy Families)	0 (0.0)
Medicare or Medicaid	6 (20.0)

Concept Mapping and Interview Results

The concept mapping results reflected both app content and features: parental priorities and app features. The in-depth interviews resulted in thematic areas containing 257 individual total codes which also fell into these areas. The parental priority themes included the following: desired areas for improvement, routine, mealtime or child feeding behaviors, active play or physical activity, and sleep. The app features' themes included recipes, goal tracking, grocery shopping or meal planning, and tips and notifications. Representative quotes from the identified themes are shared in Table 2.

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Table 2. Representative quotes from the in-depth interviews by thematic areas.

Themes	Quotes
Desired areas of improvement	• I care about, of course, my children and their well-being. That they stay happy and healthy; mentally, physically, emotionally. (Mother of 2 boys ages 3 and 6 years old) • I'm always up for changes, improvements, anything that I can do that'll make anything easier or more efficient because a lot of times I'll do things the hard way instead of an easier way. I don't know why. My dad always said that I do everything the hard way. (Mother of a 4-year-old boy and a 1-year-old girl)
Routine	• We do try to follow [a routine] just because it tends to let our girls have a better, you know, day, especially when they're on their routine- and if they're not in routine, they tend to act out more. So, we do try to... but we don't always follow it, and sometimes it bites us in the [expletive] so on those days it's a little more difficult. (Mother of 2 girls 7 and 2 years old)
Mealtime and child feeding behaviors	• She's very picky. And I have a lot of issues with my weight and I'm afraid that she's going to too. So, I try to like- "Oh well here, I'm eating broccoli. Do you want to eat this? Because dinosaurs eat broccoli" because she likes dinosaurs so she's like, "No it's OK- I'm a dinosaur that doesn't like broccoli." (Mother of 2 girls ages 6 and 4 years old)
Planning grocery shopping	• I do better if I have a list. Sometimes we'll make a list on my phone before I go into the store, so I have something to make sure I get everything. And then a lot of times we'll use Click List, which makes it a lot easier because then everything that we need is all right there, like we have to order it that way, so that makes it a lot easier[…] Sometimes I'm still a pencil paper person too. I kind of do all of it. (Mother of a 4-year-old boy and a 1-year-old girl)
Active play or physical activity	• Then I know at school, right now they only get to go outside if it's warm enough so he hasn't been outside much, and I can tell on the days when he's been able to play outside at school versus when he hasn't. (Mother of a 3-year-old boy)
Sleep	• They report his behavior at school because sometimes he does not get good reports and his behavior at school- and I've told them it is directly related to sleep. […] That's one of the biggest factors like nights where I know that he's not slept as much, or if they've said he's took a nap or not. It's most directly related to his bad behavior, a lot of times at school, it'll be one the number one thing. So that is important. (Female caregiver to a 4-year-old boy)
App features	
Recipes	• The recipes that get more attention for me are ones I might actually use instead of just browsing would be the ones that's catered for the kids. Or to make it better for them or like a kid twist on something you know, that would be what I would want. (Caregiver to a 4-year-old boy)
Goal tracking	• I know at home sometimes we'll set goals for him. If there's an area that we see, an area of concern, then we'll do like a sticker chart like that I would use in school with a student to meet a certain goal, and we'll talk about that you have to do these three out of the five times. And so, I think if there was an app that would probably be easier than creating sticker charts all the time. (Mother of a 5-year-old boy)
Grocery shopping and meal planning	• I would be interested in it [a shopping list feature] if it was kid friendly and simple. Like if it would be probably like the simplest and quickest kind of interface. Some have gotten to cluttered and have to many things going on, to many things to edit, so, simple is best. (Caregiver to a 4-year-old boy)
Tips and notifications	• I would just say simple. As a parent with everything else on my plate, simplicity is the easiest way[…] if I'm looking for something in particular, I want to be able to find it as quickly as I can. (Mother of 2 boys ages 2 and 4 years old)

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Parental Priorities

Figure 1 displays the combined point and cluster map for the parental priorities area, which shows each of the 23 items in relative positions based on similarity (ie, items close together were often sorted together by participants) and grouped into thematic clusters, providing understanding of perceived commonality. The resulting clusters were as follows: (1) Building Good Relationships, (2) Forming Boundaries, and (3) Creating Healthy Eating Habits. These cluster names were developed from pile names participants created in the sorting process and reflect the major desired areas for app content. Table 3 includes all of the concept mapping items grouped by cluster and sorted by the average rating for each item; the highest rated items for each cluster are shown in italics.

Figure 1. Parental priorities combined point and cluster concept map.

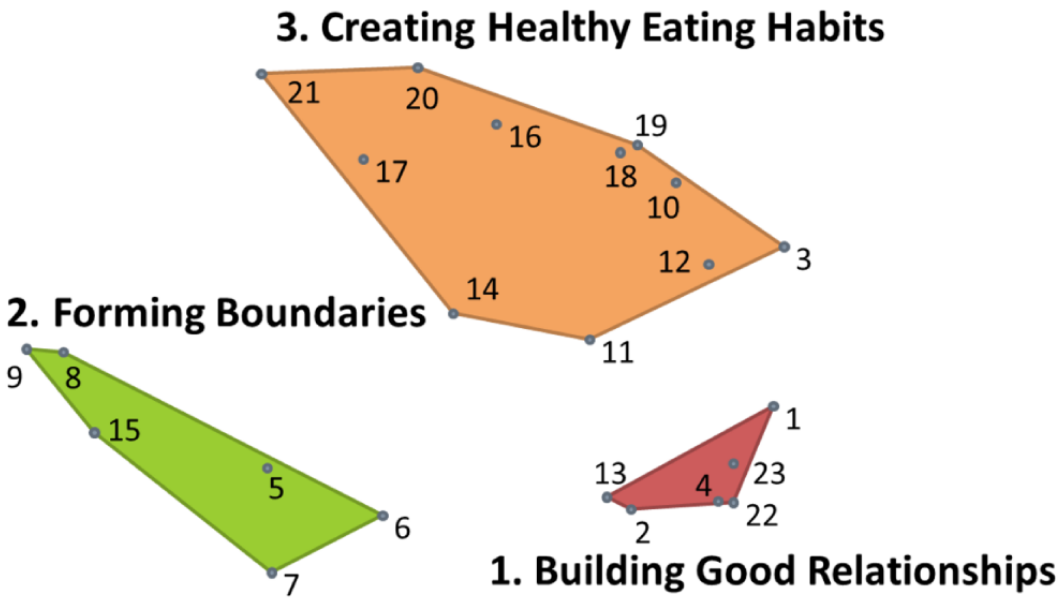

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Table 3. Concept mapping items grouped by cluster with average item ratings (highest rated for each cluster in italics).

Cluster and item	Statement	Average rating (Importance: 1=not at all to 5=extremely)
Parental properties		
1. Building good relationships		
1	*Taking care of my child's health*	*4.96*
22	*Being a good parent*	*4.92*
2	Talking and listening to my child	4.88
23	Helping my child feel good about their body as they grow up	4.88
4	Spending quality time with my child	4.79
13	Playing with my child	4.67
2. Forming boundaries		
6	*Setting and sticking to boundaries that are clear*	*4.50*
5	*Establishing and sticking to a daily routine*	*4.17*
7	How to reward my child for good behavior	4.08
8	Limiting my child's time using a phone or tablet	4.00
15	Getting my child to bed on-time	4.00
9	Limiting my child's time watching TV	3.67
3. Creating healthy eating habits		
3	*Having a variety of healthy food choices at home*	*4.63*
12	*Being a good role model for my child by eating healthy*	*4.42*
19	Getting my child to eat vegetables	4.38
18	Getting my child to eat healthy food	4.29
11	Encouraging exercise or physical activity for my child	4.25
10	Making sure my child doesn't drink too much sugar	4.13
14	Being a good role model for my child by exercising	4.04
16	Preparing more meals at home	3.92
17	Cooking with my child	3.67
21	Ways to address my child's picky eating	3.58
20	Quick and easy recipes for my family	3.50
App features		
1. Eating healthy		
1	*Healthy recipes*	*4.42*
4	*Easy recipes*	*4.29*
5	*Quick recipes*	*4.29*
3	Recipes for kids	4.17
11	Add recipes to a meal plan	4.08
8	Recipe tips	4.04
6	Search and filter recipes	3.92
7	View recipe nutrition facts	3.88

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Cluster and item	Statement	Average rating (Importance: 1=not at all to 5=extremely)
10	Make a meal plan	3.83
12	Tips about child health and nutrition	3.79
9	Make a grocery list	3.71
2	Recipes that can fit my family's dietary needs (eg, vegetarian, gluten free, no dairy, allergies, etc.)	3.50
2. Using the app		
13	*App alerts to view tips about child health and nutrition*	*3.50*
31	*Links to videos about child health and nutrition*	*3.50*
23	*Configure app preferences*	*3.25*
22	Setup my family profile—selecting a photo or avatar	2.88
28	Using the app with other family members	2.54
26	Sharing my goal progress with friends and family	2.08
25	Sharing my goal progress with other app users	2.04
27	Sharing my goal progress on social media	1.83
3. Setting goals		
20	*Set and track goals about making food more child friendly*	*3.88*
30	*Rewards or points for reaching my goals*	*3.79*
14	Quizzes to assess my child's health and well being	3.63
29	Getting feedback on how to improve on my goals	3.50
15	Set and track goals about my child's health and well being	3.42
24	Set and track goals about what my child eats and drinks	3.42
16	Set and track goals about my child's physical activity	3.33
18	Set and track goals about my child's mealtime routine	3.33
21	Reminder alerts to track goals for my child daily	3.29
19	Set and track goals about eating together as a family	3.21
17	Set and track goals about my child's bedtime	3.13

Building Good Relationships

Items in the Building Good Relationships cluster with the overall highest importance ratings included: "1. Taking care of my child's health" (4.96 out of 5) and "22. Being a good parent" (4.92 out of 5), which highlights the importance of overall child well-being. To begin the interviews, we asked about what is most important as a parent or caregiver of your 2- to 5-year-old child or children. Several parents mentioned child happiness or child emotional or mental health as a main priority. Parents also mentioned spending time with their child, active listening, and communication with their child as important aspects of their parenting style. Many parents stated their child's health in general was most important, while other parents mentioned specific areas of child health such as healthy eating and physical activity. Other areas of priority included building and sticking to a routine, school readiness, and participation in religion.

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Forming Boundaries

The Forming Boundaries cluster spoke to the participant-identified need for routine and time management. Items “6. Setting and sticking to boundaries that are clear” (4.50 out of 5) and “5. Establishing a daily routine” (4.17 out of 5) had the highest importance ratings in the cluster. Caregivers described a routine or schedule to establish consistency and reliability for their children. The morning routine, although often the most stressful or hectic, was integral to several families, especially those with a strict morning schedule. Evening routines were often described as a way to establish togetherness and connection with their children, whether through mealtime, playtime, or screen time. Bedtime routines varied for families but were the most commonly described area of routine. Caregivers described that their schedules were highly dependent on a variety of factors such as non-autonomous work schedules, unemployment, appointments, busy lifestyles, child health, and their child’s mood or behavior.

Many of those who said that their routine was important or somewhat important emphasized that “life is easier with routine, more difficult without,” and that their children were motivated by or thrived on routine. However, not all caregivers identified as planners; ie, several caregivers explicitly mentioned they do not adhere to a routine or *play it mostly by ear.* Whether parents viewed routine as important or not, they were able to describe scenarios where lack of structure was linked to child behavior issues.

Appropriately, the screen time–related items fell in this cluster, including items “8. Limiting my child’s time using a phone or tablet” and “9. Limiting my child’s time watching TV.” Interestingly, the phone or tablet item had a higher importance rating than watching TV (4.00 compared to 3.67 out of 6), suggesting phones and tablets may be a particular area of focus for screen time strategies. Tips for screen time reduction were desirable among interview participants. Barriers included: apartment living or not having a yard, child injuries, busy schedules, younger children (eg, infants) in the household, child health issues, and caregiver being unconcerned about screen time.

Similarly, the only sleep-related item, “15. Getting my child to bed on time,” fell into this cluster. Most interview participants described a bedtime routine for their young children and stated that their child had a set bedtime. Participants who stuck to a routine described their child’s sleep and sleep compliancy as easy, with good quality and quantity. Alternatively, some caregivers described children who had difficulty falling asleep, resisted sleep, or had issues with waking regularly in the night. Several sleep improvement strategies included having a light, night light, or red light in the room; reading to children before bed; use of supplemental melatonin; soft music; and limits on screen time. Participants also described barriers, such as the use of screens, continuation of breastfeeding, and co-sleeping.

Creating Healthy Eating Habits

The food and nutrition items grouped together as its own cluster (Creating Healthy Eating Habits), including a variety of eating and meal planning or preparation items. The most highly rated were as follows: “3. Having a variety of healthy food choices at home” (4.63 out of 5), followed by “12. Being a good role model for my child by eating healthy” (4.42 out of 5) and “19. Getting my child to eat vegetables” (4.38 out of 5). Mealtime and child feeding were major themes of the interviews. Participant responses were mixed if planning healthy meals was easy, difficult, or somewhere in-between. Many participants stated they actively try to prepare and provide healthy meals for themselves and their children. However, barriers to planning healthy meals included busy schedules or time, finances, food allergies or intolerances in the household, caregivers identifying as poor cooks, and having to tend to more than one young child. Convenience food and eating out were mentioned by parents as a strategy to address busy schedules.

Barriers to desirable child feeding included the child wanting to eat different foods than those prepared, frequent snacking, and wanting to eat close to bedtime. Picky eating was the most frequently raised barrier; only 5 caregivers stated their child was not a picky eater. Successful strategies to combat picky eating included eating meals with children or modeling healthy eating, cooking or preparing food with children, making food child-friendly, and keeping foods separated or compartmentalized on the plate or during serving. Unsuccessful strategies included food coloring or telling the child that a favorite character or animal eats the food. Many parents also stated encouraging vegetable eating was an important part of child feeding. Notably, item “21. Ways to address picky eating” had the second-lowest importance rating in the cluster (3.50 out of 5); this rating may indicate participant preferences toward broadly increasing positive strategies and healthy choices rather than a focus on specific strategies geared toward picky eating.

Some parents practiced strict restriction of what they considered unhealthy or junk foods, while others allowed children to have unimpeded access to snacks high in sugar, fat, and excess calories. A few caregivers expressed concern over their own weight and how this extended to their concern about child overweight or obesity. Although located in the Building Good Relationships cluster, participants highly rated item “23. Helping my child feel good about their body as they grow up” (4.88 out of 5), further emphasizing participant concerns about weight and body image as it relates to food choices.

The diversity of thought around meal planning and grocery shopping may be reflected by the lack of highly rated items. For example, items such as “16. Preparing meals at home,” “17. Cooking with my child,” and “20. Quick and easy recipes for my child” that correspond to planning and preparing meals fell at the bottom of the ratings for the Creating Healthy Eating Habits cluster (3.92, 3.58, and 3.50 out of 5, respectively). The relatively lower ratings of these items may be due to the wide range of opinions and strategies used by study participants. Participants who identified as meal planners described their motivations and strategies, including budgeting, shopping for staples, or sticking to the list. Some parents found it easier to buy only a few items at a time, while others found it easier to shop in bulk—using storage capacities of their pantries and freezers. Key facilitators included proximity to the grocery store, sharing tasks with another parent or caregiver, and allowing children to choose items at the store. Barriers included busy

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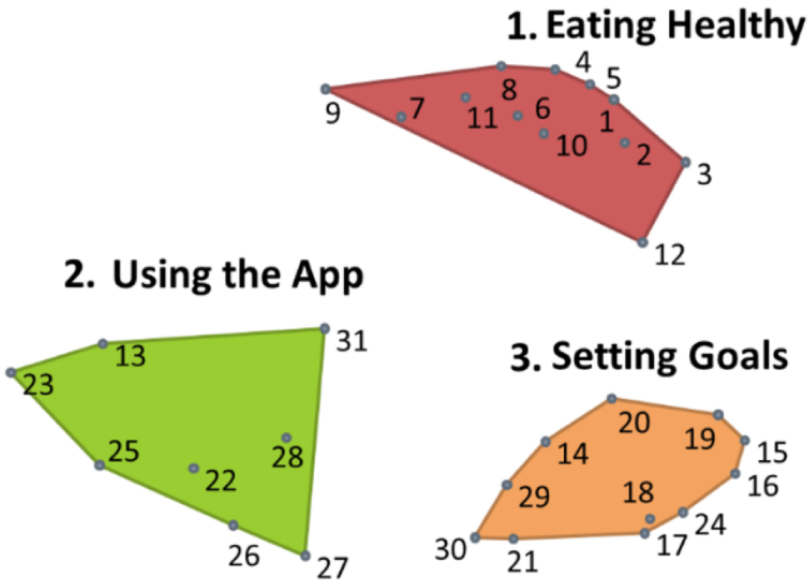
schedules, lack of time, finances, child misbehavior, and shopping with children present.

App Features

Figure 2 shows the combined point and cluster map for the App Features area. The App Features map included the following clusters: (1) Eating Healthy, (2) Using the App, and (3) Setting Goals; likewise, these cluster names were developed from participant pile names in the sorting activity. In the interviews, participants were asked about their current use of apps, especially those that helped with parenting. The type of apps most frequently used by participants to help with parenting were social media (eg, Facebook, Instagram, Snapchat), which caregivers used to follow nutrition-related content, such as recipes, and for parenting advice or finding childcare. Many parents said they used apps to search for and view recipes, including through social media pages, Pinterest, YouTube, and WIC apps. Other participants preferred to use general search engines to find recipes.

Figure 2. Application features combined point and cluster concept map.



Eating Healthy

The concept mapping results support a high interest level in recipes. Items “1. Healthy recipes” (4.42 out of 5), “4. Easy recipes” (4.29 out of 5), and “5. Quick recipes” (4.29 out of 5) had the highest ratings in the Eating Healthy cluster, indicating participants are likely to use these features often or all the time. Recipe viewing was among the most popular desired app features in the interviews; however, some participants did mention they either do not use recipes or are not interested in looking up recipes in an app feature. Participants expressed interest in recipes for the entire family, which could include kid-friendly options, rather than child-specific recipes. Caregivers’ desire for planning features like a grocery list maker and meal planning tools was also desired; however, in the concept mapping results, items around meal planning and grocery lists were not as highly rated as those related to recipes. When discussing this as an app feature, participants explained how meal or grocery shopping features may be more likely to be used if they are kept simple.

Setting Goals

The concept mapping findings also support the popularity of goal-tracking features. Item “20. Set and track goals about making food more child-friendly” (3.88 out of 5) had the highest rating for potential use among a variety of goal-tracking items in the Setting Goals cluster. Tracking features, especially goal tracking (eg, healthy eating, sticking to a routine, sleep, etc.) were also among the most desirable features among interview participants. Alternatively, some caregivers mentioned that, due to a lack of time or disinterest, they do not wish to log items or meticulously keep track of child-related goals on their phone. Some parents said this type of activity is already intuitive for them, so the feature would be unnecessary. Other participants said they already use a form of goal tracking that the app would allow them to simplify.

Using the App

Items “13. App alerts to view tips about child health and nutrition” (3.50 out of 5) and “31. Links to views about child health and nutrition” (3.50 out of 5) had the highest ratings among the Using the App cluster, supporting participants’ desire for helpful tips and notifications. The next highest rated item was “23. Configure app preferences,” suggesting that participants would like to tailor the app settings to their preferences. In the interviews, helpful tips and notifications were welcomed by caregivers; however, many wanted to be clear about the desired frequency at which they wished to be

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notified on their phone. Developmental milestone tracking, general parenting tips, and the desire for everything to be in one place were desirable app features. Resoundingly, caregivers also voiced that simplicity and efficiency were important to them in an app.

Synthesis of Parental Priorities and App Features

Table 4 presents a list of possible content and features for a novel mobile app to improve health behaviors among preschool-aged children, based on the combined interview and concept mapping results. The first column depicts the topic areas of the overarching interview codes, the second column lists possible app content areas based on interview subcodes for parental priorities, and the third column lists possible app features based on interview subcodes along with the features rated as most desired in the concept mapping data, which are indicated in bold italics. By first understanding parental priorities, we ensured our resulting app content will be grounded in user-centered needs. In particular, parental feedback pointed to the need for a holistic app with a variety of health topics in one place, including a strong focus on food and nutrition, routines and time management, along with general parenting tips, each of which correspond to the clusters from the concept mapping process (Creating Healthy Eating Habits, Forming Boundaries, and Building Good Relationships). Informed by the concept mapping rating data, we gained information on ways to focus the development of our novel mobile app through the inclusion of quick, easy, and child-friendly recipes; grocery list or meal planning tools; goal tracking; helpful parenting tips; and the ability to control settings, such as notifications and recipe filters, to customize the experience for individual users. As a whole, exploring parental priorities and mobile app features in combination ensured our app development will be informed by both the desired content and functions that target users (parents with preschool children) would like to have.

Table 4. Summary of possible app content and features based on interview and concept mapping results (most desired features in italics).

Interview topic	Parental priorities: possible app content	Parental interests: possible app features
Food and nutrition	• Mealtime or eating behavior (eg, picky eating) • Making/planning healthy meals	• *Quick, easy recipes*: • Kid-friendly; cooking with kids • Sort or filter ingredients; allergies • Grocery list or meal planning • Picky eating and child nutrition tips
Other health-related	• Limiting screen time • Dental health • Activities for children	• *Desire for multiple health topics in one place (holistic)* • Active play and activities for children tips • Features for parent and child
Routine and time management	• Time management/planning • Managing work responsibilities and parenting	• *Goal tracking* • *Ability to control settings* • Sleep (bedtime/nap) tracking • Ability to share success
Behavioral issues	• Discipline and rule setting • Sticking to boundaries • Reacting mindfully to behavior and patience • Influencing your child	• *General parenting tips* • Interaction with other parents or users • Account for other family members or parent
Developmental milestones	• Potty training • Improving speech • Socialization and interacting with others • Improving sensory development	• Developmental milestone tracking • Communication with health care provider

Discussion

Principal Results and Comparison With Prior Work

Concept mapping has been used on projects focused on childhood obesity prevention programs for adolescents [36] or for the development of culturally appropriate interventions [37], as well as for areas such as sugary drink consumption among children [38], food parenting practices [39], and overall childhood thriving [40]. To our knowledge, however, our study is the first application of the method to guide the development of a health behaviors app for parents of preschool-aged children. In this study, we used a novel, convergent mixed methods approach to identify parental child health priorities and mobile app features that parents or caregivers would prefer to use. Through the use of qualitative interviews, we were able to describe the breadth of parenting challenges and experiences the participants faced. With the addition of concept mapping activities, we were able to identify converging themes and assess priorities among the provided information.

Overall, the participants in this study indicated psychosocial health and general wellbeing, rather than specific behaviors, as their primary focus when expressing their interest in improving health among their preschool-aged children for mobile app content. Using previous research, 12 behavioral factors were identified related to childhood overweight and obesity that

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parents identified when thinking about the health of their child [10,11]. Parent and caregiver responses in this study suggest the importance of establishing a routine and setting boundaries, particularly in areas such as screen time and sleep behaviors. Although healthy eating arose as the most desired topic for resources for young children, participants described a wide variety of preferences around meal planning, grocery shopping, and ways to improve food-related behaviors. Notably, our participants described the importance of all of the related areas identified in the previous literature as important app content to building healthy behaviors for preschool-aged children, including nutrition, physical activity, media use, and sleep.

For specific app features, parents indicated their top choices as (1) quick, easy, and child-friendly recipes; (2) goal-tracking features; and (3) the use of tips and notifications. Goal-setting has been a common behavior change feature used in mobile health applications for children in previous studies with techniques used such as rewards for making progress [18,41,42]. However, there has been a significant gap in that many of the mobile health applications do not feature the involvement of health professionals [18], and few apps exist with the intention of parents using them to modify their children's health behaviors [16,17,43]. In the recent review on goal-setting applications for parents and children, 9 applications were identified that allowed goal-tracking in the setting of health-related behaviors of children, with 6 focused on nutrition or mealtime, 5 focused on physical activity or screen time, 7 focused on sleep, and 6 focused on personal hygiene. None of the apps allowed a parent to specifically recommend goals for each child [17]. Furthermore, matching the divergent views about healthy eating strategies, our participants expressed diversity of thought on their potential use of meal planning or grocery shopping features, though many indicated they would use such features in an app. Additionally, participants expressed interest in tailoring the tips or notifications to a variety of use preferences. As with the health behaviors, our participants described a desire to have everything in one place, so they can find what they need quickly and easily depending on specific needs for their child.

Nutrition and facilitating family mealtimes and daily routines were clearly identified as priorities for this sample of parents and caregivers. The implications of the diverse needs, preferences, and priorities for child health described here may indicate that utility and engagement with mobile tools rest in the balance of simplicity with a choice of multiple features and content foci. Shopping, recipes, and cooking were central to the concerns expressed by these individuals. App features focused on recipes may be designed to incorporate multiple needs and priorities. For example, in order to support the "ease" of healthy meal preparation, provide a recipe feature that allows filtering by time to prepare, provide recipes that address different dietary requirements based on allergies or cultural preferences, or make a shopping list easy to create based on items needed for recipes. Given the preference for a one-stop mobile app, we anticipate that parents will be more engaged with apps that incorporate the whole child and provide behavioral, social, and psychological wellness resources as well.

Limitations

The study sample is representative of relatively lower income families who use public assistance programs; however, the sample included primarily non-Hispanic white and married participants whose perspectives may not represent those of other ethnicities or demographic groups. Future studies in this area should recruit and stratify participants of diverse backgrounds, including single parents and non-traditional family structures, to uncover differences in needs or desires. In addition, individuals choosing to participate in this type of study may be more engaged with parenting practices and improving their child's health than the general population, resulting in selection bias. The use of technology, such as Zoom, can also be a concern among this population; as such, we provided one-on-one assistance to ensure participants felt comfortable using the platform. Additionally, the study had a relatively small sample size, although appropriate for a qualitative approach. Likewise, the purpose of concept mapping is to identify consensus but is dependent upon the composition of the participant sample. Within the concept mapping data, high importance ratings with low variability are often seen, as items are included in the brainstorming list based on their potential importance; we experienced this issue in our data. However, by using multiple methods to triangulate our findings, we feel confident in the ability of our results to accurately capture the perceptions of parents of young children.

Conclusions

For our team, this formative research provided the groundwork for the development of a novel mobile app, including both content and features, for parents and caregivers of preschool-aged children focused on guided goal setting across the domains of diet, physical activity, media use, and sleep. A convergent mixed methods approach provided high-quality data on diverse parental perceptions and challenges and needs for families. Specific app features identified to meet family needs should be designed closely with a diverse set of families and tested using rigorous designs to identify the mechanisms of action that mobile apps may use for efficacious healthy parenting outcomes. This study makes important contributions to the mHealth field for understanding what parents or caregivers of young children want from mobile apps to support building healthy behaviors and routines. The findings can inform future research on the development and evaluation of existing or new mobile apps.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Semistructured discussion guide for interview questions.
[PNG File , 547 KB - pediatrics_v8i1e65451_app1.png]

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Abbreviations

mHealth: mobile health
REDCap: Research Electronic Data Capture

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SNAP: Supplemental Nutrition Assistance Program
WIC: Special Supplemental Nutrition Program for Women, Infants, and Children

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Adapting Cognitive Behavioral Therapy for Adolescents in Iraq via Mobile Apps: Qualitative Study of Usability and Outcomes

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Abstract

Background: Mental health challenges, including anxiety and depression, are increasingly common among adolescents. Mobile health (mHealth) apps offer a promising way to deliver accessible cognitive behavioral therapy (CBT) interventions. However, research on the usability and effectiveness of apps explicitly tailored for adolescents is limited.

Objective: This study aimed to explore the usability, engagement, and perceived effectiveness of a mobile CBT app designed for adolescents, focusing on user experiences and mental health outcomes.

Methods: A qualitative study was conducted with 40 adolescents aged 13 - 19 years (mean age 15.8, SD 1.9 years; 18/40, 45% male; 22/40, 55% female) who engaged with a CBT app for 4 weeks. Mental health diagnoses included anxiety (20/40, 50%), depression (15/40, 38%), and both (5/40, 13%). Of these, 10 (25%) of the 40 participants had previous CBT experience. Feedback was gathered through focus groups and individual interviews, and thematic analysis identified key themes related to usability, engagement, and perceived effectiveness. Quantitative data on mood and anxiety scores were analyzed with paired *t* tests.

Results: The mean usability score was 3.8 (SD 0.6), and the mean effectiveness score was 3.9 (SD 0.7). Older participants (aged 16 - 19 years) reported significantly higher usability (mean 4.1, SD 0.4) and effectiveness scores (mean 4.3, SD 0.5) compared to younger participants (aged 13 - 15 years) (P=.03). Females had higher usability (mean 4, SD 0.6) and effectiveness scores (mean 4.2, SD 0.7) than males (mean 3.6, SD 0.7, and mean 3.5, SD 0.8, respectively; P=.03). Participants with prior CBT experience had 2.8 times higher odds of reporting high usability scores (95% CI 1.6 - 5; P=.002) and 3.1 times higher odds of reporting high effectiveness scores (95% CI 1.7 - 5.6; P=.001). Usability challenges included complex navigation (20/40, 50%), interface design issues (12/40, 30%), and content overload (8/40, 20%). Factors positively influencing engagement were motivation driven by personal relevance (20/40, 50%) and gamification features (10/40, 25%), while lack of personalization (14/40, 35%) and external distractions (18/40, 45%) were significant barriers. Mood improvement (15/40, 38%) and learning new coping skills (12/40, 30%) were the most reported outcomes.

Conclusions: The mobile CBT app shows potential for improving adolescent mental health, with initial improvements in mood and anxiety. Future app iterations should prioritize simplifying navigation, adding personalization features, and enhancing technical stability to support long-term engagement.

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KEYWORDS

cognitive behavioral therapy; CBT; psychotherapy; mHealth; app; adolescents; teenager; mental health; usability; engagement; anxiety; depression; user experience; UX; focus group; interview; digital health

Introduction

Mental health challenges among adolescents have become increasingly prevalent, with issues like anxiety, depression, and stress-related disorders affecting a significant portion of this population [1-4]. Adolescence is a critical developmental period marked by emotional, cognitive, and social changes, which can increase vulnerability to mental health disorders [5-7]. The World Health Organization estimates that up to 20% of adolescents experience mental health conditions, highlighting the urgent need for effective and accessible interventions [8-10].

In response to this growing demand, mobile health (mHealth) apps have emerged as a promising solution for delivering mental health care [11-14]. These apps offer a flexible, cost-effective,

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and private means for adolescents to access psychological interventions, which may otherwise be limited due to stigma, lack of resources, or geographical barriers [15-19]. Among the various therapeutic approaches, cognitive behavioral therapy (CBT) has proven to be particularly effective in addressing common adolescent mental health issues like anxiety and depression [20-24]. CBT focuses on helping individuals identify and modify negative thought patterns and behaviors, making it well suited for delivery via mobile platforms that offer interactive and self-guided modules [25-28].

Despite the promise of mobile CBT apps, there remains a significant research gap regarding their usability and effectiveness for adolescents [29,30]. Most existing studies focus on adult populations or general app evaluations without considering younger users' unique needs and preferences [31,32]. Adolescents may have different expectations for user experience, engagement, and motivation when interacting with digital health tools [33,34]. Additionally, this age group's developmental and emotional characteristics necessitate a design that fosters engagement and provides adequate support [35-39].

In Iraq, mental health services face significant barriers due to stigma, lack of resources, and geographical constraints, which limit adolescents' access to traditional therapy. Postconflict instability, socioeconomic challenges, and strained health care systems have compounded mental health issues among Iraqi youth, creating a need for innovative solutions tailored to this population. Adolescents in Iraq, particularly those in low-resource settings, may be unable to access face-to-face therapy due to the limited availability of mental health professionals and the high costs associated with treatment.

While the potential of mobile CBT apps is evident, there is a lack of research on their usability and effectiveness among adolescents, particularly in regions like Iraq. This study aims to address this gap by exploring the usability, engagement, and outcomes of a mobile CBT app tailored specifically for adolescents in Iraq. The findings will provide valuable insights into how digital mental health tools can be optimized to better serve this vulnerable population in low-resource settings.

This study aimed to evaluate the usability, engagement, and perceived effectiveness of a mobile CBT app for adolescents, with a focus on user experiences and its impact on mental health outcomes.

Methods

Participants

The study recruited adolescents aged 13 - 19 years who were experiencing mental health challenges, including anxiety and depression. A convenience sampling method was used to select participants from various sources, including local schools, mental health clinics, and online mental health communities. Participants were referred by counselors or health care providers and expressed interest in participating. Inclusion criteria required that participants had a self-reported diagnosis of anxiety or depression, regular access to a smartphone, and, for those aged <18 years, parental consent. A sample size of 40 adolescents was chosen for an in-depth qualitative analysis of diverse perspectives while maintaining manageability for detailed thematic analysis. The study was conducted in Mosul, Iraq, ensuring a regional context for the findings. Data confidentiality and participant anonymity were prioritized throughout the study. Each participant was assigned a unique identifier code used in place of personal information during data collection, transcription, and analysis. This ensured that no identifying details were linked to the responses. Informed consent was obtained from all participants, outlining their rights to privacy and the confidential handling of their data. Interview and focus group recordings were securely stored in encrypted files, accessible only to authorized research team members. All transcripts were deidentified prior to analysis to protect participant identities further, and findings were reported in aggregate to prevent any individual from being identified.

Intervention

Participants were introduced to a CBT mobile app designed specifically for adolescents. The app was commercially available and selected based on its adherence to established CBT principles, as well as its focus on common adolescent mental health issues such as anxiety, depressive thoughts, and stress management. The app featured interactive modules, journaling functions, mood tracking, and self-assessment tools, all aimed at guiding users through CBT-based interventions. The selection of the app was influenced by its popularity, user ratings, and evidence-based framework, ensuring that it met the study's requirements for delivering structured CBT exercises. Participants were asked to engage with the app for 4 weeks, with a recommendation to complete at least 3 CBT exercises per week, though they were free to use it at their discretion.

Study Design

The study adopted a qualitative approach to gather rich, in-depth insights into the participants' experiences with the mobile CBT app. Data were collected through focus groups and one-on-one semistructured interviews after the 4-week intervention period. This design allowed for exploring the app's usability, engagement, and perceived outcomes from the adolescent perspective. The qualitative approach was well suited in understanding users' subjective experiences and identifying themes related to app interaction and mental health improvement.

Data Collection

Data collection focused on both app interaction and user feedback. The following methods were used.

App Usage Metrics

In-app data were collected to track the frequency of app usage, time spent on activities, completion of CBT modules, and interaction with various app features (eg, journaling and mood tracking).

User Feedback

Participants provided feedback through focus groups and interviews, where they discussed their experiences with the app. Topics of discussion included usability (ease of navigation and design preferences), engagement (motivation to use the app and consistency of use), and perceived outcomes (changes in mood,

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anxiety, or stress levels). Interviews were recorded and transcribed for analysis.

Outcome Measures

The study evaluated the following outcomes.

Usability

This included ease of navigation, design intuitiveness, and app aesthetics. Participants shared feedback on the app's user-friendliness and any barriers they encountered.

Effectiveness

Participants self-reported any changes in their mental health symptoms, particularly about anxiety and depression. Symptom reduction was assessed using qualitative descriptions of mood changes and mental health improvements throughout the study.

Overall Satisfaction

Participants reflected on their satisfaction with the app, including its features, content relevance, and overall impact on their mental health. Satisfaction was gauged through subjective feedback on whether they would recommend the app to peers or continue using it poststudy.

Ethical Considerations

This study was conducted in accordance with the ethical guidelines set in the Declaration of Helsinki and was approved by the institutional review board of the University of Ninevah (approval reference number: NURIRB/041/2023). All the processes involving human subjects were reviewed and deemed ethically acceptable by the institutional review board. As most participants were minors aged <18 years, extra ethical precautions were exercised. For participants aged <18 years, written informed consent was obtained from parents or their legal guardians and assent from the adolescents. The assent forms were read in age-specific terms so the minors would clearly understand the purpose of the study, procedures to be followed, risks and benefits, if any, and their rights, such as withdrawal from the study at any time without any penalty. Parents and guardians received full written and verbal explanations of the study, including confidentiality protocols and data privacy protections, so that participation would be based on fully informed decision-making. All data were anonymized and stored securely to protect participant privacy and confidentiality. Identifying information was stored separately from the main dataset and was accessible only to authorized research team members. No financial incentives or rewards were promised to the participants or their families for participating in this study, so as to avoid coercion or undue influence.

Results

Age, Usability, and Effectiveness

The study found that age was slightly correlated with app usability and effectiveness. Older adolescents (aged 17 - 19 years) generally reported higher usability scores and perceived greater effectiveness than younger participants (Table 1). This could be due to increased digital literacy and maturity in using therapeutic tools among older users, who may navigate the app more intuitively and apply CBT techniques more consistently.

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Table . Demographic characteristics (N=40) and correlation with usability and effectiveness outcomes for the CBT[a] app.

Characteristic	Participants, n (%)	Usability score, mean (SD)	Effectiveness score, mean (SD)	Preferred features	Notable observations
Age (years)					
13 - 15	15 (38)	3.2 (0.5)	3.4 (0.6)	Gamification and mood tracking	Less consistent engagement but reported mood improvements
16 - 19	25 (62)	4.1 (0.4)	4.3 (0.5)	Journaling and thought reframing	Higher digital literacy correlated with better usability
Gender					
Male	18 (45)	3.6 (0.7)	3.5 (0.8)	Gamification and relaxation techniques	Gamification boosted engagement; preferred reward-based elements
Female	22 (55)	4.0 (0.6)	4.2 (0.7)	Journaling and mood tracking	Consistent journaling and tracking helped manage emotions
Mental health diagnosis					
Anxiety	20 (50)	4.0 (0.5)	4.1 (0.6)	Mood tracking and relaxation techniques	Frequent mood tracking to manage anxiety triggers
Depression	15 (38)	3.7 (0.6)	3.8 (0.5)	Journaling	Journaling as a primary emotional outlet
Both	5 (12)	3.5 (0.7)	3.6 (0.8)	Combination of all features	Mixed feature use, desire for more personalization
Previous CBT experience					
Yes	10 (25)	4.2 (0.4)	4.3 (0.6)	Thought reframing and relaxation	Higher familiarity led to easier app navigation
No	30 (75)	3.5 (0.6)	3.6 (0.7)	Mood tracking and gamification	Accessibility for beginners; tutorial recommended

[a]CBT: cognitive behavioral therapy.

Gender Differences

Gender differences were evident in feature engagement and overall satisfaction with the app. Female participants reported using journaling and mood tracking more frequently and found these features particularly beneficial for managing their emotions. Males, however, demonstrated a stronger preference for gamification elements, suggesting they might respond better to reward-based interactions within the app. This result indicates that gender-sensitive adaptations, like balancing gamified elements with reflective exercises, could optimize engagement.

Mental Health Diagnosis

Diagnosis type influenced how participants interacted with different app features. Adolescents diagnosed with anxiety frequently engaged with mood tracking to monitor their anxiety triggers and reported that it helped them feel more in control. In contrast, participants with depression found journaling more beneficial, as it provided an outlet for emotional expression. Those with both anxiety and depression reported mixed results, finding both features helpful but expressing a need for more personalized guidance. These findings suggest that tailoring app features based on specific mental health diagnoses may enhance effectiveness.

Previous CBT Experience

Prior CBT experience was associated with higher usability scores. Participants familiar with CBT concepts found the app easier to navigate and were able to engage more readily with tools like thought reframing and relaxation exercises. Those without prior CBT experience still reported short-term improvements, indicating that the app is accessible for beginners, though they noted that a brief tutorial on CBT basics could improve initial engagement.

Interaction Between Characteristics

When analyzing the interaction between age and diagnosis, older adolescents with anxiety showed a unique pattern of consistent engagement with mood tracking and relaxation exercises, possibly due to increased awareness of their symptoms and the therapeutic benefits of tracking. This contrasts with younger adolescents with depression, who were less consistent with engagement but reported substantial short-term mood

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improvements when they did engage, highlighting age and symptom-specific usage patterns.

Usability Challenges

Overview

Several usability challenges were identified through participant feedback (Table 2). While the majority of adolescents found the app's interface visually appealing, many encountered issues related to its design and navigation. For example, one participant stated, "It was hard to find the tools I needed; sometimes I got lost in the app" [Participant 3, female, 16 years old].

Table . Themes identified in usability challenges (N=40).

Usability challenge	Description	Values, n (%)
Complex navigation	Difficulty in finding features or completing multistep tasks	20 (50)
Interface design	Issues with text size, button placement, or layout on mobile devices	12 (30)
Content overload	Feeling overwhelmed by the amount of content in some sections	8 (20)

Complex Navigation

Of the 40 participants, 20 (50%) reported difficulty navigating through the app, particularly when attempting to access multistep CBT modules. They expressed a desire for clearer instructions and a more simplified user interface.

Interface Design

Of the 40 participants, 12 (30%) mentioned that the app's text size and button placement were not user-friendly, especially when using smaller mobile devices. This affected their overall experience and led to frustration in some cases.

Content Overload

Of the 40 participants, 8 (20%) felt overwhelmed by the amount of information presented in certain sections of the app. They indicated that the extensive content occasionally discouraged further use.

Engagement

Participant engagement with the app varied and was influenced by several factors, including personal relevance and gamification features (Table 3).

Table . Factors influencing engagement with the CBT[a] app (N=40).

Factor	Description	Values, n (%)
Motivation (personal relevance)	Continued use linked to personal mental health needs and recognition of the app's benefits	20 (50)
Gamification and rewards	Positive response to interactive features and rewards	10 (25)
Personalization	Engagement hindered by lack of tailored content and goals	10 (25)

[a]CBT: cognitive behavioral therapy.

Motivation and Personal Relevance

Of the 40 participants, 20 (50%) who found the app's content personally relevant and aligned with their mental health needs reported higher levels of engagement. These participants were more likely to use the app consistently throughout the 4-week period. For example, one participant noted, "The rewards made it fun and kept me coming back" [Participant 5, male, 17 years old].

Gamification and Rewards

Of the 40 participants, 10 (25%) responded positively to the app's gamified elements, such as rewards for completing exercises and interactive features like mood tracking. They reported that these features enhanced their motivation to continue using the app.

Lack of Personalization

Of the 40 participants, 10 (25%) noted that the absence of personalization options, such as customized goals or tailored content, negatively impacted their long-term engagement with the app.

Perceived Effectiveness

The majority of participants reported experiencing positive mental health outcomes, although the duration of the benefits varied (Table 4). For example, one participant stated, "The app gave me exercises that helped calm me down before an exam" [Participant 2, male, 14 years old].

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Table . Perceived effectiveness of the app (N=40).

Effectiveness outcome	Description	Values, n (%)
Mood improvement	Participants reported a reduction in anxiety or improved mood after using the app	15 (38)
Learning coping skills	Users noted acquiring new coping mechanisms for managing stress and negative thoughts	12 (30)
Short-term benefits	Short-term improvements, but benefits were not sustained without continuous app use	13 (32)

Mood Improvement

Of the 40 participants, 15 (38%) reported a noticeable reduction in anxiety levels and an improvement in their mood after completing CBT exercises, particularly those focused on breathing techniques and cognitive restructuring.

Learning Coping Skills

Of the 40 participants, 12 (30%) highlighted that they learned new coping mechanisms, such as identifying and challenging negative thought patterns, which helped them manage day-to-day stress.

Short-Term Benefits

Despite these positive outcomes, 13 (32%) out of 40 participants mentioned that the improvements were short-term and did not last without regular app usage. This suggests that sustained engagement is necessary for long-term benefits.

Barriers to App Usage

Several barriers were identified that limited participants' consistent use of the app or reduced its perceived effectiveness (Table 5).

Table . Barriers to app usage (N=40).

Barrier	Description	Values, n (%)
App functionality issues	Technical problems like slow loading times or app crashes	8 (20)
Lack of personalization	Limited customization options for individual needs	14 (35)
External distractions	Schoolwork, social media, or lack of time impacting regular usage	18 (45)

App Functionality Issues

Of the 40 participants, 8 (20%) experienced technical problems, such as slow load times or occasional crashes, which discouraged them from using the app regularly.

Lack of Personalization

As previously mentioned, 14 (35%) out of the 40 participants felt that the lack of individualized content limited their overall engagement and the app's relevance to their specific mental health needs. One participant shared, "I felt like the app understood what I was going through, and that kept me using it" [Participant 7, male, 15 years old].

External Distractions

Of the 40 participants, 18 (45%) cited external distractions, such as schoolwork, social media, and general time constraints, as reasons for inconsistent app usage. They suggested that push notifications or reminders could help them stay on track with their CBT exercises. A participant commented, "Knowing others were going through the same thing made me feel less alone" [Participant 4, female, 16 years old].

Data Analysis Process

A thematic analysis was used to systematically explore the data gathered from focus groups and individual interviews. This qualitative approach is particularly suited to understanding the nuanced experiences of participants, as it allows for the identification of patterns and themes within textual data [40]. The analysis followed an inductive approach, where themes were derived directly from the data without imposing pre-existing frameworks, ensuring that the findings reflect participants' perspectives authentically [41].

Steps of Thematic Analysis

The steps of thematic analysis were as follows:

1. Data Familiarization: all interview transcripts were thoroughly reviewed to immerse the research team in the data and gain an initial understanding of the content.
2. Coding: initial codes were generated to highlight recurring patterns, unique responses, and significant statements related to usability, engagement, and perceived effectiveness.
3. Theme Development: codes were then grouped into broader themes that encapsulated the key insights, such as barriers to engagement, facilitators of usability, and outcomes of perceived effectiveness.
4. Review and Refinement: themes were refined iteratively to ensure they were distinct, relevant, and reflective of the dataset as a whole.

This method is appropriate for the study as thematic analysis provides flexibility in analyzing diverse qualitative data and is well suited for understanding user experiences with interventions

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such as mobile CBT apps [42]. It enables researchers to capture both explicit content and latent meanings in the data.

Adequacy of Sample Size

The sample size for this study is adequate based on qualitative research standards. Data saturation—a point where no new themes or insights emerge—can often be achieved with 6 - 12 interviews, depending on the study's scope and participant homogeneity [43]. In this study, combining focus groups and individual interviews ensured a rich dataset that captured a range of perspectives while adhering to the principle of saturation.

Discussion

Principal Findings and Interpretation

This study explored the usability, engagement, and perceived effectiveness of a mobile CBT app designed for adolescents facing mental health challenges, such as anxiety and depression. The findings provide valuable insights into the potential of mobile CBT apps while highlighting areas for improvement, especially for adolescents in low-resource settings like Iraq.

Usability and Personalization

One key finding was the usability challenges reported by participants, including complex navigation and nonintuitive design. Participants frequently mentioned difficulties in locating tools or navigating through the app's interface. This underscores the need for developers to prioritize user-centered design that is simple, clear, and adaptable to different devices and screen sizes.

Features such as guided tutorials and step-by-step walkthroughs can facilitate easier navigation for adolescents with varying levels of digital literacy. Additionally, the app should be rigorously tested across multiple devices to ensure smooth performance and minimize technical barriers that deter consistent use.

A significant recommendation based on the feedback is the incorporation of personalization features, which could enhance the app's effectiveness and user engagement. Developers could implement adaptive algorithms that adjust content based on user input and progress, allowing the app to deliver more targeted interventions. For example, users could set personal mental health goals, such as reducing anxiety before exams, and the app could tailor CBT exercises accordingly to align with these objectives. Additionally, personalized content delivery based on self-assessment responses could ensure that users receive modules or exercises most relevant to their emotional state or specific stressors. Regular mood check-ins could further refine these recommendations, offering targeted suggestions that align with the user's evolving needs and experiences.

Consistent with earlier studies, such as Zhang et al [44], the app demonstrated potential in improving adolescents' mental health outcomes by providing accessible and flexible therapeutic tools. Previous work has highlighted the importance of user-friendly interfaces in promoting app adherence [45], and this study reinforces those conclusions. Participants' feedback about challenges in navigating the app echoes findings from Cheng et al [46], where adolescents reported that complex interfaces reduced their motivation to engage consistently.

Furthermore, the study aligns with the conclusions of Miller et al [47], which emphasized the critical role of personalization in enhancing the efficacy of digital interventions. Like Milleret al [47], our results suggest that tailoring app content to users' unique needs and progress is key to maintaining engagement and achieving desired outcomes.

The study revealed that engagement was strongly influenced by participants' perceptions of the app's relevance to their specific mental health needs. Participants who felt that the app effectively addressed their challenges were more likely to use it consistently, a finding supported by Banneyer et al [48], who demonstrated that content alignment with user needs significantly improves adherence to digital mental health interventions. Gamification features, such as badges, levels, and progress tracking, were identified as key motivators that sustained interest and encouraged continued use. These findings align with Ng and Wong [49], who reported that gamification elements enhance user engagement by creating a sense of achievement and progress.

Additionally, social features like anonymous peer support or community forums emerged as promising strategies for fostering connection and reducing feelings of isolation. This observation resonates with Silberg et al's [50] findings, who highlighted the role of social support mechanisms in increasing the acceptability and usage of mental health apps. In collectivist cultures like Iraq, where community and social bonds are deeply valued, enabling adolescents to share their progress or experiences anonymously could enhance engagement by leveraging these cultural strengths. This aligns with Patel et al [51], who noted the importance of culturally sensitive features in ensuring the success of digital health interventions. Future research should investigate the impact of such social features in different cultural contexts to determine their broader applicability and effectiveness.

Perceived Effectiveness

The perceived effectiveness of the app was influenced by its ability to address specific mental health challenges faced by participants. Such feedback highlights the importance of targeted interventions that address adolescents' real-world stressors. Participants also emphasized the need for evidence-based tools that provide tangible benefits. Incorporating features that explain the rationale behind each exercise and how it aligns with CBT principles could enhance perceived effectiveness and build user trust.

The findings align with prior research on adolescent mHealth engagement, such as those of Ghosh et al [52] features like personalization, gamification, and caregiver endorsement are critical for adolescent engagement in mHealth apps. Similarly, Oakley-Girvan et al [53] emphasized the importance of adaptive content and user-centered design in sustaining engagement. These studies underscore the importance of tailoring mHealth interventions to meet the unique needs of adolescent users while addressing cultural and contextual factors.

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Long-Term Benefits and Sustainability

While most participants reported short-term improvements in mood and anxiety, the benefits were not sustained without regular app usage. This finding highlights the need for future mobile CBT apps to incorporate features that foster long-term engagement and sustained mental health improvements. Features such as regular reminders, progress tracking, and reinforcement of positive behaviors over time could play a crucial role in maintaining user involvement. For instance, push notifications reminding users to complete CBT exercises, celebrate milestones, or provide motivational messages have been shown to improve engagement and adherence in similar interventions [51].

Additionally, there is significant potential to integrate digital and human support in future app iterations. Adolescents could benefit from a hybrid model that combines the self-guided app with access to mental health professionals or peer mentors when needed. This approach aligns with findings from Gentry et al [54], which demonstrated that blending digital tools with human interaction significantly enhances mental health outcomes. Similarly, Patel et al [51] emphasized that hybrid models are particularly effective in resource-limited settings, where direct access to therapists is scarce. In regions like Iraq, where mental health resources are constrained, a blended approach could address both accessibility and sustainability challenges. By combining the strengths of digital and human support, mobile CBT apps could ensure broader and more enduring benefits, providing an effective solution for sustaining mental health improvements over time.

Implications for Future Development

The findings of this study highlight several key recommendations for the future development of mobile CBT apps for adolescents, particularly in low-resource settings like Iraq:

- Simplify navigation to enhance usability, ensuring the app is easy to use across different devices and levels of digital literacy.
- Incorporate adaptive personalization that tailors content based on individual user needs, goals, and progress.
- Gamify engagement to sustain motivation and encourage regular use, with a focus on rewards that resonate with the adolescent user base.
- Address external barriers such as distractions and time constraints by providing flexible features like push notifications and offline accessibility.
- Consider cultural and regional factors when designing apps, ensuring that features such as peer support align with the social values of the target audience.

Recommendations

Enhance Personalization

Adaptive Content Delivery

Integrate artificial intelligence–based algorithms to tailor content to the user's progress, mood, and engagement level. For example, adaptive modules can adjust the difficulty of activities based on the user's performance or offer reminders tailored to individual schedules.

User-Centered Goal Setting

Allow users to set personal goals within the app, such as managing daily stress or improving sleep. Personalized progress tracking and feedback can enhance motivation and sustain engagement over time.

Localized and Culturally Relevant Content

Incorporate content that resonates with the cultural background and life experiences of adolescents in Iraq, such as language options and culturally sensitive scenarios that foster user connection and comfort.

Incorporate Gamification Elements

Reward Systems and Badges

Introduce badges, points, or achievements for completing exercises, engaging regularly, or reaching personal milestones. A reward system can make engagement feel more rewarding and less clinical.

Interactive Challenges and Quests

Design challenges that encourage users to engage with the app routinely, such as completing daily mindfulness exercises or participating in weekly reflections. This can add a playful dimension to the app while reinforcing positive habits.

Social Sharing Features

Users can share their achievements with peers or within safe, moderated groups. Social elements can increase accountability, foster community, and provide an additional layer of engagement.

Streamline Navigation and Interface Design

Simplified User Flows

Minimize the steps required to reach core functionalities like exercises or mood tracking. Intuitive navigation should allow users to quickly locate and engage with tools, even if they only have a few minutes available.

Onboarding Tutorials

A brief, interactive onboarding process can familiarize new users with app functions, making it easier to navigate from the start. Offering short tutorials on new features introduced in updates can also enhance usability.

Improve Technical Stability

Offline Functionality

Given connectivity challenges, especially in rural areas, consider building offline capabilities for essential features, allowing users to complete exercises or track their mood without internet access.

Regular Testing and Updates

Frequent testing for bugs, usability issues, and prompt updates will improve overall stability and user satisfaction.

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Conclusions

Overall, this study demonstrates that mobile CBT apps hold great promise for improving adolescent mental health, particularly in low-resource settings like Iraq. By addressing usability challenges, enhancing engagement through personalization and gamification, and overcoming barriers to usage, mobile CBT interventions can become more effective and accessible tools for young people. As digital health solutions continue to evolve, developers should prioritize user-centered, flexible designs that cater to the unique needs of adolescents in diverse cultural contexts. Future research should explore how to extend the long-term impact of these interventions, potentially through hybrid models that combine self-guided app use with professional support.

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Authors' Contributions

RHI, MHY, MQH, SHAM, MFA and OAM conceived the study. RHI analyzed the data and wrote the first draft. All the authors have read and approved the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
mHealth: mobile health

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Original Paper

The Impact of Parental Support on Adherence to Therapist-Assisted Internet-Delivered Acceptance and Commitment Therapy in Primary Care for Adolescents With Anxiety: Naturalistic 12-Month Follow-Up Study

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Abstract

Background: Mental health problems among adolescents are increasing, and internet-delivered acceptance and commitment therapy (iACT) constitutes a possible way to improve access to care while reducing costs. Nevertheless, few studies have investigated iACT for adolescents in regular primary care nor the role of parental support.

Objective: This is an exploratory evaluation investigating iACT, with or without parental support, for adolescents. The aims were to examine treatment adherence, symptoms of anxiety and depression, psychological flexibility, and overall functioning.

Methods: Adolescents with anxiety were recruited within the regular primary care patient flow during the implementation phase of therapist-assisted iACT for adolescents. Assessment and inclusion were executed face-to-face. Due to organizational reasons, the assignment of treatment methods could not be randomized. Adherence was investigated by measuring the number of completed modules. Outcome measures were collected by self-assessment questionnaires including the Revised Children's Anxiety and Depression Scale and Avoidance and Fusion Questionnaire for Youth, as well as interviews using the Children's Global Assessment Scale. The analysis was performed as an exploratory evaluation using descriptive data for treatment adherence and nonparametric within-group analysis with the Wilcoxon signed rank test for related samples and treatment outcomes. This evaluation is naturalistic, and the results are preliminary and of a hypothesis-generating character and should be handled with caution.

Results: The iACT group without parental support (n=9) exhibited a gradual dropout throughout the treatment period (n=5), whereas the iACT group with parental support (n=15) exhibited the lowest number of dropouts from treatment before completion (n=2), of which all occurred during the second half of treatment. The within-group, per-protocol analyses for the Revised Children's Anxiety and Depression Scale indicated reduced symptoms of anxiety and depression at the 12-month follow-up (z score: –2.94; P=.003; r=–0.6). The within-group, per-protocol analyses for the Avoidance and Fusion Questionnaire for Youth indicated increased psychological flexibility at the 12-month follow-up (z score: –2.54; P=.01; r=0.55). Nevertheless, no differences in overall functioning measured by the Children's Global Assessment Scale were found.

Conclusions: The results indicate that parental support might play a role in treatment adherence in iACT for adolescents with anxiety. Moreover, the outcome measures suggest that iACT for adolescents in primary care could constitute an effective treatment for both anxiety and depression, as indicated by the symptom reduction and increased psychological flexibility, maintained at

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the 12-month follow-up. Nevertheless, due to a small and gender-biased sample size with a large proportion of dropouts and missing data, a nonrandomized assignment of intervention, and an analysis limited to within group, this study should be considered an explorative evaluation rather than an outcome study.

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KEYWORDS

adolescents; parental support; anxiety; depression; primary care; mental health; ACT; acceptance and commitment therapy; iACT; internet-delivered acceptance and commitment therapy

Introduction

According to the National Board of Health and Welfare in Sweden, mental health among children and young people has deteriorated, both based on self-reported psychological symptoms and on diagnosed mental disorders [1]. Anxiety and depression have been identified as significant factors, of which anxiety is the most common [2]. Furthermore, both anxiety and depression are associated with social withdrawal, adverse effects on academic performance, functional impairment, and ultimately, risk factors for suicide [3,4]. For adolescents with generalized anxiety disorder (GAD), separation anxiety disorder, and social phobia, the selective serotonin reuptake inhibitor Sertraline, as well as cognitive behavioral therapy (CBT), are the recommended treatment methods [1]. According to the Swedish National Board of Health and Welfare, CBT is well documented, recommended as a first intervention [5], and considered an effective treatment for anxiety disorders in children and adolescents [6].

In Sweden, primary care services include performing an initial assessment on children and adolescents regarding symptoms, symptom severity, and eventual need for treatment. If an anxiety disorder is assessed to be mild, an intervention shall be offered, and if moderate to severe, the patient shall be triaged to psychiatric care [5]. Furthermore, early intervention is crucial in preventing chronic mental illness [7], but many adolescents do not seek help from mental health care. O'Dea et al [8] have identified a lack of awareness among the population of signs of mental ill health, limited access to health care, and costs as possible obstacles. The authors suggest internet-based CBT (iCBT) as a way of increasing accessibility to treatment while reducing costs and that iCBT exhibits similar effect sizes as face-to-face treatment.

In a systematic review and meta-analysis, Vigerland et al [9] evaluated 25 studies on iCBT, including only studies in which the mean participant age was younger than 18 years. Of the studies, 7 studies were based on a Swedish population and 6 studies were on anxiety. The authors concluded that iCBT has positive outcomes, may be feasible, and exhibited moderate effect sizes compared to the waitlist. In a Danish randomized controlled trial (RCT), 70 adolescents with anxiety disorders were randomized into either iCBT or waitlist, and the iCBT group exhibited significant improvement based on both adolescent and parent ratings and that iCBT exhibited moderate to large effect sizes between groups [10]. Moreover, in an Australian RCT, 115 adolescents with anxiety from a community sample were randomized to either iCBT, face-to-face CBT, or waitlist conditions. At the 12-month follow-up, the authors found no significant differences regarding treatment outcomes between the groups and concluded that iCBT offers reduced therapist time and hence increased accessibility [11]. In a Swedish study, 120 adolescents were randomized to either standard iCBT, iCBT with learning support, iCBT with chat, or iCBT with learning support and chat. The group with learning support initially exhibited better outcomes but the difference was not sustained at the 6-month follow-up, and the authors determined iCBT to be an effective treatment method for adolescents with anxiety and depression. The authors found small effect sized on secondary outcomes related to anxiety and that the effect sized indicated the benefits of memory support during iCBT [12]. Nevertheless, in all the abovementioned studies, the participants were recruited either via advertisements or referral to secondary care. Thus, none of the studies were conducted in regular primary care.

Acceptance and commitment therapy (ACT) is a third-wave behavioral therapy oriented at acceptance and mindfulness and aimed at increasing psychological flexibility, defined as the ability to be present and act accordingly in line with one's values [13]. Face-to-face ACT is considered an effective treatment for children and adolescents with anxiety disorders [14,15] and exhibits small to medium effect sizes regarding anxiety and depression [16]. In a Swedish study, Nissling et al [17] investigated the effectiveness of internet-delivered ACT (iACT) on adolescents with anxiety by randomizing 52 participants aged 15-19 years from all over Sweden into either iACT or waitlist. Both groups improved but the participants in the intervention group exhibited significantly higher improvements regarding anxiety and exhibited moderate effect sizes between groups. The authors concluded that iACT is effective in improving quality of life and psychological flexibility, which in turn was associated with reduced anxiety symptoms. Another study randomized 348 adolescents to either (1) iACT student coach and a digital coach group, (2) only iACT digital coach group, or (3) no intervention. The authors found significant improvements in the iACT groups compared to the control group regarding reduced anxiety and increased valued action and self-compassion [18].

Few studies have examined iACT for adolescents in a routine primary care setting. To broaden the understanding of iACT in primary care for adolescents with anxiety, the Internet Mediated Psychological Treatment-Acceptance and Commitment Therapy (IMPACT) project was conducted as an ongoing evaluation during the implementation of iACT for adolescents in the region Västra Götaland in southwestern Sweden. The intervention in focus is the same as that in the study by Nissling et al [17] and contains ACT features [19].

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In the first IMPACT paper, the authors highlighted the importance of parental involvement in iACT for adolescents, suggesting it might compensate for low treatment motivation [20]. In the second IMPACT paper, the authors concluded that the role of the parents needs clarification [21]. Attention to parental engagement in mental health treatments of adolescents has increased in recent years, and in 2015, a review of 23 papers was conducted by Haine-Schlagel and Walsh [22]. The results indicated potential links between parental participation and positive outcomes. The authors concluded that further research is needed to determine treatment factors, as well as organizational factors, regarding parental engagement in mental health treatment for both children and families. Moreover, Lundkvist-Houndoumadi et al [23] performed a phenomenological analysis of 24 semistructured interviews with Danish families in which the youth received CBT for anxiety with parental involvement. The authors concluded that the therapists' expectations of the parents to be cotherapists were difficult to implement in some cases due to the family dynamics and the expectations and resources among the parents. Overall, there seems to be a need for further information regarding the parental role in iCBT and iACT for adolescents and how the parents can support the adolescent's treatment. Haine-Schagel and Walsh [22] have concluded that research regarding parental engagement would benefit from more studies on specific parent-supportive behaviors in clinical interactions [22].

In summary, few studies have investigated iACT for adolescents in a routine primary care setting nor the role of the parents. Therefore, the IMPACT project aimed to conduct an ongoing evaluation of introducing iACT for adolescents with anxiety in primary care. This is the third part of the IMPACT project and is aimed at conducting a follow-up 12 months after receiving iACT with or without parental support. The primary outcomes consist of treatment adherence and symptoms of anxiety and depression, and the secondary outcomes consist of psychological flexibility and overall functioning in adolescents. Thus, the aims of this evaluation can be concretized as follows:

1. Is there a connection between parental support and adherence to iACT for adolescents with anxiety?
2. Does iACT for adolescents with anxiety result in decreased symptoms of anxiety and depression between pretreatment and 12 months after terminating treatment?
3. Does iACT for adolescents with anxiety result in increased psychological flexibility between pretreatment and 12 months after terminating treatment?
4. Does iACT for adolescents with anxiety result in improved overall functioning between pretreatment and 12 months after terminating treatment?

Methods

In this section, the study design, participants, procedure, intervention, measures, data analysis, and ethical considerations are presented.

Study Design

Initially, the intention was to perform a follow-up of iACT during the implementation phase in primary care and to conduct between-group analyses. However, due to organizational limitations, the authors instead opted for a pragmatic approach to the data. Consequently, the analysis was converted into an exploratory evaluation of iACT for adolescents with anxiety in primary care.

The IMPACT project was conducted within the regular patient flow during the implementation phase and due to organizational reasons, randomization of the participants could not be made. Using a non-RCT, the therapists assigned the participants to either iACT with or without parental support or treatment as usual (TAU), consisting of face-to-face treatment for anxiety individually or in a group format. Therefore, the authors had limited insight into the assignment process. Therefore, this study is naturalistic and the results are preliminary and of a hypothesis-generating character.

Quantitative data were collected before, during, and after treatment, and follow-ups were performed 6 and 12 months after terminating treatment. In this evaluation, pretreatment and the 12-month follow-up are being compared. Due to difficulties in recruiting therapists, the sample size is relatively small, which further decreases the quality of the data, furthermore, the amount of missing data is relatively large.

No a priori power analysis was conducted, so between-group analyses could not be made. Therefore, the TAU group is not included in this evaluation, adherence measures are analyzed using descriptive data, and outcome measures are analyzed using within-group analyses. Therefore, the results are treated as an explorative evaluation of iACT in practice rather than a scientific study.

Participants

The participants were recruited from adolescents seeking help in primary care for anxiety symptoms at 3 different health care centers located in southwestern Sweden and specialized in treating adolescents with mental health issues. Previously, there was no iACT program for young people in Sweden, and the treatment program was developed and adapted for the 13-18 years age group, hence the age group that was studied. The inclusion criteria consisted of being aged 13-18 years; having access to a computer, iPad, or smartphone with internet access; being able to read and write in Swedish; and having been diagnosed with mild to moderate anxiety such as GAD, social phobia, panic disorder, or unspecified anxiety disorder. The exclusion criteria consisted of having a neuropsychiatric diagnosis, intellectual disability, bipolar disease, suicidality, or ongoing psychotherapeutic treatment or daily consumption of benzodiazepines.

This evaluation originally included 35 participants aged 13-18 years. Of these participants, 9 participants received iACT without parental support; 15 participants received iACT with parental support; and 11 participants received TAU, of which, 8 participants received group therapy and 3 participants received individual therapy. Besides providing iACT, 2 of the health care centers involved in the study only provided group therapy, whereas the third only provided individual therapy. Since no power analysis was performed before the data collection, comparisons between groups could not be made, hence the TAU

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group was excluded from this evaluation. Table 1 demonstrates the distribution of age and gender among the participants.

Table 1. The distribution of age and gender among the participants.

Variable	Frequencies		
	iACT[a] without parental support (n=9)	iACT with parental support (n=15)	TAU[b] (n=11)
Age group (years), n (%)			
13-15	8 (89)	10 (67)	9 (82)
16-18	1 (11)	5 (33)	2 (18)
Sex, n (%)			
Female	8 (89)	15 (100)	10 (91)
Male	1 (11)	0 (0)	1 (9)
Other	0 (0)	0 (0)	0 (0)

[a]iACT: internet-delivered acceptance and commitment therapy.

[b]TAU: treatment as usual.

Procedure

Patients aged 13-18 years, accompanied by a parent, seeking help in primary care for anxiety problems were informed about the study and were offered participation by the therapist. All the adolescents included provided verbal consent and the parents provided written consent prior to participation. The patient and the parent participated in an assessment and inclusion meeting conducted by a participating therapist. The parent was subsequently led to another room to fill in a questionnaire whereas the adolescent was interviewed further.

After the assessment, all the participants who met the inclusion criteria were assigned by the therapist to either iACT, with or without parental support, or TAU. The assignment of groups was not randomized, and the authors have no information on how many patients were excluded from the study by the therapists nor how the therapists assigned the patients into groups.

Furthermore, the participating adolescents completed questionnaires before, during, and after treatment, as well as 6 and 12 months after treatment termination, and participated in diagnostic clinical interviews before and after treatment, as well as 12 months after treatment. To ensure the integrity of the adolescents and data security, the forms were distributed via the survey platform Esmaker [24], if possible, and otherwise in paper format. The paper forms and interview protocols were also added to a research journal to collect additional data such as other ongoing treatments.

The recruitment process took place from 2018 to 2020, hence parts of the data collection coincided with the COVID-19 pandemic, during which some upper secondary schools in Sweden introduced distance learning for periods of time while other schools did not [25]. It is possible that the pandemic affected the number of participants in the study. Furthermore, due to the difficulty of recruiting therapists, the number of participants in the study is relatively low. Despite the low number of participants, the recruitment was terminated due to financial reasons.

Intervention

In this study, the participants were recruited from 3 health care centers that were specialized in adolescent mental health and located in southwestern Sweden: Gothenburg, Borås, and Uddevalla. These centers form a part of primary care and are specialized in helping patients aged 6-18 years. The therapists in this study were either licensed psychologists or intern psychologists, and as a part of implementing iACT at these centers, they participated in a 2-day course and received specific training in iACT for adolescents.

iACT Without Parental Support

These participants received a guided, internet-based, self-help program called Anxiety Help for Adolescents (in Swedish: Ångesthjälpen Ung) developed by Psykologpartners W&W AB. The program is adapted for patients aged 13-19 years with mild to moderate anxiety, for example, social phobia, GAD, panic disorder, obsessive-compulsive disorder, or unspecified anxiety disorder [19].

The iACT intervention consists of 8 modules and the recommended treatment duration is 10 weeks with weekly feedback from the therapist. The program is adapted to the target group of adolescents regarding formulations, concretizations of theoretical concepts, and clinical examples, as well as the overall structure, and presents different strategies through text, videos, exercises, and forms. There is a messaging function in which the therapist and the patient can communicate asynchronously, and the therapist can initiate conversations through telephone, video calls, or physical meetings at the clinic. The therapist supports the patient through motivation, giving feedback, answering questions, and prompting upcoming parts of the program [19]. For a detailed list of contents of the iACT intervention, see Multimedia Appendix 1.

iACT With Parental Support

These participants were assigned to the iACT program described above, with the addition of receiving parental support on how to support their adolescent's anxiety regulation. Both the participants and parents were initially given information about the content and structure of the iACT program [19].

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Subsequently, the parents took part in 3 physical meetings during their adolescent's treatment period, either individually or in groups, and were conducted with the help of a manual (Multimedia Appendix 2). The content included psychoeducation about anxiety and different reactions, examples of different anxiety disorders, and behavioral strategies to handle anxiety such as exposure, relaxation, breathing, balance activity, and rest. All the information was condensed into a pamphlet called More Than Afraid (in Swedish: Mer än rädd) [26].

TAU Group

The participants in the TAU group received the treatment they would normally be offered at the clinics, consisting of face-to-face treatment for anxiety individually or in a group format, both 8 weeks long, as conventional in clinical settings. The TAU group is not included in this evaluation since the groups could not be compared.

Measures

The adolescent filled in the following forms before, during, and after treatment, as well as 6 and 12 months after treatment:

- Revised Children's Anxiety and Depression Scale (RCADS-Children, 47 items), consisting of the 2 main scales, anxiety and depression, and the 6 subscales, social phobia, panic disorder, GAD, compulsive disorder, separation anxiety, and depression, on which higher scores indicate a higher number of symptoms. The subscales exhibit a high internal consistency (α=.78-.88) in a sample of 513 children in the United States [27,28].
- Avoidance and Fusion Questionnaire Youth (AFQ-Y8), designed to measure the level of psychological flexibility in youth aged 12-20 years: higher scores indicate higher levels of psychological inflexibility. In a Swedish sample of 62 children undergoing cancer treatment, AFQ-Y8 exhibited acceptable internal consistency (α=.76), good test-retest reliability (ICC=0.64), and convergent validity (r=0.42) [29].

Furthermore, the adolescent was interviewed before and after treatment and 12 months after completion. The assessments were performed by a psychologist or intern psychologist using the following measures:

- The Mini International Neuropsychiatric Interview for Children and Adolescents was used for diagnostics [30] and exhibits validity and test-retest reliability comparable to other standardized screening tools [31,32].
- The Children's Global Assessment Scale (CGAS) was used to assess overall functioning. The interviewer performs an assessment of the adolescent's level of functioning on a scale from 1 to 100, of which a higher score indicates a higher level of functioning [33]. CGAS exhibits high interrater and test-retest reliability, as well as high discriminant and concurrent validity [34-36].

Data Analysis

This study aimed to investigate whether there is a connection between parental support and adherence to iACT for adolescents with anxiety and whether the treatment results in differences in symptoms of anxiety and depression, psychological flexibility, and overall functioning at 12 months after terminating treatment.

Due to a nonrandomized design, a small sample, a large dropout, and the fact that no a priori power analysis was made, the data are nonparametric, which makes between-group comparisons less meaningful. Therefore, the TAU group (n=11) is not included in this evaluation. Adherence was analyzed using descriptive data and Meier-Kaplan survival analysis, a statistical method used for measuring the distribution of time of occurrences in cohort groups [37]. In this study, dropout is defined as terminating the iACT program before the last module. Meanwhile, the outcome measures were analyzed using within-group comparisons.

Adherence was analyzed for all participants receiving iACT without parental support (n=9) and with parental support (n=15), presented in separate groups. In contrast, for the outcome measures, all participants receiving iACT are presented as 1 group, including both with and without parental support due to small groups. In the outcome measures, the pretreatment measurement and the 12-month follow-up were compared and only included participants completing both the premeasurement and the 12-month follow-up.

For the outcome measures, patient-rated scores using RCADS and AFQ-Y8, as well as therapist-rated scores using CGAS and within-group analyses were performed using the nonparametric statistical method Wilcoxon signed rank test for related samples. Effect sizes were calculated based on the formula described by Field [38] and were interpreted as 0.10-<0.3 (small effect), 0.30-<0.5 (moderate effect), and ≥0.5 (large effect). The within-group analyses were performed in SPSS Statistics (version 29; IBM Corp).

Ethical Considerations

This evaluation constitutes a part of the research project IMPACT in 2017-2021 (Swedish National Research Register; ID: 240221), approved by the Regional Ethics Committee in Gothenburg (Dnr: 703-17). The IMPACT project was designed to conduct an ongoing evaluation of introducing iACT for adolescents with anxiety in primary care during the implementation phase, and this evaluation is a 12-month follow-up. The participants have been informed that their participation is voluntary and that they have the right to cancel without further explanation. Moreover, the participants have been informed that participation in the study will not in any way affect their future opportunities for care and treatment at the health center and that participation in the study will not be mentioned in medical records. Both accessing care and participating in the study were free. Furthermore, the participants have been informed about how the data will be managed, including confidentiality aspects, as well as analysis and presentation. The confidentiality of all participants is thus guaranteed, and consent from all participants has been obtained including both adolescents and parents. Digital forms were collected using the survey platform Esmaker [24], and data were analyzed using SPSS Statistics.

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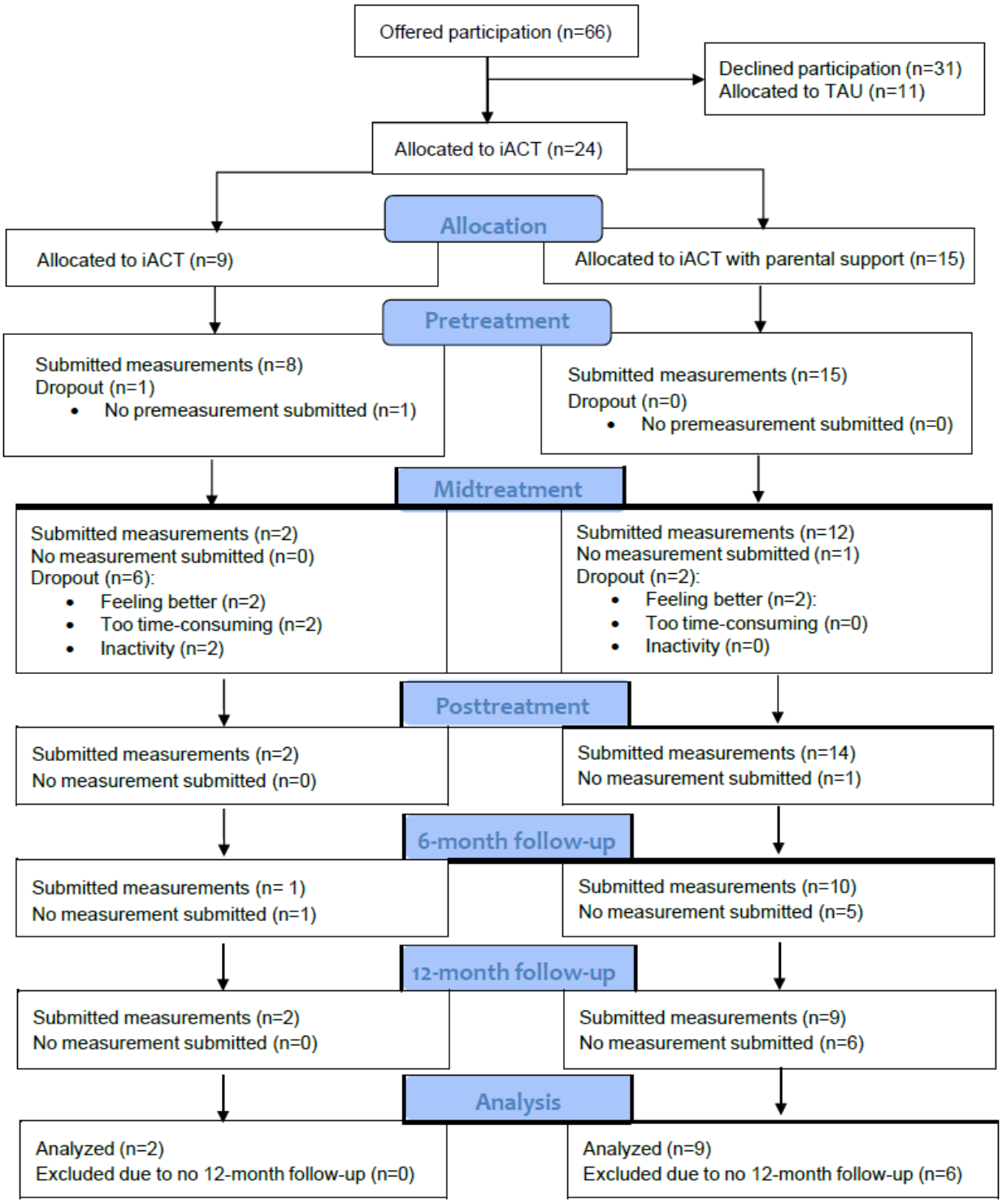
Results

Overview

In this section, the results are presented regarding treatment adherence and outcome measures based on the questions of the aims. Adherence is presented for all participants (n=35), and the participants receiving iACT are presented in 2 separate groups: iACT without parental support and iACT with parental support. The outcome measures are presented for the participants who completed the assessments for both the pretreatment and the 12-month follow-up (n=11). Moreover, the iACT participants are presented as 1 group, regardless of whether they have received parental support or not. Below, the primary outcomes are presented. Figure 1 demonstrates a CONSORT (Consolidated Standards of Reporting Trials) flow diagram of the study.

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) Flow diagram of internet-delivered Acceptance and Commitment Therapy (iACT) and treatment as usual (TAU).



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Is There a Connection Between Parental Support and Adherence to iACT for Adolescents With Anxiety?

For the analyses regarding adherence to treatment, the participants were presented in 2 groups: iACT without parental support (n=9) and iACT with parental support (n=15). Table 2 demonstrates descriptive statistics for the number of completed modules or sessions at the time of terminating the program.

Table 2. Descriptive statistics for the number of completed modules.

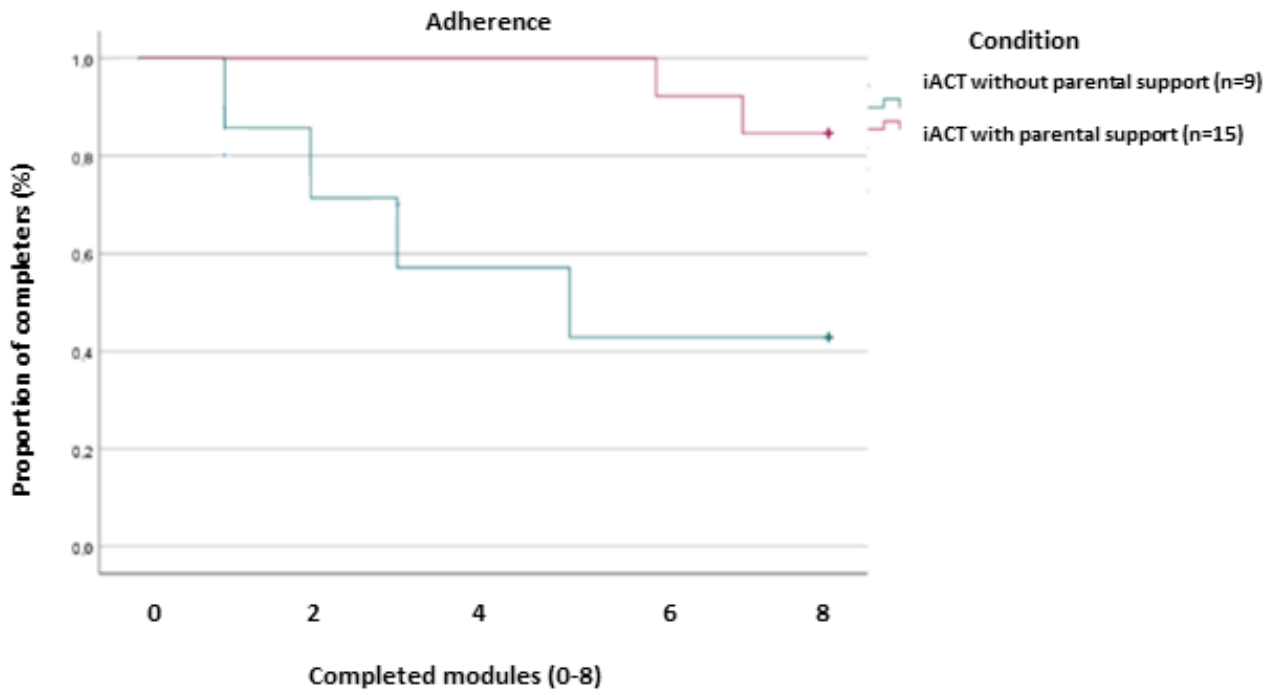
Completed modules or sessions(%)	iACT[a] without parental support (n=9), n (%)	iACT with parental support (n=15), n (%)
<25	2 (22)	0 (0)
25-50	1 (11)	0 (0)
50-75	1 (11)	1 (7)
75-100	5 (56)	14 (93)

[a]iACT: internet-delivered acceptance and commitment therapy.

The participants receiving iACT without parental support (n=9) exhibited a gradual dropout rate throughout treatment, of which 5 participants dropped out before treatment completion. In contrast, the participants receiving iACT with parental support (n=15) exhibited the least number of dropouts (n=2), of which all occurred during the second half of the treatment.

Figure 2 demonstrates a Meier-Kaplan graph illustrating the dropouts. The x-axis represents at which module the dropout occurred, with 0 indicating dropout before initiating treatment and 8 representing complete treatment. The y-axis represents the percentage of participants remaining in treatment.

Figure 2. Proportion of dropouts between groups of internet-delivered Acceptance and Commitment Therapy (iACT) with or without parental support.



Does iACT for Adolescents With Anxiety Result in Decreased Symptoms of Anxiety and Depression Between Pretreatment and 12 Months After Terminating Treatment?

In this section, the results of the patient-rated RCADS scores are analyzed for all participants completing both the premeasurement and the 12-month follow-up (n=11). In this section, the participants receiving iACT are in the same group, regardless of whether they have received parental support or not. Table 3 demonstrates descriptive statistics for the therapist-rated measurement points on RCADS.

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Table 3. Descriptive statistics for the measurement points on RCADS[a].

iACT[b] (n=11)	Score, mean (SD)	Score, median (IQR)	Score, range
RCADS			
Pretreatment	71.7 (17.5)	70 (65-86)	41-104
Posttreatment	52.9 (22.3)	52 (38-71)	25-98
6-month follow-up	47.1 (26.9)	40 (27-63)	13-104
12-month follow-up	49.3 (25.4)	44 (32-63)	18-111
RCADS—Anxiety			
Pretreatment	58.6 (14.1)	58 (52-71)	33-84
Posttreatment	42.9 (17.9)	42 (32-53)	21-83
6-month follow-up	38.5 (22.4)	30 (22-46)	12-87
12-month follow-up	39.4 (19.8)	39 (24-49)	15-88
RCADS—Depression			
Pretreatment	13.1 (4.4)	14 (8-17)	6-20
Posttreatment	10.0 (5.4)	10 (5-16)	3-18
6-month follow-up	8.5 (5.3)	9 (4-12)	1-17
12-month follow-up	9.8 (6.2)	8 (5-14)	3-23

[a]RCADS: Revised Children's Anxiety and Depression Scale.

[b]iACT: internet-delivered acceptance and commitment therapy.

The results from the Wilcoxon signed rank test for related samples for the RCADS total scores demonstrated a decrease in symptoms of anxiety and depression and a large effect size for the RCADS total scores from preassessment to the 12-month follow-up (*z* score: –2.81; *P*=.005; *r*=0.60). When analyzing anxiety and depression scores separately by subscales, reductions between the pretreatment assessment to the 12-month follow-up assessment for both anxiety (*z* score: –2.81; *P*=.005; *r*=0.60) and depression (*z* score: –2.67; *P*=.008; *r*=0.57) and large effect sizes were obtained. Below, the secondary outcomes are presented.

Does iACT for Adolescents With Anxiety Result in Increased Psychological Flexibility Between Pretreatment and 12 Months After Terminating Treatment?

In this section, the results of the patient-rated AFQ-Y8 scores are analyzed, indicating the adolescent's self-rated levels of psychological flexibility. In this section, the participants receiving iACT are presented in the same group, regardless of whether they have received parental support or not. Table 4 demonstrates descriptive statistics for the therapist-rated measurement points on AFQ-Y8 and CGAS.

Table 4. Descriptive statistics for the measurement points on AFQ-Y8[a] and CGAS[b].

iACT[c] (n=11)	Score, mean (SD)	Score, median (IQR)	Score, range
AFQ-Y8			
Pretreatment	18.8 (5.8)	21 (12-22)	11-30
Posttreatment	14.9 (7.7)	13 (10-20)	3-30
6-month follow-up	12.3 (7.6)	11 (7-17)	3-27
12-month follow-up	12.7 (6.7)	11 (8-17)	5-29
CGAS			
Pretreatment	64.1 (5.8)	65 (60-65)	55-75
Posttreatment	72.7 (13.3)	75 (55-85)	55-90
12-month follow-up	70.0 (14.3)	70 (55-85)	45-85

[a]AFQ-Y8: Avoidance and Fusion Questionnaire for Youth.

[b]CGAS: Children's Global Assessment Scale.

[c]iACT: internet-delivered acceptance and commitment therapy.

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The results from the Wilcoxon signed rank test for related samples for the AFQ-Y8 demonstrated increased psychological flexibility from preassessment to the 12-month follow-up (*z* score: –2.54; *P*=.01; *r*=0.55).

Does iACT for Adolescents With Anxiety Result in Improved Overall Functioning Between Pretreatment and 12 Months After Terminating Treatment?

In this section, the results of the therapist-rated CGAS scores are presented. The results from the Wilcoxon signed rank test on the CGAS total scores indicated no difference between measurement points from pretreatment to the 12-month follow-up for the iACT group (*z* score: –0.51; *P*=.96; *r*=0.146).

Discussion

Overview

This evaluation aimed to investigate whether there is a connection between parental support and adherence to iACT for adolescents with anxiety and whether iACT for adolescents with anxiety results in a difference in symptoms of anxiety and depression, psychological flexibility, and overall functioning, between the pretreatment measurement and 12 months after terminating treatment. In this section, the principal findings, limitations, and implications will be discussed in contrast to other studies. Overall, the results must be handled with caution due to the nonrandomized design, small sample size, and large amount of missing data.

Principal Findings

Overview

The IMPACT project was conducted as an ongoing evaluation to broaden the understanding of iACT for adolescents with anxiety in a routine primary care setting during the implementation phase. In the first IMPACT paper, Weineland et al [20] concluded that the interviewed therapists were positive to iACT for adolescents but also identified challenges such as motivating patients. In the second paper, Lilja et al [21] found that the interviewed parents expressed uncertainty about their role in the treatment and clearer parental treatment support was suggested. This is the third part of the IMPACT project, consisting of a follow-up on adolescents with anxiety 12 months after receiving iACT, with or without parental support regarding treatment adherence, symptoms of anxiety and depression, and psychological flexibility, as well as overall functioning. The primary outcomes are discussed below.

Is There a Connection Between Parental Support and Adherence to iACT for Adolescents With Anxiety?

Regarding treatment adherence, the participants receiving iACT with parental support exhibited later and fewer dropouts than the participants receiving iACT without parental support. These findings might be due to the idea suggested by Weineland et al [20] that parental support could compensate for low treatment motivation among adolescents. However, due to the nonrandomized design and small sample size in this, further research is needed to test this hypothesis in RCTs and with larger samples. Other potential mediating effects could be giving the parents a deeper understanding of anxiety in both themselves and the adolescent, as well as how to support their adolescent and function as a cotherapist alongside the therapist. In addition, in each group, 2 participants discontinued treatment due to feeling better, indicating that dropouts from treatment are not necessarily negative.

In previous research, the authors have pointed to potential connections between parental support and positive treatment outcomes in children and families [22], including that some parents need support in their role as cotherapists in treatment [23]. The current research on the role of motivation in iACT for adolescents with anxiety is currently limited. Nevertheless, in a Norwegian study, Fjermestad et al [39] concluded that motivation predicts early alliance in CBT for youth with anxiety. Furthermore, in a Danish study by Stjerneklar et al [10], both the parents and the therapists were encouraged to help motivate the adolescent in their iCBT, in which iCBT exhibited moderate to large effect sizes between groups on anxiety compared to the waitlist.

Furthermore, iACT with parental support can be considered a complex intervention, which can be defined as an intervention consisting of multiple components. Complex interventions cause challenges in the development and identification [40] and Hasson and von Thiele Schwartz [41] claim that complex interventions tend to be at a disadvantage in research due to the difficulty in isolating them from the context. The authors argue that this applies to a large amount of psychological treatment methods, compared to medical treatments.

Does iACT for Adolescents With Anxiety Result in Decreased Symptoms of Anxiety and Depression Between Pretreatment and 12 Months After Terminating Treatment?

Outcome measures were investigated using a within-group analysis, in which the iACT-group demonstrated reduced symptoms of anxiety and depression between the preassessment and 12-month follow-up. Multiple previous studies have indicated positive treatment outcomes for iACT for adolescents with anxiety [9-12], but few have performed follow-ups at 12 months after treatment or longer. In the meta-analysis by Vigerland et al [9], of the papers on iACT for children and adolescents with anxiety, 2 papers had a 1-year follow-up: Spence et al [11] concluded that the improvements in both CBT and iACT were maintained at the 12-month follow-up and Tillfors et al [42] discovered significant improvements in iACT for high school students with anxiety disorder, maintained at the 12-month follow-up. Nevertheless, none of the studies included follow-ups more than 1 year after treatment, hence the long-term effects of iACT for adolescents with anxiety should be investigated further.

In this evaluation, in 2 of the cases, the results of Mini International Neuropsychiatric Interview for Children and Adolescents and CGAS exhibited an increase in symptoms and a decrease in functioning between the post and 12-month follow-up. Therefore, the interviewer had the impression that the COVID-19 pandemic influenced the results. In both cases, of which 1 participant from the iACT group and 1 from the

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TAU group, the participant was diagnosed with social phobia at the 12-month follow-up and described that at least some of the symptoms were due to returning from distance to classroom learning. In addition, the authors suspect that the pandemic itself could have affected the anxiety levels and functioning of the participants, for example, fear of the disease itself or uncertainty about the future.

In a Swedish study, the authors surveyed 1818 adolescents, of which approximately 80% transferred to distance learning during the pandemic. The authors concluded that most of the participants experienced decreased mental health, especially female participants and those in distance learning. The authors also discovered that distance learning could result in less victimization and poorer mental health overall [43]. In another Swedish study, 3068 participants aged 16-17 years filled in a questionnaire about the impact of the COVID-19 pandemic from December 2020 to March 2021. The author concluded that female participants reported more worry than male participants and that participants with a lower socioeconomic background reported higher levels of worry in general, except for climate anxiety [44].

In an international systematic review and meta-analysis of 74 papers on anxiety among children and adolescents during the pandemic, the authors concluded that anxiety levels were more prevalent among female participants than male participants in North America and Europe than South America and Asia, during the second wave of COVID-19 and school closures [45]. A Finnish study surveyed 450,000 participants aged 13-20 years about the pandemic. The authors discovered that social anxiety increased from 2013 to 2021, especially among the female participants, and that unmet needs for schoolwork support, and fear of getting infected by COVID-19 or transmitting it to others were associated with high levels of social anxiety. Nevertheless, the authors observed no clear connection between time spent in distance learning and levels of social anxiety [46].

Furthermore, in an American study, 280 high schoolers were surveyed on social anxiety and the use of technology. The author discovered a positive relationship between social anxiety and a preference for using technological communication instead of face-to-face communication [47]. In an international study, 2665 participants aged 18-25 years from 121 countries, of which the majority from Australia, the United States, and the United Kingdom, were surveyed on social restrictions related to COVID-19 and its effect on loneliness, social anxiety, and depression. The authors concluded that reductions in social restrictions resulted in an increase in social anxiety due to having to readjust to the social environment [48]. In other words, the relationship between the COVID-19 pandemic and anxiety among youth is a complex matter with a diversity of outcomes, of which multiple possible scenarios might have affected the results of this study.

In this study, COVID-19 can be considered a confounding factor, which Jager et al [49] defined as a risk factor, unequally distributed among the participants, and not included in the causal pathway. Pourhoseingholi et al [50] define confounding factors as a variable affecting the variables studied but not their relationship. To prevent or reduce the confounding factors, Jager et al [49] suggest using exclusion criteria, for example, participant age, randomizing the assignment to groups, matching participants for example in pairs with or without exposure, or stratifying the participants into subgroups. Pourhoseingholi et al [50] mention that stratification is suitable with a low number of strata, whereas multivariate models, such as analysis of covariance, as well as logistic and linear regression, can be used with a larger number of covariates and confounders. The secondary outcomes are discussed below.

Does iACT for Adolescents With Anxiety Result in Increased Psychological Flexibility Between Pretreatment and 12 Months After Terminating Treatment?

In this evaluation, the analyses of AFQ-Y8 demonstrated an increase in psychological flexibility between the pretreatment measurement and the 12-month follow-up. These results are in line with previous research, concluding iACT to be effective in reducing symptoms of anxiety and increasing psychological flexibility, as well as suggesting a possible link between anxiety levels and psychological flexibility [17].

Does iACT for Adolescents With Anxiety Result in Improved Overall Functioning Between Pretreatment and 12 Months After Terminating Treatment?

In this evaluation, the analyses of overall functioning using CGAS did not indicate differences between the pretreatment measurement and the 12-month follow-up. However, in a meta-analysis of 9 RCTs on iACT for pediatric anxiety disorders, of which 7 included CGAS as a measure of functioning, the authors concluded that their confidence in the effect of iACT on functioning is low [51].

In summary, the results of this evaluation support a possible connection between parental support and adherence to iACT for adolescents with anxiety. Further research is needed to investigate the nature of the connection. Furthermore, the analyses of the outcome measures indicate reduced symptoms of anxiety and depression and increased psychological flexibility between the pretreatment measurement and the 12-month follow-up but no difference regarding overall functioning. However, due to a nonrandomized design, a small sample size, and a large amount of missing data, the results are uncertain, and the generalizability is severely limited.

Limitations

In this evaluation, the participants were recruited within the regular patient flow in primary care, which on one hand increases the ecological validity of the study but on the other hand decreases the control of several third variables influencing the groups. Performing pragmatic evaluations on how the treatment method works under regular conditions is a concrete way to achieve local evidence. Evaluating iACT the way it is provided in clinical practice, without adding resources or excluding patients for the sake of the evaluation, can provide a closer input on the actual effect, which in turn can increase the external validity.

Due to organizational problems in conducting the study, the participants could not be randomized and were instead assigned

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to iACT or TAU following a nonrandomized design. Since the authors could not control the assignment of treatment method, no conclusions on eventual differences in treatment outcomes between groups could be made. Therefore, the TAU group was omitted from this evaluation and the internal validity is reduced.

This evaluation took place during the implementation phase of iACT in primary care, which poses its own unique challenges. Hasson and von Thiele Schwarz [41] suggest that performing follow-ups and giving feedback are ways to increase the motivation to implement a new method. In other words, the evaluation itself can influence the object of evaluation. During the IMPACT project, one of the staff members at one of the clinics involved mentioned that the project helped them initiate the implementation.

For the therapists involved in this study, the implementation phase included a learning phase in assessing and assigning iACT to patients. In the first IMPACT paper, the interviewed therapists discussed which patients iACT can be helpful for. The therapists concluded that iACT is more suitable for patients with self-discipline, acceptance of personal responsibility, capability of introspection, and appreciation of working independently with the program. Furthermore, the therapists concluded that iACT is better suited for patients with anxiety rather than depression and that the symptoms should not be too severe, wide-ranging, or long-standing, and that the patient preferably should be in the upper teens. Furthermore, several therapists expressed that iACT is less suitable for patients with learning disabilities, neuropsychiatric illness, or dyslexia [20].

The participant recruitment took place between 2018 and 2020, hence parts of the data collection took place during the COVID-19 pandemic. The authors suspect that the pandemic influenced the anxiety and functioning of the participants both directly, such as fear of infection, and indirectly such as transferring between distance and classroom learning in some cases. Ideally, the authors could have addressed this during the study, for example, by specifically asking about the effect of the pandemic. Thus, the results should be handled with caution.

The sample size in this study is relatively small, especially in the subgroup analyses, which severely limits the generalizability of the results. Furthermore, this evaluation contained a relatively large amount of missing data in proportion to the sample size. In a review paper, Kang [52] reviews techniques for managing missing data and argues that the best method is prevention, for example, by minimizing the number of follow-ups. The data collection for the IMPACT project consisted of surveys before, during, and after treatment and at 6- and 12-month follow-ups, as well as interviews before, during, after, and 12 months after treatment. It is possible that the number of measurements might have had an impact on the participation, for example, by reducing the motivation to participate. On the other hand, a larger number of measurement points, as well as both written and spoken, results in more opportunities to collect data.

In this evaluation, missing data were handled by complete case analysis, which Kang [52] does not recommend with small sample sizes. Applying the last-observation-carried-forward method would have increased the amount of data included in the analyses. However, since the previous measurements occur closer to the treatment phase, this could also create a bias in the data. Furthermore, due to a large number of missing data, the authors determined that the last-observation-carried-forward method would risk being too misleading; therefore, only participants with complete data were included in the analysis.

Regarding dropouts, Kang [52] recommends documenting the reason and thus enabling further analysis. In this evaluation, treatment adherence was investigated by analyzing the timing and reason behind the dropouts. Nevertheless, more actions could have been taken in preventing and investigating the dropouts. In a Swedish RCT, 162 adults were investigated regarding their participation in iACT to explore variables predicting dropout, adherence, and outcomes. The authors concluded that the level of treatment credibility predicted dropouts whereas attrition was associated with higher levels of impulsivity and low levels of intrinsic treatment motivation [53].

The generalizability of the results in this evaluation is limited due to the small and gender-based sample of young people that were included. To achieve a better understanding of mental health in male adolescents and to enhance primary care services, it is important to address gender bias in future research and clinical work. Furthermore, the amount of missing data was relatively high, which further reduced the possibility of drawing conclusions based on the data.

Due to limitations in the study design regarding a small and gender-biased sample size with a large proportion of dropouts and missing data, a nonrandomized assignment of intervention, and analysis limited to within-group, this investigation should be considered an explorative evaluation of a new method rather than a scientific outcome study. Further research on iACT in the regular patient flow in primary care is needed.

Conclusions

This evaluation consists of a follow-up on adolescents, 12 months after receiving iACT, with or without parental support. Due to a large amount of missing data, the results should be viewed as an evaluation rather than a scientific study. Adherence to treatment was investigated, indicating that parental support could increase adherence to iACT, which in turn might improve the conditions for young patients undertaking iACT treatment. The results also underscore the importance of parental involvement in the treatment of adolescents with mental illness. More research is needed to explore the relationship between parental support and treatment outcomes and how clinicians can facilitate the process.

Future research should investigate internet-based treatments for adolescents in primary care with additional, possibly digital, parental support programs in RCTs. After the IMPACT project was conducted, an internet-delivered parental support program was developed, in which information about how to support the adolescent during treatment was added [19]. Further research is needed on parental support in this format as well. Moreover, further research is needed on involving next of kin in health care in general.

Furthermore, the analyses of the outcome measures suggest that iACT might be an effective treatment for both anxiety and

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depression and has the potential to be an effective treatment of comorbidity and a broader spectrum of anxiety problems.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
The contents of the internet-delivered acceptance and commitment therapy (iACT) intervention translated into English.
[PDF File (Adobe PDF File), 147 KB - pediatrics_v8i1e59489_app1.pdf]

Multimedia Appendix 2
User manual for the Anxiety School (Användarmanual till Ångestskolan in Swedish).
[PDF File (Adobe PDF File), 468 KB - pediatrics_v8i1e59489_app2.pdf]

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Abbreviations

ACT: acceptance and commitment therapy
AFQ-Y8: Avoidance and Fusion Questionnaire for Youth
CBT: cognitive behavioral therapy
CGAS: Children's Global Assessment Scale
CONSORT: Consolidated Standards of Reporting Trials
GAD: generalized anxiety disorder
iACT: internet-delivered acceptance and commitment therapy
iCBT: internet-based cognitive behavioral therapy
IMPACT: Internet Mediated Psychological Treatment-Acceptance and Commitment Therapy
RCADS: Revised Children's Anxiety and Depression Scale
RCT: randomized controlled trial
TAU: treatment as usual

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Original Paper

Changes in Internet Activities and Influencing Factors for Problematic Internet Use During the COVID-19 Pandemic in Korean Adolescents: Repeated Cross-Sectional Study

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Abstract

Background: As adolescents increasingly engage with digital experiences, the internet serves as a platform for social interaction, entertainment, and learning. The COVID-19 pandemic accelerated this trend, with remote learning and restricted physical interactions driving changes in internet behavior. Adolescents spent more time on gaming and social media, reflecting a notable shift in use patterns.

Objective: We hypothesized that the COVID-19 pandemic changed internet use patterns among Korean adolescents, including content types, time spent on web-based activities, and pathological use prevalence. Additionally, we anticipated that these changes would correlate with shifts in adolescents' psychological status during the pandemic.

Methods: Data from 827 adolescents aged 12 to 15 years (n=144 in 2018, n=142 in 2019, n=126 in 2020, n=130 in 2021, n=143 in 2022, and n=142 in 2023) were gathered over 6 years from 43 middle schools across 16 regions and 1 hospital in South Korea. The demographic data collected included age, sex, and school year. Participants also provided information on their internet use patterns and levels of internet addiction. Additionally, psychological status, including mood, anxiety, attention, and self-esteem, was assessed.

Results: There were significant differences in the depression scale (Patient Health Questionnaire 9). The Patient Health Questionnaire 9 scores for 2018, 2019, and 2023 decreased compared to those in 2020, 2021, and 2022 (F_5=3.07; P=.007). Regarding changes in internet use behavior, game playing among adolescents decreased after the pandemic compared to before, while watching videos increased. Additionally, the rate of problematic internet use was highest for games before COVID-19, but after COVID-19, it was highest for videos, and this trend continued until 2023 (χ^2_3=8.16, P=.04). Furthermore, this study showed that the Young's Internet Addiction Scale (YIAS) score was highest in the game group in 2018 compared to other groups before COVID-19 (F_5=14.63; P<.001). In 2019, both the game and video groups had higher YIAS scores than other groups (F_5=9.37; P<.001), and by 2022, the YIAS scores among the game, video, and Social Network Service groups did not differ significantly. The degree of influence on the severity of internet addiction was also greatest for games before COVID-19, but after COVID-19, the effect was greater for videos than for games.

Conclusions: During the COVID-19 pandemic, internet use for academic and commercial purposes, including remote classes and videoconferences, increased rapidly worldwide, leading to a significant rise in overall internet use time. The demand for and dependence on digital platforms is expected to grow even further in the coming era. Until now, concerns have primarily focused on the use of games, but it is now necessary to consider what types of internet behaviors cause problems and how to address them.

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KEYWORDS

coronavirus pandemic; internet use pattern; internet games; short-form videos; social network system; depressed mood; internet use; pandemic; internet; COVID-19; video; internet behavior; social media; internet addiction; depression; anxiety; digital platforms; mobile phone

Introduction

Background

Since its first appearance in a psychiatric context in 1998 [1], the maladaptive and addictive use of the internet, often referred to as internet addiction or internet use disorder, has been increasingly addressed over the past two decades. The internet use rate of Korean adolescents was around 50% in 1999, rising to 99.5% in 2023 [2,3].

Among adolescents, internet applications have shifted from being a supportive function to dominating their daily lives, sometimes leading to addictive use. Both the American Psychiatric Association and the World Health Organization have acknowledged this behavioral phenomenon in their classification manuals, the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5; since 2013 as a condition for further study) and the forthcoming *International Classification of Diseases, 11th Revision* (in the chapter on "Disorders due to behavioral addictions"). However, several authors have criticized this decision, citing a lack of conceptual and empirical foundations [4-9]. Moreover, Griffiths [10] insisted that the context (activities) of internet use is far more important than the amount of time spent on web-based activities.

In almost all studies, adolescents and young adults are consistently identified as the group with the highest prevalence of internet use. As adolescents increasingly engage in digital experiences, the internet serves as a versatile platform for social interaction, entertainment, and information acquisition [11]. Empirical studies have explored the intricate relationships between different types of internet activities and their associated risks. For instance, the problematic use of video games, social media, and the internet has been linked to various mental health issues, such as emotional distress, self-esteem problems, and attention problems, among adolescents [12]. A systematic review of the literature by Coutelle et al [13] suggested that psychological status including inattention, anxiety, and depression significantly impact internet addiction. Additionally, the heterogeneity in internet behavior patterns during the pandemic underscores the importance of considering individual differences when addressing problematic internet use [14].

The COVID-19 pandemic's impact on internet use highlights the need to understand the complexities of adolescent web-based activities and their mental health. In a review of longitudinal or repeated cross-sectional, follow-up studies, Wolf and Schmitz [15] declared that the COVID-19 pandemic and related stressors could impact the mental health of children and adolescents. Moreover, latent profile analyses reveal distinct patterns of internet and gaming use, suggesting that adolescents' engagement with digital platforms can be categorized into different profiles based on the intensity and type of use [16-18].

The COVID-19 pandemic further accentuated the use of digital platforms, as social restrictions necessitated remote learning and limited physical interactions. This shift resulted in altered internet behavior patterns among adolescents, with a notable increase in the time spent on internet gaming and social media [11,16].

Hypothesis

We hypothesized that the COVID-19 pandemic changed psychological status, as well as internet use patterns regarding internet content, use time, and pathological use, in Korean adolescents. Additionally, the severity of pathological internet use was influenced by psychological factors, including mood and attention, during the COVID-19 pandemic.

Methods

This study is a repeated cross-sectional study that tracked data from 827 students over 6 years.

Participants

Over 6 years, data from 827 adolescents (n=144 in 2018, n=142 in 2019, n=126 in 2020, n=130 in 2021, n=143 in 2022, and n=142 in 2023) aged 12 to 15 years were gathered from 43 middle schools across 16 regions and 1 hospital in South Korea.

Through a web-based advertisement on the Korean Game Culture Foundation website from January 1, 2018, to December 30, 2023, a total of 69 middle schools from 32 regions and 2 hospitals from 2 regions in South Korea applied to the Visiting Game Class program for game literacy education. Of these, 43 middle schools from 16 regions and 1 hospital were selected through the multistage sampling method. First, the selection was divided by region and hospital; 16 (50%) out of 32 regions were randomly selected, and 1 (50%) of the 2 hospitals in each selected region was chosen at random. Then, among the 52 schools within these 32 regions, 44 (85%) schools were selected. However, 1 school deferred its participation to 2024 due to its academic schedule, so it did not contribute to the research data. Trained agents from the Korean Game Culture Foundation visited schools and hospitals to conduct an investigation.

Ethical Considerations

All data collected by the agents were anonymized, and participants were rewarded with school supplies worth approximately US $10. Approval for the current study was granted by the Institutional Review Board at Chung-Ang University (1041078-202201-HR-052). We obtained informed consent for research participation from both the students and their parents.

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Demographics and Internet Use Patterns

The demographic data collected included age, sex, and school year. Participants also provided information on their internet use patterns and levels of internet addiction. We defined "problematic internet use" as answering "yes" to the following questions: "Did you hear that people important or close to you consider your internet use to be a problem or suggest you meet a doctor or specialist for it?" [19].

The Young's Internet Addiction Scale (YIAS), a commonly used instrument for assessing internet addiction and web-based activities such as gaming, was used. This scale comprises 20 items, each rated on a 5-point Likert scale. The internal consistency of the Korean version of the scale has been reported to range from 0.90 to 0.93.

Psychological Assessment Scales

The Patient Health Questionnaire 9 (PHQ-9) was used to assess depression, with each item rated on a Likert scale from 0 to 3. A cutoff score of 10 (out of 27) was used to indicate depression. Park et al [20] validated the Korean version of the PHQ-9, which demonstrated an internal consistency of α=.81.

The DuPaul Attention-Deficit/Hyperactivity Disorder (ADHD) scale, particularly the ADHD symptom severity scale (ADHD Rating Scale [ARS]), includes 18 items, with 9 items dedicated to inattention and 9 to hyperactivity [21]. So et al [22] validated the Korean version of the ARS (K-ARS) and reported an internal consistency ranging from 0.77 to 0.89.

The Social Phobia Inventory (SPIN) is a self-report questionnaire consisting of 17 items designed to measure three dimensions of social anxiety. Cho et al [23] developed a Korean version of the SPIN (K-SPIN) and reported a high internal consistency with a Cronbach α of 0.91.

The Two-Factor Self-Esteem Scale (SE) is based on a modified version of the Rosenberg Self-Esteem Scale. It conceptualizes self-esteem as an individual's perception of their worth, incorporating elements of self-respect and self-confidence [24]. This scale contains 10 statements that assess overall feelings toward oneself. Participants indicate their level of agreement on a 4-point Likert scale, ranging from 1 (disagree completely) to 4 (agree completely). The internal consistency of the Korean version of the scale, referred to as the Self-Esteem Scale-Korean, has been reported with a Cronbach α of 0.79 [25].

Data Analysis

Demographic characteristics, including age, school year, and internet use time across years, were analyzed using ANOVA tests. Sex and internet activity across years were analyzed using chi-square tests. The YIAS scores and psychological scale scores, including PHQ-9, K-ARS, K-SPIN, and SE were also analyzed using ANOVA tests. The correlations between age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, and YIAS were assessed using Pearson correlation analyses. The correlations between sex (IT activity) and age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, and YIAS were assessed using Spearman correlation analyses. The correlation between sex and IT activity was assessed using Kendall tau-b correlation analysis.

We conducted hierarchical linear regression analyses using YIAS scores as the dependent variable to identify factors influencing the severity of problematic internet use. In Model 1, we tested the associations of demographic factors with the severity of problematic internet use. In Model 2, psychological factors were added to test their associations beyond the effects of demographic factors. In Model 3, internet use time was added to test its association beyond the effects of demographic and psychological factors. Finally, in Model 4, internet activities were added to test their associations beyond the effects of demographic factors, psychological factors, and internet use time. Statistical significance was set a priori at α=.05 (two-sided) to limit type-I error. All analyses were conducted using the *Complex Samples* module of the *PASW* statistics software package (version 19; IBM Corp).

Results

Demographic and Clinical Characteristics

There were no differences in sex ratio and age across the 6 years. Similarly, there were no differences in the scores of the self-esteem, social anxiety, and attention scales over the same period. However, significant differences were observed in the PHQ-9 scores (F_5=3.07; P=.007). The PHQ-9 scores for 2018, 2019, and 2023 were lower compared to those in 2020, 2021, and 2022. Additionally, there was a significant difference in internet use time (F_5=6.30; P<.001). Internet use time was highest in 2020 and 2021, followed by 2022 and 2023, and lowest in 2018 and 2019 (Table 1).

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Table 1. Demographic characteristics.

	2018 (n=144)	2019 (n=142)	2020 (n=126)	2021 (n=130)	2022 (n=143)	2023 (n=142)
Demographic characteristics						
Sex, n (%)						
Male	83 (57.6)	80 (56.3)	74 (58.7)	77 (59.2)	80 (55.9)	86 (60.6)
Female	61 (42.4)	62 (43.7)	52 (41.3)	53 (40.8)	63 (44.1)	56 (39.4)
Age (years), mean (SD)	13.56 (1.10)	13.59 (0.59)	13.55 (1.11)	13.34 (1.33)	13.35 (0.73)	13.64 (0.92)
IT use pattern						
Internet use time[a], mean (SD)	2.82 (1.23)	3.09 (1.67)	3.55 (1.14)	3.69 (1.78)	3.21 (1.01)	3.20 (1.71)
YIAS[b], mean (SD)	45.08 (15.67)	43.87 (12.83)	43.87 (13.17)	45.08 (13.81)	44.41 (13.05)	44.32 (14.61)
Psychological scales						
SE[c], mean (SD)	27.09 (5.09)	27.20 (3.13)	27.33 (7.16)	28.15 (5.33)	27.89 (5.02)	27.04 (3.21)
PHQ-9[d,e], mean (SD)	9.69 (7.76)	9.88 (5.24)	11.90 (4.66)	11.13 (6.84)	11.13 (5.93)	9.58 (7.14)
K-SPIN[f], mean (SD)	18.58 (11.05)	18.65 (11.92)	19.61 (11.51)	20.11 (12.75)	19.39 (13.51)	18.37 (12.89)
K-ARS[g], mean (SD)	10.37 (7.98)	9.19 (8.82)	9.17 (8.09)	10.01 (9.37)	10.10 (9.96)	9.28 (9.30)

[a]F_5=6.30; P<.001; 2018=2019<2022=2023<2020=2021.

[b]YIAS: Young's Internet Addiction Scale.

[c]SE: Two-Factor Self-Esteem Scale.

[d]PHQ-9: Patient Health Questionnaire 9.

[e]F_5=3.07; P=.007; 2018=2019=2023<2020=2021=2022.

[f]K-SPIN: Korean version of the Social Phobia Inventory.

[g]K-ARS: Korean version of the Attention Deficit/Hyperactivity Disorder Rating Scale.

The Correlations Between All Variables

In the comparison of variable correlations, PHQ-9 scores were positively correlated with K-ARS scores (r=0.45; P<.001). YIAS scores were positively correlated with PHQ-9 scores (r=0.43; P<.001) and K-ARS scores (r=0.43; P<.001; Table 2).

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Table 2. Correlation matrix of all variables[a].

Variables	Age	Sex	SE[b]	PHQ-9[c]	K-SPIN[d]	K-ARS[e]	IT use time	IT activity	YIAS[f]
Age									
r	1	–0.05	–0.04	0.04	0.07	0.10	0.09	0.09	0.05
P value	__g	.11	.25	.31	.06	.004	.007	.03	.09
Sex									
r	–0.05	1	–0.06	–0.01	0.05	–0.32	0.02	0.15	–0.07
P value	.11	—	.12	.55	.19	.75	.53	<.001	.03
SE									
r	–0.04	–0.06	1	–0.03	–0.21	–0.13	–0.02	–0.04	–0.02
P value	.25	.12	—	.38	<.001	<.001	.49	.21	.25
PHQ-9									
r	0.04	–0.03	–0.03	1	0.14	0.45	0.07	0.08	0.43
P value	.31	.55	.38	—	<.001	<.001	.05	.02	<.001
K-SPIN									
r	0.07	0.05	–0.21	0.14	1	0.28	0.05	0.06	0.18
P value	.06	.19	<.001	<.001	—	<.001	.16	.08	<.001
K-ARS									
r	0.10	–0.32	–0.13	0.45	0.28	1	0.08	0.04	0.43
P value	.004	.75	<.001	<.001	<.001	—	.03	.29	<.001
IT use time									
r	0.09	0.02	–0.02	0.07	0.05	0.08	1	0.52	0.08
P value	.007	.53	.49	.05	.16	.03	—	.14	.04
IT activity									
r	0.09	0.15	–0.04	0.08	0.06	0.04	0.52	1	0.03
P value	.03	<.001	.21	.02	.08	.29	.14	—	.34
YIAS									
r	0.05	–0.07	–0.02	0.43	0.18	0.43	0.08	0.03	1
P value	.09	.03	.25	<.001	<.001	<.001	.04	.34	—

[a]Pearson correlation: age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, YIAS; Spearman correlation: sex, IT activity versus age, SE, PHQ-9, K-SPIN, K-ARS, IT use time, YIAS; Kendall tau-b: sex, IT activity.

[b]SE: Two-Factor Self-Esteem Scale.

[c]PHQ-9: Patient Health Questionnaire 9.

[d]K-SPIN: Korean version of the Social Phobia Inventory.

[e]K-ARS: Korean version of the Attention Deficit Hyperactivity Disorder Scale.

[f]YIAS: Young's Internet Addiction Scale score.

[g]Not applicable.

Changes in Internet Activities of Korean Adolescents Over 6 Years

Over the past 6 years, the population engaged in gameplay had decreased, while the population watching videos had increased. In 2018, a total of 51.4% (74/144) of the population engaged in gameplay, and 29.9% (43/144) watched videos. By 2022, these figures had shifted to 32.9% (47/143) for gameplay and 35.7% (51/143) for video watching, and in 2023, to 35% (50/142) for gameplay and 37.8% (54/142) for video watching (2022: χ^2_3=11.20, *P*=.01; 2023: χ^2_3=12.32, *P*=.006). Similarly, in 2019, a total of 46.2% (66/142) engaged in gameplay and 35% (50/142) watched videos. By 2022, these figures had changed to 32.9% (47/143) for gameplay and 35.7% (51/143) for video watching, and in 2023, to 35% (50/142) for gameplay and 37.8% (54/142) for video watching (2022: χ^2_3=8.68, *P*=.03; 2023: χ^2_3=8.16, *P*=.04; Figure 1).

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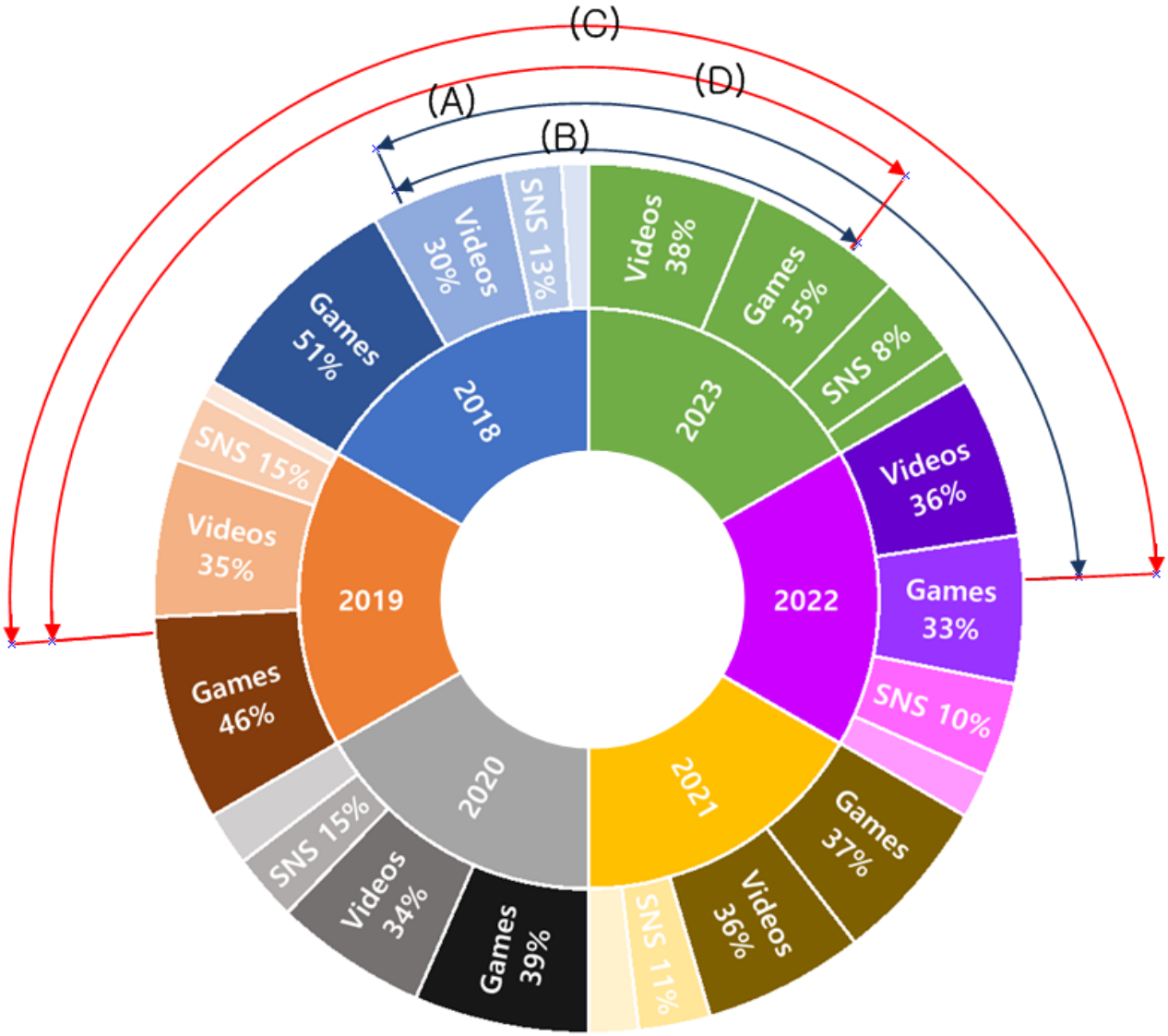
Figure 1. Changes in internet activities of Korean adolescents over 6 years (chi-square test). (A) Comparison of internet activities between 2018 and 2022 (χ^2_3=11.20, *P*=.01); (B) comparison of internet activities between 2018 and 2023 (χ^2_3=12.32, *P*=.006); (C) comparison of internet activities between 2019 and 2022 (χ^2_3=8.68, *P*=.03); and (D) comparison of internet activities between 2019 and 2023 (χ^2_3=8.16, *P*=.04). SNS: Social Network Service.



Differences in Problematic Internet Use for 4 Activities in Korean Adolescents Over 6 Years

Until 2019, the proportion of problematic internet use was highest in the gaming group among the 4 types of internet use. However, the proportion of problematic internet use in watching videos abruptly increased in 2020 and has maintained its top position until 2023. The proportion of problematic internet use in Social Network Service (SNS) use continuously increased until 2021 but decreased in 2022 and 2023 (Figure 2).

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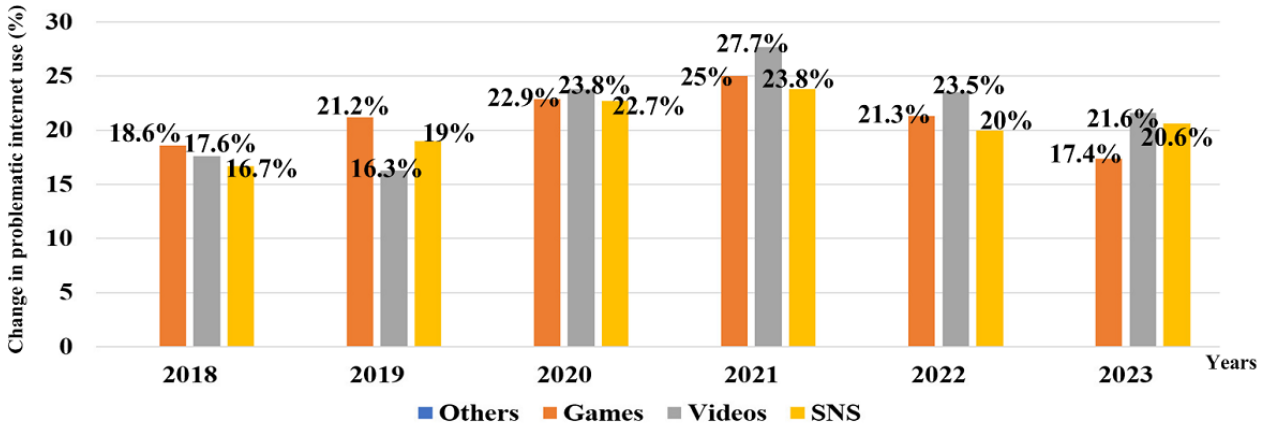
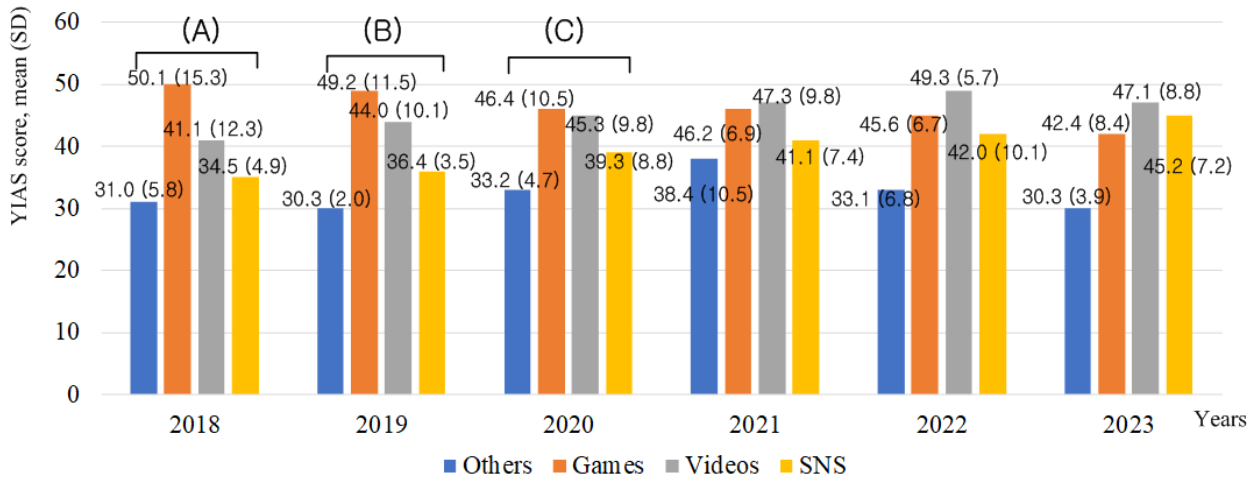
Figure 2. Changes in problematic internet use for 4 activities in Korean adolescents over 6 years. SNS: Social Network Service.



Differences in YIAS Scores for 4 Activities in Korean Adolescents Over 6 Years

In 2018, the YIAS scores for gameplay (mean 50.1, SD 15.3) were the highest compared to other activities. The YIAS scores for watching videos (mean 41.1, SD 12.3) were higher than those for SNS use (mean 34.5, SD 4.9) and other activities (mean 31.0, SD 5.8; F_3=14.63; P<.001). In 2019, the YIAS scores for gameplay (mean 49.2, SD 11.5) and watching videos (mean 44.0, SD 10.1) were higher than those for SNS use (mean 36.4, SD 3.5) and other activities (mean 30.3, SD 2.0; F_3=9.37; P<.001). In 2020, the YIAS scores for gameplay (mean 46.4, SD 10.5) and watching videos (mean 45.3, SD 9.8) were higher than those for SNS use (mean 39.3, SD 8.8) and other activities (mean 33.2, SD 4.7; F_3=4.98; P=.003). In 2021, there was no significant difference between the scores of the four activities (F_3=2.33; P=.08). In 2022, the YIAS scores for other activities (mean 33.1, SD 6.8) were significantly lower than those for gameplay (mean 45.6, SD 6.7), watching videos (mean 49.3, SD 5.7), and SNS use (mean 42.0, SD 10.1; F_3=6.83; P<.001). However, there was no significant difference between the scores for gameplay, watching videos, and SNS use. In 2023, the YIAS scores for other activities (mean 30.3, SD 3.9) were significantly lower, than those for gameplay (mean 42.4, SD 8.4), watching videos (mean 47.1, SD 8.8), and SNS use (mean 45.2, SD 7.2; F_3=4.73; P=.004). However, there was no significant difference between the scores for gameplay, watching videos, and SNS use (Figure 3).

Figure 3. The changes in YIAS scores for 4 activities in Korean adolescents over 6 years. (A) Game>Videos>SNS=Others (F_3=14.63; P<.001). (B) Game=Videos>SNS=Others (F_3=9.37; P<.001). (C): Game=Videos>SNS=Others (F_3=4.98; P=.003). SNS: Social Network Service; YIAS: Young's Internet Addiction Scale.



Differences in Influencing Factors for YIAS Scores

Considering the beta values of Model 4, the order of statistically significant influences on the severity of internet addiction in 2018 was as follows: game playing, PHQ-9 scores, watching videos, K-ARS scores, and IT use time (Table 3 and Table S1 in Multimedia Appendix 1). In 2019, the order was game playing, watching videos, PHQ-9 scores, K-ARS scores, and IT use time (Table 3 and Table S2 in Multimedia Appendix 1). In 2020, the order was K-ARS scores, game playing, and watching videos (Table 3 and Table S3 in Multimedia Appendix 1). In 2021, the order was PHQ-9 scores and watching videos (Table 3 and Table S4 in Multimedia Appendix 1). In 2022, the order was watching videos, game playing, PHQ-9 scores, K-ARS scores, and SNS use (Table 3 and Table S5 in Multimedia Appendix 1). In 2023, the order was PHQ-9 scores, K-ARS scores, watching videos, SNS use, and game playing (Table 3 and Table S6 in Multimedia Appendix 1).

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Table 3. Differences in influencing factors for YIAS[a] scores over 6 years.

Variables	2018	2019	2020	2021	2022	2023
Demographic factors						
Age	—[b]	—	—	—	—	—
Sex	—	—	—	—	—	—
Psychological test						
SE[c]	—	—	—	—	—	—
PHQ-9[d]	X2[e] (0.40)	X3 (0.30)	—	X1 (0.51)	X3 (0.31)	X1 (0.57)
K-SPIN[f]	—	—	—	—	—	—
K-ARS[g]	X4 (0.23)	X4 (0.30)	X1 (0.60)	—	X4 (0.25)	X2 (0.33)
IT use time	X5 (0.17)	X5 (0.13)	—	—	—	—
IT activity						
Game	X1 (0.52)	X1 (0.39)	X2 (0.24)	—	X2 (0.37)	X5 (0.24)
Videos	X3 (0.26)	X2 (0.36)	X3 (0.24)	X2 (0.25)	X1 (0.43)	X3 (0.28)
SNS[h]	—	—	—	—	X5 (0.25)	X4 (0.26)

[a]YIAS: Young's Internet Addiction Scale.
[b]Not applicable.
[c]SE: Two-Factor Self-Esteem Scale.
[d]PHQ-9: Patient Health Questionnaire 9.
[e]Xn (beta value): X: statistically significant; n: ranking; 1: most effective factor.
[f]K-SPIN: Korean version of the Social Phobia Inventory.
[g]K-ARS: Korean version of the Attention Deficit/Hyperactivity Disorder Rating Scale.
[h]SNS: Social Network Service.

Discussion

Principal Findings

The goal of this study was to examine changes in internet use patterns among adolescents, from before to after the outbreak of the COVID-19 pandemic. Our findings revealed several changes in internet use time and patterns, as well as shifts in problematic use behavior before, during, and after COVID-19.

The results showed that PHQ-9 scores were low before and after the COVID-19 pandemic, but high from 2020 to 2022, when the pandemic was at its peak. This aligns with previous studies indicating a high proportion of adolescents experiencing depression and anxiety during the pandemic [26,27]. The COVID-19 pandemic brought significant changes to adolescents' lives, potentially acting as environmental stressors [28]. To avoid exposure to the virus, young people actively avoided social activities, and many children and adolescents were confined to their homes for extended periods due to lockdowns. This social isolation has been associated with an increased risk of depression and anxiety in children and adolescents [29]. Additionally, the fear of infection itself was linked to anxiety and depression [30]. With the lifting of lockdowns, most people have resumed their lives, and depression and anxiety likely diminished since the peak of the pandemic due to the development of coping mechanisms and hopeful news about vaccines during the "honeymoon phase" of the disaster [31-33].

Similar results regarding the relationship between mental health and internet addiction during the COVID-19 pandemic were reported in several studies [34,35]. Ye et al [34] reported that depression is positively correlated with internet addiction during the COVID-19 pandemic. Moreover, adolescents with depressive disorders could have a higher risk of internet addiction. In a meta-analysis, Tang et al [35] reported that the association between problematic smartphone use and depressive symptoms became stronger after the COVID-19 outbreak.

To our knowledge, there is evidence of changes in internet use patterns during the pandemic, including increased dependence on the internet [36]. In a large, national youth sample, cross-sectional study conducted in the United States during the early period of the COVID-19 pandemic, the absolute time of internet use among teenagers more than doubled compared to prepandemic times [37]. Additionally, a systematic review and meta-analysis of screen time among children and youth aged 0 to 21 years before and after the pandemic showed a 1.6-fold increase in screen time during the pandemic [38]. Similarly, in this study, from 2020 to 2021, during the COVID-19 outbreak, adolescents used the internet more than before, and their internet use time decreased as the COVID-19 peak passed. Previous studies have shown that internet use time increased as physical activity decreased due to the lockdowns caused by COVID-19 [39,40]. These results may reflect decreased screen time as physical and offline activity increased when daily life recovered after COVID-19 [41].

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During the pandemic, teenagers increased their internet use for various purposes, such as interacting with friends, doing homework, enjoying games, and attending remote classes [42]. Generally, internet addiction is suspected when an individual devotes excessive time to internet use [43]. Excessive internet use is known to likely lead to internet addiction, especially in children and adolescents [44]. Similarly, as adolescents spend more time on web-based activities during the pandemic, many studies have shown an increased risk of internet addiction. For instance, a study examining internet addiction in Taiwanese high school students during COVID-19 found a 24.4% rate of addiction, indicating an increase compared to prepandemic levels [45]. In a longitudinal study on the developmental qualities of children and adolescents during the COVID-19 pandemic, Wang et al [46] suggested that the pandemic may lead to a decline in positive youth development, making them more vulnerable to internet addiction. Additionally, a study conducted in India investigated the effect of the COVID-19 lockdown on internet addiction in late teenagers, showing a 14.84% increase in internet gaming disorder (IGD) frequency compared to previous studies in the same region [47]. However, most studies focused only on excessive internet use and did not differentiate specific internet activities. Therefore, to address problematic internet use among adolescents, it is necessary to examine in more detail which specific internet activities are problematic.

Looking at the changes in internet use behavior that this study focused on, game playing decreased in adolescents after the pandemic compared to before the pandemic, and watching videos increased further. In addition, in this paper, the problematic internet use rate of games was the highest before COVID-19. Still, after COVID-19, the problematic internet use rate was the highest in the video group, and this trend continued until 2023. In addition, as our study showed, the YIAS score was the highest in the game group in 2018 compared to other groups before COVID-19. Still, in 2019, the YIAS scores in the game and video groups were higher than other groups, and the YIAS scores between the game, video, and SNS groups did not differ significantly as we went into 2022. The degree of influence on the severity of internet addiction was also the largest in the game group before COVID-19, but the effect on the video group was greater than in the game group after COVID-19.

Similar to these findings, several studies have reported significant changes in how individuals allocate time across different activities during the COVID-19 pandemic, noting increased SNS use, watching videos, and more, not just gaming [36,48,49]. According to a probability-based tracking survey of tweens and teens in the United States, there was no significant difference in teen gaming time between 2019 and 2021. Still, the time spent watching videos increased significantly, up to 23 minutes daily [50]. As several reports suggest, overall, the global gaming market has shrunk since the COVID-19 pandemic [51], and gaming users' gaming hours have declined since the peak [52]. On the other hand, the video-related industry has grown significantly as lockdowns have made it one of the major recreational activities [53]. According to Morse et al [54], TV or streams or movies have emerged as a new leisure activity, with activities experiencing the greatest increase during COVID-19. Another study suggests that Netflix, Hulu, and Amazon Prime Video are now recognized as some of the most important TV networks and video sources for the younger adult generation, further highlighting the popularity of streaming services [55]. Similarly, other studies point to the problematic use of SNS platforms, including video consumption by adolescents [36,56,57].

In the paper by Nawaz et al [36] on technology utilization in the new post–COVID-19 era, social networking platform engagement has increased markedly as study participants have been given more time for web-based social interaction. Meanwhile, in one study conducted in Italy, video consumption through certain platforms, like TikTok, during the COVID-19 pandemic strongly predicted social media addiction [56]. In addition, similar to previous studies that revealed that adolescents' social anxiety can lead to problematic social media use [57]; the increasing web-based social interaction trend, rather than internet gaming, reflects the growing dependence on digital connections as a coping mechanism during physical distancing and quarantines, with web-based streaming services, including videos, also experiencing notable use increases [36]. Taken together, even before COVID-19, video-sharing platforms such as YouTube [58] and social media platforms such as Instagram or Snapchat were already gaining popularity [59]. However, short video consumption worldwide saw the fastest and largest increase in the early stages of the pandemic, especially among those aged 15-29 years [60], where teenagers would have sought self-expression and social rewards by recording and communicating their daily lives [61]. Furthermore, the rise in the use of SNS and video apps during COVID-19 suggests a shift in overall trends during physical distancing, searching for information, and using platforms to help maintain social relationships [62].

As mentioned in the previous results, the COVID-19 pandemic has significantly changed people's lives worldwide, with internet use at the center of this change. Although internet use has alleviated mental health symptoms for many and helped them cope with new trends [63,64], adolescents have been able to devote more time to web-based activities, especially during emotionally demanding times, which can lead to problematic use [65]. It is essential to provide guidance to reduce the risk of such addiction. Adults should observe how much time adolescents spend on web-based activities (eg, playing games and watching videos) and help them manage these activities [48].

However, problematic internet use has not yet been sufficiently discussed. The American Psychiatric Association included IGD in *DSM-5* [66], and the World Health Organization included gaming disorder in the *International Classification of Diseases, 11th Revision* [67], but current societies present only diagnostic criteria for games. This study shows that games no longer account for a high percentage of adolescents' problematic internet use time. In addition, the *DSM-5* acknowledges the limitations of the absence of well-studied subtypes for IGD and acknowledges that there are limitations to the diagnosis, such as the fact that it is not clear which game type is specifically included in IGD diagnosis [66]. Furthermore, a survey of

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adolescents in China on IGD, problematic smartphone use, and problematic SNS use found that each has a different core symptom, with problematic SNS use requiring a different therapeutic approach as it shows a different core symptom [68]. Similarly, as Griffiths [10] argued in his study on the concept of internet addiction and IGD, it should be understood that people addicted to web-based activities, such as web-based games, web-based gambling, web-based sex, and web-based shopping, should not be defined as people with internet addictions, but rather as people with game addictions, sex addictions, or shopping addictions, who are engaged in addictive behavior using the internet as a tool. Chen et al [69] reported that problematic smartphone use was associated with the COVID-19 pandemic outbreak, whereas problematic internet gaming was not. Previous studies suggest that the focus should be on how the internet is used, rather than seeing the excessive internet use itself as the problem. It is not just gameplay time that is a problem—as individual internet behavior patterns have changed during the COVID-19 pandemic, these points should be considered when solving problematic internet use.

Limitations

There are some limitations to this study. First, there may be sampling errors in representing the overall internet use patterns of teenagers, as the survey only included teenagers aged 13 to 15 years. Second, because this study did not track the same population over 6 years, it was unable to fully capture the trends in internet addiction and patterns of internet use among adolescents. Third, this study could not fully capture changes in internet addiction and mental health because it was not a longitudinal study within a single group.

Although literature on the pandemic has surged with the global spread of COVID-19, little has been studied about the changes in media and content use caused by the pandemic [70]. To the best of our knowledge, this is the first study to focus on changes in internet use patterns due to the pandemic. The strength of our study lies in surveying the same teenage group over 6 years before, during, and after COVID-19 and further investigating which types of internet use were identified as problematic. Based on these changes in internet use patterns and problems among teenagers, this study contributes to the literature on understanding the trends in internet use behavior caused by COVID-19 and helps predict future changes in internet use.

Conclusions

During the COVID-19 pandemic, academic and commercial internet use through remote classes and videoconferences increased rapidly worldwide, leading to a rise in overall internet use time. The demand for digital platforms will continue to grow in the coming era. Until now, discussions have primarily focused on the use of games, but it is now necessary to consider what types of internet behavior cause problems and how to address them.

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Data Availability

The datasets generated and analyzed during this study are not publicly available as they contain information that could compromise the privacy and consent of the research participants but are available from the corresponding author upon reasonable request.

Authors' Contributions

SIK and DHH contributed to the study design, data collection, and initial drafting of the manuscript. JCJ and SY participated in data analysis and interpretation and revised the manuscript critically for important intellectual content. JCJ and SIK assisted in developing the research methodology and contributed to data validation and visualization. DHH supervised the study, provided resources and funding, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Hierarchical linear regression analyses.
[DOCX File , 28 KB - pediatrics_v8i1e66448_app1.docx]

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Abbreviations

ADHD: attention-deficit/hyperactivity disorder
ARS: Attention-Deficit/Hyperactivity Disorder Rating Scale
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
IGD: internet gaming disorder
K-ARS: Korean version of the Attention-Deficit/Hyperactivity Disorder Rating Scale
K-SPIN: Korean version of the Social Phobia Inventory

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PHQ-9: Patient Health Questionnaire 9
SE: Two-Factor Self-Esteem Scale
SNS: Social Network Service
SPIN: Social Phobia Inventory
YIAS: Young's Internet Addiction Scale

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Original Paper

Effects of Web-Based Single-Session Growth Mindset Interventions for Reducing Adolescent Anxiety: Four-Armed Randomized Controlled Trial

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Abstract

Background: Anxiety disorders are the most common mental health conditions worldwide, yet 65% of those affected do not access services. The high prevalence of anxiety and the low rate of intervention uptake highlight the urgent need to develop timely, scalable, and effective interventions suitable for adolescents. This study adapted existing single-session interventions (SSIs) to further develop an SSI focused on a growth mindset regarding negative emotions for adolescent mental health.

Objective: The study aims to compare the effectiveness of 4 SSIs, SSI of a growth mindset for anxiety (SIGMA), SIGMA with boosters (SIGMA-Booster), SSI of a growth mindset of personality (SSIGP), and an active control group (support therapy [ST]), in reducing adolescent anxiety.

Methods: Classes from each secondary school were randomized to 1 of 4 intervention conditions: SIGMA, SIGMA-Booster, SSIGP, or ST. Each intervention took approximately 45 minutes online. Participants reported on anxiety symptoms (primary outcome), depressive symptoms, suicidal/self-harming thoughts, perceived control, hopelessness, attitude toward help-seeking, and psychological well-being (secondary outcomes) at preintervention, 2-week follow-up, and 8-week follow-up. Participants also completed a feedback scale postintervention. Generalized estimating equations were used to examine the effectiveness of the SSIs.

Results: A total of 731 adolescents from 7 secondary schools were randomized. The intent-to-treat analysis found a significant decrease in anxiety symptoms. The mean and 95% CI at baseline were 6.8 (6.0-7.6) for SIGMA-Booster, 6.5 (5.8-7.3) for SIGMA, 7.0 (6.2-7.7) for SSIGP, and 6.9 (6.1-7.7) for ST. At the 2-week follow-up, the mean and 95% CI were 5.9 (5.1-6.7) for SIGMA-Booster, 5.7 (4.9-6.5) for SIGMA, 5.4 (4.6-6.2) for SSIGP, and 5.7 (4.9-6.4) for ST. At the 8-week follow-up, the mean and 95% CI were 5.9 (5.1-6.7) for SIGMA-Booster, 5.3 (4.5-6.0) for SIGMA, 5.6 (4.8-6.4) for SSIGP, and 5.8 (5.1-6.6) for ST. These reductions were observed across all 4 groups. Moderation analysis found that participants with higher motivation for change, higher baseline anxiety scores, and fixed mindsets showed greater improvements in anxiety symptoms. Most participants (459/731, 62.8%) viewed the feasibility and acceptability of the SSIs positively.

Conclusions: The SSI for all 4 groups was effective in reducing anxiety and depression among adolescents over 8 weeks. Our data suggest the potential benefits of brief web-based interventions for adolescents, which could serve as scalable, destigmatized, and cost-effective alternatives to school-based programs. The intervention effects may have been underestimated, as this study did not exclude adolescents with minimal or no anxiety symptoms. Future studies should focus on the specific effects of interventions for adolescents with varying levels of anxiety symptoms.

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Trial Registration: ClinicalTrials.gov NCT05027880; https://clinicaltrials.gov/ct2/show/NCT05027880

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KEYWORDS

belief-in-change; growth mindset; mental health; secondary school students; brief intervention; randomized controlled trial

Introduction

Background

Anxiety is one of the leading causes of illness and disability among adolescents aged 10-19 years [1]. Approximately 6.5% of adolescents worldwide and 6.9% in Hong Kong have been diagnosed with anxiety disorders [2,3]. In Hong Kong, for example, 1 in 4 secondary school students experienced high subclinical anxiety symptoms over a 3-month period, requiring clinical intervention [4]. Based on prevalence rates and local youth population data [5], it is estimated that approximately 85,000 secondary school students in Hong Kong require help and intervention for anxiety symptoms.

However, an estimated 65% of individuals with generalized anxiety disorder in Hong Kong did not access mental health services [6]. Among those who sought help, the median waiting time from symptom onset to receiving public child and adolescent psychiatric services was 58 weeks. Meanwhile, the cost of private treatment was reported to be HK $3000 (US $386) per monthly consultation, making it unaffordable for many families, who were left with no choice but to wait for public services [7]. Existing approaches, such as clinic-based treatments provided by highly trained mental health professionals, face significant limitations, including lengthy waitlists, high costs, and challenges in large-scale dissemination. This traditional setting further restricts access to services in special circumstances, such as during the COVID-19 pandemic [8]. Moreover, adolescents with mental health symptoms are particularly vulnerable to stigma and discrimination and may be reluctant to seek school-based interventions [9]. Even among youth who access care, most drop out prematurely, completing only 3-4 therapy sessions on average [10]. While natural remission without treatment may occur, it is uncommon [11]. Given these challenges, there is a clear need to develop briefer, scalable, nonstigmatizing, and youth-friendly interventions for adolescents with general anxiety symptoms. A brief intervention that fosters insight or reduces anxiety about mental health symptoms may help alleviate mental health problems and support remission.

Single-session interventions (SSIs) are structured programs designed to involve only 1 visit or encounter with a clinic, provider, or program [12]. These interventions can function as stand-alone treatments or as adjuncts to clinical services. Notably, research has shown that the number of sessions is not related to the magnitude of the treatment effect [13]. As a very brief intervention consisting of just 1 session, SSIs have demonstrated a relatively substantial effect on youth psychiatric problems. A previous meta-analysis [14] reported a mean postintervention effect size of 0.32 (Hedges *g*), with the largest effect size observed for anxiety (0.56). Although the effects of SSIs were moderated by follow-up length, with smaller effect sizes observed in follow-ups exceeding 13 weeks [14], Schleider and Weisz [15] still found significant improvements in youth depression and perceived behavioral control following growth mindset SSIs, with effects lasting up to 9 months compared with an active control. They also found that enhancing belief in personality change improved treatment access for adolescent depression [16], although no significant changes were recorded for general anxiety, social anxiety, or conduct problems [17]. Walton and Wilson [18,19] emphasized the importance of precise interventions that target the underlying psychological processes contributing to social or psychological problems, as well as the need for an adaptive context to maximize the potency of brief interventions. Thus, the effectiveness of SSIs is closely tied to their content (what to intervene) and implementation strategies (how to intervene).

Given the substantial evidence linking fixed mindsets to youth mental health problems [20] and the positive effects of growth mindset SSIs on anxiety-related outcomes [21], this study developed and examined the efficacy of growth mindset SSIs for adolescent anxiety in the Chinese context. Although some cultural adaptations of growth mindset SSIs have been made for non-Western populations, such as Indian adolescents [22], few studies have examined growth mindset SSIs in the Chinese context, particularly for anxiety-related outcomes [23]. We aimed to advance the existing literature by implementing and comparing different domains of growth mindset and developing implementation strategies for SSIs among Chinese adolescents. First, this study developed the SSI of a growth mindset for anxiety (SIGMA). As fixed mindsets about negative emotions (beliefs that one's negative emotions cannot change) have been closely associated with adolescent depression and anxiety [24,25], interventions that promote growth mindsets about negative emotions (beliefs in the changeability of one's negative emotions) may help alleviate worry and anxiety in adolescents. Second, to examine the effectiveness of SIGMA, we adapted the existing SSIs into Chinese and compared them with SSI of a growth mindset of personality (SSIGP) and support therapy (ST) [15,26]. Third, we collected feedback from social workers and counselors based on the principle of patient and public involvement, and they suggested that boosters could help strengthen the effectiveness of brief interventions. Thus, we designed booster reminders for SIGMA and examined whether reinforcing the core messages of the intervention with boosters would strengthen its effectiveness. A deviation from the 3-arm intervention protocol is that we increased the sample size of participants receiving SIGMA with booster (SIGMA-Booster) messages, establishing it as an independent group. As a result, the SIGMA-Booster group and the SIGMA group now have sample sizes equivalent to the other 2 groups (SSIGP and ST), rather than selecting only half of the original SIGMA group to receive booster messages. We proposed this 4-arm randomized controlled trial to provide evidence on the effectiveness of

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SIGMA (including SIGMA and SIGMA-Booster) and compare it against the existing growth mindset intervention (SSIGP) and support theory as an active control. Beyond its research significance, the study's findings could have broad implications for mental health care practice and policy. If the SSIs in this study are found to be effective, they could be scaled up in schools and community settings, offering a cost-effective and accessible solution to address youth mental health needs. This could reduce the burden on overstretched traditional mental health services and inform public health policies, such as integrating SSIs into school mental health programs or national strategies.

Objectives

The primary objective of the study was to evaluate the effectiveness of a single-session growth mindset intervention for negative emotions (abbreviated as SIGMA) in reducing general anxiety symptoms among secondary school students.

The secondary objective was to compare the effectiveness of the aforementioned programs on secondary outcomes, including reductions in depressive symptoms, suicidal/self-harming thoughts, and hopelessness, as well as increases in perceived control over emotions, attitudes toward help-seeking, and psychological well-being.

Study Hypothesis

- Hypothesis 1: SIGMA (including SIGMA and SIGMA-Booster) and SSIGP are more effective than the active control, ST, in the primary outcome of (1) reducing general anxiety symptoms, and in the secondary outcomes of (2) reducing depressive symptoms, (3) reducing suicidal/self-harming thoughts, (4) reducing hopelessness, (5) enhancing perceived control, (6) increasing positive attitudes toward help-seeking, and (7) enhancing psychological well-being.
- Hypothesis 2: SIGMA (including SIGMA and SIGMA-Booster) is more effective than SSIGP in the outcomes listed from (1) to (7).
- Hypothesis 3: The effectiveness of SIGMA-Booster is greater than that of SIGMA in the outcomes listed from (1) to (7).
- Hypothesis 4: The effectiveness of SIGMA is greater in participants with higher motivation for change than in those with low or no motivation.
- Hypothesis 5: The effectiveness of SIGMA is greater in participants with higher baseline anxiety levels than in those with lower baseline anxiety levels.
- Hypothesis 6: The effectiveness of SIGMA is greater in participants with a more fixed mindset at baseline than in those with a more growth-oriented mindset at baseline.

Methods

Ethical Considerations

This study received ethical approval from the Hong Kong Polytechnic University Institutional Review Board (reference number HSEARS20201004001-01) and complied with institutional guidelines and the Declaration of Helsinki. Parental consent and student assent were obtained for all participants. Participants were informed of their right to withdraw at any time without penalty. Data were anonymized (eg, school names removed, unique codes assigned) and stored securely. Participants who completed the entire study received HK $100 (US $13) worth of supermarket coupons as compensation, while participating schools were provided with aggregate mental health reports for institutional support purposes.

Study Design

The study design was described in the published protocol [27]. The trial was prospectively registered at ClinicalTrials.gov (NCT05027880) under the trial ID NCT05027880.

Unlike the published protocol, we made SIGMA-Booster a separate arm to examine whether booster reminders would help promote the long-term effects of the SSI. Based on the principle of patient and public involvement, we consulted the targeted participant population as well as their teachers and counselors. They suggested that boosters, as reminders, should be helpful for long-term changes. Thus, we designed 5 boosters and printed them into folders to be used as weekly reminders between the 2- and 8-week follow-ups (from week 3 to week 7). Only the SIGMA-Booster group received these boosters.

Thus, 4 classes from the same grade of the participating school were randomized (using computer-generated random numbers) into the (1) SIGMA group, (2) SIGMA-Booster group, (3) SSIGP group, and (4) ST group (active control condition group), all of which received the ST intervention at the same time (Figures 1 and 2). Participants in the SIGMA-Booster arm received the SIGMA intervention along with weekly reminders of key intervention messages as boosters from weeks 3 to 7. Two schools did not have enough classes in 1 grade, so classes from other grades at those schools were invited to join the study. All participants received regular interventions at school. Three repeated assessments were conducted for the 4 groups simultaneously at (1) baseline, (2) 2 weeks postintervention, and (3) 8 weeks postintervention. The cluster randomization at the classroom level helped balance the risk of contamination between the experimental and active control groups, as well as account for school heterogeneity due to factors such as school culture, schedule, and management.

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Figure 1. Design of the 4-arm waitlist randomized controlled trial. SIGMA: single-session intervention of a growth mindset for anxiety; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.

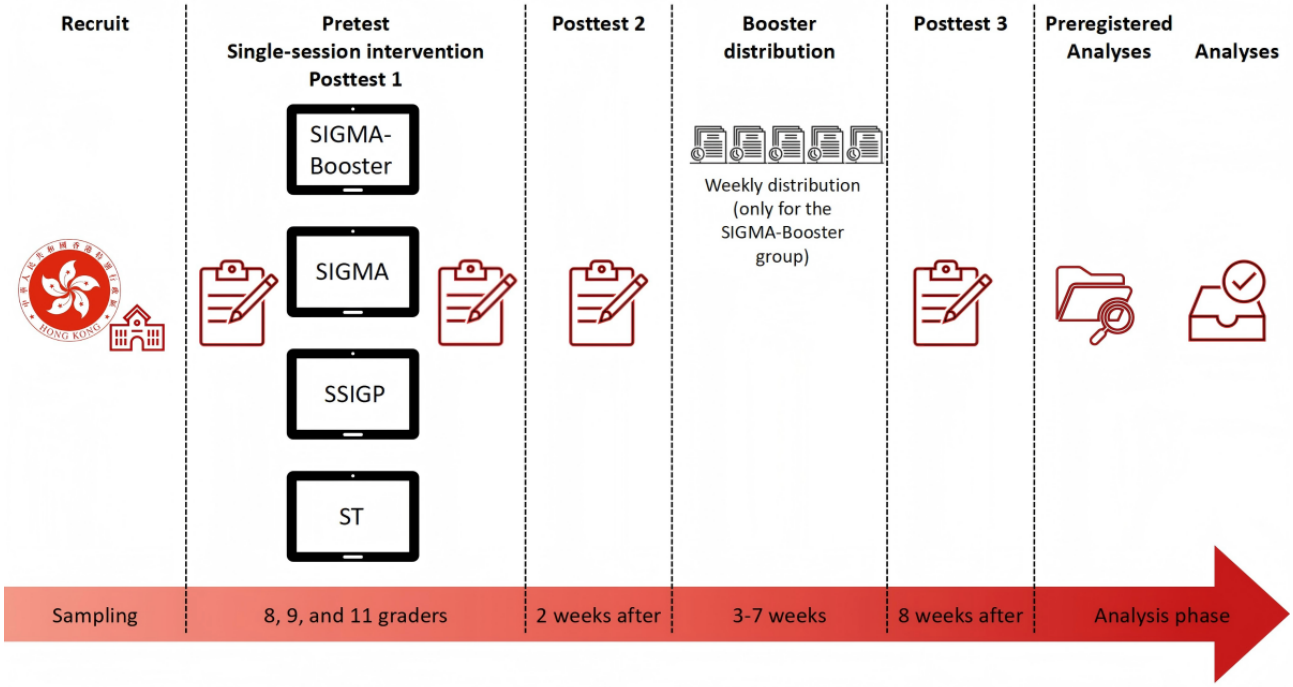
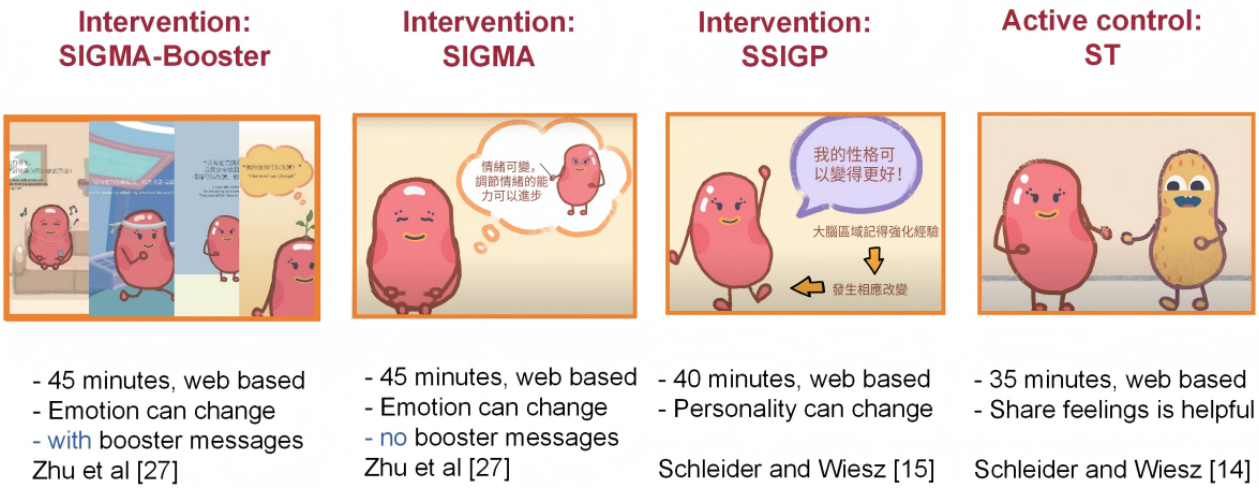


Figure 2. Intervention designs. SIGMA: single-session intervention of a growth mindset for anxiety; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



Participants

Seven schools from Hong Kong Island, Kowloon, and the New Territories participated in the study. These included schools that used English, Chinese, and mixed English and Chinese as the teaching medium. We targeted participants from form 2 to form 3 (grades 8-9). If a school did not have 4 classes in 1 grade, or if the number of eligible participants in a class was too few, we invited additional classes from other grades to participate.

Inclusion Criteria

Eligible participants were recruited from the 7 secondary schools through cluster randomized sampling. We included participants who (1) were Chinese youth able to read and write Chinese, (2) had sufficient visual and auditory abilities to complete the intervention and assessment, and (3) were able to give assent to participate in the study. As 2 schools did not have enough classes in 1 grade and invited classes from other grades to participate, a few participants above the age of 16 years were included, which did not follow the inclusion criteria outlined in the protocol (12-16 years old).

Exclusion Criteria

Exclusion criteria included (1) lack of parental consent; (2) inability to stay focused for the duration of the intervention, which is approximately 45 minutes; and (3) intellectual disability or severe illness or pain that could introduce significant bias in the students' health and mental health conditions. Eligible participants were not screened for anxiety symptoms, so this study comprehensively examined the efficacy of the interventions among students with absent, mild, moderate, and severe levels of anxiety.

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Procedure

The school and student recruitment process included the following steps: First, we sent research invitations to schools randomly selected from the school list. Invitations ceased when 7 schools agreed to participate. To ensure sufficient participant recruitment, we recruited 1 additional school beyond the protocol's plan. Four classes from the same selected grade(s) at each school were randomly chosen to join the study. The 4 selected classes were then randomized to the SIGMA condition, SIGMA-Booster condition, SSIGP condition, and the active control condition using random numbers. All students in those classes were invited to participate, with final participation contingent upon parental consent and students' assent.

After providing consent, students scanned a QR code to access the baseline questionnaire and the intervention program via the Qualtrics survey system (SAP SE). Students within the same class were assigned to the same intervention conditions. The interventions were conducted separately for each group in the school activity rooms, which were equipped with sufficient computers or tablets and headphones (Figure 3). All intervention activities were self-administered and delivered in a web-based format. The principal investigator (SZ) and well-trained research assistants remained in the intervention rooms to provide guidance and assistance if needed. All groups in the same school received interventions concurrently to minimize the influence of the time factor.

Figure 3. Intervention in a classroom.

Trial Power and Sample Size

To ensure the sample size was sufficient to test the hypotheses, a small to medium effect size (Cohen *d*=0.33) was used based on prior research [15]. Power was set at 0.80, and α was set at .05. A final sample size of 584 (146 per arm) was required. Considering the attrition rate from our previous studies in school settings (<20%), the baseline recruitment target was set at 732 participants (183 per arm). We ultimately recruited 731 participants. As the number of participants in each class varied, the final number of participants in each of the 4 arms differed.

Measures

Primary Outcome

Anxiety symptoms, measured using the 7-item Generalized Anxiety Disorder (GAD-7) scale [28,29], were the primary outcome. The 7 items assessed whether anxiety symptoms had bothered the individual during the previous 2 weeks, with frequency ranging from 0 (not at all) to 3 (nearly every day). Example items included: "Feeling nervous, anxious, or on edge" and "Not being able to stop or control worrying." The GAD-7 is a self-rating scale that effectively reflects symptom severity in adolescents and is highly correlated with clinician-administered ratings of anxiety symptoms. It is brief and suitable for self-report studies [30]. The Cronbach α for the scale was 0.93 [31]. By summing the scores of the 7 items, the following classifications were used: 0-4 indicated the absence of anxiety symptoms, 5-9 indicated mild anxiety, 10-14 indicated moderate anxiety, and 15-21 indicated severe anxiety. Based on the severity of anxiety, participants were categorized into 2 groups: the high anxiety group (scores of 10-21) and the nonhigh anxiety group (scores of 0-9) in this study.

Secondary Outcomes

The 9-Item Patient Health Questionnaire

The 9-item Patient Health Questionnaire (PHQ-9) [32,33] was used to assess participants' depression levels and suicidal/self-hurting thoughts over the previous 2 weeks, with frequency ranging from 0 (not at all) to 3 (nearly every day). The first 8 items (PHQ-8) were used to measure depression severity (sum of the 8 items), while the last item assessed suicidal/self-hurting thoughts. Responses of 1-3 on the last item were coded as "yes," and a response of 0 was coded as "no." Example items from the PHQ-9 included "Little interest or pleasure in doing things" and "Feeling down, depressed, or hopeless." The item assessing suicidal/self-hurting thoughts was "Thoughts that you would be better off dead or of hurting yourself in some way."

Perceived Control

The Anxiety Control Questionnaire [34] is a 15-item tool that measures participants' perceived control over their anxiety. The Emotion Control subscale, 1 of the 3 validated subscales, consists of 5 items (eg, "I am able to control my level of anxiety"), including 1 reverse-scored item (When I am anxious, I find it hard to focus on anything other than my anxiety). Responses are rated from 0 (strongly disagree) to 5 (strongly agree). The sum of the 5 items indicates the level of perceived control. The Cronbach α was 0.73.

Hopelessness

The 4-item Helplessness subscale of the Demoralization Scale [35] was used to measure participants' outlook on the future. Each item was rated on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). The sum of the 4 items

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was used to assess hopelessness, with a higher score indicating a correspondingly higher level of hopelessness. An example item was "I feel hopeless." The Cronbach α for the Chinese version of this Helplessness subscale was 0.72 [36].

Attitude Toward Seeking Help

We used 3 items from the Attitude Toward Seeking Counselling Help Assessment [37] to measure participants' understanding of counseling and attitudes toward seeking counseling help. Example items included "If I believed I was having a mental breakdown, my first inclination would be to get professional attention" and "Professional counseling and treatments can help people improve mental health." The Cronbach α was 0.72 [37]. Additionally, 2 items were used to assess participants' intention to seek help. The 2 items were "When I encounter difficulties, I will not ask for help from teachers" and "When I encounter difficulties, I will not ask for help from social workers/counselors." These 5 items were rated on a 7-point Likert scale, ranging from 1 (strongly disagree) to 7 (strongly agree). After reverse-scoring the 2 help-seeking intention items, the sum score of the 5 items represented participants' attitudes toward seeking help, with a higher score indicating more positive attitudes toward seeking help.

Psychological Well-Being

The short version of the 14-item Warwick-Edinburgh Mental Well-Being Scale (WEMWBS-14) [38,39] was used to measure the extent to which participants generally experienced well-being states. The WEMWBS-14 consists of 14 items, each rated on a 5-point Likert scale ranging from 1 (none of the time) to 5 (all of the time). The sum score of the 14 items indicated the participants' overall well-being level. An example item was "I have been feeling optimistic about the future." The scale's Cronbach α was 0.93.

Fidelity Checking and Intervention Feedback

Mindsets of Negative Emotions

The validated Chinese version of the 12-item Mindset of Depression, Anxiety, and Stress Scale (MDASS) was used to assess participants' beliefs regarding the changeability of negative emotional states, such as depression, anxiety, and stress [24]. Sample items included: "When you have a certain level of depression, you really cannot do much to change it," "To be honest, people cannot really change how anxious they are," and "No matter how hard people try, they cannot really change the level of stress that they have." Each item was scored on a 6-point Likert scale ranging from 1 (strongly disagree) to 6 (strongly agree); a higher score indicated a more fixed mindset toward negative emotions (Cronbach α=0.94). It included 3 subscales: depression mindset, anxiety mindset, and stress mindset, with 4 items in each subscale. The Cronbach α values for the 3 subscales were 0.91, 0.89, and 0.90, respectively [24]. By summing the total score, we defined fixed and growth mindsets using a cutoff score of 42, which was calculated by adding the midpoint (ie, 3.5) of the 6-point scale for the 12 items. Individuals scoring equal to or greater than 42 were considered to have more fixed mindsets, while those scoring below this cutoff were considered more inclined to have growth mindsets.

Mindset of Personality

Three items from implicit theories of personality [40,41] were used to measure the belief in the changeability of personality on a 6-point Likert scale, ranging from 1 (strongly disagree) to 6 (strongly agree). A higher score indicated a more fixed mindset of personality. A sample item was "People can do things differently, but the important parts of who they are can't really be changed." The Cronbach α was 0.85.

Motivation to Apply What Was Learned From the Program

In addition to the baseline assessment, immediately after the intervention, participants were asked to rate the extent to which they would like to apply the intervention content and improve their emotion regulation on a 6-point Likert scale (1-6), with a higher score indicating higher motivation. We defined high and low motivation groups based on the median cutoff after summing the 2 motivation items.

The Intervention Feedback Scale

This scale was developed based on the Theoretical Framework of Acceptability, which includes 7 component constructs: affective attitude, burden, intervention coherence, perceived effectiveness, opportunity costs, self-efficacy, and ethicality [42]. A general acceptability item, 6 items corresponding to the 6 components of the Theoretical Framework of Acceptability (excluding ethicality), and 4 items—including an open-ended written feedback item—were integrated to comprehensively assess the acceptability of the intervention. These items were drawn from the well-validated Program Feedback Scale [43]. For the Feedback Scale, except for the open-ended item, the other 10 items were assessed on a 5-point scale (eg, "How acceptable was the intervention to you?" with responses ranging from "1=completely unacceptable" to "5=completely acceptable"). The Feedback Scale was administered immediately after the intervention.

Attention-Checking Items

To ensure data quality and assess participant attention, 2 attention-checking items were included at all assessment points (baseline and follow-up surveys). These items directly instructed participants to select a specific option based on the given instructions. A sample question was "Please select 'strongly agree' for this item."

Sociodemographic Information

Sociodemographic information of participants was collected at baseline to examine group variability in factors such as gender, age, grade, ethnicity, and socioeconomic status (SES).

Data Analysis

We used an intention-to-treat approach in our primary analysis, where all participants who consented to participate were included. Participants who completed all assessments and passed both attention-checking items at each assessment point were classified in the per-protocol population. A per-protocol analysis was conducted as a sensitivity analysis. Multilevel modeling was used to account for the cluster randomization of classes within the same school [44]. All percentages and scores were presented with 1 decimal place. To examine the effects of the interventions, generalized estimating equations were used to

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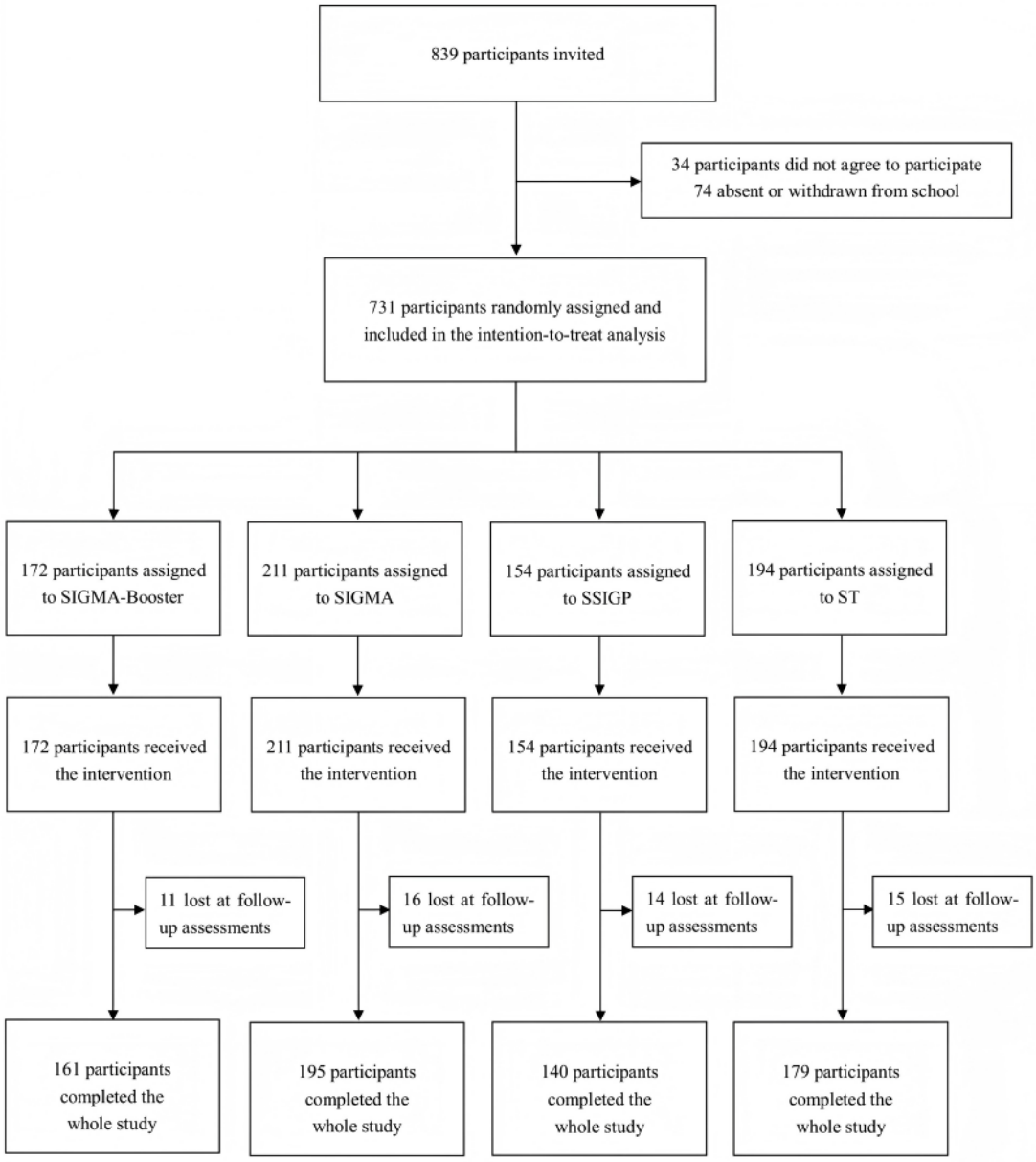
test the group effect, time effect, and their interaction effect on outcome measures. A statistically significant interaction effect indicated the effectiveness of the treatments. Additionally, we calculated effect sizes using estimated marginal means. These effect sizes, expressed as Cohen *d*, compared mean gain scores reflecting changes in each outcome from baseline to the 2 follow-ups for youth receiving the mindset versus active control interventions. The effect sizes were also compared between participants in the intervention group who received booster messages and those who did not. Additionally, we tested the following moderators on the effectiveness of the treatment for the primary and secondary outcomes: baseline anxiety level (dichotomized by the severity of GAD-7), motivation for change (dichotomized by the median of the sum motivation score on the 2 motivation items), and mindset group (fixed vs growth). The corrected quasi-likelihood under the independence model criterion (QICC) for the models with and without the moderator was examined, with evidence of a moderation effect indicated by a smaller QICC for the models including the moderator. Multiple comparisons were not conducted, and a *P* value of <.05 was considered statistically significant. Data analysis was performed using SPSS version 26 (IBM Corp.).

Results

Recruitment

Figure 4 depicts the CONSORT (Consolidated Standards of Reporting Trials) diagram of the recruitment and participation flow (also see Multimedia Appendix 1). A total of 731 participants were recruited and randomized into 4 groups: SIGMA-Booster (n=172, 23.5%), SIGMA (n=211, 28.9%), SSIGP (n=154, 21.1%), and ST (n=194, 26.5%). All participants received the interventions and were contacted for follow-ups. All participants were included in the intention-to-treat analysis. No participants explicitly requested to be removed from the trial.

Figure 4. CONSORT (Consolidated Standards of Reporting Trials) flowchart. SIGMA: single-session intervention of a growth mindset for anxiety; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



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Baseline Characteristics of Participants

Table 1 summarizes the baseline characteristics of the recruited participants. Of the 731 participants, 421 (57.6%) were girls. Statistical differences in grade and age were observed among the 4 groups, as some schools selected classes from 2 different grades. However, there were no statistical differences in ethnicity or SES.

There were no significant differences between the intervention groups on the primary and secondary outcome measures at baseline: anxiety symptoms, $F_{3,727}$=0.25, P=.86; depressive symptoms, $F_{3,727}$=0.13, P=.94; suicidal/self-hurting thoughts, χ^2_3 (N=731)=3.66, P=.30; perceived control, $F_{3,727}$=0.31, P=.82; hopelessness, $F_{3,727}$=0.74, P=.53; attitude toward seeking help, $F_{3,727}$=0.61, P=.61; and psychological well-being, $F_{3,727}$=0.63, P=.60.

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Table 1. Sample characteristics.

Variables	SIGMA-Booster[a] (n=172)	SIGMA[b] (n=211)	SSIGP[c] (n=154)	ST[d] (n=194)	Overall (N=731)	*P* value
Age						<.001
Mean (SD)	14.0 (0.9)	14.0 (1.0)	14.5 (1.5)	13.8 (0.8)	14.1 (1.1)	
Range	12-16	12-18	12-20	12-18	12-20	
Missing, n (%)	0 (0)	1 (0.5)	0 (0)	0 (0)	1 (0.1)	
Gender, n (%)						.005
Male	55 (32.0)	94 (44.5)	64 (41.6)	97 (50.0)	310 (42.4)	
Female	117 (68.0)	117 (55.5)	90 (58.4)	97 (50.0)	421 (57.6)	
Ethnicity, n (%)						.67
Chinese	168 (97.7)	204 (96.7)	152 (98.7)	189 (97.4)	713 (97.5)	
Other	4 (2.3)	7 (3.3)	2 (1.3)	5 (2.6)	18 (2.5)	
Grade, n (%)						<.001
Secondary 2	80 (46.5)	99 (46.9)	59 (38.3)	135 (69.6)	373 (51.0)	
Secondary 3	92 (53.5)	112 (53.1)	69 (44.8)	59 (30.4)	332 (45.4)	
Secondary 5	0 (0)	0 (0)	26 (16.9)	0 (0)	26 (3.6)	
Socioeconomic status, n (%)						.75
Low	0 (0.0)	1 (0.5)	1 (0.6)	0 (0)	2 (0.3)	
Medium	139 (80.8)	172 (81.5)	120 (77.9)	151 (77.8)	582 (79.6)	
High	33 (19.2)	38 (18.0)	33 (21.4)	43 (22.2)	147 (20.1)	
Willingness to participate in emotional control course (1-6), mean (SD)	3.5 (1.3)	3.5 (1.3)	3.3 (1.3)	3.4 (1.4)	3.4 (1.3)	.69
Willingness to improve emotional control (1-6), mean (SD)	4.2 (1.3)	4.0 (1.2)	4.0 (1.3)	4.0 (1.4)	4.0 (1.3)	.46
Mindset of anxiety (4-24), mean (SD)	14.6 (4.2)	13.8 (4.6)	14.5 (4.6)	13.7 (4.7)	14.1 (4.5)	.17
Mindset of depression (4-24), mean (SD)	13.6 (4.9)	12.8 (5.2)	13.4 (5.0)	12.8 (5.2)	13.1 (5.1)	.32
Mindset of stress (4-24), mean (SD)	15.5 (4.8)	14.3 (5.0)	14.6 (5.2)	14.9 (5.4)	14.8 (5.1)	.14
Mindset of personality (3-18), mean (SD)	13.5 (3.2)	13.0 (3.5)	13.0 (3.2)	13.1 (3.5)	13.1 (3.4)	.51
7-item Generalized Anxiety Disorder (0-21), mean (SD)	6.9 (5.1)	6.6 (5.4)	7.0 (5.1)	6.9 (5.8)	6.8 (5.4)	.86
8-item Patient Health Questionnaire-8 (0-24), mean (SD)	7.3 (5.6)	7.1 (5.7)	7.2 (5.4)	7.4 (5.6)	7.2 (5.6)	.94
Anxiety Control Questionnaire—Emotion Control (0-25), mean (SD)	13.6 (5.0)	13.5 (4.9)	13.7 (4.8)	13.2 (5.4)	13.5 (5.0)	.82
Demoralization Scale—Helplessness (4-20), mean (SD)	9.8 (3.6)	10.2 (4.0)	9.6 (3.8)	9.9 (4.0)	9.9 (3.9)	.53
Attitude Toward Seeking Help (5-35), mean (SD)	19.3 (4.6)	19.3 (5.6)	18.7 (5.2)	19.4 (5.6)	19.2 (5.3)	.61
Warwick-Edinburgh Mental Well-Being Scale (14-70), mean (SD)	41.7 (9.9)	42.3 (11.0)	43.1 (10.8)	43.0 (11.0)	42.5 (10.7)	.60
Suicidal/self-hurting thoughts, n (%)						.30
Yes	53 (30.8)	78 (37.0)	50 (32.5)	55 (28.4)	236 (32.3)	
No	119 (69.2)	133 (63.0)	104 (67.5)	139 (71.6)	495 (67.7)	

[a]SIGMA-Booster: SIGMA with boosters.

[b]SIGMA: single-session intervention of a growth mindset for anxiety.

[c]SSIGP: single-session intervention of a growth mindset of personality.

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[d]ST: support therapy.

Changes in Primary and Secondary Outcomes

For the primary outcome, we found a significant main effect of time (P<.001), but no significant main effect of group (P=.88) or group-by-time interaction (P=.54). Participants in all 4 intervention groups showed significant improvement in anxiety symptoms at both the 2- and 8-week follow-ups: $P_{2\ weeks}$=.02 and $P_{8\ weeks}$=.02 for SIGMA-Booster; $P_{2\ weeks}$=.006, $P_{8\ weeks}$<.001 for SIGMA; $P_{2\ weeks}$<.001, $P_{8\ weeks}$<.001 for SSIGP, and $P_{2\ weeks}$<.001, $P_{8\ weeks}$=.003 for ST. This improvement was sustained at the 8-week follow-up, and no significant differences were observed between the 2- and 8-week follow-ups: P=.99 for SIGMA-Booster, P=.17 for SIGMA, P=.46 for SSIGP, and P=.59 for ST (Multimedia Appendix 2 and Figure 5). When comparing the changes from baseline to follow-up between each pair of groups, the SSIGP intervention appeared to be more effective than SIGMA (including SIGMA and SIGMA-Booster) in reducing general anxiety symptoms. However, the effect sizes ranged from very small to small (Table 2).

Figure 5. The 7-item Generalized Anxiety Disorder scale (total score) changes over time. Each dot represents the mean score of each group at each time point. Each line around the dot represents the 95% Wald CI of the mean. SIGMA: single-session intervention of a growth mindset for anxiety; SIGMA-B: SIGMA-Booster; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.

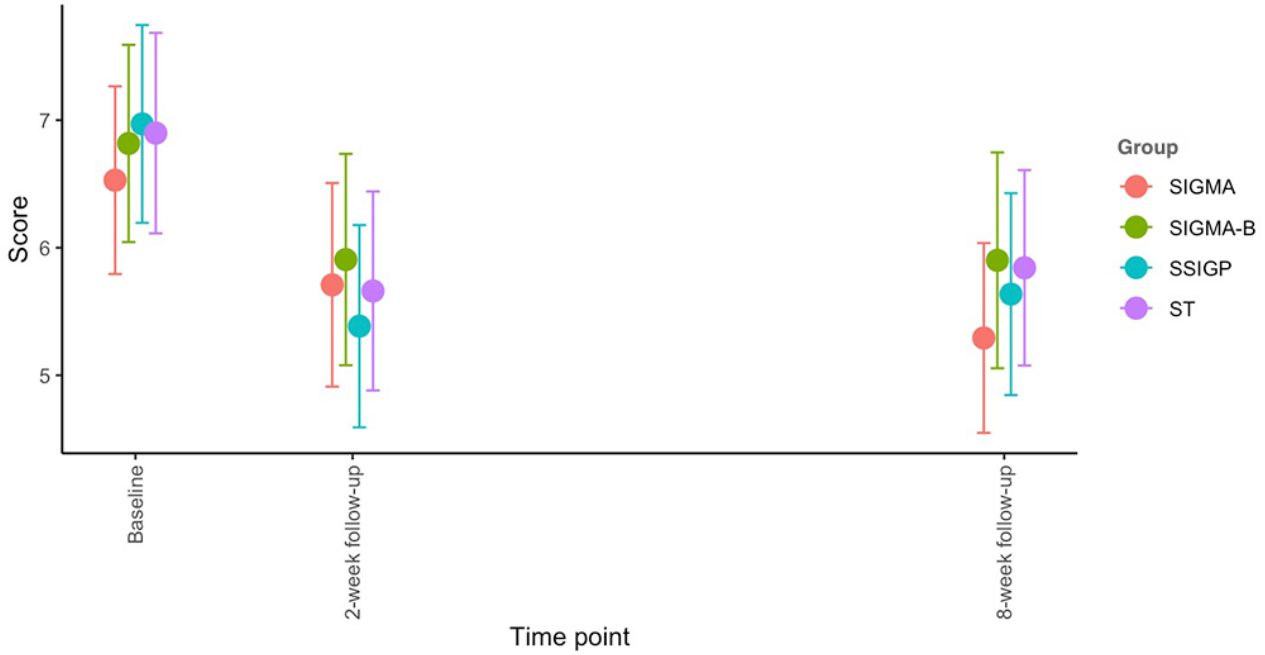

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Table 2. Effect sizes[a] of the treatment and intention-to-treat population.

Outcome variables	2-week follow-up, Cohen *d* (SE)	8-week follow-up, Cohen *d* (SE)
7-item Generalized Anxiety Disorder		
SIGMA-Booster[b] versus SIGMA[c]	–0.02 (0.12)	0.06 (0.12)
SIGMA-Booster versus SSIGP[d]	0.13 (0.13)	0.08 (0.13)
SIGMA-Booster versus ST[e]	0.06 (0.13)	0.03 (0.13)
SIGMA versus SSIGP	0.14 (0.15)	0.02 (0.15)
SIGMA versus ST	0.08 (0.15)	–0.03 (0.15)
SSIGP versus ST	–0.06 (0.15)	–0.05 (0.15)
8-item Patient Health Questionnaire		
SIGMA-Booster versus SIGMA	0.06 (0.13)	0.01 (0.13)
SIGMA-Booster versus SSIGP	0.10 (0.13)	–0.03 (0.13)
SIGMA-Booster versus ST	0.06 (0.13)	–0.04 (0.13)
SIGMA versus SSIGP	0.04 (0.15)	–0.04 (0.15)
SIGMA versus ST	–0.002 (0.15)	–0.05 (0.15)
SSIGP versus ST	–0.05 (0.16)	–0.01 (0.16)
Suicidal/self-hurting thoughts		
SIGMA-Booster versus SIGMA	0.20 (0.13)	0.18 (0.13)
SIGMA-Booster versus SSIGP	0.18 (0.13)	0.27 (0.13)
SIGMA-Booster versus ST	0.03 (0.13)	0.04 (0.13)
SIGMA versus SSIGP	–0.02 (0.15)	0.09 (0.15)
SIGMA versus ST	–0.17 (0.15)	–0.14 (0.15)
SSIGP versus ST	–0.15 (0.15)	–0.23 (0.15)
Anxiety Control Questionnaire—Emotion Control		
SIGMA-Booster versus SIGMA	–0.004 (0.13)	–0.01 (0.13)
SIGMA-Booster versus SSIGP	–0.03 (0.13)	0.05 (0.14)
SIGMA-Booster versus ST	–0.14 (0.13)	–0.26 (0.13)
SIGMA versus SSIGP	–0.03 (0.15)	0.06 (0.15)
SIGMA versus ST	–0.13 (0.15)	–0.25 (0.15)
SSIGP versus ST	–0.10 (0.15)	–0.31 (0.16)
Demoralization Scale—Helplessness		
SIGMA-Booster versus SIGMA	0.24 (0.13)	0.16 (0.12)
SIGMA-Booster versus SSIGP	0.07 (0.13)	0.05 (0.12)
SIGMA-Booster versus ST	0.20 (0.13)	0.08 (0.13)
SIGMA versus SSIGP	–0.18 (0.15)	–0.11 (0.15)
SIGMA versus ST	–0.04 (0.15)	–0.08 (0.15)
SSIGP versus ST	0.14 (0.15)	0.03 (0.15)
Attitude Toward Seeking Help		
SIGMA-Booster versus SIGMA	–0.03 (0.11)	0.05 (0.11)
SIGMA-Booster versus SSIGP	–0.15 (0.11)	–0.05 (0.12)
SIGMA-Booster versus ST	–0.12 (0.12)	0.08 (0.12)
SIGMA versus SSIGP	–0.12 (0.14)	–0.09 (0.14)
SIGMA versus ST	–0.09 (0.14)	0.03 (0.14)

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Outcome variables	2-week follow-up, Cohen *d* (SE)	8-week follow-up, Cohen *d* (SE)
SSIGP versus ST	0.04 (0.14)	0.12 (0.15)
Warwick-Edinburgh Mental Well-Being Scale		
SIGMA-Booster versus SIGMA	0.02 (0.12)	0.02 (0.13)
SIGMA-Booster versus SSIGP	0.02 (0.13)	0.10 (0.13)
SIGMA-Booster versus ST	–0.08 (0.12)	–0.11 (0.13)
SIGMA versus SSIGP	–0.003 (0.16)	0.08 (0.16)
SIGMA versus ST	–0.10 (0.15)	–0.13 (0.16)
SSIGP versus ST	–0.10 (0.16)	–0.21 (0.15)

[a]Effect size values were calculated by subtracting the latter group's mean gain score from the former group's mean gain score for each outcome from baseline to the 2- and 8-week follow-ups, then dividing by the pooled SD of all participants at baseline.

[b]SIGMA-Booster: SIGMA with boosters.

[c]SIGMA: single-session intervention of a growth mindset for anxiety.

[d]SSIGP: single-session intervention of a growth mindset of personality.

[e]ST: support therapy.

For the secondary outcomes, all the main effects of time were significant, while the main effects of group and the interaction effects of group and time were insignificant (main effects of group: P=.87 for depressive symptoms; P=.41 for suicidal/self-hurting thoughts; P=.97 for perceived control; P=.73 for hopelessness; P=.87 for help-seeking attitude; P=.39 for psychological well-being and interaction effects; P=.85 for depressive symptoms; P=.10 for suicidal/self-hurting thoughts; P=.20 for perceived control; P=.23 for hopelessness; P=.33 for help-seeking attitude; and P=.68 for psychological well-being), similar to the primary outcome. Specifically, the results for depressive symptoms mirrored those for anxiety (main effect of time, P<.001 and main effect of group, P=.87). All 4 groups showed a reduction in depressive symptoms at follow-ups, and the effects observed at the 8-week follow-up were comparable to those at the 2-week follow-up (see Multimedia Appendix 2 and Figure 6). Moreover, the effect sizes for the comparison between groups on the changes from baseline to follow-ups were all very small (Table 2). Second, a significant main effect of time was found for suicidal/self-hurting thoughts (P=.005), but the main effect of group was not significant (P=.41). Specifically, the SIGMA group showed a reduction in suicidal/self-hurting thoughts at both the 2- and 8-week follow-ups, with the effect sustained at the 8-week follow-up compared with the 2-week follow-up. The SSIGP group showed a significant reduction in suicidal/self-hurting thoughts at the 8-week follow-up (P<.001), but not at the 2-week follow-up (P=.14). The other 2 groups did not report significant changes in suicidal/self-hurting thoughts at either follow-up with $P_{2\ \mathrm{weeks}}$=.50, $P_{8\ \mathrm{weeks}}$=.96 for SIGMA-Booster and $P_{2\ \mathrm{weeks}}$=.75, $P_{8\ \mathrm{weeks}}$=.61 for ST (see Multimedia Appendix 2 and Figure 7). Both the SIGMA and SSIGP interventions appeared to be more effective in reducing suicidal/self-hurting thoughts than the SIGMA-Booster and ST, although the effect sizes were small (Table 2). For the other secondary outcomes, the main effects of time were significant for all variables (for perceived control, P=.03; for hopelessness, P<.001; for help-seeking attitude, P<.001; and for psychological well-being, P<.001). However, the main effects of the group were not significant (P values ranged from .39 to .97). For perceived control, only the ST group reported significant improvement at both the 2- and 8-week follow-ups ($P_{2\ \mathrm{weeks}}$=.02, $P_{8\ \mathrm{weeks}}$=.007). The ST intervention appeared to be more effective than the other 3 groups in improving perceived control, though the effect sizes were small (Table 2). For hopelessness, both the SIGMA and ST groups showed significant improvement at both the 2-week (P<.001 for SIGMA and P<.001 for ST) and 8-week follow-ups (P=.001 for SIGMA and P=.005 for ST), while the SSIGP group only reported significant improvement at the 8-week follow-up (P=.02). The SIGMA group seemed to outperform the SIGMA-Booster group in reducing hopelessness, although the effect sizes were small (Table 2). For help-seeking attitude, both the SIGMA-Booster and SSIGP groups reported significant improvement at both the 2-week (P=.01 for SIGMA-Booster and P<.001 for SSIGP) and 8-week follow-ups (P=.01 for SIGMA-Booster and P=.003 for SSIGP), while the SIGMA and ST groups showed significant improvement only at the 2-week follow-up (P=.006 for SIGMA and P<.001 for ST). For psychological well-being, the ST group showed significant improvement at both the 2- and 8-week follow-ups with P=.01 and P<.001, respectively, while the SIGMA-Booster and SIGMA groups demonstrated significant improvement only at the 8-week follow-up with P=.02 (Multimedia Appendix 2). The effect sizes for changes in attitude toward seeking help and psychological well-being were all very small between groups. The only effect size that reached a small magnitude (>0.2) was for the improvement in psychological well-being at the 8-week follow-up, where the ST group showed greater improvement compared with the SSIGP group (Table 2).

The sensitivity analysis conducted for the per-protocol population showed results similar to those of the intention-to-treat population. The specific results of the sensitivity analysis can be found in Multimedia Appendix 3.

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Figure 6. The 8-item Patient Health Questionnaire scale (total score) changes over time. Each dot represents the mean score of each group at each time point. Each line around the dot represents the 95% Wald CI of the mean. SIGMA: single-session intervention of a growth mindset for anxiety; SIGMA-B: SIGMA-Booster; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.

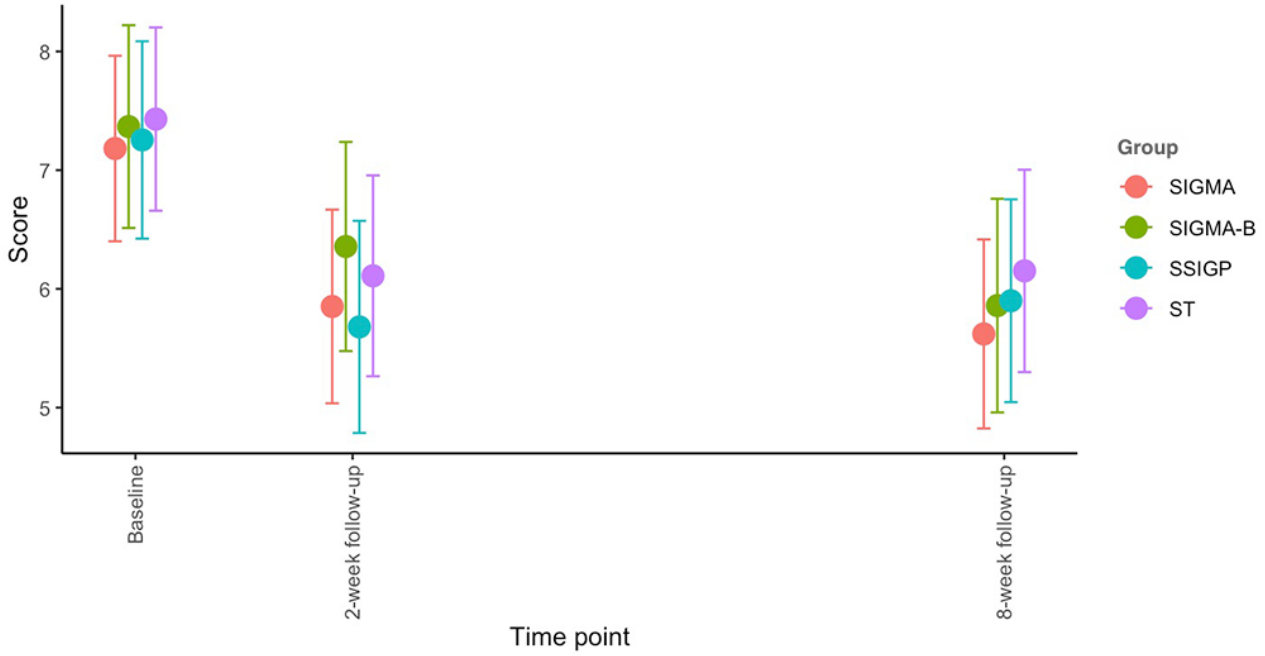
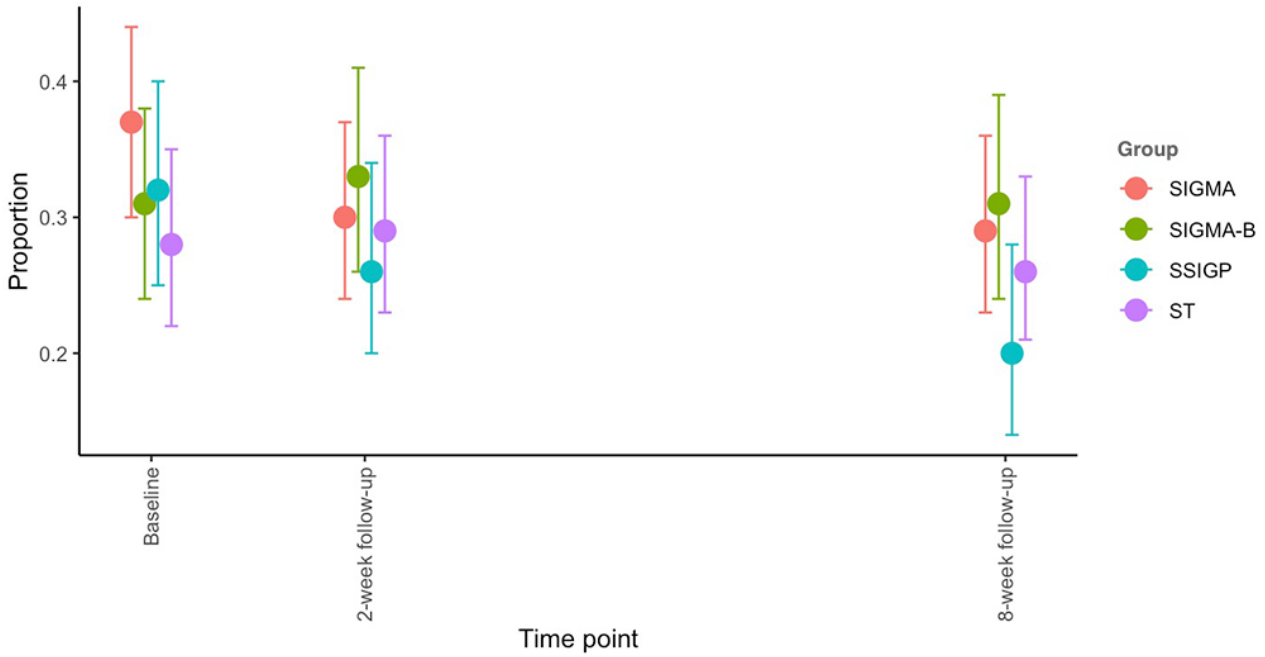


Figure 7. The proportion of participants with suicidal/self-hurting thoughts changes over time. Each dot represents the mean score of each group at each time point. Each line around the dot represents the 95% Wald CI of the mean. SIGMA: single-session intervention of a growth mindset for anxiety; SIGMA-B: SIGMA-Booster; SSIGP: single-session intervention of a growth mindset of personality; ST: support therapy.



Moderation Analysis

We conducted moderation analyses based on baseline anxiety (high/low), motivation to change (high/low), and mindset (growth mindset vs fixed mindset). Including these moderation factors improved model fit, as indicated by the decreases in QICC, ranging from 210 to 31,519.23. This was true for all outcomes, except for suicidal/self-hurting thoughts when motivation level was used as the moderator. These results indicate that baseline anxiety level and mindset had moderating effects on all outcome measures, while motivation level moderated all outcomes except for suicidal/self-hurting thoughts. Participants with higher baseline anxiety, greater motivation to change their situation, and a more fixed baseline mindset showed greater improvements in the outcome measures (see Multimedia Appendices 4-6 for details).

Intervention Feedback

Participants' feedback on the SSIs is detailed in Table 3. Most participants reported understanding (536/731, 73.3%) and

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agreeing (504/731, 68.9%) with the intervention content. More than half found the intervention helpful (465/731, 63.6%) and interesting (417/731, 57.0%). Some indicated that they liked the course (404/731, 55.2%) and expressed a willingness to recommend it to others (402/731, 55.9%). Additionally, 437 out of 731 (59.8%) reported increased confidence in their ability to cope with emotions following the intervention. Meanwhile, very few found this course burdensome (28/731, 3.8%) or interfering (70/731, 9.58%). The findings showed that 459 out of 731 (62.8%) participants indicated that they accept or highly accept the intervention. However, about 237 (32.4%) participants were neutral, indicating that there is still significant room for improvement.

Table 3. Feedback on the intervention.

Variables	SIGMA-Booster[a] (n=172), n (%)	SIGMA[b] (n=211), n (%)	SSIGP[c] (n=154), n (%)	ST[d] (n=194), n (%)	Overall (N=731), n (%)
Like this course	93 (54.1)	113 (53.6)	87 (56.5)	111 (57.2)	404 (55.3)
Understand this course	124 (72.1)	149 (70.6)	116 (75.3)	147 (75.8)	536 (73.3)
This course is useful	104 (60.5)	128 (60.7)	102 (66.2)	131 (67.5)	465 (63.6)
Recommend this course to others	92 (53.5)	117 (55.5)	81 (52.6)	112 (57.7)	402 (55.0)
This course is interesting	91 (52.9)	113 (53.6)	88 (57.1)	125 (64.4)	417 (57.0)
Agree with this course	115 (66.9)	143 (67.8)	106 (68.8)	140 (72.2)	504 (68.9)
Emotional control improved after this course	100 (58.1)	128 (60.7)	85 (55.2)	124 (63.9)	437 (59.8)
Burden in joining this course	9 (5.2)	6 (2.8)	5 (3.2)	8 (4.1)	28 (3.8)
Affect other arrangement due to joining this course	20 (11.6)	15 (7.1)	16 (10.4)	19 (9.8)	70 (9.6)
Acceptance to this course	103 (59.9)	127 (60.2)	110 (71.4)	119 (61.3)	459 (62.8)

[a]SIGMA-Booster: SIGMA with boosters.

[b]SIGMA: single-session intervention of a growth mindset for anxiety.

[c]SSIGP: single-session intervention of a growth mindset of personality.

[d]ST: support therapy.

Discussion

Overview

Contrary to our hypotheses, we found that all 4 SSIs, including ST, significantly reduced general anxiety symptoms and improved some secondary outcomes. Although the core messages delivered in approximately 40 minutes differed among these interventions, nearly all improvements in the 4 groups were sustained from the 2-week to the 8-week follow-ups. These findings provide evidence for the effectiveness of low-dosage nonpharmacological interventions in improving youth mental health outcomes. SIGMA, which enhances the belief in change regarding negative emotions, showed an intervention effect on all outcome measures except perceived control. The SSIGP, targeting personality mindset, was more effective in reducing self-harm and suicidal thoughts. ST had a greater effect on perceived control. Surprisingly, the SIGMA-Booster group, which received booster messages, did not achieve better results than the SIGMA group. By contrast, the SIGMA group outperformed the SIGMA-Booster group in outcomes such as reducing suicidal and self-harming thoughts as well as hopelessness. The SIGMA interventions were not more effective than SSIGP, particularly in the primary outcome of reducing anxiety symptoms. Moreover, the ST intervention was especially effective in improving perceived control, outperforming the other 3 interventions. Moderation tests revealed that some adolescents benefited more from the interventions. Consistent with our hypotheses on moderation effects, participants showed greater improvement if they had more severe anxiety symptoms, stronger baseline fixed mindsets, and a greater motivation to change. Although the effect sizes for group comparisons on outcome changes were small, it is encouraging that SSIs produced sustained outcomes over 8 weeks.

Our findings align closely with existing research on SSIs for youth psychiatric problems. A previous meta-analysis by Schleider and Weisz [14] found that a young person receiving an SSI had a 58% likelihood of performing better than a youth in the control group. The effect sizes varied depending on the control conditions, with larger effect sizes observed in studies with no-treatment or waitlist controls (0.41) compared with those with active controls (0.14). In our study, the effect sizes for SIGMA versus SSIGP at the 2-week follow-up were approximately 0.14 (SIGMA vs SSIGP: 0.14 and SIGMA-Booster vs SSIGP: 0.13), while the effect sizes for SIGMA versus ST were smaller. The finding that SSIs were effective for multiple outcomes, including anxiety and depression symptoms, aligns with a recent umbrella review on SSIs, which showed that over 80% of reviews reported significant positive effects on at least one outcome [21]. In summary, our study provides additional evidence supporting the modest yet significant clinical utility of certain SSIs for youth, including those targeting anxiety symptoms [21].

The design of the interventions and the implementation of the RCT for SSIs provided valuable insights and implications for local practice. Generally, these SSIs were designed following recommended guidelines to ensure the efficacy of brief

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interventions [45-47]. First, we formed a youth advisory group to ensure the content was relevant to the target users. Second, we incorporated cartoons and animated videos into the intervention. The cartoon heroine, “Hong Dou” (the Red Bean), and her friends were created by artists and digital designers to make the animations and videos more engaging. As a result, the intervention videos effectively captured participants’ attention. Third, because SSIs should be highly focused on delivering 1 or a few core messages, each SSI in our study conveyed a single core message to participants. We reinforced learning through multiple methods, including examples, testimonials, authoritative research findings, and saying-is-believing exercises. Fourth, to ensure active participation in the online web-based intervention, we embedded it in the Qualtrics survey tool and included interactive exercises after each session. Participants received timely feedback on these exercises. Feedback from participants indicated that the SSIs in our study were well-suited to adolescents’ needs and expectations for mental health care. This study provides a clear protocol for implementation, including content and strategies, which will be valuable for the future use and development of SSIs.

This study is a pioneering investigation into web-based SSIs among Chinese adolescents. The efficacy of SSIs, particularly self-administered web-based interventions, has been understudied. This study examined the effects of SSIs on mental health among Chinese adolescents using a cluster RCT design. The 4 conditions in this study showed improvements in mental health over 2 weeks, with the effects sustained after 8 weeks. There were no significant group differences among the 4 conditions. As the interventions were implemented at different times across the academic year in different schools, any potential school schedule effects were minimized. On the one hand, these results suggest that providing low-dosage self-help interventions may help adolescents gain insights and strategies for managing their emotions and coping. On the other hand, an RCT with an added waitlist control group would be valuable for further testing the effectiveness of the intervention.

The SIGMA-Booster group did not show a better effect at the 8-week follow-up. There may be several reasons for this. First, there may be no difference between the booster and nonbooster groups. If an SSI has instilled changes in the emotional mindset, those changes could be long-lasting. Second, the booster group might have a greater effect in the longer term, so a more extended follow-up would be necessary to capture any differences between the booster and nonbooster groups. Third, the booster design in this study may not have been effective. Future studies should carefully examine the format and content of booster interventions.

This study makes several significant contributions. First, the SSIs developed and tested with an RCT could serve as an alternative mental health service for adolescents. Although the effect size of the SSI was small, it can benefit a proportion of youth who would otherwise go without services. It can also support youth on the waitlist for psychiatric services by fostering intrinsic motivation and reducing hesitation to seek treatment. It can also complement multisession psychosocial treatments [21]. Second, these SSIs expanded existing mindset interventions to include emotional mindset and adapted them to the Chinese context. This project may provide a generalizable model for the development and implementation of SSIs for youth in the Chinese context. Third, this study initiated the development and evaluation of boosters for SSIs. Although we did not find significant differences among the groups, the findings of this study could serve as a foundation for further research. In summary, the easy-access self-help program enables adolescents with anxiety symptoms to receive timely help and may help reduce the risk of worsening anxiety symptoms and the development of comorbid mental health issues before they can access therapy from a trained therapist or psychiatrist.

Limitations

There are limitations to consider. First, because this study did not exclude individuals based on the severity of their anxiety symptoms, the efficacy of the interventions in reducing anxiety symptoms among students without anxiety or with very low levels of anxiety may not have been significant, potentially affecting the overall statistical significance. However, future RCT studies could examine the differentiated impacts on youth across a broader range of anxiety problems through subgroup analyses. In this study, we simply divided participants into 2 groups (high baseline anxiety and low baseline anxiety) and examined the moderation effects. Second, there was no waitlist control group, as all groups received specific interventions, with even the control group receiving ST (active control). Adding a waitlist control group would help provide a better understanding of the overall effect of SSIs. Third, although we used cluster randomization at the classroom level to balance the risk of contamination between groups and school heterogeneity, and employed multilevel modeling to account for the clustering of classes within the same school, it was still challenging to completely eliminate the risk of contamination. Students in different classes may interact and share information about their interventions, which could potentially influence the outcomes. Fourth, the study only included a follow-up period of 8 weeks, which may not have allowed us to capture the long-term effects. Future studies with a longer follow-up period will be necessary to better understand the sustained impact of the interventions.

Conclusions

This study presents evidence-based implementation of web-based single-session growth mindset interventions for adolescent anxiety and compares the efficacy of SSIs using growth mindsets on negative emotions and personality, along with an active control group. The findings support that the easy-access self-help program led to improvements in adolescent anxiety, depression, and suicidal and self-harm thoughts at the 8-week follow-up. These interventions may enable adolescents with anxiety symptoms to access timely help, reducing the risk of worsening anxiety symptoms and the development of comorbid mental health issues before they can access therapy from a trained therapist or psychiatrist. This study also provides an example of implementing SSIs among Chinese adolescents and will contribute to the development of easy-access, low-cost, and scalable interventions for mental health promotion among young people.

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Acknowledgments

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Data Availability

Data are not publicly available but can be obtained for proper purposes by contacting the corresponding author.

Authors' Contributions

SZ designed the intervention and the evaluation study initially. YH assisted in the intervention design and implementation. SZ and DQ drafted the first draft of the report. PL contributed to the data analysis plan. ST, KLC, QC, and JS provided comments and revised the first draft. SZ developed all aspects of the proposal and manuscript related to the implementation of intervention and data collection. All authors edited and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 2556 KB - pediatrics_v8i1e63500_app1.pdf]

Multimedia Appendix 2
Generalized estimating equation results for the intention-to-treat population.
[DOCX File , 23 KB - pediatrics_v8i1e63500_app2.docx]

Multimedia Appendix 3
Generalized estimating equation results for the per-protocol population—presented as estimated marginal means (SE).
[DOCX File , 33 KB - pediatrics_v8i1e63500_app3.docx]

Multimedia Appendix 4
Moderating effect of baseline anxiety levels on treatment outcomes.
[DOCX File , 53 KB - pediatrics_v8i1e63500_app4.docx]

Multimedia Appendix 5
Moderating effect of baseline motivation levels on treatment outcomes.
[DOCX File , 52 KB - pediatrics_v8i1e63500_app5.docx]

Multimedia Appendix 6
Moderating effect of baseline growth mindset levels on treatment outcomes.
[DOCX File , 50 KB - pediatrics_v8i1e63500_app6.docx]

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Abbreviations

CONSORT: Consolidated Standards of Reporting Trials
GAD-7: 7-item Generalized Anxiety Disorder
MDASS: Mindset of Depression, Anxiety, and Stress Scale
PHQ-9: 9-item Patient Health Questionnaire
QICC: Corrected Quasi-Likelihood under the Independence Model Criterion
SES: socioeconomic status
SIGMA: single-session intervention of a growth mindset for anxiety
SSI: single-session intervention
SSIGP: single-session intervention of a growth mindset of personality
WEMWBS-14: 14-item Warwick-Edinburgh Mental Well-Being Scale

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Original Paper

Developing Digital Mental Health Tools With Culturally Diverse Parents and Young People: Qualitative User-Centered Design Study

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Abstract

Background: Approximately 39% of young people (aged 16-24 y) experience mental ill health, but only 23% seek professional help. Early intervention is essential for reducing the impacts of mental illness, but young people, particularly those from culturally diverse communities, report experiencing shame and stigma, which can deter them from engaging with face-to-face services. Digital mental health (DMH) tools promise to increase access, but there is a lack of literature exploring the suitability of DMH tools for culturally diverse populations.

Objective: The project was conducted in partnership with a large-scale national DMH organization that promotes evidence-based early intervention, treatment, and support of mental health in young people and their families. The organization wanted to develop a self-directed web-based platform for parents and young people that integrates psychological assessments and intervention pathways via a web-based “check-in” tool. Our project explored the views of culturally diverse parents and young people on the opportunities and barriers to engagement with a web-based DMH screening tool.

Methods: We conducted a 2-phase qualitative study aiming to identify potential issues faced by culturally diverse communities when engaging with DMH tools designed for the Australian public. We worked with 18 culturally diverse participants (parents: n=8, 44%; young people: n=10, 56%) in a series of design-led workshops drawing on methods from speculative design and user experience to understand the opportunities and barriers that organizations might face when implementing population-level DMH tools with culturally diverse communities. NVivo was used to conduct thematic analyses of the audio-recorded and transcribed workshop data.

Results: Five themes were constructed from the workshops: (1) trust in the use and application of a DMH tool, (2) data management and sharing, (3) sociocultural influences on mental health, (4) generational differences in mental health and digital literacy, and (5) stigma and culturally based discrimination in mental health support.

Conclusions: The emergent themes have important considerations for researchers wishing to develop more inclusive DMH tools. The study found that healthy parent-child relationships will increase engagement in mental health support for young persons from culturally diverse backgrounds. Barriers to engagement with DMH tools included culturally based discrimination, the influence of culture on mental health support, and the potential impact of a diagnostic label on help seeking. The study’s findings

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suggest a need for culturally safe psychoeducation for culturally diverse end users that fosters self-determination with tailored resources. They also highlight important key challenges when working with culturally diverse populations.

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KEYWORDS

digital mental health; young people; cultural diversity; web-based and mobile health interventions; qualitative methods; user-centered design; human-computer interaction

Introduction

Background

Approximately 13% of the global population living with mental health problems are young people (aged 16-24 y) [1]. Young people with mental health disorders also experience higher rates of morbidity and mortality risk than the general population, leading to a 10- to 20-year reduction in life expectancy [2,3]. These rates were compounded during the COVID-19 pandemic, during which globally 1 in 4 young people experienced clinically elevated levels of depression, and 1 in 5 experienced clinically elevated levels of anxiety [4]. Nevertheless, during this period, there was no concurrent increase in the uptake of mental health support [5]. For young people, untreated mental health problems can have long-lasting impacts due to the important social, emotional, and cognitive developmental changes that are being experienced simultaneously [6].

Cultural Diversity in the Context of Australia

Australia is a culturally diverse society, with 27.6% of its population born overseas [1]. This diversity spans across differences in cultural identity, language, country of birth, religion, heritage, and national origin [7]. Shaped by a legacy of colonialism, racial inequality has influenced Australia and its relationship with racial and ethnic minority immigrants [8] and First Nations peoples [9].

Studies have identified higher rates of mental ill-health among culturally diverse groups compared to the broader Australian population [10,11]. This is, in part, due to mental health risk factors, such as language barriers, cultural adjustment, the loss of family connection, and an inability to apply knowledge and occupational skills to attain meaningful employment, all of which hinder active participation in society for people from culturally diverse backgrounds [12]. Young people from culturally diverse backgrounds tend to be the most reluctant to seek help, and if they do, they typically turn to informal sources such as family, friends, and elders [13,14]. Among those who have sought professional support, many report that the types of support they were offered were inaccessible, culturally inappropriate, or lacking cultural relevance [15-17].

Common barriers to mental health care for culturally diverse communities include a lack of information and knowledge about available services, language differences, culturally specific conceptions of mental health, and lengthy waitlists [18-22]. Discrimination can be experienced throughout a person's mental health journey, with studies showing that culturally diverse people are far less likely to engage in mental health visits or seek specialist care than White ethnic groups [23]. Research has also found that clinicians are less likely to involve culturally diverse patients in friendly discussions or include them in the treatment decision-making process [24]. Instead, people from culturally diverse backgrounds tend to access mental health services through clinical emergency services during an acute crisis rather than accessing early interventions before the problem is severe, hindering their prospect of recovery [25,26]. People from culturally diverse backgrounds in Australia also experience more involuntary hospital admissions for mental health treatment [16].

Current Landscape of Digital Mental Health Tools and Opportunities

Digital mental health (DMH) tools (eg, apps and web-based services) delivered through smartphones [27-31], computers [32,33], and wearable devices [34,35] hold promise for overcoming many of the aforementioned barriers [36]. DMH tools can include self-directed online interventions [37,38], mental health screenings or "check-ins" to assess mental health status [39], digital health apps that allow the real-time monitoring of mental health [40,41], chatbots to support help seeking [42], and even interventions on specialist technologies such as virtual reality headsets [43,44]. Studies have shown that young people and parents prefer digital treatment over face-to-face care [45,46]. DMH tools offer easily accessible, low-cost services to address common mental health problems [47,48]. Self-directed DMH tools may offer alternative or complementary options to face-to-face clinical care, with the potential to provide support to people on waitlists for clinical care in remote locations or those who may not have the financial means to seek face-to-face treatment [43]. There is increasing interest in developing culturally sensitive DMH tools [17,49], with some DMH apps and online platforms being designed especially for ethnically diverse groups [50]. However, such examples remain limited; moreover, considerations of diversity, equity, and inclusion are rarely integrated into their design or evaluation [51].

Online self-screening tools provide useful information about self-reported mental health symptoms, offering clinical cutoffs to indicate when further assessment or support is needed, along with relevant resources for support. They also allow anonymous pathways for disclosing mental health symptoms and offer digital interventions [4,52,53] that have been shown to be fundamental for the mental health journey of culturally diverse users because digital interventions and resources are more likely to reach culturally diverse populations who may not have access to or are not yet engaging in mental health support [54]. Large-scale DMH platforms that incorporate screening, access to online clinicians, self-directed resources, and curated suites of trusted apps are increasingly being adopted by public health organizations across Western contexts (eg, the UK National

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Health Service's Talking Therapies program) [48]. However, while these public-facing DMH tools are intended for use by all of society, they tend to be designed by and for the dominant Western culture [55].

In addition, DMH tools hold the potential for supporting mental health beyond traditional 1-to-1 contexts. Online health-oriented communities offer benefits such as peer support networks (eg, Headspace and Orygen both offer online youth mental health support in Australia). Similarly, social media groups focused on mental health have been shown to play a substantial role for end users in rural areas, where geographic location limits access to mental health service providers [56]. These groups provide support for guided online therapy [57], skills building [58], symptom monitoring [59], and social connection [60,61]. However, among culturally diverse communities, where English may be a second language, willingness to engage in these types of peer support offerings tends to be lower [50].

Designing With Diverse Populations

There is increasing recognition of the importance of designing digital services tailored for culturally diverse populations using responsive and inclusive design processes. Many researchers and designers in this space have adopted participatory research and user-centered approaches wherein members of the community are involved in the design process to identify their unique needs, goals, and concerns and to ensure that these are considered and integrated into the final service design [62-67]. Technologies developed for an underserved community are most impactful when designed with members of that community [68]. The use of user-centered approaches has been shown to improve the acceptability, effectiveness, and contextual relevance of novel technologies for communities [55]. Engaging members of the community in a design process often requires creative methods and tools to ensure that it is safe, beneficial, and easy for them to participate. Some studies have used creative tool kits, personas, and vignettes to scaffold design thinking [69,70].

User-centered design approaches that recommend the inclusion of meaningful engagement with consumers and carers in the service design are also increasingly recognized among mental health researchers and practitioners, including government agencies [71]. Research interest in culturally sensitive design through participatory research and user-centered design methods is mounting [72-74]. However, despite the political and cultural shift, there is still only a small, though growing, body of work in the field of human-computer interaction that explores the needs of culturally diverse populations in the area of DMH services [17,49,75,76]. While these studies provide useful insights, they tend to focus on a single community or culture and offer specific rather than generalized interventions. While there are steps being taken to engage culturally diverse communities in technology design across various fields of research, there are still various mental health factors that could impact the uptake of novel DMH tools (eg, cultural concepts of mental health and stigma around mental health). As such, it is vital that we aim to better understand how to design tools that account for these factors and enhance service engagement for culturally diverse communities. For the successful implementation of clinical innovations at a public scale, novel digital solutions need to be designed *with* diverse populations to ensure that these solutions meet their needs [17,77]. Engaging with the perspectives of groups considered marginalized and those outside Western traditional norms will help ensure that DMH tools are designed more inclusively [78,79].

Building on these insights, we worked with culturally diverse young people and parents to design a national digital self-directed mental health check-in tool, called Growing Minds Check-In (GMCI), for the Australian public. The GMCI aims to provide an assessment of mental health and well-being symptoms as well as recommendations to tailored online mental health services and information. This study engaged with user-centered design due to the restrictions on the level of involvement the participants would have on the final production of the GMCI. Due to the narrow development timelines, the participants in this study were able to contribute to the design process but did not have decision-making powers; instead, they were involved in appropriate ways throughout the development of the GMCI [80]. We conducted a 2-phase study aiming to identify potential issues faced by culturally diverse communities when engaging with DMH tools such as the GMCI. The purpose of this study is to describe the attitudes, barriers, and benefits associated with DMH tool engagement among culturally diverse parents and young people. This information is likely to be relevant to DMH interventions for parenting and child well-being; it may also be relevant to other online programs, especially those delivered as universal public health interventions. We propose a set of design strategies for developing public-facing DMH tools and provide reflections on our own design process and the challenges we faced while engaging with culturally diverse communities in research.

Methods

Study Context

This project was conducted in partnership with the Growing Minds Australia Clinical Trials Network, Australia's first clinical trials network for child and youth mental health research [81]. It is part of the first phase of design for the Growing Minds Australia Clinical Trials Network flagship trial, the GMCI: a national online platform for parents and young people that integrates a mental health and well-being "check-in" with personalized feedback and suggestions for online mental health services and resources. We came into the project with the aim of focusing inquiry on how the future-facing platform could be designed more inclusively to ensure that it is relevant and accessible for diverse communities. We used a speculative DMH app containing features similar to those proposed by digital phenotyping software that could collect both passive and active data.

The study comprised 2 phases to engage groups of parents and young people from culturally diverse backgrounds with lived experience of mental health challenges. The first was a scoping phase that applied user-centered design methods, which included using speculative DMH tools to tease out potential benefits, concerns, and trade-offs. The second was a prototype exploration phase, whereby a proposed nationwide mental health screening

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tool was used as an artifact for participants to determine possible challenges and ethical issues that culturally diverse populations may face when engaging with DMH tools. This included a facilitated emotional walk-through of the screening tool using a workbook, followed by a data consolidation workshop where participants reflected on their experiences of using the tool. We aimed to identify the potential benefits and possible challenges of using a large-scale web-based check-in service and incorporate these insights into a more inclusive design for future DMH technologies. The design justice framework was applied to the design of the research questions (RQs), the activity schedule, and the analysis of the findings. This approach promotes the exploration of how benefits and burdens are distributed across groups, challenging design-driven inequalities by using an intersectional lens that considers race, gender, sexual orientation, and culture [82,83]. This framework incorporates participatory and user-centered design methods that prioritize community needs and encourage researchers to consider how power can shape participation in the design processes [82] (Figure 1).

Figure 1. Visualization of the study design. DMH: digital mental health.

Ethical Considerations

Our study received ethics approval from Monash University (31138). All participants were provided with an explanatory statement detailing the project and were asked to read and sign a consent form before participating. These documents were provided to participants in advance of the workshops. Consent and demographic information (eg, country of origin and culture they identify with, years lived in Australia, and languages spoken at home) were collected before the workshops began. Participants across all study phases were compensated Aus $40 (US $24) per hour for their time. Data was anonymized with all names removed from the data. Names were changed during transcription before any analysis commenced.

Recruitment

We partnered with a multicultural community mental health organization to recruit participants and facilitate the workshops. We used the organization's advertising channels to recruit participants who were involved as volunteers with the organization and were likely to be mental health literate. Workshop participants were required to have a high school level of spoken English due to time limitations and budget restrictions, which precluded the use of translators. Calls for participation in the workshops were advertised through flyers distributed via the community organization. For inclusion in the study, participants needed to identify as either having lived experience with mental health problems or having children who had experienced mental health challenges. These workshops were conducted in person and therefore limited to communities living in Victoria, Australia. A majority of the participants (12/18, 67%) were from South or East Asia, reflecting the demographic composition of the Australian population [1]. In phase 2, we included an Anglo-Australian participant (P8) who was recommended as a research participant by the mental health organization. Although not from a culturally diverse background, this participant was an experienced peer support worker with multicultural populations, had lived experience of complex mental health challenges, and was a parent. Phase 1 and phase 2 participant demographics are presented in Table 1.

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Table 1. Phase 1 and phase 2 participant demographics.

Phases and participant IDs	Age (y)	Parent or young person	Duration of residence in Australia (y)	Self-identified cultural background	Languages spoken at home
Phase 1					
P1	65	Parent	35	Indian	English, Tamil, and Hindi
P2	57	Parent	35	Indian	English and Tamil
P3	53	Parent	23	Indian	Tamil
P4	67	Parent	50	German	German and English
P5	48	Parent	48	Italian	Italian and English
P6	58	Parent	41	Indian	Hindi, Punjabi, and English
P7	67	Parent	67	Australian and German	English and German
YP1	22	Young person	3.5	Turkish	Turkish
YP2	16	Young person	7	German and Indian	German and English
YP3	22	Young person	11	Malaysian	Cantonese and English
YP4	21	Young person	4	Indian	Hindi
YP5	23	Young person	21	Han Chinese	Mandarin Chinese
YP6	22	Young person	12	Australian Chinese	Mandarin Chinese
YP7	18	Young person	17	Malaysian	English
YP8	24	Young person	5	South African	Zulu
YP9	24	Young person	11	Malaysian Chinese	Cantonese, Mandarin, and Bahasa Melayu
YP10	21	Young person	20	Indian or Hindu	English and Tamil
Phase 2					
P1	65	Parent	35	Indian	English, Tamil, and Hindi
P2	57	Parent	35	Indian	English and Tamil
P3	53	Parent	23	India	Tamil
YP3	22	Young person	11	Malaysian	Cantonese and English
YP4	21	Young person	4	India	Hindi
YP10	21	Young person	20	India or Hindu	English and Tamil
P7	67	Parent	67	Australian and German	English and German
P8	47	Parent	47	Australian	English

Phase 1: Contextual Inquiry Through User-Centered Design

Overview

We conducted 2 user-centered design workshops: one with 10 young people (female: n=7, 70%; male: n=3, 30%; aged 16-25 y) and another with 8 parents of young people (female: n=4, 50%; male: n=4, 50%; aged 21-67 y). Each workshop included a researcher facilitator and a cofacilitator provided by the mental health organization who assisted with recruitment. Power imbalances were mitigated by conducting the workshops at an office space provided by the multicultural organization, where participants were affiliated and felt comfortable. The workshops ran for 3 hours with a 20-minute refreshment break. We examined 3 broad RQs:

1. How do culturally diverse end users perceive the value of mental health data? With whom would they share their mental health data? How might their mental health data differ in the future?
2. How is screening information communicated and understood? What impact would this have on therapeutic relationships?
3. What are the social factors that influence the likely use and application of DMH technologies? Are culturally diverse users concerned about third-party use of their data?

We aimed to not only explore the inclusion of culturally diverse communities in the design of a digital platform but also consider the impact of future data use, particularly how an end user's sensitive data may later be used. Given the propensity for alternative data use by third parties, we wanted to better understand the degree to which culturally diverse end users

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worried about how their data may be used and whether they felt it would have future implications.

The workshop sessions followed a semistructured activity guide that was developed by the authors and reviewed by colleagues independent of the study (refer to Multimedia Appendix 1 for details). We began each session with an icebreaker activity and initiated a group discussion to set the context for the following activities. Using a whiteboard and markers, we asked participants about their understanding of mental health and what makes for good and poor mental health. This activity was intended to provide insight into the participants' mental health literacy. We then provided participants with a speculative design probe, the "mental health vault" (Figure 2), to unpack abstract conceptions of sensitive digital health data. The vault included 3 layers to indicate varying levels of personal information that may be uncovered by DMH tools: (1) a locked safe represented by a metal box (most personal), (2) an inner layer bound by a thick metal chain, and (3) an outer layer framed by a thin rope (least personal). The activity schedule included four activities: (1) digital vault, (2) blank keys, (3) data sharing, and (4) future forecasting. These activities were centered on an imagined DMH tool that could actively and passively collect end user data, which differs from the GMCI's intended use and functionality as a web-based tool that provides personalized feedback and suggestions for online mental health services and information matched to need.

Figure 2. The "digital vault" activity in phase 1.

Activity 1: Digital Vault

The aim of this activity was to address RQ 1 by gauging participants' level of understanding of mental health data, how sensitive they perceived the data to be, and with whom they would want to share the data. To scaffold their thinking, we provided stimuli picture cards of potential mental health data points (eg, a diary, a mobile phone, GPS data, survey test results, and social media data) and asked participants to place each card, depending on how secure they felt each data point was, within the different layers of the vault (ie, inside the metal box, within the chain, or in the outer rope layer). The most private data points were placed inside the metal box, while the least private were positioned in the outer rope layer. After participants arranged the cards according to their preferences, we asked them to describe what each layer represented to them and why they placed each data point where they did (eg, why they would be okay with sharing social media data publicly but not their survey test results).

Activity 2: Blank Keys

The aim of this activity was to understand whom the participants were willing to share their data with and their reasons, addressing RQ 1. Using an inductive approach, we used this component of the activity to leverage and broaden the discussion to generate ideas on new "trusted" or "nontrusted" people that the participants could think of on their own, without the researcher's prompts or suggestions. We gave participants 6 blank paper "keys" and asked them to write down the individuals (eg, their imam, family member, or teacher) to whom they would be willing to grant access to the vault. They then placed each key in the vault layer they felt most comfortable allowing that individual to access. Next, we asked participants to use these blank keys to write down who they thought might "rob" the vault and to place the newly labeled keys in the layer of the vault they felt the "data robber" might access. The activity schedule script included the following prompt: "Now let's imagine digital bank robbers broke into your vault. What is the worst thing that can happen? Who might the robbers be? Why would they want your data? Which specific area of the vault would they be most interested in?"

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Activity 3: Data Sharing

Building on the digital vault scenario, we introduced a "digital vault manager" who has access to the data contained in the digital vault and could use the data to identify mental health issues. This activity addressed RQ 2 and RQ 3. We then asked the participants whether they would want anyone to know about mental health challenge identified, and if so, whom they would share it with. This activity was designed to get participants thinking about their individual perspectives as well as how others may feel about having their personal data shared with the intention of helping individuals or their community (eg, whether a school or current employer should be notified).

Activity 4: Future Forecasting

This activity examined how screening information is likely to be communicated, understood, and applied in face-to-face sessions with a clinician. This activity addressed RQ2 and RQ3. We asked participants to imagine that the digital vault had been passively collecting data and had generated a prediction about their mental health over the next 20 years. First, we gathered emotional reactions to the prediction using printed emoji faces and by asking participants to indicate how they felt about having predictions made about them. Next, through a discussion-based activity, we explored how the prediction their trust, and sense of empowerment, and agency, as well as how and by whom the prediction would best be communicated. The activity schedule script included the following prompt: "Do you feel empowered knowing this prediction in advance so you can seek help? Do you trust its accuracy? Would you prefer your GP [general practitioner] or mental health clinician had told you? Would you trust it more if your GP told you? Are you concerned about who else is accessing this digital vault from some years ago?"

The findings from the future-facing DMH tool discussion in phase 1 were used to frame the emotional walk-through activity and focus groups with parents and young people in phase 2. We considered the benefits, burdens, and trade-offs that the culturally diverse participants discussed in these workshops and wove them into the emotional walk-through activity in an attempt to highlight challenges with an existing system that could then feed into a future design. This activity series was designed to address RQs 1 to 3.

Phase 2: Emotional Walk-Through

Using a user experience technique traditionally referred to as a cognitive walk-through, we aimed to explore participants' emotional responses as they engaged with the interface [84,85]. We adapted a walk-through user testing methodology [86] and created a 6-page emotional walk-through booklet (Figure 3) that was distributed to participants along with a link to a prototype of the web-based mental health screening platform intended for national deployment in the near future. This was a written task that was designed to help facilitate discussion and ideas about the issues we intended to explore in the prototype testing workshop. Participants (parents and young people) were then invited to take part in a joint consolidation workshop to discuss their thoughts in further detail. We supplied participants with a booklet that was designed by the team, 2 weeks before the workshop to allow them time in their daily schedule to complete the booklet and explore GMCI prototype. Participants used their completed booklets during the session as mnemonic aids to recall their thoughts and experiences. A total of 6 participants (parents: n=3, 50%; young people: n=3, 50%; female: n=3, 50%; male: n=3, 50%) agreed to participate in the joint consolidation workshop. The aim was to elicit their thoughts and feelings about DMH data as they completed the web-based mental health check-in journey. The booklet included a range of questions designed to gauge emotional reactions as well as rating scale assessments as participants used the web-based screening platform. Within each section of the booklet, we included ethical considerations to encourage participants to consider the social impact of the DMH tools, including their understanding of mental health, how their community understands mental health, views on data privacy and management, how they would like to receive feedback about their mental health, and whether they felt they could challenge a mental health assessment. Participants then took part in the consolidation workshop to discuss their experience of using the prototype and to consolidate their ideas and expectations of engaging with an online mental health screening service. The session was broken down into four parts:

1. What are the motivations, benefits, and challenges of accessing such a tool?
2. Where does the data entered on the web go?
3. How well did the participants understand the feedback supplied? Did it resonate with their cultural background?
4. What suggestions did the participants have to make this tool more accepted within specific communities (dos and don'ts).

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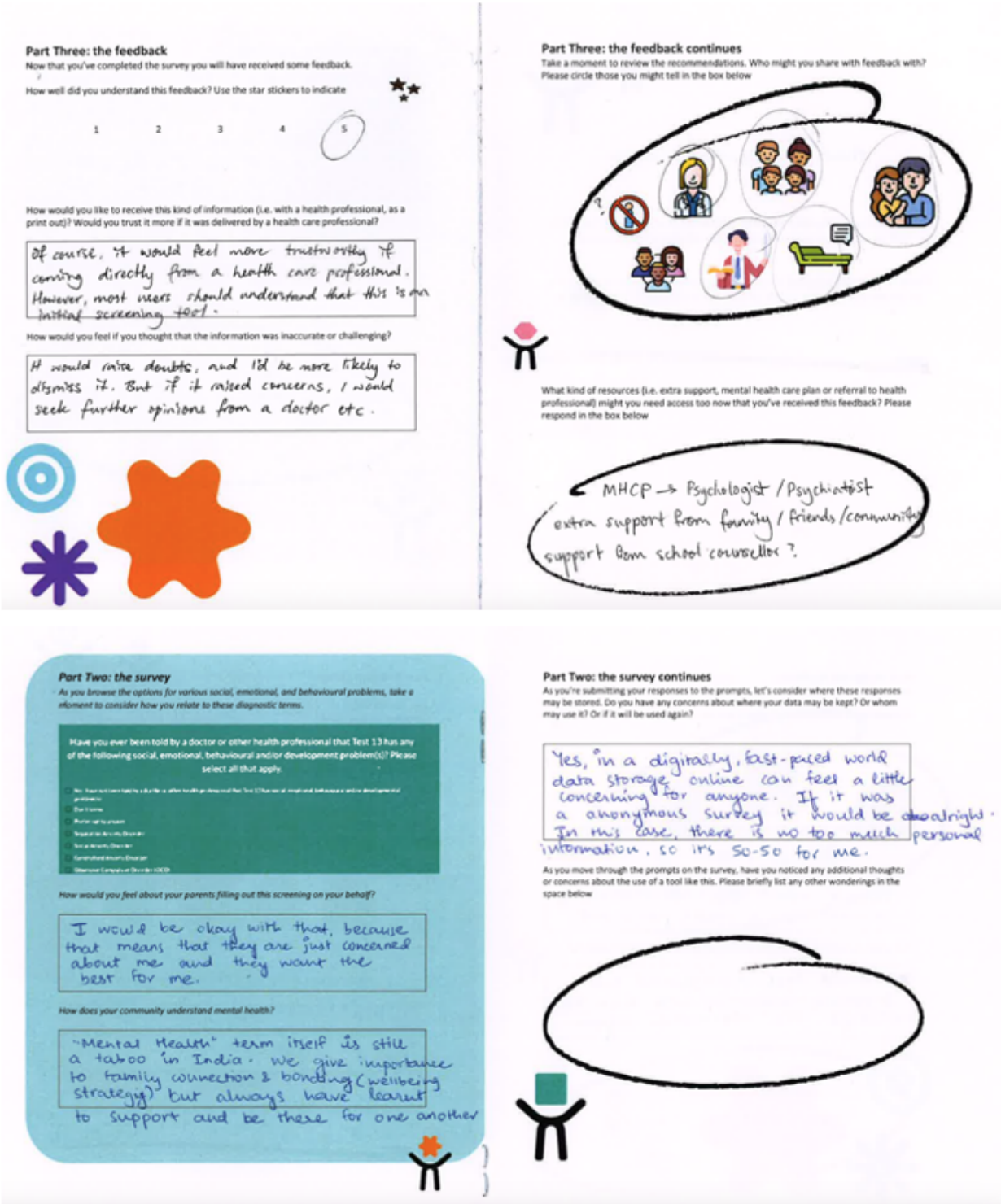
Figure 3. A completed emotional walk-through booklet in phase 2.1.



Positionality Statement

Our authorship team represents a variety of cultural backgrounds and perspectives on the topic, shaped by our own experiences. We took part in this research because we believe strongly in fostering equal access to mental health services for culturally diverse end users. Our team comprises 8 authors: 5 (62%) female individuals with European, Anglo-Celtic, and Irish heritage; and 3 (38%) male individuals with Anglo-Celtic, Anglo-Australian, and Filipino heritage. Of the 8 authors, 3 (38%) are first-generation migrants to Australia; 4 (50%) identify as parents; and 3 (38%) work with young people, parents, caregivers, and families. Our team consists of clinical and registered psychologists, a neuroscientist and bioethicist, a human-computer interaction and design practitioner, and researchers working in DMH and responsible innovation. We are committed to extending our knowledge and understanding of culturally diverse research practice to empathize and engage with research involving culturally diverse parents and young

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people in this work. This commitment has informed our approach to the study design and data analysis.

Data Analysis

Audio recordings from all 3 face-to-face workshops (phase 1: n=2, 67%; phase 2: n=1, 33%) were transcribed and thematically analyzed using NVivo software (Lumivero). An inductive thematic analysis was conducted on all transcripts, without a preexisting coding framework, to identify themes and subthemes [87]. Initial codes were generated by IB to organize the data from phase 1 into potential items of interest. Three additional researchers (AC, RM, and JPS) familiarized themselves with the data from phase 1 and reviewed the initial codes. Iterative coding was then completed by IB, and 21 subthemes were generated that informed the design of the emotional walk-through. Three additional research members (AC, RM, and JPS) cross-coded themes from the emotional walk-through booklets and transcripts from the consolidation workshop. The codes were reviewed to ensure that the themes were clear and descriptive. The coded data from both phases were combined for analysis with 5 themes. In each workshop, an activity schedule was used to scaffold free-flowing discussion among participants. Variations in participant opinions were coded and contrasted to develop the subthemes. Participants were collaborative and brought culturally diverse and unique experiences, offering rich anecdotes in each session.

Results

Five major themes were developed from the analysis of the data collected from both phases: (1) trust in the use and application of a DMH tool, (2) data management and sharing, (3) sociocultural influences on mental health, (4) generational differences in mental health and digital literacy, and (5) stigma and culturally based discrimination in mental health support.

The Potential Impact of DMH Tools on Interpersonal and Therapeutic Relationships

The discussions on how DMH tools may impact the therapeutic relationship with a current or future clinician varied; however, both groups (parents and young people) expressed greater trust in a clinician in a face-to-face setting than in a digital tool. Participants in both groups also agreed that they would be more likely to trust a mental health recommendation or diagnosis generated by a DMH tool if a clinician was involved at some point:

> *I feel like I would still and then like accept whatever the app tells me, but it will be very helpful if the psychiatrist or psychologist are linked with this app. Like they sort of like, acknowledge that this app is useful or something like that.* [YP5]

Participants acknowledged that they would seek advice from a DMH platform if a clinician was hard to access or as a first step in help seeking. However, some participants (YP10, YP7, YP5, and P2) felt that it was hard to know where to search and stated that they would use DMH tools as a screening tool but would seek help from a trusted health professional, such as a GP, psychiatrist, or psychologist, regarding the information provided by a DMH tools. Conversely, other participants found face-to-face interactions to be "embarrassing" (YP10), "confronting" (P8), or rushed:

> *I feel like because GPs usually see patients 15 minutes per block, it feels that it's quite rushed and sometimes GPs wouldn't take the time to go over time...it will make us feel that we're not as like important.* [YP9]

Once a recommendation or treatment suggestion has been provided by DMH tools, participants in both groups (P6, YP5, and P3) expressed a desire to process it on their own first:

> *I would want to see the information first and then several steps down the road, consulting with a specialist might be an option.* [P3]

Once they had reached a point of acceptance regarding the recommendation or treatment suggestion, there was variability in whom they would share the data with, with disclosures to family, friends, and practitioners varying within both groups. Some parents (P1, P2, and P3) preferred to be given the recommendation before sharing it with their children. Two younger participants (YP2 and YP5) were happy to share the information with their parents and siblings, while many of the other young participants (YP1, YP3, YP8, YP9, and YP10) indicated that they would prefer to share it with a trusted contact or friend—rather than with their parents and siblings—who they believed would help put them in touch with a professional or assist in accessing additional resources.

One young person (YP3) suggested having the option to choose to download feedback from a DMH tool depending on the severity of the user's mental health problems. Another young person made the following suggestion:

> *If you delete it, they ask you, "Are you sure?" or like, "Are like are you too busy?" "Is it distracting?" Like it ask you the reasons why you are downloading it. Have you met your match? [similar to a dating app] I think the same should be with the app. Like if you don't like the app, but you still, you downloaded this, but you still feel like you need someone to talk to, call these numbers. And it shouldn't be triple zero, because why would I call triple zero in my, like I don't...maybe triple zero can be like the last thing, but like call this person or locate the nearest center or psychologist, or locate your nearest person or something else.* [YP8]

Suggestions were made in regard to having a trusted contact who would receive a notification if a user was determined to be at high risk for poor mental health, with the understanding that the trusted person would not be obligated to assume responsibility. Two parents (P7 and P8) emphasized the importance of a DMH tool's recommendation or resource that offered access to peer support networks. Another suggestion was for the user to predetermine a lower threshold for a risk notification if they were at risk of increased suicidality, allowing earlier intervention:

> *There's blurred lines to it, but at least like...having an accountability system...accepting, declining, being able to be there, or if I'm not, if I can be an emergency contact, but I'll accept, just going through*

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> *this with you. Like, being there with you but I will not be your emergency contact. Like, I can share experience. In the case where it is an emergency, I don't want to be an emergency contact, but I can maybe assist you in contacting your emergency contact or something.* [YP8]

Participants agreed that DMH tools should offer additional resources and alternative options once a screening or check-in is initiated, such as "resources to learn more about what I might be going through" (YP4). Both parents and young people emphasized that healthy parent-to-parent and child-to-parent relationships were important in cases where parents chose to complete a screening on behalf of their child. A parent elaborated as follows:

> *Obviously we agree to disagree on a lot of topics, but you know, after a certain years, you know your child very well. And...it depends on the relationship between the father and the mother as well.* [P2]

The closeness between parent and child would be a significant factor in the quality of input into a DMH tool's screening process, which would then impact the meaningfulness of any subsequent recommendation or prediction:

> *It'd be a case of if you could offer it as a dual package. So if the child was up to do it with their parents as one option, then you'd have, so you'd have three options, you'd have an adult, you'd have the youth separate, and then you'd have a child and a youth and a parent combo...there's something to suit everyone depending on their communication space with their family members and how open they are to their mental health.* [P10]

DMH tools were suggested as a complementary support alongside a clinician in both phase 1 workshops. Additional benefits of using DMH tools included setting reminders or nudges to promote healthy activities such as going for a walk or engaging in mindfulness meditation. A participant in the workshop for young persons also suggested that DMH tools could be useful for users with acute mental health challenges:

> *I think it would be good for bipolar disorder. For example, if you were able to get a new notification about your hyper episode, then you would able, you wouldn't be able to change your episodes like change your, arrange your calendar according to that.* [YP1]

In relation to the technology, a young person described enjoying how music apps and YouTube catered to her mood:

> *So I relate how I'm feeling, even if it's like a chronic like mental illness, like how I'm feeling is through my algorithm of my music. So like I'd be on YouTube and I'd probably right now I'm, like...I just figured out I had ADHD so like I'm like constantly watching things that have to do with that. So like I feel like different platforms can algorithmize my personal experience.* [YP8]

Another young person echoed this and made the following suggestion:

> *I think technology in essence should be supporting humans and human work, rather than trying to replace it. Um, if my GP or my psychologist fails to diagnose or intervene with me early, I recognize that everything they know about me is what I've told them, and those people are human. It's people they might miss things. So I'll be more than happy for this sort of data to assist in diagnosing me. Um, and together it will be more valid that just one source or the other.* [YP7]

In summary, when considering how results are communicated and what impact DMH tools may have on clinical practice, culturally diverse end users wanted to first process a recommendation or prediction on their own, viewed DMH tools as complementary to face-to-face clinical intervention, and were open to having a trusted contact with whom a recommendation or prediction could be shared.

Data Management and Sharing

Conversations in both phases established that participants had a moderate level of understanding about their personal data and how to manage the data. They acknowledged being aware of daily data collection via internet searches and app use and that the data can be outsourced to different countries and third parties through data harvesting (P3, YP10, P2, P7, YP7, YP8, and YP5). A participant in the workshop for young persons suggested that some data have to be shared to build more accurate and personalized apps:

> *I feel like data collection should be a two-way street. If you, I mean, like it should be mutual benefit, right?* [YP7]

Unauthorized data access by governments, concerns after experiences with surveillance measures during the COVID-19 pandemic, recent government health data breaches, and identity theft were key concerns of participants (P8, P7, P2, YP9, P6, and P5). A participant shared another concern:

> *It could be mental health related or something else related. And then that information goes to your doctor, you consult a specialist or a GP or someone. And then it goes back to your insurance provider. And the insurance provider knows about it and straight away your premium goes up because they classify you as a high risk.* [P3]

By contrast, young people were more open to having their data tracked or shared, having grown up with much of their information already available on the web and accessible by others. However, a young person acknowledged the difficult dilemma of accepting data collection in exchange for a more personalized online experience but described it as a "gray area" when it comes to broader data collection, stating as follows:

> *When they click "Accept All," that gives a warrant basically, and that's nothing that you can do because the website can just say, "You said, 'Accept All'" and continue. That's the warrant for me to say...to collect all your data and personalize it for you. And I feel like it's, it's quite a grey area basically.* [YP7]

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Another young person expressed uncertainty regarding their preference for certain data points to be collected or tracked by specific services:

> *I would want my location to be tracked by medical services. Say, for example, I get hurt and then, um, my phone...like my watch has this thing where it says, "Accident Detected." But I think about who gets access to what data and what they do with it and I think that's also really hard to track so it depends.* [YP2]

In summary, culturally diverse mental health service users valued data about mental health, with variation in openness to data sharing and how the data may be shared in future.

Sociocultural Influences on Mental Health

Participants' experiences with mental health were grounded in sociocultural complexities, with variations in cultural understandings of mental health, help seeking, parental influence, community and spiritual support, and migration status, all playing a role in diverse communities' engagement with DMH support.

Many of the participants (YP7, YP1, YP8, and P8) self-identified as having lived experience with mental ill-health and discussed the importance of self-understanding when it came to mental well-being. Parents, in particular, recognized the importance of acceptance and education around mental health:

> *Probably because nobody wants to tell anyone, I'm going through not a very nice day or I'm going through mental health issues, so basically we have to come out of that state so we have to educate ourselves there's no point in just keeping everything to yourself.* [P2]

Participants agreed that, outside of the family unit, their ethnic communities placed more importance on family connection and bonding than mental health specifically. This was highlighted in the comment written by a young person in the emotional walk-through booklet:

> *The "Mental health" term itself was still a taboo in India. We give importance to family connection and bonding (as a well-being strategy) but always have learnt to support and be there for one another.* [YP4]

In addition, some participants (P1, P7, and YP4) discussed how their communities relied on religious leaders for mental health support rather than accessing formal care. However, the dominant cultural lens within a household impacted whether mental health was openly discussed. A parent explained as follows:

> *I would say it's very culturally influenced. From my perspective, the culture which we're connected to, you know. For everything there is a step-up process for you to understand, you know, why this is done, why it is not done. The reasons behind it. So where we grew up in our culture, we explain to them why we are doing this, to keep them on track. To keep you calm. It will protect you. The faith base.* [P1]

Migratory experiences and differences in the availability of support depending on visa status were also significant:

> *When I came from Turkey to here, one of the biggest surprises I have come across was the, how common suicide was among younger generations of Turkish people here. I was shocked, I lived in Turkey for 19 years, and I'd never even heard of someone who has heard of someone else's suicide. Like, never even came across it from the third degree or fourth degree. Many here, I spoke to a family member of someone who was a victim to suicide. The mother told me about her son's suicide, and I was so shocked. And then I heard the same story from multiple other people as well, and it just made me realize how widespread it was here, in younger generations of Turkish people.* [YP1]

In summary, sociocultural factors influenced the use and application of DMH tools, with culturally diverse end users describing how their culture informed their understanding of mental health and help seeking.

Generational Differences in Mental Health and Digital Literacy

There were notable differences between the 2 generations across both study phases, particularly in terms of accessing mental health professionals, digital literacy, and whether participants were first- or second-generation migrants. Language barriers were identified, with a parent stating as follows:

> *That support is lacking. So you can imagine for some of these cultural communities, English might be a barrier, language might be a very big barrier.* [P6]

Parents (P6, P2, P8, and P3) preferred confiding in a close friend and face-to-face interactions over digital therapies. By contrast, young people (YP8, YP10, YP3, and P8) seemed more willing to share their mental health experiences. A young person stated as follows:

> *I know that like when I was a young teenager, going through my rebellious phase in an ethnic household where I didn't feel like it was safe to open up to my parents, the online anonymous aspect was what made online like, Tumblr, a safe place for me to, I guess, voice my mental health concerns about myself.* [YP5]

Some parents also believed that young people were more mentally healthy and digitally literate:

> *I think teenagers today are really, because they do things like that in school now, they understand about self-care, they do mindfulness, they do all that sort of thing as teenagers now in high schools and things. I think that the word self-care is so synonymous now, everyone knows what that means. There's depths of it, of course, but to a teenager even knowing, and they know how much time they spend, too much time on social media, they know they need to get more sleep, but you know, when they do all those things and they know they shouldn't eat McDonald's every day, they're not silly, these kids are smart.* [P8]

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As a first-generation migrant, a parent felt that it was important not to impose her own cultural rules on her Australian-born children:

> *Because they're going to be Indian Australians, or Indian whatever it is. Deep down, they're Indian, they grew up as Australian children. They're more Australian than Indian sometimes. So we don't, um, there's no hard and fast rules. We can't tell them, you have to get up at 5 o'clock and pray.* [P2]

The discrepancy between how young people perceived mental health challenges compared to their parents was regularly raised, with a young person elaborating as follows:

> *I think another aspect of like, immigrant parents on things about mental health, gender identity, sexuality that's a big thing that, I know people, who are even single parents, who come from the immigrant background, they don't understand what their young child is going through with gender identity and all that stuff, because it's...it wasn't really a thing when they were growing up, and, suddenly it's become something now, and they don't know how to deal with it.* [YP10]

In summary, generational differences were a central social factor that influenced the use and application of DMH tools.

Stigma and Culturally Based Discrimination

Challenges with mental health stigma were discussed in both phases, with participants explaining that different cultural beliefs informed alternative explanations for poor mental health. Moreover, concerns were expressed that assigning a mental health diagnosis to a young person could lead to further marginalization because it might trigger defensive barriers in community members and contribute to increased ostracization. These experiences were centered on both internalized and externalized mental health stigma from family, friends, and extended cultural communities (P6, P3, P2, YP7, and YP3).

When discussing a potential mental health diagnosis for a child or young person, a parent stated as follows:

> *It's denial first, thinking that nothing is wrong with your child...automatically you think, my child is fine, there's nothing wrong...So the acceptance [of poor mental health] is going to be very difficult.* [P2]

For a young person with culturally diverse parents, the experience of mental ill-health was particularly challenging:

> *When my parents found out that I had some mental health issues...I noticed changes in their behaviors and in terms of my parents and carers being from an ethnic environment, they're very judgmental. I just feel like my parents have zero understanding on mental health and mental illness so they wouldn't take any of that as a form of "I need help." They'll take it as I'm being ungrateful.* [YP7]

A parent described how "mental illness ignites defensive barriers within people" (P6), suggestive of an internalized resistance that may impact help seeking in a community. A young person stated as follows:

> *It might also depend on the person and if they have internalized stigma. I think if an app has some sort of measure that can account for that [internalized stigma]. And that can frame the message depending on that, it would be really nice. So, even in ethnic communities, even if somebody is seeking help, for example. Learning that you're depressed can be quite burdensome on your own mental health. The diagnosis might actually worsen your situation. Because the view of depressed people within your culture might always be these helpless people who cannot do anything basically.* [YP1]

Regarding the diagnostic potential of DMH tools, parents were cautious about making their children "feel like they're different" (P8). A parent described how the diagnosis could be enduring and punitive:

> *You're assuming the parent can put a diagnosis on a condition and that's going to stick somehow. Because you're sort of leading them down a particular path. I'm a great believer in diagnoses, but a diagnosis can be a sentence. Rather than a word, you know.* [P7]

There were concerns that a diagnosis can result in "lifelong stigma for a child or young person" (P7). A parent put it as follows:

> *You know what, suddenly my kid gets this thing as a mental health patients, that's the end of their life. For the rest of their life they'll be on medication or for the rest of their life they'll be on this. They're branded like that.* [P2]

There was a perception among some parents that they would "lose face" and be stigmatized in the eyes of their community if they or their child received a mental health diagnosis:

> *When we talk about the ethnic communities, for them, their saving face becomes a very big issue. And you know, none of them want to lose face in the community in public and what have you. If somebody else doesn't even use their name then, for them, that stigma sort of stays, it's always going to take me years to rebuild that trust again.* [P6]

Participants in both phases raised concerns about culturally based discrimination when seeking mental health support, including an inequity in the availability of psychological assessments, screenings, and support. Psychological assessments and mental health screenings were identified as a form of systemic discrimination by the young participants, who noted how most tools are only available in English, with questions reflecting Western understandings of mental health. This often results in people performing poorly due to an inability to understand the questions and being misdiagnosed. A young person described her lived experience of working in a Turkish-speaking psychologist's office in Australia and raised her concern about the limited number of bilingual psychologists:

> *They were one of the few Turkish-speaking psychologists we had, four or five months of waitlists. So, it was cheaper than private practitioners. Only 20% of the fee would be paid out of pocket. And it*

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> *was impossible to get through. Even if you have, um, some sort of government supplement like Medicare or some sort of private insurance, it was just impossible to make an appointment with her. And the same thing was the case for our Bosnian psychologist and our other psychologist as well.* [YP1]

Difficulties accessing mental health support were raised across both groups, with participants discussing the challenges, such as visa status, that migrants face when accessing mental health services, which can prevent them from receiving the same standard of support as other residents. This was particularly important for young international students waiting for permanent residency visas:

> *But because they're still waiting for that process to get their PR [permanent residency visa]. They're [asylum seekers] still in our schools. They go to private schools. They're living a good life. But because they're asylum seekers. We're international students. We don't have access to Medicare.* [YP2]

Discrimination from family members, friends, ethnic communities, and third-party systems upon receiving a mental health diagnosis was a concern raised by both groups (YP5, YP6, P6, and YP1). Both groups identified concerns about future discrimination from third parties who may use their mental health diagnoses to deny visa applications, steal their identities, or charge them higher insurance premiums (P1, P3, P5, P6, YP5, and YP6). In summary, stigma and diagnostic barriers, culturally based discrimination, and third-party access that may impact visa status and migration were central concerns.

Discussion

Principal Findings

The aim of the project was to explore the views of culturally diverse parents and young people on the opportunities and barriers to engagement with a web-based DMH screening tool. Through this work, we have explored the benefits, burdens, and trade-offs of using DMH tools from the perspectives of culturally diverse end users. On the basis of these findings, we provide our provisional set of reflections on the future of culturally sensitive DMH tools. Consideration of parental influence based on their country of origin, culture, and level of mental health literacy and how that is paired with raising a child in Australia is complex. Young people were perceived to have a higher level of general mental health and digital literacy, with greater awareness of their mood and self-care routines, as well as an understanding of healthy diet and lifestyle routines. They were also more willing to share information about their mental health with others. These generational differences highlight the importance of accounting for perceived barriers such as the influence of culture on mental health support, culturally based discrimination in seeking mental health support, and how a diagnostic label may impact the likelihood of engaging in help seeking.

Leveraging Family Connectedness

We found that our participants' understanding of their mental health was centered on their connection to family and parent-child relationships. Our findings suggest that family ties and family connectedness may influence the uptake of mental health treatments or interventions or whether and with whom DMH tool recommendations are shared. For culturally diverse youth, families provide an immediate social context (eg, as YP4 wrote in the emotional walk-through booklet: "The 'Mental health' term itself was still a taboo in India. We give importance to family connection and bonding [as a well-being strategy] but always have learnt to support and be there for one another"). Previous research found that the pace of cultural adaptation differs between parents and young people who resettle in Australia, with young people adapting faster but finding it hard to become independent from their families [16,88].

Family connectedness has been linked with lower odds of significant stress and despair for youth during acculturation and may protect them from other risk factors. In fact, the quality of family relationships can have a positive effect on well-being [89-91]. More research identifying positive family processes (eg, closeness with both mother and father) that build emotional well-being in culturally diverse young people is needed [92]. We found that familial influence informed young people's understanding of mental health, which, according to some parents, could be explained and managed through religious practices or alternative methods. This is an important finding because it suggests that future iterations of DMH tools should emphasize the inclusion of culturally sensitive parental support and psychoeducation on mental health problems. It also highlights the importance of engaging community leaders, elders, religious leaders, or mental health advocates from different cultures and communities to gather their insights on and explanations of well-being and mental health to ensure that the technologies are culturally safe. We suggest that culturally appropriate and culturally informed psychoeducation for families is needed to encourage community buy-in, ultimately leading to more effective DMH tools for culturally diverse populations. This education would have to be offered thoughtfully, paired with data governance education to promote digital literacy and awareness of the insufficiently regulated data industry and unregulated practices that exist currently.

Culturally Based Discrimination: Stigma, Loss of Face, and Collectivist Approaches to Mental Health

Barriers such as stigma, shame, and perceived judgment from community members were regularly raised. Many parents voiced concern about losing face in their community. Collectivist cultures that share a collective identity, emotional dependence, and shared duties and obligations operate under a "we" consciousness. These cultures are common outside Western societies that prioritize individualism [93]. The difference between individualism and collectivism ought to be considered when creating DMH tools, building an awareness that psychological support may be shared within a broad family network and that the "burden of results" may not be carried by the individual alone in collectivist communities. People from many collectivist cultures may struggle to understand the typical individualistic approach to treatment because they expect to receive care within the context of their family [94].

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Some people may also have deeply held negative beliefs or attitudes toward those experiencing mental health challenges, making it important to design mental health services that incorporate informal support avenues (eg, friends and family) on which individuals may rely for help [95,96]. Loss of face is an important cultural factor in the Asian context and has been found to be a significant predictor of self-stigma and public stigma that impacts attitudes toward help seeking [97-99], especially given that community belonging plays a large role in migrant mental health [12].

Culturally diverse communities may minimize the reporting of psychological symptoms or may be resistant to sharing personal health information because of mistrust, perceived racism, or a sense that public mental health services do not accommodate or respect their cultural beliefs [100,101]. Culturally sensitive psychoeducation within communities is needed to combat stigma. To achieve this, we suggest engaging with community and religious leaders as well as mental health advocates with lived experience of mental health challenges, given their influential reach among diverse end users, to promote community-informed education, self-determination, and self-advocacy. DMH tool designs should offer transparent data collection policies, with tiered consent, to ensure that end users feel comfortable sharing their data, and this should be paired with the inclusion of digital navigators, who are members of health care teams dedicated to help end users [102].

Young people in our study voiced concern about the lack of culturally and linguistically diverse clinicians and assessment tools, noting that information was mostly communicated in English using a Western framework for assessing mental health. Research has found that diagnostic assessments tend to not be sensitive to racial and ethnic minority populations due to their exclusion from mental health research [103,104]. Furthermore, culturally diverse community members are less likely to have satisfactory access to mental health support and are less likely to receive a diagnosis for a mental health condition [105,106]. If DMH tools are to be relevant, accessible, and effective for culturally diverse populations, future designs and implementations must be available in languages other than English and incorporate cultural approaches to mental health. The very term *mental health* is a Western concept, and Western cultural traditions and understandings have informed much of the theory, practice, and understandings of mental health, including within psychology and psychiatry, with a central focus on individual pathology instead of sociocultural contexts and determinants [107,108]. Furthermore, how patients from culturally diverse backgrounds express their symptoms may vary, making it challenging to accurately diagnose or treat their conditions [104]. Individualized models of care may not be appropriate for those who are accustomed to community- or family-focused models of care [108]. The British Psychology Society proposed the power threat meaning framework as a nonmedicalized and nondiagnostic approach that instead describes how coping and survival mechanisms are adapted based on lived experience, previous threats, and social context, accounting for cultural differences in the experience and expression of distress, with less emphasis placed on Western views [109].

We ought to consider how to design culturally sensitive DMH tools that are informed by attitudes from diverse communities and encourage self-determination and cultural context within a well-being framework. One suggestion is for DMH tool developers to offer enhanced psychoeducation that is culturally safe and fosters self-determination, with tailored psychological assessments and resources that account for language variations and barriers for users coming from collectivist cultures whose conceptions of mental health vary from the Western medicalized understanding.

Medicalization by Design

Concerns were raised about making a child or young person feel different. Participants worried that “a diagnosis may worsen your situation,” suggesting that a diagnostic label or the detection of a mental health problem, as well as the diagnostic process itself, may further marginalize diverse communities through the medicalization of culturally appropriate cognitions or behaviors. Medicalization pathologizes behaviors according to a Western psychiatric framework, putting the responsibility back on the individual to stay healthy without considering other important social factors [110,111]. Online screening tools and mobile apps are being designed to promote well-being and provide psychological support, but they can also work to endorse ongoing surveillance [112] of mood and activity and set expectations about healthy behaviors and cognitions. A shift is needed in how mental health is conceptualized and designed for in a way that accounts for cultural barriers that may limit engagement and usability for diverse end users of DMH tools [109]. Importantly, we need to invest in community-led practices that promote community leadership in the design and innovation of DMH tools [82] to avoid built-in discrimination that reproduces inequities due to normative or Western-oriented assumptions about mental health [113]. We suggest that when designing DMH tool outputs, such as the communication of health information, recommendations for services and interventions, and referral pathways, the reported symptoms entered by the end user are phrased in a way that avoids pathologization and diagnosis. Currently, DMH platforms tend to recommend resources on anxiety, depression and suicidal ideation, and eating disorders [39,114]; however, we believe that it is imperative that symptoms are spoken about in clusters, rather than specifying specific diagnostic criteria that may then pigeonhole or “label” an end user without appropriate access to clinical care.

Attitudes Toward Data Collection Are a Two-Way Street

When using DMH tools, participants felt that there was less concern about privacy and data sharing when the data collected were more generalized. This is consistent with a recent study on diverse communities using mindLAMP, a DMH platform, where participants wanted their DMH apps to pull data from their current health care records to enhance app personalization [115]. Participants acknowledged that innovations and interventions require consent for collecting substantial amounts of data to tailor services or for platforms to “algorithmize my personal experiences”; however, research has found that DMH tools are often not culturally tailored or responsive due to

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culturally diverse or racial and ethnic minority populations often not being considered in their development and evaluation [116,117]. Young people from culturally diverse communities recognized that they would need to provide access to personal digital health data to realize the benefits promoted by DMH tools. Critics have argued that young people may not comprehend the longevity and potential harms of a digital footprint and that thoughtful education and support around this is important for their future privacy [118]. While research has demonstrated an unwillingness from end users to share their sensitive health data with commercial organizations [23,119-121], there was a sense in our findings that participants expected an "algorithmized experience," which would require health data to be treated as open data [122]. Due to the sensitive nature of mental health data, further education on data governance and the potential reuse of big data is recommended for young people, given the nature of cross-sectoral data sharing. One approach may be incorporating speculative design approaches, such as the one suggested in the study by McNaney et al [23], to engage young people in discussions around their digital futures, the potential harms of data sharing, and the misuse of their data.

In both phases, the participants identified concerns about data breaches, including potential identity theft and the impact it could have on visa and migration status. These concerns are reflected in the literature, with 1 study finding that nearly half of the DMH apps surveyed did not have a privacy policy, although it is known that health care apps often share data points (eg, age, contact information, and other user data) with multiple third parties for commercial purposes [123,124]. Efforts have been made to establish ethical standards for digital data gathered from DMH tools, including accounting for data breaches, which advise developers to account for hidden assumptions and unintended consequences [125]. Regulations such as the General Data Protection Regulation in Europe and similar privacy acts being developed in Brazil, Chile, and Canada aim to protect data privacy. However, even the General Data Protection Regulation has limitations, particularly in the context of emerging generative artificial intelligence innovations.

Reflections and Limitations

This study sought to engage with culturally diverse representatives in relation to cultural background and lived experience of mental health challenges. To achieve this, we approached an organization focused on multicultural mental health that advertised the study, recruited participants, and supplied bicultural workers for our study. While we were able to have meaningful discussions in our workshops, the participants were all affiliated with the organization, meaning that the sample was not necessarily representative of a truly culturally diverse population, given that each participant was already mental health literate, able to communicate in English, and held a preconceived understanding of mental health, rather than being a layperson. The addition of an Anglo-Australian participant was also a limitation. Future research needs to engage with a broader range of culturally diverse participants, including those with less digital and mental health literacy and those who may be in a more contemplative stage of their mental health journey and possibly unaware of support services. Future research might consider recruiting through youth organizations or well-being counselors who may have access to a more culturally diverse range of participants who reflect a more culturally diverse picture of mental health literacy and help seeking. Future research should also engage in participatory action research methods (eg, co-design and coproduction) that allow end users to develop RQs and study designs. However, this approach can present additional challenges to building social capital and gaining trust to engage with culturally diverse end users in a meaningful way, and this needs to be factored into study timelines. Our study was bound to an innovation timeline, making the recruitment of a truly diverse sample impossible. We were conscious that we did not invite the participants to review the data analysis or final manuscript, which could have reduced the power imbalances further by allowing the participants to join as coresearchers in the project from start to finish. Future iterations would benefit from inviting culturally diverse participants on board as coresearchers, not just as participants. We believe that it is important to embed the voices of diverse community members within a research project throughout its lifespan.

Most of our participants were from South-East Asia. While this is an accurate reflection of the majority of culturally diverse Australians [1], it may not capture the views of ethnic and racial minority cultures within Australia. We hoped to avoid essentializing all experiences as one by including quotes from individuals because we believe that culturally diverse communities do not share a single common experience due to varying sociopolitical differences such as age, culture, and citizenship. The median age of the young participants was relatively high, with one aged 16 years and one aged 18 years, while the remaining participants were aged 20 to 22 years. As such, our findings may not reflect the views of younger adolescents. Future endeavors should aim to apply the insights gained from this research in the development and pilot testing of DMH interventions and applications by evaluating their effectiveness and refining them based on the outcomes.

Conclusions

Inclusive design considerations for the future development of DMH tools that account for culturally based discrimination, are culturally safe, consider family and cultural influence on mental health support, and are thoughtful in how mental health problems are detected and communicated to end users would improve engagement in DMH tools and help seeking. We recommend encouraging culturally sensitive psychoeducation, thoughtful nonpathologizing language that avoids providing a specific diagnosis, and the inclusive involvement of community leaders and mental health advocates in the future design of DMH tools to ensure that they are designed to meet the needs of culturally diverse end users.

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Authors' Contributions

The study was designed by IB, AC, RM, and JCN. IB prepared the first draft of the manuscript. All authors contributed to and approved the final manuscript.

Conflicts of Interest

This study was funded by the Growing Minds Australia Clinical Trials Network. JCN, LAT, and PO are listed as principal investigators on this grant, and the positions of JCN, LAT, and TC are supported by this funding.

Multimedia Appendix 1
Digital mental health co-design workshop schedule.
[DOCX File , 23 KB - pediatrics_v8i1e65163_app1.docx]

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Abbreviations

DMH: digital mental health
GMCI: Growing Minds Check-In
GP: general practitioner
RQ: research question

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Children's and Their Parents' Experiences With Home-Based Guided Hypnotherapy: Qualitative Study

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Abstract

Background: Management of children with functional abdominal pain (FAP) or irritable bowel syndrome (IBS) is difficult in primary care. When education and reassurance do not alleviate symptoms, primary care physicians lack treatment options for children with FAP or IBS. Home-based guided hypnotherapy is a promising treatment because of its accessibility. To address feasibility, it is of utmost importance to take experiences from children and their parents into account.

Objective: We aimed to explore children's and their parents' experiences with home-based guided hypnotherapy for children with FAP or IBS.

Methods: This qualitative study used open-ended questions from a questionnaire and in-depth semistructured interviews with children and their parents who had a hypnotherapy intervention prescribed. The interviews were audio-recorded and transcribed verbatim. Data were collected and analyzed iteratively using thematic content analysis.

Results: A total of 76 children were eligible, and we collected questionnaire data from 56 children. A total of 23 interviews were conducted with 10 children and 15 parents. Six themes emerged from questionnaire data and interviews: impression of the exercises, not for everyone, influence of perceived effect, integrating exercises in daily life, content and practicalities of the website, and customization to personal preferences. Children with FAP or IBS experienced home-based guided hypnotherapy and the exercises differently, ranging from boring to fun. From interviews with the parents, it emerged that hypnotherapy is not suitable for everyone; for example, when children are very young or have a low developmental level, cannot sit still, cannot surrender to the exercises, or are too energetic or stressed, it might be difficult to comply. Experiences were shaped by the influence of a perceived effect and to which extent children were able to integrate exercises in daily life. The content and practicalities of the website also influenced experiences, and hypnotherapy that is adaptable to personal preferences, including by appearance and content, would be highly appreciated.

Conclusions: The children and parents experienced home-based guided hypnotherapy differently, ranging from boring to fun. Hypnotherapy might be difficult or boring for some children. The children enjoyed hypnotherapy when they liked the topic or story, felt positive effects, could easily integrate exercises in daily life, or enjoyed the website in general. The children's experiences and adherence can be further improved by adding short exercises and customizing hypnotherapy to their personal preferences on the website's appearance and content. This could increase effectiveness but must be studied further.

Trial Registration: ClinicalTrials.gov NCT05636358; https://clinicaltrials.gov/study/NCT05636358

International Registered Report Identifier (IRRID): RR2-10.1136/bmjopen-2022-069653

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KEYWORDS

qualitative study; primary health care; children; functional abdominal pain; irritable bowel syndrome; hypnotherapy; eHealth; abdominal pain; child; parents; accessibility; questionnaire; interviews; thematic analysis; home guided; primary care; mobile phone

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Introduction

Disorders of gut-brain interaction such as functional abdominal pain (FAP) and irritable bowel syndrome (IBS) are chronic pain conditions without organic cause [1]. These disorders are common in primary care, as a general practitioner (GP) sees approximately 10 children with disorders of gut-brain interaction each year [2,3]. Dutch GPs diagnose FAP or IBS when after medical history and physical examination, no underlying tissue damage, somatic causes, or metabolic or anatomic abnormalities can explain the symptoms of the child [4]. FAP and IBS are associated with lower quality of life, school absence, and higher anxiety and depression scores [5,6], and around 50% of children in primary care still report abdominal complaints one year later [7]. Management consists of education and reassurance, but if this fails to alleviate symptoms, there are few evidence-based treatment options in primary care. Children with abdominal pain and their parents report a desire for receiving a specific diagnosis and a need for information about its cause and treatment options [8-10]. Children often adopt coping mechanisms by themselves, such as reassurance and a calm approach, distraction techniques, breathing exercises, and bedtime meditation [11]. Hypnotherapy could be a treatment option, as it has shown to be effective in children referred to secondary pediatric care [12,13]. However, it has not been studied in primary care. Research in primary care is important because a different setting, selection of patients, and organization of care might influence treatment effects.

With hypnotherapy, a patient is induced into a hypnotic state and guided to suggestions by a therapist or by listening to audio-recorded exercises in their home environment (ie, home-based guided hypnotherapy) [13,14]. Home-based guided hypnotherapy is promising in primary care because of its accessibility [15]. Very few mild to moderate side effects of hypnotherapy are reported [16], and the fact that children can do it by themselves without involvement of others makes primary care an interesting setting. Experiences with home-based guided hypnotherapy in children with FAP or IBS have not been studied yet. Insights in experiences of children and their parents are important for successful implementation [17]. In this study, we aimed to explore experiences of children with FAP or IBS and their parents with home-based guided hypnotherapy, and to capture their ideas about potential areas for improvement.

Methods

Design

This qualitative study is part of the ZelfHy study, a randomized controlled trial (RCT) evaluating the effectiveness and cost-effectiveness of home-based guided hypnotherapy in children with FAP or IBS in primary care (ClinicalTrials.gov NCT05636358) [18]. The participants in the intervention group had access to a 3-month, home-based, guided hypnotherapy program. This study used questionnaire data of open questions and log data from the ZelfHy study of participants who received the intervention, and in-depth, semistructured interviews with a purposively selected sample of children and their parents.

We followed the Consolidated Criteria for Reporting Qualitative Research [19].

Home-Based Guided Hypnotherapy Program

The children in the intervention group of the RCT received standard care and home-based guided hypnotherapy for 3 months. Before starting, a researcher explained hypnotherapy, its benefits for abdominal pain, and access methods during a video call with the child, parent, or both. They were also advised not to discuss the pain. The hypnotherapy program included 5 exercises: 1 breathing and relaxation exercise and 4 visualization exercises: “the favorite place” or “the favorite place+ rainbow” (age-dependent), “the rainbow planet” or “air balloon” (age-dependent), “the beach without worries,” and “the slide.” Two exercises comprised 2 versions with adjustments in language: for children aged <12 years and ≥12 years. Exercises were audio-recorded by a hypnotherapist. Instructions and exercises were hosted on a responsive website, as shown in Figure 1. All exercises were immediately available, but the children were guided to listen to the first 2 exercises for the first 2 weeks, adding new exercises every 1 to 2 weeks. They could choose and repeat exercises whenever they wanted. The children were encouraged to practice at least five times a week for 15 - 20 minutes daily for over 3 months. Automatic email reminders were sent after 14 and 28 days of inactivity to improve compliance.

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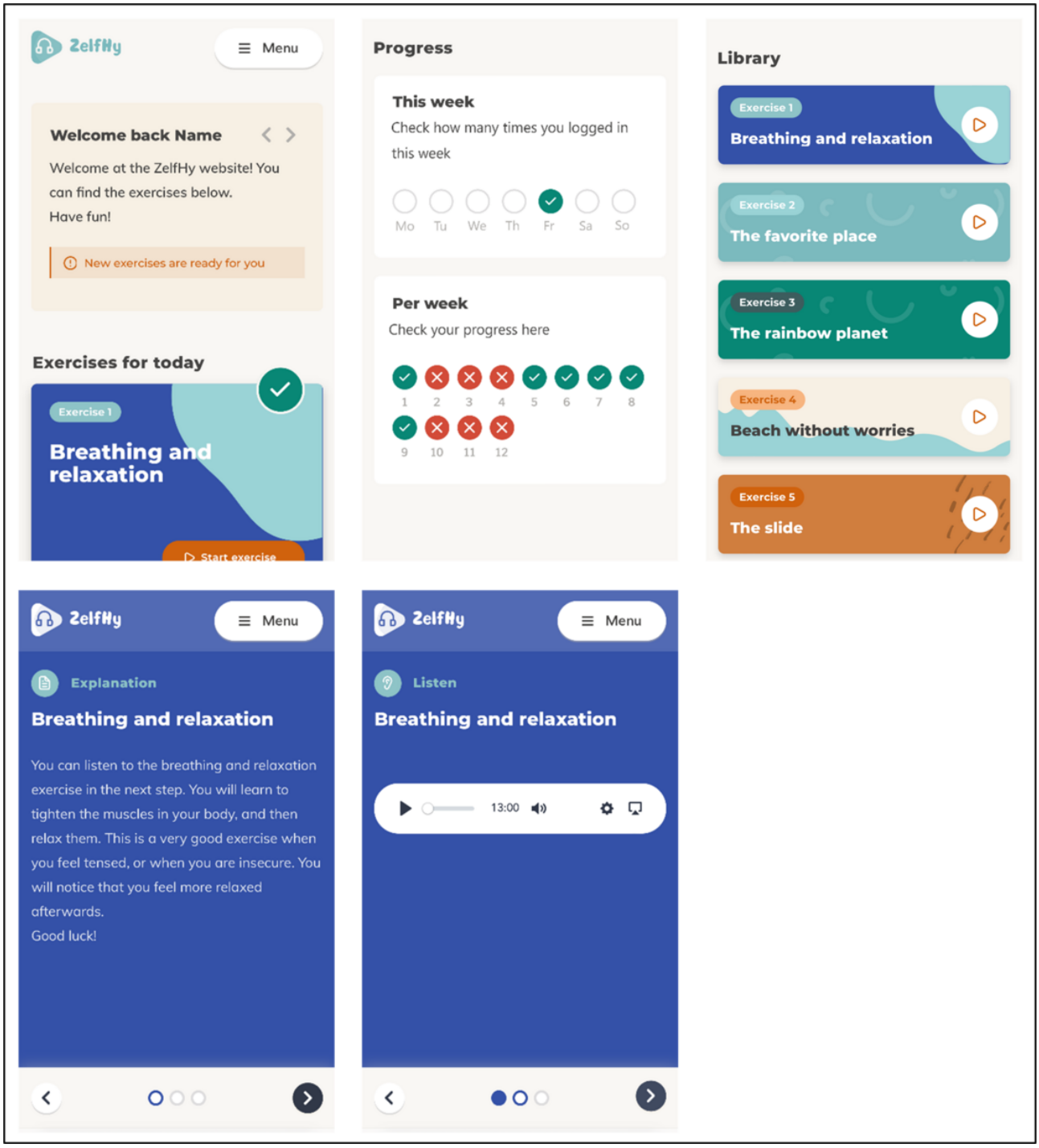
Figure 1. Screenshots of the website taken from a smartphone.



Patient Participation

One mother of a girl aged 9 years and one male adolescent aged 19 years who both finished the intervention were engaged, and both received a voucher. Patient participation included attending 2 research team meetings and member checking the final results. The 2 research team meetings included discussion of the interview guide before the interviews, and discussion of topics, codes, and preliminary themes after the first interviews.

Recruitment and Participants

In this qualitative study, all the children and their parents in the intervention group of the RCT were included. Children aged 7 - 17 years with FAP or IBS according to their GP participated in the RCT. Exclusion criteria for participation in the RCT were a concomitant organic gastrointestinal disease, being managed for abdominal pain by a pediatrician, intellectual disability, psychotic disorders, a history of hypnotherapy in the past year, and poor comprehension of the Dutch language. Detailed information of recruitment methods for the ZelfHy study are described elsewhere [18].

All the children and their parents were invited to answer the questionnaire. Additional inclusion criteria for in-depth interviews for this study were that the children had to be within the 3-month intervention time frame at that time, and live in the

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Northern or Middle part of the Netherlands because of travel convenience. Purposive sampling was used to achieve diversity in age, gender, and therapy adherence based on automatically logged data for the user interactions. The first author, a female primary care researcher, invited parent-child dyads for interviews via telephone approximately 6 weeks after they started the intervention. We assumed that halfway through the intervention, the children listened to all exercises and were able to recall and express their experiences. In practice, with time delay such as decision to participate and setting a date for the interview, interviews would be held in weeks 8 - 12. The authors believe that this was enough time to shape experiences.

Data Collection

Questionnaire data consisted of open-ended questions regarding what they liked and disliked generally, and for each exercise separately (Multimedia Appendix 1). Questionnaire data were collected through an electronic data capture system at 3 months follow-up between March 2021 and January 2024. The parents completed the questionnaire for the children aged <12 years, and the children aged ≥12 years completed the questionnaire themselves, with parental help as needed. Additionally, we collected log data from the intervention consisting of how long the children listened to each exercise per session. A session was defined as a log-in and start of at least one exercise. In accordance with a previous study on the effectiveness of hypnotherapy, we defined adequate use as starting at least four different exercises [18,20].

From May 2023 to December 2023, a female primary care researcher and trained interviewer (ING) and a female social scientist with expertise in qualitative research and trained interviewer (MAA) conducted semistructured interviews. The first author had contact via telephone with the parents for study procedures for the ZelfHy study before the interview. The interviews took place at the participant's home, except for the children with low adherence. For convenience, the parents of these children were interviewed by telephone and they did not necessarily have to live in the Northern or Middle part of the Netherlands. Interviews were recorded using a digital voice recorder and transcribed verbatim. Field notes and short memos were written during and after each interview.

To develop the semistructured interview guide, we used sensitizing concepts from literature and expert discussion with the research team which consisted of a female primary care researcher, a female primary care research assistant, one female epidemiologist, one female social scientist, and two female GPs. The interview guide consisted of open-ended questions about the children's and parents' experiences with the therapy (Multimedia Appendix 2). Interviews were performed until data saturation was reached (ie, interviews no longer generated relevant concepts). We completed 3 additional interviews with the children and their parents in which no new codes were found. Iterative meetings with the research group were held to evaluate and update the interview guide for new concepts and discuss data saturation.

Data Analysis

Thematic content analysis was conducted as proposed by Braun and Clarke for questionnaire data and interview transcripts [21]. First, all questionnaire data and 10 interview transcripts were read and inductively and independently coded by ING (both questionnaire data and interview transcripts), GAH (questionnaire data and female epidemiologist), and ALvdV (interview transcripts and female primary care research assistant). ING coded the remaining transcripts and ALvdV checked the coding of these transcripts. Inconsistencies between coders were discussed until consensus was reached. Consequently, emerging themes and subthemes were discussed and redefined with the research team until consensus was reached. In one of these meetings, a mother and adolescent were part of the research team. Illustrative quotes were translated from Dutch to English by a native English speaker and editor, and the first author checked whether their meaning was retained. All analyses were facilitated using Atlas.ti (version 23; ATLAS.ti Scientific Software Development GmbH) software.

Ethical Considerations

The Medical Ethics Review Committee of the University Medical Center Groningen, the Netherlands, confirmed that the Medical Research Involving Human Subjects Act which includes the Declaration of Helsinki, did not apply to this qualitative study (number 202200110). All the participants gave informed consent. Participant data were deidentified after the interviews. No compensation was provided.

Results

Participants

In total, 76 children were eligible from the intervention group of the RCT. Their median age was 9.1 (IQR 8.1 - 11.2) years and 51 (67.1%) children were female. Of these 76 children, 20 children did not log in (n=10) or failed to complete the questionnaire for other reasons (n=10), resulting in questionnaire data from 56 children (Figure 2). For in-person interviews, 29 children were eligible because they were within the 3-month intervention period and lived in the Northern or Middle part of the Netherlands. We invited 19 children to participate in an in-person interview, of which 9 declined to participate because of personal circumstances (n=3), no interest (n=3), or no further reason (n=3). In addition, 3 parents of the children with low adherence were invited for a telephone interview. Interviews contained 13 children, of which 4 did not fill in the questionnaire. A total of 23 interviews were conducted, which lasted 19 - 63 minutes for in-person interviews and 5 - 11 minutes for telephone interviews. The in-person interviews included 10 children and 12 parents, of which 2 interviews were performed with both parents. The telephone interviews included 3 parents of the children with low adherence (Table 1).

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Figure 2. Flowchart of participants. Asterisk (*) denotes that 20 in-person interviews were conducted: 10 with children and 10 with parents.

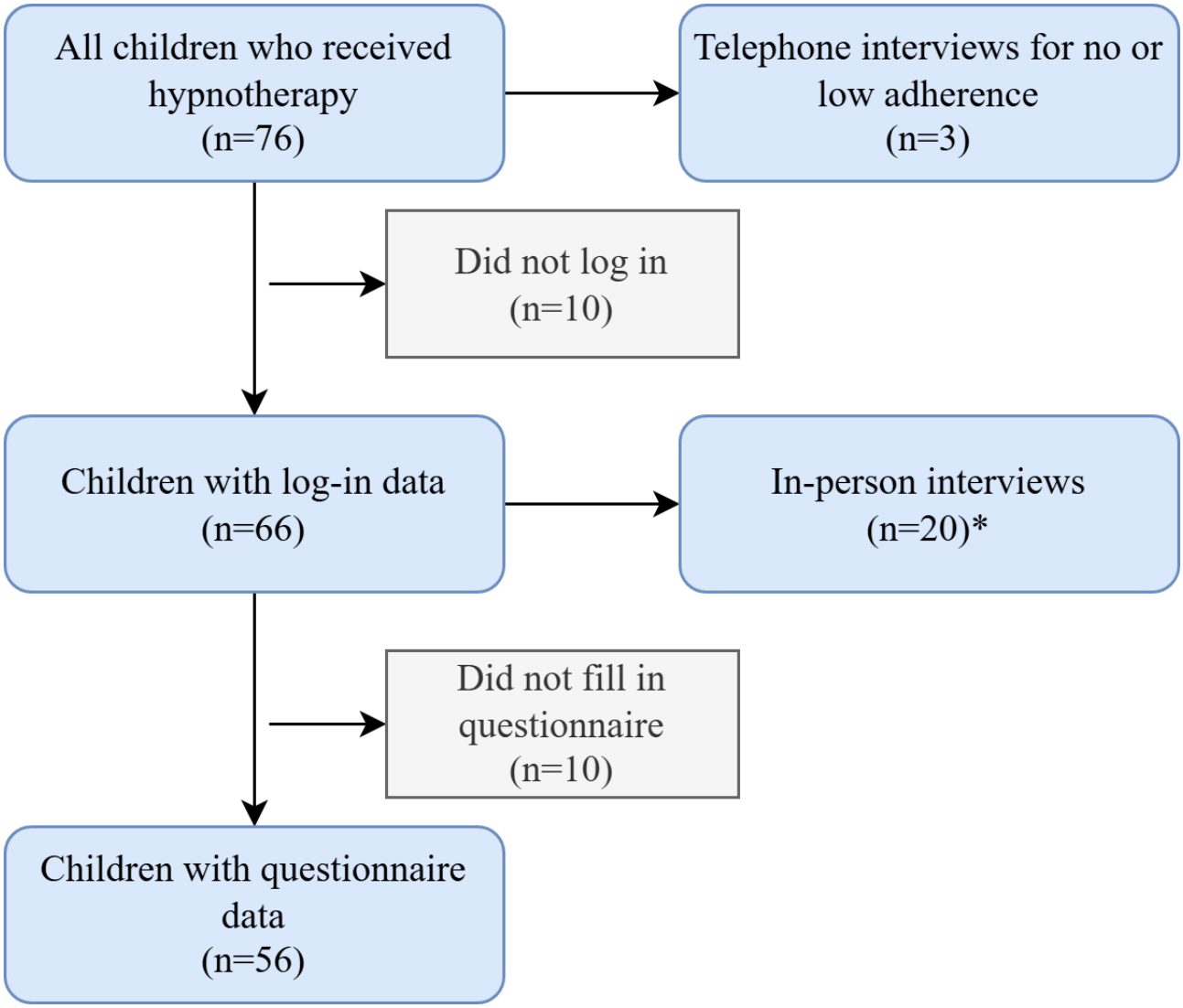

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Table . Characteristics of interviewed participants.

ID	Gender	Age (years)	Gender of parent	Age of parent (years)	Parental educational level[a]	Sessions (n)[b]	Favorite exercise
1	Girl	8	Female	41	High	10	The rainbow planet
2	Girl	11	Female	36	High	31	The favorite place
3	Girl	12	Female	42	Low	12	The slide
4	Girl	11	Female and male	40 (mother) 45 (father)	High (mother) High (father)	46	The favorite place
5	Girl	13	Female	50	Intermediate	14	Beach without worries
6	Boy	9	Female	44	High	29	The slide
7	Girl	7	Female	37	High	63	The slide
8	Boy	13	Female	43	Intermediate	46	Beach without worries
9	Girl	9	Female	38	High	22	The favorite place
10	Girl	8	Female and male	46 (mother) 44 (father)	High (mother) High (father)	55	Beach without worries
11[c]	Girl	10	Female	Unknown	Unknown	0	Unknown
12[c]	Boy	12	Female	Unknown	Unknown	1	Unknown
13[c]	Girl	10	Female	Unknown	Unknown	8	Unknown

[a]Educational level was considered low (primary and lower secondary), intermediate (secondary vocational), or high (Bachelor's degree or higher).

[b]Number of sessions until the date of the interview.

[c]Telephone interviews were conducted with a parent only.

Adherence to Hypnotherapy

Of the 66 children that did log into the website, 3 children did 1 exercise, 3 children did 2 exercises, 8 did 3 exercises, 8 did 4 exercises, and 44 children did all 5. Consequently, 52 of 76 (68.4%) children adequately adhered to the intervention. The children did on average 25.5 (SD 23.2) sessions (median 17, range 1 - 89), and listened to more than one exercise in an average of 6.8 (SD 9.0) sessions (median 4, range 0 - 43). Log data per exercise are described in Table 2.

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Table . Log data per exercise.

	Total	Exercise 1: breathing and relaxation	Exercise 2[a]: The favorite place	Exercise 2[b]: The favorite place and rainbow	Exercise 3[a]: The rainbow planet	Exercise 3[b]: The air balloon	Exercise 4: Beach without worries	Exercise 5: The slide
Duration (min:s)	—[c]	13:00	14:18	18:00	16:50	11:47	14:29	14:30
Duration listened, (min:s), median (minimum-maximum[d])	—	12:15 (00:05-26:30)	12:20 (00:05-28:40)	14:45 (00:05-22:15)	15:55 (00:05-34:20)	11:05 (00:05-13:40)	13:50 (00:05-31:00)	13:55 (00:05-36:50)
Children ever started (n)	66	66	50	11	46	10	51	51
Sessions per child, median (minimum-maximum)	17 (1 - 89)	4 (1-30)	5 (0 - 41)	2 (0 - 19)	5 (0 - 63)	3 (0 - 21)	3.5 (0 - 36)	3 (0 - 48)

[a]Exercise in the version for children aged <12 years.

[b]Exercise in the version for children aged ≥12 years.

[c]Not applicable.

[d]Maximum duration is higher than the exercise's length when children listened to the same exercise multiple times consecutively.

Experiences From Children and Their Parents

Overview

From questionnaire data and interviews, we found 6 themes that capture experiences from the children and their parents: impression of the exercises, not for everyone, influence of perceived effect, integrating exercises in daily life, content and practicalities of the website, and customization to personal preferences. For every quote, corresponding IDs from Table 1 are listed.

Impression of the Exercises

We found varying impressions of the therapy, ranging from nice, fun, and easy to stupid, boring, and difficult.

> *Then you have the feeling that you are really on a beach, and you can put all the feelings you don't want into a sand castle, so I really like that.* [Child 10]
>
> *The exercises themselves are a bit boring, because you have to keep doing the same thing every day.* [Child 2]

Most children felt relaxed during or after listening to an exercise and often had a positive association with a topic or liked the story in the exercises. The children enjoyed that they could choose what they wanted to see or do in their imagination.

> *And I really like the slide exercise because I like sliding a lot, and you can choose a color, and you can choose how fast you want to go.* [Child 1]

Although most of the children liked to visualize during the exercises, some of the children thought too little was happening. The children had conflicting ideas about exercises that required more physical activity such as stretching and relaxing muscles, or writing down colors and feelings.

> *I find the exercises boring because you just have to listen. I would rather have something to do, like filling in the colors of the rainbow planet.* [Child 1]
>
> *I liked just listening instead of having to actually do things.* [Child 5]

The children particularly enjoyed exercises in the beginning, when they were new and the children did not yet know what would happen. For some of the children, exercises became boring over time.

> *Because I know the exercise very well I can't really imagine anything different than what I do now when I listen to the exercise.* [Child 3]

The other children enjoyed knowing the exercises well.

> *Now I already know a few pieces by heart, so then I enjoy listening to them over and over again.* [Child 4]

Each exercise was experienced differently with diverse positive and negative aspects. An overview of impressions per exercise is presented in Multimedia Appendix 3.

Not for Everyone

From interviews with the parents it emerged that they expected both boys and girls with FAP or IBS to be suitable for hypnotherapy. However, some of the parents were more skeptical about a child's age or developmental level. Although children of all ages thought that the exercises were easy or somewhat childish, a few of the children noted that exercises were too difficult; they included difficult words or were spoken too fast. Some of the parents of children aged 7 or 8 years noted that their child was around the minimal age or level to remain focused for the entire exercise or understand why these exercises could help.

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> *If she is just a bit older maybe then it might be a bit more effective. That she would understand it a bit better, and be better able to recall things in certain situations.* [Mother 7]

The parents also noted that certain characteristics could help the children in doing hypnotherapy successfully, such as being calm, creative, less rational, and having patience and high imaginary skills. The parents mentioned that energetic children might benefit most from relaxing but might need more time and practice. Indeed, some of the children did not like that they had to sit or lay still.

> *Because then I start thinking, shall I sneak and read something or just keep my eyes open, because I'm bored. I can't sit still. Look, I'm always fidgeting with my fingers.* [Child 1]

Some of the children needed time to become used to the exercises and understand how to follow instructions. A few of the children were never able to surrender to the exercises because, for example, they could not imagine the suggestion, they did not like the stories, or they felt something and could not give in to the feeling.

> *My child often strongly resisted doing the exercises because they made her sleepy and she didn't want to give in to that. "Because of them I can't hear my own dreams anymore."* [Mother of girl aged 8 years, 24 sessions, reported in the questionnaire]

The parents mentioned that sometimes when their child was too energetic or too stressed from events or stimuli, they could not concentrate and do the exercises in order to relax.

> *Now I had the idea that it even worked against her, that she first had to deal with her own things, and that hypnotherapy… that it wouldn't go together.* [Mother 1]

Influence of Perceived Effect

Feeling an effect of the therapy affected experiences of the children. Although a few of the children experienced less abdominal pain but did not like the exercises, most did. Primarily because it made their belly feel good, or because their pain decreased or disappeared. They also experienced other effects such as greater confidence, better sleep, more energy, more relaxation, a clearer mind, and more frequent school attendance.

> *I really like it, because you know that it relaxes you a lot.* [Child 3]

When the children experienced less abdominal pain either through the exercises or for another reason, some of the children and parents felt less need to continue the exercises and quit.

> *When she was in pain and started an exercise, it helped to reduce the pain. But when she did not have pain, she did not feel like doing the exercises or see the benefit of them.* [Mother 13]

Some of the children were not able to relax during the exercises, and felt that the exercises did not help to remove their pain. They felt stressed because it did not work for them. Doing hypnotherapy felt like an obligation; this resulted in resistance or discontinuation.

> *We have decided not to do the exercises anymore because they led to more frustration than success.* [Mother of girl aged 9 years, 9 sessions, reported in the questionnaire]

Integrating Exercises in Daily Life

Many of the children enjoyed doing the exercises on their own, without involvement of others who could distract them. A few of the children mentioned that they would not do hypnotherapy in the presence of friends, because they would not like to explain what it is, or be different from their friends or classmates. The other children sometimes listened together with their parents or siblings which made them feel more relaxed. The parents also played an important role by reminding their children to do the exercises, because they did not come up with it themselves, were not in the mood, or forgot it.

> *Stimulate her to do the exercises. She doesn't think to do them or ask for them. So I have to motivate her a bit.* [Mother 1]

Most of the children listened to exercises before going to sleep. Taking a device to their room was sometimes difficult for the parents because they usually withhold their children from screen time before bedtime. The children and parents appreciated that the exercises were easily accessible for the children to listen at home where they felt comfortable and at ease, such as on their bed.

> *I really like that you don't have to go anywhere. That you can just sit or lie down in your own house, in your comfort zone.* [Child 8]

Most of the children accomplished making it a routine in their daily schedule which made listening to the exercises easier and more fun.

> *He definitely doesn't want to skip it in the evening. It becomes a kind of evening ritual: tooth-brushing, pajamas on and listen, and then to bed.* [Mother 8]

The parents appreciated being able to use this as a tool when necessary, such as when their child was stressed or energized and needed to relax. Not all of the children and parents managed to integrate hypnotherapy into their routine. Some of the children were put off by doing hypnotherapy again because of the time constraint. A few of the parents noted that there is not enough time in a day to add 15 minutes of hypnotherapy, because it was not feasible to do it before school or before bedtime.

> *Because sometimes the exercises are long, you sometimes practice a bit less, or maybe even not at all.* [Mother 9]

The parents from the children with low adherence mentioned that they never started hypnotherapy because the children and their parents could not find a good moment in the first place.

> *Several times we thought of it, but then we thought, ah, we'll do it later. And every time that later never came.* [Mother 11]

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Content and Practicalities of the Website

Information was perceived as clear and interesting, though there might have been somewhat too much information for younger children according to the parents. The distinction between exercises and explanation was not always clear on the website. The children thought that there was an extra exercise, but felt disappointed when they saw it was an explanation only.

Insight in log-in data (ie, a small red cross for not logging in, or a green check for logging in, both per day and weekly over the entire 3 months) was experienced both positively and negatively. For some of the children this insight motivated them to do the exercises and obtain more green checks, and for others this worked counterproductively; they felt frustrated, angry, or ashamed.

> *If I haven't practiced for a couple of weeks, for example, because I am busy, then I feel a bit, uh different, that I haven't done it right, that there will be red crosses.* [Child 3]

For most of the participants, the website functioned well technically. However, some of the children experienced that the exercise stopped when the screen automatically turned off. This got them out of their concentration and affected their experiences negatively.

> *So then she's totally caught up in the story, and then she has to turn all the way around, click on that thing and install herself again.* [Mother 1]

The children preferred using different devices, such as a smartphone, tablet, or computer. Many of the participants noted that a website was unpractical, since the children needed to fill in their log-in codes every time, were dependent on a parent nearby, or were unable to do it on the go. Sometimes, this made doing the exercises a barrier for the children. The parents suggested the use of an app instead of a website.

> *If he could just do it in an app, that you just use a password one time and then you can just turn it on, then it would have been easier and he would have done it more quickly.* [Mother 6]

Customization to Personal Preferences

The first aspect that the children would have liked to customize is appearance of the website and the exercises. The children and parents would have preferred to choose from different voices which can differ in speed. Overall, the children liked the looks of the website, but they had different ideas: some liked it simple as it is, others would have liked brighter colors such as pink and purple. The children would have liked to choose between colors on the website, change the background, and add illustrations to the exercises.

> *I thought that the colors could have been brighter. And just as with the iPad you can choose a background, I would like that you could also choose a background here. It really doesn't look so nice, so you think, now, I'm going to do some ZelfHy exercises.* [Child 1]

The second aspect that the children and parents would prefer to customize relates to the content. Most importantly, the participants would have liked more exercises. Only a few of the participants found 5 exercises sufficient. Animals, love, music, flowers, favorite animation, traveling, games, hobbies, and sports were recommended by the children as preferred topics to add more attractive exercises. According to the parents, topics should also be suitable for a child's age or level to be more effective.

> *Because I notice that not every exercise is suited for her. That you could better, yeah, make more personalized exercises. And with things going on in her own environment, because that is, of course, different for a 7-year-old than for a 17-year-old.* [Mother 7]

Additionally, choosing from exercises with different duration, particularly exercises of shorter duration (eg, between 5 and 10 min) is expected to enhance adherence. Shorter exercises would allow children to do an exercise quickly during a weekday, and to combine more exercises in 1 session. In contrast, a few of the parents hypothesized that shorter exercises might yield less effect than long exercises. The participants noted that a combination of shorter and longer exercises would be nice. Longer exercises are deemed useful in the beginning, and once children understand how they work, shorter exercises are expected to keep children more focused and satisfied.

> *I certainly think that the more often you practice, then I can imagine that at a certain point you want to go through such an exercise more quickly, because you have already formed a certain image of it, or you have given it certain colors, or you have associated a certain emotion with it. Then it doesn't have to take so much time.* [Mother 6]

Some of the participants noted that it would be more motivating if the website contained games, or if they could unlock new exercises. The parents also noted that a scoring or rewarding system could help to increase adherence.

> *You could attach a kind of gamification to it, so that the child gets a certain reward when she has done it, so that she wants to do the exercises.* [Father 4]

Discussion

Principal Results

Adherence to hypnotherapy varied greatly: some of the children never started hypnotherapy, some only logged in a handful of times, and most of the children adequately adhered to hypnotherapy by starting at least four exercises. The children experienced home-based guided hypnotherapy differently, both in general and per exercise. From interviews with the parents it emerged that hypnotherapy was sometimes difficult for those children who were young or had a low developmental level, could not sit still or surrender to the exercise, or were too energetic or stressed. Experiences were shaped by the influence of perceived effects, the ability to integrate exercises in daily life, and content and practicalities of the website. Ultimately, the children and parents would appreciate a therapy that can be customized to personal preferences for appearance and content.

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Comparison With Prior Work

This is the first study to evaluate experiences of children and their parents with home-based guided hypnotherapy, other studies evaluated other self-guided interventions for children with abdominal pain. A mixed methods study assessing an online self-guided intervention found that children aged 9 - 15 years were satisfied with the intervention [22]. In our sample, we found more variation in the children's experiences, ranging from boring to fun. Possible explanations for this disparity could be that we included a larger sample, also included children with low adherence, and that children with questionnaire data had a broader age range, namely 7 - 17 years. Notably, it was a different intervention and this study showed that characteristics of the website or intervention also influence a child's experiences. The mixed methods study found that children learned to cope with their pain through relaxation or distraction and felt better in general [22]. This is consistent with our findings that experiences of children were influenced by a perceived effect.

In our study, a long duration of the exercises was one of the reasons why everyday adherence was difficult. Some children easily integrated the exercises into daily life, but others had difficulties to make it a routine. The parents who motivated and stimulated their child to listen to an exercise were helpful in integrating exercises in daily life. A mixed methods study assessing a guided imagery app also found no consensus on preferable exercise duration when asking children and parents [23]. In contrast, another study assessing guided imagery found that sessions lasting 10 to 25 minutes were enjoyable, children needed no help or reminders from parents, and most children listened to the exercises more often than instructed [24]. Our results add to the knowledge that preferences for duration of exercises are dependent on children's characteristics, ability to do the exercises, parental involvement and ability to integrate exercises in daily life. Home-based guided hypnotherapy that includes exercises with varying durations would allow that it is suitable and fitting for everyone, because it can be adjusted to children's preferences and time available at that moment.

The children and parents liked the look of the website in general, and a few experienced small technical issues that negatively affected their experience. Another study also mentioned small technical issues in an online intervention [25]. Consistent with a previous study using an app, the log-in procedure was easy [23]. However, in our study, the log-in procedure was also perceived as inconvenient, because it was not easy to use on the go. The parents suggested that an app could solve this inconvenience. A study assessing desirable components in a digital management app for children with long-term, chronic conditions found no agreement on preferences for either a website that is suitable on multiple devices versus an app [26]. This is consistent with our results and suggests that an app is favored, but flexibility of use on other devices should also be taken into account.

This study amplifies what has been found before, that children enjoy being able to do an intervention at home. eHealth interventions can increase adherence to treatment and improve outcomes which might influence effectiveness of the therapy [20,27]. Between the children and parents, there are many individual preferences regarding number and duration of exercises, topics, voices, and looks. Additionally, the child's age or level plays an important role. Consistent with prior literature, rewarding systems or gamification is important in eHealth interventions for children [23,28]. Our study emphasizes the importance of tailoring hypnotherapy to children's age or developmental level, customizing it according to their personal preferences regarding appearance and content, and incorporating gamification components to enhance engagement.

Strengths and Limitations

An important strength of this study is that we interviewed both children and their parents, with varying adherence ranging from zero adherence to daily adherence for 3 months. Interviews with the parents followed after interviews with children and allowed for more depth. Interviews were performed in their home environment, which allowed for a safe environment, and we therefore believe that we captured honest answers.

One limitation is that we primarily interviewed children and young adolescents (age range 7 - 13 y). Therefore, our results might not be generalizable to adolescents. We aimed to interview adolescents aged 14 to 17 years old, but failed because very few adolescents participated in the RCT. Although questionnaire data did include adolescents, and we included an adolescent for member checking, more research is needed on experiences of hypnotherapy among adolescents. Another limitation is that we failed to interview more fathers, as they were not at home during the interview. We believe that this minority of fathers did not influence our study results, because the 2 included fathers did not introduce new themes.

Clinical and Research Implications

This study highlights the importance of personalized home-based guided hypnotherapy to improve a child's experience, and possibly to increase adherence. This is of essence in eHealth, where patients themselves are responsible for following the therapy. Hypnotherapy that is fun to do at home and fitted to each child might be easy to adhere to and more prompting for GPs to promote. Primary care might be a beneficial setting for home-based guided hypnotherapy, as GPs manage most children with these complaints. Providing a self-managing intervention in this setting might prevent referrals to pediatric care and reduce costs [29,30].

Conclusions

The children's and parents' experiences varied greatly and were partly influenced by the topic or story in the exercise. For children who are young or have a low developmental level, cannot sit still, are unable to surrender to exercises, or are too energetic or stressed, home-based guided hypnotherapy might be difficult and needs optimization. Children liked hypnotherapy when they felt positive effects, could easily integrate the exercises in their daily life, or enjoyed the website's content and usability. Children who did not feel effects or found exercises too long often disliked hypnotherapy. A website or an app that is easily accessible and contains short exercises could increase its use. Hypnotherapy that is adaptable to personal preferences on appearance and content could boost the

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experiences. In turn, positive experiences might lead to higher adherence, which potentially increases the effect of hypnotherapy and should be studied further.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Open-ended questions from the questionnaire.
[DOCX File, 14 KB - pediatrics_v8i1e58301_app1.docx]

Multimedia Appendix 2
Interview guides.
[DOCX File, 18 KB - pediatrics_v8i1e58301_app2.docx]

Multimedia Appendix 3
Impressions per exercise.
[DOCX File, 17 KB - pediatrics_v8i1e58301_app3.docx]

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Abbreviations

FAP: functional abdominal pain
GP: general practitioner
IBS: irritable bowel syndrome
RCT: randomized controlled trial

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Digital Interventions for Patients With Juvenile Idiopathic Arthritis: Systematic Review and Meta-Analysis

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Abstract

Background: Juvenile idiopathic arthritis (JIA) is a chronic rheumatic condition requiring long-term, multidisciplinary treatment, which consumes significant health care resources and family energy. This study aims to analyze the effectiveness of digital interventions on patient outcomes in individuals with JIA.

Objective: This meta-analysis aimed to evaluate the impact of digital interventions on alleviating symptoms and improving overall well-being in children and adolescents with JIA.

Methods: A systematic search of 5 databases identified randomized controlled trials assessing the impact of digital interventions on physiological and psychological outcomes in adolescents and children (average age ≤19 y). Outcomes included pain, physical activity, health-related quality of life, self-efficacy, and disease-related issues. A total of 2 reviewers independently screened papers and extracted data on intervention functionalities and outcomes, assessing the risk of bias. A meta-analysis using a random-effects model synthesized the results.

Results: The review included 11 studies involving 885 patients with JIA. Digital interventions included educational (eg, self-management training), therapeutic (eg, pain management), and behavioral (eg, promoting physical activity) approaches. These were delivered through websites, telephone consultations, video conferences, apps, and interactive games, with durations ranging from 8 to 24 weeks and no clear link observed between intervention length and outcomes. Compared with conventional control groups, digital interventions were significantly effective in alleviating pain (standardized mean difference [SMD] −0.19, 95% CI −0.35 to −0.04) and enhancing physical activity levels (SMD 0.37, 95% CI 0.06-0.69). Marginal improvements in health-related quality of life, self-efficacy, and disease-related issues were observed, but these did not reach statistical significance (SMD −0.04, 95% CI −0.19 to 0.11; SMD 0.05, 95% CI −0.11 to 0.20; and SMD 0.09, 95% CI −0.11 to 0.29, respectively). The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach rated the quality of evidence for pain, health-related quality of life, self-efficacy, and disease-related issues as moderate, while the evidence quality for physical activity was assessed as low.

Conclusions: Digital interventions can alleviate pain and enhance physical activity in patients with JIA. However, given the limited sample size and high risk of bias in some studies, further high-quality research is needed to improve the treatment and management of JIA.

Trial Registration: PROSPERO CRD42023471223; https://www.crd.york.ac.uk/PROSPERO/view/CRD42023471223

(JMIR Pediatr Parent 2025;8:e65826) doi:10.2196/65826

KEYWORDS

juvenile idiopathic arthritis; digital intervention; application; children health care; pediatrics

Introduction

Juvenile idiopathic arthritis (JIA) is a prevalent chronic rheumatic ailment affecting children, causing joint pain and inflammation that can disrupt their daily lives [1]. During flare-ups, it can hinder academic performance, social interactions, and normal activities [2], while the complexity of treatment and associated complications further strain health care systems and drive up costs [3-6]. Since JIA requires ongoing monitoring and treatment [7,8], patients face a lifelong responsibility for managing the disease as they grow older [9]. Consequently, patients are encouraged to actively engage in lifestyle modifications and health-related decision-making [10]. Physical activity, including aerobic fitness and strength training, is recognized as a helpful nondrug intervention, offering

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potential benefits in improving overall well-being and lessening the impact of JIA symptoms [11-13].

Internet-based digital tools, including mobile applications, websites, and other platforms, have become essential components of nonpharmaceutical interventions. These tools enable remote interaction and offer timely responses, making health care resources more accessible [14]. They can provide tailored rehabilitation interventions for pediatric chronic diseases and transitional care [15], such as fostering healthy behavioral habits through social media–based peer coaching [16]. Several mobile medical applications have been developed for adolescents and young individuals with JIA [17-22]. However, the research on their effectiveness has yielded varied results. While some studies have shown promising outcomes in terms of pain alleviation and physical function improvement, others have not replicated these results [22-24]. This variability in research findings highlights the need for further investigation and systematic evaluation to better understand the most effective components and digital health solutions in this domain, ensuring an accurate assessment of the evidence.

To date, previous reviews have assessed the effectiveness of mobile and e-medical interventions in aiding children and adolescents with JIA [25,26]. However, existing reviews have not focused on analyzing randomized controlled trials (RCTs), which could yield more precise results and reduce heterogeneity. The inclusion of only a minimal number of relevant outcomes (n≤3) in some meta-analyses, such as physical activity, limits the interpretation of findings cautiously and results in the absence of an effective theory of digital interventions for patients with JIA. Consequently, it remains unclear whether such interventions enhance clinical outcomes. Furthermore, as research on mobile medical interventions for JIA patients continues to evolve, it is essential to promptly integrate new research findings. This underscores the necessity for a fresh comprehensive evaluation of clinical interventions in this domain.

Therefore, our study aims to address these gaps by conducting a thorough analysis of digital interventions and their impact on clinical outcomes for patients with JIA.

Methods

Overview

This study follows the guidelines published in Preferred Reporting Items for Systematic reviews and Meta-Analyses [27] and the Cochrane Handbook of Systematic Reviews [28]. The priori protocol for the review is published in the International Prospective Register of Systematic Reviews (PROSPERO CRD42023471223).

Search Strategy

The research was conducted with the guidance and support of institutional librarians. A subject-specific librarian, along with researchers ZR and YC, developed a search strategy without language restrictions, which was used to conduct a comprehensive search in PubMed, Embase, Cochrane Library, Ovid, and Medline [29], covering records from the earliest available to the latest date. The search used Boolean operators in combination with Medical Subject Headings terms and free-text keywords to identify studies on the impact of digital interventions on JIA. The following search string was used as an example: (“Juvenile Idiopathic Arthritis” OR “Pediatric Rheumatic Diseases” OR “Juvenile Chronic Arthritis”) AND (“mHealth” OR “Digital Health” OR “Mobile Health”) AND (“Randomized Controlled Trial” OR “RCT” OR “Clinical Trial”). The full search strategy is provided in Multimedia Appendix 1, the specific keywords used for the search are provided in Multimedia Appendix 2.

The studies identified through this strategy were managed through the literature management software, Zotero (Corporation for Digital Scholarship). The 2 authors, ZR and YC, screened the identified studies, in line with predefined inclusion and exclusion criteria. Any discrepancies during this process were resolved through discussion between the researchers. Multimedia Appendix 1 shows the detailed search formulas. RCTs of any design, including crossover, multicenter, and cross-over trials, that were published in English are included in this review.

Participants

Episodes of JIA typically manifest in individuals before the age of 16 years [30]. However, considering the chronic nature of the condition and the need for ongoing treatment, the minimum age for inclusion in international pediatric treatment reference populations has risen to an average of 18.7 (SD 2.6) years.

Hence, for the purpose of this review, the term “children and adolescents” refers to individuals between the ages of 1 and 19 years [31]. The study population comprises children and adolescents diagnosed with JIA by a rheumatologist, ranging from 1 to 19 years old. Infants and neonates under the age of 1 year were excluded from the study population.

Intervention

In assessing the effectiveness of interventions for JIA recovery, the study focused on digital platforms such as somatic gaming, smart applications, teleconferencing, televideo, and health websites.

Control Condition

All types of control groups were considered in this study, including waitlists, physical therapy or minimal intervention groups, alternative treatments, and standard care delivered through web-based health care websites and apps. For example, the control group may use platforms like jong-en-reuma.nl, which provides information on medical issues and emotional support [32].

Outcome

Primary Outcome

There were 2 primary outcomes: pain (47-item Recalled Pain Inventory and 11-point Numeric Rating Scale) and physical activity (7-day activity diary [subjective], accelerometer [objective measurement], and Duruoz Hand Index Questionnaire.

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Secondary Outcome

There were 2 secondar outcomes: health-related quality of life (Juvenile Arthritis Quality of Life Questionnaire, Pediatric Quality of Life Arthritis Module, Dutch Consensus Health Assessment Questionnaire Disability Index, and Pediatric Quality of Life Inventory [version 4.0]), self-efficacy (Children's Arthritis Self-Efficacy scale and Dutch Arthritis Self-Efficacy Scale), and illness-related issues (Medical Issues, Exercise, Pain, and Social Support questionnaire).

Risk of Bias

Risk of bias was assessed using the risk of bias tool of the Cochrane Handbook for Systematic Reviews [28]. Quality of evidence for outcomes was assessed according to the 5 Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) domains, including study limitation (risk of bias), inconsistency, indirectness, imprecision, and publication bias [33]. The bias was assessed by the 2 independent authors, ZR and YL. Any discrepancies were resolved through discussion and reexamination within the research group.

Data Extraction and Analysis

In order to identify and present common statistical descriptions of methodological heterogeneity, a descriptive integrated methodology was used. All findings were interpreted within the context of each study, considering the total number of studies and the assessed risk of bias. Using Review Manager (RevMan) software (version 5.4; Cochrane), this study conducted a random-effect meta-analysis to compare the standardized mean difference (SMD) for parameters across at least 3 studies between patients receiving general care and those using internet-based interventions. SMD and 95% CI were calculated using baseline and study end scores inputted into RevMan 5.4. Forest plots were generated using random-effect models for continuous data, presenting a summary of the effect distribution. Cohen's general rule of experience was applied, where an SMD of 0.2 signifies a "small" effect, 0.5 denotes a "moderate" effect, and 0.8 indicates a "large" effect. Furthermore, subgroup analysis was conducted to assess the impact of professional caregivers and intervention tools on the efficacy of e-medical intervention outcomes. Heterogeneity within the compiled studies was evaluated using I^2 statistics, and the carat test was used to assess significance. Heterogeneity levels were classified as low (I^2<25%; P>.1), moderate (I^2=25% - 49%), or high (I^2>50%).

Results

Literature Selection

We initially identified 1155 studies. After excluding duplicate studies (n=296) and irrelevant studies (n=694), 165 studies remained for abstract evaluation. A total of 154 studies were excluded for the following reasons: conference proceedings (n=47), not trials (n=28), and not RCTs for JIA (n=79). Ultimately, 11 RCTs were included in the meta-analysis. The screening process is illustrated in Figure 1.

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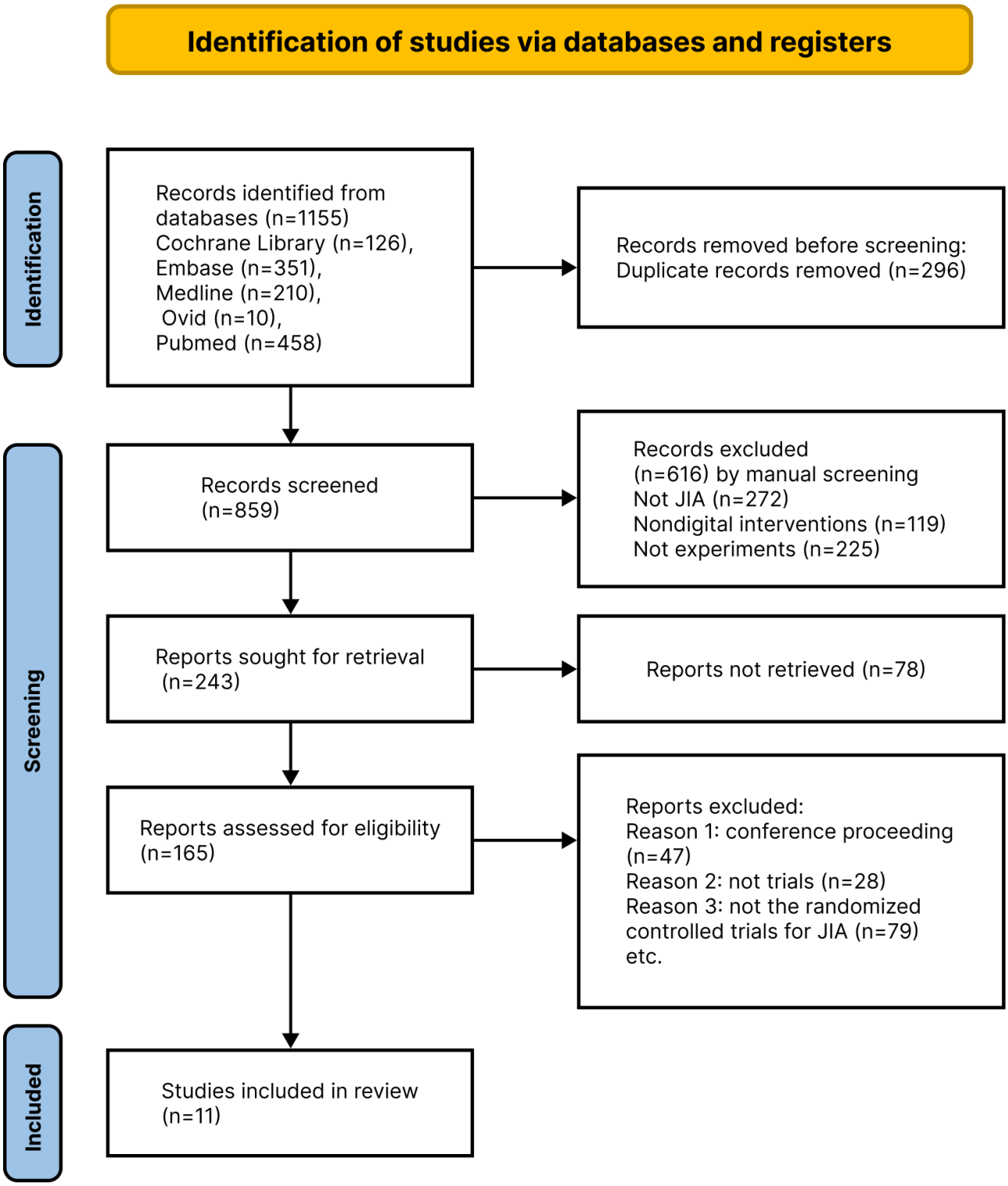
Figure 1. Summary of the study selection process using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses). JIA: juvenile idiopathic arthritis.



Participant Statistics

Table 1 shows the population characteristics, interventions, outcomes and study types of the 11 studies. Of these studies, 3 were from the Netherlands [32,34,35], 5 from Canada [36-40], and 1 each in the United States, Switzerland, and Turkey [38,40,41]. These studies included 289 individuals, predominantly female children and adolescents (663/885, 74.9%). A variety of juvenile arthritis subtypes were observed, with oligoarthritis being the most prevalent subtype (259/885, 29.3%). Almost all studies, with the exception of one [42], accounted for disease activity. The duration of the disease since diagnosis was documented in the majority of studies (7/11) [32,35-37,39,40,42].

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Table . Population characteristics, interventions, outcomes, and study types of the 11 studies.

Author, country	Particular year	Average age (years)		Percentage of women, n/N (%)		Subtypes of JIA[c]	Participants		Outcomes	Type of study
		IG[a]	CG[b]	IG	CG		IG	CG		
Lelieveld et al [34], the Netherlands	2010	10.6 (1.5)[d]	10.8 (1.4)[d]	15/16 (88)	14/16 (88)	55% Persistent oligoarticular, 6% extended oligoarticular, 27% polyarticular, and 12% systemic	Internet-based meeting	__[e]	Physical activity level, number of days with ≥1 hour of moderate to intense activity per day, aerobic capacity, maximum heart rate, and resting heart rate.	Pilot randomized controlled trial
Stinson et al [36], Canada	2010	14.4 (1.3)[d]	14.8 (1.7)[d]	15/22 (68)	16/24 (67)	22% oligoarticular, 9% oligoarticular-extended, 24% polyarticular (RF–)[f], 7% polyarticular (RF+), 7% systemic, 7% psoriatic, 20% enthesitis-related, and 7% Unknown or other	Internet intervention	Attention control	Healthy life-related quality (primary outcome), pain intensity, stress, knowledge, adherence, and self-efficacy (secondary outcomes)	Experimental randomized controlled trial

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Author, country	Particular year	Average age (years)		Percentage of women, n/N (%)		Subtypes of JIA[c]	Participants		Outcomes	Type of study
		IG[a]	CG[b]	IG	CG		IG	CG		
Stinson et al [37], Canada	2016	14.11 (1.53)[d]	14.42 (2.04)[d]	17/18 (94)	14/14 (100)	19% Polyarthritis (RF positive), 19% polyarthritis (RF negative), 3% polyarthritis (RF status unknown), 31% oligoarthritis, 25% psoriatic arthritis, and 3% enthesitis-related arthritis	Skype group	Standard care only	Feasibility (primary outcome) Self-management, self-efficacy, pain, social support, and health-related quality of life (secondary outcome)	Experimental randomized controlled trial
Ammerlaan et al [32], the Netherlands	2017	19.1 (2.7)[d]	19.1 (2.9)[d]	29/35 (83)	30/32 (94)	21% Oligoarticular JIA, 36% polyarticular JIA, 12% systemic JIA, and 31% other	Specific internet project intervention and designated website	Standard care and designated website	Self-efficacy (primary outcome), self-management, disease activity, health-related quality of life absence from courses , medication use, and adherence (secondary outcomes)	Randomized controlled trial

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Author, country	Particular year	Average age (years)		Percentage of women, n/N (%)		Subtypes of JIA[c]	Participants		Outcomes	Type of study
		IG[a]	CG[b]	IG	CG		IG	CG		
Armbrust et al [35], the Netherlands	2017	9.7 (8.7 - 11.3)[g]	10.2 (9.0 - 10.8)[g]	21/28 (75)	12/21 (57)	24% Persistent oligoarticular JIA, 14% extended oligoarticular JIA, 37% polyarticular JIA, 4% rheumatoid factor positive, 4% enthesitis-related JIA, 4% psoriasis-related JIA, and 12% systemic JIA	Internet intervention, school and physical education	Access to standard care, school and physical education	Physical activity (primary outcome), exercise capacity, healthy life–related quality, disease activity, functional capacity, pain and well-being, and school engagement (secondary outcomes)	Multicenter randomized controlled trial
Ramelet et al [43], Switzerland	2017	—[h]	—	8/14 (57)	6/10 (60)	29% enthesitis-related JIA, 5% undifferenciated JIA, 27% oligoarticular JIA, 7% polyarticular JIA, 2% systemic JIA, and 30% other	Medical and telephone care consultations	Medical consultations only	Satisfaction (primary outcome), morning stiffness, and pain (secondary outcome)	Cross-over randomized clinical trial
Arman et al [42], Turkey	2019	12.36 (2.98)[d]	13.16 (3.35)[d]	21/25 (84)	21/25 (84)	44% oligoarticular JIA and 56% polyarticular JIA	Practice everyday activities with video-based games (Xbox 360 Kinect)	Practice daily activities with real-life materials	Upper extremity function (primary outcome), pain, upper extremity muscle strength, grip and pinch strength, and time-based activity performance (secondary outcome)	Randomized clinical trial

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Author, country	Particular year	Average age (years)		Percentage of women, n/N (%)		Subtypes of JIA[c]	Participants		Outcomes	Type of study
		IG[a]	CG[b]	IG	CG		IG	CG		
Chadi et al [38], Canada	2019	15.4 (13-18)[i]	15.2 (13-17)[i]	7/9 (78)	7/9 (78)	—	Take video conferencing courses at home	Take offline courses in hospital	Acquisition of positive thinking skills (primary outcome), mood and anxiety, self-esteem, illness perception, salivary cortisol changes (secondary outcome)	Pilot randomized controlled trial
Connelly et al [41], United States	2019	14.6 (1.8)[d]	14.5 (1.7)[d]	98/144 (68)	111/145 (77)	21% Oligoarticular (extended or persistent), 45% polyarticular (RF-, RF+ ,or RF unknown), 34% other (enthesitis-related JIA, psoriatic, systemic, and undifferentiated)	Teens taking charge	An educational website	Pain interference and intensity, health-related quality of life (primary outcome), self-efficacy, pain coping, emotional regulation, and condition knowledge (secondary outcome)	Multicenter randomized clinical trial
Stinson et al [39], Canada	2020	14 (1.5)[d]	14.5 (1.7)[d]	63/88 (72)	91/131 (70)	2% Systemic, 21% oligoarthritis, 11% oligoarthritis—extended, 23% polyarthritis (RF-), 9% polyarthritis (RF+), 11% psoriatic arthritis, 16% enthesitis-related arthritis, 4% undifferentiated, and 3% other	Specific website and phone consultations	Public website and telephone consultation	Pain intensity, pain interference and HRQL[j] (primary outcomes), emotional symptoms, compliance, coping, knowledge, and self-efficacy (secondary outcomes)	Randomized controlled trial

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Author, country	Particular year	Average age (years)		Percentage of women, n/N (%)		Subtypes of JIA[c]	Participants		Outcomes	Type of study
		IG[a]	CG[b]	IG	CG		IG	CG		
Lalloo et al [40], Canada	2021	14.9 (1.7)[d]	15.1 (1.6)[d]	23/29 (79)	24/31 (77)	5% Systemic, 16% oligoarthritis, 9% oligoarthritis-extended, 24% polyarthritis (RF–), 5% polyarthritis (RF+), 12% psoriatic arthritis, 21% enthesitis-related arthritis, 5% undifferentiated, and 3% other	iCanCope application version, including symptoms tracking and other functions	A version of icancope that only contains the symptom following feature	Participant accrual and attrition rates, success rate of app deployment, acceptability and compliance (primary outcomes), pain intensity, pain-related activity limitations, and health-related quality of life (secondary outcomes)	Randomized controlled trial

[a]IG: intervention group.
[b]CG: control group.
[c]JIA: juvenile idiopathic arthritis.
[d]Mean (SD).
[e]Not available.
[f]RF: rheumatoid factor.
[g]Median (IQR).
[h]This study only showed the mean age of the overall group (13.1 years).
[i]Median (age range).
[j]HRQL: health-related quality of life.

Intervention Group

Overview

Table 2 demonstrates main digital tools and methods. A total of 6 studies implemented internet-based physical activity intervention programs, health management websites, and telephone support initiatives. Among these, 4 studies included routine telephone consultations and interviews. In addition, 1 study used video conferences for skills training [38], while another used self-management pain applications on mobile phones for experimentation [40]. In addition, an emotional games-based task-oriented activity training study was conducted [42]. All interventions examined lasted at least 8 weeks, with the longest intervention cycle spanning 18 months [35].

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Table . Main intervention methods.

Author, country	Digital tools or methods					Duration of intervention
	Specific websites	Telephones	Videoconferencing	Application	Somatosensory game	
Lelieveld et al [34], the Netherlands	✓					17 weeks
Stinson et al [36], Canada		✓				12 weeks
Stinson et al [37], Canada		✓				8 weeks
Ammerlaan et al [32], the Netherlands	✓					24 weeks
Armbrust et al [35], the Netherlands	✓					18 months
Ramelet et al [43], Switzerland		✓				12 months each
Arman et al [42], Turkey					✓	8 weeks
Chadi et al [38], Canada	✓		✓			8 weeks
Connelly et al [41], United States	✓					12 weeks
Stinson et al [39], Canada	✓	✓				12 weeks
Lalloo et al [40], Canada				✓		8 weeks

Functional Classification of Interventions

Digital interventions for patients with JIA are versatile, serving multiple functions. The purposes of these interventions include promoting physical activity (n=4), facilitating self-management for establishing healthy habits and reaching milestones (n=4), providing education on disease and health-related knowledge (n=8), offering stress relief to improve mood (n=4), and enhancing communication skills for better integration into school and society (n=7). Furthermore, half of the studies (n=7) supplemented the digital intervention program with telephone and video communication to augment its positive impact on children.

Statistics of Digital Interventions

A total of 8 studies used internet-based interventions based on previously developed projects or applications (Table 3). In addition, 3 studies used the Teens Taking Charge website as an intervention [36,39,41]. Furthermore, 2 studies used Rheumates@Work as an intervention [34,35]. For the experimental group's digitization project, 1 study used iPeer2Peer [37], Challenge your arthritis [32], and iCanCope [40]. Of all the intervention schemes, only 1 study referenced the theoretical framework as nursing guidance for their intervention schemes [43]. Care assessments conducted by nurses were guided and documented using Cox's interaction model of client health behavior [44] to ensure the continuity of care for children and their families.

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Table . Names and functions of digital intervention tools.

Author, country	Intervention project name	Main functions					Additional functions
		Promote physical activity	Set goals	Health education	Manage emotions	Integrate into school or society	Video or phone consultation
Lelieveld et al [34], the Netherlands	Rheumates@Work	✓		✓			
Stinson et al [36], Canada	Teens Taking Charge	✓	✓	✓	✓	✓	✓
Stinson et al [37], Canada	iPeer2Peer			✓	✓	✓	✓
Ammerlaan et al [32], the Netherlands	Challenge your arthritis		✓			✓	
Armbrust et al [35], the Netherlands	Rheumates@Work	✓		✓		✓	
Ramelet et al [43], Switzerland	__[a]			✓		✓	✓
Arman et al [42], Turkey	Xbox 360 Kinect	✓					
Chadi et al [38], Canada	—			✓	✓		✓
Connelly et al [41], United States	Teens Taking Charge			✓	✓		✓
Stinson et al [39], Canada	Teens Taking Charge		✓			✓	✓
Lalloo et al [40], Canada	iCanCope		✓	✓		✓	

[a]Not available.

While enhancing self-management skills is vital for facilitating health care transition [45], only 2 RCTs [32,37] explicitly reported on self-management outcomes. The remaining articles primarily integrated self-management as a core component of digital interventions, with considerations on health education, goal setting, and mood management.

Control Group

One study in this review did not specify the care received by the control group [34]. A total of 5 studies compared the intervention group to a control group that received standard or offline care (without internet and eHealth interventions) [35,37,38,42,43]. One study solely used telephone coaching communication [36]. A total of 4 studies compared a control group using a public website or eHealth with limited functionality to an intervention group receiving a specific digital design program [32,39-41]. The control groups in all trials assessed patients' results at pretest and posttest.

Risk of Bias Assessment

The results of the risk of bias assessment indicate that the criteria most commonly unmet were the blinding of outcome assessment and the adequacy of outcome data (Figure 2). Half of the studies (5/11 and 6/11) were deemed to have a high risk of bias in these 2 categories. In contrast, studies concerning randomized sequence generation were predominantly evaluated as having a low risk (9/11). Furthermore, 7 studies exhibited a medium risk of bias, while 4 studies were categorized as having a high risk of bias.

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Figure 2. Risk of bias summary [32,34-43].

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Quality of Evidence Rating

Table 4 presents the key comparative results with GRADE ratings. A total of 3 primary outcomes are rated as moderate quality, while 2 primary outcomes are rated as low quality.

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Table . Main comparative findings and recommendation grading.

Author (Year of publication)	Outcome	OR[a] (95% CI)	Studies (patients), n	Risk of bias	Inconsistency	Indirectness	Inaccuracy	Publication bias	Quality of evidence
Stinson et al [36] (2010), Stinson et al [37] (2016), Ammerlaan et al [32] (2017), Connelly et al [41] (2019), and Stinson et al [39] (2020).	Pain	−0.19 (−0.35 to −0.04)	5 (653)	Downgrade (High risk of incomplete data)	Nondegradation	Nondegradation	Nondegradation	Nondegradation	Moderate
Lelieveld et al [34] (2010), Ammerlaan et al [32] (2017), Armbrust et al [35] (2017), and Arman et al [42] (2019).	Physical activity	0.37 (0.06-0.69)	4 (160)	Downgrade (High risk of selective reporting)	One level down (low overlap)	Nondegradation	Nondegradation	Nondegradation	Low
Stinson et al [36] (2010), Stinson et al [37] (2016), Ammerlaan et al [32] (2017), Armbrust et al [35] (2017), Connelly et al [41] (2019), and Stinson et al [39] (2020).	Health-related quality of life	−0.02 (−0.17 to 0.13)	6 (702)	Downgrade (High risk of incomplete data)	Nondegradation	Nondegradation	Nondegradation	Nondegradation	Moderate
Stinson et al [36] (2010), Stinson et al [37] (2016), Ammerlaan et al [32] (2017), Connelly et al [41] (2019), and Stinson et al [39] (2020).	Self-efficacy	0.05 (−0.11 to 0.20)	5 (653)	Downgrade (High risk of incomplete data)	Nondegradation	Nondegradation	Nondegradation	Nondegradation	Moderate
Stinson et al [36] (2010), Stinson et al [37] (2016), Chadi et al [38] (2019), Connelly et al [41] (2019), and Stinson et al [39] (2020).	Disease-related issues	0.09 (−0.11 to 0.29)	5 (604)	Downgraded one level (high risk of blinding of outcome assessments)	One level down (low overlap)	Nondegradation	Nondegradation	Nondegradation	Low

[a]OR: odds ratio.

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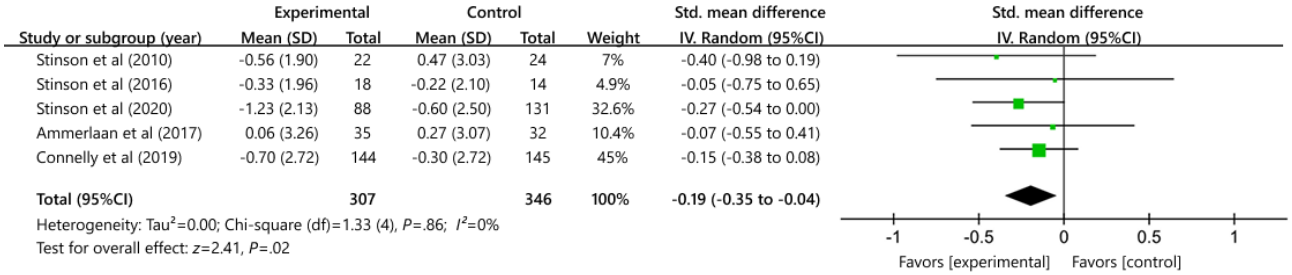
Meta-Analysis Results

Pain

Figure 3 depicts the impact of digital medical intervention on pain outcomes relative to all other control conditions. This analysis is based on findings from 5 studies involving 653 participants. A significant effect in favor of the intervention was observed (SMD −0.19, 95% CI −0.35 to −0.04; P=.86; I^2=0%). Several studies posed a high risk of bias, resulting in a moderate GRADE rating for the quality of evidence after the intervention.

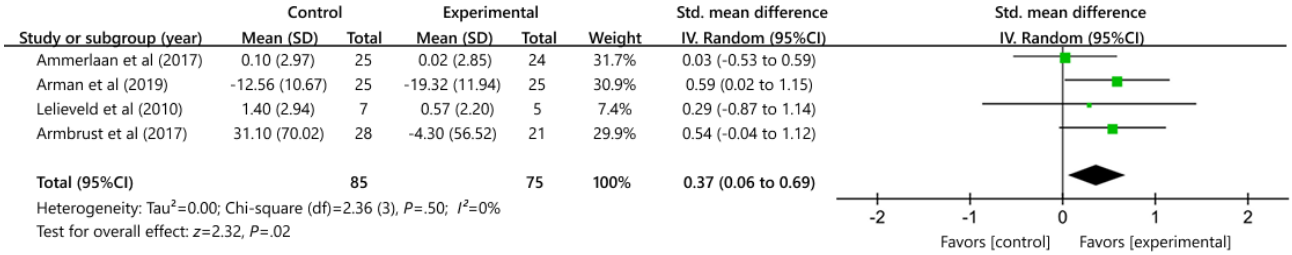
Figure 3. Effectiveness of digital health on pain outcomes [32,36,37,39,41].



Physical Activity

Figure 4 demonstrates the results of the effectiveness of using digital health care on patients' physical activity compared to using usual care and public websites. This analysis is based on findings from 4 studies involving 160 participants. The digital intervention had a statistically significant positive effect (SMD 0.37, 95% CI 0.06-0.69), and the results were not highly heterogeneous (P=.50; I^2=0%). Several studies posed a moderate-to-high risk of bias and inconsistency, resulting in a low GRADE rating for the quality of evidence after the intervention.

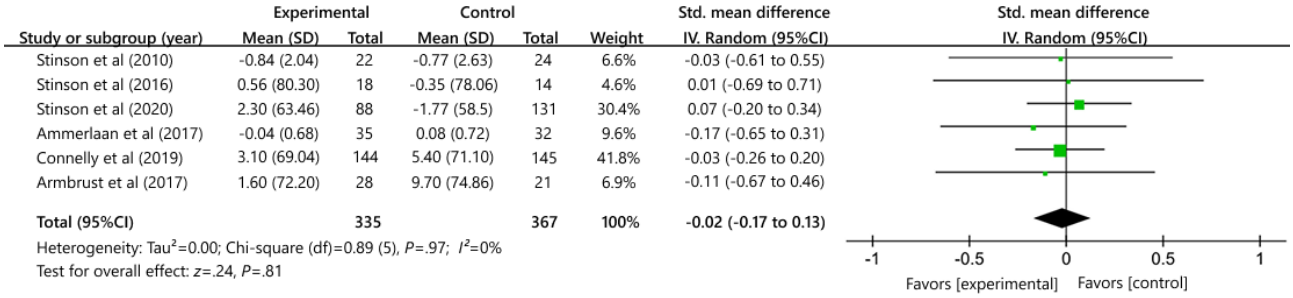
Figure 4. Effectiveness of digital health on physical activity outcomes [32,34,35,42].



Health-Related Quality of Life

A total of 6 studies with 702 participants comparing digital interventions and control conditions did not show a difference in health-related quality of life between the 2 intervention conditions (SMD 0.02, 95% CI −0.17 to 0.13); heterogeneity (P=.97; I^2=0%; Figure 5). Using the GRADE approach, the quality of evidence was rated moderate because of the high risk of bias in most studies (ie, incomplete data).

Figure 5. Effectiveness of digital health on health-related quality of life [32,35-37,39,41].



Self-Efficacy

A total of 5 studies with 653 participants comparing digital interventions and control conditions did not show a difference in self-efficacy between the 2 intervention conditions (SMD 0.05, 95% CI −0.11 to 0.20); heterogeneity (P=1.00; I^2=0%; Figure 6). Using the GRADE approach, the quality of evidence was rated moderate because of the high risk of bias in most studies (ie, incomplete data).

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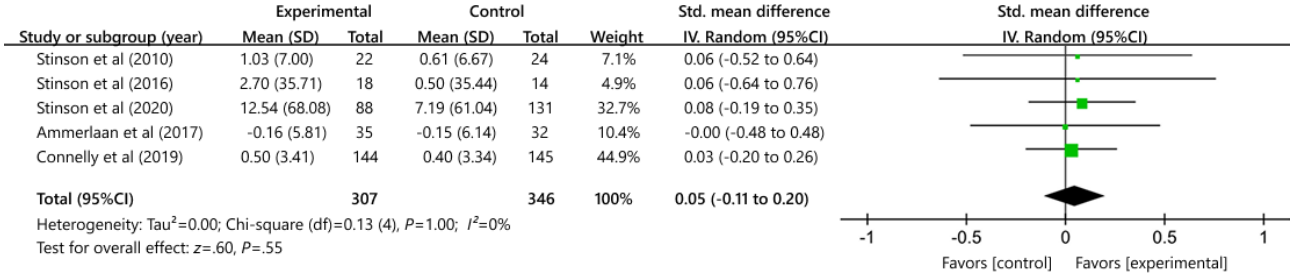
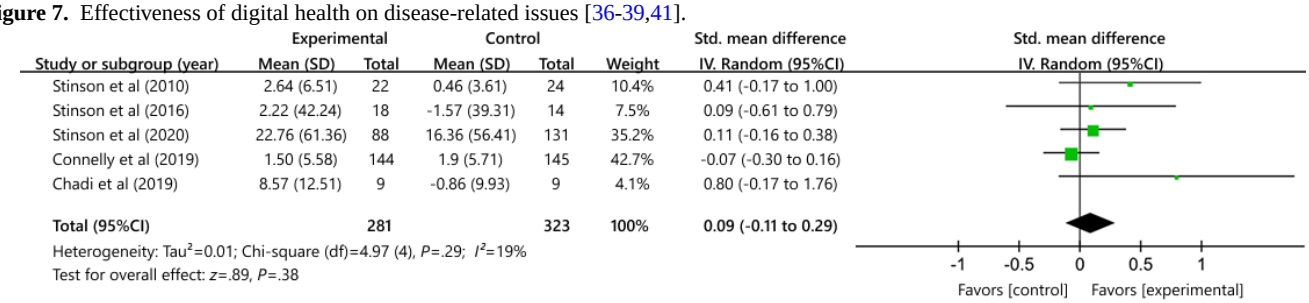
Figure 6. Effectiveness of digital health on self-efficacy outcomes [32,36,37,39,41].



Disease-Related Issues

Figure 7 demonstrates the effectiveness of interventions using digital health technology on patient outcomes for disease-related problems compared with other control conditions. A total of 5 studies included 604 participants (SMD 0.09, 95% CI −0.11 to 0.29) suggests that the effect is ultimately insignificant. The results exhibit minimal heterogeneity (P=.29, I^2=19%). The evidence following the intervention was assessed as moderate in quality using the GRADE methodology, owing to the presence of bias risk and inconsistency across certain studies.

Figure 7. Effectiveness of digital health on disease-related issues [36-39,41].

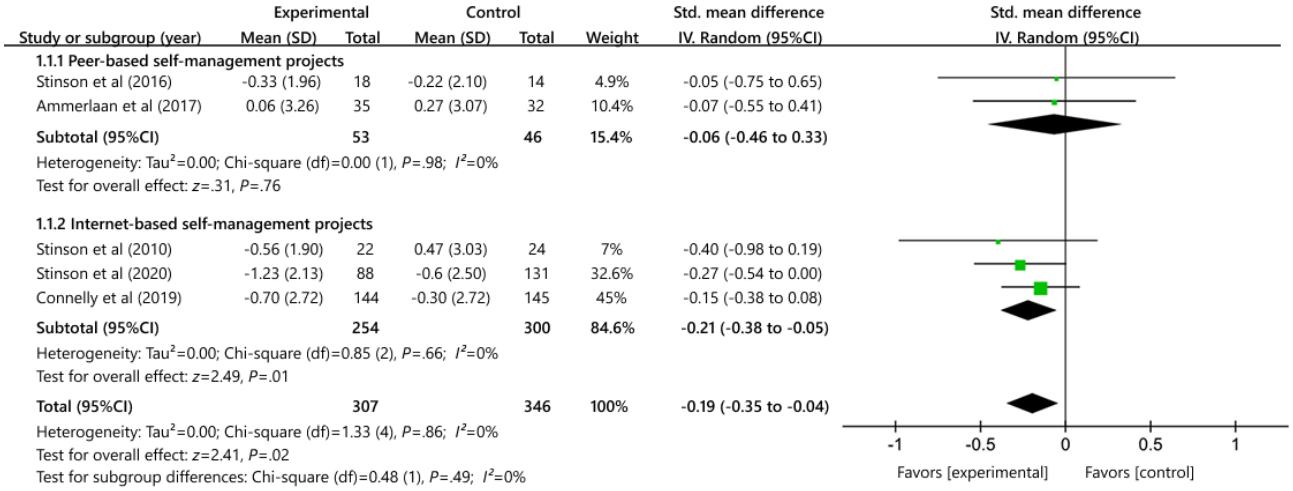


Subgroup Analysis

Effects of Peer Mentoring on Pain Outcome

The subgroup analysis revealed that the internet-based self-management program (n=3) resulted in a moderate effect size in pain reduction (SMD −0.21, 95% CI −0.38 to −0.05; heterogeneity χ^2_2=0.85; P=.66; I^2=0%; Figure 8). However, our findings showed no significant effect of iPeer2Peer and Challenge Your Arthritis (n=2) on pain (SMD −0.06, 95% CI −0.46 to 0.33; heterogeneity χ^2_1=0.00; P=.98; I^2=0%). Subgroup differences in pain outcomes were not significant between peer mentoring programs and other internet programs (P=.49; I^2=0%).

Figure 8. Effects of peer mentoring on pain outcomes [32,36,37,39,41].



Effects of Physicians on Disease-Related Issues Outcome

The disease-related issues in studies with physicians improve more than those without physicians as the main component of the intervention (SMD 0.51, 95% CI 0.01 to 1.02 and SMD 0.01, 95% CI −0.16 to 0.18, respectively; Figure 9). However, the difference was not statistically significant (SMD 0.09, 95% CI −0.01 to 0.29; heterogeneity χ^2_4=4.97; P=.29; I^2=19%).

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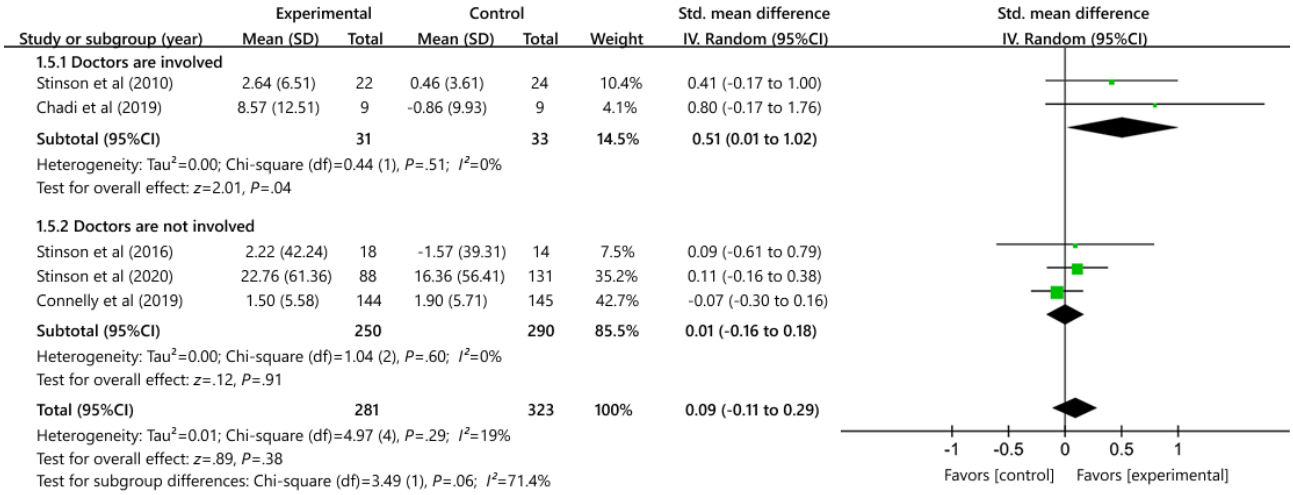
Figure 9. Effectiveness of e-health on disease-related issues when physicians are involved [36-39,41].



Discussion

Principal Findings

This systematic review comprehensively assessed studies on the effectiveness of digital interventions in aiding children and adolescents with JIA from physical and psychologically perspectives. According to the findings, patients who received digital medical technology interventions had significantly better physical activity outcomes (SMD 0.37, 95% CI 0.06-0.69) and experienced a reduction in pain outcomes (SMD −0.19, 95% CI −0.35 to −0.04) in comparison with those who received standard care. However, our research did not identify significant enhancements in disease-related issues (SMD 0.09, 95% CI −0.11 to 0.29), health-related quality of life (SMD −0.02, 95% CI −0.17 to 0.13), or self-efficacy (SMD 0.05, 95% CI −0.11 to 0.20).

Primary Findings

Overview

The use of digital interventions delivered through the internet or mobile devices has expanded mental health practices for children and adolescents facing JIA in local contexts [46,47]. These interventions offer flexible training schedules, overcome constraints of space and time [48], ensure anonymity, and allow for behavioral adaptation. Nevertheless, our findings indicate that interventions using digital medical technology have a more pronounced impact on physiological outcomes, aligning with earlier research conducted by Butler et al [26]. This emphasis on physiological outcomes may be attributed to the inclusion of components targeting physical activity and motor skills in the interventions, such as fitness regimens, varied exercises, and intensive training. However, the interpretation of psychological outcomes is more complex, influenced by various factors including personal psychological state, social environment, and cultural background. In addition, achieving and sustaining psychological transformations often requires an extended period. While these potential reasons have not been examined, our findings indeed illuminate the distinct physiological and psychological effects of digital medical interventions, offering a new perspective for understanding and evaluating their merits. Further investigation is needed to compare the impacts of digital medical interventions on physiological and psychological outcomes, and to identify strategies for optimizing intervention effectiveness in diverse contexts.

Pain

Our findings demonstrated a notable reduction in pain-related outcomes following the implementation of digital interventions. Two of these studies focused on young patients with JIA transitioning to adult care facilities, who demonstrated high self-efficacy and positive attitudes. In addition, 3 studies implemented a telephone-based therapeutic communication intervention. Subgroup analysis outcomes revealed that patients using an internet-based self-management program (Teens Taking Charge) [36,39,41] experienced a great reduction in pain symptoms compared with those using a peer-directed self-management program [32,37]. These findings align with a pilot feasibility study on peer coaching for adolescents with chronic pain [18], where the control group showed superior pain reduction status. This discrepancy may be attributed to the absence of explicit pain symptom sections in the self-management programs examined, which focused instead on social relationships and goal-setting. In contrast, the control group's website included comprehensive content addressing pain understanding and management, alongside audio and video features. In addition, Dennis et al [49] demonstrated that trained peer mentors could provide informational, evaluative, and emotional support to individuals with similar conditions, albeit without explicitly addressing pain relief. Hence, there is a need for studies about the usability of digital tools for managing pain symptoms in future research. These tools should go beyond mere documentation of pain symptoms and incorporate functionalities aimed at alleviating functional limitations, providing medication and exercise guidance, and offering strategies for managing low mood. Such enhancements are essential for improving the quality of life for patients coping with pain [50].

Physical Activity

Engaging in physical activity is essential for managing arthritis in patients [51]. Consistent with previous research findings [26], 4 findings emphasized the positive impacts of the internet interventions on physical activity. The majority of these studies

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incorporate clinically recommended activity training, which increases physical activity levels and improves endurance among patients. Studies suggest that individuals with arthritis can prevent disability and complications by promoting healthy physical activity throughout their lives [52]. However, as demand for face-to-face health care interventions for supporting physical activity adoption and maintenance increases, resource constraints become more pronounced [53]. In a previous study, serious games were used in joint rehabilitation for patients with JIA [54-56]. The findings indicated that these interventions led to increased levels of physical activity among the patients. Our findings support this observation, as 1 of the 4 studies using video games for task-oriented activity training [42] showed improvements in patient outcomes. However, concerns have arisen regarding potential inaccuracies in the effectiveness of exercise diaries and activity monitoring accelerometers used by children. Therefore, there is a need for more accurate methods of data acquisition. We advocate for the development of additional digital tools that integrate health education and physical activity-focused content.

Secondary Findings

The secondary outcomes such as self-efficacy, health-related quality of life, and perception of disease-related issues did not show statistical significance. The previous research shows similar results. Lancaster et al [57] and Newby et al [58] did not find positive impacts of digital interventions on self-efficacy and quality of life. This discrepancy may be attributed to the measurement of self-efficacy which may not be adequately tailored to the conceptual, linguistic, and objective needs of children [32]. However, it is anticipated that improvements in quality of life may require more time to manifest [59], and changes might not be evident during shorter intervention periods. The Medical Issues, Exercise, Pain, and Social Support questionnaire, encompassing inquiries regarding medical matters, physical activity, psychological well-being, and social support [60], may experience compromised efficacy if a patient is insensitive to one of its components, indicating a limited awareness of disease-related concerns.

Other Findings

It is worth noting that not all psychological interventions are ineffective. The subgroup findings show that when physicians are involved in intervention implementation, children and adolescents show improved understanding of disease-related issues. Previous research shows that online health communities involving both patients and health care providers can improve mental health in chronic conditions by allowing patients to consult and interact with physicians [61,62]. Physicians provide essential health knowledge, emotional support, and guidelines for the use of medical supplies, which is crucial for improving the health status of individuals with chronic conditions [63]. To improve intervention outcomes, digital interventions should incorporate features for real-time interaction with healthcare providers, enabling physicians to offer clinical insights and socioemotional support, thereby strengthening the doctor-patient relationship and improving health outcomes.

Furthermore, video-based mindfulness interventions have shown benefits for populations with chronic illnesses and other conditions [64,65]. A study comparing the efficacy of online mindfulness interventions and in-person interventions in enhancing the mental well-being of patients with JIA observed a notable decrease in anxiety and depression [38]. This reduction may be attributed to adolescents experiencing greater ease and relaxation in the familiar setting of their homes [66]. Furthermore, Voerman et al [67] found that digital interventions incorporating cognitive behavioral therapy led to significant improvements in the psychological and social outcomes of patients. Specifically, relaxation exercises and cognitive behavioral therapy effectively reduced pain frequency in children and adolescents, alleviating depressive symptoms and functional disorders [68]. Future investigations should aim to integrate a theoretical framework that addresses the psychological dimensions of the condition, ensuring a more comprehensive approach to intervention design.

Limitations

Half of the studies (5/11) used digital tools that have been developed for over a decade, they may thus fail to represent the latest advancements in communication technologies and platforms. However, our findings indeed show their continued relevance and effectiveness. Second, the results of this review demonstrate that, from a statistical perspective, digital interventions are effective for certain patient outcomes. However, considering factors such as individual differences and variability in clinical environments, their clinical significance remains to be further validated. Future research should provide stronger evidence from a clinical perspective. Furthermore, the included studies are predominantly conducted in North American and European nations. As such, the findings of this analysis may not be universally applicable and may only offer insights into the integration of digital interventions within this specific population.

Conclusions

This systematic review analyzes self-reported outcomes in patients with JIA, including pain, physical activity, quality of life, self-efficacy, and disease-related issues. The findings from 11 RCTs demonstrate that digital interventions significantly alleviate pain and improve physical activity. These results highlight the potential of digital tools to enhance JIA management and patient outcomes, providing a strong case for their integration into clinical practice. Future studies should consider the inclusion of physicians in digital interventions to better understand their impact on outcomes.

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Data Availability

The meta-analysis conducted in this study is based on data retrieved from the following open-source databases: MEDLINE, PubMed, Embase, Ovid, and Cochrane. The data from these databases are publicly available and can be directly accessed through their respective websites or DOI links. The analyses presented in this paper are based on these public datasets, and the specific data retrieval dates and search strategies have been detailed in the Methods section of the paper.

Authors' Contributions

ZR had full access to all of the data in the study and took responsibility for the integrity of the data and the accuracy of the data analysis. ZR and YC contributed to the study concept and design. All authors contributed to the acquisition, analysis, or interpretation of data. ZR contributed to the drafting of the manuscript. All authors contributed to the critical revision of the manuscript for important intellectual content. YL and ZR performed statistical analysis. YC and ZR contributed to administrative, technical, or material support. YL and YC performed supervision.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File, 42 KB - pediatrics_v8i1e65826_app1.docx]

Multimedia Appendix 2
Medical Subject Headings (MeSH) terms and free-text keywords.
[DOCX File, 18 KB - pediatrics_v8i1e65826_app2.docx]

Checklist 1
PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) 2020 checklist.
[DOCX File, 34 KB - pediatrics_v8i1e65826_app3.docx]

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Abbreviations

GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
JIA: juvenile idiopathic arthritis
RCT: randomized controlled trial
RevMan: Review Manager

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Novel Profiles of Family Media Use: Latent Profile Analysis

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Abstract

Background: Over the past 3 decades, digital and screen media have evolved from broadcast, stationary platforms to a complex environment of interactive, omnipresent, mobile media. Thus, clinical guidance centered around unidimensional concepts such as "screen time" must be modernized to help families navigate the intricate digital ecosystems of readily available entertainment and information.

Objective: This study aimed to identify and examine distinct latent profiles of media use in families with young children. We hypothesized that latent profile analysis (LPA) would identify different media use profiles characterized by more heavy, reactive, individual, and permissive media use and more intentional, regulated, or shared uses of media.

Methods: We analyzed data from 398 preschool-aged children. English-speaking parents were recruited through community settings. Participants completed surveys regarding several aspects of family media use, such as child device use or activities, parent concerns and attitudes, limit setting and mediation, parent media use, and technology interference, examined in an LPA. The number of latent media profiles was determined using Bayesian Information Criteria. Parents also completed validated scales of parenting stress, depression symptoms, parenting style, child behavior, child sleep, and household disorganization. Multivariable logistic regression was used to examine parent, child, and household predictors of group membership.

Results: The LPA yielded 2 distinct groups that differed in the duration of media used by parents and children, to calm children or help them fall asleep. Statistically significant differences between groups included: families in group 1 (n=236, which we termed social-emotional drivers) had parents who preferred interactions via text or email to in-person (P=.01) and were more likely to use media to calm their children (P=.03); in contrast, families in group 2 (n=162, intentional media) used more task-oriented media, like audio and nongame apps (P=.01), had more concerns about effects of media on child language development (P=.04), and used more media restrictions (P=.01). In regression models, female sex of the parent respondent, greater number of siblings, and later child sleep midpoint independently predicted group 1 membership.

Conclusions: Findings suggest divergent family media use patterns that can be categorized into 2 main media user groups: those using media to buffer social situations or regulate emotions and those planning mobile device use around functional purposes and concerns around media exposure. Profiles were associated with household size and child sleep. More research is needed to examine the impact of social and emotional uses of media on child outcomes.

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KEYWORDS

preschool; child; digital media; mobile media; media use; latent profile analysis; computer use; LPA; technology use; survey; questionnaire; pediatrics

Introduction

Background

The landscape of digital technology use has changed dramatically over the past few decades. Digital and screen media have evolved from broadcast, stationary platforms, where screens stay put, plugged into the wall, and messages are transmitted broadly in a one-to-many model, to a world of interactive, mobile media, where screens can follow users wherever they go and interact in a bidirectional manner. For this reason, researchers have questioned whether clinical guidance centered around unidimensional concepts such as "screen time" are helpful to parents trying to navigate digital ecosystems of readily available entertainment and information [1], particularly considering families' increased technologic dependence during and following the COVID-19 pandemic.

Distinctions between traditional (eg, television [TV]) and mobile, interactive media are important for several reasons.

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First, the portability and easy accessibility of mobile media inherently allows for more spontaneous and reactive use patterns in which the technology becomes increasingly integrated into daily routine and activities [2,3]. Second, small, handheld screens are more difficult for parents to monitor [4]. And third, mobile media use has rapidly become exceedingly common, even in infants and toddlers. As of 2017, 98% of homes of children 0 - 8 years old had a mobile device, and one third of all screen time in that same age group, who use on average almost 2.5 hours of screen media per day, was mobile [5].

Previous Work

In light of modern technologic advances, new ways of studying, conceptualizing, and framing media use guidance have been proposed. Young children's media use has been conceptualized as the "3 Cs", that is, content, context, and the individual child given the important role each of these factors plays in shaping child responses to media [6]. However, pervasive use of mobile media by families with young children requires new concepts such as use of devices for on-demand calming and keeping children occupied during daily activities.

To capture holistic patterns of family media use, it is also important to consider parents' mobile device use, which interrupts parent-child interaction [7] and is associated with less responsiveness [8], but is an important part of parent social connection, work-life, and day-to-day functioning [9]. Parents' mediation behaviors (practices such as coviewing, teaching children about media content, or setting limits) also shape children's responses to media [10]. Finally, child and parent media use are highly correlated [11], yet are usually studied in isolation. One previous attempt to describe family-level media behaviors [12] primarily focused on viewing duration and type of media use, rather than the several contextual variables or social-emotional drivers of media use in the current digital environment.

Goal of This Study

The current study aims to identify patterns that include the aforementioned concepts, examined through latent profile analysis, to try to identify patterns and concepts that might generate insights for clinical guidance and future research. Specifically, we sought to identify novel patterns of family media use that consider child duration and frequency of media activities; child use to keep occupied, regulate behavior, or fall asleep; parent attitudes about child use; limit setting and mediation; parent media use; and "technoference" (ie, technology interference in parent-child activities). We hypothesized that latent profile analysis (LPA) would identify different media use profiles characterized by more reactive, heavy, individual, and permissive media use; and more intentional, regulated, or shared uses of media. We examined these patterns and their associations with parent, child, and household characteristics within a large cohort of preschool-aged children, as early childhood is an important time of establishing media use habits [13].

Methods

Overall Study Design

We analyzed data from the Preschooler Tablet Study, a longitudinal cohort study (NICHD R21HD094051) examining associations between early childhood digital media use and social-emotional development. The present analysis used REDCap (Research Electronic Data Capture) [14] and Qualtrics survey data from the baseline data collection wave (August 2018-May 2019).

Ethical Considerations

The study was approved by the University of Michigan Institutional Review Board (HUM00131980). Parents provided electronic informed consent for themselves and on behalf of their young children. Participants were informed that they could opt out of the study at any time. Data downloaded from REDCap and Qualtrics were stored on secure password-protected servers at the University of Michigan. Data was not de-identified prior to analysis; all participants were assigned a study ID number that only linked to identifying information on REDCap, a HIPAA-secure database to which only approved study personnel had access. Participants received $40 for completing data collection procedures.

Participants

Parents of young children were recruited through flyers posted in community centers, preschools, childcare centers, and pediatric clinics in southeast Michigan, as well as our university's online participant registry and social media advertisements. Interested parents who contacted the study team were emailed a link to an eligibility questionnaire. Eligibility criteria is shown in Textbox 1. To improve generalizability, participating children did not need to regularly use mobile devices to be included in the study.

Textbox 1. Study inclusion and exclusion criteria.

Inclusion criteria:

- Parent was legal guardian of a 3 - to 4.99-year-old child.
- Parent lived with the child at least 5 days per week.
- Parent understood English sufficiently enough to complete questionnaires and provide consent.
- The family owned at least 1 Android or iOS tablet or smartphone.

Exclusion criteria:

- Child developmental delays.
- Use of psychotropic medication.

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Survey Measures: Child, Parent, and Household Characteristics

After providing electronic informed consent, respondent parents completed web-based surveys with a variety of questionnaires to assess characteristics of the child, parent, and household, as well as family media use practices. Demographic characteristics were collected for children's age, sex, race, ethnicity (investigator-defined categories shown in Table 1), daycare or preschool enrollment, average sleep pattern (sleep onset and wake time, from which duration and midpoint were calculated, as well as sleep latency and overnight awakenings), prematurity, and whether they were an only child; parent age, gender, educational attainment, marital status, and employment status. We also used validated questionnaires to assess parent depression symptoms (Centers for Epidemiologic Studies-Depression Scale) [15], parenting stress (Parenting Stress Index-Short Form) [16], and parenting styles (laxness and harshness subscales of The Parenting Scale) [17]; as well as household income, size, composition, and disorganization (Chaos, Hubbub, and Order Scale) [18]. Child self-regulation abilities were assessed with the Emotional Reactivity subscale of the Child Behavior Checklist-Preschool [19], the Surgency subscale of the Rothbart Child Behavior Questionnaire-Very Short Form [20], and the Behavior Rating Inventory of Executive Function-Preschool [21].

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Table . Participant sociodemographic characteristics.

Characteristics			Values
Parent			
	Age, mean (SD)		34 (4.7)
	Sex, n (%)		
		Male	25 (6.3%)
		Female	373 (93.7%)
	Education, n (%)		
		≤High school or GED[a]	25 (6.3%)
		Some college or a 2-year degree	126 (31.7%)
		4-year college degree	100 (25.1%)
		Advanced degree	147 (36.9%)
	Marital status, n (%)		
		Married or has a partner	360 (90.9%)
		Single, separated, or divorced	36 (9.1%)
	Employment, n (%)		
		Unemployed	110 (27.6%)
		Part-time	76 (19.1%)
		Full-time	185 (46.5%)
		Multiple jobs	27 (6.8%)
	Scales, mean (SD)		
		Depression symptoms (CES-D[b] score)	9.32 (8.87)
		Parenting Stress Index percentile	44.6 (32.9)
		Parenting Scale – Laxness Subscale	2.61 (0.76)
		Parenting Scale – Overreactivity Subscale	2.56 (0.74)
Child			
	Age, mean (SD)		3.85 (0.54)
	Sex, n (%)		
		Female	186 (46.7%)
		Male	212 (53.3%)
	Race/ethnicity, n (%)		
		Asian or Pacific Islander	11 (2.8%)
		Black or African American, non-Hispanic	20 (5.1%)
		Hispanic, any race	26 (6.6%)
		Multiple races, non-Hispanic	32 (8.1%)
		Native American or Alaska Native	5 (1.3%)
		White, non-Hispanic	302 (76.3%)
	Only child, n (%)		
		Yes	69 (17.3%)
		No	329 (82.7%)
	Child gestational age, n (%)		
		<37 weeks (premature)	32 (8%)

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Characteristics			Values
		37 weeks or later	366 (92%)
	Child preschool or child care, n (%)		
		Center-based child care	250 (65.8%)
		Home-based child care	30 (7.9%)
		Stays home with parent or caregiver	100 (26.3%)
	Sleep, mean (SD)		
		Sleep duration	10.8 (0.8)
		Sleep midpoint (number of hours after 12 AM)	1.87 (0.82)
		Sleep latency >30 min	106 (26.6)
		Overnight awakenings	226 (60.4)
	Scales, mean (SD)		
		CBQ-VSF[c] Surgency Subscale	4.40 (0.86)
		BRIEF-P[d] General Executive Composite	49.2 (12)
		CBCL-P[e] – Emotional Reactivity Subscale	3.69 (2.82)
	Household, mean (SD)		
		Income-to-needs ratio	2.95 (1.71)
		CHAOS[f] score	3.29 (2.93)

[a]GED: General Educational Development.
[b]CES-D: Centers for Epidemiologic Studies-Depression
[c]CBQ-VSF: Child Behavior Questionnaire Very Short Form
[d]BRIEF-P: Behavior Rating Inventory of Executive Function-Preschool
[e]CBCL-P: Child Behavior Checklist–Preschool
[f]CHAOS: Chaos, Hubbub, and Organizational Scale

Survey Measures: Media Use

Parents also completed a 75-item questionnaire about family media use derived from the CAFE (Comprehensive Assessment of Family Exposure) Consortium Qualtrics Survey, which has been described elsewhere [22]. This survey asks about technology and device ownership, content and context of media use, parent media use, and mediation practices (refer to Textbox 2 for constructs assessed). Questions on the survey addressed types of devices in the home and locations of those devices, parent attitudes toward media and concerns regarding child use of media, duration of use on weekdays versus weekends, time of use and environmental context of use (for example while falling asleep or while in transit), usual content (for example streaming video versus playing games), family interactions around media, and media-use functions.

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Textbox 2. Media-related constructs assessed through the CAFE (Comprehensive Assessment of Family Exposure) questionnaire.

A. Child ownership and frequency of activities

A1. Child ownership of mobile media device

A2. Child keeps device in bedroom

Frequency of mobile device use for specific activities:

(A3. Watch TV; A4. Watch movies; A5. Play games; A6. Use apps that are not games; A7. Read electronic books; A8. Listen to music or audiobooks; A9. Take photos; A10. View photos/videos)

B. Child instrumental or regulatory uses of media

B1. Use of media during travel in car or public transit

B2. Use of TV to calm when upset

B3. Use of mobile devices to calm when upset

Use of all types of screen media by parent for specific purposes related to child:

(B4. To educate child; B5. Calm child down; B6. Keep child busy; B7. Communicate with family and friends; B8. Because child enjoys it)

B9. Use of devices at bedtime

B10. Use of devices while falling asleep

C. Parent media knowledge and attitudes

Parent concerns that child will:

(C1. Be exposed to inappropriate content; C2. Become inattentive as a result of using screen media; C3. Become addicted to screen media; C4. Miss out on other important opportunities that are more valuable than screen media; C5. Be exposed to harmful electromagnetic waves; C6. Have poorer language development).

D. Mediation strategies

Presence of media content limits:

(D1. Parents blocks specific media content on TV/devices; D2. Parent uses web blockers/controls; D3. Parent only allows child to watch “child-friendly” content; D4. Parent uses ratings to decide what child will watch; D5. Child media use only allowed if parent is in the room).

D6. Media time limits are consistently enforced

D7. Media content limits are consistently enforced

D8 – D22: Valkenburg Mediation Scale (Social Coviewing, Instructive Mediation, and Restrictive Mediation)

E. Parent media use

Outside of work hours, parent feels:

(E1. The need to stay connected to work almost constantly; E2. The need to stay connected to friends and social media almost constantly; E3. It is easy to multitask between children and using a phone or mobile device; E4. Sometimes overwhelmed by how much they have to do on their phone or mobile device; E5. That they prefer to interact with others via texting, email, or social media, rather than in person; E6. Using their phone or mobile device allows them to “escape” a little bit while they’re with their children; E7. Sometimes “addicted” to mobile media like smartphones or tablet devices).

Frequency of specific activities during a typical weekday (Monday-Friday):

(E8. Watch TV; E9. Use the computer; E10. Read traditional books; E11. Read electronic books; E12. Play videogames on console game player; E13. Use an iPad, iTouch, or similar device (not including a smartphone); E14. Use a smartphone for things like texting, playing games, watching videos, checking email, or surfing the internet).

Frequency of specific activities during a typical weekend day (Saturday-Sunday):

(E15. Watch TV; E16. Use the computer; E17. Read traditional books; E18. Read electronic books; E19. Play videogames on console game player; E20. Use an iPad, iTouch, or similar device (not including a smartphone); E21. Use a smartphone for things like texting, playing games, watching videos, checking email, or surfing the internet).

F. Technoference

Frequency of parent phone use during specific activities:

(F1. During meals; F2. While getting child(ren) ready for school; F3. During playtime; F4. During bedtime routine; F5. While driving child(ren) to or from activities or when riding on public transportation; F6. At the playground).

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Data Analysis

Of the 423 participants who provided consent and completed surveys, we excluded participants who did not complete (n=19) or had substantial missing data (n=6) on the media use questionnaire. This left 398 participants in this study available for the LPA. All media variables were included in LPA, a person-centered statistical method to identify distinct groups of participants with similar median profiles within each group. Using Bayesian Information Criteria (BIC), the LPA with the lowest BIC value yielded 2 distinct groups.

Wilcoxon Mann-Whitney tests were used to compare media use questionnaire items between the groups identified by the LPA. Then separate multivariable logistic regression models were built to estimate the odds of being in group 1 versus group 2 for each set of parent (Model I), child (Model II), and household (Model III) predictors. As our approach was exploratory, we started with including all parent, child, or household characteristics in each respective model and conducted backward elimination, resulting in the most parsimonious model that retained only variables showing significant associations at a *P* value of <.05. For all characteristics significantly associated with group membership in Models I, II, or III, we built a combined Model IV to test which characteristics were independently associated with group membership.

Results

Participant Demographics

Parents were 93.7% female (373/398), 34 (SD 4.7) years old, and 62% (247/398) had a 4-year college degree or more; children were 3.8 (SD 0.54) years old, 76.3% (302/398) were White and non-Hispanic, and 82.7% (329/398) had siblings in the household (Table 1).

Evaluation Outcomes

Latent profile analysis yielded 2 distinct groups of media users (Figure 1). Families in group 1 (n=236) were more likely to prefer interactions through text, email, or social media rather than those in person (*P*=.01) and more likely to use TV shows or DVDs to calm their children (*P*=.03). Parents in group 1 used their mobile device more frequently during the week to read electronic books (*P*=.04). In contrast, group 2 (n=162) used more task-oriented media, including more audio and nongame apps (*P*=.01), had more concerns about effects of media on language development (*P*=.04), and used more media restrictions (*P*=.01).

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Figure 1. Latent Profile Analysis: media use profiles. Standardized means by variable for group 1 versus group 2. Lettering describes variable type: A. child ownership and frequency of activities; B. child instrumental or regulatory uses of media; C. parent media knowledge and attitudes; D. mediation strategies; E. parent media use; F. technoference.

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As shown in Figure 1, several additional variables approached significance (*P*<.20) that warrant mention. Parents in group 1 were more likely to feel overwhelmed by how much they have to do on their phone or mobile device (*P*=.12) and reported that using the phone or mobile device allowed them to "escape" a little bit while with their children (*P*=.14). They were more likely to watch TV or DVDs (*P*=.15) or use the computer (*P*=.10) over the weekend than were families in group 2. Group 1 families also reported using more content restrictions for what their children see in the media with internet filters, parental controls, or apps to block certain websites (*P*=.11) , as well as use of parental media websites (eg, common sense media) to decide what types of programs are appropriate for their child. Finally, group 1 families were more likely to use their mobile device to take photos (*P*=.11).

Group 2 families preferred using their mobile devices to view photos or home videos (*P*=.13) in addition to the other task-oriented media described above. They also noted concerns that children will become inattentive as a result of using screen media (*P*=.11) and more frequently restrict the amount of child viewing (*P*=.06).

In logistic regression models (Table 2), the only parent characteristic that was significantly associated with group 1 membership (vs group 2) in Model I was female parent sex. In Model II, children with longer duration of sleep had lower odds of group 1 membership, while those with later sleep midpoint and prematurity showed increased odds of group 1 membership. Households with more siblings had a borderline increased odds of group 1 membership in Model III. With all characteristics considered in the same model (IV), independent associations remained for female parent sex, greater number of siblings, and later child sleep midpoint.

Table . Multivariable logistic regression models predicting group assignment.

Model and variable		Group 1 (social-emotional drivers) versus group 2 (intentional media), aOR[a] (95% CI)
Model I: parent characteristics		
	Parent sex (male vs female)	0.36 (0.16-0.84)
Model II: child characteristics		
	Sleep duration (per 1 hour)	0.72 (0.55-0.95)
	Sleep midpoint (per 1 hour)	1.5 (1.13-1.98)
	Prematurity (no vs yes)	2.26 (1.06-4.8)
Model III: household characteristics		
	Number of siblings (per sibling)	1.23 (0.998-1.5)
Model IV: all characteristics		
	Parent sex (male vs female)	0.3 (0.12-0.76)
	Number of siblings (per sibling)	1.27 (1.02-1.57)
	Sleep midpoint (per 1 hour)	1.51 (1.1-2.07)

[a] aOR: adjusted odds ratio

Discussion

Principal Findings

This study used a wide range of questions about child, parent, and household context of media use to identify coherent patterns of media use that are relevant to pediatric research or clinical intervention. Latent profile analysis results suggest that people may be predisposed to different media-use patterns based on individual motivations. Group 1 preferred text and email interactions to those in-person and used media to calm their children. These behaviors may be interpreted as use of media based on social-emotional drivers. In contrast, group 2 used media for more functional purposes. This group preferred more nongame and audio applications. They seemed warier of media, placed more restrictions around child media use, and had more concerns about the effect of media on child development. Though these findings in some way confirmed our initial hypothesis, that some types of media users are predisposed to more reactive-use patterns (group 1), while others are more predisposed to intentional and regulated uses of media (group 2), the tendency to use media as a sort of social-emotional buffer was not a factor we considered in our initial hypothesis.

When examining the overall patterns of media use between groups, a few theoretically coherent concepts arise. In group 1, described as using media based on social-emotional drivers, there appeared to be more parent use of media as an "escape" from childrearing demands, such as more parental media during the weekends, which is typically time families are together during the day. In previous qualitative work, parents have described using mobile devices and social media as a "virtual escape" when their child stresses them out [9], when they want to avoid parenting tasks [23], or when intentionally not wanting to engage with difficult child behavior [24]. Furthermore, compared with parents in group 2 who were more likely to view, but not take, photos or home videos on a mobile device, group 1 families took photos on their device more frequently, an action that by definition interrupts a social moment and introduces a

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physical barrier between the individual taking the photograph and the subjects.

In group 2, parent media use appeared more goal oriented, and more limits and restrictions were placed on child media use, which may be related to greater concerns about media's effects on child wellbeing. This pattern of device usage has been described as "instrumental" (ie, goal directed and purposeful) rather than "ritualistic" in previous work [25], and is hypothesized to be related to the individual motivations for engaging with technology. In this study, we describe this pattern of device usage as intentional, similarly noting that this type of media use is meant to fulfill a purpose rather than for pleasure or distraction. Though we did not observe increased odds of group 2 membership based on measures of parental mental health or child behavior, a recent study using latent class analysis found stronger well-being indicators for "family-engaged adolescents" who live in families with family-owned devices, positive parent relationships, and lower parental social media use [26]. Higher wellbeing also occurred in teens who placed lower importance on technology and were expected to follow household technology rules. Future research may therefore examine the relationship between these multiple classes of media users in a longitudinal manner to determine if "intentional" media-use families who set early boundaries around child media use are more likely to have "family-engaged adolescents" with better social-emotional outcomes.

It is surprising that socioeconomic status, parenting stress, household disorganization, and child behavioral difficulties were not associated with membership in group 1. In previous research, longer screen time duration and higher parent technology interference have been linked with higher parenting stress [27-29]. Recent work has also suggested that children's screen time is a marker of family distress due to multiple psychosocial factors [30]. However, these studies only examined the variable of screen time, while our approach identified larger family media use patterns that appear independent of socioeconomic factors in this cohort.

We did find that mothers are more likely to use media as a social-emotional buffer and that this type of media use is more common in larger families. It is possible that mothers or parents of larger families may experience higher caregiver burden and, as a result, are using media for more self-regulatory purposes and to calm or manage child behavior more frequently. Indeed, use of digital technology as a "babysitter," to provide caregiver respite or allow parents time to tend to other tasks, is a concept that is well-described in research literature and mainstream news, albeit with some differences in acceptance across cultures [31-35]. Evidence suggests that use of media to occupy children may be especially relevant in homes where children require more attention or behavioral management due to temperament differences [36], or where there is limited support for the primary caregiver. One study found that parents who lack support from a partner or who are uncertain about their parenting skills were more likely to use media as a distractor and concluded that "media are thus especially used as a distractor in the family when parents feel that it is difficult to keep the household going by themselves" [34].

Another correlate of group membership was later sleep midpoint (ie, the calculated midpoint between reported average sleep onset and wake time), with group 1 having later sleep midpoints than group 2. This may be explained by the fact that group 2, despite any significant difference in overall parenting style, seemed more prone to limit setting. What is perhaps most surprising about our study findings are the variables that did not predict group membership including parent education, marital status, employment, and child behavior variables such as emotional reactivity and surgency. Although human-computer interaction research has identified individual predictors of smartphone usage habits such as personality [37], attachment style [38], and executive functioning [39], we found no associations of parenting style (such as laxness vs harshness), parenting stress, or depression symptoms with group membership.

Limitations

Our study was limited in generalizability due to our study population which included mostly White, non-Hispanic, higher-educated, and female-parent responders. While our cohort reflected the racial and ethnic diversity of our local area, results may not be generalizable to other populations. In addition, the data we analyzed on media use was all from self-report questions, which can lead to single-reporter bias. We also reported on several associations that did not achieve significance, but were near significant, that we included in our results as we felt the data helped to demonstrate an overall trend. Greater insight into the reasons for media use may have been gleaned from a mixed methods approach, where follow up semistructured interviews could have explored themes related to media as a social-emotional buffer versus to fulfill a desired goal.

Conclusions

Results of our study suggest that people likely do have different motivations behind their use of digital media that may be reflected in their usage patterns. The significance of these different media usage patterns for the long-term outcomes of children and families is yet to be determined. It is possible, and in fact likely, that each pattern of media use may be considered adaptive in certain situations and maladaptive in others. By having a better understanding of why and how different families use media in their daily lives, pediatric care providers can provide more individualized anticipatory guidance regarding technology use by the whole family, including limit setting, use of media for calming, and how devices impact family dynamics. For example, by understanding that a parent is more prone to using mobile media to calm their child, a pediatrician might suggest that such a parent reflect on the frequency with which they use such calming techniques to ensure that they are also providing their child opportunities to practice frustration tolerance using techniques that go beyond distraction with media.

The research implications of our study may allow us to classify the media use patterns of families to better examine the long-term effects of media use on child health and development. Follow up studies could examine trajectories of profiles over childhood to determine their stability and how they relate to

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child outcomes over time. Future research directions should also include nationally representative populations, objective device use data, or reports from multiple household members (eg, parents and children).

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Authors' Contributions

NH conceptualized and contributed to the design of the study, reviewed all data, participated in the statistical analysis, drafted the initial manuscript, and reviewed and revised the manuscript. JR was the primary investigator on the grant award for the original study, contributed to the conceptualization of the current study, advised on study design, reviewed data, participated in the statistical analysis, and reviewed and revised the manuscript. HMW advised on study design, conducted the statistical analysis, summarized the study data, developed related figures and tables, and contributed to, reviewed, and revised the manuscript. ALM advised on study design, reviewed data and outcomes, reviewed and revised the manuscript. NK advised on study design, directed and oversaw the statistical analysis, reviewed study data, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Conflicts of Interest

NH has ownership interest in Arbor Autism Centers LLC. In the past year, JR received fees from Melissa & Doug LLC and research funding from Common Sense Media. HMW reported receiving grants from the National Institute of Child Health and Human Development outside the submitted work. ALM reported receiving grants from the National Institutes of Health outside the submitted work. NK reported receiving grants from the National Institutes of Health outside the submitted work.

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Abbreviations:

BIC: Bayesian Informed Criteria
CAFE: Comprehensive Assessment of Family Exposure
DVD: digital versatile disc
LPA: latent profile analysis
REDCap: Research Electronic Data Capture
TV: television

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Usability and Acceptability of a Pregnancy App for Substance Use Screening and Education: A Mixed Methods Exploratory Pilot Study

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Abstract

Background: Increasing opioid and other substance use has led to a crisis of epidemic proportions, with substance use now recognized as a leading cause of maternal morbidity and mortality in the United States. Interventions will only be effective if those who would benefit are identified early and connected to care. Apps are a ubiquitous source of pregnancy information, but their utility as a platform for evaluating substance use during pregnancy is unknown.

Objective: This study aims to explore the usability and acceptability of a pregnancy app for opioid and other substance use screening and education.

Methods: This mixed methods, exploratory pilot study examined adult pregnant people with a history of substance use who were recruited from outpatient and inpatient settings at a tertiary care obstetric hospital. After completing a baseline survey collecting demographics, substance use, and technology use, participants accessed an existing pregnancy support app for 4 weeks. Qualitative methods were used to measure the acceptability of embedding substance use screening, education, and information within the tool. App use frequency and access to substance use educational content and treatment referral information were evaluated.

Results: The 28 female participants had a mean (SD) age of 31 (0.46) years; most were White (21/28, 75%) and Medicaid insured (26/28, 93%), with an annual household income of <US $30,000 (16/28, 57%). The mean gestational age at enrollment was 22 weeks. Almost half (13/28, 46%) were taking medication for opioid use disorder (methadone or buprenorphine). Other substances used included tobacco (22/28, 79%), marijuana (20/28, 71%), illicit opioids (9/28, 32%), alcohol (6/28, 21%), and stimulants (4/28, 14%), including cocaine, amphetamines, and benzodiazepines (2/28, 7%). Most (19/28, 68%) reported previously using one or more prenatal apps and 11% (3/28) cited prenatal apps as their most frequently used source of pregnancy information. After approximately 4 weeks of app exposure, 71% (20/28) logged in at least weekly, 89% (25/28) were satisfied with the app, and 96% (27/28) reported that the app was a helpful source of support. In cognitive interviews, participants reported that app-based disclosure of substance use could be easier than disclosing in person due to reduced stigma. However, participants expressed concerns about not knowing who would have access to this information.

Conclusions: Incorporating substance use supports into a pregnancy app was found to be acceptable among those using substances. Participants reported frequent baseline use of prenatal apps, showed a high level of engagement with the pregnancy app during the study, and demonstrated interest in expanding the substance use support elements of this app. Embedding substance use screening, information, and connection to care into a tool with wide-scale use during pregnancy has the potential to identify at-risk individuals who may otherwise not be identified during routine prenatal care. It also has the potential to connect individuals, who might otherwise be hesitant to disclose their substance use, to recovery or harm reduction resources.

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KEYWORDS

substance use disorder; substance use screening; mHealth; mobile health apps; pregnancy; technology

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Introduction

Substance use during pregnancy has increased significantly over the past two decades [1-4], with almost 3% of pregnant people having a formal substance use disorder diagnosis [5]. Opioid use disorder during pregnancy has more than quadrupled in the past 20 years and is now a leading cause of maternal death in the United States [6-12]. Observed rates of other substance use during pregnancy have also increased in recent years, including cannabis, alcohol, sedatives, and stimulants. Actual numbers may be higher due to lack of reporting [5]. Additionally, concurrent substance use, such as marijuana use paired with opioid use, can further increase the risk of preterm birth and low birth weight infants [13] and may impact infant development and longer-term learning, memory, and impulsivity [10,11]. This increase in the prevalence of substance use is concerning and suggests an increased need for effective screening and resource provision to pregnant people.

Early identification and intervention are critical for reducing adverse maternal and neonatal outcomes associated with substance use [14]. As a result, major professional organizations, including the American College of Obstetricians and Gynecologists, recommend that all pregnant people be verbally screened for substance use with a validated tool at least once during pregnancy [15,16]. Despite this, 20% - 30% of obstetric providers do not routinely screen for substance use, and less than half routinely refer patients with a positive screen to substance use treatment resources [17,18]. Moreover, due to stigma, judgment, and fear of mandated reporting requirements, many pregnant people are hesitant or choose not to disclose substance use to their health care providers [12,19-21]. In a study of 422 pregnant people who presented for their first obstetric appointment, 46% of those who had a urine drug test positive for a nonprescribed substance chose to not disclose their substance use when verbally screened by their provider [22].

Mobile health (mHealth) technology has been successfully used to evaluate and deliver interventions related to tobacco, alcohol, and illicit substances, including opioid use, in nonpregnant populations [23-25]. In a study evaluating interest in using digital platforms to monitor recovery trajectories among 259 patients in substance use treatment, 70% of participants expressed interest in using a relapse prevention app [26]. Additionally, a study of 202 individuals using a recovery support app demonstrated high levels of usage of the app and articulated that further expanding the app to provide additional recovery-related resources could increase the likelihood of continuing to use the app in the future [27]. Further, in an evaluation of 316 patients engaged in a Veteran's Affairs (VA) substance use treatment program, more substance use was disclosed through an indirect method (self-completed questionnaire), as opposed to a direct method (verbal disclosure), suggesting that creating an accessible space for indirect disclosure may be beneficial for people who use substances [28].

Pregnancy apps are a common information source used by patients during pregnancy and allow for intimate, self-guided touchpoints for those seeking health-related resources, guidance, and information outside of clinical care settings [29,30]. As such, the American College of Obstetricians and Gynecologists supports mHealth as a suitable means for supplementing obstetric health care [31]. Due to their frequent use, mHealth tools may be an additional way to identify patients who are unwilling to disclose their substance use in traditional, in-person health care settings by mitigating stigma and bias associated with in-person substance use evaluations [29,32].

The purpose of this study was to explore the usability and acceptability of an existing prenatal mHealth app, MyHealthyPregnancy, as a tool in which substance use screening, education, and information could be provided as part of routine prenatal care among pregnant people with substance use. For an mHealth app to be acceptable, the patient population of interest must generally engage with mobile technology during their pregnancy, demonstrate interest in accessing information from the app, and importantly, trust the app as a setting for substance use disclosure [33-36]. Therefore, the specific objectives of this study were to understand, among pregnant people with a history of opioid or other addictive substance use, (1) general technology and mobile app usage, (2) willingness to disclose substance use through a pregnancy app, (3) interest in obtaining substance use education and information through a prenatal app, and (4) perspectives regarding how a pregnancy app could assist with substance use–related needs.

Methods

Study Sample

From April to August 2021, we conducted a mixed methods, exploratory pilot study to understand the usability and acceptability of a prenatal support app for substance use screening, education, and information during pregnancy. Pregnant people with substance use were recruited from inpatient and outpatient settings at an academic, tertiary care women's hospital including prenatal clinics, substance use treatment programs, and inpatient antepartum hospital units. Participants were eligible if they were pregnant, at least 18 years of age, less than 37 weeks gestation, had regular access to a smartphone (Android or iOS), and had a history of substance use during or within 3 months prior to their pregnancy, as determined through either self-report, *ICD-10* (*International Classification of Diseases*, *Tenth Revision*) diagnoses coding cord or evidence of substance use on urine drug testing in the electronic health record. In prior research, a sample size of approximately 30 participants has been determined to be sufficient to understand app usability and acceptability [37].

Ethical Considerations

The study was reviewed by the University of Pittsburgh institutional review board (STUDY18120026). Participants provided written informed consent. All audio and transcribed materials were stored on a secure, password- and firewall-protected university network drive or server, and all data were deidentified prior to analysis. Participants received US $25 for their participation in this study.

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MyHealthyPregnancy mHealth App

The MyHealthyPregnancy app is a pregnancy mHealth tool that offers evidence-based, prenatal educational content organized by the user's weeks of gestation, a diary to document the user's pregnancy experiences, a fetal movement counter, a contraction timer, and routine screenings for symptoms and psychosocial risks. The app also functions as a risk assessment tool that may use patient-entered data (eg, symptoms, language, mood, sleep, and psychosocial screeners) to identify possible risks during pregnancy (eg, intimate partner violence, depression, and pre-eclampsia) and resources tailored to the risks identified. When users start the onboarding process to begin using the app, they are asked, "Do you currently use any of the following?" for various substances, including alcohol, tobacco (and vaping), marijuana, narcotics or opioids, heroin or fentanyl, benzodiazepines, cocaine or amphetamines, and other drugs. Depending on the substance disclosed, the user will be directed to substance-specific local, regional, and national recovery resources.

Educational content about substance use (eg, content regarding the risks of substance use during pregnancy, information on substance use treatment resources) is accessible to users through the app's "Learning Center" and "Resources" sections. These resources and articles were designed, in collaboration with clinical experts, to offer the same information as would be provided in routine prenatal care if substance use was disclosed to a provider. MyHealthyPregnancy was launched for beta-test evaluation at the University of Pittsburgh Medical Center health system in September 2019, with research demonstrating its effectiveness as a complementary tool to prenatal care [38-42].

Study Procedures

After signing a written informed consent, participants completed a baseline survey assessing demographics, substance use, pregnancy history, and technology and app use behaviors (Multimedia Appendix 1). Research staff then assisted participants with downloading the app on their smartphones and provided an overview of the sections of the MyHealthyPregnancy app before having participants self-navigate through the app on their phones. At this time, participants additionally consented to the sharing of identifiable data for research purposes and the publication of anonymized aggregate data through the app. Figure 1 shows sample screens from the app.

After navigating through each section of the app, research staff asked participants to relay their thoughts regarding the app and substance use–related content through a "think-aloud" technique [43-46]. Following the think-aloud sessions, participants engaged in a cognitive interview to further understand the acceptability of the app for substance screening and evaluation [47-51]. Examples of questions used during the cognitive interview included, "If you were actively using a substance, how do you think that you may feel about disclosing substance use on an app?", "How do you feel about tracking substance use–related information in an app?", and "Is there information you feel more comfortable sharing through the app compared to when you are talking directly to your provider?" Participants also completed a usability survey regarding the app's features (Multimedia Appendix 2) [52,53]. Participants were then encouraged to use the app as much or as little as they wished over the next 4 weeks.

At-home app usage was measured and transmitted through a secure HIPAA (Health Insurance Portability and Accountability Act)-compliant server to the research staff. For privacy protection, access to the app was protected by a password set up by the individual user. The password reset function required app users to provide their unique user ID and then complete instructions on resetting their password via a personalized SMS text message sent to their own, prespecified contact number. For sensitive questions embedded in the app (eg, substance use, reports of intimate partner violence), an icon was displayed that reminded users that information they shared might be transmitted to their health care provider. Participants were then recontacted by research staff by phone or in person to complete a brief follow-up survey regarding their impressions of independently using the app and any additional feedback or suggestions (Multimedia Appendix 3). The think-aloud sessions, cognitive interviews, and follow-up interviews were audio-recorded.

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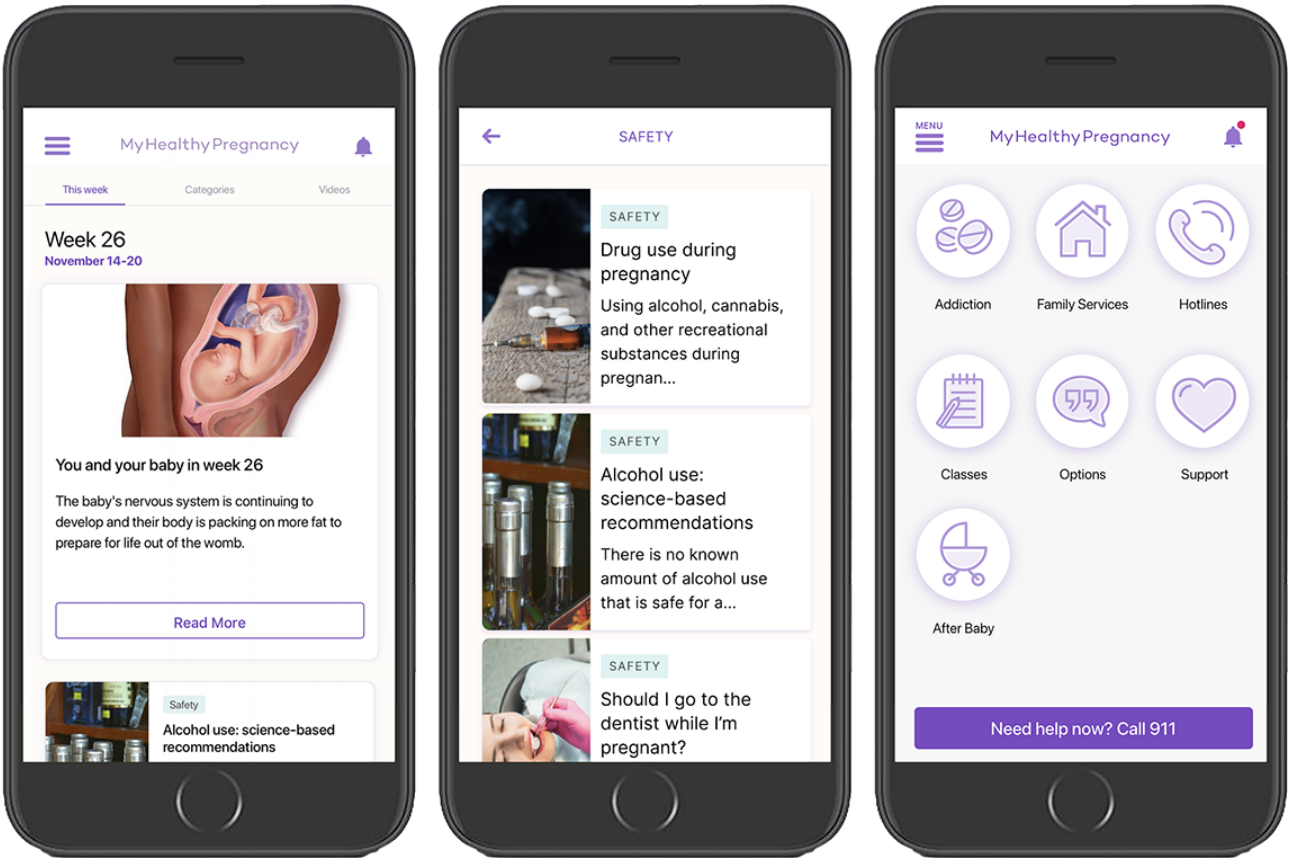
Figure 1. MyHealthyPregnancy sample screens offering substance use–related content and resources.



Data Analyses

Quantitative Analyses of Usability and Acceptability

Preliminary analyses evaluated survey and app usage data for completeness and accuracy and addressed any issues with data quality. Summary statistics were used to describe the participant characteristics, technology and mobile app use behaviors, assessments of app usability and acceptability, and participant-endorsed options for how a pregnancy app could assist with substance use. These statistics include means and standard deviations (or medians and quartiles for skewed distributions) for continuous variables and frequencies and proportions for categorical variables. Where appropriate, 95% CIs are included for means and proportions. IBM SPSS Statistics for Windows version 26 was used for quantitative statistical analysis [54].

Qualitative Analyses of Usability and Acceptability

Audio recordings from think-aloud sessions, cognitive interviews, and follow-up interviews were transcribed verbatim. Qualitative analyses were conducted using the Consolidated Framework for Implementation Research (CFIR)-based deductive analysis approach (directed content analysis), which is a rapid qualitative analytic method [53]. Prior to conducting the interviews, a preliminary codebook (in Microsoft Excel, version 16.54) was created by the research team. After the interviews were conducted, HF reviewed the transcripts using notes taken during the interviews to identify any additional codes or themes focused on understanding participants' experiences and perceptions of the app. The revised codebook was then used to code the transcripts for perspectives regarding the incorporation of substance use information in a pregnancy mHealth app.

Results

Study Sample

Over a 4-month enrollment period, 66 pregnant individuals were screened for eligibility, 24 declined to participate, and 6 did not meet study eligibility criteria. Among those that declined, the reasons provided were lack of interest in the study and limited time to attend study debriefs. Among those who did not meet the eligibility criteria, 5 participants did not have access to a smartphone due to rehabilitation facility or sober community living rules, and 1 participant was more than 37 weeks pregnant. Among the 36 participants who enrolled, 3 participants chose not to continue the study prior to using the app, 3 participants were unable to be reached for follow-up assessments, and 2 participants were found to no longer meet eligibility criteria due to fetal demise or lack of consistent access to a smartphone. Thus, 28 participants completed all study tasks and created the analytic sample.

Table 1 describes the characteristics of study participants. Most participants were White (21/28, 75%), Medicaid insured (26/28, 93%), and had an annual household income of less than US $30,000 (16/28, 57%). For 18% (5/28) of participants, this was their first pregnancy. The mean (SD) gestational age of participants at the time of enrollment was 22 (7.3) weeks. Substances used among participants consisted of tobacco (22/28, 79%), marijuana (20/28, 71%), illicit opioids (9/28, 32%),

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alcohol (6/28, 21%), stimulants (4/28, 14%), including either cocaine or amphetamines, and benzodiazepines (2/28, 7%). Approximately 46% (13/28) of participants were currently taking medication for opioid use disorder (eg, methadone or buprenorphine). Some individuals (4/28, 14%) used marijuana only. All remaining participants used a combination of 2 or more substances.

Table . Participant characteristics (n=28).

Demographics			Values
Age (years), mean (SD)			31 (4.6)
Race, n (%)			
	White		21 (75)
	Multiracial		5 (18)
	Black or African American		2 (7)
Ethnicity, n (%)			
	Hispanic or Latino		2 (7)
Marital status, n (%)			
	Married		7 (25)
Insurance, n (%)			
	Medicaid		26 (93)
Highest level of completed education, n (%)			
	Some high school		7 (25)
	High school or general equivalency diploma		8 (29)
	Some college, trade school, or associate's degree		11 (39)
	Bachelor's degree		1 (4)
	Master's degree		1 (4)
Employment, n (%)			
	Full- or part-time employed		9 (32)
Income (US $), n (%)			
	<30,000		16 (57)
	30,000 - 60,000		3 (11)
	60,000 or more		4 (14)
	Unsure		4 (14)
Pregnancy history			
	Gestational age at enrollment (weeks), mean (SD)		22 (7.3)
	Primiparous, n (%)		5 (18)
Substance use history,[a] n (%)			
	Tobacco		22 (79)
	Marijuana		20 (71)
	Opioids		15 (54)
		MOUD[b]	13 (46)
		Illicit opioid use	9 (32)
	Alcohol		6 (21)
	Stimulants (ie, cocaine and amphetamines)		4 (14)
	Benzodiazepines		2 (7)

[a]Type of substances used within 3 months prior to pregnancy or during pregnancy.

[b]MOUD: medication for opioid use disorder.

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Table 2 describes the technology behaviors and mobile app usage of participants. Texting (27/28, 96%) was the most commonly reported mode of communication, followed by phone (22/28, 79%), email (18/28, 64%), and social media (16/28, 57%). Health care providers (20/28, 71%) and mHealth apps (3/28, 11%) were the most frequently reported sources of pregnancy-related information followed by the internet or websites, family members, and friends. Health care providers were also noted to be the most trusted source of pregnancy-related information (27/28, 96%). mHealth apps were commonly used by participants, with 68% (19/28) reporting the use of a pregnancy app at the time of their enrollment and 26% (5/19) reporting that they used 2 or more pregnancy apps.

Table . Technology and mobile app use behaviors (n=28).

Technology use and communication during pregnancy		Values, n (%)
Source *most frequently* used for pregnancy information		
	Health care provider	20 (71)
	mHealth[a] apps	3 (11)
	Internet or websites	2 (7)
	Family members	2 (7)
	Friends	1 (4)
Source *most trusted* for accurate pregnancy information		
	Health care provider	27 (96)
	mHealth apps	1 (4)
Preferred methods of communication		
	Texting	27 (96)
	Phone	22 (79)
	Email	18 (64)
	Social media platforms	16 (57)
	Video calling or conferencing	11 (39)
	Apps	2 (7)
Smartphone ownership		28 (100)
Pregnancy app use (yes/no)		19 (68)
	Use of 2 or more pregnancy apps	5 (26)

[a]mHealth: mobile health.

Quantitative Analyses of Usability and Acceptability

Table 3 describes participants' experiences with the app. Measurements of the *usability* of the MyHealthyPregnancy app include participants' level of satisfaction with the ease of using the app and satisfaction with the time it took to use the app. Measurements of the app's *acceptability* include participants' overall satisfaction with the app, satisfaction with the interface, and how helpful the app was as a source of support. During the 4-week period, daily app use was the most common (12/28, 43%), and educational materials related to substance use were engaged with by the majority of participants (19/28, 68%). Acceptability and usability were generally high.

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Table . MyHealthyPregnancy usability and acceptability (n=28).

	Values, n (%)
Acceptability	
The app was a helpful source of support in pregnancy	27 (96)
Liked the way the app looks	27 (96)
Overall, I am satisfied with the interface of the app	25 (89)
Overall, I am satisfied with the app in general	25 (89)
Usability	
I am satisfied with the ease of using the app	23 (82)
I am satisfied with the time it took to use the app	22 (79)
It was easy to navigate through the app	27 (96)
Engagement[a]	
Daily	12 (43)
Weekly	8 (29)
Monthly	5 (18)
Substance use resource utilization	
Participants who browsed substance use educational materials	19 (68)
Participants who accessed substance use treatment referral information	2 (7)

[a]Frequency of app logins within a 4-week period.

Participant-endorsed options for how a pregnancy app could assist with substance use–related behaviors are described in Table 4. Almost all participants (27/28, 96%) expressed a desire to use an app to block phone calls or SMS text messaging from people who had a negative effect on substance use behavior, while more than half desired the ability to track substance use, cravings, or treatment medications. The least endorsed options included information on infectious disease prevention (5/28, 18%), harm reduction (4/28, 14%), or intimate partner violence (3/28, 11%).

Table . Participant endorsed options for how a pregnancy app could assist with substance use (n=28).

Options	Values, n (%)
Blocking phone calls or SMS text messaging from people who have had a negative effect on recovery	27 (96)
Tracking incidences of substance use or cravings	19 (68)
Receiving reminders to take substance use treatment medications (eg, MOUD)[a]	16 (57)
Information about support groups for parents with substance use disorders	12 (43)
Neonatal opioid withdrawal syndrome information	9 (32)
Infectious disease prevention information	5 (18)
Harm reduction information	4 (14)
Intimate partner violence resources	3 (11)

[a]MOUD: medication for opioid use disorder (eg, methadone or buprenorphine)

Qualitative Analyses of Usability and Acceptability

In cognitive interviews, participants shared their perspectives regarding substance use disclosure through a pregnancy app and how a pregnancy app could be useful for people using substances or with a substance use disorder. Five major themes were identified from these debriefs (Table 5). Participants felt that substance use disclosure on an app may be associated with less stigma than in-person disclosure (theme 1). However, they also noted that their comfort with disclosure would vary by the type and legality of the substance (theme 2). Participants expressed concerns related to who could access substance use information (eg, health care professionals and social services providers) on a pregnancy app and concerns related to being permanently labeled as someone with an addiction (theme 3). Despite concerns, participants did believe that pregnancy apps could be a useful source of substance use information and education (theme 4) and felt that combining pregnancy and substance use information on a single app was the most desirable approach (theme 5).

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Table . Participant perspectives regarding disclosure and incorporation of substance use information in a pregnancy mobile health app.

Theme	Example quote
Theme 1: Substance use disclosure on an app may be associated with less stigma than in-person disclosure	"I would feel a little more comfortable if I put it in the app than talking to an individual. The app doesn't judge you, like a human being would"
Theme 2: Disclosure comfort varies by type and legality of substance	"I definitely felt more comfortable disclosing legal drug use. For example, I do have my medical marijuana card, that is something I have no problem sharing, or alcohol and cigarettes, but yes, the non-legal ones, I would be a little nervous."
Theme 3: Concerns related to who could access disclosed substance use information	"Depending on what information I divulged, what would happen to that information? For example, would that be sent to a doctor? If it would be sent to a doctor or another professional or even a social worker… even though it would be confidential, I would just be worried I'd be labeled...and I will never be able to get away from my past addiction."
Theme 4: Prenatal apps could be a useful source of substance use information, education, and resources	"For the women who have no support or anyone to talk to, I really do think it is an effective tool to give them a little bit of encouragement and accurate information or just a guide: here are some resources, here is someone you could talk to."
Theme 5: Combining pregnancy and substance use information on a single app is desired	"Having it within a pregnancy app is kind of better personally just because it is all in one place...I've had recovery apps before, and I have fallen off of them. Actually, I completely forgot about them. So, like with pregnancy and having a kid and like getting ready for stuff, the simpler the better. So, if I don't have to go to multiple apps, that is great."

Discussion

Principal Results

Opioid use and the use of other addictive or illicit substances remain a significant and growing public health crisis in the United States. One significant barrier to providing early intervention during pregnancy is identifying individuals at risk and connecting them to care in a way that feels comfortable to them and through a mechanism which is engaging. One solution to identifying and engaging with pregnant individuals using opioids and other substances is through prenatal care apps. However, reaching pregnant individuals who use substances through more holistic prenatal care apps requires that the prenatal app be engaging and that app users who use substances must be willing to share their substance use through the app and act upon the information provided to them about recovery.

In this mixed methods, exploratory pilot study, incorporating substance use screening, information, education, and support into an existing prenatal app was found to be acceptable among pregnant people with substance use. Overall, participants showed high levels of interest in and engagement with MyHealthyPregnancy. Moreover, they reported being generally supportive of using an mHealth app as a means to access nonjudgmental resources for substance use during pregnancy. Our findings also indicate that there are multiple ways that an app could support individuals who use substances including blocking phone calls or SMS text messaging, providing information about recovery-oriented support groups, and offering resources regarding common co-occurring conditions (infectious disease acquisition, intimate partner violence, and harm reduction) [55].

Consistent with prior research demonstrating a high level of mHealth app usage among pregnant people (greater than 50%), most participants (19/28, 68%) reported that they had already used a prenatal app before starting the study, with some participants reporting the use of multiple prenatal apps [30,56-58]. In our study, apps were also identified, more generally, as a trustworthy, and easy-to-access source of pregnancy-related information, second only to health care providers. This aligns with other research findings demonstrating pregnant patients' appreciation for the accessibility and reliability of information found in prenatal apps [59]. Our study demonstrated a high level of engagement with our prenatal app, with 71% (20/28) logging in on a daily or weekly basis, similar to engagement levels that are considered high among other prenatal apps[60]. Together these findings suggest that a prenatal app-based intervention could be a beneficial strategy for information sharing between pregnant people who use substances and their providers, as this population already engages with and trusts this type of technology.

Our findings also indicate a high level of acceptability with incorporating substance use–related information into a pregnancy app. App usage data indicated that many participants browsed recovery-related educational materials on the app. These data align with other research demonstrating that people generally do not like moving between different apps to achieve their goals and prefer integrated technology tools, as well as prior findings showing that substance use screening and intervention in an app-based format has high acceptability and usability among patients [61,62]. Our participants expressed their interest in an expansion of substance use support capacity of the prenatal app, in alignment with prior research demonstrating that mHealth interventions are effective in areas including smoking cessation and addressing substance use during pregnancy[63]. Finally, many participants volunteered that disclosing substance use on an app may be easier than disclosing substance use in person, aligning with the current literature suggesting that self-report questionnaires and eHealth screenings could assist in creating more opportunities for disclosure than in-person evaluations alone [28,29,64].

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However, many participants expressed concerns about disclosing substance use on an app because they would not know who might have access to this information, similar to prior research demonstrating patient concern about data security even in general prenatal apps [58]. Concerns about prosecution and child welfare involvement are previously reported barriers to substance use disclosure, which can lead to delays in seeking prenatal care and engaging in substance use treatment [65,66]. Mandatory reporting laws and the potential for child protective services involvement are major barriers to seeking treatment among pregnant people with opioid use disorder [67]. Any app that collects sensitive patient health information is required to comply with HIPAA. Moreover, any app that offers a substance use disorder treatment service must comply with the Opioid Addiction Recovery Fraud Prevention Act of 2018, which requires transparent and fair practices around how private health information is shared [68]. However, concerns about seeking and engaging in substance use treatment during pregnancy legitimately extend to disclosure and substance use treatment seeking through digital health means. In prior qualitative research, parents note that mandatory reporting regulations are biased, unjust, and stigmatizing and assert that stress stemming from the potential involvement of child welfare agencies has had a pronounced and detrimental impact on their families [67,69,70]. Moreover, since the 2022 *Dobbs v. Jackson* Supreme Court decision that ended federal protections for abortion, there have been increasing reports of digital health data being subpoenaed to criminalize pregnant individuals, further legitimizing caution around disclosure of certain health behaviors, especially during pregnancy [71,72].

Given both the concerns and interest voiced by our participants regarding embedding substance use screening and connection to care into a prenatal app, providers should familiarize themselves with any prenatal or substance use support apps available to patients prior to recommending them, including evaluating the evidence base, equity focus, and HIPAA protections afforded to such tools [73]. We additionally suggest that any providers discussing such apps with patients also educate patients about their rights and privacy related to disclosing substance use or other sensitive information in these apps. Providers can also encourage patients to share feedback about which apps they have found useful (or not) to support provider recommendations.

Limitations

There were several study limitations. First, approximately 36% (24/66) of those approached for study participation declined to enroll. Because many of those who declined to participate lacked interest in study participation, our sample may have been biased toward those who are more willing to use mHealth technology for health engagement or toward those with fewer reservations about disclosing substance use. In addition, all participants enrolled in the study had a known history of substance use. As such, their behaviors and perspectives may not be generalizable to pregnant people who have never disclosed their substance use within a health care setting. Next, our study sample was small and consisted of predominantly non-Hispanic White individuals, which limits the degree to which we can generalize our findings. Opioid overdose rates among Black individuals exceed those of White individuals by 4-6 times, and there are significant disparities in the receipt and use of medication for opioid use disorder between non-Hispanic White and Black and Hispanic pregnant individuals [74,75]. Thus, our findings cannot be generalized to those who may be at highest risk of not receiving adequate care. While the sample size for this exploratory pilot study was aligned with norms for thematic saturation for qualitative interview feedback to offer initial data on acceptability, a larger randomized trial with intentional demographic sampling would be required to adequately test implementation or intervention effects of incorporating substance use screening and content into the mHealth tool [76-78].

Conclusions

In this study, pregnant people with substance use found an existing pregnancy app to be an acceptable means of incorporating substance use supports and screening. Participants were already frequent users of prenatal apps and showed a high level of engagement with the prenatal support app in the study. At the completion of the study, participants expressed positive feelings about the usability of the app and interest in expanding the of the substance use support features of this app although some notable concerns relating to data privacy were raised. Given the prevalence of technology and app usage among pregnant people and the rise in substance use during pregnancy, mHealth technology should be considered a complement to in-person prenatal substance use screening and evaluation. Providing opportunities for substance use disclosure and resource provision through an acceptable digital platform that people are already using for pregnancy could result in earlier treatment engagement, along with improved outcomes among those who use substances. Our findings highlight this as an acceptable and desirable approach.

There is an ethical imperative for any prenatal app incorporating substance use–related content to clearly communicate both the confidentiality constraints of the tool and the potential consequences of disclosure prior to screening. As a way to address app users' concerns, developers should consider designing data collection so that any sensitive data are deleted as soon as possible or are only stored locally and not in a location that could be at risk of subpoena. App developers should also be sure to communicate clearly to app users about privacy and seek active consent for the collection or storage of any sensitive data. Finally, app developers should consider instating a policy prohibiting engagement in third-party data sharing, with the exception of HIPAA-compliant data sharing with the health care provider. Policy makers should ensure clear communication with providers about their rights related to substance use disclosure during pregnancy and potential legal repercussions. Health care providers considering using pregnancy apps, particularly for substance use screening or treatment referral, should evaluate whether the apps are evidence-based and adherent to strict policies around data protections. This may include being proactive about self-education regarding HIPAA privacy rules, as well as the state and institutional protections in place, so that they can communicate these clearly to their patients when recommending that patients share sensitive information through these tools.

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Lastly, additional research is needed to prospectively evaluate and test patient-centered substance use screening and connection to recovery resources within pregnancy apps, as well as to understand and measure the rates of disclosure rates across substances. We recommend that any individuals involved in the development, use, or evaluation of pregnancy tools, which may provide these services, draw on established frameworks that center the needs and values of the target population, while proactively addressing health disparities as a strategy to advance health equity and improve health outcomes [73]. Through a personalized approach to health care, prenatal health apps can play a role in identifying and supporting pregnant people with substance use.

Acknowledgments

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Conflicts of Interest

EEK is an investigator on grants to Magee-Womens Research Institute from the National Institutes of Health, Gilead, and Merck outside of the submitted work. TK is an investigator on grants to the University of Pittsburgh from the National Institutes of Health outside of the submitted work. TK is a cofounder of Naima Health, which provided app usage data for this study. The other authors report no conflicts of interest.

Multimedia Appendix 1
Baseline survey questions.
[DOCX File, 26 KB - pediatrics_v8i1e60038_app1.docx]

Multimedia Appendix 2
Usability survey questions.
[DOCX File, 19 KB - pediatrics_v8i1e60038_app2.docx]

Multimedia Appendix 3
Follow-up survey questions.
[DOCX File, 17 KB - pediatrics_v8i1e60038_app3.docx]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
HIPAA: Health Insurance Portability and Accountability Act
***ICD-10*:** *International Classification of Diseases, Tenth Revision*
mHealth: mobile health
VA: Veterans Affairs

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Original Paper

Simulation of Contraceptive Access for Adolescents and Young Adults Using a Pharmacist-Staffed e-Platform: Development, Usability, and Pilot Testing Study

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Abstract

Background: Offering contraceptive methods at pharmacies without a prescription is an innovative solution to reduce the incidence of unintended pregnancies among adolescents and young adults (AYA). Pharmacy-prescribed contraception may increase the convenience, simplicity, and affordability of contraceptives.

Objective: The aim of this study was to develop, pilot test, and evaluate the acceptability and feasibility of a telemedicine electronic platform app simulating pharmacist prescribing of contraceptives to AYA as well as assess agreement between pharmacist-simulated contraceptive approvals and contraception as prescribed in routine clinic visits.

Methods: This study was conducted in two phases: (1) development and usability testing of a prototype app to simulate pharmacists prescribing contraceptives to AYA and (2) pilot testing the app in a simulation for AYA requesting contraception from a pharmacist with pharmacist review and request approval or rejection. Eligibility criteria in both phases included the following: assigned female sex at birth, age 15-21 years, seeking contraceptive services at an academic adolescent medicine clinic, prior history of or intention to have penile-vaginal intercourse in the next 12 months, smartphone ownership, and English language proficiency. Phase 1 (usability) involved a video-recorded “think aloud” interview to share feedback and technical issues while using the app prototype on a smartphone and the completion of sociodemographic, sexual history, and perception of the prototype surveys to further develop the app. Phase 2 (pilot) participants completed phase 1 surveys, tested the updated app in a simulation, and shared their experiences in an audio-recorded interview. Descriptive analyses were conducted for quantitative survey data, and thematic analyses were used for interview transcripts.

Results: Of the 22 participants, 10 completed usability testing, with a mean age of 16.9 (SD 1.97) years, and 12 completed pilot testing, with a mean age of 18.25 (SD 1.48) years. Three issues with the prototype were identified during “think aloud” interviews: challenges in comprehension of medical language, prototype glitches, and graphic design suggestions for engagement. Usability testing guided the frontend and backend creation of the platform. Overall, participants agreed or strongly agreed that using an app to receive contraceptives would make it easier for teens to access (n=19, 86%) and make contraceptive use less stigmatizing (n=19, 86%). In addition, participants agreed that receiving contraception prescriptions from a pharmacist without a clinic visit would be safe (n=18, 82%), convenient (n=19, 86%), acceptable (n=18, 82%), and easy (n=18, 82%). Pharmacists and medical providers had 100% agreement on the prescribed contraceptive method for pilot participants.

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Conclusions: AYA found contraceptive prescription by a pharmacist via an app to be highly acceptable and provided critical feedback to improve the design and delivery of the app. Additionally, pharmacist contraceptive approvals and contraception as prescribed in routine clinic visits were identical.

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KEYWORDS

adolescent; contraception; telemedicine; user-centered design; young adult; reproductive; design; usability; experience; mHealth; mobile health; app; youth; teenager; drug; pharmacology; pharmacotherapy; pharmaceutics; medication; pharmacy; digital health; platform; access

Introduction

Pregnancy rates among adolescents and young adults (AYA) 15-19 years old have dropped from 61.8 births per 1000 in 1991 to 13.5 in 2022, while AYA 20-24 years old reported a record low pregnancy rate of 60.4 births per 1000 [1]. For 2010-2019, pregnancy rates declined the most for youth 19 years old and younger, a 50% decrease, followed by a 29% drop for 20-24 year olds [2]. Evidence suggests the decline in pregnancy rates may be attributed to increased access to comprehensive sex education, use of contraceptives and health care, and not due to decreased sexual activity [3]. However, sexually active AYA, aged 15-24 years, were the most likely age group to experience unintended pregnancies in the United States [2,4]. Despite evidence showing the value of access to sex education and contraceptive services in reducing pregnancy rates among AYA, laws restricting access to both are increasingly being introduced and passed in US state legislatures. Legal restrictions intensify barriers, such as cost, attending appointments, stigma, and more to accessing contraceptives [5,6], which disproportionately affects low-income, disabled, racial or ethnic minorities, and other marginalized women and other birthing people [7]. Pharmacist-prescribed contraception—a strategy already used in high-income and many low- and middle-income countries but rarely in the United States—is one such strategy. In 2019, the American College of Obstetricians and Gynecologists recommended pharmacist-prescribed contraception without age restrictions as a necessary step to increase over-the-counter access to hormonal contraception and reduce the rate of inconsistent or nonuse of contraception [8].

In prior research, women and other birthing people voiced “convenience, simplicity, [and] affordability” as primary benefits of pharmacist-prescribed contraception [9]. In a study in California among 426 women and other birthing people, pharmacy access for emergency hormonal contraceptive (EHC) was preferred to clinician prescription as it was perceived to be faster (54%) and more convenient (47%) than seeking physician prescription [10]. Another study found that 68% of women who were at risk for unintended pregnancy reported they would prefer to obtain the contraceptive pill, patch, ring, or EHC from a pharmacy rather than a clinic if pharmacist prescribing was an option [9]. Moreover, 41% of those not currently using contraception reported they would start a contraceptive method via pharmacist prescribing if available [10]. Provision of EHC via community pharmacies has increased the use of EHCs; moreover, expanding access in this way is estimated to prevent almost half (1.3 million) of the 3 million unintended pregnancies annually [11]. Centering patient priorities for access, as well as patient preferences for method choice, is a key tenet of reproductive justice and high-quality contraceptive care.

Historically, women and other birthing peoples’ safety has been the most common concern regarding contraception delivery without a clinician-provided prescription [9]. However, multiple studies demonstrate that patients can accurately self-screen for contraindications to contraceptive use using medical checklists [12,13]. One study found greater than 93% of 328 patient-physician concordance for risk factor identification [12]. In another study, self-screening by patients using a medical checklist of contraindications was found to have greater sensitivity (83.2%) and specificity (88.8%) than a patient self-completed clinician questionnaire, which asked them to simply consider their medical history to determine the presence of contraindications (56.2% sensitivity; 57.6% specificity) [13]. This means when using a medical checklist of contraindications, women were able to accurately self-screen for contraindications to combined hormonal contraception [13]. Given the consistency of evidence supporting patient ability to medical self-screen for contraceptive contraindications, the American College of Obstetricians and Gynecologists endorses patient use of self-screening tools to determine eligibility for over-the-counter access to hormonal contraception [8].

Pharmacist-prescribed contraception innovations will need to develop strategies for successful implementation prior to widespread scaling [14]. Implementing screening tools has proved challenging for non-sexual health services for select populations, like youth [14]. Developing outreach strategies for youth and other vulnerable populations may require careful consideration. Attention to the training of point-of-service staff may facilitate service delivery and uptake. Studies of pharmacy staff indicate greater hesitancy and a desire for more intense training before providing sexual health services compared to non-sexual health services [15]. Attention to training and post-training support services may be necessary to ease implementation challenges. Newer technologies, like telemedicine, that allow skilled providers to deliver services across a distance may be valuable in bridging this gap until larger numbers of pharmacists are comfortable delivering pharmacist-prescribed sexual health services. Combining innovations such as telehealth and pyxis machines can allow pharmacists who are trained and comfortable providing sexual health services to AYA to do so.

There is limited research on pharmacist-prescribed contraception for US adolescents [4]. This study sought to develop an e-platform app called Birth Control Pass (BCPass) to simulate

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pharmacists prescribing contraceptives to AYA, test the acceptability and feasibility of pharmacist-delivered contraception among AYA as a proof of concept, and determine the concordance between pharmacists and providers on the appropriate contraceptive method(s) to be prescribed to participants.

Methods

Overview

This study occurred in 2 phases. In Phase I, the e-platform was developed, and participants were recruited to engage in usability testing. In Phase 2, participants pilot-tested the e-platform.

Participants and Setting

Eligible participants for both study phases were patients seeking contraceptive initiation services at a subspecialty academic adolescent medicine clinic, ages 15-21 years old, assigned female sex at birth, with a prior history of or intention to have penile-vaginal intercourse in the next 12 months, owned a smartphone and could read and speak English. Usability testing of the prototype was completed in April of 2021. Modifications were made to the app to address participants' concerns and implement suggestions through iterative usability testing between developers and the study team. Pilot testing of the final prototype occurred between October 2021 and August 2022.

Ethical Considerations

Institutional Review Board approval was granted by the Children's Hospital of Philadelphia (20-017957). Participants received a $20 US gift card for their time and effort. Precautions were taken to secure participants' personal information to ensure confidentiality including, the use of study identification numbers that were assigned to participants and used in place of participants' name and other private information on data collection forms.

Recruitment Strategy

For both study phases, the study team reviewed clinic schedules daily to identify patients with contraceptive appointments on the same day or the following clinic day. Clinic staff also referred patients for recruitment. Patients were approached in person at their medical appointment, by phone call, or via SMS text message. Consent was obtained via wet-ink signature on paper forms or electronic consent (e-consent) on Children's Hospital of Philadelphia's Research Electronic Data Capture (REDCap) [16,17] data collection application. Consent was provided either by legal guardians who attended clinic visits with patients 17 years old and younger or by the patients themselves, who were legally eligible to consent for themselves if they attended clinic visits alone [18] or were older than 18 years old. Participants were informed that by engaging in the research study, they would be testing the e-platform interface that simulated pharmacist prescribing but that they would not receive contraception as part of the study activities. Participants understood that contraception would be provided by their clinician during their scheduled medical visit, as per usual clinical care guidelines. Participants engaged with the e-platform either before or after their scheduled medical visit.

Study Procedures

Phase 1: Development and Usability Testing

We created the BCPass prototype by modifying a large pediatric hospital system's app for employee COVID symptom check-in. The goal of the prototype was to simulate patient medical screening, patient contraceptive choice, and pharmacist contraceptive prescribing. The prototype first collected contact and self-screening information related to background and medical history. Next, participants were instructed to review content about contraceptive methods using a direct link to the educational website bedsider.org [19] and indicate their preferred method. Responses on the self-screening form were linked directly to medical contraindications to contraceptive prescribing per the Centers for Disease Control and Prevention US Medical Eligibility Criteria to facilitate rapid prescribing decision-making [20]. The prototype app included only a front-end interface for usability testing participants, but there was no backend personal health information data storage or pharmacist involvement. The study team explained to participants how the final app would work, including that if the participant had questions during the simulation, they had the option to call a pharmacist via the app ("Ask a Pharmacist" call button). Additionally, once the request for the preferred contraceptive method was submitted, a pharmacist would review and complete a "Pharmacist Approval Assessment Form" indicating if they would prescribe the contraceptive and approve dispensing or reject the request.

Participants completed web-based multiple-choice and short-answer surveys regarding their sociodemographic, sexual history, and attitudes regarding pharmacist-prescribed and app-delivered contraception. Next, they tested the prototype in a video-recorded "think aloud" interview [21], capturing the participants' initial impressions of the prototype, technical issues, and feedback while they actively engaged with the app prototype on their own smartphones. Studies using the "think aloud" methodology have proven to be successful at identifying usability problems without requiring a large number of subjects [21]. Participants were prompted to remark on ease of use, design aspects that are confusing or that slow task completion, and graphical elements, such as font size, ratios of images to words, and color schemes. The study team observed this process and took structured notes to capture information regarding domains from the sociotechnical model to ensure the optimization of service delivery [22]. Following prototype testing, participants' attitudes toward receiving contraception from a pharmacist and an app were assessed on a 5-point Likert scale: 1=strongly disagree, 2=disagree, 3=unsure, 4=agree, and 5=strongly agree. A 7-point Likert scale was used to evaluate the usefulness, ease of use, effectiveness, reliability, and satisfaction with the prototype (1=strongly disagree, 2=disagree, 3=somewhat disagree, 4=neither agree nor disagree, 5=somewhat agree, 6=agree, 7=strongly agree). Analyzed usability testing data was presented to the study team and app developers to inform the development of the app frontend and backend, along with iterative testing and weekly meetings (Figure 1). Special care was taken to thoroughly test each "click" on the app, and automated messages were reviewed to ensure ease of access and fluidity.

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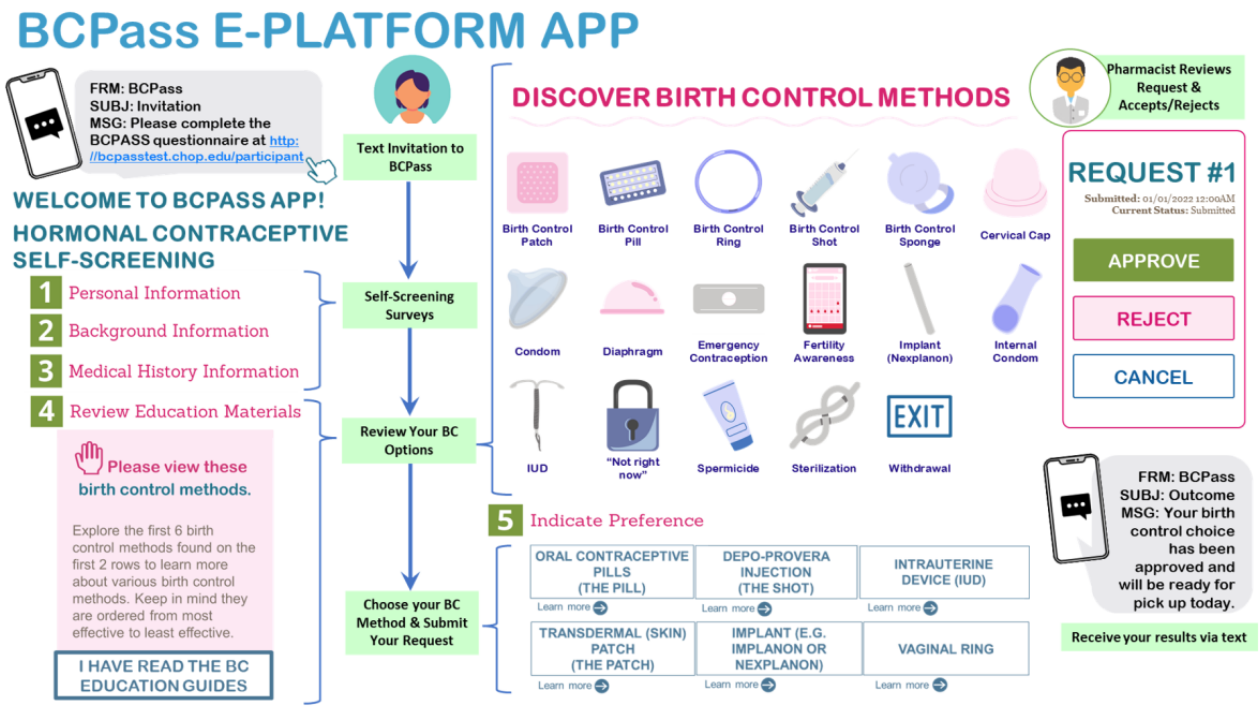
Figure 1. Birth Control Pass (BCPass) e-platform app overview. Overview of the BCPass app, invite link, participant-entered information, education information review [19], preferred contraception option, and the pharmacist review and outcome. "Discover Birth Control Methods" was adapted from the bedsider.org birth control dashboard webpage [19].



Phase 2: Pilot Testing

Once a fully functional app was developed, a study pharmacist was trained to implement the study protocol, and AYAs were recruited to pilot test the intervention. Pilot participants completed web-based surveys regarding their sociodemographic, sexual history, and attitudes toward receiving contraception from an app and a pharmacist. Next, participants completed a simulation exercise, which included completing a medical history form to identify contraindications to contraception, learning about contraceptive options via bedside.org [19], and selecting a contraceptive method. As part of the simulation, a text or email was sent to their smartphone with a link to the app. After they submitted their request for a contraceptive method, the study pharmacist accessed the request on the backend to review and complete the "Pharmacist Approval Assessment Form." Participants then received an automated SMS text message to confirm if the pharmacist accepted (prescribed the contraceptive and approved dispensing), rejected (shared information to call the clinic that provides contraceptive care), or requested additional information (when participants requested methods unavailable for pharmacist prescribing, such as long-acting reversible contraceptives and injectable medroxyprogesterone acetate).

Following the simulation, pilot participants completed a web-based survey to evaluate the usefulness, ease of use, effectiveness, reliability, and satisfaction on 5-point and 7-point Likert scales. Participants then engaged in a brief audio-recorded interview that solicited feedback on the app and participants' decision-making process in selecting a contraceptive method. After participants completed their clinic visit, the contraceptive method prescribed during their routine appointment was abstracted from their electronic medical record.

Analysis

Data analysis was conducted at two time points following phase 1 and phase 2, respectively. Deidentified survey demographics, sexual history, and Likert responses were exported from REDCap to Microsoft Excel for analysis. Descriptive analysis was computed for demographics and sexual history (proportions), and mean score and standard deviation were calculated for Likert questions. Audio from the "think aloud" video interview (usability) and feedback interview (pilot) were transcribed and manually coded by two coders until a 95% agreement regarding the themes was reached. For usability testing, participant comments and suggestions were categorized based on the type of modifications needed to the app (ie, wireframe, self-screening comprehension, and graphics). Interview data from the pilot testing was similarly thematically coded to reflect perceptions about the app's effectiveness, acceptability, feasibility, and participants' contraceptive decision-making. Effectiveness was defined as the e-platform success in simulating a birth control prescription. Acceptability or satisfaction with the e-platform was defined as participants' perceptions when using BCPass. Feasibility (BCPass practicality for learning about and accessing birth control) was defined by BCPass's usability or ease of use in navigating the e-platform and submitting a request for birth control. Lastly, birth control decision-making was based on participants' considerations made when indicating their birth control preference before and after using BCPass. Using the codebook, two coders not involved in usability qualitative analysis (one assisted with e-platform modifications and data collection, and the other helped with qualitative analysis only) classified statements in each thematic

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area as positive, neutral, or negative. Finally, we assessed concordance between the contraceptive method selected at the medical visit (electronic medical record data) and the pharmacists' decision to approve or reject the participant's request for a contraceptive method.

Results

Participant Characteristics

In total, 22 AYA participated: 10 in phase 1 (usability testing) and 12 in phase 2 (pilot testing). On average, participants were 17.64 (1.50) years old, had some high school education (n=13), graduated from high school (n=4) or had some college (n=5), and had previously used contraception (n=17). See Table 1 for participant demographics and sexual history.

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Table 1. Usability and pilot testing participant demographic and sexual history.

Characteristics	Usability testing (n=10)	Pilot testing (n=12)	Totals (N=22)
Age (years), n (%)			
15-16	3 (30)	1 (8)	4 (18)
17-18	7 (70)	7 (58)	14 (64)
19-21	0 (0)	4 (34)	4 (18)
Race or ethnicity, n (%)			
Black or African American	Unknown[a]	6 (50)	Unknown[a]
Hispanic or Latinx	Unknown[a]	1 (8)	Unknown[a]
White (non-Hispanic or Latinx)	Unknown[a]	5 (42)	Unknown[a]
Education, n (%)			
Not graduated high school	8 (80)	5 (42)	13 (59)
High school degree or General Education Development	1 (10)	3 (25)	4 (18)
Some college	1 (10)	4 (33)	5 (23)
Number of sex partners, n (%)			
None	4 (40)	2 (17)	6 (27)
Less than 3	3 (30)	8 (66)	11 (50)
Between 3 and 5	2 (20)	0 (0)	2 (9)
More than 5	0 (0)	2 (17)	2 (9)
Preferred not to say	1 (10)	0 (0)	1 (5)
Ever taken a pregnancy test, n (%)			
No	6 (60)	6 (50)	12 (55)
Yes	4 (40)	6 (50)	10 (45)
Ever been pregnant, n (%)			
No	10 (100)	12 (100)	22 (100)
Yes	0 (0)	0 (0)	0 (0)
Used birth control to prevent pregnancy, n (%)			
No	3 (30)	2 (17)	5 (23)
Yes	7 (70)	10 (83)	17 (77)
Ever used condoms during sex, n (%)			
No	3 (30)	2 (17)	5 (23)
Yes	7 (70)	10 (83)	17 (77)
Frequency of condom use[b,c], n (%)			
Never	0 (0)	1 (10)	1 (6)
Sometimes	2 (29)	6 (60)	8 (47)
Always	4 (57)	3 (30)	7 (41)
Unknown	1 (14)	0 (0)	1 (6)
Ever had a sexually transmitted infection[b], n (%)			
No	8 (80)	8 (67)	16 (73)
Yes	2 (20)	3 (25)	5 (23)
Unknown	0 (0)	1 (8)	1 (4)

[a]Race or ethnicity was not self-reported by usability participants in this phase of the study. Electronic medical record race and ethnicity data is not self-reported and may misidentify participants. Therefore, this study only reports self-reported information collected during the pilot testing phase.

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[b]Due to rounding, some totals may not correspond with the sum of the separate figures.

[c]Participants were only asked about their frequency of condom use if they answered yes to using condoms during sex. Participants could have responded yes to ever using condoms, but they may not currently be using them.

Quantitative Survey: Acceptability and Feasibility of Pharmacist- and App-Delivered Contraception

Pharmacist-Prescribed Contraceptives

Usability and pilot participants (N=22) agreed receiving a contraceptive prescription from a pharmacist without a clinic visit would be safe (mean 4.27, SD 0.88), convenient (mean 4.50, SD 0.74), easy (mean 4.32, SD 0.89), and acceptable (mean 4.27, SD 1.08; Table 2). If they had the option to receive contraception from a pharmacist without a clinic visit, 14 of 22 participants reported they were likely or very likely to do so.

Table 2. Perceptions of pharmacist and app-delivered contraception (N=22, Likert Scale 1-5).

	Mean (SD)
Safety, convenience, acceptability, and ease receiving birth control	
Getting birth control prescribed by a pharmacist would be safe	4.27 (0.88)
Getting birth control from a pharmacist would be convenient	4.50 (0.74)
Getting birth control from a pharmacist would be acceptable to me	4.27 (1.08)
I think it would be easy to receive birth control from a pharmacist	4.32 (0.89)
Getting birth control from an app would be safe	3.82 (1.14)
Getting birth control from an app would be convenient	4.45 (1.01)
Getting birth control from an app would be acceptable to me	3.95 (1.17)
I think it would be easy to use an app to get birth control	4.36 (1.00)
Advantages of using an app to receive birth control	
It would be easier for teenagers to get oral contraceptives	4.55 (0.74)
It would feel less embarrassing	4.27 (0.98)
It is less stigmatizing, meaning more normal to use	4.45 (0.86)
Fewer teenagers would get pregnant	4.32 (0.99)
It would be more confidential	3.82 (1.30)
Disadvantages of using an app to receive birth control	
Teenagers might not use condoms to protect against sexually transmitted diseases	3.91 (0.87)
Teenagers need a doctor to decide if oral contraceptives are safe for them	3.73 (1.12)
Teenagers might have sex at a younger age	3.14 (1.32)
Teenagers might use oral contraceptives incorrectly	3.36 (1.05)
Teenagers might not get tested for sexually transmitted diseases	3.55 (1.26)
Oral contraceptives might cost more over the counter	3.50 (0.86)
Teenagers might not talk to their parents about birth control	4.00 (0.87)
I have no worries (concerns) about teens using a medication dispensing machine to get birth control	3.09 (1.11)
Social approval	
Most people who are important to me would approve of me using an app to get birth control	3.64 (1.14)
Most teens like me would use an app to get birth control	4.27 (0.77)
Teens my age would use an app to get birth control	4.23 (0.97)
Parents or family would support me using an app to get birth control	3.32 (1.30)
My romantic partner(s) would support me using an app to get birth control	4.09 (1.06)
The decision to use an app to get birth control would be totally up to me	4.18 (1.10)
I am confident that I could use an app to get birth control	4.09 (1.19)

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Receive Contraceptives Through an e-Platform App

Usability and pilot participants (N=22) agreed that receiving contraception using an app would be safe (mean 3.82, SD 1.14), convenient (mean 4.45, SD 1.01), easy (mean 4.36, SD 1.00), and acceptable (mean 3.95, SD 1.17) (Table 2). Additionally, participants were confident they would be able to use an app to get contraception (mean 4.09, SD 1.19) and agreed most teens would use an app to get contraception (mean 4.27, SD 0.77). A potential advantage recognized by participants of using an app would include fewer teenagers experiencing an unintended pregnancy (mean 4.32, SD 0.99), getting contraception would be less embarrassing (mean 4.27, SD 0.98), and less stigmatizing (mean 4.45, SD 0.86). Participants agreed a potential disadvantage of receiving birth control from an app is that it may lead teens to not talk to their parents about birth control (mean 4.00, SD 0.87) or a possible decrease in condom use and an increase in sexually transmitted infections among teens (mean 3.91, SD 0.87). See Table 2 for additional insight into participants' attitudes toward pharmacists and app-delivered contraceptives.

E-Platform App Survey Feedback

Overall feedback on the BCPass app simulation during prototype and final productive testing was positive (Table 3). Participants agreed that BCPass was simple to use (mean 6.33, SD 1.24) and pleasant to interact with (mean 6.00, SD 1.64). Additionally, participants felt the app could do everything they would want it to be able to do for contraceptive delivery (mean 6.15, SD 1.23) and agreed they would use it again (mean 6.29, SD 1.54).

Table 3. BCPass app simulation feedback (N=22, Likert scale 1-7).

	Mean (SD)
BCPass was simple to use	6.33 (1.24)
BCPass was easy to learn and use	6.43 (1.02)
I believe I could become productive quickly using BCPass	6.05 (1.51)
The way I interact with BCPass is pleasant	6.00 (1.64)
I like using BCPass	6.00 (1.44)
BCPass can do everything I would want it to be able to do	6.15 (1.23)
I would use BCPass again	6.29 (1.54)

Clinician- and Pharmacist-Prescribed Contraception Concordance

A comparison of piloting participants who indicated a contraceptive preference (n=9) and what was prescribed revealed pharmacist contraceptive decisions and contraception methods as prescribed in routine clinic visits were identical. One of the 8 participant requests was rejected by the pharmacist because of a contraindication. This participant noted in their feedback interview that they requested a method they knew was contraindicated because it was their first choice over the contraception method they were prescribed. Three participants selected "I don't know" at the end of the simulation. One remained undecided following their clinic appointment. Another selected "I don't know" because they had an IUD at the time of the study but knew their first-choice method was contraindicated. The third selected a method at their clinic appointment. Of the 12 participants, one did not attend their clinic appointment, so it is unknown what they would be prescribed.

Qualitative Feedback

Usability Testing Think Aloud Data and Resultant e-Platform App Modifications

In an analysis of usability testing phase data, participants identified modifications related to addressing prototype wireframe glitches, self-screening comprehension, educational resource engagement, and app aesthetics. The prototype's wireframe glitches were anticipated as it was designed as a temporary test environment, and once the production frontend, patient-facing screen, backend, and developer view were created, the issues were resolved.

While navigating the prototype, participants requested clarification on the medical history questionnaire, indicating comprehension concerns. For example, participants asked if the transdermal skin patch was the same patch with which they were familiar. Additionally, participants asked what constitutes prolonged immobility or a bad reaction to hormonal contraception. The study team revised any questions that were identified as confusing and may be perceived as confusing to participants' peers. Examples and lay language were used for questions that required more medical terminology, such as including the more popular names for contraceptive methods in parentheses next to the full names (ie, oral contraceptive pill ["the pill"], transdermal hormonal patch ["the patch"], and injectable medroxyprogesterone acetate ["the shot"]).

Participants' feedback on the lack of educational material and the app's aesthetics were closely associated concerns. Numerous participants noted they skipped the mandatory contraceptive method educational website, explaining they did not see the link or felt it was not important. The color palette and ambiguity of the "Ask a Pharmacist" call button and bedsider.org weblink were noted as weaknesses. The team determined adding color and images was a solution to attract participants' attention to educational materials. A welcome page was created to introduce the purpose of BCPass and provide written instructions on how to contact the study pharmacist via the "Ask a Pharmacist" call button.

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Pilot Testing Interview Feedback

The following four primary themes emerged during the coding process: (1) the perceived effectiveness of the BCPass app, (2) AYA's perceptions of using BCPass (usefulness as a standalone or compared to the standard of care), (3) BCPass practicality for learning about and accessing contraception via an app, and (4) AYA's considerations when selecting a contraceptive method before and after the BCPass simulation.

Of the 12 pilot participants, one interview was not completed because the study team could not reach the participant; thus, the results reflect 11 of the 12 participants. A quarter of the 11 pilot participants commented on receiving contraceptive prescriptions through BCPass from a pharmacist easily in the simulation. One participant expressed that BCPass may be unrealistic outside of the simulation due to safety concerns they had in making contraception more accessible to AYA without additional educational discussions with a provider. Due to the nature of the simulation, participants understood they would not receive a method as part of the study; therefore, the perceived effectiveness of BCPass was minimally mentioned.

> *"The only thing that surprised me was that um you can literally just just get it. Like you don't like need any doctor's approval like just being able to get it"* [Participant 1, selected implant in BCPass]

BCPass was highly acceptable among the 11 AYA pilot participants. The majority of pilot participants (73%) found BCPass to be quick, easy, convenient, and accessible. More than half (64%) found the process to be enjoyable and a good accessible option for other AYAs to request contraception compared to the standard of care of receiving contraception from a clinician after a medical appointment. Many participants stated they liked receiving contraception information from BCPass as well as avoiding a trip to a clinic and potentially uncomfortable conversation with a clinician (55%). Yet 18% of participants expressed they would also like the option to talk to a clinician by phone or in person in addition to the option they were given to talk to a pharmacist through BCPass. Some participants (18%) felt BCPass may not be adequate for AYA due to the possible need for more direct clinician oversight for young people and those with complex care needs.

> *"I also really liked the idea of not having to go to the doctor and have an awkward conversation about getting birth control"* [Participant 2, selected oral contraceptives in BCPass]

> *"I like that it was fast and convenient and I didn't have to go see a doctor. I could do it right on my phone. Um, I liked that it like also gave me a little feel about all the different kinds of birth control methods because I think that we are not often given information about all of them"* [Participant 3, selected IUD in BCPass]

A majority of the 11 pilot participants (91%) reported that BCPass was easy, quick, and convenient to use, with straightforward instructions and easy-to-answer questions. A third (36%) stated the information they received as part of the BCPass simulation was comparable to what they received at a medical appointment, including a participant stating the BCPass questions and education materials helped them determine what contraceptive method was best for them. While many usability concerns were addressed in the first phase of the study, 64% of participants shared feedback to further improve the experience for AYA. Suggestions included shortening the questionnaire, clarifying questions, deleting repetitive questions, and improving the delivery of educational materials.

> *"I liked how, I enjoyed how easy and self-explanatory a lot of the questions get… Sorry about that. I enjoyed mostly the descriptive questions that I was asked so that I was more sure about the pathway I would like to take while using that"* [Participant 4, selected Depo-Provera injection in BCPass]

Finally, participants were asked about their preferred contraceptive method selected using BCPass. Most of the 11 (82%) pilot participants reported prior use of the method they chose in the BCPass simulation. More than half (64%) cited their medical history and side effects associated with their preferred method when explaining their decision. Additional considerations participants noted were the delivery of contraception (eg, shot, long-acting reversible contraceptives, daily oral pill) (27%) as well as discussions they have had with family and friends (27%).

> *"I felt like it [the patch] was the easiest one to remember and it was something I didn't have to take every day and was something I only have to remember once a week. I feel like it would be easy on my time and my hobbies I tend to forget about stuff"* [Participant 5, selected transdermal patch in BCPass]

Prior to the BCPass simulation, two of the 11 (18%) pilot participants stated they did not have a single preferred contraceptive method in mind. After completing the simulation, they were able to more confidently select the method that they felt would work best for them. These participants credited the BCPass simulation questionnaire and educational materials in their decision-making process.

> *"Um I would definitely say that like IUD now. Originally, I would say 50-50 percent, like I would've leaned either way. But now using the app I would definitely say that I would have rather used the IUD because it's more, I don't want to say more protective. But like, it's better, it's like safer, better protection"* [Participant 3, selected IUD in BCPass]

Discussion

Principal Findings

We found that an app for pharmacist delivery of contraception, BCPass, was acceptable and usable for AYA. Participants liked how easy, convenient, and fast BCPass was to request contraception. Once the concerns addressed in the usability phase were incorporated, there were no glitches experienced, and few participants felt the app survey was too long or had confusing questions. Also, more education may be needed to ensure AYAs feel safe requesting contraception from a pharmacist. Finally, we identified 100% agreement between

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pharmacist contraceptive approvals in the simulation and contraception as prescribed in routine clinic visits.

Our findings are consistent with prior research on this topic in older adult women. In one survey study, women and other birthing people (≥18 years) reported receiving contraception from a pharmacist may be more convenient, faster, and easier compared to getting contraception from a clinician [10], which mirrors AYA's beliefs in this study. Additionally, this study found AYA-reported advantages of using an app included improving access to contraception by reducing the stigma and embarrassment of using contraception, reducing the burden of scheduling and attending clinic visits, and reducing the number of teenagers who become pregnant. In our study's feedback interview, most pilot participants emphasized their favorite aspect of BCPass was how quick and convenient it was compared to the standard of care while still receiving the contraceptive information they desired.

We did not identify any discordance between simulated pharmacist approvals and clinicians, as prescribed in clinic visits, suggesting the safety of having youth self-screen for medical contraindications. Women and other birthing people have previously been shown to safely and accurately complete self-screening medical history questionnaires and identify contraindications [12,13]. Like the older cohort, this study has shown AYA were capable of reporting their medical history, reviewing education materials, and selecting a contraceptive method they wish to use without forgoing a medical professional's review. While this study made edits, such as including more lay language and providing examples to some questions, to the medical contraindications to contraceptive prescribing per the Centers for Disease Control and Prevention US Medical Eligibility Criteria [20], once these changes were made to accommodate AYA's readability and comprehension level, they were able to successfully communicate their own medical history with a pharmacist through the app. A few pilot participants noted in their feedback interview they were surprised how easy completing the simulation was because questions regarding medical history were primarily all yes or no with an option to write in additional information for context with the study pharmacist. Some participants even found questions on their contraception preferences and reviewing educational materials more helpful in picking their preferred contraception than speaking to a clinician. Additionally, the feedback from the pilot phase reflected AYA's thoughtful consideration and awareness of their medical history, as well as side effects when planning to request contraception.

Of note, only one participant expressed concerns that contraception prescription without a clinician's oversight could be dangerous for AYA by making contraception too accessible, but several felt that they would prefer to discuss it with a provider. This data suggests the BCPass educational materials and access to call a pharmacist were not as effective as they needed to be to assure safety. While most participants liked the educational materials, a few did not feel it was enough to educate AYA on side effects. This finding suggests a need to include multimodal educational material, including more visual and audio materials. Additionally, participants who questioned the safety of BCPass also did not view pharmacists as being as knowledgeable as clinicians in prescribing contraception, which contrasts with physicians and midlevel practitioners in other studies who have supported pharmacist-initiated access to contraceptives [15]. Safety concerns indicated educational information presented needs to not only address contraception concerns but also inform AYA of the pharmacist's credibility and remind future users that pharmacists provide medical care already, such as vaccine delivery and drug interaction information [23].

Limitations of this study include the small sample size, single-city site, and limited rounds of usability testing. In addition, current state policy allows only for the simulation of pharmacist prescriptions. Following usability testing and additional app modifications, the platform was not retested again in another usability round before it was launched in the pilot testing phase. We focused on contraceptive methods for pregnancy prevention only and did not include the myriad of other reasons AYA may use contraception (eg, menstruation management, acne treatment, gender-affirming care, and medical conditions such as endometriosis). In addition, some participants completed the BCPass simulation following their medical appointment, which was not documented but is an important consideration for future larger-scale testing of the simulation. Future studies should further inform apps' usefulness in improving access to contraception for a broad range of indications via pharmacist prescription. Additionally, future research should explore the acceptability and feasibility of BCPass for key populations, including but not limited to girls, women, and other birthing people who are low income, living with disabilities, and sexual and gender minorities, to navigate barriers to accessing contraception. At the time of this study, pharmacist dispensing of contraceptives was not legal in the state of Pennsylvania, where this study took place, and 29 other US states. During a time with increasingly restrictive laws on connecting AYAs to contraceptives and other family planning resources, implementing methods to increase access to contraception is more important than ever because AYAs are particularly vulnerable to these restrictions.

Conclusions

Our results indicate that the BCPass app has the potential to be a valuable tool to improve access to contraception more equitably by facilitating contraceptive education, person-centered decision-making, and convenient delivery. BCPass and other electronic health solutions can supplement traditional care models and can be easily scalable, time-efficient, and cost-effective to assist AYA with navigating barriers to accessing contraceptives. Our results, demonstrating high acceptability and usability, suggest the potential of apps as supplemental effective tools to expand access to contraception for AYA during this time of increasing restrictive laws and policies impacting AYA reproductive health.

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Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

AYA: adolescents and young adults
BCPass: Birth Control Pass
EHC: emergency hormonal contraceptive
REDCap: Research Electronic Data Capture

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Original Paper

Developing an Evidence- and Theory-Informed Mother-Daughter mHealth Intervention Prototype Targeting Physical Activity in Preteen Girls of Low Socioeconomic Position: Multiphase Co-Design Study

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Abstract

Background: Preteen girls of lower socioeconomic position are at increased risk of physical inactivity. Parental support, particularly from mothers, is positively correlated with girls' physical activity levels. Consequently, family-based interventions are recognized as a promising approach to improve young people's physical activity. However, the effects of these interventions on girls' physical activity are often inconsistent, with calls for more rigorous, theory-informed, and co-designed family-based interventions to promote physical activity in this cohort.

Objective: This study aimed to use co-design methods to develop an evidence- and theory-informed mother-daughter mobile health intervention prototype targeting physical activity in preteen girls.

Methods: The intervention prototype was developed in accordance with the United Kingdom Medical Research Council framework, the Behaviour Change Wheel, the Theoretical Domains Framework, and the Behaviour Change Techniques Ontology. The Behaviour Change Intervention Ontology was also used to annotate the intervention characteristics. The co-design process incorporated three phases: (1) behavioral analysis, (2) the selection of intervention components, and (3) refinement of the intervention prototype. Throughout these phases, workshops were conducted with preteen girls (n=10), mothers of preteen girls (n=9), and primary school teachers (n=6), with additional input from an academic advisory panel.

Results: This 3-phase co-design process resulted in the development of a theory-informed intervention that targeted two behaviors: (1) mothers' engagement in a range of supportive behaviors for their daughters' physical activity and (2) daughters' physical activity behavior. Formative research identified 11 theoretical domains to be targeted as part of the intervention (eg, knowledge, skills, and beliefs about capabilities). These were to be targeted by 6 intervention functions (eg, education, persuasion, and modeling) and 27 behavior change techniques (eg, goal setting and self-monitoring). The co-design process resulted in a mobile app being chosen as the mode of delivery for the intervention.

Conclusions: This paper offers a comprehensive description and analysis of using co-design methods to develop a mother-daughter mobile health intervention prototype that is ready for feasibility and acceptability testing. The Behaviour Change Wheel, Theoretical Domains Framework, and Behaviour Change Techniques Ontology provided a systematic and transparent theoretical foundation for developing the prototype by enabling the identification of potential pathways for behavior change. Annotating the Behaviour Change Intervention Ontology entities represents the intervention characteristics in a detailed and structured way that supports improved communication, replication, and implementation of interventions.

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KEYWORDS

physical activity; preteen girls; socioeconomic position; maternal support; mHealth; intervention; co-design; pediatric; daughter; design; development; behavior change technique; Behaviour Change Wheel; sedentary; inactivity

Introduction

Background

Globally, 81% of adolescents are not meeting the recommended physical activity (PA) guidelines [1], with PA levels regressing annually throughout adolescence [2,3]. This rate of decline is more pronounced in girls than boys [1,4] and is most apparent during the transition period from primary to secondary school [5,6]. Studies also indicate that children of lower socioeconomic position (SEP) are less likely to be physically active than those of higher SEP [7-9]. Indeed, this is noteworthy in girls of low SEP, as evidence indicates that this cohort experiences a steeper decline in PA than their more advantaged peers at the transition to adolescence [4,9], putting them at a greater risk of obesity, type 2 diabetes, and cardiovascular disease [8,10]. Most interventions targeting children's daily PA levels have taken place during school hours [11]; however, children are reported to be less active during time spent outside of school, such as at weekends or holidays [12]. Thus, there is a need to also promote PA outside of the school context [13].

Families are a central foundation of support and guidance for children and adolescents in shaping healthy PA behaviors particularly outside of school [14]. Parental support is an umbrella term used to represent numerous support behaviors for PA such as encouragement, logistical support, or coactivity [14,15]. This type of parental support is positively correlated with child PA [16,17], with some evidence for stronger effects for girls when they are supported by their mothers rather than by other family members [18,19]. While there has been a growing interest in family-based PA interventions to promote girls' PA, the evidence for such interventions is mixed [20-22]. These inconclusive findings may be due to factors such as poor study design, small sample sizes, the use of self-report measures, the lack of theory to underpin interventions, the absence of the participant voice in the intervention development process [20,23], and differences between modes of delivery (eg, face-to-face vs eHealth or mobile health [mHealth]) [22,23]. Rapid developments in technology in recent decades have seen an increased use of eHealth and mHealth as modes of delivery for promoting PA in preschoolers [24], children and adolescents [25-27], families [22], and individuals of low SEP [28]. Meta-analyses of eHealth and mHealth PA interventions have reported positive effects for PA-related outcomes in children and adolescents, such as steps per day [25,26] and total PA [26,29], with a lack of improvement in moderate to vigorous PA stated as a limitation [25,29]. Considering the prevalence of smartphone phone use across children, adolescents, and adults [30,31] and the cost-effectiveness, reach, and scalability of mHealth interventions [25,26], there is a pressing need for more robust theory-based mHealth interventions to harness the potential of digital platforms for enhancing PA [22,24,25], particularly for individuals of low SEP [28].

Intervention Development

There is increasing recognition of the need for guidance to support the robust design of interventions targeting health behaviors such as PA. Specifically, the United Kingdom Medical Research Council (MRC) has developed a framework for complex interventions that provides a systematic process for developing and evaluating interventions across 4 interacting stages [32]. Within this process the importance of using theory, considering context, developing and refining a program theory and related logic model, and engaging with stakeholders is emphasized [32]. Theory offers a valuable organizing framework for the development of effective interventions and is necessary to test hypothesis, identify constructs that effect behavior, and enable study replication and generalization [33,34]. There have been mixed findings reported regarding the effectiveness of interventions that are underpinned by theory [35,36], predominantly explained by a lack of clarity as to how a particular theory's constructs (ie, mechanisms of action) are targeted and measured within interventions [33,35]. The Behaviour Change Wheel (BCW) builds on MRC guidance and offers a practical guide for how to develop theory- and evidence-based interventions [37]. The BCW is a synthesis of 19 frameworks for classifying behavior change and facilitates the mapping of intervention targets (ie, the behavior, the population, and the context) to specific mechanisms of action (ie, the processes through which behavior change occurs) [38]. At the core of the BCW is the Capability, Opportunity, and Motivation–Behavior (COM-B) model, which proposes that Capability, Opportunity, and Motivation interact to influence behavior. *Capability* refers to the individual's physical and psychological ability to enact the behavior. *Opportunity* denotes the social and physical resources that facilitate or hinder the behavior. Finally, *Motivation* is defined as the reflective or automatic processes that enable the behavior [37]. The BCW contains 9 different intervention functions that can be applied to target the desired behavior and 7 categories of policy that can be used to deliver these intervention functions. The BCW and associated elements have been successfully used in different contexts to develop interventions promoting PA [39-41]. For example, while using the BCW as part of the development process for a PA app, Truelove et al [39] targeted individuals' physical and psychological capabilities, physical and social opportunities, and reflective and automatic motivation to increase PA levels in Canadian adults. To achieve this, the intervention functions of education, persuasion, incentivization, training, environmental restructuring and enablement were chosen from the BCW to be included in the app, alongside 2 policy categories (communication and marketing, and environment and social planning) to support the delivery of the intervention functions [39]. One study has used the BCW to develop a mother-daughter PA intervention for adolescent girls [41] by selecting 6 intervention functions (education, persuasion, incentivization, training, modeling, and enablement).

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The COM-B components of the BCW can be further understood by using the Theoretical Domains Framework (TDF) [42]. The TDF is a validated integrative framework of 14 theoretical domains synthesized from 128 theoretical constructs and 33 behavioral change theories [42]. Additionally, the TDF presents a comprehensive grouping of the overlapping constructs within behavioral theories and supports the identification and selection of relevant mechanisms of action (eg, knowledge and beliefs about capabilities) for targeting within interventions [37,43]. The TDF has been applied across a variety of settings to inform the development of PA interventions [44,45]. For example, a study by McQuinn et al [45] identified the TDF domains of social influences, environmental context and resources, behavioral regulation, beliefs about capabilities, goals, and reinforcement as target mechanisms of action for a co-designed school-based intervention promoting PA in adolescent girls. However, to date, no intervention has used the TDF to identify mechanisms of action for an intervention promoting PA in preteen girls and maternal PA support behaviors.

An intervention achieves its functions through the use of behavior change techniques (BCTs), which are "the smallest part of the behaviour change intervention content that are that are observable, replicable and on their own have the potential to bring about behavior change" (eg, self-monitoring of behavior and problem-solving) [46]. The Behaviour Change Techniques Ontology (BCTO) offers a reliable and extensive classification system for behavior change intervention content. Using the BCTO is considered best practice, as it contains considerably more BCTs than the original BCT Taxonomy version 1 (BCTTv1), has more precise and clear groupings, labels and definitions, and links to other characteristics of an intervention, such as mechanisms of action [47]. The influence of intervention content (eg, BCTs) on behavior can differ depending on how it is delivered to participants, and therefore vary its effectiveness [48]. The recently developed Behaviour Change Intervention Ontology (BCIO) assists researchers to fully specify and classify intervention characteristics (eg, delivery) in a way that supports improved communication, replication, and implementation of effective interventions [46]. Within the BCIO, the delivery of an intervention is divided into the following components: (1) mode of delivery (ie, the medium through which an intervention is provided) [49], (2) intervention setting (ie, the setting where an intervention takes place) [50], (3) intervention schedule (ie, the timing of intervention components), and (4) intervention style of delivery (ie, the manner in which the intervention is delivered) [48]. Using the BCIO entities to annotate the delivery of an intervention increases our understanding of how the effect of intervention content differs according to the mode and style within which it is delivered [48]. While using the BCIO may be time consuming for researchers, it is increasingly used for evidence synthesis [51,52] and intervention development [53,54]. The BCIO has not yet been applied in PA interventions as it is a new development and is only recently available. To our knowledge, this is the first study to use the BCIO entities to annotate the characteristics of an intervention targeting PA in children.

Objectives

Alongside this increased emphasis on a systematic theory-informed intervention development, a collaborative approach to intervention design involving the end users of research is essential. Co-design methods ensure meaningful involvement of the end user in the research process [55] by enabling the specific needs and preferences of the target population to be recognized and allowing for the identification of potential implementation challenges early in the intervention development process [56]. Indeed, research that involves end users in the design process leads to interventions that are more contextually relevant and thus more effective [57]. However, while there is a continued call for greater involvement of young people in the research process through participatory methods such as co-design [58,59], only a few studies on family-based interventions targeting girls' PA [41] or on PA in teenage girls from lower SEP have applied such methods [45,60]. Therefore, the purpose of this study was to provide a detailed outline of the systematic process undertaken to using the BCW and TDF to develop an evidence-based and theoretically informed behavior change intervention, using co-design methods, to promote PA in preteen girls incorporating maternal support behaviors, before preliminary testing for feasibility and efficacy.

Methods

Overview

This study was informed by the initial development stage of the MRC framework for complex interventions [32]. In line with MRC guidelines, a program theory and logic model were developed and refined throughout the intervention development process. A program theory is a tool that can be used to unpack the relationship between the intervention activities and intended outcomes [61]. Logic models can assist in visually representing the program theory to effectively communicate with research team members and stakeholders [61]. The intervention prototype developed across 3 phases (Figure 1). Phase 1 was guided by the steps in the BCW process [37] and also incorporated the TDF to identify more specific mechanisms of action [42]. Phase 2 involved co-design workshops with stakeholders (ie, mothers, preteen girls, and primary school teachers) to identify potential intervention components and mode of delivery. In phase 3, the prototype was refined through an iterative and dynamic process based on evidence, theory, and input from additional co-design workshops with stakeholders (ie, mothers, preteen girls, and primary school teachers). An academic advisory panel provided guidance throughout the process. The BCIO entities were annotated to report the intervention characteristics; some of the BCIO unique identifiers are provided in the manuscript, with a full list available in Multimedia Appendix 1.

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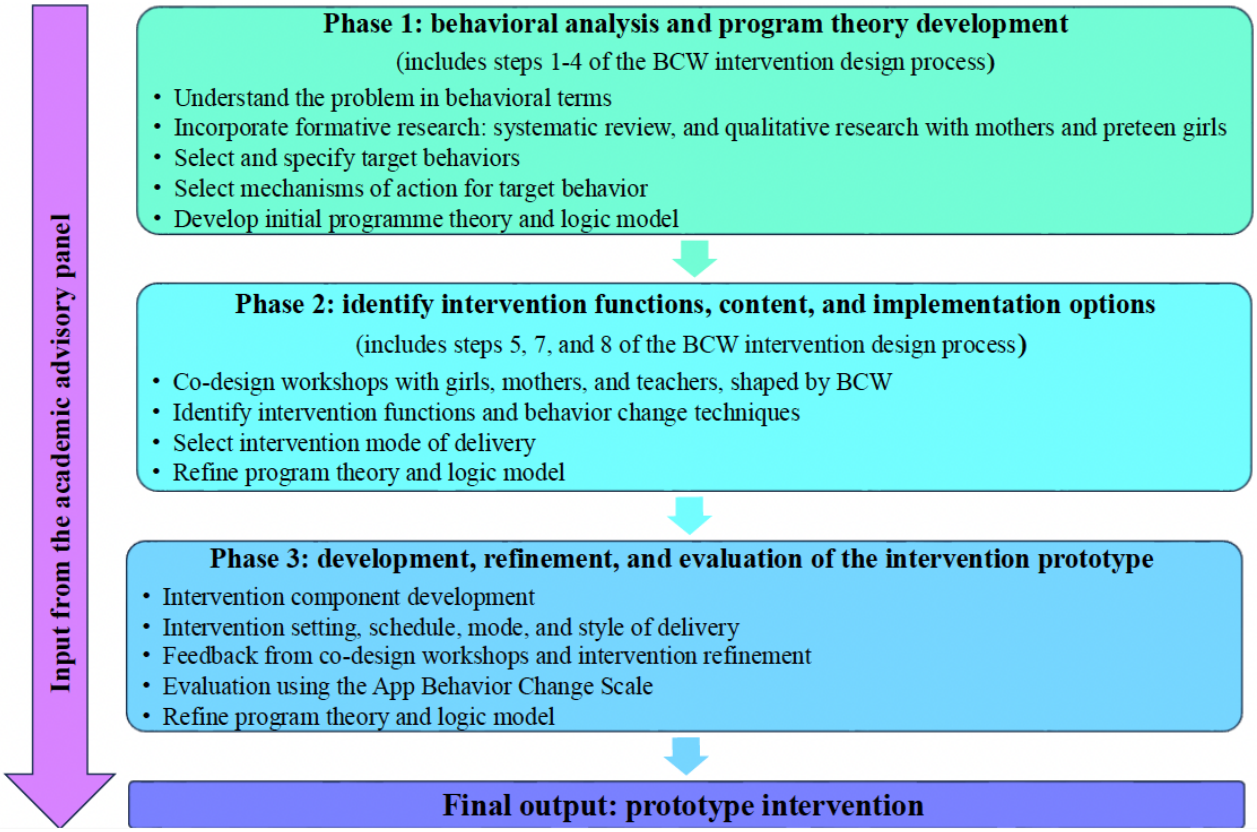
Figure 1. Overview of the intervention development process. BCW: Behaviour Change Wheel.



Ethical Considerations

Ethics approval was obtained by the University College Dublin's Human Research Ethics Committee (LS-22-62) before study commencement. No payments or incentives were offered for participation. Information packs containing information sheets and consent and assent forms were distributed to mothers, children, and teachers alike.

Recruitment

Co-Design Participants

A suburban primary school identified by the Department of Education's Delivering Equality of Opportunity in Schools (DEIS) program was identified as suitable for this study. The Department of Education uses the DEIS classification system to support students attending schools situated in communities at risk of social and economic disadvantage [62]. To classify schools as meeting the DEIS criteria, data from the Department of Education's online database and the HP Deprivation Index for Small Areas (HP Index) are used [62]. The HP Index is a process that measures the relative affluence or disadvantage of small geographical areas using categories such as demographic growth, dependency ratios, education levels, single parent rate, overcrowding, social class, occupation, and unemployment rates [62]. The school in this study is a mixed primary school based in a suburban town located 10 km from Dublin city center, Ireland, with approximately 520 pupils and 33 teachers. After discussions between the lead author (CB) and the school principal, the school principal invited mothers and female guardians of girls aged 10 to 12 years, girls aged 10 to 12 years, and teachers to take part in the study. All girls who were aged between 10 and 12 years and from fourth, fifth, or sixth class were eligible to take part.

Academic Advisory Panel

As part of the research process, an academic advisory panel was established to discuss the findings from the co-design workshops, the use of theory, and support the research team (CB and JM). This panel consisted of 3 academics (GO'D, AK, and RER) with expertise in PA, sedentary behavior, and the development of complex interventions and co-design methodologies. Both GO'D and AK are experienced qualitative researchers and have conducted previous studies exploring PA and sedentary behavior using the TDF, and RER is an experienced researcher with an applied focus on PA during life transitions.

Intervention Prototype Development Process

Phase 1: Behavioral Analysis and Program Theory Development

Phase 1 included steps 1 to 4 of the BCW intervention design process [37]. In line with this approach, the definition of the problem in behavioral terms (step 1) was based on findings from previous literature (ie, preteen girls are not active enough) [1,4]. A systematic review of mother-daughter interventions and formative qualitative research (ie, interviews with 29 mothers of preteen girls and 19 focus groups with 107 low-SEP preteen girls) was then conducted to further understand the problem and the related factors. This was followed by selection and specification of the intervention target behaviors (steps 2 and 3 of the BCW process). After these steps, CB and JM used the TDF to identify the barriers and enablers of the target

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behaviors. These were presented to the academic advisory panel (GO'D, AK, and RER) to establish what needs to change to achieve the target behaviors (step 4; Multimedia Appendix 2 [6,14,63-76]). This led to the selection of specific mechanisms of action to be targeted within the proposed intervention. An initial program theory and related logic model for the intervention were then developed.

Phase 2: Identify Intervention Functions, Content, and Implementation Options

This phase includes steps 5, 7, and 8 of the BCW intervention design process [37]. Three co-design workshops took place at the school premises during school hours and were facilitated by CB and JM. Three separate groups took part in a co-design workshop: (1) mothers of preteen daughters (n=9), (2) preteen girls (n=10), and (3) teachers (n=6). The workshops took place in April 2023, with a mean duration of 52 (SD 1.9) minutes. The aim of these workshops was to identify potential intervention functions, BCTs, and modes of delivery to target the proposed mechanisms of action identified in phase 1. A range of age-appropriate and interactive methods were used in these co-design sessions (Multimedia Appendix 3). For example, to encourage participants to think about the practical application of their suggestions to a wide variety of mothers and girls, personas of mothers and girls who were individually, socially, and geographically diverse were provided [77]. Using the information gathered from these co-design sessions, along with findings from phase 1 and further consultation with the academic advisory panel (GO'D, AK, and RER), intervention functions (step 5), BCTs (step 6), and a proposed mode of delivery (step 8) were selected by the research team (CB and JM). The program theory and logic model were also refined.

Phase 3: Development, Refinement, and Evaluation of the Intervention Prototype

This phase involved incorporating the findings from phase 2 into the development of the intervention components. A second series of co-design workshops (n=3) took place in the school premises during school hours and were facilitated by CB and JM. The same participants as phase 1 took part. The three separate workshop groups were (1) mothers of preteen daughters (n=6), (2) preteen girls (n=10), and (3) teachers (n=3). The workshops took place in June 2023, with a mean duration of 44 (SD 5) minutes. The aim of the workshops was to obtain participants' feedback on the acceptability of the proposed intervention components (Multimedia Appendix 4). Following these workshops, the research team (CB and JM) discussed the findings from the workshops, the proposed intervention components, and the use of theory with the academic advisory panel (GO'D, AK, and RER). The 21-item App Behavior Change Scale [78] was also used by the research team to ensure that relevant behavior change components were appropriately included. This scale has been used in several studies targeting PA to assess intervention effectiveness [39,79]. The program theory and logic model were refined for the final time.

Results

Phase 1: Behavioral Analysis and Program Theory Development

As described in the Introduction section, the identified problem behavior was the decline in PA as children transition to adolescence, with this decrease in activity levels particularly prevalent for girls of lower SEP [1,4]. Children whose parents support PA are likely to have higher overall levels of activity than children whose parents do not support their PA, with stronger effects when that support is provided by a parent of the same gender [80,81]. The formative research related to this study is described in previous studies, [82-84] therefore a brief description of it is provided here. A review of behavior change theories and techniques used in mother and daughter PA interventions highlighted a lack of clarity as to why interventions were effective or not and the increased need for a stronger theoretical basis for future interventions as well as enhanced reporting of how these interventions are developed [82]. Qualitative formative work with mothers of preteen girls highlighted barriers and enablers related to engaging in PA-supportive behaviors with their daughters [83]. These ranged from individual-level factors such as their PA-related identity and their confidence to engage in supportive behaviors to social and environmental factors such as the role of other family members and the infrastructure within their communities and their daughters' schools [83]. Finally, qualitative work was conducted with preteen girls who discussed barriers and enablers to their PA, such as the importance of skills and confidence to support their engagement in PA and strengthen their self-identity for PA alongside the important role of family members, friends, teachers, and coaches [84]. On the basis of this formative work, 2 related behaviors were deemed appropriate to target as part of the intervention. The first behavior was to improve mothers' support for their preteen daughters' PA and, in doing so, indirectly increase the likelihood of preteen girls engaging in PA. The second behavior being targeted was to increase preteen girls' PA. These behaviors are presented in Table 1 in terms of who needs to perform the behavior, when, where, and with whom.

The academic advisory panel then reviewed the analysis of the barriers and enablers to the target behaviors. Following discussion with the advisory panel, the research team then chose 11 of the 14 TDF domains as proposed mechanisms of action for enabling these target behaviors (Table 2).

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Table 1. Specification of target behaviors of interest.

	Target behavior 1	Target behavior 2
What behavior	Improve mothers' PA[a] support behaviors (eg, encouragement, logistical support, coactivity, and environmental and regulatory support) for their preteen daughters	Increase preteen daughters' PA (includes active travel, sport, family activities [bike rides and walks], and outdoor play)
Who	Mothers of preteen daughters of low SEP[b]	Preteen daughters of low SEP
When	Daily	Daily
Where	In their household residence (BCIO[c]: 026009), sport and exercise facility (BCIO: 026030), and outdoor environment (BCIO: 026044)	In their household residence (BCIO: 026009), sport and exercise facility (BCIO: 026030), and outdoor environment (BCIO: 026044)
With whom	Preteen daughters	Friends, mothers, and other family members

[a]PA: physical activity.

[b]SEP: socioeconomic position.

[c]BCIO: Behaviour Change Intervention Ontology.

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Table 2. Mechanisms of action, intervention functions and behaviour change techniques for mother-daughter intervention.

Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA[a] support and promoting PA in preteen girls	BCTs[b] from BCTO[c] for improving maternal PA support and promoting PA in preteen girls
Knowledge Develop mothers' and daughters' understanding of the following: • The rationale and purpose of the program • The types and benefits of PA and PA guidelines • How to be physically active • The types and benefits of maternal PA support behaviors • How to perform maternal PA support • Typical challenges experienced by mothers while engaging in PA support (eg, pushback from daughter) • Typical challenges experienced by preteen girls while engaging in PA support (eg, friends not active) • Available resources to facilitate engagement in PA and PA support	*Education* • About the rationale and purpose of the program • About ways of enacting desired behavior and avoiding undesirable ones • Provide credible, appealing information that can be used to enact target behavior • Provide clear, consistent, and standardized messages about maternal PA support and PA • Provide information to address prevalent misconceptions about maternal PA support and PA behaviors	• Instruct how to perform behavior BCT (BCIOd:007058) • Inform about health consequences BCT (BCIO:007063) • Inform about social consequences BCT (BCIO:007064) • Inform about environmental consequences BCT (BCIO:007176) • Present information from credible influence BCT (BCIO:007075)
Skills Develop skills to do the following: • Select and engage in PA and PA-supportive behaviors • Apply problem-solving and set and review personalized goals for PA and PA support behaviors • Monitor progress of physical activity behaviors • Monitor progress in supporting daughter to be active; overcome the challenges encountered while engaging in selected PA and PA support behaviors	*Training* • Practice and engage in PA support and PA behaviors • Engage in problem-solving and select and review goals related to target behavior • Monitor progress when engaging in PA support and PA behaviors • Engage in behavioral strategies to overcome challenges associated with providing support or being active	• Goal strategizing BCT (BCIO:007008) • Provide feedback on behavior BCT (BCIO:007023) • Self-monitor of behavior BCT (BCIO:007024) • Instruct how to perform behavior BCT (BCIO:007058) • Demonstrate the behavior BCT (BCIO:007055) • Practice behavior BCT (BCIO:007094) • Context-specific repetition of behavior BCT (BCIO:007096) • Set graded tasks BCT (BCIO:007100)
Social role and identity • Develop mothers' identity as a person who provides support for their daughters' PA • Develop mothers' and daughters' identity as a person who is physically active	*Education* • About how to link supportive and PA behaviors to other intrinsic goals • Provide information about positive experiences when supporting their daughter to be active or being active and how to overcome associated challenges • Provide information about extra resources available to help mothers provide support or preteen daughters be active when program ends *Persuasion* • Highlight compatibility with current identity, but expand it to include maternal PA identity or PA behaviors and social identities • Emphasize the role of mother as change agent for daughter and in family	• Social support BCT (BCIO:007028) • Inform about social consequences BCT (BCIO:007064) • Prompt social comparison BCT (BCIO:007073) • Practice behavior BCT (BCIO:007094) • Present information from credible influence BCT (BCIO:007075) • Identify self as role model BCT (BCIO:007158) • Reframe past behavior BCT (BCIO:007056) • Adopt changed self-identity BCT (BCIO:007160)

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Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA[a] support and promoting PA in preteen girls	BCTs[b] from BCTO[c] for improving maternal PA support and promoting PA in preteen girls
Beliefs about capabilities Improve perceived competence in ability to do the following: • Perform selected PA and PA support behaviors • Use problem-solving, goal setting, and action planning to engage in PA and PA support • Ability to monitor progress • Overcome challenges encountered while enacting PA and PA support • Engage in long-term PA and PA support behaviors	*Persuasion* • Enhance perceived competence to problem solve, actions plan, select and monitor goals, and self-monitor PA support and PA behaviors • Encourage mothers to believe that providing support is possible or daughters to believe that being active is possible, even given constraints of their circumstances *Enablement* • Assist mothers or daughters in problem-solving and action planning to overcome barriers to providing support or being active *Modeling* • Present real-life examples of mothers or preteen girls in similar circumstances	• Goal strategizing BCT (BCIO:007008) • Social support BCT (BCIO:007028) • Instruct how to perform behavior BCT (BCIO:007058) • Demonstrate the behavior BCT (BCIO:007055) • Practice behavior BCT (BCIO:007055) • Set graded tasks BCT (BCIO:007100) • Advise how to reduce negative emotions BCT (BCIO:050344) • Persuade about personal capability (BCIO:007137) • Prompt focus on past success BCT (BCIO:007139) • Prompt self-talk BCT (BCIO:007140)
Beliefs about consequences • Enhance mothers' expectations related to the positive consequences of engaging in selected PA support • Enhance mothers' and daughters' expectations related to the positive consequences of engaging in selected PA behaviors	*Education* • Explore beliefs and attitudes related to PA and the associated health benefits • Explore beliefs and attitudes between providing PA support and expected outcomes *Persuasion* • Enhance beliefs that being physically active has positive health benefits in the short and long term • Provide expert information about how, where, and why to be active • Enhance beliefs that providing support for daughters' PA would be beneficial • Provide expert information about the short- and long-term benefits of providing PA support *Modeling* • Provide demonstrations of mothers of teen girls or preteen girls to show the benefits they received as a result of providing support or being active	• Inform about health consequences BCT (BCIO:007063) • Inform about social consequences BCT (BCIO:007064) • Inform about environmental consequences BCT (BCIO:007176) • Monitor emotional consequences BCT • (BCIO:007066) • Demonstrate the behavior BCT (BCIO:007055) • Prompt social comparison BCT (BCIO:007073) • Present information from credible influence BCT (BCIO:007075)
Intentions • Increase mothers' and daughters' autonomous motivation to • Engage in and maintain selected PA or PA support behaviors • Engage in problem-solving and setting and reviewing goals to facilitate engagement in selected PA and PA support behavior • Engage with tools to monitor progress	*Education* • Inform about importance of formulating intentions of how and where to provide support or be active *Persuasion* • Encourage mothers and daughters to consider why being active might be important to them and the benefits they will receive • Encourage mothers to consider why providing PA support may be important to them and how it would benefit their daughter and other family members *Modeling* • Provide demonstrations of mothers and preteen girls describing their experiences of setting short- and long-term intentions to be provide support or be active and the associated benefits	• Set behavior goal BCT (BCIO:007003) • Inform about health consequences BCT (BCIO:007063) • Inform about social consequences BCT (BCIO:007064) • Inform about environmental consequences BCT (BCIO:007176) • Instruct how to perform behavior BCT (BCIO:007058) • Demonstrate the behavior BCT (BCIO:007055) • Prompt social comparison BCT (BCIO:007073) • Present information from credible influence BCT (BCIO:007075)

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Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA[a] support and promoting PA in preteen girls	BCTs[b] from BCTO[c] for improving maternal PA support and promoting PA in preteen girls
Goals • Support mothers and daughters to • Use action planning, problem-solving, and goal setting to facilitate engagement in selected PA and PA support behaviors • Use tools to monitor progress • Overcome challenges encountered while setting and reviewing goals	*Training* • Select and review personalized goals related to the target behavior *Enablement* • Provide support and guidance for setting realistic goals for mothers to provide support or to preteen girls to be physically active • Affirm small achievable and interim goals and successes • Prompt planning to provide PA support or be active during and after the intervention	• Set behavior goal BCT (BCIO:007003) • Goal strategizing BCT (BCIO:007008) • Action planning BCT • (BCIO:007010) • Provide feedback on behavior BCT (BCIO:007023) • Self-monitor behavior BCT (BCIO:007024) • Instruct how to perform behavior BCT (BCIO:007058) • Demonstrate the behavior BCT (BCIO:007055) • Practice behavior BCT (BCIO:007055) • Set graded tasks BCT (BCIO:007100)
Environmental context and resources • Provide knowledge of and access to a variety of PA opportunities available so that mothers can support daughters' PA and daughters can engage in PA • Provide materials or equipment so that mothers can support their daughters PA or daughters can be active	*Environmental restructuring* • Provide mothers or preteen daughters with practical equipment that can enable them to be active, for example, skipping ropes and balls • Provide mothers and daughters with access to feasible and realistic options that enable them to be active during and after the intervention *Enablement* • Provide practical support for mothers and daughters to action plan and problem solve to engage in PA support and PA behaviors	• Goal strategizing BCT (BCIO:007008) • Action planning BCT (BCIO:007010) • Social support BCT (BCIO:007028) • Present information from credible influence BCT (BCIO:007075) • Add objects to the environment BCT (BCIO:007156)
Social influences • Develop mothers' and daughters' understanding of the type of support available to them regarding supporting their daughters' PA and being active • Develop mothers' and daughters' ability to engage with the social support available to them	*Modeling* • Provide demonstrations of other mothers and girls describing their experiences for seeking and receiving social support and the benefits they received as a result *Enablement* • Prompt mothers and preteen daughters to seek social support and provide examples of types of social support available to them	• Social support BCT (BCIO:007028) • Advise to seek instrumental support BCT (BCIO:007030) • Demonstrate the behavior BCT (BCIO:007055) • Prompt social comparison BCT (BCIO:007073) • Present information from credible influence BCT (BCIO:007075) • Provide positive social consequence for behavior BCT (BCIO:007265) • Persuade about personal capability BCT (BCIO:007137)
Emotion • Promote positive and reduce unpleasant emotions associated with providing PA support (eg, embarrassment while being active with daughter) and being active (eg, enjoyment in activities)	*Persuasion* • Help mothers and daughters recognize the positive feelings associated with providing support or being active *Enablement* • Provide safe and nonjudgmental environment for mothers or daughters to explore emotions around providing support or being active • Provide opportunities for mothers or daughters to evaluate their emotional state after providing support or being active	• Goal strategizing BCT (BCIO:007008) • Social support BCT (BCIO:007028) • Monitor emotional consequences BCT (BCIO:007066) • Present information from credible influence BCT (BCIO:007075) • Advise how to reduce negative emotions BCT (BCIO:050344) • Reframe past behavior BCT (BCIO:007056)
Behavioral regulation Develop mothers' and daughters' ability to do the following: • Select and apply PA or PA support behaviors into their daily life • Implement tools to monitor PA or PA support progress	*Training* • Provide means so that mothers and daughters can assess their progress during the intervention and in the future *Enablement* • Provide opportunity, support, and tools to self-monitor PA support or PA behaviors and related habits	

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Mechanisms of action and what needs to happen for behavior change to occur	Intervention functions for improving maternal PA[a] support and promoting PA in preteen girls	BCTs[b] from BCTO[c] for improving maternal PA support and promoting PA in preteen girls
		• Goal strategizing BCT (BCIO:007008) • Action planning BCT (BCIO:007010) • Self-monitor behavior BCT (BCIO:007024) • Instruct how to perform behavior BCT (BCIO:007058) • Demonstrate the behavior BCT (BCIO:007055) • Practice behavior BCT (BCIO:007055) • Substitute behavior BCT (BCIO:007095) • Context-specific repetition of behavior BCT (BCIO:007096) • Provide positive social consequence for behavior BCT (BCIO:007265) • Advise how to reduce negative emotions BCT (BCIO:050344) • Prompt self-talk BCT (BCIO:007140)

Phase 2: Identify Intervention Functions, Content, and Implementation Options

The co-design workshops led to a number of recommendations from preteen girls, mothers, and teachers. These recommendations are illustrated in Table 3 using exemplar quotes and were categorized under a range of intervention functions as per the BCW intervention design process [37]. The intervention functions included education, training, persuasion, modeling, enablement, incentivization, and environmental restructuring. Potential modes of delivery discussed included face-to-face delivery, remote synchronous delivery (eg, Zoom Communications, Inc), or the use of a mHealth application. The mothers' group recommended the use of a mHealth application as a potential mode of delivery. These recommendations informed the selection of potential intervention functions, BCTs, and a proposed mode of delivery (ie, mHealth application) for each target behavior by the research team and were presented to the academic advisory panel for review. The final listing of intervention functions and BCTs for each mechanism of action are presented in Table 2. The academic advisory panel suggested applying of the principles of self-determination theory (SDT) [85] to the mHealth application content to enhance the communication style within which it is delivered [48].

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Table 3. Summary table of the co-design workshops.

	Summary of the recommendations from workshops	Example quotes	Related intervention functions
Improving mothers' knowledge and understanding of PA[a] and PA support	• Provide mothers with information about the different types of PA, the benefits of PA, how to be active, and how much PA is recommended for daughters and themselves • Provide mothers with information and instruction about how to support their daughters, particularly as they transition into teenage years • Provide mothers with more information about what is available to them in their local area for their daughters to be active or for them to be active with their daughters • Information could be provided through videos, social media, websites, an app, parent-teachers association, and word of mouth	• "Maybe something about their mental and physical development, psychosocial development at this age that would help mothers understand what they're going through." [Imelda, daughter in fifth class] • "Making sure mothers know how often children, girls at that age should be exercising each week. Maybe if they're not conscious that they're doing their weekly exercise, how are they supposed to pass it on to their children." [Kate, primary school teacher] • "if you were thinking of an app and giving people ideas, could add the likes of yoga and stuff." [Susan, daughter in sixth class]	• Education • Training
Persuading mothers to support their daughters to be active	• Present mothers with examples of other mothers, coaches, teachers, and local sports partnership representatives explaining how, where, and the benefits of supporting daughters to be active • Provide examples of other mothers supporting their daughters to be active, how they overcame challenges, and being active themselves or with their daughters or family members • Use mainstream media, social media, videos, websites, apps, and word of mouth to promote positive messages	• "Or other mammies probably. I think other mammies would be good to see. Well, if they can balance it, I'm sure there's ways around that we can balance it." [Niamh, daughter in fourth class] • "Someone giving them their personal story" [Sharon, primary school teacher] • "an app would be great because the kids are on it...you can challenge your friends or family members and track what you have done." [Sinead, daughter in sixth class]	• Persuasion • Modeling
Practical help for mothers to engage in support behaviors	• Assistance with cost of activities, thus provide opportunities to try out in school or community for free first • Provide materials for mothers to plan, record, and monitor their PA support behaviors at their own time and pace • Feedback on behavior, in particular, if they engage in activities with daughters, either through technology or in person	• "And the cost of living at the moment is crazy as well. Like you should be really dropping. If the cost of it came down a bit, I think a lot more people would do it, absolutely." [Michelle, daughter in fourth class] • "If you're doing that at your own pace, in your own time. There was ideas on of, you can do this today, tomorrow, next week, or whatever, but also a blank space that you could fill in what you've done. I wasn't able to do this, but I did this, or we done that." [Sinead, daughter in sixth class] • "You can break it into profiles like you can have yours, your partners, your daughters, whatever. It's under the one branch, basically. But you have your own little sections as well, where there's probably things tailor-made for you for that age group. You put in your age, you put in your interest or something...Like Netflix." [Imelda, daughter in fifth class]	• Incentivization • Environmental restructuring

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	Summary of the recommendations from workshops	Example quotes	Related intervention functions
Social support for mothers	• Provide opportunities for mothers to get support from other mothers of preteen daughters, for example, Facebook group • Opportunities to get to know other mothers at daughters' activities	• "every club should have a mammies group." [Niamh, daughter in fourth class] • "then you could have like a chat group for them (mothers) on the app." [Susan, daughter in sixth class] • "Yeah, support network through your app, through your group or whatever. Just like, oh, I've done this week, you might like it or I found this video, you might like it whatever." [Anna, primary school teacher] • "Because some of the other parents have groups themselves where they can keep in contact. If one parent doesn't want to do it, the second parent may motivate them to do it. While we're all doing this together." [Joe, primary school teacher]	• Enablement
Improving daughters' knowledge and understanding of PA	• Provide daughters with information and instructions about the different types of PA, the benefits of PA, how to be active in their leisure time, and how much PA is recommended • Provide daughters with information about what is available to them in their local area to be active. Information could be provided through videos, social media, websites, an app, and word of mouth	• "tips on how to play a game or rules of the game." [Emily, fifth class] • "we could have like speakers, people going into the classroom and talking to girls to join sports." [Sophie, sixth class] • "Some people post on YouTube how to do skills. If you're a beginner and you want to learn some skills, you could just look at some YouTube videos and then that would do it." [Robyn, sixth class] • "But the danger is that there are parents who don't know and don't care, and they probably won't look at an app. I would be afraid of that happening...let the child have their own profile." [Jennifer, daughter in sixth class]	• Education • Training
Persuading daughters to be active	• Provide encouragement for daughters with examples of coaches, teachers, and local sports partnership representatives explaining how, where, and the benefits of being active • Provide examples of other preteen girls and older adolescent girls being active and how they overcame challenges • Use mainstream media, social media, videos, websites, apps, and word of mouth to promote positive messages	• "You could tell them how worth it will be when they get stronger and healthier and they can run more. Basically, classes, carrying, and shopping, you'll just get quicker and it'll become easier." [Emily, fifth class] • "They might because they are their own age feel like they are like them." [Aisling, fifth class] • "Probably get girls that do sports, like making ads or something. If girls are watching their phones and you could do that." [Evie, sixth class] • "Like that, if there were videos that they (girls) could click into." [Sharon, primary school teacher]	• Persuasion • Modeling
Practical help for daughters to engage in leisure time PA	• Cost of activities is a barrier, so provide opportunities to try them out in school or community for free first (initial cost) • Provide materials for daughters to plan, record, and monitor their PA behaviors, including opportunity to arrange a reward of their choice for themselves • Feedback on behavior if they engage in activities • Provide equipment and merchandise for daughters to practice with at home, for example, footballs, basketballs, skipping ropes, T-shirts, jerseys, hoodies, water bottles, and merchandise	• "You can write a to-do list, so that way you can be more motivated to keep on schedule."[Emily fifth class] • "They could lend them a ball to practice." [Maisie, fifth class] • "Something like if you have all the jumpers and the jersey's, it makes you feel a part of the team, so you want to go again because you are part of this team." [Evie, sixth class] • "If you could practice it at home to see if you like it." [Sarah fourth class]	• Incentivization • Environmental restructuring
Social support for daughters			• Enablement

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	Summary of the recommendations from workshops	Example quotes	Related intervention functions
	• Provide opportunities for daughters to get support from other preteen girls, for example, bringing friends to activities and opportunities to ask girls their own age about certain activities • Opportunities to get to know other girls at activities. Can be organized by coaches, teachers, and other club members	• "They could get a friend to join with them so that they have someone to talk to." [Aisling, fifth class] • "Maybe if one of your friends was not on the team can now join the sport, you could even ask them if they wanted to come down to maybe one of your matches so they could have a look and see what the sport is all about and that might make them want to join." [Sophie sixth class]	

[a]PA: physical activity.

Phase 3: Development, Refinement, and Evaluation of the Intervention Prototype

Intervention Component Development

The research team developed separate mobile apps for each target behavior (ie, mothers' support behaviors and preteen daughters' PA) using the *Pathverse* app design platform for mHealth research [86]. This platform enables researchers to develop mobile apps for testing without the requirement of software developers. It is a "no-code" development platform, which allows researchers to create a mobile app with "drag and drop" features instead of coding [87]. The *Pathverse* platform includes features such as the design of customized multimedia content, implementation of participant surveys, provision of self-monitoring tools, setting of personalized goals, the customization of app notifications, digital badges, and a community group chat option [86]. Intervention components were developed within this platform to ensure that the relevant mechanisms of action were targeted and the related BCTs were enacted. Examples of how the intervention components relate to the targeted mechanisms of action are provided in Tables 4 and 5 for mothers and preteen daughters, respectively. For example, for the mothers' intervention, app module 3 titled "What does supporting your daughter involve?" includes infographics about the benefits of and the different ways for mothers to support their daughter to be active. It also includes videos of mothers describing their experiences of engaging in different supportive behaviors. Similarly, in the daughters' intervention, app module 3 titled "Why should you be active?" includes infographics and a video about the benefits of being active as well as a video of a preteen girl describing her experiences of engaging in PA. The mechanisms of action that these modules target are "knowledge," "beliefs about consequences," and "social influences."

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Table 4. Intervention components mapped to the mechanisms of action in the mothers' intervention.

	Intervention components, activities, and resources	Mechanisms of action
Week 1: introduction to the study and group meeting (included after feedback from the co-design workshops, session 2)	• Face-to-face meeting with the mothers who are taking part in the study and introducing them to the research team and providing information about the study and consent forms, equipment and merchandise that are part of study (eg, footballs, skipping rope, yoga mat, T-shirts, and water bottles), demonstration of how to download the app and navigate the modules and features of the app, and inform mothers that they will receive certificate for taking part at the end of the study.	• Knowledge • Beliefs about consequences • Environmental context and resources
App module 1: getting started	• Includes a video with a welcome message and brief description about the study; a video demonstrating how to use the app and answer survey questions; and a survey with questions about demographics, PAa levels, and providing support for daughter's activities	• Knowledge
App module 2: what is PA and why is it important?	• Includes infographics about the module objectives, PA and benefits of being active, how active adults should be, how active children and teenagers should be, the benefits of PA for children and adolescents, and how active our teenage girls currently are • A multiple-choice challenge question about how active children should be and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences
App module 3: what does supporting your daughter to be active involve?	• Includes infographics about the module objectives; why mothers were chosen for the study; the benefits of and ways to support their daughter to be active, for example, providing transportation to their daughter's activities; spectating at daughter's activities; and how and where mothers can be active with their daughters • A video with a mother of preteen girls describing her experience of spectating at her daughter's activities • A multiple-choice challenge question about what a mother can do to help support their daughter to be active and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Social influences
App module 4: who can help you support your daughter?	• Infographics about the module objectives, the benefits of social support, having families as a source of support, how friends can support, how neighbors and people in the local community can support, how a daughter's friends can facilitate providing support, how coaches and teachers can support, and how support groups both web-based and in the local community can help mothers • A video of mothers of preteen girls describing how they avail the social support available to them • A multiple-choice question about who can help mothers with the day-to-day challenges of supporting their daughter to be active and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Intentions • Social influences

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	Intervention components, activities, and resources	Mechanisms of action
App module 5: tips to help you support your daughter	• Infographics about the module objectives, the challenges mothers face when supporting their daughter and how to overcome them, to remember why supporting their daughter can help do what is important to them, tips for how to get started when feeling overwhelmed, details about shared decision-making and how it could be helpful, and how to manage a lapse in behavior • A video with tips and advice from a role model, for example, mother of an athlete and how they support their daughter • A multiple-choice questions about the types of support messages mothers would like to receive throughout the study as push notifications (eg, reminders, encouragement, praise, affirmations, or inspirational) and a digital badge of congratulations for reaching the end of the module	• Knowledge • Skills • Identity • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion
App module 6: next steps: planning to support your daughter	• Includes infographics about the module objectives, what is goal setting, why and how to set goals, challenges associated with goal setting and how to overcome them, and showing mothers how they can self-monitor their progress in the app • Provide selection goals related to maternal PA support (eg, spectate at daughter's activity and mother and daughter coactivity) • Mothers select and set a PA support goal of their choice, including when and where and how often the support behavior would be enacted, and a digital badge wishing mothers "good luck" with their chosen goal	• Knowledge • Skills • Beliefs about capabilities • Beliefs about consequences • Intentions • Goals • Behavioral regulation
App module 7: booster module (included after feedback from co-design workshops, session 2)	• Includes infographics about the module objectives; recap on maternal PA support behaviors; how to overcome potential barriers to providing support, for example, using if...then statements; and how lapses in behaviors are normal • A video with messages of encouragement and support from other mothers of teenage girls and a digital badge of congratulations for reaching the end of the module	• Knowledge • Identity • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion • Behavioral regulation
App module 8: final module	• Includes infographics with a summary of the study, recap on maternal PA support behaviors, goal setting, how to overcome challenges, where to look for social support, and what to do next • A survey with questions about PA levels for mothers and daughters and regarding providing support for daughter's activities • A survey providing feedback about acceptability and feasibility of the study and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Intentions • Social influences • Behavioral regulation
App icon: resources	• Links to external websites providing information on local resources, family support services, and community events. Includes podcasts about parenting for PA with a focus on mothers and girls, videos of skills or activities that mothers can practice with daughter (eg, yoga, exercises, and football skills), and videos of other mothers of preteen girls discussing and sharing their experiences	• Knowledge • Skills • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion
App icon: goals	• Summary of goals set for the duration of the study • Mothers can review progress of goals set in the module, for example, spectate at daughter's activity or walk to school with daughter twice a week. Mothers can manually set and record additional goals of their choice	• Intentions • Goals • Behavioral regulation

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	Intervention components, activities, and resources	Mechanisms of action
App icon: trackers history	• Option available for mothers to self-monitor their progress of goals set that are paired with a smartwatch that is synced with the app, for example, step count and exercise minutes. Mothers can self-monitor their daily steps and exercise minutes manually. Mothers manually self-monitor an activity (eg, walked to school with daughter), rate their enjoyment factor, and record any notes or points of interest	• Intentions • Goals • Behavioral regulation
App icon: chat	• A feature that enables mothers to join a community forum to send and receive messages to and from the research team; an interactive forum where mothers share their experiences and strategies with other mothers who are partaking in the study; and avail of opportunities to meet other mother and daughter participants for group activities, as per information provided by the research team or as suggested by other participants	• Social influences • Emotion
Intervention feature: motivational messages	• Tailored prompts or cues sent as push notifications to mothers that are relative to their chosen goals and generic messages of encouragement, praise, or inspiration that change each day	• Beliefs about capabilities • Identity • Social influences • Emotion
Week 8: conclusion of study and group meeting (included after feedback from co-design workshops, session 2)	• Face-to-face group meeting with mothers to award mothers with a certificate of completion, receive feedback on the intervention, and answer any questions	• Social influences

[a]PA: physical activity.

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Table 5. Intervention components mapped to the mechanisms of action in the preteen girls' intervention.

	Intervention components, activities, and resources	Mechanisms of action
Week 1: introduction to the study and group meeting (included after feedback from the co-design workshops, session 2)	• Face-to-face meeting with the girls who are taking part in the study and introducing them to the research team and providing information about the study and consent forms, equipment and merchandise that are part of study (eg, footballs, skipping rope, yoga mat, T-shirts, and water bottles), demonstration how to download the app and navigate the modules and features of the app, and answers to queries or concerns girls may have • Inform girls that they will receive a certificate for taking part at the end of the study	• Knowledge • Beliefs about consequences • Environmental context and resources
App module 1: welcome to our study	• Includes a video with a welcome message and a brief description about the study; a video demonstrating how to use the app and answer survey questions; a survey with questions about demographics, PAa levels, and being active, and a digital badge of congratulations for reaching the end of the module	• Knowledge
App module 2: what is PA?	• Includes infographics about the module contents, what is PA, how active preteen girls need to be, and different ways to be active • A multiple-choice challenge question about how many minutes per day should preteen girls be active for and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences
App module 3: why should you be active?	• Infographics about the module objectives and the benefits of being active • Videos about the benefits of being active, with a preteen girl describing her experiences of being active and the associated benefits • A multiple-choice challenge question about the benefits of being physically active and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Social influences
App module 4: how can you be active?	• Includes infographics about the module objectives; walking or wheeling to school; outdoor play in the neighborhood with friends; going to local parks, woods, and playgrounds with family members; walking the dog as a way to be active; and yoga as a way to be active • Videos about ways in which preteen girls can be active, of interview with famous female sports stars describing their experiences of playing sport and being active, with mothers and daughters dancing together as a way to be active, and of exercises that can be implemented at home as a way to be active • A question about favorite way to be active and a digital badge of congratulations for reaching the end of the module	• Knowledge • Skills • Beliefs about consequences • Intentions • Social influences
App module 5: who can you be active with?	• Includes infographics about the module objectives, who can support girls to be active and the benefits of social support, having fun with friends at school, playing with children in the neighborhood, and being active with family members • Video of other preteen girls sharing their experiences of who they are active with • A multiple-choice question about who girls can be active with and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Intentions • Social influences

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	Intervention components, activities, and resources	Mechanisms of action
App module 6: tips to help you be active	• Includes infographics about the module's objectives; why some girls do not want to be active; about how family members or friends can support you to be active; and remembering why you chose to be active, with a support message about what to do when feeling overwhelmed and with a support message about staying positive in times of self-doubt and how to manage a lapse in behavior • A video of preteen and teenage girls sharing their experiences and how they overcame challenges with being active. A video of a famous female sports star discussing their role models, how they overcame challenges related to staying active, and who supported them along the way. A video demonstrating ways to stay active at home • An infographic with a question about tips to help girls be active • A digital badge of congratulations for reaching the end of the module	• Knowledge • Skills • Identity • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion
App module 7: let us get moving	• Includes infographics about the module's objectives, goal setting what is it, why and how to set goals, the challenges associated with goal setting and how to overcome them, and showing girls how they can monitor their progress in the app • Provide a selection of goals related to leisure time PA for girls to choose from • Girls select a goal of their choice, including when and where the activity would be enacted and with whom, and a digital badge wishing girls "good luck" with their chosen goal	• Knowledge • Skills • Beliefs about capabilities • Beliefs about consequences • Intentions • Goals • Behavioral regulation
App module 8: booster module (included after feedback from the co-design workshops, session 2)	• Includes infographics about the module's objectives; revision of PA behaviors; revision of benefits of being active; how to overcome potential barriers to providing support, for example, using if...then statements; and how lapses in behaviors are normal • A video with support messages from other teenage girls and a digital badge of congratulations for reaching the end of the module	• Knowledge • Identity • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion • Behavioral regulation
App module 9: final module	• Infographics about the module's objective; recap on PA and benefits of PA; recap on goal setting; and recap on how to overcome challenges, where to look for social support, and what to do next • A survey with questions about PA levels and being active. A survey providing feedback about acceptability and feasibility of the study and a digital badge of congratulations for reaching the end of the module	• Knowledge • Beliefs about consequences • Intentions • Behavioral regulation
App icon: resources	• Links to websites of resources available to them in their local area • Podcasts about PA, with a focus on girls • Videos of other preteen girls and their experiences	• Knowledge • Skills • Beliefs about capabilities • Beliefs about consequences • Intentions • Social influences • Emotion
App icon: goals	• Summary of goals set for the duration of the study • Girls can review progress of goals set in the module (eg, walk or wheel to school with mother twice a week and practice skills at home) • Girls can manually set and record additional goals of their choice	• Intentions • Goals • Behavioral regulation

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	Intervention components, activities, and resources	Mechanisms of action
App icon: trackers	• Option available for girls to self-monitor their progress of goals set that are paired with a smartwatch that is synced with the app (eg, step count and exercise minutes) • Girls can self-monitor their daily steps and exercise minutes manually • Girls manually self-monitor an activity (eg, practiced skills), rate their enjoyment factor, and record any notes or points of interest	• Intentions • Goals • Behavioral regulation
App feature: motivational messages	• Tailored prompts or cues sent as push notifications to girls that are age appropriate and relative to their chosen goals. Generic messages of encouragement, praise, or inspiration that change each day	• Beliefs about capabilities • Identity • Social influences • Emotion
Week 8: conclusion of study and group meeting (included after feedback from the co-design workshops, session 2)	• Face-to-face group meeting with girls to award girls with a certificate of completion, receive feedback on the intervention, and answer any questions	• Social influences

Intervention Delivery

Intervention delivery was considered from 4 perspectives: mode of delivery, intervention setting, schedule, and delivery style in line with the BCIO [49]. As described in Phase 2: Identify Intervention Functions, Content, and Implementation Options section, the intervention's mode of delivery is primarily through a mobile app with a face-to-face component at the start and end of the intervention. The settings where the intervention takes place for mothers and daughters are at their household residences, local sport and exercise facilities, or in outdoor environments (ie, local parks, greens, forests, or beaches). The time frame chosen for the intervention schedule is based on the findings from formative research, which suggested that mother-daughter interventions lasting <12 weeks were likely to be more effective [82], and from engagement with participants in the co-design sessions and the academic advisory panel. The 8-week intervention schedule starts with face-to-face sessions for both mother and daughter participants. Over the course of the first 2 weeks of the intervention, 5 short modules are released for the participants to complete. Following completion of the modules, both mothers and daughters are then required to select and set a goal of their choice related to the target behavior (module 6). They then self-monitor their progress for 6 weeks. A booster module summarizing the intervention content is released during week 5 of the intervention, and there is a final module to be completed at the end of the intervention. To conclude the intervention and answer any questions, a second face-to-face session is held with the mothers and daughters. Figure 2 provides an overview of the intervention schedule and details of the core learning outcomes of the modules for both apps.

To ensure the communication style in which the intervention content (ie, BCTs) is delivered is collaborative, autonomy supportive, and person centered [48], the principles of SDT [85] were applied. According to SDT, autonomous motivation for a behavior is developed through the satisfaction of the basic psychological needs of autonomy, competence, and relatedness [85]. The need for autonomy refers to a mother's or daughter's desire to have choice and to feel empowered in directing their own behavior [85]. For example, in the app, the goal-setting feature supports the basic need of autonomy by providing mothers and daughters with choices and options, enabling them to make decisions and take responsibility about how they chose to support their daughter or be active. The need for competence relates to a mother's or daughter's need to feel capable of achieving a desired outcome [85]. To illustrate, whenever mothers or daughters log activities on the app, it represents a confirmation that they sustained the behavior and thus enhances their feelings of competence. The need for relatedness denotes an individual's aspirations to feel a sense of belonging and connectedness with others [85]. For instance, the messaging feature enables mothers to connect with others who face the same challenges or achieve the same goals, thus promoting a sense of belonging and providing an opportunity to develop meaningful relations with other participants (Table 6).

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Figure 2. Intervention schedule. PA: physical activity.

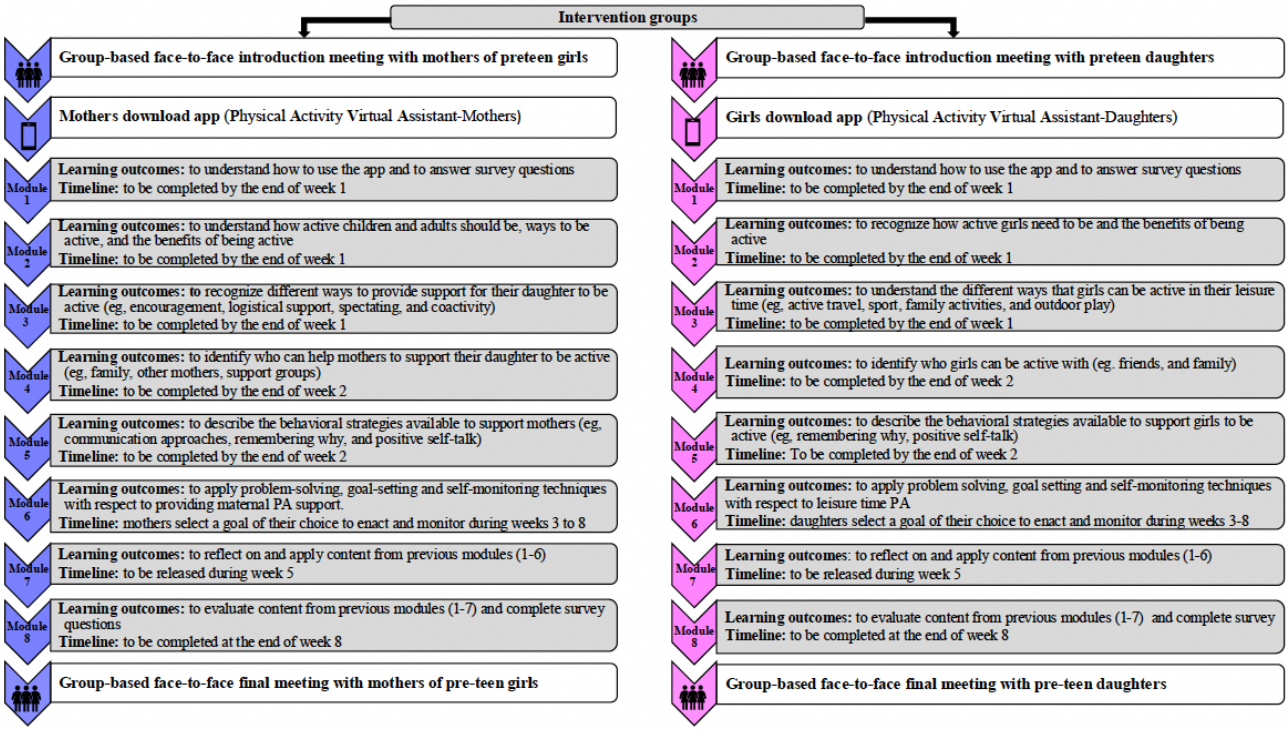

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Table 6. Intervention delivery style, illustrating how app features align with the principles of self-determination theory.

App features	Description	Expected benefit
Autonomy-supportive features		
Goal setting	• This feature provides mothers and daughters with the option to choose from a set of predefined activities or exercises they wish to perform • Mothers and daughters have the option to proactively set a goal they will perform, which is related to either maternal support for PAa or daughters' leisure time activity	• The goal-setting feature supports the basic need of autonomy and promotes autonomous motivation by providing mothers and daughters with choices and options, enabling them to make decisions and take responsibility about how they choose to support their daughter and be active
Reminders	• The app will provide a reminder that is delivered as a push notification around the time the mothers and daughters should perform a specific activity • The reminders are set by the mothers and daughters while they are selecting their goals and are optional	• This feature helps mothers and daughters stay organized and on track with regard to the target behaviors • To reduce the feeling of acting out of pressure or control, this is an optional feature and can only be activated by the mothers and daughters
Motivational messages	• Feature with preset messages delivered as push notifications that provide encouragement, praise, and inspiration to perform target behaviors • Messages are not task inherent and are provided to mothers and daughters at specified time intervals regardless of performance or completion of target behaviors • A feature that allows mothers and daughters to write a brief message about why it is important for them to continue engaging in the target behavior. This self-directed message is available whenever needed and can be delivered as a push notification at chosen time intervals	• Mothers and daughters provided feedback regarding the time and type of messages they would like to receive in an earlier module; the messages are tailored to suit their preferences • The messages provide a meaningful rationale for engaging in the target behaviors • The self-directed messages enable mothers and daughters to reflect on why they want to engage and sustain the behaviors
Competence-supportive features		
Self-monitoring	• Provides mothers and daughters with option to self-record the accomplishment of a goal or the completion of a task related to the target behaviors • Mothers and daughters can record information about what happened on specific days (eg, bad weather, lots of homework, and stress at work) and rate their enjoyment factor while partaking	• Whenever mothers or daughters log an activity, it represents a confirmation that they sustained the behavior and thus enhances their feelings of competence • The information entered helps mothers and daughters know themselves and understand their personal circumstances that influence the target behavior • By entering data into the app, mothers and daughters express their interest in maintaining the behaviors
Activity feedback	• Provides mothers and daughters with information about how the task that was performed and provides them with details of their overall progress toward completing a predefined set of activities or goal. The information might be accompanied by a score (eg, step count) or encouragement message or badge (well done for completing the module) • Timing of feedback is important to avoid unsatisfactory results such as underachievement; therefore, mothers and daughters choose to view their own feedback rather than receiving it unexpectedly • The activity feedback needs to be personal, nonevaluative and specific to the task performed.	• Positive feedback shows growth or improvement trends and enhance mothers' and daughters' sense of competence • Activity feedback in the form of encouragement messages or badges can foster positive emotions toward the target behavior
Relatedness-supportive features		
Community forum	• Enables mothers and daughters to connect with other participants where they have the opportunity to interact and connect with others • The research team will also facilitate opportunities for participants to meet and participate in activities through the group chat feature	• Messaging enables mothers and daughters to connect with other participants who face the same challenges • They can share experiences, provide and receive support, and experience a sense of belonging and relatedness

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App features	Description	Expected benefit
Modeling videos or podcasts	• Videos or podcasts of other mothers of preteen daughters and preteen girls sharing their experiences are embedded throughout the app's modules and in the resources icon	• These videos or podcasts provide mothers and girls with information and advice from other mothers and daughters who face similar challenges, which can help satisfy their need for relatedness and support their autonomous motivation to perform the target behavior over time

[a]PA: physical activity.

Feedback From Co-Design Workshops and Intervention Refinement

After the development of the intervention content and delivery (with separate mobile apps for mothers and daughters), a second series of workshops was held to present the mobile apps to mothers, preteen girls, and teachers. All groups acknowledged how the intervention content was informative and persuasive, as shared by Sadie, fifth class:

> *Instead of just getting girls to join sports, giving good reasons as well. Instead of saying like, do you want to try this and try this? It was giving good reasons.*

The girls found the videos of other girls' experiences regarding being active useful and inspiring, particularly those with girls their own age and a little older than them, as described by Sophie, sixth class:

> *Because if they're girls older, like what Evie said, they can be like role models. If they're the same age as you, then they could inspire you to join a team as well.*

This was a similar finding for the mothers and teachers, who recognized how videos demonstrating experiences of "other mothers and girls they can relate to" (Kate, primary school teacher) would encourage maternal PA support and girls to be active. The mothers' and teachers' groups provided positive feedback when exploring the resources feature, which presented what was available to them in their local community for supporting their daughter to be active, as described by Susan, who has a daughter in sixth class:

> *That's brilliant. Little bits like that on it, You just let people know (about the resources feature) and you just click the link then and pick it up.*

Several amendments were suggested at these workshops, which were then included in the final version of the intervention. For example, the mothers and teachers' groups suggested that it would be important to have an initial and final group-based face-to-face session as part of the intervention, as shared by Emer, a primary school teacher:

> *I think at the start, if you get them in like...that first meeting and first introduction thing is crucial. They feel invested in it.*

As a result of this feedback, we introduced both an initial and final group-based face-to-face intervention sessions. Specifically, the initial session will enable mothers and preteen daughters to meet other users of the smartphone app and develop social connections, which can then be reinforced through using some of the social support features on the app. It would also allow mothers and preteen daughters to get instruction from the research team as to how to use the features of the smartphone app. The final face-to-face session will allow mothers and preteen daughters to share their experiences and provide an opportunity to sustain their social network developed as part of the intervention. It was also suggested to avoid providing all the modules on the app at once, instead phasing them in over a few weeks to prevent mothers and daughters from feeling overwhelmed by the information. This recommendation was shared by Michelle, whose daughter was in fourth class:

> *I'd phase it in, different bits of information every couple of weeks...I think if you throw too much at people, they won't bother looking at it. It's just too much information...People don't like too much information at once. It just bugs them.*

Further suggestions were for a booster module to be added to the app to provide a reminder of the key features of the intervention content and for a podcast with parenting tips for teenage daughters to be added to the resources feature as "there's a lot of challenges out there. People are looking for...Looking for help and guidance." (Jennifer, daughter in sixth class).

Evaluation of the Intervention Prototype and Logic Model

The App Behavior Change Scale [78] was used as a checklist by the research team to assess the behavior change elements of the apps. Both proposed mobile apps included 18 items on the scale, indicating a high number of BCTs embedded in the apps and strong behavior change potential (Multimedia Appendix 5 [78]). The academic advisory panel reviewed and agreed on the final intervention prototype as well as the refined program theory. Figure 3 is a logic model that represents the program theory of the mother-daughter intervention. It depicts the flow of the intervention from (1) the identification of the problem (ie, preteen girls are not active enough) to (2) the inputs (ie, target behaviors of maternal PA support and preteen girls' PA), to (3) the mechanisms of action (ie, Table 1), to (4) the intervention components (ie, Tables 4 and 5), to (5) outputs (ie, mothers and daughters develop knowledge and understanding and improve motivation to enact target behaviors), to (6) short-term outcomes (ie, mothers and daughters enact target behaviors), to (7) long-term outcomes (ie, mothers and daughters maintain target behaviors), and finally (8) overall outcomes of the intervention (ie, improved PA levels in preteen girls). The app targeting mothers will be called the Physical Activity Virtual Assistant for Mothers (PAVA-M), whereas the app targeting their preteen daughters will be called Physical Activity Virtual Assistant for Daughters (PAVA-D) (Figures 4 and 5).

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Figure 3. Logic model of the intervention prototype. mHealth: mobile health; PA: physical activity; TDF: Theoretical Domains Framework.

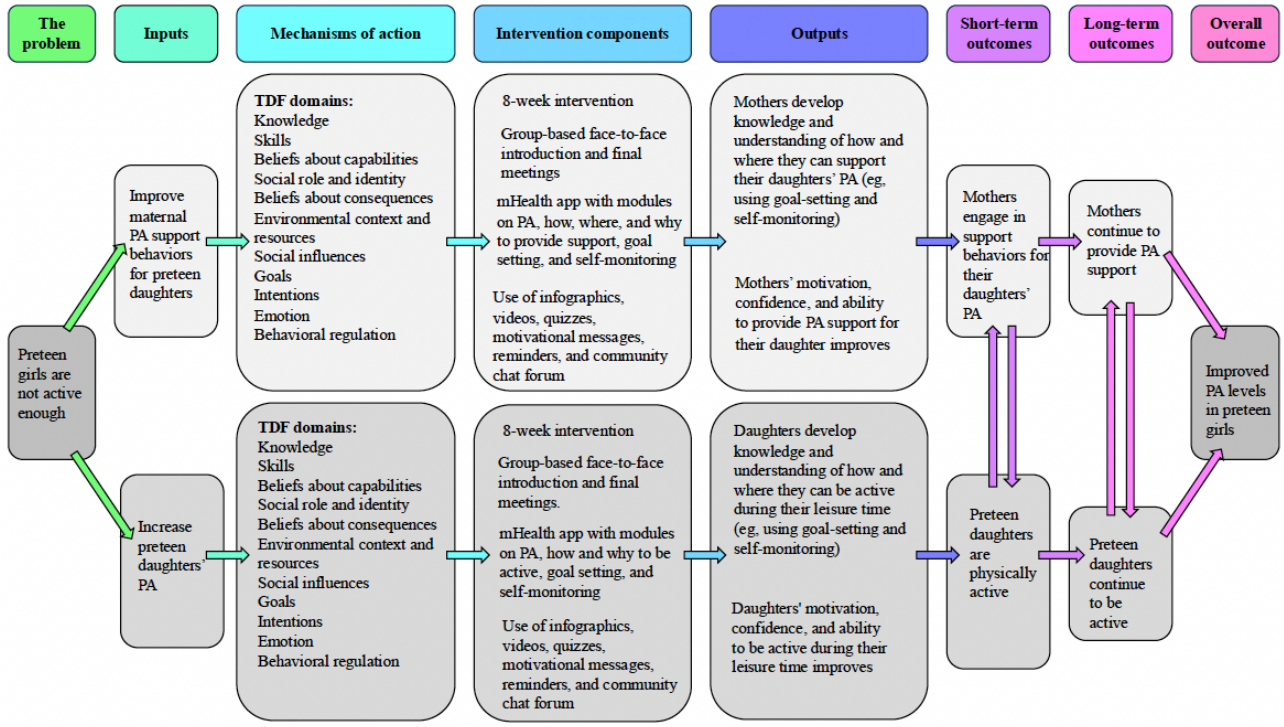

Figure 4. Screenshots from the mothers' mobile app prototype.

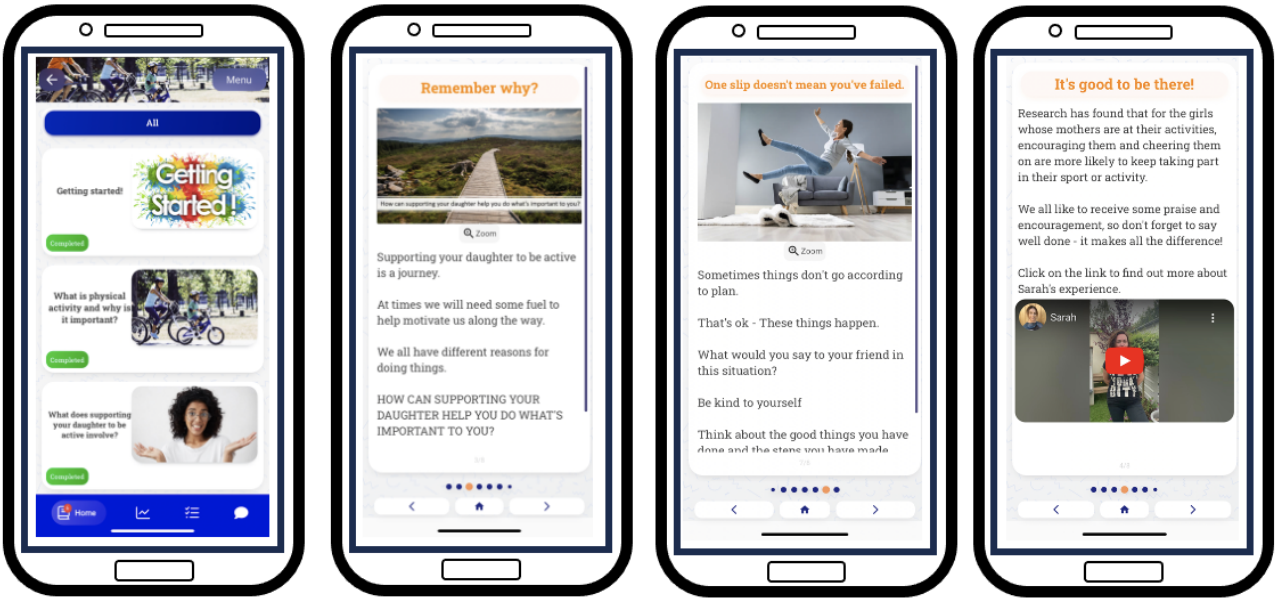

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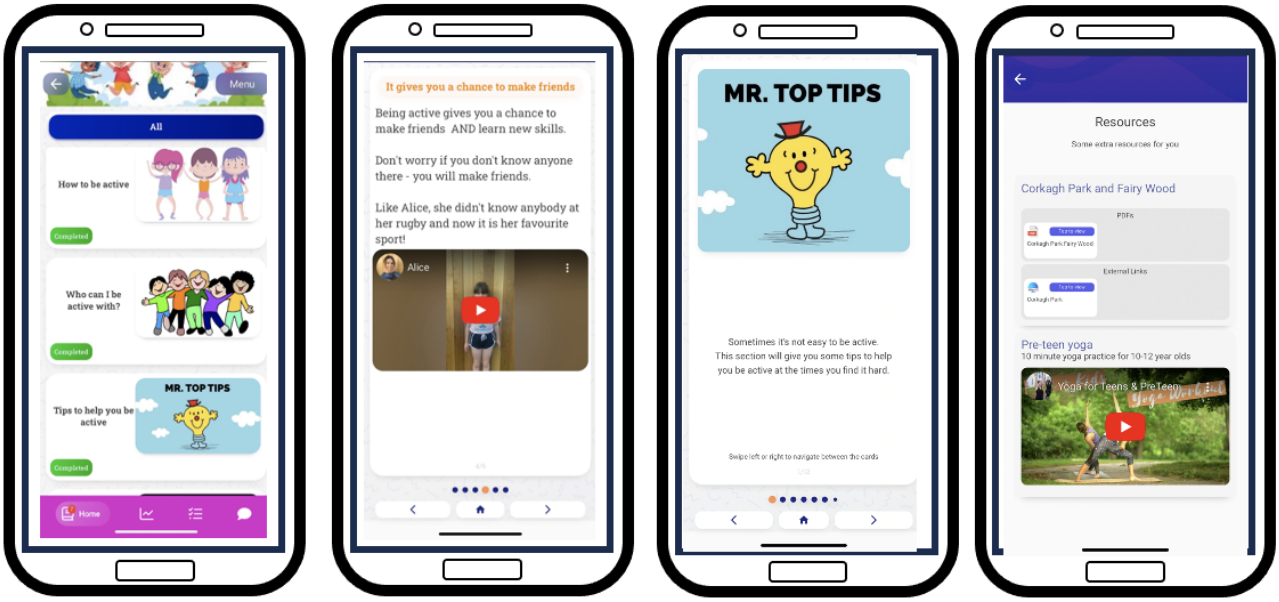
Figure 5. Screenshots from the daughters' mobile app prototype.



Discussion

Principal Findings

This paper describes the systematic process to develop an evidence- and theory-informed intervention, using co-design methods, to increase PA in preteen girls of low SEP by incorporating maternal supportive behaviors. This is noteworthy given that levels of PA decline with age in preteen girls of low SEP [4,9], placing them at elevated risk of obesity, type 2 diabetes, and cardiovascular disease [8,10]. In keeping with MRC guidance, the intervention was refined through an iterative and dynamic process based on evidence, theory, feedback from co-design workshops with mothers of preteen daughters, preteen girls, and primary school teachers and input from a multidisciplinary academic advisory panel. This process resulted in the development of an intervention with 2 target behaviors, one targeting mothers' supportive behaviors for their daughters' PA and the other targeting preteen daughters' PA directly, which is ready for feasibility and acceptability testing.

The systematic approach applied in this study was guided by the BCW framework for developing interventions [37]. Using the BCW facilitated a rigorous analysis of the problem and how it could be potentially addressed. It also enabled the consideration and incorporation of evidence from several sources: the extant research literature, formative research [82-84], as well as the judgments of the academic advisory panel. We followed a step-by-step process that involved the following: identifying and specifying the target behaviors; conducting a thorough analysis of the barriers and enablers to these behaviors; using the TDF to identify the proposed mechanisms of action; and selecting feasible intervention functions, BCTs, and delivery methods. One study has used the BCW to develop a mother-daughter PA intervention for adolescent girls [41], but to our knowledge, this is the first study to use the BCW and TDF in conjunction with the BCIO to target children's PA through a theory-informed family-based intervention.

The intervention prototype incorporates 27 BCTs, which is greater than the average of 8 to 10 BCTs per intervention reported in recent systematic reviews of family-based interventions targeting health behaviors such as PA [82,88]. There is some evidence to suggest that more effective interventions include a greater number of BCTs [89]. Furthermore, interventions that include a greater number of BCT clusters, with a threshold of at least 3 clusters, increase the likelihood of intervention effectiveness [90]. There were 13 BCTs clusters within the intervention prototype, and we incorporated particular clusters and specific techniques that have shown promise in theory-based interventions. For example, identity is an important mechanism of action for the promotion and maintenance of PA in adults and young people [63,91] and for providing parental PA support [64]. Our intervention is one of the few to include BCTs, which strengthen maternal identity for PA support and mother and daughter PA identity such as "reframe past behaviour BCT," "identify self as role model BCT," and "adopt changed self-identity BCT" [64]. In addition, this study incorporates BCTs that have proven effective in mother-daughter PA interventions and more broadly in health behavior change research. These include selecting a relevant behavioral goal, self-monitoring progress toward that goal, and developing problem-solving skills to address potential challenges [82,92-94].

This study engaged with end users (eg, mothers and preteen girls) and other relevant stakeholders (eg, primary school teachers) in the intervention development process using co-design methods. Despite continued advocacy for engaging children and adolescents in co-design methods, there is a paucity of studies targeting family-based PA that have applied such methods, in particular when it comes to children aged 10 to 12 years [59]. To the best of our knowledge, this is the first intervention prototype that meaningfully engaged with girls aged 10 to 12 years throughout the entire development process. The girls provided information into the selection of intervention components and towards the acceptability of intervention

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materials and resources [95]. Interestingly, the girls in the study suggested that a video of teenage girls slightly older than they were (ie, aged 13-14 years) describing how they overcame challenges to PA would be relatable and helpful for promoting PA in their cohort, an approach that the research team had not considered. Therefore, by including girls aged 10 to 12 years in the co-design process, this study increased the likelihood of acceptability and implementation at the intervention testing stage [56,96]. Furthermore, there is a lack of resources dedicated to detailing and evaluating the process of engaging with participants using co-design methods in the development of interventions [55,97]. As a result, there may be a need to develop guidance as to how to report the use of co-design principles in studies similar to the Template for Intervention Description and Replication (TIDieR) checklist [98] or the BCIO [46].

The mode of delivery of the intervention was another important intervention component. The selection of the mobile app was driven by the end users who wanted flexibility in how they engaged with the intervention. Indeed, mothers in the study highlighted the importance of being able to complete the intervention at their own pace, thus recommending a mobile app as the primary mode of delivery. Mothers often describe barriers to engaging in PA related to household, family, and occupational responsibilities [83]. Thus, the mobile app may allow individuals to complete intervention content at their own pace and facilitate adherence to the intervention. There is increased use of mobile apps as a mode of delivery for PA interventions [22,99,100]. However, research to date in children and adolescent populations is less frequent and is typically poorly designed [100]. Consequently, there is a need for further systematic theoretically informed research on the use of mobile apps with this population, a need which this study attempts to address. One of the challenges in using mobile apps as the mode of delivery for interventions is the cost of development of such apps, which can be prohibitive [101]. This study used the Pathverse platform to address this issue, as it provided our team with a rapid and cost-effective tool for creating and refining the intervention content [86,102]. Alongside the use of the BCW and related elements, we used the App Behavior Change Scale as a checklist during the development of the intervention to maximize the behavior change potential of the applications. However, it is important to note that the App Behavior Change Scale only measures the theoretical behavior change potential of the application, and it does not attempt to investigate the relationship between the actual features of application and behavioral outcomes [39]. Future work should consider the uptake, engagement, and user retention of the app by following frameworks such as the Reach, Effectiveness, Adoption, Implementation, and Maintenance framework [103].

An important component within intervention development is how an intervention is delivered, including the style of delivery of the intervention [48]. Typically, this focuses on human to human interaction; however, there is an increasing realization of the importance of considering a person-centered intervention delivery style, which is reflective and empathetic when designing applications and their related content [104]. Consequently, the principles of SDT [85] were applied to the intervention, ensuring that BCTs and specific features used in the intervention mapped to the basic psychological needs of autonomy, competence, and relatedness proposed by SDT [105-107]. Indeed, there is a growing body of work highlighting how applications underpinned by the SDT principles can strengthen digital therapeutic alliance and increase engagement in behaviors such as PA [107,108].

Future Directions

This study took place within the intervention development phase of the MRC framework [32]. Future research would involve using a no-code development app [102] to assess the feasibility of the intervention and inform decisions about how to progress to the following phases of intervention evaluation and implementation [32]. After engagement with the co-design participants, it was suggested that it was most feasible to promote this intervention via the school environment although it is targeting girls' PA outside of school hours. The school setting can reach children and adolescents of diverse racial and socioeconomic backgrounds and provides a ready-made social network for both mothers and daughters to engage with when undertaking the intervention [109,110]. Furthermore, it would allow for tailoring of the intervention resources within the school and local community that could support increased leisure time PA [109,110]. This is in line with research by Pfledderer et al [111] and van Sluijs et al [23] who recommend that interventions consider both family and community engagement (eg, family based and linked to school) to promote children's and adolescents' PA, particularly for underserved populations such as children and adolescents of low SEP. Although our preference is for mothers and daughters to take part in the intervention, the separate mobile app mode of delivery allows preteen girls to partake in the intervention regardless of their mothers' participation. This is an important feature, given that reaching parents of low SEP is often a challenge for interventions [112].

A limited number of these interventions are scaled-up and applied in real-world settings, identifying a significant research practice gap [113,114]. A recent review by Crane et al [115] found that health interventions (including PA interventions) that followed a research pathway were approximately 3 times more likely to have a positive effect on population health. Therefore, in line with recommendations by McKay et al [113], our future research would involve continuous planning for scaling-up, developing scale-up pathways, and evaluation of the scale-up throughout the duration of the intervention. Schools serving children with low SEP are frequently underresourced and often need more support to reach the same outcomes as their more advantaged counterparts [109,113]. To this end, maintaining relationships with schools and local community partners is essential in the scaling-up process to establish trust and identify potential implementation barriers [113,114]. This would involve hosting meetings with principals, teachers, and administrators to understand the pressing issues in their school environment; engaging with teachers, coaches, and local community partners to overcome implementation barriers; and developing collaborative strategies to encourage mothers and daughters to be physically active and sustain activity levels after the intervention [116]. Finally, based on the findings from this study, potential avenues for future research could be additional studies to evaluate the long-term effectiveness and sustainability

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of the intervention, research exploring the factors influencing parental engagement in family-based mHealth interventions, and investigation into the impact of mobile app on PA behavior change in children and adolescents.

Strengths and Limitations

This study used a systematic, evidence- and theory-based approach to integrate a body of evidence from a systematic review, 2 qualitative studies, an academic advisory panel, and end users' knowledge to co-design and develop a novel intervention to promote PA in preteen girls of low SEP. The uniqueness of this study lies in following the first phase of the MRC framework, while using the BCW, the TDF, BCTO, and input from co-design workshops, which offered procedural direction, structure, and transparency. Annotating the BCIO entities enabled us to represent the intervention characteristics in a detailed and structured way, which can be used across contexts and disciplines. In addition, the entities' unique identifiers will facilitate the use of artificial intelligence including machine learning–based methods in data extraction and evidence synthesis [46]. Family-based PA interventions have been the focus of previous research [21,117]. However, no digital intervention to date has specifically focused in promoting PA in preteen girls of low SEP complemented by maternal support behaviors. Thus, this work fills an important gap by seeking to support an at-risk group. Furthermore, the involvement of key stakeholders in the development process is a key strength of this study. It ensures that the content of the intervention was adapted to accommodate the users' needs, making it useful and relevant, thus increasing the likelihood of a more feasible, acceptable, and ultimately effective intervention [56,118].

Our work has some limitations. First, the highly structured and systematic approach used to develop this intervention prototype takes a significant amount of time and resources. For example, using the BCW, the TDF, and the BCTO requires considerable skills and training. Second, the process of converting BCTs into intervention content can be open to interpretation, and the research team had to make subjective and pragmatic decisions regarding intervention content throughout the process [119,120]. Third, we did not collect additional information regarding mothers' backgrounds such as their educational levels and PA experience as part of the co-design workshops. Finally, similar to other research [45], we used DEIS schools to recruit low-SEP preteen girls and their mothers. However, the data might not be fully representative of the target population, as DEIS schools are categorized by district, and it is possible that some girls or mothers in the school might not be of low SEP. Continued efforts should be made to target this cohort, for example, using household income or area level socioeconomic status.

Conclusions

In conclusion, this study uses a systematic evidence- and theory-based approach incorporating findings from a systematic review, formative qualitative research with mothers and preteen girls, input from an academic advisory panel, and knowledge from end users. This process was used to co-design an mHealth intervention prototype aimed at promoting PA in preteen girls, with a focus on maternal support behaviors, and is now ready for feasibility and acceptability testing. The novel contribution of this study lies in the use of theory and the meaningful involvement of key stakeholders throughout the development process. In addition, this study offers a practical example of how to integrate evidence, theory, and stakeholder engagement, which can be adjusted and tailored to fit different contexts and populations. Finally, the comprehensive annotation of the BCIO entities denotes the intervention characteristics in a structured manner that enables improved communication, replication, and implementation of interventions.

Acknowledgments

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Authors' Contributions

CB and JM conceptualized and led on the idea of Physical Activity Virtual Assistant for Mothers (PAVA-M) and Physical Activity Virtual Assistant for Daughters (PAVA-D). GO'D, AK, and RER helped develop the idea of PAVA-M and PAVA-D and provided guidance based on their expertise, including the section of mechanisms of action, behavior change techniques, and intervention components. CB and JM led on the co-design workshops and development and adaptation of the intervention content. CB and JM drafted the original manuscript. GO'D, AK, and RER reviewed the initial content and structure of the manuscript. All authors have read, revised, and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Behavior change intervention glossary.
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Multimedia Appendix 2
Barriers and enablers to target behaviors.
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Multimedia Appendix 3
Co-design session 1.
[DOCX File , 9452 KB - pediatrics_v8i1e62795_app3.docx]

Multimedia Appendix 4
Co-design session 2.
[DOCX File , 613 KB - pediatrics_v8i1e62795_app4.docx]

Multimedia Appendix 5
App Behavior Change Scale.
[DOCX File , 19 KB - pediatrics_v8i1e62795_app5.docx]

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Abbreviations

BCIO: Behaviour Change Intervention Ontology
BCT: behavior change technique
BCTO: Behaviour Change Technique Ontology
BCW: Behaviour Change Wheel
COM-B: Capability, Opportunity, and Motivation–Behavior
mHealth: mobile health
MRC: Medical Research Council
PA: physical activity
PAVA-D: Physical Activity Virtual Assistant for Daughters
PAVA-M: Physical Activity Virtual Assistant for Mothers
SDT: self-determination theory
SEP: socioeconomic position
TDF: Theoretical Domains Framework
TIDieR: Template for Intervention Description and Replication

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Development of Chatbot-Based Oral Health Care for Young Children and Evaluation of its Effectiveness, Usability, and Acceptability: Mixed Methods Study

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Abstract

Background: Chatbots are increasingly accepted in public health for their ability to replicate human-like communication and provide scalable, 24/7 services. The high prevalence of dental caries in children underscores the need for early and effective intervention.

Objective: This study aimed to develop the 30-Day FunDee chatbot and evaluate its effectiveness, usability, and acceptability in delivering oral health education to caregivers of children aged 6 to 36 months.

Methods: The chatbot was created using the artificial intelligence (AI) chatbot behavior change model, integrating behavioral change theories into content designed for 3 - 5 minutes of daily use over 30 days. A pre-post experimental study was conducted from December 2021 to February 2022 in Hat Yai District, Songkhla Province, and Maelan District, Pattani Province, Thailand. Fifty-eight caregivers completed a web-based structured questionnaire at baseline and 2 months post baseline to evaluate knowledge, protection motivation theory-based perceptions, and tooth-brushing practices. Usability was assessed via chatbot logfiles and a web-based questionnaire at 2 months post baseline. Acceptability was evaluated through three methods: (1) open-ended chatbot interactions on day 30, (2) a web-based structured questionnaire at 2 months post baseline, and (3) semistructured telephone interviews with 15 participants 2 weeks post intervention. Participants for interviews were stratified by adherence levels and randomly selected from Hatyai and Maelan districts. All self-reported variables were measured on a 5-point Likert scale (1=lowest, 5=highest).

Results: The chatbot was successfully developed based on the 4 components of the AI chatbot behavior change model. Participants had a mean age of 34.5 (SD 8.6) years. The frequency of tooth brushing among caregivers significantly improved, increasing from 72.4% at baseline to 93.1% two months post baseline (P=.006). Protection motivation theory-based perceptions also showed significant improvement, with mean scores rising from 4.0 (SD 0.6) at baseline to 4.5 (SD 0.6) two months post baseline (P<.001). The chatbot received high ratings for satisfaction (4.7/5, SD 0.6) and usability (4.7/5, SD 0.5). Participants engaged with the chatbot for an average of 24.7 (SD 7.2) days out of 30. Caregivers praised the chatbot's content quality, empathetic communication, and multimedia design, but noted the intervention's lengthy duration and messaging system as limitations.

Conclusions: The 30-Day FunDee chatbot effectively enhanced caregivers' perceptions of oral health care and improved tooth-brushing practices for children aged 6 - 36 months. High user satisfaction and engagement demonstrate its potential as an innovative tool for oral health education. These findings warrant further validation through large-scale, randomized controlled trials.

Trial Registration: Thai Clinical Trials Registry Tctr20210927004; https://www.thaiclinicaltrials.org/show/Tctr20210927004

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KEYWORDS

chatbot; conversational agents; tele-dentistry; oral health behavior; in-person toothbrushing; hands-on; children; covid-19; oral health education; development.

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Introduction

Chatbots have emerged as a socially responsible technology to bridge socioeconomic disparities and promote equitable access to high-quality health care [1,2]. Chatbots are digital tools that emulate human conversation and have the potential to promote health education, support behavior changes, and deliver health care, especially for clinical or vulnerable populations. Their adaptability also makes them suitable for deployment in a variety of sizeable and diverse samples [3]. Chatbots provide flexible, on-demand support, offering personalized assistance and content with continuous availability, helping to mitigate the limitations of traditional telehealth services [4]. Overall, chatbots offer a humanized interaction that can support health care professionals in managing and preventing conditions on a societal scale [5].

Multiple studies attest to the effectiveness of incorporating chatbots in health care, illustrating their role in facilitating a modification of health-related behaviors [3,6-8]. However, the existing literature on the use of chatbots for dental health purposes is limited [9,10], and few studies have explored the complicated process of constructing chatbots with oral health goals in detail.

Zhang et al [11] suggested some guidelines for the development of an artificial intelligence (AI) chatbot for behavior modification with the formulation of a theoretical framework that consists of four essential components: (1) specifying chatbot characteristics and understanding user backgrounds, (2) establishing relational capacity, (3) establishing persuasive capacity using behavioral-based theory, and (4) implementing an evaluation mechanism to assess outcomes.

Early childhood caries (ECC), identified as a significant chronic disease, emerges from the dynamic interplay of various risk and protective factors over time [12]. In Thailand, the earliest detection of noncavitated caries occurred at 9 months of age, while cavitation was first identified at 10 months of age [13]. In this context, parental tooth brushing, conducted twice daily with a rice-sized amount of fluoridated toothpaste, has been proven to be a pivotal strategy for reducing dental caries in children [12], whereas systematic reviews revealed that the effectiveness of simple health education in preventing ECC is restricted [14]. In line with a review regarding oral health promotion for ECC, home visits, and hands-on techniques for dental health education substantially enhance habit formation and effectiveness [15]. In addition, caregivers should receive practical training and empowerment from oral health professionals [16]. However, these interventions must be tailored to each individual, requiring not only highly skilled dental personnel but also considerable time and financial resources [17]. Chatbots have the potential to serve as a scalable model for skill development, motivation, problem-solving, and continuous follow-up, replicating the advantages of home visits.

Habits emerge as a consequence of acquiring repeated patterns of behavior, originating from consistent contextual stimuli, and they are formed through automated responses to the conditions in which they happen [18]. The research findings revealed that the time required to form habits varied, with values ranging from 18 to 254 days, depending on the level of complexity or challenge associated with a particular behavior [19]. Monitoring and reinforcement are effective ways to develop healthy habits [19,20] toward caries prevention in children [15], however, interaction with health professionals often requires traditional onsite visits, substantial time, and financial cost [21,22].

The protection motivation theory (PMT), a key theory in health psychology, explains how people change their behavior based on their evaluation of threats and their ability to cope with them [23,24]. The threat appraisal component of the PMT comprises 2 key elements: the individual's assessment of the disease's severity (perceived severity) and the probability of developing the disease (perceived vulnerability). The PMT additionally specifies that attitudes and behavior modification are indirectly influenced by the emotional state of fear arousal, which occurs through the evaluation of the danger's severity. The coping appraisal of the model comprises the individual's response efficacy, which is the expectation that implementing the recommendations will eliminate the threat, and self-efficacy, which is the belief in one's own ability to effectively execute the recommended course of action. Behavior performance should be significantly influenced by the intentions that are mediated by the cognitive predictors of threat and coping appraisals [25,26]. Kimhasawad et al [27] used a PMT-based education program to guide caregivers of 9 - to 12-month-old infants in adopting proper tooth brushing techniques, revealing that this approach effectively motivated and increased awareness, leading to a positive change in the oral health behavior of caregivers.

Currently, there is no standard evaluation method for a health care chatbot [28,29]. The concepts of usability and acceptability were identified as important factors for evaluating the use of chatbots [17]. However, there are differing definitions and some overlap between these terms [29,30]. Our study adopted broad interpretations of these concepts: usability as use, engagement, and ease of use; acceptability as satisfaction; continued use intention; and appropriateness. In addition, the frameworks of Zhang et al [11] and Denecke et al [31] were applied for content evaluation integrating usability and acceptability. This comprehensive evaluation provides a holistic assessment of the factors influencing chatbot adoption [32].

Therefore, the study aimed to elucidate the chatbot development process using PMT and Zhang's model. In addition, the pre-post study sought to assess the effectiveness, usability, and acceptability of a developed chatbot, the "30-Day FunDee," which was intended to educate caregivers of children between 6 and 36 months regarding oral health.

Methods

Figure 1 illustrates the comprehensive process involved in the defining framework, development, and evaluation of the 30-Day FunDee oral health promotion chatbot.

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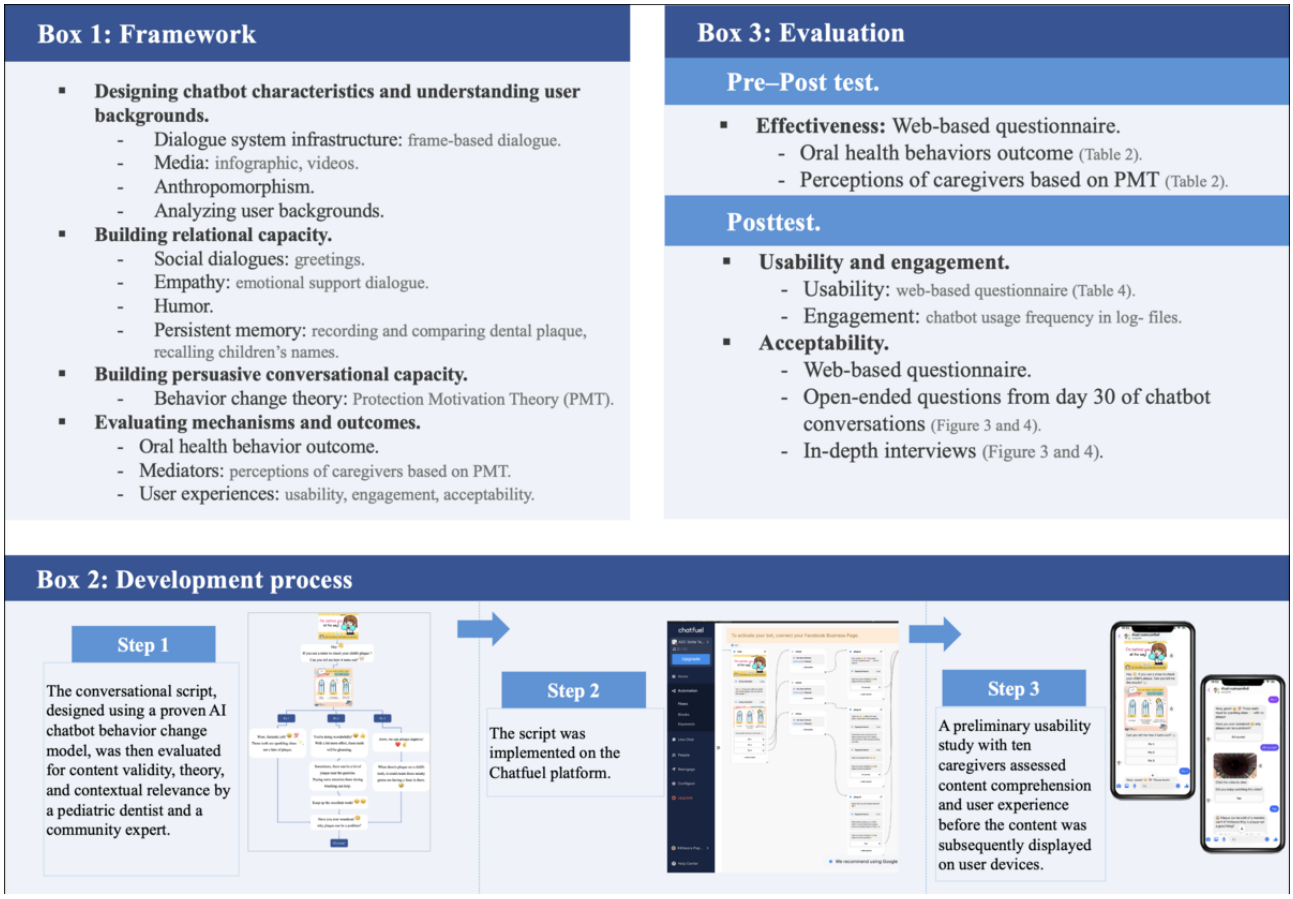
Figure 1. Framework, development, and evaluation of the 30-day FunDee chatbot. AI: artificial intelligence.



Defining a Framework for the 30-Day FunDee Chatbot

Designing Chatbot Characteristics and Understanding User Background

The objectives and target audience were specified for educating and assisting Thai caregivers with oral hygiene care for children aged 0 to 3 years. Designing chatbot characteristics encompassed dialogue system infrastructure, media, and anthropomorphism [11] as shown in Figure 2. The chatbot's dialogue system infrastructure is frame-based, enabling users to select their responses. The chatbot created a variety of media, including simple and clear language, illustrations, written text, audio components, conversational dialogue, infographics, animations, animated songs, and videos with authentic and animated content. Moreover, within the anthropomorphic realm, "Dr. Pin" the chatbot's dentist avatar, was depicted as a kind, charming, empathetic, and attentive caregiver for children's oral health.

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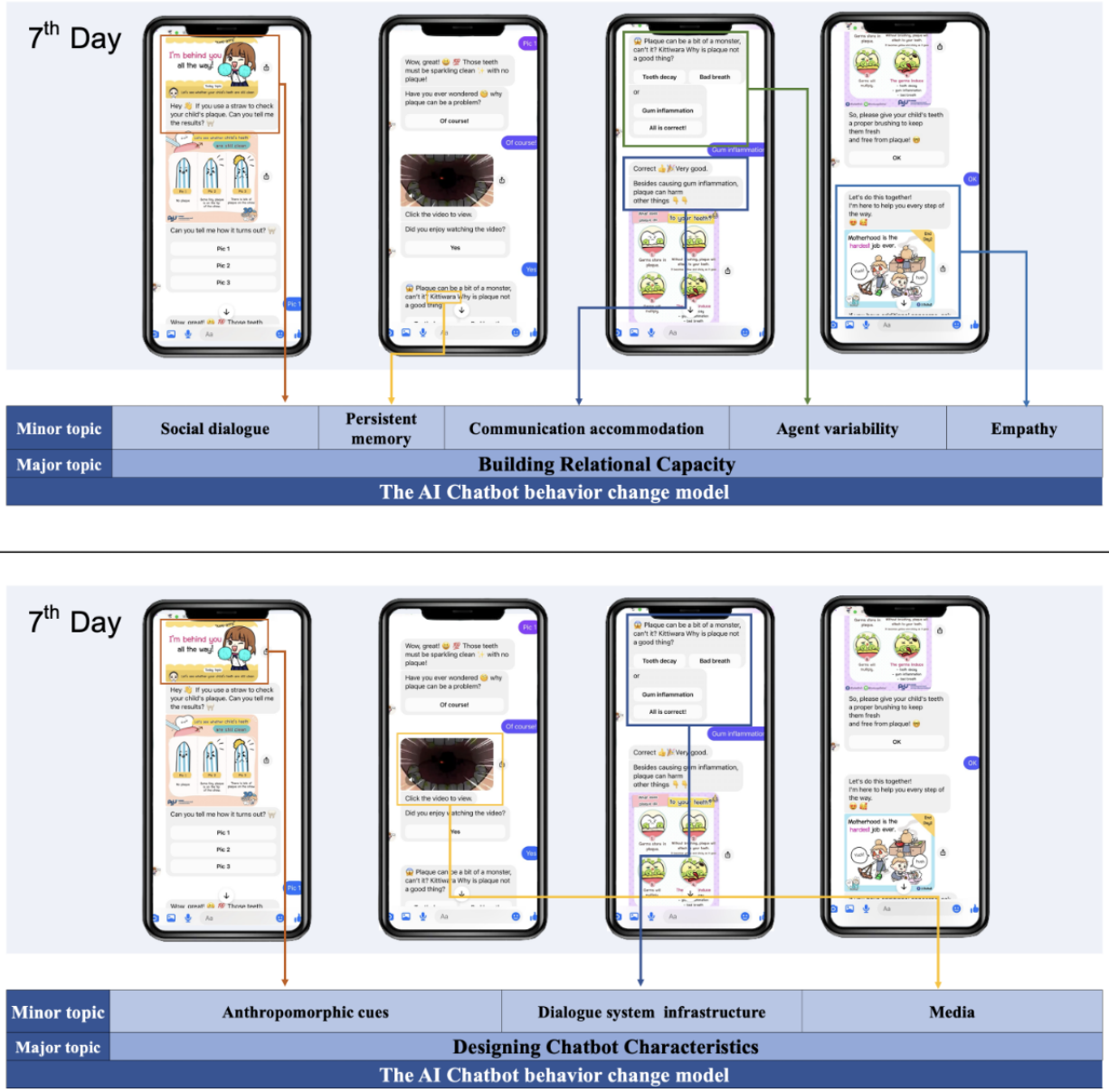
Figure 2. Screen example of the chatbot translated from Thai to English, showing dialogues that incorporate the design characteristics of the AI behavior change model on the seventh day. AI: artificial intelligence.



Understanding the user's background is critical in designing chatbots for behavior change [11,33]. Based on previous studies [34-36], the majority of caregivers were 20- to 40-year-old mothers with low to middle socioeconomic status who were responsible for nurturing their children, especially in relation to their children's tooth brushing. The chatbot's role was to assist users in overcoming obstacles and offering emotional support in childcare. Due to internet availability, both urban and rural caregivers could access the chatbot.

The content of the 30-Day FunDee chatbot was influenced by pediatric and community dentistry experts' recommendations and qualitative research insights on Thai caregivers' experiences with children's tooth-brushing behaviors [35,36], insights from community caregivers, inquiries from dental clinics, and knowledge gained from the earlier 21-Day FunDee chatbot, which is mentioned elsewhere [9]. Therefore, the updated chatbot was extended from 21 to 30 days, including more various media and dialogues, especially focusing on tooth-brushing practices.

Building Relational Capacity

Building relational capacity involves using elements such as social dialogues, empathy, relationship discussion, humor, self-disclosure, persistent memory, and agent variability [11,29]. Daily, the chatbot initiated conversations with charming greetings and concluded with farewell messages (Figure 2) that conveyed understanding and encouraged parents or caregivers in childcare [11]. For goal setting [37], daily welcome cards were designed with topics to be discussed.

The chatbot was designed to consistently display comprehension, empathy, and emotional support during interactions, especially when users encountered obstacles.

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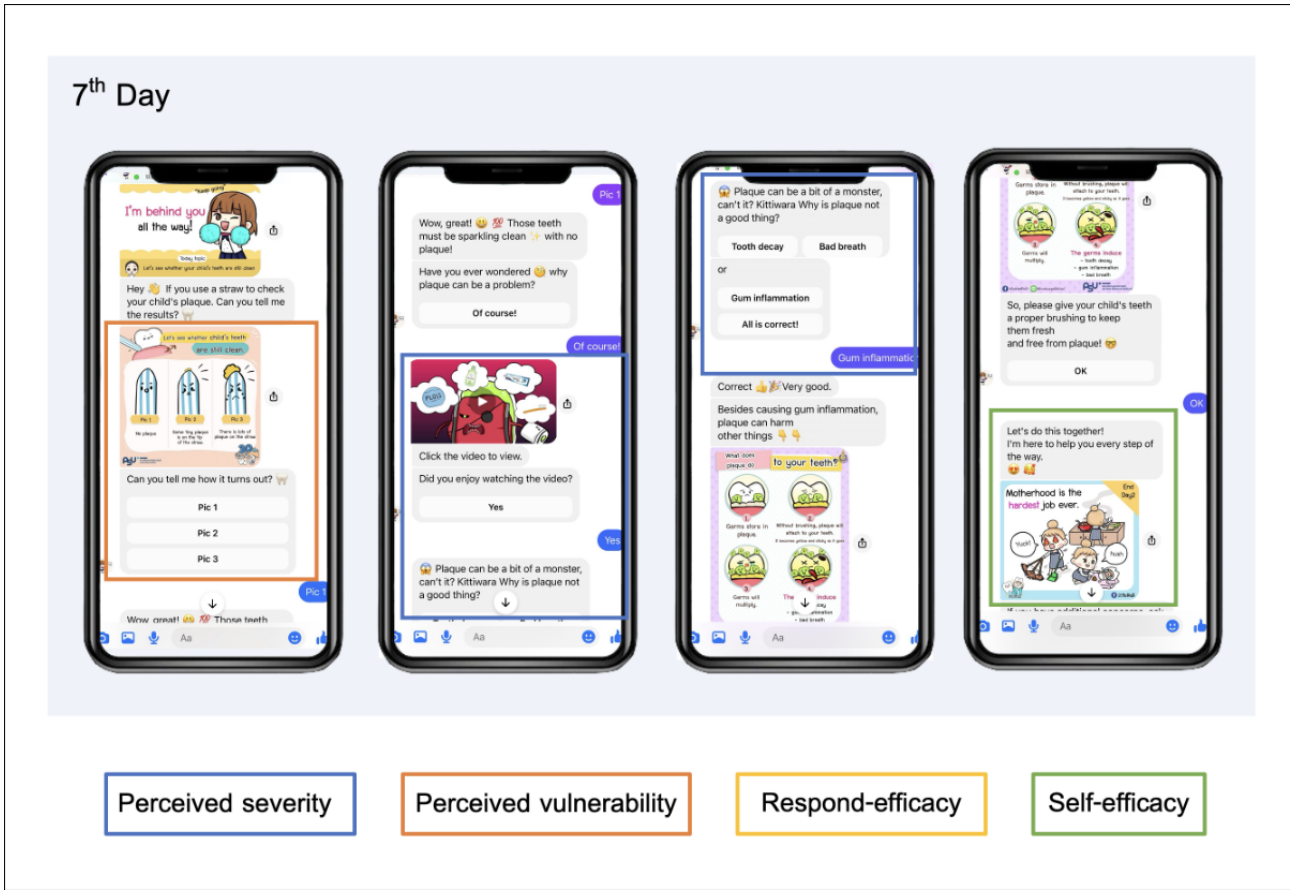
Emojis and animated GIFs conveying positive feedback and emotions were incorporated to increase engagement. Progress tracking enabled self-comparison and confidence-building over time. Periodic child dental plaque assessments prompted reflection on tooth-brushing techniques. Positive reinforcement was provided when plaque decreased, while setbacks received encouragement without punishment. Conversation features like remembering children's names, revisiting prior discussions, and using age-appropriate informal language aimed to simulate natural human-to-human dialogues. These elements enhanced the user experience and facilitated task completion [37,38] (Figure 2).

Building Persuasive Conversational Capacity

Overview

The 30-Day FunDee chatbot, meticulously designed, provided oral health education to caregivers based on PMT (Figure 3) for behavior modification by systematically sequencing threats and coping topics. Examples of chatbot topics are shown in the following sections.

Figure 3. Screen examples of chatbot dialogues translated from Thai to English, incorporating protection motivation theory (PMT) on the seventh day.



Perceived Severity

The importance of primary teeth, the consequences of dental infections, and anticipating problems from poor oral health care were discussed.

Perceived Vulnerability

The chatbot instructed caregivers on the child's dental plaque assessment and provided animation and infographics explaining plaque. Periodic plaque checks were encouraged, and an API enabled tracking of plaque levels over time.

Belief in Response Efficacy

Benefits and instructions, especially for tooth brushing, were incorporated into a variety of videos, infographics, and games. The chatbot also asked caregivers about children's sugar intake and diet to discuss potential health impacts.

Belief in Self-Efficacy

The chatbot was designed to increase caregiver self-efficacy for children's oral health management through motivational techniques and daily emotional support. At the end of each conversation, it expressed empathy for mothers' exhaustion and encouraged overcoming obstacles.

Chatbot Development Process

The development of chatbots followed a systematic, 3-phase process, as illustrated in Figure 1. The first step involved designing the conversational flow, which included scripts, infographics, videos, and other content. This step was crucial to ensure that the chatbot can engage effectively with users. This phase followed an established AI chatbot behavior change model and PMT, which guided the creation of responsive conversations tailored to encourage specific behavioral outcomes. The next step involved implementing the conversational flow using the Chatfuel platform, which enabled the transformation of the predesigned scripts into interactive

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conversations accessible on users' devices. The Chatfuel platform facilitated the efficient deployment of the chatbot design, ensuring seamless operation and scalability to accommodate the intended target audience, without advanced programming skills and includes push message functionality [39]. Given that over 80% of Thailand's population uses Facebook [40], Facebook Messenger was chosen as the delivery platform using Chatfuel.

The final step involved presenting the chatbot's content on user devices. After implementation, the chatbot became accessible, with its content displayed across various devices. This stage completed the chatbot's development, enabling it to interact with users as intended and deliver the conversations crafted during the initial phase. The chatbot used persuasive communication, including comprehension, empathy, and suggestions, to address the child's oral health challenges. It used a decision tree with recommended responses along with natural language understanding [37]. A pediatric dentist and a community expert evaluated the content validity, theoretical basis, and contextual appropriateness. A preliminary usability study with 10 caregivers evaluated content understanding and user experience.

Chatbot Evaluation

Chatbot evaluation should assess user patterns, user experience, conversation quality, perceived relational ability, and behavior outcomes [11,31]. This chatbot was evaluated on all aspects with the exception of oral health examinations due to COVID-19 pandemic operation limitations.

Participants and Recruitment

From December 2021 to February 2022, a total of 66 caregivers were recruited using convenience sampling including 29 caregivers from the Early Childhood Development Center at the Faculty of Medicine, Prince of Songkla University, Hat Yai District, Songkhla Province, and 37 caregivers from the Early Childhood Development Center in Maelan District, Pattani Province, Thailand. The inclusion criteria for caregivers were as follows: (1) currently caring for children aged 6 to 36 months with at least 1 tooth; (2) their children had no disabilities or significant underlying medical conditions that could have affected their oral health; and (3) equipped with electronic devices such as computers, tablets, or mobile phones, allowing for daily internet access and a propensity to interact via Facebook Messenger. The exclusion criteria were (1) caregivers who could not speak, read, or write Thai and (2) caregivers who were opposed to the data collection.

The sample size was calculated using G*Power software (version 3.1; Heinrich Heine University Dusseldorf) to determine the mean difference in the frequency of tooth brushing per day between pre- and postintervention time points. An effect size of 0.4283, derived from unpublished data of a previous multicenter study conducted across 6 provinces in southern Thailand that evaluated the effectiveness of a chatbot in promoting tooth-brushing behaviors among 398 children aged 6 months to 2 years [41], was used. Additional parameters included a correlation coefficient of 0.5, an α level of .05, and a power of 0.8. The calculation indicated a minimum of 60 participants was required. To account for a 10% dropout rate, the target sample size was increased to 66 participants to ensure sufficient data for analysis.

Initial contact involved outreach at childcare centers and communication with caregivers via Line or phone calls to assess eligibility and interest in participation. After identifying eligible caregivers, researchers scheduled appointments to provide detailed study information. Invitation letters were distributed by the research team (Multimedia Appendices 1 and 2).

Data Collection

Self-Reported Oral Health Behavior, Usability, and Acceptability

At baseline and 2 months later, a structured self-administered questionnaire (Multimedia Appendices 3 and 4) via Google Forms gathered information regarding participant characteristics and the effectiveness of chatbot use in terms of tooth-brushing behaviors and PMT-based oral health perceptions. At 2 months, usability and overall user satisfaction measures were added.

Oral hygiene behaviors were assessed using categorical questions on tooth cleaning methods, fluoride toothpaste use, and toothpaste amount.

Oral health perceptions were assessed using 14 items based on PMT including perceived severity (5 items), vulnerability (1 item), response efficacy (4 items), and self-efficacy (4 items), measured on a 5-point Likert scale.

A 5-point Likert scale, ranging from 1 (lowest) to 5 (highest), was used for all variables. The mean (SD) for each group was calculated by averaging the total items in each category. Negative items were reverse-scored before calculating the mean. The mean scores were interpreted as follows: 1.0 - 1.79 were the lowest perceptions, 1.8 - 2.59 were low, 2.6 - 3.39 were moderate, 3.4 - 4.19 were high, and 4.2 - 5.0 were highest.

The usability test was designed in relation to models of Denecke et al [31] and Zhang et al [11], consisting of 15 items. This measured user experience (3 items), conversation quality (4 items), perception of relation and capacity (2 items), self-esteem (4 items), and usefulness (2 items) on a 5-point Likert scale with the same calculation and interpretation methods as shown above. In addition, the engagement was quantified by analyzing use days from chatbot logfiles.

The assessment of acceptability was conducted using 3 different methodologies. First, on day 30, participants interacted with the chatbot, responding to open-ended prompts designed to elicit both positive and negative use experiences. Second, a structured questionnaire was administered 2 months post baseline. It consisted of 1 item evaluating overall user satisfaction using a 5-point Likert scale, ranging from 1 (lowest) to 5 (highest).

Two weeks post intervention, semistructured in-depth telephone interviews were conducted. Participants (n=15) were stratified into 4 groups based on adherence levels and were randomly selected from the Hatyai and Maelan districts with equal distribution: 100% adherence (30 d, n=4), 80% - 99% adherence

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(24 - 29 d, n=4), 50% - 79% adherence (15 - 23 d, n=4), and <50% adherence (<15 d, n=3).

Participants were contacted to schedule interviews. Nonresponders were replaced through random selection until quotas were met, except in group 4, where participants were unreachable. Interviews, lasting 10 - 15 minutes, covered the study's objectives; interview methods; and explored satisfaction, dissatisfaction, feedback, and suggestions. Field notes were recorded during each interview.

Quality Control of Questionnaire and In-Depth Interview

The content and construct validity of the questionnaires and guiding questions for in-depth interviews were evaluated by 3 experts: a community dentist, a pediatric dentist, and a dentist from a public hospital. The usability test, adapted from Denecke et al [31] and Zhang model frameworks [11], was validated by the same 3 experts. Reliability for PMT-based perceptions was determined using Cronbach α (α=0.85). Face validity of the overall questionnaire was established through pilot telephone interviews with 10 caregivers. The in-depth interview guidelines were validated by 3 experts. To ensure triangulation, 2 additional independent researchers conducted content analysis. Multiple data collection methods were used to assess acceptability.

Statistical Analysis

Descriptive statistics were presented as means (SD) for continuous variables, and frequency (percentage) for categorical variables. Within-group comparisons were used for the nominal/categorical data, and chi-square or Fisher exact tests were used. For continuous data, paired *t* tests were used. Satisfaction scores were reported as the mean (SD) on a 5-point scale. IBM SPSS Statistics for Windows (version 29.0.0.0 (241); IBM Corp) was used.

Analysis of Qualitative Data

The responses of the participants from in-depth interviews were analyzed thematically using an inductive method guided by the procedure outlined by Jang et al [42] and Fitzpatrick et al [37]. Data from in-depth interviews and open-ended queries were analyzed using thematic analysis [43,44] and reported in terms of frequency.

Ethical Considerations

Adhering to social distancing measures recommended during the COVID-19 pandemic, participants attended group Zoom information sessions where researchers explained the study comprehensively. To ensure privacy, attendees could use pseudonyms and disable cameras. The researcher outlined the following: (1) study purpose; (2) data handling procedures; (3) privacy measures; and (4) participant rights, including voluntary participation, and withdrawal options. Questions could be asked during the session or privately via Zoom chat. Verbal consent was obtained during the session, with the completion of the web-based questionnaire (Google Forms) serving as additional confirmation. Participants could withdraw by not completing the questionnaire. Privacy measures included guidelines against sharing others' identities or comments outside the session, and secure data storage with restricted access to research team members only. The protocol was registered to the Thai Clinical Trials Registry (TCTR20210927004) and approved by the Institutional Review Board of the Faculty of Dentistry at Prince of Songkla University (EC6407-053).

Results

Characteristics of Participants at the Baseline

Initially, 66 individuals were enrolled in the study, but following the 30-day postintervention period, 8 enrollees were excluded due to loss of follow-up.

The demographic and socioeconomic status of participants (n=58) were presented below (Table 1). The mean participant age was 34.5 (SD 8.6) years, and 87.9% (n=51) were mothers. The mean child age was 20.9 (SD 7.9) months. Of the participants, 55.2% (n=32) participants obtained oral hygiene advice via the web. Most web-based use was 51.7% (n=30) of the participants for between 3 and 5 hours per day, then >6 hours per day (15/58, 25.9%) and followed by 1 - 2 hours per day (13/58, 22.4%). Daily internet use was 72.4% (n=42) during the week.

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Table . Demographic and socioeconomic characteristics of study participants (N=58).

Demographic characteristics	Values, n (%)
Caregiver's education level	
Lower than Bachelor degree	26 (44.8)
Bachelor degree or higher	32 (55.2)
Religion	
Buddhism	26 (44.8)
Islam	32 (55.2)
Caregiver's occupation	
Stay-at-home parent	18 (31)
Civil servant	23 (39.7)
Employee	8 (13.8)
Private sector employee	4 (6.9)
Farmer	2 (3.4)
Business owner	3 (5.2)
Family income	
Not enough	5 (8.6)
Enough	53 (91.4)

Oral Health Behaviors

Results from the posttest showed that tooth brushing by caregivers and the use of fluoride toothpaste and smear-sized toothpaste improved significantly (Table 2).

Table . Oral health behaviors among study participants at baseline and after 2 months from the first day of intervention (N=58). Fisher exact test significance level: $P<.05$.

Behaviors	Preintervention, n (%)	Postintervention, n (%)	*P* value
Teeth cleaning method			.006
Improper or no tooth brushing[a]	16 (27.6)	4 (6.9)	
Tooth brushing by caregiver	42 (72.4)	54 (93.1)	
Frequency of tooth brushing			<.001
<1 time/day	21 (36.2)	8 (13.8)	
≥2 times/day	37 (63.8)	50 (86.2)	
Use of Fluoride toothpaste (Yes)	31 (53.4)	49 (84.5)	.001
Smear-sized toothpaste used	34 (58.6)	48 (82.8)	.008

[a]Improper tooth brushing is defined as insufficient cleaning, rinsing with water only, using a cloth for cleaning, or allowing the child to brush independently.

Perceptions of Caregivers Based on PMT

All perceptions of caregivers based on PMT showed significant improvement from high to highest perceptions, except for perceived vulnerability, which improved but without a statistically significant difference (Table 3).

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Table . Perceptions of caregivers based on protection motivation theory (PMT) toward oral health behavior (total score=5). Paired *t* test significance level: *P*<.05.

	Preintervention, mean (SD)	Postintervention, mean (SD)	*P* value
PMT parameters			
Perceived severity	4.0 (0.9)	4.5 (0.7)	<.001
Perceived vulnerability	4.3 (1.1)	4.6 (0.9)	.56
Response-efficacy	3.9 (0.8)	4.4 (0.8)	.04
Self-efficacy	3.9 (0.9)	4.3 (0.7)	.001
Overall	4.0 (0.6)	4.5 (0.6)	<.001

Usability and Engagement

The usability levels were highest in every category (Table 4). Of those who completed the program, 32.8% of the study participants were fully engaged in using the chatbot. The average chatbot user engagement was 24.7 days (SD 7.2), with an additional insight into weekly engagement of 5.8 days (SD 1.7).

Table . Usability on the chatbot (N=58).

Usability items (total score=5)	Values, mean (SD)
User experiences	4.6 (0.6)
Convenience	4.6 (0.7)
Acceptable performance and acceptance	4.6 (0.7)
Conversational quality	4.7 (0.6)
Understandable media	4.7 (0.6)
Reliable content	4.8 (0.7)
Appropriate content order	4.6 (0.8)
Linguistic features, naturalness, and fluency conversational quality	4.8 (0.6)
Perception of relational and capacity	4.7 (0.6)
Rapport perception of relation and capacity	4.6 (0.8)
Self-efficacy and perceived social support	4.8 (0.6)
Increased self-esteem	4.6 (0.6)
Usefulness of chatbot	4.8 (0.5)
Overall average score	4.7 (0.5)

Acceptability

In the structured questionnaire, overall satisfaction was rated 4.7 out of 5 (SD 0.6). Open-ended questions from day 30 of chatbot conversations (42 users) and in-depth interviews (15 users) revealed 4 major themes through thematic analysis: content, user learning, media, and process (Figure 4). Most users expressed positive feedback on the value of the content and the engagement methods, particularly empathetic communication and media. However, the duration of chatbot interactions and issues with the messaging system were identified as key barriers to sustained engagement (Figure 5).

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Figure 4. Thematic map of favored chatbot features of chatbot users' experience, drawn from in-depth interviews and open-ended questions. (Number in bracket: number of users).

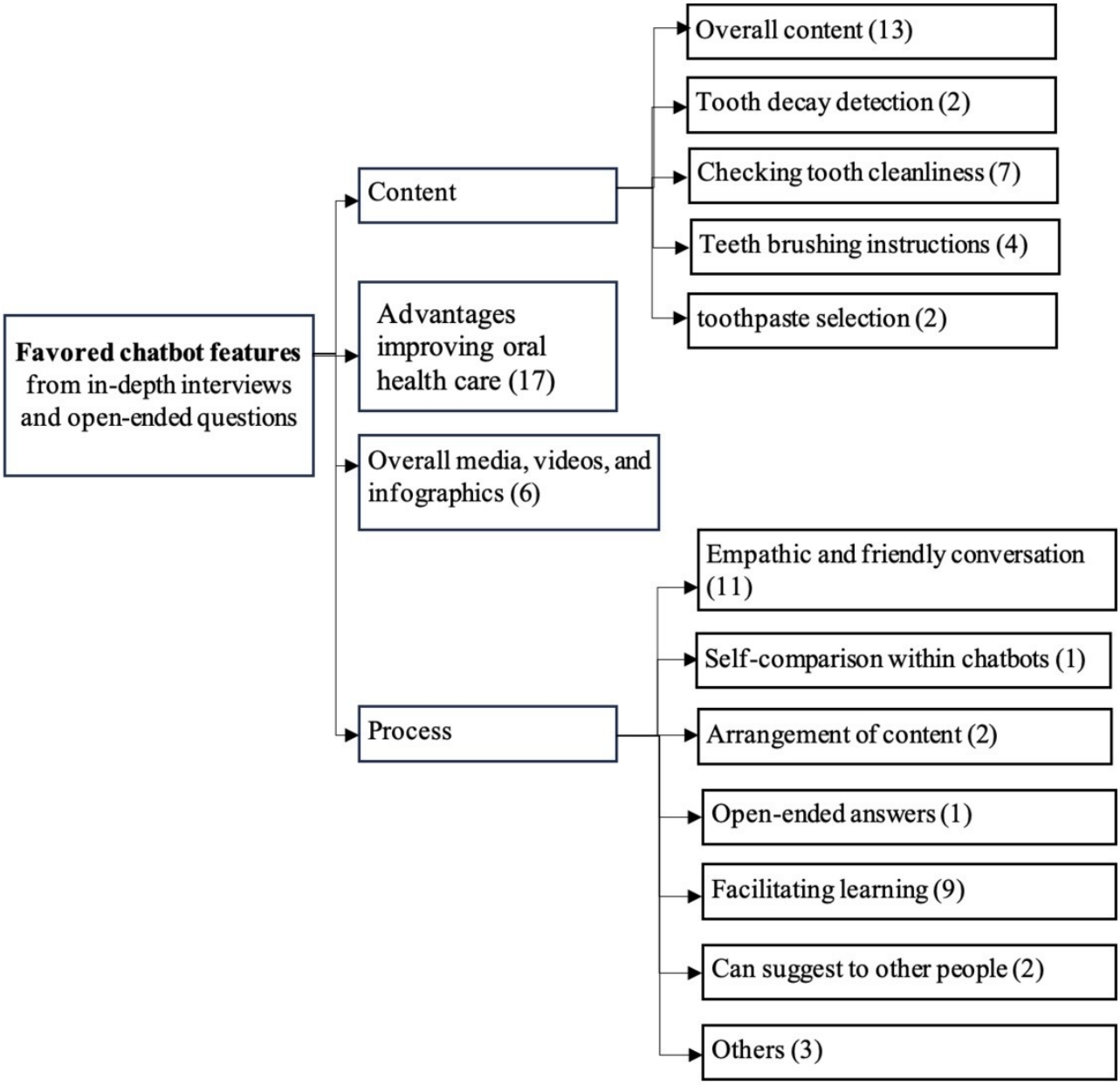

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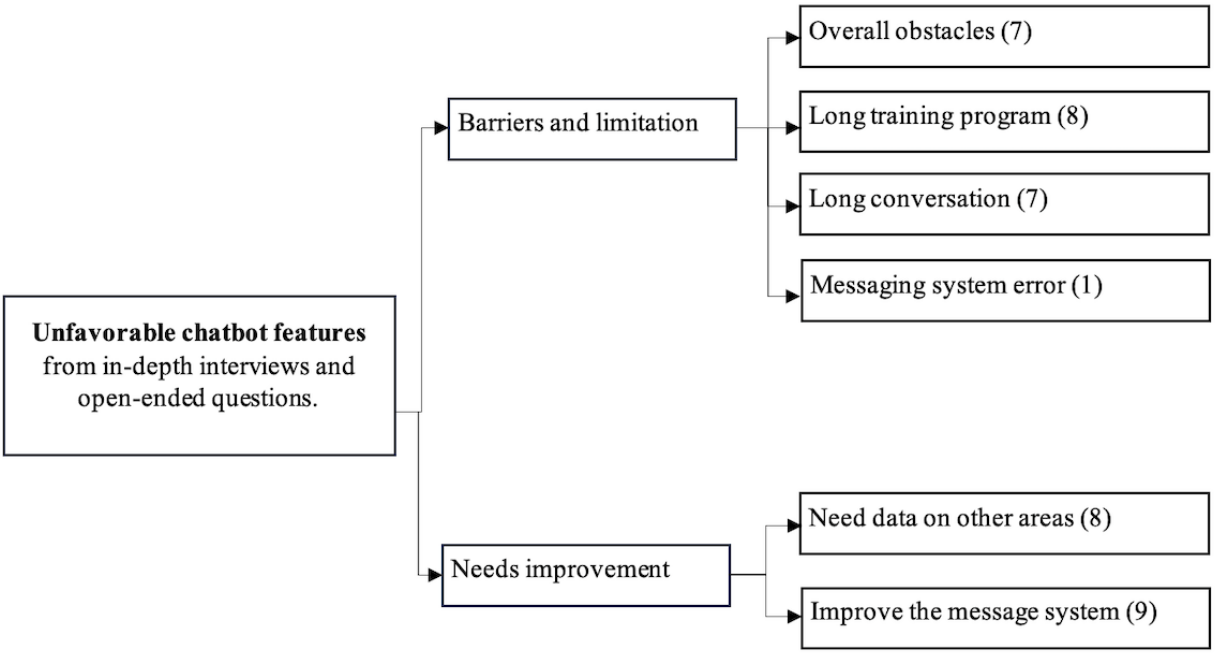
Figure 5. Thematic map of unfavorable chatbot features of chatbot users' experience, drawn from in-depth interviews and open-ended questions. (Number in bracket: number of users).



Discussion

Principal Findings

The study indicates that using the "30-Day FunDee" chatbot significantly improved PMT-related perceptions and tooth-brushing behavior for young children. High levels of acceptability and usability were reported for the chatbot acceptability and usability were reported.

Several studies supported that knowledge and attitudes regarding tooth brushing can evolve and that alterations in tooth-brushing practices are influenced by or linked to this factor [45,46]. Caregiver-led tooth brushing for children twice daily with a rice-sized amount of fluoridated toothpaste has been proven to be a key strategy for preventing dental caries in children younger than 3 years [12]. In the study, tooth brushing by caregivers increased significantly from 72.4% to 93.1% (a significant increase of approximately 22%). The dedication of caregivers to twice-daily brushing and the use of fluoride toothpaste for children significantly grew, with an increase of approximately 22.4% (from 63.8% to 86.2%) and 31.1% (from 53.4% to 84.5%), respectively. These results go beyond those of other studies involving similar age groups, whether they used traditional oral health education with or without in-person tooth-brushing training [22,47].

Oral health professionals should provide caregivers with practical training and empowerment regarding the prevention of tooth decay in young children [15,16,48]. Within the framework of this chatbot interface, caregivers are expected to autonomously acquire the skill of proper tooth brushing through the use of educational content, encompassing videos, images, and textual information. The resultant feedback on this intervention demonstrated noteworthy effectiveness, reflecting an elevated tooth-brushing behavior and satisfaction level, quantified with a score of 4.7 out of 5. Additionally, media preferences were thoroughly explored through in-depth interviews and open-ended questions within the chatbot interface.

Meta-analyses indicate that 4 key factors within the PMT including perceived severity, perceived vulnerability, response efficacy, and self-efficacy contribute significantly to changes in health behaviors [49]. Perceived severity significantly increased, likely due to integrating PMT principles into the chatbot design and content structure. As in prior research, the perceived severity of the condition (cancer) impacted intentions to prevent disease, suggesting fear appeals influenced the perceived threat of disease [50]. In addition, the systematic review identified self-efficacy within the PMT's coping appraisal construct as the most effective predictor and promoter of physical activity participation [51]. Our findings align with these studies, demonstrating improvements in perceived severity, response efficacy, and self-efficacy.

In this chatbot on perceived vulnerability, we requested caregivers evaluate their children's dental plaque to determine their abilities in tooth brushing. We hypothesized that there would be a significant difference in perceived vulnerability, however this was not supported. Nevertheless, such interactions still improve oral health behaviors in children [27]. Caregivers, with a strong belief in response efficacy, are more likely to change their behavior to take care of their children [27,52]. In this study, we aimed to share tooth-brushing techniques using various media such as conversational text, infographics, both real-life and animated images, and videos. This finding is consistent with the excellent level of user satisfaction observed regarding the understandable media and reliable content

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displayed. Self-efficacy is a significant component that plays a critical role in influencing the improvement of health behavior [27,45,46,53].

Consistently maintaining oral health behaviors, crucial for the success of preventing caries, should be upheld over an extended period [54]. As habit formation typically takes place within a range of 18 to 254 days [19], we anticipate that the 30-day exposure to the intervention and the subsequent 60 days from the first day of intervention to the evaluation day will sufficiently ensure a lasting behavioral change.

Behavior change theories were recommended in interventions promoting change, including in-person and digital formats. These approaches emphasized goal-setting, self-monitoring, reviewing goals, addressing obstacles, providing motivation, feedback, social support, and individualized guidance and education [21,55,56]. The 30-Day FunDee chatbot study incorporated these techniques.

Integrating behavior change methods into chatbot interventions likely improved targeted behaviors and overcame limitations of conventional in-person interventions, including restricted health care professional interaction, declining motivation over time, and insufficient access to education. Thus, chatbots may elicit positive behavior changes by addressing the restrictions of traditional approaches [3].

The research involves designing a satisfaction assessment using a web-based questionnaire that was applied to evaluate the design of the AI behavior change model [11]. The evaluation focused on user experiences, conversational quality, perception of relational capacity, self-esteem enhancement, and chatbot usefulness. The results indicate the highest satisfaction across all evaluated criteria and that it was effective enough to increase tooth brushing behavior. Powerful chatbots, such as the 30-Day FunDee chatbot, are not only capable of simple conversation, but also of oral health education and self-training.

The average duration of chatbot engagement, which was 5.8 days per week in this study, is a salient feature. Due to the increased level of satisfaction, this duration is especially noteworthy; it exceeds Todaki's 5.1 days-per-week engagement during a similar 4-week study period [42], but is inferior to Woebot's 6.1 days-per-week engagement in a shorter 2-week study period [37]. Observations from both our own investigations and other research [42] indicate that the chatbot exhibited notable use during the initial week, followed by a decline in use from the second to the fourth week. User feedback revealed 3 key reasons: excessive workload strain, preference for shorter programs, and reliance on chatbot notifications. These findings indicate a misalignment between chatbot functionality and user needs, consistent with previous research highlighting drawbacks such as extended training programs and technical errors [37,42]. Future iterations will prioritize content condensation, enhanced user engagement, and potential platform optimization or replacement to address these challenges and improve overall chatbot efficacy.

According to the challenges of chatbot development in public health, establishing rapport and cultivating relationships with users through compassionate and personalized interactions is critical for a sustained and engaging intervention [3,4,57]. This study aligns with previous research findings, where the term "empathic and friendly conversation" emerged during in-depth interviews and open-ended questions. Similarly, studies on other chatbots corroborated these benefits [37,42,58].

The strengths of this study focus on systematically planning, developing, analyzing, and assessing the chatbot. It was meticulously designed based on behavior modification theory and principles of AI chatbot behavior change. This resulted in profound understanding, facilitating improvement, development, testing, and evaluation of interactive programs to align with the goals. This included the capacity to discuss, summarize outcomes, and conduct extensive comparative analyses with other study findings. The ultimate goal is to formulate guidelines for the next phase of chatbot development.

Our research possesses limitations due to a pre-post design, potentially introducing a maturity bias and consequently, possibly overestimating the chatbot's effectiveness in enhancing oral health behavior. In the research methodology, a self-administered web-based questionnaire was used, raising concerns about compromised validity.

In order to improve the applicability of our results, we recommend that future research use randomized trials involving a wide range of demographic groups and conduct a more extensive evaluation of caries prevention. Furthermore, to enhance the effectiveness, user-friendliness, and acceptance of chatbots, efforts should be made to incorporate adaptive learning and AI-driven conversational methods.

Conclusion

In summary, this research suggests that the 30-Day FunDee chatbot can be an effective, highly usable, and acceptable resource for individuals seeking oral health information and children's caries prevention. Such a tool could be developed in the next phase of chatbots to serve as a scalable complement to conventional treatment approaches.

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Authors' Contributions

KP, JH, and SP developed the research framework through the design of the study and a comprehensive literature review, the creation of the chatbot, and the collection and analysis of data. SN contributed to the research design and data presentation. KP and JH authored the preliminary version of the manuscript. All authors (KP, JH, SP, and SN) conducted a review and revision of the manuscript to finalize the version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
English invitation letter.
[DOCX File, 28 KB - pediatrics_v8i1e62738_app1.docx]

Multimedia Appendix 2
Thai invitation letter.
[DOCX File, 32 KB - pediatrics_v8i1e62738_app2.docx]

Multimedia Appendix 3
English structured self-administered questionnaire.
[DOCX File, 2139 KB - pediatrics_v8i1e62738_app3.docx]

Multimedia Appendix 4
Thai structured self-administered questionnaire.
[DOCX File, 2438 KB - pediatrics_v8i1e62738_app4.docx]

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Abbreviations

AI: artificial intelligence
ECC: early childhood caries
PMT: protection motivation theory

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Review

Extended Reality (XR) in Pediatric Acute and Chronic Pain: Systematic Review and Evidence Gap Map

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Abstract

Background: The use of extended reality (XR), including virtual reality (VR) and augmented reality (AR), for treating pain has accelerated in the last 10 years. XR is an attractive biobehavioral intervention that may support management of pain or pain-related disability. Reviews of the literature pertaining to adults report promising results, particularly for acute procedural pain.

Objective: This study aimed to (1) summarize the available evidence with respect to feasibility, safety, and effectiveness (pain intensity) of XR for pediatric acute and chronic pain; (2) summarize assessment tools used to measure study outcomes; and (3) identify gaps in evidence to guide future research efforts.

Methods: This study is a systematic review of the literature. Multiple databases (CINAHL, Cochrane Central, Embase, MEDLINE, PsycINFO) were searched from inception until March 2023. Titles, abstracts, and full-text articles were reviewed by 2 team members to determine eligibility. Articles were included if the (1) participants were aged 0 to 18 years; (2) study intervention was VR or AR; (3) study outcomes included safety, feasibility, acceptability, or effectiveness on the outcome of pain; and (4) study design was observational or interventional. Data were collected on bibliographic information; study characteristics; XR characteristics; outcome domains; outcome measures; and study findings pertaining to safety, feasibility, and effectiveness.

Results: We included 90 articles in the review. All included studies used VR, and 93% (84/90) studied VR in the context of acute pain. Of the 90 studies, 74 studies were randomized trials, and 15 studies were observational. Safety was assessed in 23 studies of acute pain, with 13 studies reporting no adverse events and 10 studies reporting events of low concern. Feasibility was

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assessed in 27 studies. Of the 84 studies of acute pain, 62% (52/84) reported a positive effect on pain intensity, 21% (18/84) reported no effect, and 13% (11/84) reported mixed effects. All 6 studies of chronic pain reported a positive effect on pain intensity. An evidence gap map was used to illuminate gaps in specific research areas stratified by subtypes of pain. Risk of bias assessment revealed 67 studies had a moderate risk of bias, 17 studies had a high risk, and 5 studies were deemed to be low risk.

Conclusions: The current body of literature around XR for pediatric pain is focused on acute pain with promising results of safety and effectiveness on pain intensity. The literature pertaining to chronic pain lags behind, limiting our ability to draw conclusions. The risk of bias in studies is problematic in this field, with the inherent challenge of blinding participants and researchers to the intervention. Future research should aim to measure effectiveness beyond pain intensity with a consistent approach to measuring key outcome domains and measures. Current efforts are underway to establish expert consensus on best research practices in this field.

Trial Registration: Prospero CRD42022307153; https://www.crd.york.ac.uk/PROSPERO/view/CRD42022307153

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KEYWORDS

virtual reality; augmented reality; extended reality; acute pain; chronic pain; pediatrics; adolescents; safety; feasibility; effectiveness; evidence gap map; child; children; VR; XR; biobehavioral; intervention; systematic review

Introduction

Acute and chronic pain are common among children [1-3] and can result in negative short and long-term health and mental health consequences. Within pediatric populations, acute pain can negatively impact treatment adherence such as vaccination schedules [4] and routine port access [5] and can worsen outcomes in the context of surgery and rehabilitation [6,7]. Additionally, acute pain can transition into chronic pain if not adequately assessed, managed, and treated [8]. If not addressed in childhood, these pain and other health-related problems often continue into adulthood and therein increase risk for functional disability and mental health challenges including depression, suicidality, and substance use, with particular concern for opioid use or misuse [9-12].

Technologies have been emerging to support the management of pain for both acute and chronic pain, including the integration of extended reality (XR) into clinical care. XR is most often inclusive of virtual reality (VR) and augmented reality (AR), which aim to immerse a person or patient in a simulated environment that they perceive to be real [13]. In the context of VR, youth are transported to a new or alternative environment, while AR alters or enhances the environment in which the youth is already existing [14].

The integration of XR into health care has been a rapidly growing area of clinical research and treatment, with promise surrounding the management of pain across a variety of acute and chronic conditions for youth and adults [15-17]. Much research has been conducted in the acute pain management context and specifically surrounding wound care, venipuncture (“needle pokes”), and minor procedures (eg, dental fluoride therapy, orthopedic pin removal). Among adults, XR has also been used commonly to manage chronic pain such as low back pain or fibromyalgia [18,19]. Together, results to date indicate that XR holds great promise for supporting biopsychosocial treatment for pain management for youth and adults; however, consistency in measurement as well as defined outcomes for assessing the effectiveness of XR research are missing, thereby limiting the ability to coordinate research efforts and examine effectiveness on a large scale.

One reason for the variability and the lack of consensus in technology and outcomes in XR research is related to the rapid adoption and evolution of technology (ie, hardware and software). Since the initial studies of XR for pain began in the 1980s, the rate at which XR is being evaluated and integrated into clinical care for pain management has sharply increased, with over 250 PubMed-indexed studies published since 2020 alone compared with the total 78 studies published in the 20 years preceding. Identifying a core outcome set for XR trials in pain is needed given the rapid adoption and evolution of this technology into clinical research and the potential for XR to provide breakthroughs in the treatment and management of acute and chronic pain. We undertook this task and, as a part of this effort, conducted a systematic review to summarize the current state of the literature with a specific aim toward understanding how researchers are currently assessing XR effectiveness.

Therefore, the purpose of this systematic review was to describe the feasibility, safety, and effectiveness of XR for pediatric acute and chronic pain. Moreover, this review collated current research to establish an evidence and gap map for guiding future research efforts. Finally, given the variability in XR study treatment outcomes, this review also assessed the measurement tools that have been used to measure outcomes in XR research. Together, these findings provide an updated description of the state of the field and highlight a path forward for improving the application, feasibility, and effectiveness of XR research in the context of pediatric acute and chronic pain.

Methods

Search Strategy

The systematic review protocol was registered on PROSPERO (#CRD42022307153). The literature search strategy was developed in consultation with a medical librarian who executed the searches. Examples of search terms (including MeSH terms) included “virtual reality,” “pain,” “treatment outcome,” “safety,” and “feasibility studies.” A randomized controlled trial (RCT)

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hedge or study-type filter was not applied as it was considered too limiting for the overall search. Major electronic databases (CINAHL, Cochrane Central, Embase, MEDLINE, PsycINFO) were searched from database inception to March 2023. The full search strategy is included in Multimedia Appendix 1.

Selection Criteria

The inclusion criteria for the current review included (1) participants aged 0 to 18 years; (2) study intervention of XR (VR or AR); (3) study outcomes of safety, feasibility, acceptability, or effectiveness on the outcome of pain; and (4) observational or interventional study design. For this review, XR was defined as "technology that blurs the lines between the physical and virtual worlds, creating a sense of immersion and enhancing the realism of virtual experiences" [20-22]. Additionally, the age criterion was not applied until screening to allow for a comprehensive search of the literature.

Studies were excluded from the review if they were reviews, opinion papers, case studies with ≤4 participants, or conference proceedings. Studies in which the participant sample was exclusively adults (>18 years old) were excluded as well as studies in which the intervention was not deemed to align with the definition of XR (eg, intervention delivered on a computer screen or flat board display panel) or where there was insufficient description of the hardware to determine whether the intervention met the definition of XR. Although no uniform definition nor criterion exists for defining XR as immersive or not immersive, through group discussion and guided by existing definitions [23], we excluded technology where the user only existed in the real world (eg, looking at a 2D image on a computer). If a reviewer was uncertain about whether the XR trial was immersive, additional review of the study and group discussion were used to determine whether the paper was included in the review. Papers that were not available in the English language were also excluded from the review.

Study Selection

Following completion of each of the systematic literature searches, 2 reviewers independently screened titles and abstracts for inclusion following established PICO (Population, Intervention, Comparison, Outcome) strategies. Disagreements between raters were resolved by a third reviewer. Following initial review of title and abstracts, a subsequent review of retained studies was completed, reviewing complete texts to evaluate for inclusion. Disagreements between raters were resolved by the same third reviewer. All screening was completed through Covidence [24], a web-based collaboration software platform that streamlines systematic review management and allows for blinded, independent review of included studies.

Assessment of Study Quality

Assessment Tools

For studies that assessed the effectiveness of the XR intervention, a study risk of bias assessment was conducted. For RCTs, the Cochrane Risk of Bias Tool (RoB-2) was used, and for nonrandomized studies, the Methodological Index for Non-Randomized Studies (MINORS) was used. The risk of bias assessment was completed by 2 separate groups with one group conducting risk of bias for the RCTs and the other group conducting risk of bias for the nonrandomized trials. Given the distinct tools used for each group, it was deemed appropriate to allow for 2 separate coding groups.

Risk of Bias in RCTs

To assess the RCTs, the 2 reviewers used and adhered to the RoB-2 protocol [25]. RoB-2 serves as an algorithmic framework for considering the risk of bias in the outcomes of RCTs [26]. The tool asks reviewers to rate the bias in RCT protocols among 5 domains: (1) randomization process, (2) deviations from intended interventions, (3) missing outcome data, (4) measurement of the outcome, and (5) selection. Reviewers evaluated the studies independently then met to discuss agreement on rating. If the raters disagreed on a rating, a third rater resolved the disagreement. Each domain was assigned an algorithm result and an assessor's judgement of Low, Some Concerns, or High. The overall bias followed the same 3 outcomes.

Risk of Bias in Nonrandomized Studies

To assess the nonrandomized studies (eg, observational, interventional without control), the reviewers used MINORS [27]. MINORS consists of 12 method-oriented items (eg, "A clearly stated aim") to assess quality and risk of bias in nonrandomized studies. Each item is rated on a scale from 0 to 2, with 0 indicating that the item was not reported, 1 indicating that the item was reported but inadequate, and 2 indicating the item was reported and adequate. MINORS can be used for studies with or without a comparator group, with the first 8 items applying to all studies and the final 4 items specific to comparative studies. Total scores for noncomparative studies range from 0 to 16, and total scores for comparative studies range from 0 to 24, with higher scores indicating more methodological integrity. For this review, 2 raters independently rated each of the nonrandomized studies then met to compare. Each of the 12 items as well as the total scores were compared between raters. Any disagreements were resolved through discussion and, if needed, through consultation with a third rater.

Data Extraction

A data extraction form was created and pilot tested to ensure relevant data were pulled based on the form directions. A team of research assistants was trained on the data extraction form, and each research assistant independently extracted data for their assigned studies. Data extracted included study characteristics (participants, design, setting, control group), intervention characteristics (hardware, software, intervention protocols), outcome domains (safety, feasibility, effectiveness), outcome measures used, and a summary of study findings.

Data Coding (Evidence Gap Map)

All included studies were uploaded to EPPI Reviewer, software designed for systematic reviews and in support of developing evidence and gap maps. Using existing literature, authors CWH and GM developed operational definitions for each of the pain populations and target outcomes, which were reviewed by the larger author group and iterated until a final draft was created

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then used to guide coding of the studies. To code studies for the evidence and gap map, reviewers were assigned a series of studies in EPPI Reviewer and were asked to review the manuscript and code each article for the patient population (adult or pediatrics), pain population, and outcomes targeted by VR. Two training meetings were held with all reviewers to provide operational definitions, and they were asked to code a single article. A subsequent meeting was held to provide feedback and answer questions to increase consistency across coding. Once all articles were coded, any articles identified as unclear were reviewed again by a single author. Operational definitions are provided in Multimedia Appendix 2.

Data Synthesis

Included studies were summarized, and fulsome details of all included studies are provided in Multimedia Appendix 3. Additionally, descriptive statistics were used to synthesize study characteristics and aims as well as intervention characteristics. To synthesize data pertaining to outcome domains, an evidence and gap map was created. To create the evidence and gap map, 7 reviewers independently coded each study according to the study population including age (pediatric, adult) and pain type (acute pain-venipuncture, acute pain-wound care, acute pain-procedural, acute pain-other, chronic pain-cancer related, chronic pain-postsurgical/trauma, chronic pain-headache/migraine, chronic pain-musculoskeletal, chronic pain-neuropathic, chronic pain-other), as well as the pain-related outcomes targeted by the XR intervention (user experiences, participation/engagement, cognitive, behavioral, physical functioning, pain intensity, quality of life, health care utilization, safety, feasibility). Each study was also coded according to its established risk of bias (low, moderate, high). Coding was conducted through EPPI Reviewer [28], a collaborative web-based research synthesis software that supports study classification, and EPPI Mapper, a web-based program that generates evidence and gap maps based on coding conducted in EPPI Reviewer. Finally, for each of the identified pain treatment targets, the measures used to assess those targets were extracted by 2 authors and summarized to indicate the number of unique measures reported for each treatment target, and the number of studies that used the measure.

Results

Article Identification

The search identified 2656 articles across the 5 identified databases. Of the articles identified, 1041 duplicates were identified and removed prior to abstract and title screening. We screened 1615 articles for inclusion based on abstract and title, and 1125 were removed based on relevancy to the review. Of the remaining 490 studies, 15 could not be located, so 475 full-text articles were screened for inclusion. Of those, 90 studies were included in the review. The most common reason for exclusion was that the study sample was exclusively adult (170 studies) followed by determination that the XR technology was not immersive (79 studies). See Figure 1 for additional information related to the screening process.

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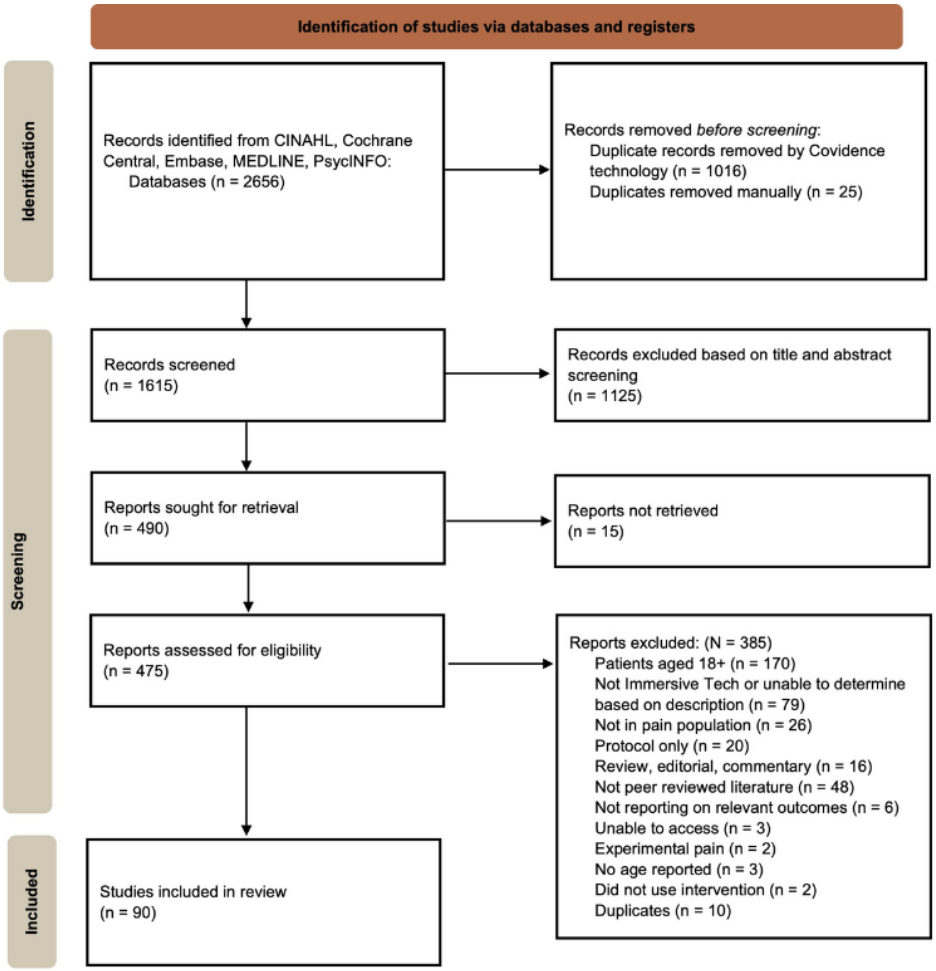
Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



Study Characteristics

Of the included articles, all 90 studies used VR technology, and no studies reported the use of AR technology. As such, when discussing XR for pediatric pain management, currently this is exclusively VR technology. Additionally, the majority of studies focused on assessment of VR in pediatric acute pain (84/90, 93%), specifically venipuncture (40/90, 48%) [29-68], burn dressing and wound care (15/90, 18%) [69-83], and minor procedures (26/90, 31%) [31,84-108], as well as other acute pain (3/90, 3%; ie, acute pain in emergency department, acute upper limb rehabilitation, vaso-occlusive crisis) [109-111]. A much smaller number of studies (n=6) examined the utility of VR in chronic pain populations including intensive pain rehabilitation (n=1) [112], chronic burn dressing (n=1) [113], chronic musculoskeletal pain (n=1) [114], chronic cancer-related pain (n=2) [115,116], and chronic abdominal pain (n=1) [117]. See Figure 2 for the summary of pain populations included across the studies. Within the 90 included studies, there were a total of 6596 participants enrolled, including 3615 enrolled in intervention arms and 2981 enrolled in control arms. Study sample sizes ranged from 5 to 254. Across studies, 3631 participants were male, while 2929 were female. The age of the participants ranged from 3 years to 18 years. Among participants enrolled in the intervention group, the mean age was 11.07 (SD 2.64) years, and in the control groups, the mean age was 10.38 (SD 2.37) years. Most studies (84/90, 93%) evaluated the use of XR in the context of pediatric acute pain management, while 7% (6/90) of the studies focused on XR in the context of pediatric chronic pain. Most studies took place in a hospital setting (63/90, 70%), and interventions were most often delivered by a researcher (36/90, 40%) or nurse (19/90, 21%). Regarding intervention design, an RCT was used 82% (74/90) of the time. See Table 1 for a full description of the study characteristics.

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Figure 2. Pain types across all included studies.

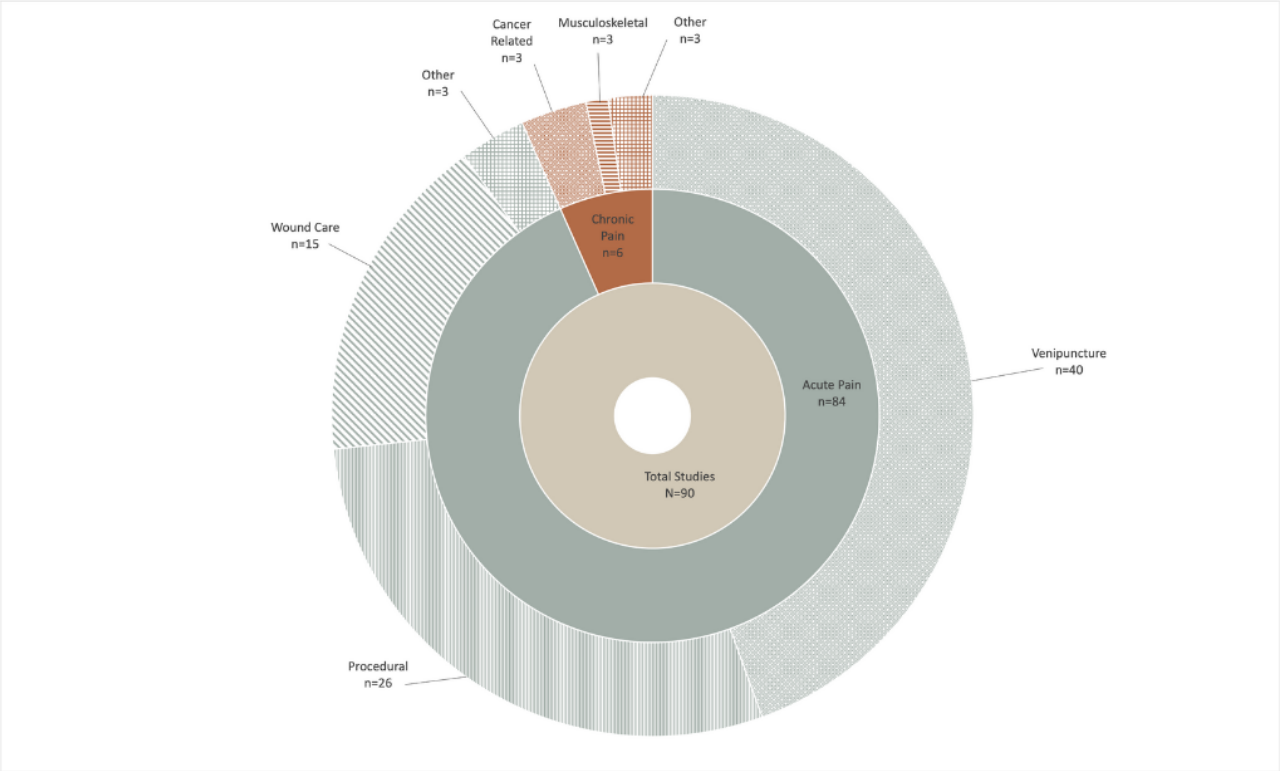

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Table 1. Study characteristics (n=90).

Characteristic	Studies, n (%)
Acute pain (n=84)	
Venipuncture	40 (45)
Procedural	26 (32)
Wound care	15 (18)
Other	3 (5)
Chronic pain (n=6)	
Cancer related	2 (33)
Musculoskeletal pain	1 (17)
Other	3 (50)
Study design	
Interventional RCT[a]	74 (82)
Interventional no control	13 (14)
Case series	1 (1)
Prospective observational	2 (2)
Study setting	
Hospital/burn center	69 (77)
Research	2 (2)
Dental	9 (10)
Home	1 (1)
Clinical	9 (10)
Sample size (n= 6596)	
VR[b] intervention	3615 (55)
Control	2981 (43)
Intervention delivered by	
Registered nurse	19 (21)
Physical therapist	2 (2)
Dentist	1 (1)
Other clinician	2 (2)
Researcher	36 (40)
Caregiver	1 (1)
Unknown	29 (32)

[a]RCT: randomized controlled trial.
[b]VR: virtual reality.

Study Quality Assessment

Where possible, studies were examined for risk of bias based on study design. Of the 90 studies, 74 studies were evaluated using the RoB-2 assessment for randomized trials and 15 studies were evaluated using the MINORS assessment for nonrandomized interventional and observational studies. We could not assess 1 study due to the study design (ie, case series: Birnie et al [34]). Results of the risk of bias assessment revealed that most included studies (67/90, 74%) had a moderate risk of bias, while 17 studies (17/90, 19%) had a high risk of bias, and 5 studies (5/90, 6%) were deemed to have a low risk of bias. To see the summary of risk of bias ratings for each study, please see Figure 3. Although sources indicating risk of bias were variable across studies, most included studies were identified as moderate or high risk of bias due to their failure to blind study participants to the intervention and researchers to who was in the intervention arm (69 studies). Increased risk of bias was also commonly identified in the randomization procedures, although to a much lesser degree (19 studies).

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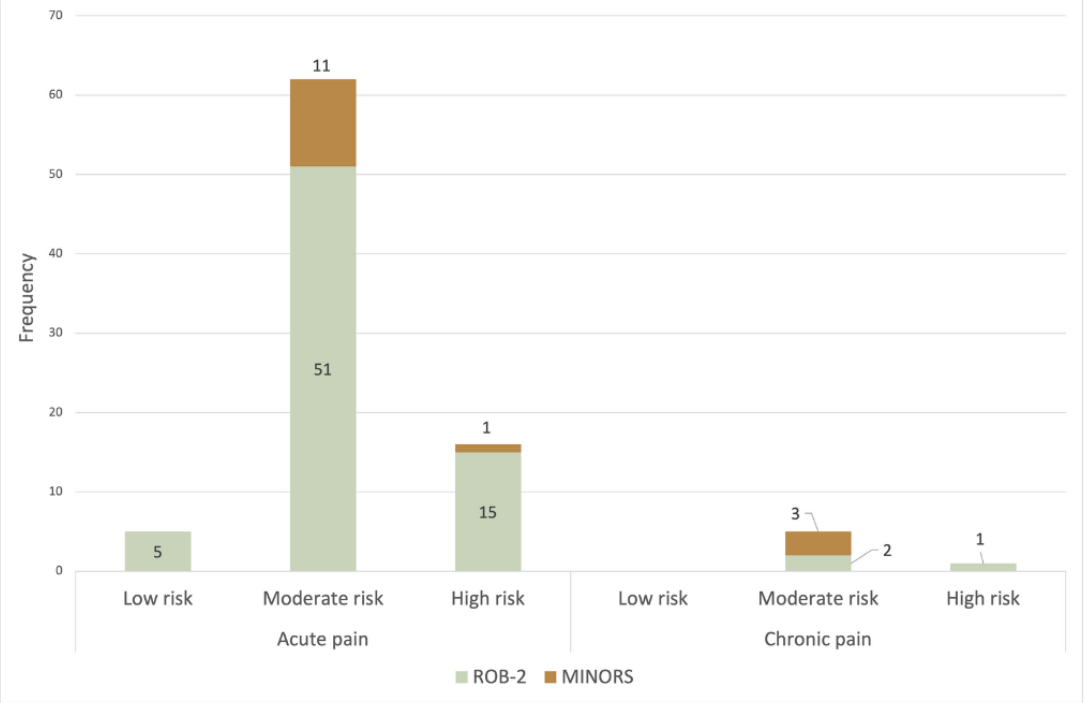
Figure 3. Risk of bias for included studies (N=89). MINORS: Methodological Index for Non-Randomized Studies; RoB-2: Cochrane Risk of Bias Tool.



XR Feasibility

Across all included studies, feasibility was evaluated 43% (39/90) of the time. Within chronic pain studies, 50% (3/6) of the studies assessed the feasibility of VR. Although limited in scope, of the 3 studies that examined feasibility, results did indicate VR to be a positive experience that supported their management of pain. Within the acute pain studies (n=84), feasibility was assessed in 35 studies. When evaluated, feasibility of VR appears to be high according to patients, caregivers, and health care staff. Feasibility was assessed in several different ways including but not limited to recruitment and withdrawal rates, satisfaction surveys, patient-reported "fun," and provider-reported disruption in clinical flow. Recruitment rates varied but indicated moderate (40/65, 62%) to high (66/71, 93%) levels of interest in VR use, and dropout rates were reported to be low. Health care professionals also indicated good feasibility. VR was perceived to not interfere with procedure time, decrease the perceived difficulty of procedures, and be easily implementable in the clinic setting, and health care staff expressed interest in repeated use. Patients and caregivers reported ease of use, high levels of satisfaction with VR, preference for VR over alternate distraction methods, and interest in repeated use in future procedures. As such, although more consistent assessment of VR feasibility is needed, the available data from the pediatric acute pain management setting suggest that VR is acceptable and feasible across stakeholders.

XR Safety

Across included studies, safety, often measured through the presence of adverse events, was measured or reported 49% (44/90) of the time. Within the chronic pain studies, only 2 studies examined the safety of the VR intervention, so conclusions regarding the safety of VR for chronic pain populations cannot be made. Among the pediatric acute pain studies, 44 studies examined safety, limiting our ability to draw robust conclusions for safety. However, when safety or adverse events were reported, most studies (31/44, 70%) reported no adverse events or no differences between their control and VR intervention groups. When adverse events were reported, they were most often mild in nature and occurred in a minority of the participants. Rates of adverse events varied, occurring in <1% to 17% of participants, with intensity and severity of the concern low (eg, nausea rating of 4/100). Two studies reported that at least 1 participant withdrew from the intervention due to reported adverse events.

XR Effectiveness

Several treatment targets emerged through the review as relevant to the effectiveness of VR for pain management. That is, targets of VR interventions for acute and chronic pain often went beyond pain intensity itself, as measures of effectiveness spanned several domains (eg, pain intensity, physical functioning, fear, anxiety). Given the wide variety of targeted outcomes, we summarized the findings across the identified target domains for acute and chronic pain. The variability in targets highlights several areas where additional research is needed to adequately examine the effectiveness of VR for pediatric pain.

Pain intensity was examined across all included studies (n=90), and overall, VR interventions demonstrated good effectiveness for reducing pain intensity (see Figure 4). Among the acute pain studies, 63% (53/84) demonstrated a positive effect (statistically significant reduction in pain) of VR on pain intensity, 21% (18/84) demonstrated no effect (nonsignificant reduction in pain or no change in pain), and 12% (10/84) demonstrated a mixed effect (different results across pain measures, pain reporter, or

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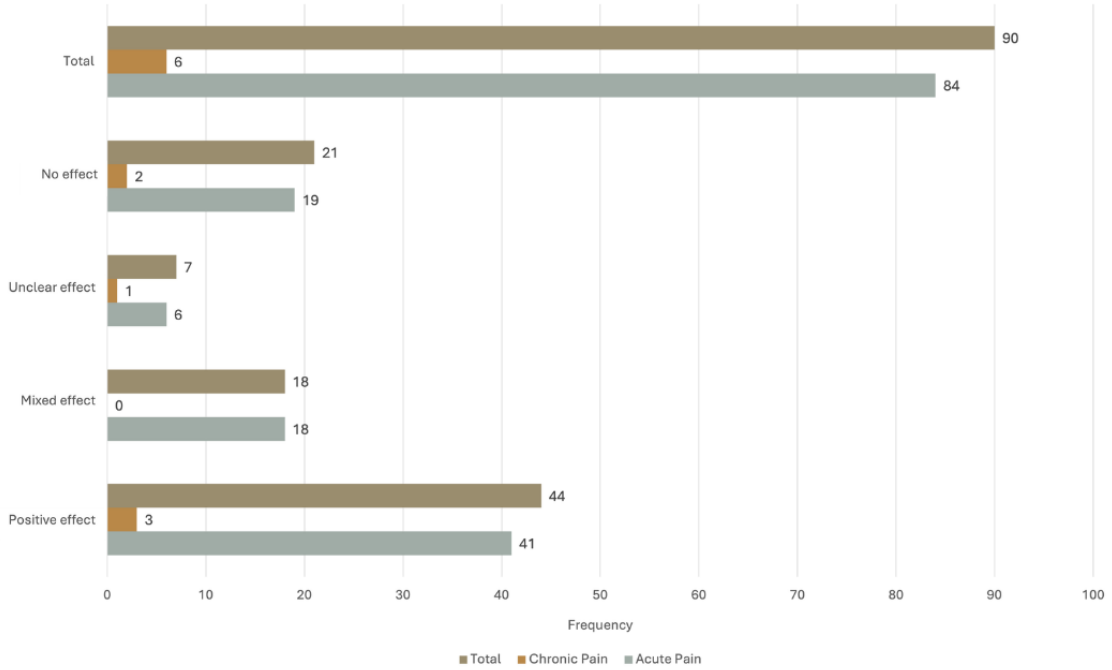
at different time points in the intervention) on pain intensity. Mixed effect findings were often due to a variable impact of VR on pain across a procedure (eg, positive impact on postprocedural pain but no effect on pain during the procedure) or variable impact of VR on pain across informants (eg, child reported improved pain, no improvement in pain reported by health care provider). No studies reported worse pain than the control or following the VR intervention. Among the chronic pain studies, 100% (6/6) of the studies demonstrated improved pain intensity in the context of the VR intervention.

Figure 4. Effects of virtual reality on pain across pediatric acute and chronic pain.



Evidence and Gap Map

There was a wide range of outcome targets across studies. We created an evidence and gap map to collate current targets of VR in pain management as well as illuminate gaps (Figure 5). Guided by the conceptual model described by Trost et al [118], we categorized studies according to their target population as well as measured outcome targets. Additionally, the risk of bias results were integrated into the evidence and gap map. Therefore, the map illustrates, across the 90 included studies, the populations and pain targets with greater amounts of research evidence and those with missing or scant research evidence as well as the quality of evidence at various intersections (eg, pediatric venipuncture research targeting anxiety and pain intensity). Specifically, for XR research, the gap map illuminated significant gaps in research using XR to support pain management in pediatric chronic pain populations. Within the chronic pain populations, no research exists related to postsurgical or trauma-related pain, headaches, or neuropathic pain. Additionally, the risk of bias across all studies was moderate to high, prompting the need for more sophisticated research designs to reduce the risk of bias, particularly as it relates to blinding the research team and study participants. Within the acute pain setting, the most studied patient populations were children undergoing venipunctures and minor procedures. Primary targets of XR intervention for acute pain include pain intensity and emotional functioning. Across acute and chronic pain, measuring the effectiveness of XR on other important outcomes such as user experience, social functioning, and quality of life are important gaps that emerged from this review.

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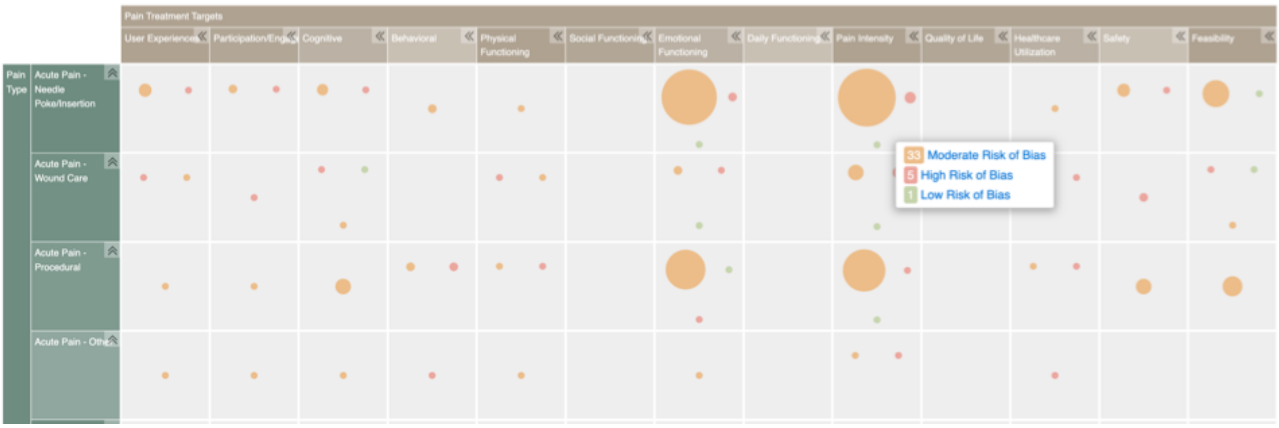
Figure 5. Snapshot of the evidence and gap map for virtual reality trials in pediatric acute and chronic pain [118]. The interactive evidence and gap map can be found in [119].



Measures in XR Research

Across all study outcomes (feasibility, safety, effectiveness targets), there was tremendous variability in the outcome measures used. As such, we identified the number of distinct measures and the frequency of measures used across each outcome, which are summarized in Table 2. Full details of the measures used within each outcome domain can be found in Multimedia Appendix 4. Measures in XR research include validated, study-specific, researcher-developed and researcher-adapted tools. Additionally, similar measures are often used in distinct ways to measure different outcomes. For example, some researchers used heart rate as a measure of physical functioning, while others used heart rate as a measure of anxiety. The outcome target with the highest number of measures was psychological constructs, which contained 31 distinct measures across 67 studies. This is unsurprising as psychological construct is a broad outcome inclusive of multiple psychological and emotional states including but not limited to anxiety, mood, fear of pain, and pain catastrophizing. The outcome target with the second highest number of measures was feasibility, which contained 14 distinct measures across 28 studies, followed by user experience, which contained 13 distinct measures across 18 studies. The number of measures used across studies for each outcome domain is summarized in Table 2. This review highlighted that there is little agreement regarding how best to measure outcomes in XR research, an important area for future study, particularly given the high number of researcher-developed or researcher-adapted measures currently being used.

Table 2. The number of measures used within each outcome domain across pediatric acute and chronic pain studies.

Outcome domain	Measures, n
Pain intensity	21
Adverse events	8
User experience	13
Psychological constructs	31
Pain interference	8
Feasibility	14
Health care utilization	9
Quality of life	2
Physiological markers	10

Discussion

Principal Findings

Overall, in the context of pediatric acute pain, specifically venipuncture and minor procedural pain, good evidence exists to support continued use of XR, as it is effective for the management of pain and emotional functioning and demonstrates good feasibility and safety. Limited evidence exists, however, to guide the use of XR research in chronic pain populations. Although initial evidence does appear promising for the utility of XR to support pain management in several chronic pain populations (eg, cancer-related pain, abdominal pain, diffuse musculoskeletal pain), more robust examination is needed as is research that assesses the safety and feasibility of implementing XR into the flow of clinical care. Another area requiring more research in pediatric populations is the subacute period (ie, up to 3 months after injury, trauma, or surgery). Research has demonstrated this period to be a vulnerable time for the development of fear avoidance related to pain and movement, which increases the risk for the transition of acute pain to chronic pain [8]. XR interventions would likely be useful during this period as both a form of distraction and to support confrontation of feared movements.

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This review indicates that most studies to date have been implemented within the context of a children's hospital, which is unsurprising given the preponderance of research focused on acute pain management. However, there is limited research to guide the implementation of XR research outside the context of a hospital setting, which may be particularly important for chronic pain patients who may be receiving care across a variety of treatment settings (eg, home, outpatient clinic, physical therapy clinic). In the adult literature, XR has been successfully implemented into community care for chronic pain management [120,121]; however, this is unstudied in pediatric populations. The use of implementation science frameworks (eg, Consolidated Framework for Implementation Research) [122] to evaluate contextual and personnel differences as they relate to technology integration in settings outside of a hospital can support these efforts.

This review also demonstrated that research to date has been exclusively on the use of VR in pediatric pain management, and, as such, little is known about the potential for AR to support acute and chronic pain. Exploration of the utility of AR is particularly relevant in the context of chronic pain where exposure to painful movements may benefit from gradation such that a young person is first fully distracted by immersion into a VR world then gradually progressed toward exposure of their environment using an AR system to continue to support distraction while increasing exposure to their lived environment [123-125].

Another finding of this review is the significant variability in the way outcomes are being measured across XR studies. That is, measurement remains an area for needed consensus to support a better ability to compare effectiveness of XR across studies. Moreover, efforts are needed and indeed underway to better define both process (eg, immersion) [23] and outcome (eg, pain intensity) variables in XR trials, which will facilitate better reporting and thus improved ability to effectively compare XR across studies. Moreover, definitions of emotional functioning were also quite varied across studies, even when similar constructs were being targeted (ie, anxiety, fear, mood). Different definitions of anxiety and fear emerged across studies as well as how they were operationalized and assessed. For example, some studies assessed anxiety vis-à-vis heart rate variability and oxygen saturation, while other studies completed self-report assessments, proxy reports, and behavioral observations. Although all approaches to assessing anxiety may be valid, it limits the comparability of anxiety as an outcome across studies. Additionally, mood was examined to a much lesser degree in the reviewed studies and warrants increased attention, particularly in the context of chronic pain or acute-to-chronic pain transition. Another challenge with comparing XR effectiveness across studies is inconsistent reporting of study protocols. In this review, several studies were excluded because of an insufficient description of the XR technology. Creation of standards for reporting for XR studies, including how to describe the technology used (eg, hardware and software) and intervention protocol (eg, number of sessions, duration of intervention), is needed to increase the ability to replicate studies and compare outcomes across studies, thereby improving our ability to understand which XR approaches are most effective, when they are most effective, and for whom they are most effective.

There are also potential outcomes or targets of XR research that warrant attention, namely social and academic functioning alongside quality of life. Given the growing feasibility of real-time social interactions in the context of XR alongside established challenges for youth with pain to engage socially with peers [126], examination of the potential for XR research to improve or support social functioning is an important area for future work. Building from existing literature that has demonstrated the effectiveness of virtual peer-to-peer pain groups [127-130], development of virtual pain groups that can target multiple domains of functioning (eg, physical functioning, social functioning) is an untapped and potentially high-yield target for XR research. Similarly, academic functioning is commonly cited as a challenge for youth with chronic pain [131,132], and although research is emerging in this domain [133], more is needed to evaluate the potential for XR research to support academic engagement and facilitate a return to school learning for youth with pain. Finally, quality of life was minimally examined in the included studies (n=2). This is likely due to the overwhelming number of studies focused on acute pain where quality of life measures may be less relevant; however, development of quality of care measures or consideration for implementation of quality of care measures that are relevant to the acute pain context may be important to truly capture the impact of XR on patients. Moreover, as additional research is conducted in the chronic pain population, where pain and anxiety may become less of an emphasis, quality of life measures will be important markers of improvement.

Finally, decreasing the risk of bias in XR studies also emerged as an important priority for future research. That is, most studies had a moderate to high risk of bias according to the RoB-2 assessment, prompting the need for more sophisticated research designs. Specific areas where innovation is needed are addressing participant blinding to the intervention and the development of prespecified analysis plans. Given the nature of XR interventions, innovation for blinding participants to their assigned group, such as the development and use of sham XR software, is needed to decrease the risk of bias. Prepublished analysis plans and transparency surrounding blinding of the analyses are also needed.

Limitations

This systematic review has some limitations that are important to note. First, the search for this systematic review was completed in March 2023 and likely omits several manuscripts published since then. Given the rapidity of XR research in pediatrics, it was not feasible for this research group to keep pace with the rate of publication. Moreover, this review was conducted with the aim of supporting the consensus conference surrounding outcomes for pediatric XR research. Future updates to this review are needed to support ongoing identification of gaps in research and inform clinical practice. Additionally, although a strength of this review is the breadth of studies included, future research could be conducted to allow for more focused assessment of efficacy, particularly as it relates to specific patient populations and XR configurations. To this end,

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future research should consider the interaction of XR interventions and child development to assess whether developmental stage or chronological age impact XR feasibility, safety, or effectiveness and guide precision medicine to match the XR intervention or configuration to best meet the needs of youth across diverse developmental stages. This review assessed the risk of bias for all included studies; however, this is not synonymous with quality and should be interpreted with caution. That is, studies may have been of high quality yet received high risk of bias scores due to their lack of blinding, a common challenge faced by XR researchers. Finally, studies were limited to the English language and excluded gray literature and conference papers, which may limit the inclusion of important research published in languages other than English and could reinforce publication bias such that studies in which XR was unhelpful or not feasible are not well represented.

Conclusion

This systematic review provides an important update regarding the state of XR research for pediatric acute and chronic pain. Review of XR feasibility, safety, and effectiveness solidified the significant potential of XR for pain management across a variety of pain presentations and for a range of diverse outcomes. Moreover, the developed evidence and gap map illuminated important gaps in the current research base that warrant attention. Finally, limitations identified in the research studies reviewed also highlight the need for innovative research designs, establishment of measurement consensus, and improved reporting standards for XR studies to more effectively establish best practices in XR intervention research and improve clinical translation of the evidence base.

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Authors declare that there was no use of GenAI in the production of the described research, analysis or interpretation of data, or in the writing of the submitted manuscript.

Data Availability

All data from the systematic review are available upon request from primary or senior authors.

Authors' Contributions

JNS, LES, DL, and JIG were involved in the conceptualization of the study, funding acquisition, and supervision as well as data analysis and review and editing of the drafted manuscript. CWH, BNR, and GM were involved in the conceptualization of the study, data curation, formal analysis, data visualization, and writing of the manuscript. CO was involved in the data curation and offered her expertise as a person with lived experience. EC was responsible for project administration and data visualization. All authors made substantial contributions to the study and provided approval of the submitted manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Librarian search strategy.
[DOCX File , 28 KB - pediatrics_v8i1e63854_app1.docx]

Multimedia Appendix 2
Operational definitions of pain populations and outcome targets to guide evidence and gap map coding.
[DOCX File , 21 KB - pediatrics_v8i1e63854_app2.docx]

Multimedia Appendix 3

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Fulsome details of 90 included VR intervention studies for pediatric acute and chronic pain.
[XLSX File (Microsoft Excel File), 46 KB - pediatrics_v8i1e63854_app3.xlsx]

Multimedia Appendix 4
Measures used across outcome domains in VR trials for pediatric acute and chronic pain.
[XLSX File (Microsoft Excel File), 14 KB - pediatrics_v8i1e63854_app4.xlsx]

Multimedia Appendix 5
PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist.
[DOCX File , 32 KB - pediatrics_v8i1e63854_app5.docx]

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Abbreviations

AR: augmented reality
MINORS: Methodological Index for Non-Randomized Studies
PICO: Population, Intervention, Comparison, Outcome
RCT: randomized controlled trial
RoB-2: Cochrane Risk of Bias Tool
VR: virtual reality
XR: extended reality

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Supervised and Unsupervised Screen Time and Its Association With Physical, Mental, and Social Health of School-Going Children in Dhaka, Bangladesh: Cross-Sectional Study

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Abstract

Background: Children's screen time has substantially increased worldwide, including in Bangladesh, especially since the pandemic, which is raising concern about its potential adverse effects on their physical, mental, and social health. Parental supervision may play a crucial role in mitigating these negative impacts. However, there is a lack of empirical evidence assessing the relationship between parental screen time supervision and health outcomes among school children in Dhaka, Bangladesh.

Objective: We aimed to explore the association between supervised and unsupervised screen time on the physical, mental, and social health of school-going children in Dhaka, Bangladesh.

Methods: We conducted a cross-sectional descriptive study between July 2022 and June 2024. A total of 420 children, aged 6 - 14 years, were enrolled via the stratified random sampling method across three English medium and three Bangla medium schools in Dhaka. Data were collected through a semistructured questionnaire; anthropometry measurements; and the Bangla-validated Strength and Difficulties Questionnaire (SDQ), Pittsburgh Sleep Quality Index (PSQI) Scale, and Spencer Children Anxiety Scale (SCAS).

Results: A total of 234 out of 420 students (56%) used digital screen devices without parental supervision. We did not find a substantial difference in the duration of the daily mean use of digital devices among the supervised students (4.5 hours, SD 2.2 hours) and the unsupervised students (4.6 hours, SD 2.4 hours). According to the type of school, English medium school children had a mean higher screen time (5.46 hours, SD 2.32 hours) compared to Bangla medium school children (3.67 hours, SD 2.00 hours). Headache was significantly higher among the unsupervised digital screen users compared to those who used digital screens with parental supervision (175/336 students, 52.1% versus 161/336 students, 47.9%; $P<.003$). Moreover, students who used digital screens without parental supervision had poor quality of sleep. Behavioral problems such as conduct issues (119/420 students, 28.3%) and peer difficulties (121/420 students, 28.8%) were observed among the participants. However, when comparing supervised and unsupervised students, we found no statistically significant differences in the prevalence of these issues.

Conclusions: The findings of the study showed that the lack of screen time supervision is associated with negative health effects in children. The roles of various stakeholders, including schools, parents, policy makers, and students themselves, are crucial in developing effective guidelines for managing screen use among students. Further research is needed to demonstrate causal mechanisms; identify the best interventions; and determine the role of mediators and moderators in households, surroundings, and schools.

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KEYWORDS

screen time; parental supervision; Strength and Difficulties Questionnaire; Spencer Children Anxiety Scale; Pittsburgh Sleep Quality Scale; children; sleep quality; headache; behavioral problems

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Introduction

To what extent can parental supervision mitigate the effects of excessive digital screens in school-going adolescents? This is becoming an increasingly common concern of parents and researchers, as digital screens fill our living spaces and take up our quality time. A recent study showed that daily screen time for users aged 16 - 64 years has increased to 6 hours 37 minutes worldwide [1]. Across age groups, 44% of all waking hours are spent on screens [1]. In 2020, the World Health Organization released a milestone report with detailed guidelines on sedentary behavior including screen time for children under the age of 5 years, defining screen time as time spent passively watching screen-based entertainment (TV, computer, or mobile devices) [2]. The American Academy of Child and Adolescent Psychiatry agreed with the findings, recommending less than 2 hours of daily screen time for children aged under 5 years, but for children aged 6 years and older, recommending "healthy habits" and to "limit activities that include screens" [3]. At present, no concrete guidelines have been presented for adolescents, although health concerns are just as pressing for them [4].

Higher sedentary behavior such as screen time is associated with a range of physical and mental health issues, including headaches, myopia, obesity, sleep disorders, behavioral disorders, and anxiety [4-8]. A study of 5844 children around the world found that children averaged 8.6 hours of daily sedentary time, associated with poor weight status and physical inactivity [9]. Lauricella and Cingel [10] found one of the most reliable predictors of higher screen time among adolescents to be parental media use, along with weaker associations with parental attitudes to technology and screen time rules.

In Asia, higher incomes and a rising middle class have led to longer exposure to screen time (>2 h a day) for children and adolescents [11,12]. Without parental intervention, excessive screen time exposure has been associated with less sleep duration among Asian preschoolers, but Lin et al [13] found parental education and awareness, among best practices, to be an effective intervention against these effects.

Bangladesh's rising socioeconomic status has contributed to an explosion in digital device access and usage across demographics [14]. Khan and Burton [15] found that almost 80% of Bangladeshi adolescents have high recreational screen time, reported at 4.0 (SD 2.2) hours per day on average, with the mean values of 4.3 (SD 2.4) hours for boys and 3.6 (SD 2.3) hours for girls. High screen time was associated with sleep disturbance and higher family income, among other factors [15]. Anjum et al [16] found a higher incidence of depressive symptoms in adolescents with higher screen time exposure (>2 h per day), alongside other physical and mental health concerns including sleep disturbance and mood disorders prior to the COVID-19 pandemic.

During the COVID-19 lockdown, Bangladeshi children began to spend much more time on the internet, for entertainment, communication, and education [17-19]. Koly and colleagues [20] noted worsening psycho-social health of school-going students in this period, associated with quarantine adaptations and difficulties with online learning. Simultaneously, Rashid and colleagues [21] found physical and mental health deterioration among secondary school students, with symptoms including headaches, backaches, visual and sleep disturbance, and depression. During the pandemic, online learning became a necessity, leading to a significant increase in children's digital screen use. While it ensured educational continuity, this shift also contributed to extended screen time, potentially indicating the physical, mental, and emotional health risks associated with excessive screen exposure [4,22].

Following the pandemic, increased digital screen time did not lessen, leading to significant adverse consequences on adolescent health [23,24]. For instance, Shuvo and Biswas [25] note that when electronic device exposure overlaps with eating times and habits, there is an increased likelihood of obesity. Meanwhile, heavier reliance on technology for education, entertainment, and socialization after COVID is associated with increased anxiety, difficulty sleeping, addiction, and various sociobehavioral difficulties [23,24,26].

In Bangladesh, there is a dearth of comprehensive academic research on the effects of screen time on adolescents, despite the fact that there is a substantial amount of empirical evidence around the world [4,22,27-34]. Furthermore, as the results are utilized to create thorough screen-use guidelines, these studies have significant policy ramifications. Furthermore, while parental supervision is crucial in preventing excessive screen time, researchers found that inappropriate methods to discipline children and adolescents may increase long-term screen use and exaggerate other adverse psychosocial effects [24,35]. Therefore, this study aimed to distinguish between the effects of supervised and unsupervised screen time on the physical, mental, and social health of Bangladeshi schoolchildren.

Methods

Study Setting, Participants, and Sampling

This was a cross-sectional descriptive study and adopted a quantitative approach. The survey was conducted between July 2022 to June 2024. We purposively selected 6 schools from the list of all schools in Dhaka North and South city corporations to ensure the equal distribution of the Bangla and English medium schools. Moreover, we considered the socioeconomic, geographic, and feasibility of data collection. During the school selection, with the approval of the school authorities, we considered children aged between 6 to 14 years who were in class 2 to class 8 and who had more than 2 hours of screen time each day as the qualifying criteria for sample inclusion. Smartphones, tablets, laptops, personal computers, gaming consoles, televisions, and portable gaming devices were among the acceptable gadgets. Children with preexisting conditions, such as physical or psychological impairment, were excluded from the study, as this might have influenced the results. We used a stratified random sampling method to recruit a total of 420 students, by including 70 students from each school (ie, 10 students from each grade from grades 2 to 8).

Data Collection Procedure

We collected data through face-to-face interviews with parents and students on school grounds. The day prior to the interview,

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study staff scheduled the appointment time with parents, and the class teacher brought the students during the lunch break. A half-hour interview period was allotted for students and an hour for parents. To check for differences in accuracy between staff and trainers (ie, psychologists who trained all the staff on each of the psychometric tools used in this study), 30 pilot tests were performed prior to the start of data collection. Interrater reliability was measured using the Cohen kappa coefficient to quantify the level of agreement between each of the three staff and trainers (n=30 nonstudy participants/staff) for all the Bangla-validated scales. On average, the calculated Cohen kappa values ranged between 0.84 and 0.89 (scores for 30 nonstudy participants/staff-trainer pairs), indicating strong agreement among the staff.

All data collection forms were checked at the field site for completeness, accuracy, and consistency. The quality control team was responsible for regular observations at school, and identical forms and tools were used across the duration of the study. Investigators personally traveled to the sites weekly to ensure proper field implementation.

Study Instruments

Screen Time

A semistructured questionnaire was developed to collect information about screen time from both parents and students. The parents' questionnaires included socioeconomic factors, pattern and quantity of child screen time usage, gadget-using behavior of the children, and parents' mediating role in screen time exposure (supervised vs unsupervised). The student's questionnaire included the type of device use, time and pattern of use, and purpose of device use. Screen time was considered to be any time spent engaging with content in front of a digital device with an electronic screen, including but not limited to iPads, gaming consoles, laptops, smartphones, tablets, and desktop devices. Students were categorized into supervised versus unsupervised based on the self-reporting information regarding the supervision. In this study, supervised screen time is defined as when parents are aware of their child's digital device usage, including what they are doing, how much time they spend, and the type of content they consume. In contrast, unsupervised screen time occurs when parents lack awareness of their child's activities, duration of use, and the content they engage with on digital devices. Similar definitions have been used in other studies [36,37].

Physical Health

Anthropometric measurements (weight and height) were collected from students on school premises during data collection. Measurements were calibrated daily before data collection to ensure standardization. The BMI (kg/m^2) was calculated and converted to z-scores, then categorized according to cut-off points given by the World Health Organization BMI-for-age growth chart for ages 5 to 19 years: underweight (<15 kg/m^2, −1 SD), normal weight (15 - 25 kg/m^2), overweight (25 - 30 kg/m^2, +1 SD), obese (30 - 40 kg/m^2, +2 SD), and morbidly obese (>40 kg/m^2, +4 SD) [38]. Additional physical health issues, such as blurred vision, headaches, indigestion, backache, and neck pain, were also asked of the students via a questionnaire. The students' physical health responses were initially categorized into four groups: "No," "Sometimes," "Often," and "Most of the time." These categories were then consolidated into two broader groups: "No" and "Yes," with "Yes" encompassing the responses "Sometimes," "Often," and "Most of the time."

Mental and Social Health

Age-appropriate Bangla-validated versions of the following scales were used to find well-being indicators for children's mental and social health.

Strength and Difficulties Questionnaire

This is a behavioral questionnaire (25 questions) designed to identify a combination of positive and negative attributes across 5 dimensions–emotional symptoms, conduct problems, hyperactivity or attention deficit, peer relationship problems, and prosocial behavior. The sum of the scores of the four negative behavior subscales represents the children's general difficult behavior with a maximum score of 40, whereas the maximum score for prosocial behavior is 10. Gustin and colleagues have verified the Strength and Difficulties Questionnaire (SDQ) against independent clinical diagnoses of Bangladeshi children [39,40].

Spencer Children Anxiety Scale

This scale is used to evaluate symptoms relating to separation anxiety, social phobia, obsessive-compulsive disorder, panic, agoraphobia, generalized anxiety, and fear of injury. Goodman et al have validated the Spencer Children Anxiety Scale (SCAS) as a reliable instrument for Bangla-speaking communities [41].

Pittsburgh Sleep Quality Index

This questionnaire has components spanning several subcategories such as subjective sleep quality, latency, duration, habitual efficiency, disturbances, sleeping medication, and daytime dysfunction. Mamun et al [42] have successfully used the Pittsburgh Sleep Quality Index (PSQI) to identify sleep-related concerns among Bangladeshi students.

Statistical Analysis

Data were entered via IBM SPSS version 20.0 (IBM Corp) and analyzed on Stata version 15.1 (StataCorp LLC). Categorical data were represented as frequency numbers and percentages, while continuous data with reasonably normal distributions were summarized as means and SDs. Nonnormal continuous data were instead summarized as medians and IQRs. Participants were categorized into two main subgroups, supervised and unsupervised. Subsequently, a comparative analysis was performed across various factors, including demographic characteristics, amount of screen time, and health metrics. To assess differences across groups, the chi-squared test for independence was employed for categorical data, and the 2-tailed unpaired *t* test for differences between proportions was used for continuous data with nearly normal distributions. A significance threshold of $P<.05$ was used to assess statistical significance.

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Ethical Considerations

This study was approved by the Institutional Review Board of icddr,b (protocol number: PR-22002). Written informed consent was obtained from all parents, and confidentiality and anonymity were maintained throughout the study. Children aged above 11 years provided assent in addition to their parents' consent. All the respondents were informed in Bengali about their rights related to their voluntary participation in the study as well as their right to withdraw from the interview at any time during the interview.

Results

A total of 420 students were enrolled based on the screening criteria. Of them, 186 (44%) children were supervised and 234 (56%) children were unsupervised. Table 1 represents the demographic summary statistics of the population. The students were between 6 and 14 years, with a mean age of 10.9 (SD 1.9) years; 207 out of the 420 children (49.3%) were girls. Of the 420 children, 292 (69.5%) belonged to single-family households. In families with 1 - 2 children, 161 out of 288 children (55.9%) were unsupervised, while for families with more than 3 children, 73 out of 132 children (55.3%) were unsupervised.

Table . Demographic and socioeconomic information of study participants.

Characteristics	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)
Child's age (years)			
Mean (SD)	10.9 (1.9)	11.0 (1.9)	10.8 (1.9)
Child's sex, n (%)			
Male	213 (50.7)	101 (47.4)	112 (52.6)
Female	207 (49.3)	85 (41.1)	122 (58.9)
Family type, n (%)			
Single	292 (69.5)	132 (45.2)	160 (54.8)
Joint	128 (30.5)	54 (42.2)	74 (57.8)
Number of children in the family, n (%)			
1 - 2	288 (68.6)	127 (44.1)	161 (55.9)
≥3	132 (31.4)	59 (44.7)	73 (55.3)
Average monthly income, n (%)			
<BDT[a] 50,000 (<US$ 420)	137 (32.6)	57 (41.6)	80 (58.4)
BDT 50,000 - 100,000 (>US$ 420 to <US$ 840)	144 (34.3)	63 (43.8)	81 (56.2)
>BDT 100,000 (>US$ 840)	139 (33.1)	66 (47.5)	73 (52.5)

[a]BDT: Bangladeshi taka.

The mean total daily screen time for the entire population was 4.6 (SD 2.3) hours. The large SD relative to the mean indicates widely varying screen habits among the study population. The range of screen time for the unsupervised group was 0.3 - 15 hours and that for the supervised group was 0 - 12 hours. The mean total daily screen time for the unsupervised group was 4.6 (SD 2.4) hours, slightly higher than the supervised group's mean of 4.5 (SD 2.2) hours. These large deviations imply factors other than supervision contribute more to total screen time.

Multimedia Appendix 1 shows the mean daily screen time spent by children categorized by age, sex, and type of school. No significant difference was observed in the mean daily screen time between different age groups (6 - 10 years vs 11 - 14 years) or between male and female participants. However, children attending English medium schools had a significantly higher average daily screen time (5.4 hours) compared to those attending Bangla medium schools (3.6 hours).

Table 2 shows the prevalence of physical symptoms among students with supervised and unsupervised use of digital devices. Overall, out of 420 students, 391 (93.1%) students experienced blurred vision, 341 (81.2%) reported abdominal pain, 336 (80%) had headaches, and 327 (77.9%) experienced dry eyes or soreness. Considering all the health issues, a higher proportion of unsupervised students experienced these problems compared to supervised students. Headaches were significantly more prevalent among the unsupervised group (175/336 children, 52.1%) than the supervised group (161/336 children, 47.9%; $P<.003$). All the data are shown in Table 2.

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Table . Prevalence of physical symptoms among study participants with supervised and unsupervised use of digital screens and devices.

Physical symptoms	Frequency (N=420), n (%)	Supervised (n=186), n (%)	Unsupervised (n=234), n (%)	*P* value
Eye problems	150 (35.7)	64 (42.7)	86 (57.3)	.62
Dry eye or soreness	327 (77.9)	150 (45.9)	177 (54.1)	.22
Blurred vision	391 (93.1)	177 (45.3)	214 (54.7)	.14
Hearing difficulty	14 (3.3)	6 (42.9)	8 (57.1)	.91
Indigestion or gas	276 (65.7)	118 (42.8)	158 (57.2)	.38
Headache	336 (80.0)	161 (47.9)	175 (52.1)	.003
Neck pain	192 (45.7)	86 (44.8)	106 (55.2)	.85
Abdominal pain	341 (81.2)	150 (44.0)	191 (56.0)	.80
Back or any other musculoskeletal problem	134 (31.9)	63 (47.0)	71 (53.0)	.44
Diabetes	4 (1.0)	0 (0.0)	4 (100.0)	.07
Change in appetite	204 (48.6)	86 (42.2)	118 (57.8)	.39
Sleep issues	82 (19.5)	32 (39.0)	50 (61.0)	.29

Table 3 shows a mean BMI of 19.3 (SD 4.7) kg/m^2 for the study population. There was a slight difference in the mean BMI between the supervised (mean 19.6 kg/m^2, SD 4.9 kg/m^2) and unsupervised (mean 19.1 kg/m^2, SD 4.4 kg/m^2) groups (*P*=.26 indicates statistical insignificance). Overall, out of 420 children, 335 (80.1%) children were healthy, 21 (5%) were underweight, and 42 (10.1%) were overweight/obese. No statistically significant differences were observed in the distribution of BMI between the supervised and unsupervised categories.

Table . Association of BMI with supervised and unsupervised digital screen use.

Characteristics	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)	*P* value
BMI, kg/m^2				.26
Mean (SD)	19.3 (4.7)	19.6 (4.9)	19.1 (4.4)	
BMI category, n (%)				.50
Underweight	21 (5.0)	9 (42.9)	12 (57.1)	
Healthy weight	335 (80.1)	143 (42.7)	192 (57.3)	
Overweight	42 (10.1)	21 (50.0)	21 (50.0)	
Obesity	16 (3.8)	9 (56.2)	7 (43.8)	
Severe obesity	4 (1.0)	3 (75.0)	1 (25.0)	

Table 4 shows the association of anxiety with supervised and unsupervised digital screen use. Out of 420 children, 414 (98.6%) children were identified within the normal range. Just 1 of the 6 children fell into the high anxiety range; only 1 was left unsupervised and the other 5 were in the supervised group. Despite the fact that there was a significant difference (*P*<.05), the small number of individuals in this group could provide an inaccurate correlation. It is recommended to conduct additional research before drawing any conclusions. There were no discernible variations between the supervised and unsupervised proportions for any specific anxiety subcategory on the SCAS.

Multimedia Appendix 2 shows the results of the SDQ scale in the 420 students; of the 420 students, 119 students (28.3%) had conduct problems, 121 students (28.8%) had peer problems, 66 students (15.7%) reported emotional problems, 73 students (17.4%) experienced hyperactivity, and 28 students (6.7%) reported prosocial behaviors. Based on the borderline/abnormal results shown in Multimedia Appendix 2, Table 5 was prepared, and it shows the distribution of supervised and unsupervised children categorized as having borderline/abnormal results for digital screen use based on the SDQ subcategories (emotional symptoms, conduct problems, hyperactivity or attention deficit, peer relationship problems, and prosocial behavior).

The percentage of unsupervised children was greater than that of supervised children among those classified as having borderline or abnormal results. The most common abnormality was peer relationship problems among the children. Of the 420 students, 121 (28.8%) had peer relationship problems: 55 students (45.38%) were supervised and 66 students (55.6%) were unsupervised. Less borderline/abnormal results were found considering prosocial behavior. Of the 420 students, 28 (6.7%) were identified with abnormal/borderline results: 11 (39.29%) were supervised and 17 (60.71%) were unsupervised.

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Table . Association of anxiety with supervised and unsupervised digital screen use by using the Spencer Children Anxiety Scale (SCAS).

SCAS	Overall (N=420), n (%)	Supervised (n=186), n (%)	Unsupervised (n=234), n (%)	*P* value
Overall				.05
Normal range	414 (98.6)	181 (43.7)	233 (56.3)	
Elevated range	6 (1.4)	5 (83.3)	1 (16.7)	

Table . Distribution of supervised and unsupervised children categorized as borderline/abnormal for digital screen use based on the Strength and Difficulties Questionnaire subcategories (emotional symptoms, conduct problems, hyperactivity, peer relationship problems, and prosocial behavior).

Category	Supervised (%)	Unsupervised (%)
Emotional symptoms	43.94	56.66
Conduct problems	45.38	54.62
Hyperactivity	47.95	52.05
Peer relationship problems	45.45	54.55
Prosocial behavior	39.29	60.71

Table 6 shows that a majority of children reported good quality of sleep on the PSQI (358/420, 85.2%). Of those who reported bad sleep, the proportions were similar between supervised and unsupervised children (14% of supervised children vs 15.4% of unsupervised children). Nonetheless, a potentially significant result was found on comparing the mean total sleeping durations: supervised children sleep on average for 7.7 (SD 1.5) hours, compared to 7.4 (SD 1.6) hours for unsupervised children (against an overall mean of 7.6, SD 1.6). However, the *P* value showed borderline significance; furthermore, if the children were subcategorized by the average hours of sleep (>7, 6 - 7, 5 - 6, and <5 hours), no significant difference was found across any subgroup between supervised and unsupervised children.

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Table . Association of quality of sleep using the Pittsburgh Sleep Quality Index (PSQI) scale with supervised and unsupervised digital screen use.

PSQI scale	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)	*P* value
Sleep status, n (%)				.69
Good sleep (global PSQI score ≤5)	358 (85.2)	160 (44.6)	198 (55.3)	
Bad sleep (global PSQI score >5)	62 (14.8)	26 (14.0)	36 (15.4)	
Sleep time				.05
Mean bedtime, PM	11:17	11:11	11:21	
Mean wake time, AM	7:19	7:24	7:16	
Total sleeping duration (h), mean (SD)	7.6 (1.6)	7.7 (1.5)	7.4 (1.6)	
Sleep quality, n (%)				.18
Very good	202 (48.1)	82 (44.1)	120 (51.3)	
Fairly good	199 (47.4)	94 (50.5)	105 (44.9)	
Fairly bad	17 (4.0)	10 (5.4)	7 (3.0)	
Very bad	2 (0.5)	0 (0.0)	2 (0.9)	
Sleep latency, n (%)				.85
0	100 (23.8)	41 (22.0)	59 (25.2)	
1 - 2	207 (49.3)	94 (50.5)	113 (48.3)	
3 - 4	105 (25.0)	48 (25.8)	57 (24.4)	
5 - 6	8 (1.9)	3 (1.6)	5 (2.1)	
Sleep duration, n (%)				.06
>7 hours	237 (56.4)	112 (60.2)	125 (53.4)	
6 - 7 hours	123 (29.3)	53 (28.5)	70 (29.9)	
5 - 6 hours	44 (10.5)	19 (10.2)	25 (10.7)	
<5 hours	16 (3.8)	2 (1.1)	14 (6.0)	
Habitual sleep efficiency, n (%)				.40
>85%	393 (93.6)	176 (94.6)	217 (92.7)	
75 - 84%	25 (6.0)	10 (5.4)	15 (6.4)	
65 - 74%	2 (0.5)	0 (0.0)	2 (0.9)	
<65%	0 (0.0)	0 (0.0)	0 (0.0)	
Sleep disturbances, n (%)				.80
0	38 (9.0)	18 (9.7)	20 (8.6)	
1 - 9	364 (86.7)	161 (86.6)	203 (86.8)	
10 - 18	17 (4.0)	7 (3.8)	10 (4.3)	
19 - 27	1 (0.2)	0 (0.0)	1 (0.4)	
Use of sleeping medication, n (%)				.30
Not during the past month	417 (99.3)	186 (100.0)	231 (98.7	
Less than once a week	2 (0.5)	0 (0.0)	2 (0.9)	
Once or twice a week	1 (0.2)	0 (0.0)	1 (0.4)	
Three or more times a week	0 (0.0)	0 (0.0)	0 (0.0)	
Daytime dysfunction, n (%)				.88

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PSQI scale	Overall (N=420)	Supervised (n=186)	Unsupervised (n=234)	*P* value
0	283 (67.4)	124 (66.7)	159 (68.0)	
1 - 2	121 (28.8)	54 (29.0)	67 (28.6)	
3 - 4	13 (3.1)	7 (3.8)	6 (2.6)	
5 - 6	3 (0.7)	1 (0.5)	2 (0.9)	

Discussion

Principal Results and Comparison With Prior Works

This study enrolled a total of 420 children, with 186 (44%) supervised and 234 (56%) unsupervised children. Unsupervised children had a slightly higher mean screen time of 4.6 (SD 2.4) hours compared to supervised children who had a mean screen time of 4.5 (SD 2.2) hours. Additionally, the study found a higher prevalence of physical symptoms and slightly different BMI distributions among unsupervised children. No significant differences in sleep quality were observed between supervised and unsupervised children, although supervised children slept slightly longer. A greater percentage of unsupervised children were categorized as having borderline or abnormal findings based on the SDQ subcategories (emotional symptoms, conduct problems, hyperactivity or attention deficit, peer relationship problems, and prosocial behavior).

Significant variations depending on the type of education were found in this study, which examined key facets of the role of parental supervision in digital screen use among students in Dhaka city. Although teenagers attending school spent a mean of 4.6 (SD 2.3) hours a day on screens, there was no discernible difference in the amount of time spent on screens between students who were under supervision and those who were not. Nevertheless, when stratified by the type of education, students in Bengali medium schools had screen time of 3.67 hours, while students in English medium schools showed considerably higher screen time (5.46 hours). This discrepancy could have several causes. In Bangladesh, English medium students often come from higher-income households that can afford the higher costs of English medium education, making them more likely to have access to personal digital devices. A similar indication was provided in an article published by The Daily Star [43]. Additionally, English medium students are typically Ordinary level (O level) or Advanced Level (A level) candidates, an internationally recognized qualification that is considered to be the equivalent of Cambridge IGCSE and UK General Certificate of Secondary Education; the preparation for these international-standard examinations necessitates greater screen exposure as part of their learning process [44]. Despite the differences in total screen time, the study did not find any correlations between parental education or income level and screen time supervision. Another study also showed the same findings that no significant association was observed between parental education or income level and screen time supervision [45].

Such trends are concerning given the established negative effects of excessive screen time on adolescent health, including obesity, diabetes, poor sleep, and increased risks of depression and anxiety [5-9]. Effective parental supervision is known to reduce screen time and mitigate these adverse effects. Parent-child interaction improved prosocial behavior and reduced psychosocial difficulties while contributing to healthier body mass indices and better sleep [11]. Furthermore, the findings of this study align with the results from previous studies [7, 9]. The empirical evidence found that parental mediation and active participation are associated with improved physical health outcomes, including BMI and sleep duration [7,9]. School-going participants in this study also reported a range of health concerns, with blurred vision, abdominal pain, headaches, dry or sore eyes, and indigestion being the most commonly noted. Such impacts are also reported by several previous studies [46-48]. A notable difference was observed between supervised and unsupervised groups specifically for headaches, with a higher proportion of unsupervised students reporting this issue. A previous study also reported that unsupervised children are more vulnerable to associated health issues [49]. Although supervision did not significantly impact other physical indicators, the findings suggested a potential association with blurred vision and diabetes. However, the small number of patients with diabetes limits the interpretability of these findings. Therefore, further research is needed to explore the effects of different supervision methods on these health concerns and to identify any potential correlations.

In contrast, the statistical significance indicates that factors other than supervision, such as lifestyle, might have a greater impact on other physical issues. For instance, a sizable percentage (28.3%) of kids showed conduct and peer relationship problems when they had results in the borderline or abnormal range on the SDQ. Despite these findings, no significant differences were observed between supervised and unsupervised groups across the SDQ subcategories, suggesting that these behavioral issues may be influenced by factors beyond supervision, including lifestyle and home or school conditions.

Furthermore, we identified a concern that supervision might exacerbate anxiety. This is because, among the 6 children who reported overall anxiety, only 1 was unsupervised. Although the result is statistically significant, this finding should be interpreted with caution due to the small sample size. Collectively, these observations highlight a significant deficiency in effective parental guidance and supervision methods among contemporary urban families in Dhaka. Therefore, further research is needed to explore the specific supervision strategies employed by parents and their impact, with the aim of developing guidelines for healthy technology use.

Finally, we explored a potential correlation between parental supervision of digital screen use and the mean total bedtime based on PSQI data, with the supervised group having slightly more sleep on average compared to their counterpart. However,

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when analyzing total sleep duration and examining differences related to supervision across various subgroups, the significance diminished, indicating that the observed differences were not conclusive. Specifically, the proportions of children who slept more than 7 hours were similar between the supervised and unsupervised groups, and these proportions did not differ meaningfully from the overall study sample. Given these borderline findings, further investigation is warranted to explore the potential associations between supervision and sleep patterns.

Limitations

This study has several limitations. First, inconsistencies emerged between the parents' and children's reports, as many parents used a broad definition of "supervised," such as occasional checks or limited awareness of the child's activities on the device. As the children's reports were found to be more reliable predictors, final supervision categorization was based on the children's statements. A similar approach has been followed previously [44]. Second, the study's scope was limited to 6 schools (3 Bangla and 3 English medium schools), which may not be representative of the broader variation between urban and rural settings or differing school resources. Third, data on technological interactions and parental mediation were collected via face-to-face interviews, which may have introduced recall bias. Finally, discrepancies between parent and child reports could not be independently verified. Future research should include diverse populations and settings to provide a more comprehensive understanding of screen time impacts.

Strengths

Despite these limitations, the strength of this study lies in its pioneering exploration of the association of parental supervision with the physical, mental, and social well-being of students in Bangladesh. Additionally, by including students from both Bangla and English medium schools, the study provides valuable comparative insights. The findings are expected to motivate and inform parents, policy makers, and educational authorities, highlighting the need for enhanced supervision and education to promote healthier and more balanced lifestyles for students. Further research is required that may explore causal relationships through experimental or longitudinal designs.

Conclusions

The results of this study enhance our understanding of how to mitigate the negative impacts of unsupervised screen time on students' well-being. Effective guidelines for managing screen use require the involvement of multiple stakeholders: schools, parents, policy makers, and the students themselves. Schools can play a crucial role in educating students about safe screen use and enforcing balanced screen time through workshops and seminars. Parents need to be informed about the risks of excessive screen time and the benefits of active supervision, adopting strategies to enhance their children's well-being. Additionally, accessible mental health services, including counseling and support groups, can help students manage stress and anxiety related to screen time. Conducting further research to develop comprehensive screen time guidelines is essential for promoting the health and well-being of future generations.

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Data Availability

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

Authors' Contributions

SHK contributed to conceptualizing, analyzing, writing, revising, and finalizing the manuscript with the support of TRS, MSH, RH, and FT. All the authors have read, revised, and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Mean daily screen time (hours) by sociodemographic characteristics.
[DOCX File, 15 KB - pediatrics_v8i1e62943_app1.docx]

Multimedia Appendix 2

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Distribution of normal and borderline/abnormal responses for the student behavior on the Strength and Difficulties Questionnaire (SDQ) scale.
[DOCX File, 14 KB - pediatrics_v8i1e62943_app2.docx]

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Abbreviations

PSQI: Pittsburgh Sleep Quality Index
SCAS: Spencer Children Anxiety Scale
SDQ: Strength and Difficulties Questionnaire

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Development of an eHealth Intervention in Pediatric Home Infusion Therapy: Interview Study of Needs and Preferences of Parents and Health Care Professionals

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Abstract

Background: With the provision of home infusion therapy in children with acute or long-term illness on the rise, eHealth technologies have the potential to bridge the transition between hospital and home. However, eHealth interventions intended to support parents in managing home infusion therapy are sparse. Gaining insight into the needs and experiences of parents and health care professionals is crucial to developing feasible and sustainable eHealth interventions that target their needs. This study describes the first phase of a research study designed to develop and evaluate an eHealth intervention to support home infusion therapy.

Objective: This study aimed to identify the experiences and needs of parents and health care professionals during home infusion therapy and their preferences for digital features in a future eHealth intervention.

Methods: A qualitative study was conducted at 3 pediatric departments at a university hospital in Denmark. We individually interviewed 17 parents of 14 children who had received home infusion therapy with a portable pump. In addition, 5 focus groups were conducted with 15 health care professionals. We conducted a qualitative content analysis of the data, which we collected from February to July 2020.

Results: We identified 6 subthemes that we merged into 3 main themes: increasing safe self-management at home; adapting information and responsibility to individual changing needs; and requesting digital features to ensure skill level, safety, and quality of care. The analysis showed that parents and health care professionals had corresponding needs and preferences, for example, a need for a high sense of safety and easier ways to communicate during home infusion therapy. Both groups emphasized the need for digital features to improve problem-solving and communication as a supplement to existing care to promote a safe environment, self-management, and quality of care. A vital issue was that an eHealth intervention should be aligned with the workflow of health care professionals and comply with regulations regarding confidentiality in communication and data sharing.

Conclusions: Our study highlights the needs that parents and health care professionals have for increased safety and easier access to communication when receiving and providing home infusion therapy. The findings will be used to help develop an eHealth intervention supporting home infusion therapy tailored to individual needs.

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KEYWORDS

pediatrics; digital; interventions; eHealth; home care; intravenous infusion; qualitative research

Introduction

Home infusion therapy for children with acute or long-term illnesses is becoming increasingly common due to its benefits, such as supporting children and their families in maintaining their everyday lives and improving the child's health outcomes [1]. This therapy can be provided by nurses in hospitals or municipalities, home care agencies, or by nonprofessional

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caregivers such as parents or guardians. Transitioning care tasks from a hospital to a home setting is complex and requires well-functioning, coordinated collaboration between health care professionals and parents [2]. Parents have reported feeling anxious and insecure if they lack support, experience with, or knowledge about care tasks such as administering medications and observing symptoms that they must manage at the hospital and at home [3]. Furthermore, studies show that parents' administration of oral medication at home is a high-risk area for medication errors [4-7]. Thus, it is vital to ensure that parents are comfortable and confident when managing care tasks at home.

eHealth interventions can be a means to support parents since they provide digital resources for managing home infusion therapy. According to the World Health Organization [8], eHealth can increase communication and data sharing between health care professionals and patients and improve accessibility and patient participation by electronic technologies. The use of eHealth expanded radically during the COVID-19 pandemic [9], but various barriers remain before integration into pediatric clinical practice is completely successful [10-13]. Studies have reported that the use of eHealth in pediatric clinical care can bridge the transition from hospital to home and increase interaction between the two by efficiently and conveniently providing information and communication [14-16]. This helps promote confident self-management among parents in treating and caring for children with various medical needs at home [2,15-17], improve symptom control in the child, and reduce parental worries and insecurity [2,18-22]. However, the availability of eHealth interventions for families of children with acute or long-term health conditions as well as the evidence supporting eHealth in pediatric clinical practice, remains still limited [23-25].

At the outset of this study, children and adolescents were given the opportunity to start antibiotic infusion therapy using a portable pump at a university hospital in Denmark and then continue treatment at home. Parents were trained by nurses and supported with printed materials and resources on the hospital's website. The provision of home infusion therapy began to expand to include other types of medications and delivery methods, thereby placing greater responsibility on the parents. No eHealth interventions were available to support home infusion therapy and there was uncertainty about the extent of parents' and health care professionals' needs and the specific content that they may need for eHealth support. Previous research have shown that extensive support is essential when parents perform caregiving tasks at home [3,26]. However, less is known about how parents and health care professionals employed at hospitals perceive their needs and preferences related to home infusion therapy and eHealth support. According to Medical Research Council's framework [27], exploring the needs of intervention users is a crucial first step in developing an intervention. Applying a participatory design [28], future users are involved to gain an understanding of their situation and respond to their experiences, needs, and preferences. This approach ensures that a future eHealth intervention would target their needs and be sustainably implemented [11,28-30]. Therefore, the aim of this study was to identify the experiences and needs of parents and health care professionals regarding home infusion therapy, in addition to their preferences for including digital features in the development of a future eHealth intervention.

Methods

Design

An exploratory qualitative design was applied to get relevant input from the users to the future development of a supportive eHealth intervention. This study is a part of the developmental phase of a larger research program with the overall goal of developing and testing an eHealth intervention to support parents and health care professionals during pediatric home infusion therapy. The Medical Research Council's framework for the development and evaluation of complex interventions [27] and a participatory design [28] framed the overall research project. The framework guides researchers through 4 interconnected phases, development, feasibility, evaluation, and implementation. Engaging the users of the eHealth intervention throughout the research study ensured the developmental relevance of our study and its feasibility in clinical practice, improving the probability of successful implementation [26].

Setting

The study was conducted in 3 pediatric departments at a university hospital in Copenhagen, Denmark, 1 specializing in oncology and hematology (20 in-patient beds), 1 in organ and infection diseases (12 in-patient beds), and 1 day hospital (7 beds), with around 2000 combined admissions annually.

Home Infusion Therapy

In 2018, the departments started offering home infusion therapy with portable pumps as an option to children with diagnoses such as cancer or with an acute infection with no underlying condition. The therapy was primarily used for intravenous antibiotic treatment and always initiated during hospitalization at an in-patient ward or in an out-patient setting. The children had a central venous catheter or midline catheter. A nurse informed and trained primarily one of the child's parents before home infusion therapy was initiated and administered the portable pump to the child at the hospital before discharge. The child returned the following day to the hospital to receive a new dose in the pump or to discontinue treatment. The parent's task was to clinically observe the child, the pump and infusion at home, and react if problems arose, such as reactions to the medicine or a pump alarm sounding. If the child had a serious reaction, the parent was instructed to immediately call an ambulance. Health care professionals also taught some parents how to change the pump medication or replace the elastomeric pump with a new one to allow the family to stay at home 1 or 2 additional days before returning to the hospital,

Participants

A purposeful sampling strategy of children, parents, and health care professionals was used to obtain rich and varied data on the home infusion therapy [31]. Inclusion criteria for children were 0 to 18 years of age, having received home infusion therapy with a portable pump with any type of medication,

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having the parent living with the child part or full time, and the parent speaking Danish or English. Most children receiving the therapy had an underlying long-term illness, but children with an acute infection with no underlying condition were also approached. In total, 14 children and their parents were informed about the study, and all agreed to participate. The children were invited to participate in an interview together with their parent, which resulted in 13 children participating, 2 of whom actively joined in. In 3 families, both parents participated and were interviewed jointly or separately (Table 1). Inclusion criteria for health care professionals were: (1) nurse or a physician, (2) working at one of the 3 departments, and (3) had experience with providing home infusion therapy. A total of 15 health care professionals were approached, and all agreed to participate.

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Table . Demographic and clinical characteristics of children and parents.

Characteristic			Participant, n
Children (n=14)			
	Age (years)		
		0 - 5	5
		6 - 11	6
		12 - 14	1
		15 - 18	2
	Sex		
		Male	11
		Female	3
	Primary diagnosis		
		Cancer	10
		Congenital lung disease	2
		Congenital autosomal disorder	1
		Stroke caused by virus infection	1
	Ethnicity		
		Danish	11
		Other	3
	Cohabiting with siblings (n)		
		0	2
		1	9
		2 - 4	3
Parents (n=17)			
	Sex		
		Female	12
		Male	5
	Partner relations		
		Cohabiting with partner	16
		Single parent	1
	Age (years)		
		31 - 40	11
		41 - 50	3
		Unknown	3
	Occupational status		
		Employed	5
		Unemployed	1
		Paid leave due to child's illness full time	10
		Paid leave due to child's illness part time	1

Data Collection

Data were collected from February to July 2020. Parents were interviewed based on a 2-part exploratory semistructured interview guide. The first part covered experiences and needs regarding home infusion therapy in terms of provision of and responsibility for it, preparation and training, and sense of safety, worries, and challenges. The second part presented concrete

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examples of digital features to generate ideas on how technology could address the needs and preferences of the child and parent, in addition to focusing on how an eHealth intervention could support home infusion therapy. We asked which digital features to include, such as possible advantages and disadvantages, experience with digital technologies, and what features are important to have in an eHealth intervention. The eHealth Literacy Framework provided the underlying inspiration for the questions in the second part to understand user needs and prerequisites when new digital health services are introduced [32]. The interviews were conducted by the first author (n=16), at one of the pediatric departments in a meeting room or an in-patient room lasting and lasted 30 to 120 minutes, though 1 was done by phone.

Health care professionals were interviewed in 5 separate focus groups with a semistructured interview guide corresponding to the guide for parents though tailored to their professional role. The focus group interviews, which lasted 60 to 90 minutes, were held in a meeting room at one of the pediatric departments. The interviews were recorded and transcribed verbatim.

Data Analysis

A qualitative content analysis of the transcribed interviews was used comprising a 5-step iterative and inductive approach based on Graneheim and Lundman [33] to identify any patterns and variations in participant experiences. First, 2 authors [HH and MLO] read the text independently to gain an overall understanding. Second, they identified meaning units in terms of words, sentences, and paragraphs that related to the study aim. Next, the meaning units were condensed, organized, and coded using NVivo software (Lumivero). Fourth, the codes were compared with identify similarities and differences, before being organized into subthemes. Finally, the subthemes were compared and analyzed, after which they were merged into main themes. The defined main themes had a consistent pattern of underlying meaning in terms of the condensed meaning units, codes, and subthemes. To strengthen the trustworthiness of the study, the same 2 authors discussed the meaning units, codes, subthemes, and themes throughout the analysis until reaching consensus. Initially, individual and focus group interviews were analyzed separately as 2 datasets. During the data analysis, it became apparent that the subthemes overlapped, and data were analyzed together. In the last phase of the analysis, all authors reflected on and discussed the main themes and subthemes.

Trustworthiness

The authors discussed the analysis, interpretations, and themes at seminars and presentations with key health care professionals involved in home infusion therapy and other researchers to enhance credibility. The authors also discussed their preunderstanding to consider how it may influence data collection and analysis, all of us are experienced in conducting qualitative studies. The first author [HH], who is a nurse, has experience with implementing home infusion therapy at the 3 departments but did not have any clinical contact with the families before the interviews. The health care professionals knew HH, which may have hampered them from freely expressing themselves, but her knowledge of home infusion therapy may also have made them feel confident enough to provide in-depth responses to the interviews.

Ethical Considerations

The Danish Protection Agency approved the study (P-2019 - 392), while approval from the Regional Research Ethics Committees for the Capitol Region of Denmark was not required since it only assesses studies that collect biological material. The study adhered to the Declaration of Helsinki, International Ethical Guidelines for Health-Related Research Involving Humans, and current Swedish and European law. All participants were assured that participation was voluntary and that they could withdraw from the study at any time without affecting their child's treatment or the health care professionals' work. All participants provided written informed consent and were assured confidentiality. When applicable, the children received age-appropriate information about the study based on their cognitive abilities, language skills, and legal guardian's preferences.

Results

Overview

The amount of experience parents and health care professionals had with home infusion therapy ranged from doing it a few to multiple times. The parents expressed that it enhanced their child's well-being and the whole family's due to having a greater opportunity to spend everyday life together more at home. They were willing to take on the additional caregiving tasks and responsibility due to the benefits associated with doing so. The health care professionals also described how the child and family benefited and how important the option of home infusion therapy was.

Three main themes were identified comprising six subthemes: (1) increasing safe self-management at home, (2) adapting information and responsibility to individual changing needs, and (3) requesting digital features to ensure skill level, safety, and quality of care (Textbox 1). The themes and subthemes were bound together in an overarching theme "managing the extended responsibility of home infusion therapy." This theme encompasses the core experience of the increased responsibility parents take on when managing the therapy and the health care professionals being responsible for therapy taking place outside the hospital. Digital features were described as means to support that responsibility.

The first and second themes describe the needs of parents and health care professionals based on current experiences with home infusion therapy, while the third main theme present the digital features proposed to meet the needs of both groups in a future eHealth intervention (Figure 1).

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Textbox 1. Main themes and subthemes.

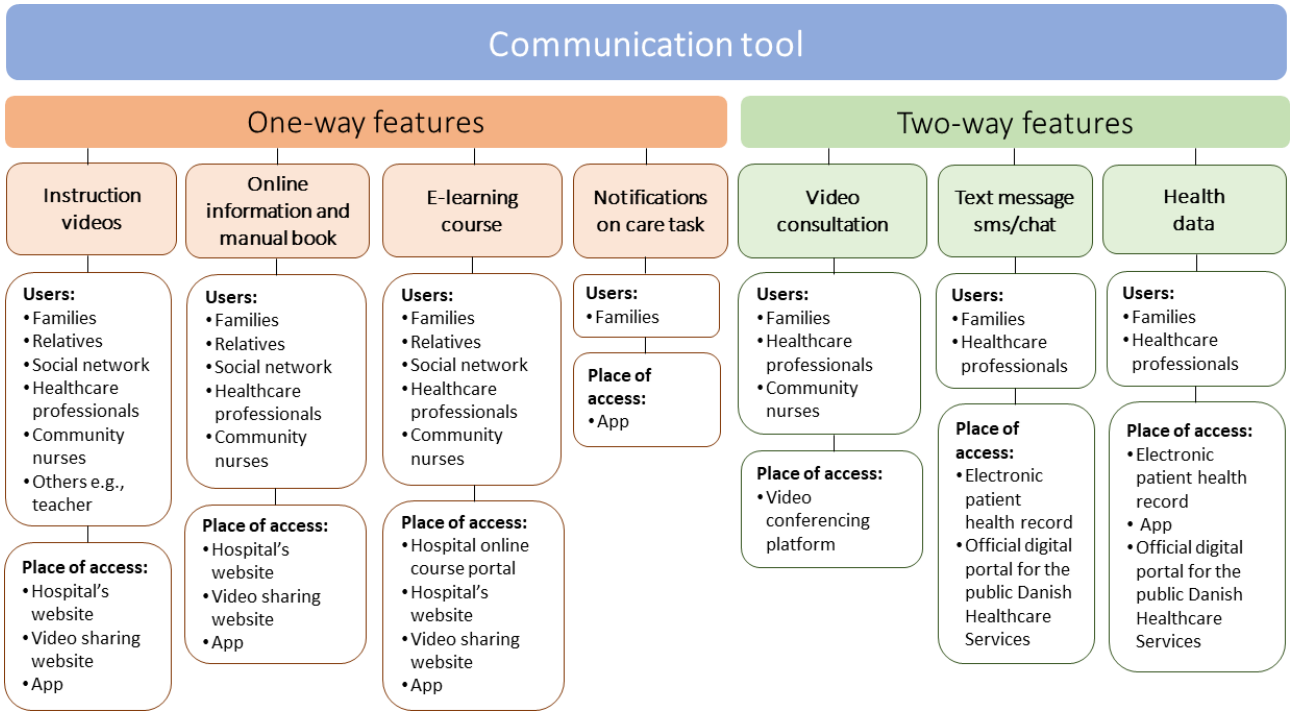
Overarching theme:

- Managing the extended responsibility of home infusion therapy

Main themes and their subthemes:

- Increasing safe self-management at home
  - Need for standardized information, training, and shared problem-solving
  - Being in control of home infusion therapy and feeling safe
- Adapting information and responsibility to suit individual needs
  - Repeating individualized information and training
  - Desire to share the responsibility
- Requesting digital features to ensure skill level, safety, and quality of care
  - Access to online one-way communication of knowledge and training
  - Access to interactive communication and support

Figure 1. Digital features proposed by parents and health care professionals for a future eHealth intervention.



Theme 1. Increasing Safe Self-Management at Home

Subtheme: Need for Standardized Information, Training, and Shared Problem-Solving

Overall, parents described that they were confident about the information and training they had received on how to manage home infusion therapy, and they had not experienced any problems with the pump or the child's health. But some felt that the information and training were too sparse. They appreciated the information booklet, even though they did not always have it with them when they needed it. The hospital website provided information and guidelines, but finding either one was sometimes difficult and time-consuming if immediate support was required.

Some parents thought that the information and training they received was inconsistent, making both them and their child feel insecure. They requested uniform guidelines and training regardless of which health care professionals or department taught them about managing the care tasks. They also felt unsure if they called for assistance and spoke with a health care professional who lacked the skills to provide support, sometimes forcing families to travel to the hospital.

> *I felt stressed when it [pump] sounded an alarm that showed 'low reservoir volume'. I think it was actually*

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> *when the infusion bag was full. And then I called the ward after trying everything I could do at home. But when you call in the evening, there isn't necessarily anyone at work who knows much about the pump. So, they didn't know what I should do either.* [Mother 232]

Health care professionals who seldom had the task of giving parents information and training about managing the portable pump worried about how to maintain their professional skill level, making them feel insecure professionally and concerned about how that could affect the children and parents.

> *We don't provide home infusion that much at our ward and the more you physically deal with it [pump] in your hands, the better, safer, and more familiar you get with it when you teach the parents.* [Health care professional 113]

Subtheme: Being in Control of Home Infusion Therapy and Feeling Safe

The parents described that the pump was easy to manage and that they did not experience many problems related to the pump and infusion, or that their child experienced adverse effects. If a pump alarm went off, they were mostly able to manage the issue at home. They felt particularly worried if an alarm sounded due to air bubbles in the infusion set. In such situations they expressed a need for different interaction than a telephone call with the health care professionals because it had the potential to resolve problems and thereby avoiding a hospital visit.

> *I think, I think that there's a need for extra support in those kinds of situations when it [pump] acts up.* [Mother 73]

Parents described how they wanted to take on responsibility for their child's home infusion therapy as it was a way to have control over their situation. Even though they generally felt secure about the information, training, and support they received, some parents still worried about something unexpected happening, making them feel vulnerable about being home alone without a health care professional nearby. They stated that they would appreciate more support to improve their sense of safety and control of the situation.

The health care professionals also described the need to have more control when discharging a child to home infusion therapy, mentioning that they felt an extended sense of responsibility toward the child and home treatment that they sometimes found difficult to fulfill since they were unable to monitor the child's condition in the same way as at the hospital. The health care professionals lacked having a sense of the family's capacity at home; for example, they could not assess whether the procedures and observations the parents took on had been performed correctly. This lack of control preoccupied them as they worried about the risk of medication errors and adverse events. The health care professionals needed reassurance that the parents had conducted the necessary observations and procedures to help increase their feeling of control concerning the treatment they had initiated, especially because they felt responsible for the child's well-being, treatment, observations, and transferring such specialized care tasks to the parents without their presence to safeguard them at home.

> *And then there's the issue of whose responsibility it is when you hand it [therapy] over to the parents? Because I agree that they only want the best for their child. There's no doubt about that.* [Health care professional 117]

Theme 2. Adapting Information and Responsibility to Suit Individual Needs

Subtheme: Repeating Individualized Information and Training

Parents described feeling mentally burdened by their child's illness, especially those whose child had long-term illness. They had difficulty remembering and comprehending information and training, causing them to request the possibility to repeat information and training once they returned home.

> *You're bombarded with things that I, as a parent, must be able to gain an overview of, including how the pump works. Then, when you get home you think: "God, what was it that they said about that?" And in that situation, it would be really nice if you could seek help [digitally/online]: "Could you tell me again, what I should do, when I should do this and that?"* [Mother 173]

The health care professionals also worried that the parents did not always have the mental surplus to handle new or additional tasks in relation to home infusion therapy. They expressed a need for providing more individualized support to parents at home as they saw the parents' mental surplus as changing over time. It was important for them to ensure that the parents felt safe and were not additionally burdened by managing home infusion therapy.

> *Maybe we could come by to force them to accept it [home infusion], because we've been used to that. Then there's a psychological aspect to it, where you constantly have to determine where they are in the treatment trajectory: "Do you still feel secure about doing home care?" Because I think the families experience a tremendous number of mental ups and downs.* [Health care professional 262]

Subtheme: Desire to Share the Responsibility

The parents described that they would like to involve other caregivers and professionals in the home infusion therapy to share the responsibility, also their child if the child wanted to be involved. Often only one parent was trained to manage the pump and medicine, leaving them with the sole responsibility. One parent said that her partner did not want to help with it due to how unsure it made him feel.

> *He's perhaps afraid of ending up doing something wrong [with the pump] that may harm our son, which I think might paralyze him a little in terms of his ability to act.* [Mother 196]

Another parent described how the partner, who had not been trained at the hospital, panicked at home when an alarm on the

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pump went off. Parents also emphasized the need for additional support to facilitate training and guidance at home to increase the sense of safety and control for the child and other caregivers with the therapy and to support shared responsibility. Like the parents, the health care professionals supported and emphasized the need for parents to share the responsibility for managing home infusion therapy, for example, with grandparents and daycare staff.

> *One of the disadvantages of home treatment is that all of the responsibility lies with one parent, or two, to manage it [the pump]. It's a great deal to have to take care of regularly.* [Health care professional 270]

However, the health care professionals found that letting the parents supervise others was challenging because they worried that training others might put an additional burden on the parent or potentially be problematic regarding quality of care and safety.

Theme 3. Requesting Digital Features to Ensure Skill Level, Safety, and Quality of Care

Subtheme: Access to Online One-Way Communication of Knowledge and Training

Parents suggested that online information, guidelines, and instruction videos would be helpful and should be easily accessible in one place, for example, the hospital's website or an app, making it more straightforward and quicker to find information and training, which would potentially allow parents to solve technical problems themselves.

> *I've actually thought of something that could be really nice, being able to watch a short video, if there's something that's tricky, instead of having to read about it. Because you can't be sure that you'll have the peace of mind to understand it [written information] when you're in the middle of a crisis.* [Mother 29]

> *Sometimes they call and say that they can't find it. They've lost their information material and manual, so they ask: "What should we do when she gets a fever or becomes flush or?"* [Health care professional F2]

If information on paper got misplaced or was forgotten, a digital version would always be available. Parents suggested that explanatory instruction videos could be developed to show how to solve the most common problems, for example, removing air bubbles in the infusion set or resolving other practical technical issues related to the pump. The health care professionals supported the idea of having information, guidelines, and instruction videos available online to provide professional reassurance that the parents could find information targeted their needs and skills. They explained that instruction videos could also meet their own needs for maintaining their skill level, along with e-learning. Furthermore, both parents and health care professionals expressed how online material would ensure that the information and skills the parents acquired were aligned with the health care professionals. However, the health care professionals had concerns about how to regularly keep online material and instruction videos updated based on the newest evidence-based practices.

Parents and health care professionals described how online guidelines and instruction videos could help bolster sharing responsibility for managing home infusion therapy for those who did not receive training at the hospital. Parents also expressed that this would be useful for children interested in self-managing their therapy, also because they were already familiar with using digital platforms with videos. Instruction videos also represent a useful tool for those who learn better visually, just as they can be subtitled or dubbed into different languages, improving access to allow more families to receive home infusion therapy.

Subtheme: Access to Interactive Communication and Support

Parents also mentioned the benefits of video consultations for receiving guidance in managing the pump and resolving any issues with the pump at home to avoid traveling to the hospital. Video consultations would also provide visual advantages that were absent in ordinary telephone conversations in terms of guidance and preventing misunderstandings.

> *A support feature would be very good to have. If you [nurses] had a smartphone available to make video calls to film what the pump says, because my wife panicked a little bit and the communication on the phone with the nurse [at the hospital] was not that great; the nurse and my wife misunderstood one another. So, I just drove him to the hospital.* [Father 112]

Health care professionals also requested the option of using video consultations to reassure parents that their observations were relevant and to guide them in shared problem-solving. Video consultations could potentially improve their sense of safety and professional control by allowing them to assess the child's condition and the parent's management of the therapy.

> *You're sure that the parents know how to change the infusion bag. And if you're in doubt at home, it's evening and you call and you can't be guided on the phone, then it would be nice be able to see it to avoid any misunderstandings.* [Health care professional 208]

However, the health care professionals had concerns. Even though the child was visible on video, they could not use their clinical judgment based on all their senses compared with face-to-face clinical observations at the hospital. They were uneasy about care becoming too digital.

> *I think it's a good idea [home care], but I also worry about not seeing the children: "How are you doing and how do you look?" Can the parents always assess that? The nursing loses something; it simply becomes too digital. That involves using your eyes, touch, and sense of smell and whatever else we run around doing.* [Health care professional 133]

Both parents and health care professionals stressed that the work procedures and settings for digital interactions would require

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aligning expectations. For example, video consultations include specific requirements, such as the need for computers with the right equipment, setting up consultations in a confidential setting, and how to manage scheduling consultations, also in the evening and at night, not to mention having skilled health care professionals available to provide support 24/7.

Parents were also interested in being able to send data to the hospital, such as their child's blood pressure or pictures of skin changes to reassure the parents and health care professionals regarding the parents' observations. However, some parents had misgivings about perhaps feeling pressured to provide more data than they could manage. In addition, parents and health care professionals alike were uneasy about when and who was responsible for assessing and reacting to the data at the hospital, and the timespan in which parents could expect to receive an answer. Managing incoming measurements would be required for this to succeed and make all parties feel safer. Furthermore, parents and health care professionals suggested that the parents could also receive notifications to ensure that care tasks like taking their child's temperature and assessing intravenous access were performed at the right time.

Discussion

Principal Findings

We found that parents and health care professionals largely had corresponding needs for safety in home infusion therapy but that their preferences for digital features in a future eHealth intervention to meet those needs were based on different rationalities. It was vital that everyone felt safe about using home infusion therapy, and they suggested various digital features to meet their needs to have consistent knowledge, problem-solving skills, reassurance that the parents could manage the home infusion therapy and their child's well-being, maintain their skill level, and share responsibility with more than one parent. They emphasized the need for an eHealth intervention that provides additional communication support to existing care to enhance safety, self-management, and quality of care.

Comparison With Previous Work

A key finding was how home infusion therapy was linked to the extended responsibility of the parents and health care professionals, the former at home without the presence of a nurse, and that latter in terms of having the professional responsibility without being present in the child's home. We suggest that this extended responsibility generates specific needs and preferences for the digital features a future eHealth intervention should have.

Parents found their responsibilities manageable and felt greater sense of control when they had adequate information and training, along with access to skilled health care professionals when contacting the hospital without these resources, they felt unsure. Two other studies describing the parents' experiences of insecurity and fear of overlooking something important when their child received home intravenous therapy suggested improvements to decrease worries, such as enhanced preparation, alignment of expectations, and accessible visually based and text-based information [3,34]. Another study also found that parental management of care for their child after surgery at home felt insecure, for example, they were unable to identify postoperative complications [35]. The information they had received was partially incomplete, and there was a gap in support at home, such as some health care professionals lacking the right knowledge to provide support contacted by parents [35]. Even though the parents in our study had some similar experiences, they were generally satisfied overall but would like to see digital features bolster existing support.

Another aspect of the extended responsibility was the health care professionals' concerns about their ability to clinically assess the child's condition and to know how the parent was managing home infusion therapy. These concerns challenged their professionalism and ethics. For them, the setup comprised nursing at a distance, causing them to worry about how to ensure quality of care. They suggested that various digital features could bridge this distance and had to correspond to the parents' needs. Both parents and health care professionals suggested monitoring, such as sending temperature data to the hospital and notifications to parents to remember tasks. These features would help meet their need for reassurance and increase their sense of safety. One study showed that participants valued notifications as reminders for activities to be carried out at home [36], while another study on designing a home monitoring system for children with a medically complex condition showed how parents preferred to track symptoms to identify early changes in their child's health that could lead to an appropriate intervention [37]. However, parents in our study also worried that they would feel pressured to provide more monitoring and data than they could manage. As a result, adjusting the amount of monitoring and continuously assessing how parents manage at home is important to avoid increased caregiver stress.

The suggestions parents and HCPs provided in our study are comparable with the study by Nkoy et al [37] on the needs of caregivers for designing a home monitoring system for children with a medically complex condition. The parents wanted a mobile health tool that included features to track symptoms and report their child's symptoms that was user friendly, in addition to having the ability to report interventions provided at home, have direct access to hospital through text messaging, and real-time sharing of data, not to mention the capacity to upload a photo or video for the health care professionals [37]. Two studies in which parents managed nursing care for children after surgery or born prematurely developed a successful eHealth tablet for the aforementioned reasons [17,38]. The parents were given an eHealth tablet before their child was discharged from a highly specialized department and that allowed them chat, make video calls, send photos, write daily reports, and get feedback from health care professionals, which facilitated early detection of complications. These features provided support and easy access to communication with health care professionals, creating a sense of security that the parents highly appreciated [17,38]. Due to similarities with our study, this suggest that a corresponding eHealth intervention could support the families and health care professionals in our study.

However, the health care professionals were also concerned that digital features might exacerbate the distance between them

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and the family, which is in line with a study on mobile health clinic appointments on parenteral nutrition at home done through a tablet [39]. Parents and health care professionals were very satisfied with how convenient and easy communication was, but the health care professionals reported that the inability to make accurate clinical assessments using the tablet was a significant challenge [39]. Research also shows that another concern is that telemedicine may depersonalize the patient and clinician relationship due to a lack of in-person interaction [11,40]. These key concerns must be taken into consideration when developing an eHealth intervention and will be explored further in the subsequent studies of the development and evaluation of the intervention in this research project.

Another concern was the reservations health care professionals had regarding workflow and setting, for example, how to organize and assess incoming data and chats at all times of day. Furthermore, organizational issues like maintaining confidentiality had to be considered when doing planned and unplanned video consultations. The study with the eHealth tablet showed that parents felt they had to wait too long to receive answers or feedback from health care professionals at the hospital [17]. Another study reported that clinicians emphasized the importance of having clear guidelines for scheduling and use of telemedicine in pediatric emergency settings [11]. Finally, a systematic review on factors concerning the success and failure of eHealth interventions also showed how workflow caused several barriers to success [41]. Accordingly, it is important to consider the needs of health care professionals, as motivating them to use telehealth can otherwise be challenging [42,43].

The extended responsibility that home infusion therapy entails emphasizes the importance of adjusting information and training, in addition to managing the capacity and needs of the individual child and parents. The parents' mental resources varied during their child's treatment, and research shows how parents obtain and act differently regarding health-related information concerning their child [35,44]. Both parents and health care professionals suggested that digital features could support the individualized aspects as the parents could, when necessary, repeat information and training, solve problems, and receive guidance. In addition, the parents and health care professionals in our study were preoccupied with sharing their responsibility with others to avoid distorting the amount of caregiving placed on one parent. Studies show that telemedicine can address these issues, by communication in greater alignment with the parents' own preferences and pace, not to mention that of families who live far from the hospital and wish to avoid the time and expense transportation and parking [17,38,45].

Strengths and Limitations

This study's strengths include its participatory design, which involved families and health care professionals at the beginning of the development process. The demographics and experiences of the sample of children with acute or long-term illness is also varied, just as both mothers and fathers were included, not to mention children to some extent. The child was invited to participate with their parent, and 13 children were present at the interview, 2 of whom participated actively. However, separate interviews would improve our understanding of the child's needs since the parent may withhold experiences and opinions due to the child's presence. Age-specific methods could have been used to involve and interview children, which would have provided additional insights into their unique needs and preferences. Children will be involved and interviewed in the evaluation study of this research project. The study is conducted in a specific geographic and health care setting, which may limit the generalizability of the findings to other countries and settings with different health care systems.

Data were collected during the early phase of the COVID-19 pandemic, and video consultations and other telehealth options were not used at the department on a regular basis at that time. This may have influenced participants' perceptions of eHealth and impacted the results in the sense that their technology readiness was limited. Since then, the use of telehealth has increased extensively in Denmark and abroad, perhaps causing our findings to appear obvious.

Conclusions

Our study highlights the need parents and health care professionals have for increased safety and easier access to communication when receiving and providing home infusion therapy. Their needs and preferences corresponded with each other, and they suggested key digital features for a pediatric eHealth intervention to provide consistent knowledge, skills, and problem-solving during home infusion therapy. The study emphasizes the need to increase access to home infusion therapy by using digital features, and our findings can provide clarity in terms of developing an eHealth intervention to support pediatric home infusion therapy tailored to individual needs.

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Conflicts of Interest

None declared.

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Multilevel Factors and Indicators of Atypical Neurodevelopment During Early Infancy in Japan: Prospective, Longitudinal, Observational Study

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Abstract

Background: The early identification of developmental concerns requires understanding individual differences that may represent early signs of neurodevelopmental conditions. However, few studies have longitudinally examined how child and maternal factors interact to shape these early developmental characteristics.

Objective: We aim to identify factors from the perinatal to infant periods associated with early developmental characteristics that may precede formal diagnoses and propose a method for evaluating individual differences in neurodevelopmental trajectories.

Methods: A prospective longitudinal observational study of 147 mother-child pairs was conducted from gestation to 12 months post partum. Assessments included prenatal questionnaires and blood collection, cord blood at delivery, and postpartum questionnaires at 1, 6, and 12 months. The Modified Checklist for Autism in Toddlers (M-CHAT) was used to evaluate developmental characteristics that might indicate early signs of atypical neurodevelopment. Polychoric or polyserial correlation coefficients assessed relationships between M-CHAT scores and longitudinal variables. L2-regularized logistic regression and Shapley Additive Explanations predicted M-CHAT scores and determined feature contributions.

Results: Twenty-one factors (4 prenatal, 3 at birth, and 14 postnatal) showed significant associations with M-CHAT scores (adjusted *P* values<.05). The predictive accuracy for M-CHAT scores demonstrated reasonable predictive accuracy (area under the receiver operating characteristic curve=0.79). Key predictors included infant sleep status after 6 months (nighttime sleep duration, bedtime, and difficulties falling asleep), maternal Kessler Psychological Distress Scale scores, and Mother-to-Infant Bonding Scale scores after late gestation.

Conclusion: Maternal psychological distress, mother-infant bonding, and infant sleep patterns were identified as significant predictors of early developmental characteristics that may indicate emerging developmental concerns. This study advances our

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understanding of early developmental assessment by providing a novel approach to identifying and evaluating early indicators of atypical neurodevelopment.

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KEYWORDS

early developmental signs; neurodevelopmental screening; risk factors; prediction; early intervention; longitudinal study

Introduction

Early identification of neurodevelopmental disorders and timely intervention are crucial for optimizing developmental outcomes in children [1]. Children exhibit considerable individual differences in their developmental trajectories during the first year of life, particularly in preverbal social behavior skills [2]. These differences have emerged as crucial areas of study in neurodevelopmental research, as some behavioral characteristics observed during infancy may represent early indicators of developmental concerns [3-5]. Similar to how the concept of mild cognitive impairment has facilitated early intervention in preclinical stages of dementia [6], identifying early indicators of developmental concerns may enable more timely and effective support strategies. However, the complex nature of early development, with its inherent variability and multiple influencing factors, has made it challenging to identify and interpret these early indicators reliably.

Multiple factors influence early childhood neurodevelopment, including prenatal conditions such as maternal immune activation [7], stress [8], and nutritional status, as well as postnatal factors including parental depression [9,10] and early life experiences [11]. Recent research has also highlighted the importance of biological factors such as cytokine profiles [12-14] and sleep-wake rhythms [15-18] in early neurodevelopment. While these factors have been studied individually, their complex interactions across time and their cumulative impact on neurodevelopmental trajectories remain poorly understood.

This study is an exploratory longitudinal investigation conducted in Japan, following mothers and children from the perinatal period (20 weeks of gestation) to the end of infancy (12 months of age). Using an innovative explainable artificial intelligence methodology, we aimed to visualize and analyze how various longitudinal factors interact to influence individual neurodevelopmental trajectories during infancy. Specifically, we assessed preverbal social behavior skills at 12 months of age as potential early indicators of developmental concerns using the Modified Checklist for Autism in Toddlers (M-CHAT) [3,5], and systematically evaluated how multiple observed factors throughout the first year of life contributed to these developmental characteristics. This approach enables a comprehensive understanding of the temporal dynamics and relative importance of various factors in shaping early neurodevelopmental trajectories, potentially identifying key time points and factors for early intervention.

Methods

Recruitment

This study is part of an ongoing multicenter Japanese longitudinal research conducted by 6 collaborating institutions—namely, Kyushu University Graduate School of Medicine, Kagawa University School of Medicine, Tohoku University Graduate School of Medicine, Kyoto University School of Medicine, Fukuoka City Children's Hospital, and RIKEN. Pregnant women were recruited between October 2018 and June 2020 at 5 of the collaborating institutions (excluding RIKEN). Overall, 200 women who fulfilled the inclusion criteria (aged ≥20 years, pregnant with a gestational period of less than 26 completed weeks, and fetus in stable condition) agreed to participate. The exclusion criteria were the requirement for proxy consent or the inability to provide voluntary consent. These criteria were established by the Ethical Guidelines for Medical and Health Research Involving Human Subjects to ensure that severe comorbidities or extreme factors would not influence the results of this study. Participants were followed up by visiting the affiliated facilities at midgestation (24 - 26 weeks), late gestation (34 - 38 weeks), at birth, and 1 month post partum. Their children were enrolled at birth and followed up by mailing questionnaires at 1, 6, and 12 months of age. By November 2022, a total of 147 participants and their children had completed the 12-month follow-up. Two patients were excluded due to meeting the exclusion criteria for chromosomal abnormalities: 1 with trisomy 21 and another with an unspecified chromosomal abnormality. The third excluded patient was born at 25 weeks' gestation weighing 734 g, thus meeting both the criteria for very low birth weight (<1000 g) and extreme preterm birth (<30 weeks). These 3 cases were consequently removed from the study population. This study was prospectively registered in the UMIN Clinical Trials Registry (UMIN000034837) on November 9, 2018. While registered in a clinical trial registry, this research is an exploratory study, not a clinical trial. It uses nonpredefined analytical methods, which distinguishes it from traditional clinical trials with preset end points and analysis plans. The registration was carried out for transparency, despite the exploratory nature precluding a detailed prespecified analysis plan. This study was reported according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

Maternal Assessment

Peripheral blood collected at mid- and late gestation and cord blood at birth was used to measure levels of 1,25-dihydroxyvitamin D, 25-hydroxyvitamin D, melatonin, and cytokines (interleukin [IL]-17A, IL-10, IL-1β, IL-6, and tumor necrosis factor). The participating mothers completed a series of questionnaires at mid- and late gestation and at 1 month

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post delivery (Multimedia Appendix 1). Maternal hematological biomarkers (vitamin D, melatonin, and cytokines) were measured from blood samples collected during prenatal check-ups and from umbilical cord blood at delivery. While prenatal check-ups typically occur during daytime hours, we did not standardize the exact timing of blood collection. Similarly, as birth times vary unpredictably, umbilical cord blood collection times were inconsistent across subjects. Maternal sleep status was evaluated using the Pittsburgh Sleep Quality Index [19] to assess the quality of sleep and the 3D Sleep Scale (3DSS) [20] to assess sleep regularity (the "sleep phase" item). The Edinburgh Postnatal Depression Scale (EPDS) [21] and Kessler Psychological Distress Scale (K6) [22] were used to assess depression and anxiety disorders, respectively, during pregnancy and post partum. The late gestation questionnaire also included the Autism-Spectrum Quotient Japanese short version (AQ-J-10) [23]. At 1 month post partum, the Japanese version of the Mother-to-Infant Bonding Scale (MIBS-J) [24] was used to assess the mothers' feelings toward their babies.

Infant Assessment and Outcomes

When the children were 1, 6, and 12 months of age, mothers completed questionnaires regarding the children's sleep status (Multimedia Appendix 2). To assess early developmental characteristics in infants, we focused on the acquisition of standard preverbal social behavioral skills and the presence of behaviors commonly associated with autism spectrum disorder (ASD). Specifically, we administered the Japanese version of the M-CHAT at 12 months of age to systematically evaluate these early developmental characteristics. The M-CHAT—a parent-completed dichotomous questionnaire designed for children aged 16 - 30 months—is an effective primary screening tool for ASD and other developmental concerns in the general population [3,5]. In our study, we aimed to identify children showing potential developmental concerns at an earlier stage, specifically at 12 months of age. To achieve this, we developed a unique 10-item version of the M-CHAT, informed by age-specific achievement rates observed in a separate observational study of the general Japanese population. Given that prelinguistic social behaviors vary significantly with age, we included in our analysis 4 age-independent ASD-specific behavioral abnormalities (Q11, Q18, Q20, and Q22) and 6 prelinguistic social behaviors (Q1, Q2, Q4, Q10, Q12, and Q14) that are reported to be consistently achieved by 12 months of age in the general population [4]. The items included were as follows: (Q1) "enjoying being swung," (Q2) "interest in other children," (Q4) "enjoying peek-a-boo," (Q10) "eye contact," (Q11) "oversensitive to noise," (Q12) "response to smile," (Q14) "response to name," (Q18) "unusual finger movement," (Q20) "wonder if deaf," and (Q22) "stares at nothing." Children who fulfilled any of the 10 total M-CHAT items (M-CHAT score ≥1 point) were defined as the M-CHAT positive group.

Statistical Analysis

Descriptive statistics were used to investigate the characteristics of the participating mothers and their infants. Continuous variables—listed as the median and IQR—included maternal age, 1,25-dihydroxyvitamin D, 25-hydroxyvitamin D, melatonin, IL-17A, IL-10, IL-1β, IL-6, tumor necrosis factor, 3DSS (phase), Pittsburgh Sleep Quality Index global score (PSQIG), EPDS, K6, AQ-J-10, MIBS-J, and umbilical artery blood pH. Categorical variables—listed as frequencies and percentages—included the child's sex, maternal smoking history, educational level of parents, annual household income, gestational age at birth, birth weight, Apgar score at 5 minutes, delivery type, answers to sleep-related questions at each period, and the M-CHAT score. Thereafter, the correlation coefficients between the variables were calculated considering the aforementioned categorical variables and 3DSS (phase), PSQIG, EPDS, K6, AQ-J-10, and MIBS-J as ordinal variables. Polyserial correlation coefficients were computed for the relationships between ordinal and continuous variables; further, polychoric correlation coefficients were computed for the relationships between ordinal variables. These polychoric and polyserial correlation coefficients, as well as Pearson correlation coefficients for continuous variable pairs, were calculated using the lavCor function from the *lavaan* package in R software (R Foundation). Wald tests were performed to assess the statistical significance of each correlation. To address the issue of multiple comparisons arising from these correlation tests, false discovery rate correction [25] was subsequently applied to the resulting *P* values. This was performed using the p.adjust() function in R software. Adjusted *P* values (p.adjust) of <.05 were considered statistically significant.

Correlation Analysis

In this study, the relationships between variables affecting the M-CHAT score were represented by network structure. The nodes were variables that showed significant polychoric or polyserial correlations with the M-CHAT score ($|r|\geq.2$, p.adjust <.05). The nodes were arranged according to the data collection period.

Classification Model for the M-CHAT Positive Group

We implemented a classification model using a logistic regression algorithm with potential regularization in the scikit-learn Python package (version 3.1.2) to predict the M-CHAT positive group in infants aged 12 months. We used features of maternal and child demographics, laboratory values, and questionnaire results from the midgestation to 12 months post partum that exhibited a significant correlation (p.adjust<.05) and $|r|\geq.2$ with the M-CHAT score. This model, overall, used 20 features. The data obtained at 12 months of age had missing values, which were completed with missForest—a modern method based on random forests that efficiently addresses missing data imputation among multivariate data without cross-validating with the test data [26]. This method involves inherent randomness, potentially leading to variability in imputed datasets. In our study, we did not set a fixed seed during the missForest imputation. The mother-child dataset was divided into a training set (N=100) for training the prediction model and a test set (N=44) for evaluating the model's performance by using the train_test_split function in scikit-learn. To address the imbalanced nature of our dataset, we used the "stratify" parameter in the train_test_split function, specifying the binary M-CHAT outcome (positive or negative) as the stratification variable. This approach ensured that the distribution of M-CHAT

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outcomes was maintained across both the training and test sets. The models were optimized by adapting a grid search method for the hyperparameter "C (regularization strength; 10^{-5}, 10^{-4}, 10^{-3}, 10^{-2}, 10^{-1}, 1, 10, 10^{2}, 10^{3}, 10^{4}, or 10^{5})," "penalty (norm of regularization; L1, L2, elastic net, or none)," and "solver (algorithm in optimization; "newton-cg," "lbfgs," "liblinear," "sag," "saga")." When specifying elastic net as the penalty, we validated by varying the l1_ratio from 0 to 1 in steps of 0.1. The performance of the logistic regression model was evaluated on the test set after ensuring missing data imputation. The model outputs class probabilities to predict the M-CHAT positive (M-CHAT score≥1) group. The optimal threshold for the model was determined by the Youden index.

The model's performance was evaluated using the area under the receiver operating characteristic and precision-recall curves. The relative importance of each feature for predicting M-CHAT scores was examined and visualized using Shapley Additive Explanations (SHAP) [27]. SHAP is a model-agnostic, game-theoretic, unified method that computes a Shapley value to account for each feature's contribution to a particular forecast. SHAP values are computed using an additive feature attribution method to approximate the Shapley value of the model's conditional expectation function. LinearExplainer [28] was used to calculate SHAP values for the logistic regression model. For the decision plotting that simulates the M-CHAT prediction pathway of each sample using SHAP, we specifically used samples with higher M-CHAT scores (M-CHAT scores 2‑4) within the M-CHAT positive group to focus on cases that might represent early developmental concerns.

Data analysis was performed using the open-source software R (version 4.1.2) and Python (version 3.8.5; Python Software Foundation). The correlation analysis results were visualized using Cytoscape (version 3.9.1; Cytoscape Consortium).

Ethical Considerations

This study was approved by the Ethics Review Committee on Research Involving Human Subjects at Doshisha University (No. 22063) and, subsequently, by the Ethics Review Committees at each affiliated institution (No. 22064). Written informed consent was provided by each pregnant woman at the time of the visit at the affiliated facility. Data was deidentified immediately upon collection. A secure, separate database is maintained to connect study IDs with participant details, accessible only to authorized personnel. The research description clearly states the following points: (1) women are free to participate in the research and withdraw their consent, (2) refusal of participation in the research has no implications per disadvantages in medical care, and (3) participation in the research entails no increased cost burden or rewards.

Results

Description of the Sample

The characteristics and results for the 144 mother-child pairs included in the final analysis are presented in Table 1 and Multimedia Appendix 2. These maternal background and perinatal data were obtained by combining information from medical records and parents' reports up to the first month postpartum check-up. The median maternal age was 36 (IQR 32-29) years, and 3 (N=144, 2%) mothers had a smoking history during their current pregnancy. The most prevalent educational level for both parents was a university degree (48/144, 33% mothers and 64/144, 44% fathers). Annual household incomes varied among the participants, with the most common bracket being 4 to 6 million yen (approximately US $36,000 to US $56,000, based on a currency exchange rate of US $1=JP ¥107-112 that was applicable during the study period) per year, reported by 46 (N=142, 32% of the population) families. Of the children, 86 (N=144, 60%) were female, 129 (N=144, 90%) were born at 37 weeks or later, and 3 (N=144, 2%) were born between 30 and 33 weeks. Birth weight ranged from 3000 g to 3999 g in 122 (N=144, 85%) children; all 5-minute Apgar scores were 7 (N=144) or higher. The median umbilical artery blood gas pH was 7.29 (IQR 7.26‑7.33). The delivery type was vaginal in 87 (N=144, 60%) cases (Table 1). Throughout the pregnancy, the 3DSS (phase) median score was 10 (IQR 9-12). From midgestation to 1-month postpartum, PSQIG exhibited an increasing trend with median scores of 5 (IQR 3-7), 6 (IQR 4.5-9), and 8 (IQR 6-10), respectively. This indicates that mothers' sleep conditions tended to worsen during the period up to 1 month after childbirth. The median EPDS scores were relatively low across all 3 time points: 3 points in midpregnancy, 4 points in late pregnancy, and 2 points at 1 month post partum. Similarly, K6 scores remained low at 1, 2, and 1, respectively. The median AQ-J-10 score at late gestation was 2 (IQR 1-3), and the median MIBS-J score at 1 month post partum was 1 (IQR 0-3; Multimedia Appendix 2).

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Table . Demographic data for the 144 mother-child pairs included in the final analysis.

Characteristics		Longitudinal group
Maternal age (years; N=144), median (IQR)		36 (32-39)
Child's sex (N=144), n (%)		
	Female	86 (60)
	Male	58 (40)
Maternal smoking status (N=144), n (%)		
	Never or exsmoker	141 (98)
	Current smoker	3 (2.1)
Maternal education (N=144), n (%)		
	Junior high	3 (2.1)
	High school	28 (19)
	Technical college	5 (3.5)
	College	33 (23)
	Junior college	17 (12)
	University	48 (33)
	Master's degree	10 (6.9)
Paternal education (N=144), n (%)		
	Junior high	7 (4.9)
	High school	37 (26)
	Technical college	3 (2.1)
	College	15 (10)
	Junior college	0 (0)
	University	64 (44)
	Master's degree	18 (12)
Annual household income (JP ¥[a]; n=142), n (%)		
	<2 million	1 (0.7)
	2 - 3.9 million	29 (20)
	4 - 5.9 million	46 (32)
	6 - 7.9 million	32 (23)
	8 - 9.9 million	19 (13)
	10 - 11.9 million	11 (7.7)
	12 - 14.9 million	1 (0.7)
	15 - 19.9 million	3 (2.1)
Gestational age at birth (wk; N=144), n (%)		
	30 - 32	3 (2.1)
	33 - 36	12 (8.3)
	≥37	129 (90)
Birth weight (g; N=144), n (%)		
	<1500	1 (0.7)
	1500 - 2999	20 (14)
	3000 - 3999	122 (85)
	≥4000	1 (0.7)
Apgar score at 5 min (N=144), n (%)		

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Characteristics		Longitudinal group
	7	1 (0.7)
	8	16 (11)
	9	116 (81)
	10	11 (7.6)
Umbilical artery blood pH (n=140), median (IQR)		7.29 (7.26 - 7.33)
Type of delivery (N=144), n (%)		
	Vaginal	87 (60)
	Cesarean	57 (40)

[a]A currency exchange rate of 107-112 JP ¥=US $1 was applicable during the study period.

The Distribution of the M-CHAT Score Among Children Aged 12 Months

The distribution of the M-CHAT scores among the 144 children aged 12 months was as follows: 105 (73%) children scored 0, 30 (21%) scored 1, 5 (3.5%) scored 2, 3 (2.1%) scored 3, and 1 (1%) scored 4. All 6 preverbal social behavior items (Q1, Q2, Q4, Q10, Q12, and Q14) used to score the M-CHAT in this study exhibited achievement rates of 95% or higher. Specifically, for the question on smiling response (Q12), only 1 parent reported that their child did not smile back when smiled at. Similarly, regarding concerns of hearing impairment (Q20), only 1 parent expressed concern that their child might be enduring hearing difficulties. Of the 39 children who scored 1 or more, 29 (74%) received scores for age-independent and ASD-specific behaviors (particularly Q11, Q18, and Q22; Multimedia Appendix 3).

Interrelationships Between M-CHAT Score and Each Variable

To examine the relationship between the M-CHAT score and other variables during each period, polychoric or polyserial correlation coefficients were calculated and presented in a heatmap (Figure 1). Using the correlation heatmap, variables that significantly correlated with the M-CHAT score were identified. The M-CHAT score was positively correlated with maternal serum melatonin levels in midgestation and cord blood IL-1β; the M-CHAT score showed a weak positive correlation with cord blood IL-10 (r=.18). By contrast, the M-CHAT score exhibited a negative correlation with maternal serum IL-1β levels in midgestation and cord blood IL-6 levels. The M-CHAT score was positively correlated with EPDS and K6 scores in late gestation and with K6 and MIBS-J scores at 1 month post partum. For infant sleep questions, the M-CHAT score was significantly correlated with shorter sleep duration, bedtime, and difficulty in falling asleep (moodiness and required time). Detailed correlation coefficients are presented in Multimedia Appendix 4.

Correlation analysis was performed to determine the interrelationships among factors potentially influencing early developmental characteristics as assessed by M-CHAT scores (Multimedia Appendix 5). Strong positive correlations (r≈1.0) were found between cord blood IL-6 and IL-1β levels and between weekday and holiday bedtimes of children aged 6 months. Nodes at late gestation, cord blood, and 1 month post partum were strongly and positively correlated with each other within the same observation period. In children aged 6 months, a negative correlation was found between “nighttime sleeping hours” and “bedtime,” and a positive correlation was found between “staying awake for ≥1 hour at nocturnal awakening” and “takes long (≥1 hour) to fall asleep.” A negative correlation was found between IL-1β levels in the midgestation period and “short sleep duration” in children aged 1 month; a positive correlation was observed between melatonin levels in midgestation and “takes long (≥1 hour) to fall asleep” in children aged 6 months. K6 and EPDS scores in the late gestation were positively correlated with K6 scores in 1 month post partum and also positively correlated with “staying awake for ≥1 hour at nocturnal awakening” in children aged 6 months. “Wakes up several times at night, does not sleep and takes several hands” in children aged 1 month was positively correlated with “takes long (≥1 hour) to fall asleep” in children aged 6 months. “Bedtime” among children aged 6 months was positively correlated with “bedtime on holidays” among children aged 12 months (Multimedia Appendix 5).

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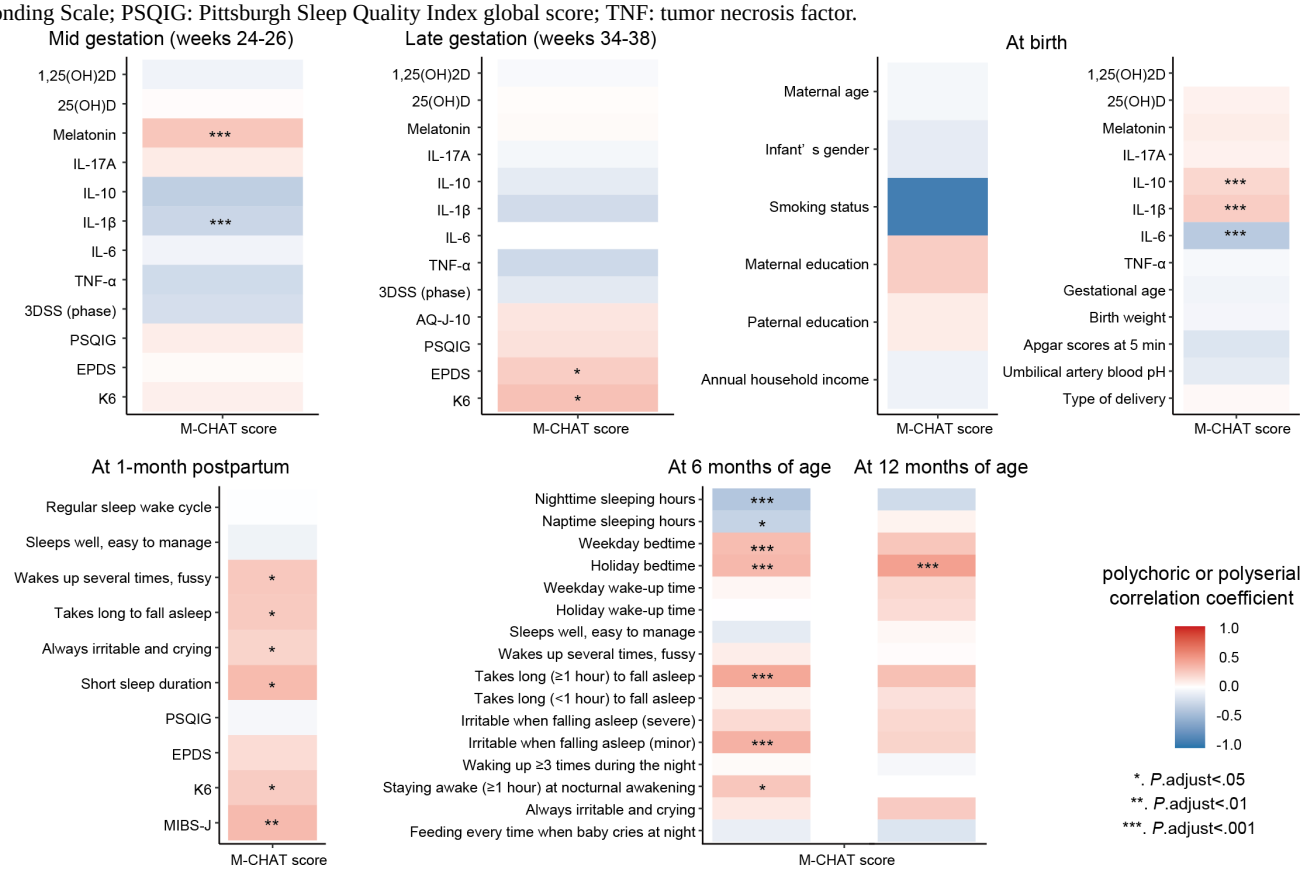
Figure 1. Heatmap of correlations between M-CHAT and each other variable. 1,25(OH)2D: 1,25-dihydroxyvitamin D; 25(OH)D: 25-hydroxyvitamin D; 3DSS: 3D Sleep Scale; AQ-J-10: Autism-Spectrum Quotient Japanese short version; EPDS: Edinburgh Postnatal Depression Scale; IL: interleukin; K6: Kessler Psychological Distress Scale; M-CHAT: Modified Checklist for Autism in Toddlers; MIBS-J: Japanese version of the Mother-to-Infant Bonding Scale; PSQIG: Pittsburgh Sleep Quality Index global score; TNF: tumor necrosis factor.



Assessment and Visualization of Factors Contributing to Early Developmental Characteristics

To assess longitudinal influences associated with early developmental characteristics as measured by M-CHAT scores, we conducted feature importance analysis using SHAP on a logistic regression model with L2 regularization ("C"=0.1, "penalty"="L2," "solver" = "liblinear," area under the receiver operating characteristic and precision-recall curves and the confusion matrix shown in Multimedia Appendix 6). The optimal threshold was determined by the Youden index to be 0.32. The logistic regression model attained reasonable predictive performance (area under the receiver operating characteristic curve=0.79, 95% CI 0.62 - 0.95; Multimedia Appendix 6). While the point estimate falls within the acceptable range (0.7 - 0.8), the CI extends below 0.7, indicating some uncertainty in its discriminative ability. The model's utility should therefore be interpreted within the context of the dataset and application. The SHAP beeswarm plot (Figure 2A) assesses the contribution of each feature of the total sample to the model. The order of the feature values obtained by SHAP and the contribution of each feature is high, and this ranking is relative, for example, it does not indicate which rank is particularly important. When examining variables in order of their contribution strength, we found high contributions from bedtime at 12 months, nighttime sleep duration and irritability at bedtime at 6 months, and maternal K6 and MIBS-J scores during late pregnancy and 1 month post partum. Specifically, later bedtimes, shorter nighttime sleep duration, higher K6 and MIBS-J scores, and irritability at bedtime promoted classification into the M-CHAT positive group. The characteristics that moderately contributed to such a classification were variables related to the sleep status of children aged 1-6 months and maternal melatonin levels. The 6 characteristics with the lowest influence were predominantly cytokine levels, EPDS score, "wakes up several times at night, does not sleep, and takes several hands" in children aged 1 month, and bedtime for children aged 6 months. The SHAP decision plot (Figure 2B) simulates the decision pathway for predicting classification into the M-CHAT positive or negative (M-CHAT score=0) groups in the order of observation period. All 9 randomly sampled cases with M-CHAT scores of 0 were correctly predicted to be the M-CHAT negative group. In some M-CHAT positive cases, the predictive risk began to increase owing to the deterioration of the maternal K6 and MIBS-J scores and infant sleep status for children aged 6 months. Conversely, there were cases in which the predictive risk did not change for maternal factors but increased rapidly for factors related to the child's sleep after 6 months of age.

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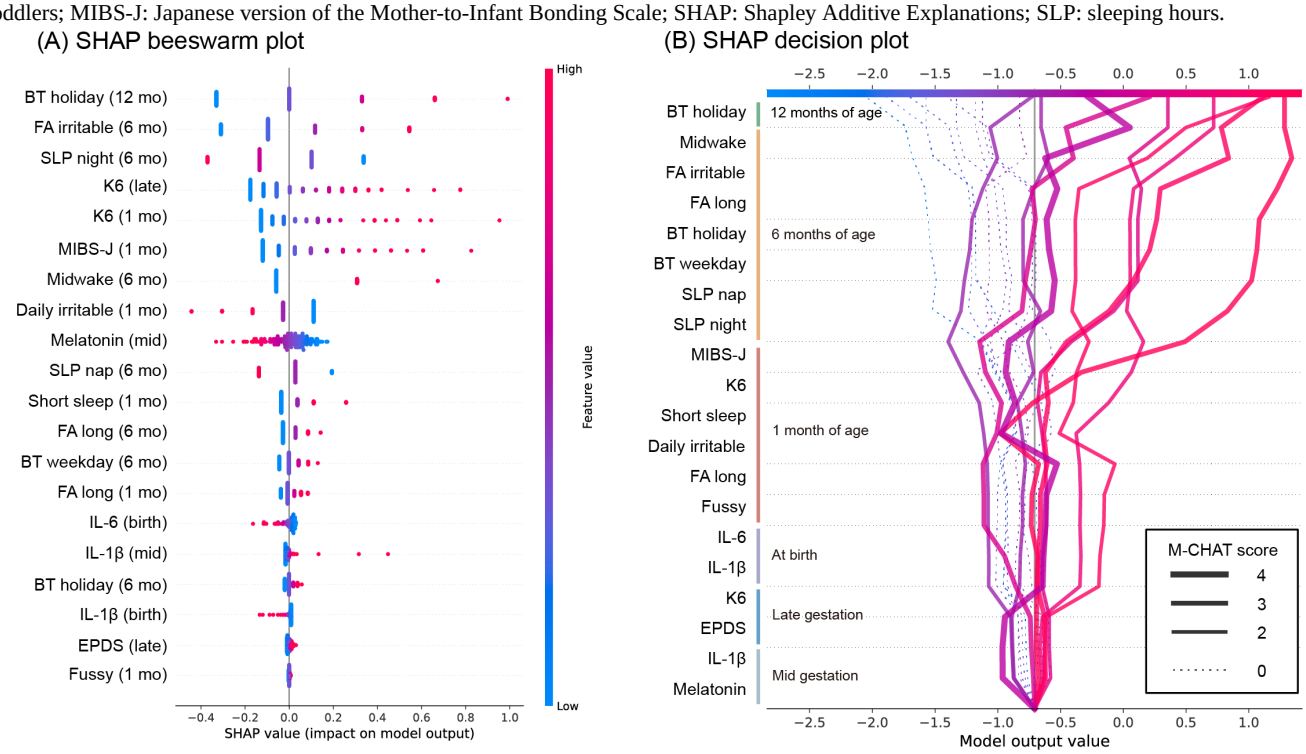
Figure 2. (A) SHapley Additive exPlanations (SHAP) beeswarm plot of the logistic regression model. (B) SHAP decision plot of 9 samples with an M-CHAT score of 0 (random sampling) and 9 samples with an M-CHAT score of 2–4, for a total of 18 samples. BT: bedtime; EPDS: Edinburgh Postnatal Depression Scale; FA: fall asleep; IL: interleukin; K6: Kessler Psychological Distress Scale; M-CHAT: Modified Checklist for Autism in Toddlers; MIBS-J: Japanese version of the Mother-to-Infant Bonding Scale; SHAP: Shapley Additive Explanations; SLP: sleeping hours.



Discussion

Temporal Dynamics of Early Developmental Characteristics: Individual Patterns and Contributing Factors

In recent years, the number of cases of neurodevelopmental disorders has increased rapidly, becoming a significant social concern. While genetic factors have been extensively studied, identifying genes that correlate with symptoms alone is insufficient to understand developmental mechanisms. The clarification of how environmental factors interact with genetic predisposition in the developmental process remains an urgent research priority [29].

In this study, we assessed early developmental characteristics through social behavior patterns and analyzed how these patterns emerge during infancy. The SHAP analysis provided a novel approach to assess and visualize how multiple longitudinal factors contribute to individual neurodevelopmental trajectories. Specifically, our analysis focused on cases showing elevated M-CHAT scores (2 - 4 points), including those exceeding the conventional ASD screening cutoff value (M-CHAT score of 3+). This analysis revealed distinct temporal patterns in the emergence of early developmental characteristics. Some cases showed an increased risk of M-CHAT positive classification during late gestation, primarily associated with elevated maternal K6 scores. Other cases demonstrated increased risk due to disrupted infant sleep patterns after 6 months of age. Additionally, we observed cases where substantial increases in K6 and Mother-to-Infant Bonding Scale (MIBS) scores at 1-month postpartum markedly elevated the predicted probability of M-CHAT positive classification.

These results indicate that early developmental characteristics associated with elevated M-CHAT scores emerge through several distinct dynamic patterns, involving multiple interacting factors. The SHAP methodology enabled the quantification of each factor's relative contribution to these patterns. Based on our findings, we suggest that targeted follow-up assessments focusing on maternal anxiety disorders in late gestation and infant sleep characteristics at 6 months—particularly sleep duration, bedtime, irritability upon falling asleep, and extended periods of wakefulness—may be particularly valuable for the early identification of developmental concerns.

Temporal Relationships Between Early Developmental Characteristics and Longitudinal Factors

Correlation analysis revealed that relatively strong correlations between factors within the same period were observed between similar factors such as maternal physical and mental status, sleep difficulties in children, and inflammatory cytokines. However, correlations between factors with different observation periods were more limited than correlations within the same period. Our analytical method does not pursue a causal relationship.

Early Sleep Difficulties as Indicators of Emerging Developmental Characteristics

Recent research has established clear interactions between sleep patterns and neurodevelopment in young children. During early brain development, sleep patterns and neural maturation progress in parallel, significantly influencing cognitive performance [16,17]. Notably, studies have demonstrated associations between infant sleep patterns and brain structure, including hippocampal volume [18]. Children who later receive

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neurodevelopmental disorder diagnoses often experience more persistent and complex sleep problems compared to their typically developing peers [30]. Several longitudinal studies have identified early sleep difficulties as potential risk indicators for diagnosis of later ASDs [18,30]. Specifically, shorter sleep duration, delayed sleep onset and wake times, and frequent midday awakenings have been associated with an increased likelihood of subsequent ASD diagnosis. The timing of sleep-related interventions appears crucial, with recommendations focusing on the period between 3 and 6 months of age, when circadian rhythms become established in the suprachiasmatic nucleus [15,31]. Our findings align with and extend this literature: M-CHAT scores at 12 months showed significant correlations with multiple sleep-related characteristics, including reduced sleep duration, later bedtime, and difficulties with sleep onset (including irritability and prolonged time to fall asleep). These results suggest that infants showing early signs of developmental concerns, as indicated by elevated M-CHAT scores, may already be experiencing sleep-related challenges. Early identification of these sleep patterns could provide opportunities for targeted interventions, potentially benefiting not only the infant's sleep and neurodevelopmental trajectory but also family functioning and overall cognitive outcomes.

Relationship Between Inflammatory Markers and Early Developmental Characteristics

Increasing evidence suggests that chronic inflammation plays a role in atypical neurodevelopment, although the underlying mechanisms remain unclear. For example, microglia, crucial for brain maturation and function, are increasingly recognized to play a decisive role in various developmental and cognitive conditions [32]. Microglia produce inflammatory mediators and reactive oxygen species, potentially leading to neuronal degeneration, white matter abnormalities, and decreased neurogenesis observed in conditions such as ASD or schizophrenia [32]. The secretion of signaling molecules and cytokines may promote crosstalk between microglia and astrocytes, leading to endothelial dysfunction and blood-brain barrier permeability impairment [33]. Multiple studies have reported increased concentrations of inflammatory cytokines such as IL-6 and IL-1β and a decrease in anti-inflammatory cytokines (IL-10 and transforming growth factor [TGF]-β) in the peripheral blood and cerebrospinal fluid of individuals with ASD [12,13,33]. The persistent elevation of these inflammatory cytokines may reflect ongoing inflammatory processes [14].

Maternal infections during pregnancy and early childhood are known to influence early development, and changes in cytokine profiles may be shaped by environmental exposures during prenatal and early childhood periods [32]. Typically, the maternal immune system shifts to a more tolerant state during pregnancy, characterized by a decrease in inflammatory cytokines and an increase in regulatory cytokines [12]. However, mothers whose children later receive neurodevelopmental diagnoses have been reported to have significantly higher levels of various inflammatory cytokines and chemokines, such as IL-1α, IL-4, IL-6, and interferon [IFN]-γ in serum during midpregnancy [34,35]. Studies have also reported alterations in melatonin secretion in individuals with ASD, particularly decreased secretion of melatonin and its metabolites at night and altered circadian rhythm [33]. Low maternal melatonin levels during pregnancy have been associated with an increased likelihood of subsequent ASD and intellectual disability diagnoses [36], although there is no consensus on this matter. Contrary to previous research, our study found associations between increased melatonin and decreased IL-1β and M-CHAT scores in midpregnancy. These associations were not observed in maternal blood in late pregnancy. Factors such as the intensity, timing, and duration of maternal inflammatory responses may be crucial for influencing the developing child's brain. Differences in sample processing and clinical sample variation may also contribute to these findings.

Higher levels of IL-1β in neonatal samples have been associated with an increased likelihood of ASD diagnosis [37]. Moreover, neonatal samples from infants later diagnosed with ASD showed decreased levels of many cytokines (IFN-γ, IL-2, IL-4, IL-6, and IL-10), suggesting reduced immune cell activity in the neonatal period [38]. Interestingly, consistent with previous studies, our analysis found significant correlations between increased IL-1β and decreased IL-6 in cord blood and M-CHAT scores. These results suggest 2 possibilities: first, the cytokine profile in umbilical cord blood samples may predict subsequent developmental characteristics similarly to neonatal samples; second, the M-CHAT assessment at 12 months may effectively identify early developmental concerns before formal diagnostic evaluations. However, these observed relationships between IL-1β and M-CHAT were derived using polychoric or polyserial correlation analysis, and statistical significance might be lost if other statistical methods accounting for outliers were applied. Given that these cytokine data showed very low predictive contribution to the model, and considering that IL-1β is a bioactive substance that can be unstable and challenging to measure in blood in clinical settings, the correlations found in this study should be interpreted with caution.

Maternal Psychological Well-Being as a Predictor of Early Developmental Characteristics

Focusing on maternal mental and physical status, it has been previously reported that persistent anxiety during pregnancy is significantly associated with ASD in children [8]; further, persistent depression is associated with developmental delay at 18 months [9]. Our study found correlations between K6, EPDS, and M-CHAT, consistent with previous reports. Notably, we identified a significant positive correlation between MIBS and M-CHAT scores at 1 month post partum. While previous studies have shown strong correlations between MIBS and EPDS from early postpartum through 12 months [10], our study is among the first to examine MIBS scores as an independent predictor of early developmental characteristics. Although enhanced parent-child bonding may not directly improve social functioning in children with ASD [39], our findings suggest that MIBS assessment may be valuable for the early identification of developmental concerns.

Our longitudinal analysis demonstrates that early postnatal maternal psychological measures—including emotional state (EPDS), psychological distress (K6), and MIBS—correlate with infant developmental characteristics as assessed by M-CHAT

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scores. These findings emphasize the importance of comprehensive maternal psychological monitoring in the postpartum period. Even when EPDS scores do not indicate clinical depression, attention to other maternal psychological indicators, particularly MIBS and K6 scores, may provide valuable insights for early developmental screening.

Limitations

This study has several limitations. First, the pathogeneses of neurodevelopmental disorders are multifactorial; therefore, the presence of unobserved confounding factors cannot be excluded when interpreting the findings of this study. The interrelationship of various sleep and psychological measures (Pittsburgh Sleep Quality Index, K6, MIBS, EPDS, etc) assessed at different time points may introduce potential biases. Parental ratings of child sleep status are inherently subjective and could be influenced by parents' own psychological stress or sleep issues, potentially affecting the results. Additionally, the collection and measurement of maternal and cord blood biomarkers lack standardized timing protocols and do not account for diurnal variations, necessitating consideration of potential measurement errors in the analysis.

Second, the sample size is small, and the results are preliminary. Future studies should validate these findings using larger samples. Only Japanese participants were included in this study, and no analysis of cultural and social influences due to racial or ethnic differences was conducted. Furthermore, there was considerable variation in the number of mother-child pairs recruited across study sites. While recruitment was not intentionally biased, potential disparities in research resources and physician-patient relationships among facilities may have influenced informed consent rates. Of note is that our longitudinal study may not be fully representative of the Japanese population.

Third, the use of M-CHAT scores at 12 months as an indicator of early developmental characteristics has inherent limitations. While M-CHAT is a validated screening tool, our assessment was based on parent-reported scoring, and due to the short observation period, we were unable to confirm subsequent neurodevelopmental diagnoses. In an ongoing study, we plan to assess ASD using the Kinder Infant Development Scale and Social Responsiveness Scale 2nd edition at 36 months of age.

Conclusions

Understanding the characteristics of early development and their predictors is essential for improving strategies for early detection and support of neurodevelopmental problems.

Our study demonstrates that a systematic analysis of multiple longitudinal factors can reveal important patterns in early development, particularly in preverbal social behaviors as assessed by M-CHAT scores at 12 months. The results indicate that early developmental characteristics are influenced by several key factors, particularly maternal-infant bonding, maternal anxiety, and infant sleep patterns. The temporal dynamics of these relationships suggest that monitoring specific combinations of factors—including maternal psychological well-being and infant sleep patterns—may enhance our ability to identify early signs of developmental concerns. Future studies with larger and more diverse population samples are needed to validate these findings and establish their generalizability for clinical practice.

Acknowledgments

We would like to dedicate this paper to our wonderful colleagues, Y Konishi and Kiyomi Tsukimori, who died during the production of this paper. KS, Y Konishi, and EK designed this study. AO, SI, Y Kasahara, KK, Y Kitadai, Y Kimura, Y Konishi, KN, HM, and SM collected the data. DK wrote the first draft of this paper and made revisions. DK, AO, TI, SO, AH, and EK collated and analyzed the data. All the authors edited this paper. This work was supported by the Japan Society for the Promotion of Science (JSPS) KAKENHI (grant JP21K02356 to AO, TI, and SM). This work has been supported by RIKEN Healthcare and Medical Data Platform Project.

Data Availability

The data and code that support the findings of this study are available from the corresponding author, EK, upon reasonable request. The data are not publicly available as it contains information that could compromise the privacy of research participants.

Conflicts of Interest

Y Kimura received collaborative research funding and patent royalties from Atom Medical Inc. All other authors declare that they have no conflicts of interest.

Multimedia Appendix 1
Maternal and infant assessments with questionnaires.
[DOCX File, 62 KB - pediatrics_v8i1e58337_app1.docx]

Multimedia Appendix 2
Characteristics of participants.
[DOCX File, 44 KB - pediatrics_v8i1e58337_app2.docx]

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Multimedia Appendix 3
Distribution of M-CHAT scores for 12-month-old children aged 12 months. M-CHAT: Modified Checklist for Autism in Toddlers.
[DOCX File, 98 KB - pediatrics_v8i1e58337_app3.docx]

Multimedia Appendix 4
Correlation between the M-CHAT scores and each variable. M-CHAT:Modified Checklist for Autism in Toddlers.
[DOCX File, 32 KB - pediatrics_v8i1e58337_app4.docx]

Multimedia Appendix 5
Correlation analysis.
[DOCX File, 555 KB - pediatrics_v8i1e58337_app5.docx]

Multimedia Appendix 6
Logistic regression model with L2 regularization predicting the DD positive group. DD: developmental diversity.
[DOCX File, 269 KB - pediatrics_v8i1e58337_app6.docx]

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Abbreviations

3DSS: 3D Sleep Scale
AQ-J-10: Autism-Spectrum Quotient Japanese short version

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ASD: autism spectrum disorder
EPDS: Edinburgh Postnatal Depression Scale
IFN: interferon
IL: interleukin
K6: Kessler Psychological Distress Scale
M-CHAT: Modified Checklist for Autism in Toddlers
MIBS: Mother-to-Infant Bonding Scale
MIBS-J: Japanese version of the Mother-to-Infant Bonding Scale
p.adjust: adjusted *P* value
PSQIG: Pittsburgh Sleep Quality Index global score
SHAP: Shapley Additive Explanations
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology
TGF: transforming growth factor

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Original Paper

Enhancing Access to Mental Health Services for Antepartum and Postpartum Women Through Telemental Health Services at Wellbeing Centers in Selected Health Facilities in Bangladesh: Implementation Research

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Abstract

Background: Globally, 10% of pregnant women and 13% of postpartum women experience mental disorders. In Bangladesh, nearly 50% of mothers face common mental disorders, but mental health services and trained professionals to serve their needs are scarce. To address this, the government of Bangladesh's Non-Communicable Disease Control program initiated "Wellbeing Centers," telemental health services in selected public hospitals.

Objective: This study examines implementation outcomes, including adoption, accessibility, acceptability, feasibility, usefulness, need, experience, perception, and expectations of the Wellbeing Centers, with a focus on antepartum and postpartum women.

Methods: Between January 2023 and August 2024, we interviewed 911 antepartum and postpartum women receiving mental health services and 168 health care providers at 6 Wellbeing Centers in 4 districts in Bangladesh. Data collection involved both quantitative and qualitative methods. Implementation outcomes were measured following the World Health Organization's implementation research framework. Depression and anxiety symptoms were assessed using the Patient Health Questionnaire-9 and Generalized Anxiety Disorder-7 questionnaires. Descriptive statistics and adjusted odds ratios (aORs) with 95% CIs were used to evaluate the implementation outcomes. Qualitative information was obtained through in-depth interviews and key-informant interviews.

Results: Almost all health care providers (165/168, 98.2%) reported that the Wellbeing Centers were feasible to implement in their health facilities; however, about half (84/168, 50%) felt that trained staff to operate them were insufficient. Almost all women agreed that the Wellbeing Centers were acceptable (906/911, 99.8%), useful (909/911, 99.8%), and enhanced access to mental health care (906/911, 99.5%). Patients visiting district-level hospitals had higher odds of access (aOR 1.5, 95% CI 1.1-2.0) to Wellbeing Centers. Moreover, 77.4% (705/911) of women experienced depression symptoms, and 76.7% (699/911) experienced

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anxiety symptoms. About 51.8% (472/911) experienced tiredness or lack of energy, 50.9% (464/911) felt nervous, anxious, or on edge, 57.2% (521/911) felt worried, and 3.8% (35/911) had suicidal ideation almost every day. Patients visiting district hospitals had higher odds (aOR 2.6, 95% CI 1.8-3.78) of depression and anxiety symptoms compared to the patients visiting subdistrict-level hospitals. Decreasing trends in Patient Health Questionnaire-9 scores (from mean 14.4, SD 0.47 to mean 12.9, SD 0.47) and Generalized Anxiety Disorder-7 scores (from mean 13.3, SD 0.49 to mean 12.5, SD 0.48) between 2 counseling sessions indicated improved mental health in the antepartum and postpartum women. The Wellbeing Centers' services were appreciated for their privacy and being free and accessible. However, stigma, postpartum illness, and long waiting times prevented some women from using these services.

Conclusions: To our knowledge, this is the first implementation research assessing telemental health in public health facilities involving trained psychologists and psychiatrists. Our study highlighted the increased accessibility, feasibility, acceptability, and utility of Wellbeing Centers for antepartum and postpartum women in Bangladesh, supporting their scale-up in similar settings.

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KEYWORDS

Wellbeing Centers; antepartum; postpartum; depression; anxiety; implementation

Introduction

Background

Maternal mental health problems are common during pregnancy and after birth [1]. It is recognized as a global public health issue, as approximately 10% of antepartum and 13% of postpartum women experiencing some sort of mental health disorders [2]. The prevalence of maternal common mental disorders is high (49%) in Bangladesh, which underscores a need to screen for depression and anxiety symptoms during pregnancy and postpartum period [3,4]. Around 1 in 5 women experience depressive symptoms during pregnancy, and around 1 in 3 women experience anxiety in rural Bangladesh [4]. In a different study, postpartum women in rural Bangladesh reported that 11% had depressed symptoms, 35% had anxiety symptoms, and 3.4% had both depression and anxiety symptoms [5]. A recent study suggested that postpartum depression symptoms have been more common among impoverished rural mothers during the shutdown in Bangladesh [6-8].

Adverse Effects of Maternal Mental Disorders During the Antepartum and Postpartum Periods

Pregnant women with low education, history of economic difficulties, poor marital relationships, family history of any common mental disorder, poor social and partner support, bad obstetric history, current or previous exposure to violence, preference to have a male child, history of abortions, and disturbed family environment are more likely to report any kind of antepartum and postpartum mental disorders [4,9-13]. Maternal depression may cause negative health-related behaviors and adverse outcomes, including psychological and developmental disturbances in infants, children, and adolescents [14]. Women with severe mental disorders also have increased risks of pre-eclampsia, antepartum and postpartum hemorrhage, placental abruption, impaired intrauterine growth, abortion, and cesarean section, and stillbirths are associated with antepartum and postpartum depression and anxiety [14-19]. Severe mental disorders result in suicide, a leading cause of maternal death in pregnancy and the postpartum period, which contributes to maternal mortality and low quality of life [1,20,21].

Why Videoconference-Based Counseling Is Appropriate as an Intervention for Maternal Mental Disorders in the Context of Bangladesh

Early detection and treatments are necessary to address these maternal mental health issues. Maternal mental disorders are treatable using effective counseling and therapies [22]. However, the availability and access to mental health services are somewhat limited in rural Bangladesh. In addition, the number of available psychologists and psychiatrists is very low. Bangladesh has an estimated 260 psychiatrists, or approximately 0.16/100,000 population, as well as 700 nurses who provide mental health specialty care (0.4/100,000), and 565 psychologists (0.34/100,000) mostly concentrated in urban settings [23]. Providing in-person mental health care with limited capacities such as very low designated government facilities with few specialty service providers is difficult [23].

However, Bangladesh has very good network coverage, which can be used for telehealth counseling services. Telemental health services, which gained popularity during the COVID-19 pandemic, are also commonly used in Bangladesh [24]. Several studies have found that telephone-based treatment significantly improved short-term symptoms and considerably alleviated the advancement of postnatal depression [25,26]. Evidence suggests that digital psychological interventions for mental health problems in developing countries are effective when usual care for mental health problems is minimal [27]. Another study reported that mothers experienced less maternal depression after receiving videoconference-based counseling [28]. Videoconference-based counseling has emerged as a practical and efficient means of providing mental health treatment in resource-limited communities for reducing symptoms of psychiatric disorders and helping to improve quality of life [29-33].

Implementation of Wellbeing Centers in Collaboration With the Non-Communicable Disease Control Program of the Government of Bangladesh

Cognizant of this reality, the Non-Communicable Disease Control (NCDC) program of the government of Bangladesh (GoB) initiated the telemental health service called "Wellbeing Centers" in 6 public hospitals of Bangladesh to provide

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telemental health services with facilitation support from the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b). General patients along with women with maternal mental health disorders can take personalized and specialized counseling support from a pool of psychologists and psychiatrists through videoconference counseling at the Wellbeing Centers [34,35]. It is important to know whether these services are adequately benefitting the targeted population in a larger number of facilities for scaling up these Wellbeing Centers in other districts in Bangladesh since no study ever explored it in Bangladesh.

Aims

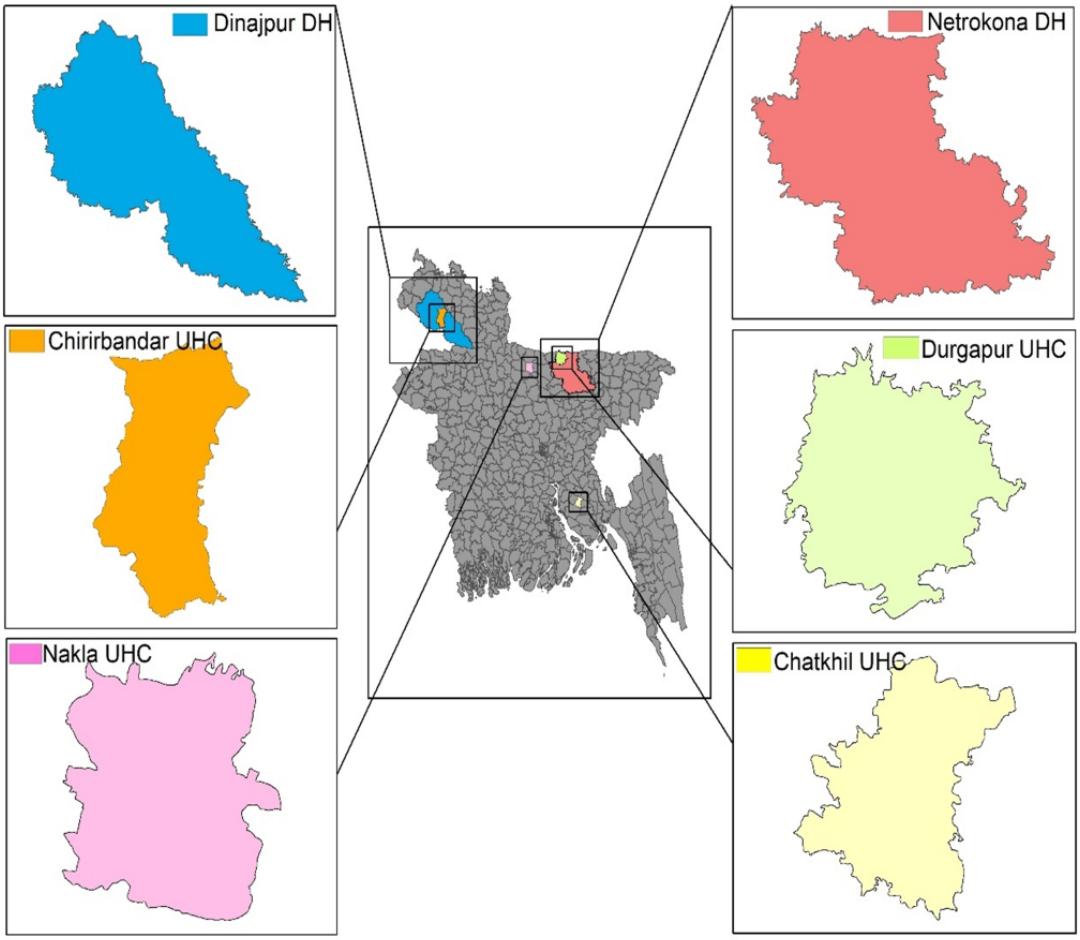
The primary aim of this study is to assess the implementation outcomes (feasibility, accessibility, adoption, acceptability, usefulness, need, experience, perception, and expectation) of the Wellbeing Centers in selected district and subdistrict hospitals of Bangladesh. We will also explore the prevalence of depression and anxiety symptoms in the targeted population as a secondary outcome for demonstrating the need for such mental health care.

Methods

Study Setting

A total of 6 Wellbeing Centers were implemented in district hospitals (DHs) and 4 *upazila* (subdistrict) health complexes (UHCs) in Dinajpur district of Rangpur division and Netrokona district of Mymensingh division. Two other subdistrict-level health care facilities were from Nakla in the Sherpur district and from Chatkhil in the Noakhali district. Selected health care facilities were Dinajpur DH, Netrokona DH, Durgapur UHC, Chirirbandar UHC, Nakla UHC, and Chatkhil UHC (Figure 1). The NCDC program of the Directorate General of Health Services suggested carrying out the Wellbeing Center services in these enlisted 6 health care facilities.

Figure 1. Study sites. DH: district hospital; UHC: upazila health complex.



Study Design

An implementation research study was conducted, where the NCDC program designed, developed, and demonstrated an implementation model to introduce Wellbeing Centers for providing telemental health services. The study used both quantitative and qualitative data collection. Implementation facilitation support was provided, and assessments were conducted by icddr,b, an international health research organization based in Bangladesh.

Study Participants

Antenatal and postnatal women who visited to the outpatient settings (mainly antenatal care [ANC] and postnatal care [PNC] corner) and received counseling from Wellbeing Centers of the 6 selected health care facilities were enrolled in this study. A total of 911 women in antepartum and postpartum periods

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received care from the Wellbeing Centers, and 168 health care facility managers and providers directly involved in the implementation were surveyed and reincluded in this analysis. The health care facility managers and providers included civil surgeons of the corresponding districts, hospital superintendents of the corresponding DHs, subdistrict health and family planning officers of the corresponding UHCs, resident medical officers (RMOs) of corresponding DHs and UHCs, physicians, and gynecological consultants from the outpatient departments.

Development of the Wellbeing Centers at the Health Care Facilities

Overview

The NCDC program of the Directorate General of Health Services, Ministry of Health and Family Welfare of Bangladesh received implementation support from the icddr,b along with other institutions, such as the National Institute of Mental Health (NIMH) and Department of Clinical Psychology, University of Dhaka, to establish the Wellbeing Centers.

Creating a Pool of Psychologists and Psychiatrists

A pool of trained psychologists and psychiatrists has been formed to deliver mental health care services. This pool of psychologists and psychiatrists was guided and mentored by professional bodies from clinical and counseling psychology and psychiatry.

Establishment of the Wellbeing Centers

Equipment and technology recourses included a computer, an internet connection, and a webcam in each Wellbeing Center at the facility. To establish an internet connection, an internet router was provided. In cases of electrifying fall, an uninterrupted power supply was used. Psychologists and psychiatrists and patients were provided with headphones to cancel or isolate ambient noise. With the help of a digital platform, appointments were scheduled. Patients were connected with the psychologists through videoconferencing. In the hospital, a room was allocated for the Wellbeing Center. This room was dedicatedly used for telemental health, maintaining appropriate privacy and confidentiality. The webcam and video monitor were placed at the client's eye level to best approximate a face-to-face interaction.

Training

Health care administrators, expertise in mental health, along with facility managers partnered with icddr,b to facilitate training and workshops for district and subdistrict-level health care providers (such as RMOs, physicians, gynecological consultants, and health workers). Additionally, the implementation support team organized the orientation of both government and program-supported health workers to promote the Wellbeing Center activities. Training content covered the use of depression and anxiety screening tools, patient reception, appointment scheduling, communicable liaison, the integration of mental health services in outpatient settings, effective web-based patient engagement, the use of technology in delivering mental health services, patient referral processes, follow-ups, and crisis management.

Service Provision

At first, women who came to seek health care service at ANC or PNC corners of the health care facilities were referred by the physicians or gynecological consultants to the Wellbeing Centers. Afterward, a health worker screened and redirected women of antepartum and postpartum to a Wellbeing Center and registered the client's through the digital platform using their name and phone number. The health worker noted the availability of psychologists, and an appointment was then fixed. By creating a digital meeting link, the patient's information and schedule were shared with the psychologists. Patients were supported by the health worker to prepare and make necessary arrangements for connecting to the psychologists through videoconference ensuring adequate privacy.

Psychologists assessed clients' mental health disorders using psychometric tools and then provided tailored counseling. Psychologists designed additional management plans and follow-ups based on the clients' improvement dimensions. When counseling proved insufficient to address moderate to severe instances, clients were referred to the NIMH's psychiatrists. Then, the health worker made an appointment and used videoconference-based counseling to connect with the psychiatrist for further treatment. Each client had a second screening by a health worker using the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder-7 (GAD-7) during follow-up sessions in order to measure the degree of change in their mental condition (Figure 2).

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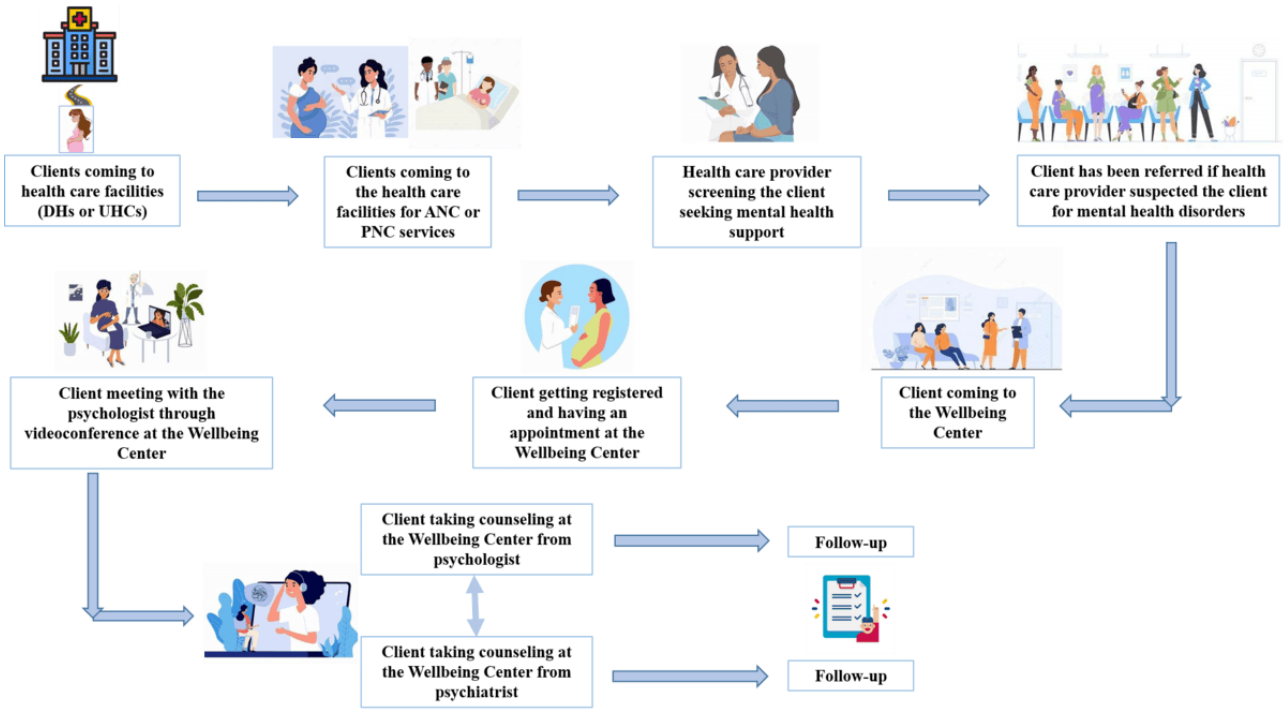
Figure 2. Mental health service delivery mechanism of Wellbeing Centers. ANC: antenatal care; DH: district hospital; PNC: postnatal care; UHC: upazila health complex.



Data Collection

Both quantitative and qualitative methods were undertaken to collect data. Quantitative data were collected using tablets, and qualitative interviews were done using audio recorders. We developed a data entry interface for this implementation research to manage data. A quantitative survey was conducted among women by trained health workers. A structured quantitative questionnaire was used to collect data on demographics [36,37], validate depression and anxiety symptom screening in outpatient settings [38-41], and assess implementation outcomes including acceptability, usefulness, and adoptability [42]. Assessment of feasibility among health facility managers was determined using the World Health Organization's (WHO) improving health system and services for mental health guideline [42]. Qualitative information was received by trained researcher using in-depth interviews (IDIs) and key informant interviews (KIIs). All data collection tools are presented in detail in Multimedia Appendices 1-4. About 10 qualitative IDIs were conducted on experiences, perceptions, and expectations regarding the videoconference-based mental health counseling among women who received ANC and PNC in the health care facilities at the Wellbeing Centers. Moreover, 15 KIIs were conducted among the health care facility managers, RMOs, physicians, psychologists, psychiatrists, and health workers. The number of antepartum and postpartum women who took follow-up sessions was 51.

Study Measures

Basic demographic information included age (years), types of care (ANC and PNC), religion, profession, education (years completed), household income (taka per month), and catchment area (subdistrict and district) were determined. The WHO's implementation research in health care guideline was followed in terms of defining acceptability, usefulness, feasibility, and adoption [42]. Table 1 provides detailed indicator information for all the implementation outcomes assessed in this study.

The PHQ-9 [43] and the GAD-7 scales [44] were used to evaluate depression and anxiety in outpatient settings, respectively [39,41]. The PHQ-9 is a 9-item questionnaire that assesses depression symptoms in a range of 0=not at all to 3=nearly every day. The PHQ-9 score ranges from 0 to 27, with mild, moderate, moderately severe, and severe depression symptoms equating to cutoff values of 5, 10, 15, and 20, respectively. The GAD-7 is a 7-item questionnaire that measures anxiety symptoms on a range of 0=not at all to 3=nearly every day. The GAD-7 scale has a score range of 0 to 21, with mild, moderate, and severe anxiety symptoms equating to cutoff values of 5, 10, and 15, respectively. Figure 3 presents the logical framework of the telemental health intervention in reducing the common mental health disorders among pregnant and postpartum women.

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Table 1. Indicators according to the objectives for all the implementation outcomes assessed in the study.

Number	Objectives	Study method	Implementation outcome	Indicators or themes
1	To assess the feasibility of the Wellbeing Center at the district-level facility	Quantitative	Feasibility	• Percentage of facility managers who feel that Wellbeing Center is implementable in the facility • Percentage of facility managers who feel that they have sufficient trained staff in their facility to implement the Wellbeing Center
2	To assess the accessibility to mental health care among antenatal and postnatal women by introducing Wellbeing Center's telemental health care	Quantitative	Accessibility	• Percentage of users who agreed that Wellbeing Center has improved their access to mental health services
3	To assess the adoption of the Wellbeing Center at district-level facility for antepartum and postpartum women	Quantitative	Adoption	• Number of women receiving services from the Wellbeing Center
4	To assess the acceptability of the Wellbeing Center at district-level facility for antepartum and postpartum women	Quantitative	Acceptability	• Percentage of users who agreed that mental health services from the Wellbeing Center are acceptable to them
5	To assess the usefulness of the Wellbeing Center at district-level facility for antepartum and postpartum women	Quantitative	Usefulness	• Percentage of users who agreed that the Wellbeing Center is useful • Change in depression and anxiety symptoms scores from first follow-up to second follow-up
6	To assess the proportion of target women with symptoms of depression	Quantitative	Need	• Percentage of users who had depressive symptoms
7	To assess the proportion of target women with symptoms of anxiety	Quantitative	Need	• Percentage of users who had symptoms of anxiety
8	To assess the experience, perception, and expectation about the telemental health counseling at the district-level facility for the antepartum and postpartum women	Qualitative	Experience, perception, and expectation	• Experience, perception, and expectation about the Wellbeing Center

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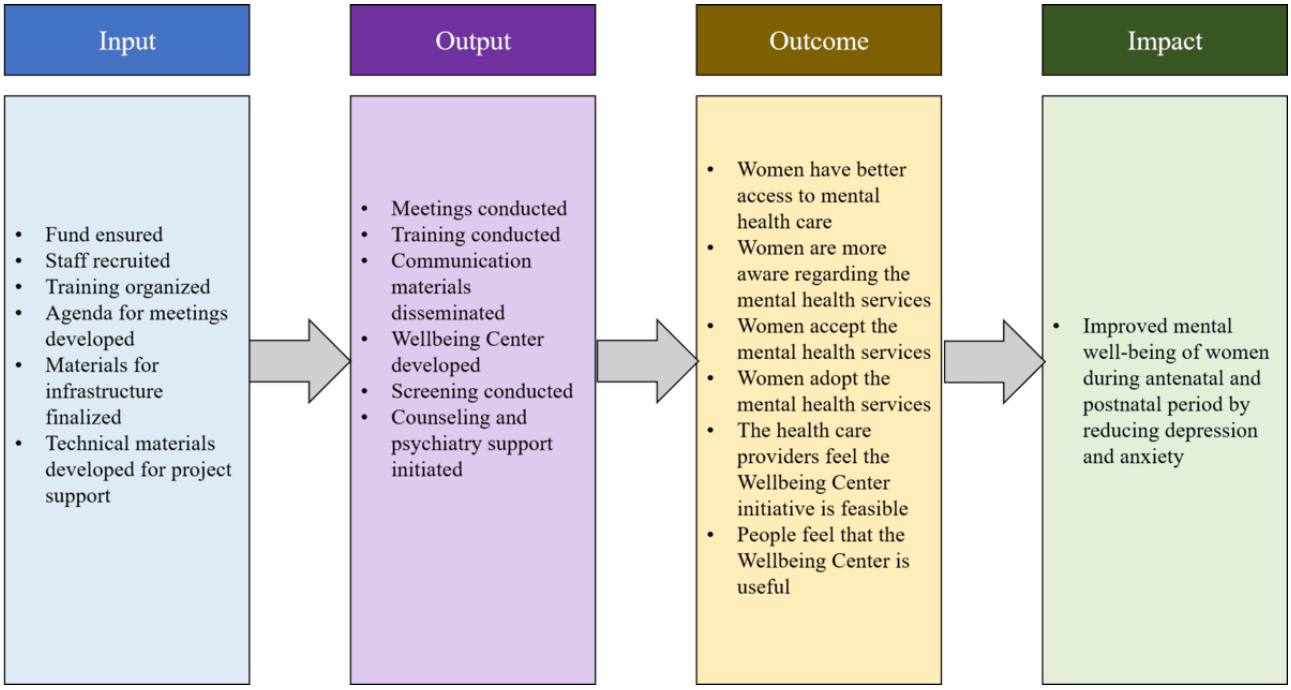
Figure 3. Logical framework of the telemental health intervention.



Data Analysis

Quantitative Analysis

Stata (version 15.0; StataCorp) was used for this analysis. We have presented descriptive statistics (frequency and percentage) with 95% CIs. For measuring the effect of various factors (age, types of care, religion, profession, education, household income, and catchment area) on the accessibility of the Wellbeing Centers and need-related indicators (depression, anxiety, and both depression and anxiety), 4 separate fitted models were constructed. Multiple logistic regression models were applied to compute the adjusted odds ratios (aORs) with 95% CI. In the adjusted models, accessibility was considered if a woman "strongly agreed" that the Wellbeing Center increased the accessibility of mental health services. Severe depression symptoms were coded as "1," and others (mild, moderate, and moderately severe depression) were coded as "0." For anxiety, severe anxiety symptoms were coded as "1," and mild and moderate anxiety symptoms were coded as "0." When a participant was found to have both severe anxiety and depression, we documented this as the co-occurrence of the 2 conditions using a binary response format (1 and 0). Wald statistics were used to assess the model adequacy. We presented the differences in depressive and anxiety symptoms of antepartum and postpartum women occurring nearly every day using radar plots. At the 5% level of significance, the statistical significance of the estimates has been reported.

Qualitative Analysis

All audio-recorded interviews, supplemented with field notes, were transcribed verbatim. The transcriptions were then read through several times by all the researchers to get more familiar with the data. The transcriptions were manually thematically analyzed using an inductive approach [45,46]. The three stages of the analysis included (1) reading the interview transcripts; (2) highlighting the related words, coding them in relation to the text, and thereafter classifying them; and finally, (3) identifying the themes with reflective notes. The data were coded and categorized according to the emerging themes. Data were analyzed by NVivo (QSR International) qualitative data analysis software. To respect the anonymity of each participant, no personal identifying information was presented in the result.

Ethical Considerations

The icddr,b Institutional Review Board granted the study ethics approval (protocol PR-22103). All the eligible women have given written informed consent prior to the enrollment. All data were anonymized or deidentified. No monetary compensation was provided to participants for this research. Consent has been granted from identifiable individual features of research participants or users in any images of the manuscript or supplementary material.

Results

Quantitative Findings

The selection process of the patients from the facilities with Wellbeing Center for antepartum and postpartum women is shown in Multimedia Appendix 5. Between January 2023 and August 2024, 16,203 patients visited the outpatient department, from whom 5863 general patients received services from Wellbeing Centers. Among them, 4450 women visiting the ANC and PNC corners received services from 6 Wellbeing Centers. We have considered only the 911 antepartum and postpartum women who received mental health services at the Wellbeing Center.

Table 2 presents the background characteristics of the antepartum and postpartum women who received services from Wellbeing Centers. The majority of the women were young adults aged 20-24 years. Most of the women (n=817, 89.7%) who received mental health services at the Wellbeing Centers and NIMH were referred during ANC visits. Only 2.2% (n=20)

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of the women were involved in any income-generating activities. In total, 54.6% (n=497) of the women completed secondary-level education, and 46.9% (n=427) were from the low-income group. A total of 70.6% (n=643) of the counseling receiving women visited the subdistrict-level facility.

Figure 4 presents the WHO-guided implementation outcomes, feasibility, accessibility, acceptability, usefulness, and need of the Wellbeing Center. Among 168 providers, almost everyone (165/168, 98.2%) reported that the Wellbeing Center is implementable at the facilities. Half of the providers (84/168, 50%) agreed that the facilities have trained staff to maintain the Wellbeing Center. Among the users, almost all antepartum and postpartum women agreed that the Wellbeing Center is increasing accessibility, and it is acceptable and useful for them, as antepartum and postpartum women experience depression and anxiety throughout the period. Around three-fourths of the users had moderate to severe anxiety or depressive symptoms, which demonstrated the need for mental health care.

Figure 5 presents the percentage of women who experienced depressive and anxiety symptoms nearly every day in the past 2 weeks, as indicated by the PHQ-9 and GAD-7 scales. Half of the women (472/911, 51.8%) experienced a lack of energy nearly every day, and 36.6% (333/911) experienced a lack of interest and pleasure. Around one-third of women faced issues with trouble falling asleep or sleeping too much and poor appetite or overeating almost every day. In total, 3.8% (35/911) had suicidal ideation almost every day. Among the anxiety symptoms, 57.2% (521/911) worried too much about different issues, and 50.9% (464/911) experienced nervousness almost every day in the past 2 weeks.

The health care providers reported the need for telemental health in their respective facility:

> *Due to the shortage of well-trained psychiatrists nearby, we have to take treatment from the divisional level health facilities, which is time-consuming and costly. Ensuring proper mental health service district and upazila-level hospital requires service like tele-mental*. [KII-15, health worker, Nokla UHC, age 42 years]

Table 3 summarizes the effect of various factors on accessibility and need-related indicators. The odds of increased perceived accessibility were lower among patients receiving PNC compared to ANC with aOR 0.45 (95% CI 0.27-0.74). Women with lower education and lower income had higher perceived accessibility. Patients visiting DHs had higher odds of perceived accessibility (aOR 1.48, 95% CI 1.1-2.0). Patients visiting DHs had 3 times higher odds (aOR 2.58, 95% CI 1.82-3.68) of experiencing both depression and anxiety symptoms, expressing the need for mental health services through the Wellbeing Center.

Figure 6 presents the change in average scores of PHQ-9 and GAD-7 between the first and second counseling sessions of the antepartum and postpartum women. The average PHQ-9 score decreased from 14.4 (SD 0.47) to 12.9 (SD 0.47), and the average GAD-7 score decreased from 13.3 (SD 0.49) to 12.5 (SD 0.48) between these 2 sessions, indicating the usefulness of Wellbeing Center. These changes were statistically significant with $P<.001$.

The proportion of people taking follow-up counseling is shown in Multimedia Appendix 6. Only 15.1% (51/338 suggestions of follow-up visits) took follow-up counseling among the patients who were suggested a follow-up session.

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Table 2. Background characteristics of the antepartum and postpartum women who received services from Wellbeing Centers (N=911).

Background characteristics	Participants, n (%)
Age (years)	
15-19	229 (25.1)
20-24	332 (36.4)
25-29	218 (23.9)
≥30	132 (14.5)
Type of contact care points at the facility	
ANC[a]	817 (89.7)
PNC[b]	94 (10.3)
Religion	
Muslim	848 (93.1)
Other[c]	63 (6.9)
Profession	
Housewife	856 (94)
Involved in income-generation activities	20 (2.2)
Other[d]	35 (3.8)
Education (years completed)	
No education	12 (1.3)
Primary	159 (17.5)
Secondary	497 (54.6)
Above secondary	243 (26.7)
Household income	
Low	427 (46.9)
Middle	217 (23.8)
High	267 (29.3)
Type of facility location	
Subdistrict	643 (70.6)
District	268 (29.4)

[a]ANC: antenatal care.
[b]PNC: postnatal care.
[c]Hindus, Buddhists, and Christians.
[d]Unemployed and unable to work due to disability.

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Figure 4. Implementation outcomes of Wellbeing Centers according to the World Health Organization guidelines.

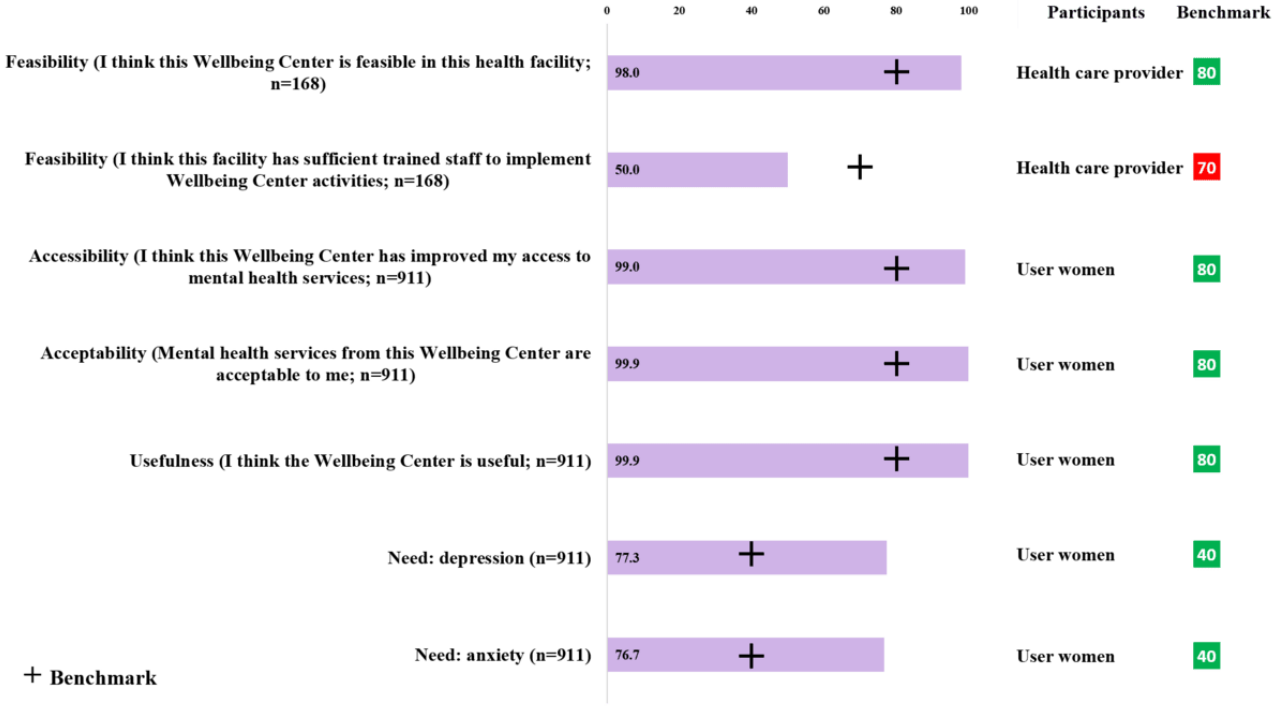

Figure 5. Need for Wellbeing Centers according to the frequency of depressive and anxiety symptoms.

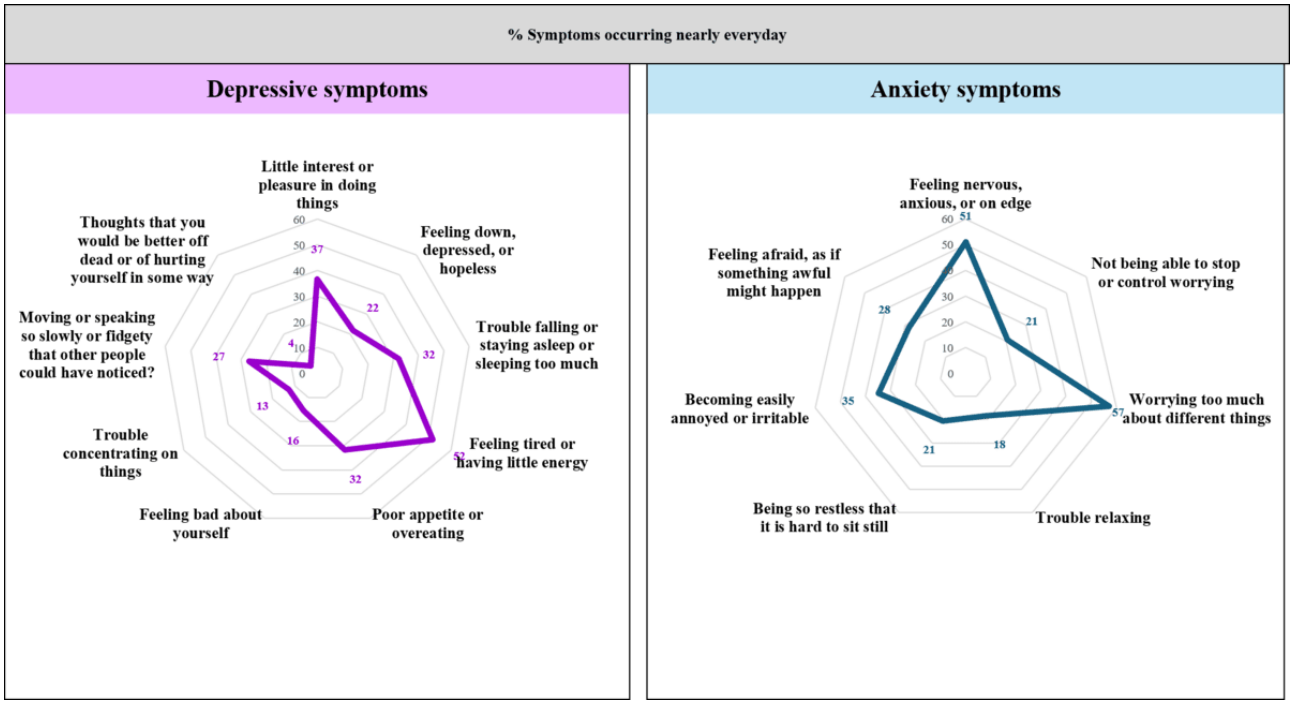

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Table 3. Factors associated with accessibility (strongly agree) and need (severe depression and anxiety symptoms) of Wellbeing Center.

	Accessibility		Both depression and anxiety	
	aOR[a] (95% CI)	*P* value	aOR (95% CI)	*P* value
Age (years)				
15-19	Reference	Reference	Reference	Reference
20-24	1.09 (0.76-1.57)	.63	1.42 (0.90-2.23)	.13
25-29	0.78 (0.52-1.17)	.22	1.01 (0.60-1.71)	.97
≥30	1.14 (0.72-1.81)	.57	0.87 (0.47-1.60)	.65
Type of contact care point at the facility				
ANC[b]	Reference	Reference	Reference	Reference
PNC[c]	0.45 (0.27-0.74)	.002	0.88 (0.48-1.62)	.68
Religion				
Muslim	Reference	Reference	Reference	Reference
Other[d]	0.56 (0.31-1.01)	.05	0.38 (0.15-0.99)	.047
Profession				
Housewife	Reference	Reference	Reference	Reference
Involved in incom- generation activities or other	1.04 (0.57-1.92)	.89	1.06 (0.48-2.32)	.89
Education				
No education or primary	Reference	Reference	Reference	Reference
Secondary	0.40 (0.27-0.58)	.001	1.02 (0.64-1.64)	.93
Above secondary	0.44 (0.28-0.69)	.001	0.89 (0.51-1.55)	.67
Household income				
Low	Reference	Reference	Reference	Reference
Middle	0.70 (0.49-0.99)	.047	0.97 (0.62-1.51)	.90
High	1.12 (0.81-1.56)	.50	1.07 (0.70-1.62)	.76
Type of facility location				
Subdistrict	Reference	Reference	Reference	Reference
District	1.48 (1.10-2.00)	.010	2.58 (1.82-3.68)	.001

[a]aOR: adjusted odds ratio.
[b]ANC: antenatal care.
[c]PNC: postnatal care.
[d]Hindus, Buddhists, and Christians.

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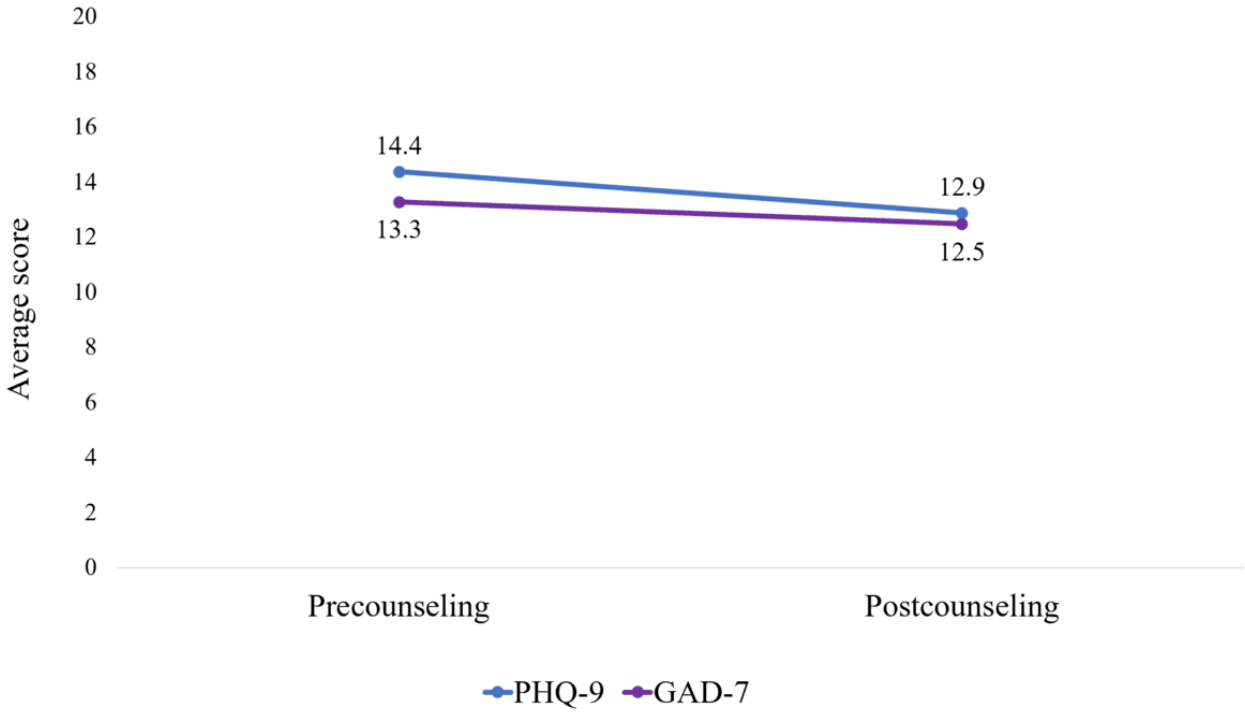
Figure 6. The usefulness of the counseling in reducing the average PHQ-9 and GAD-7 scores (n=51). GAD-7: Generalized Anxiety Disorder-7; PHQ-9: Patient Health Questionnaire-9.



Qualitative Findings

Perception and Experience Regarding Wellbeing Center Services During the Antepartum and Postpartum Periods

Positive Attitude of the Service Providers

The positive attitude of psychologists and health workers of the Wellbeing Centers strengthened the telemental health services compared to other health services. The health workers of the center cordially received the antepartum and postpartum women who were referred by the physicians. During the counseling session, psychologists listened to their problems and issues attentively and provided video counseling, which gives them better feelings about the service at the Wellbeing Center. A pregnant mother mentioned the following:

> *I feel scared to share my all problems with a physician! I just responded to what the doctor wanted to know. But in the audio-visual call, a counsellor gives a welcoming tone which influenced me to share my mental health issues clearly.* [IDI, female, age 32 years]

Cost and Accessibility

Earlier, antepartum and postpartum women who experienced mental health disorders had to get treatment from the regional medical college hospitals or have to go to specialized hospitals. Because of the Wellbeing Center, people can get mental support on their doorstep. From the Wellbeing Center, anyone can get free-of-cost and hassle-free treatment. Those who seek mental health treatment from private hospitals have to spend considerably more money on paying psychiatrist fees, unethical financial gain of clerks, medication, transportation costs, etc. Nevertheless, patients found videoconference-based counseling at the Wellbeing Centers more convenient than the traditional treatment system, as they do not require any treatment costs, and it provides easy treatment access at their doorsteps. A service receiver mentioned the following:

> *If I come here [Wellbeing Center] it will save my money and I get treatment from a good specialist that won't cost me money.* [IDI, female, age 22 years]

Privacy and Confidentiality

While the antepartum and postpartum women received counseling, nobody was present in the room to ensure privacy and confidentiality. Service receivers' privacy is a prime concern at the Wellbeing Centers, as patients receive services in a separate room that ensures privacy during the counseling. A service receiver said the following:

> *During in-person consultations, I did not freely communicate to the doctor [psychiatrist-private chamber] because of the other patient's presence in the waiting area. But in the Wellbeing Center, I do not have worries about violation of [my] privacy while getting audio-visual counseling in a separate room.* [IDI, female, age 24 years]

Name

The name of the mental health service center is Wellbeing Center to overcome the stigma and social taboo associated with psychological support needs. Whenever antepartum and postpartum women and their caregivers come to the corner, they do not hesitate to seek care. This may be due to the perception of a safe and supportive space that encourages open discussion of mental health issues without fear of judgment. The term "well-being" did not demonstrate any stigma. A health worker mentioned the following:

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We do not use the term mental health corner, instead we use "Mon-Shastho Kendro" [Wellbeing Center] to avoid the stigma. When doctors refer them to the Wellbeing Centerthey do not feel hesitation. [KII, health workers, age 33 years]

Barriers to Using the Wellbeing Center Services

Stigmas and Taboos

During the pregnancy period, mothers experience numerous negative emotions. Though they can understand that their mental condition is changing, they cannot share their problems due to stigmas and taboos. Even more, they do not disclose their mental health problems to their husbands and family members. Fear of family violence and potential disruption of marriage often prevent pregnant women from disclosing their mental health issues. A pregnant mother mentioned the following:

> *I do not share my problems with my family members, if I share my mental problems with them then they may make any comments on this that will be very frustrating to me.* [IDI, pregnant mother, age 29 years]

Postpartum Illness

During the postnatal period, mothers are unable to receive mental health treatment from the Wellbeing Center for their physical illness and lack of support from the family. Moreover, after childbirth, the physician referred the mothers to the Wellbeing Center based on the mental health examination. However, sudden release from the hospital is a reason for not receiving the services. A health worker mentioned the following:

> *Within the 42 days [postnatal period], mothers were physically sick to come. Those who are referred by the physician, sometimes get a sudden release from the hospital. Therefore, they do not come for mental health services.* [KII, health assistant, age 33 years]

Long Waiting Times

During the follow-up visit, antepartum and postpartum women have to wait in the ANC and PNC corner for taking services. Some patients were in a rush to receive the service, but it was not possible to give them an opportunity, as other patients were also on the waiting list. This may be due to the patient load and the ANC and PNC corners operating on a first-come, first-served basis. A pregnant mother mentioned the following:

> *I feel unsteady while waiting for [receiving] the mental health service. There are only three seats in the waiting room, and three mothers already waiting there to receive the service. Therefore, I and my husband have to stand up for around thirty to forty minutes which causes the irritation.* [IDI, pregnant mother, age 18 years]

Discussion

Principal Findings

Our research demonstrated that telemental health services through the Wellbeing Center are feasible, acceptable, useful, and highly needed among women. It has increased accessibility to mental health services to pregnant or postpartum women with a lower level of income and education. The health care providers felt a need for more staff with appropriate training to implement this intervention at the hospitals, who are lacking in Bangladesh. The women visiting the DHs have a higher level of depression and anxiety symptoms, demonstrating a critical need for mental health services. Our follow-up assessment scores on depression and anxiety symptoms after the first counseling sessions demonstrated a decrease in the average scores, which indicted the effectiveness of the Wellbeing Centers. The service beneficiaries recommended the intervention because of the positive attitude of the service providers; the services being free of cost, private, and confidential; and its sensitive naming. However, they also mentioned some barriers to receiving care from Wellbeing Centers, which included social stigma, postpartum illness, and long waiting times at the facility to use the service.

To the best of our knowledge, this is the first implementation research that assessed the WHO implementation outcome variables of a facility-based telemental health intervention, the Wellbeing Centers, for antepartum and postpartum women that is operated by the GoB. We have pioneered in proposing an implementation model for mental health care including a pool of trained psychologists and psychiatrists who provided counseling and medications for mental health issues through videoconferencing in the Wellbeing Centers at the public health facilities in Bangladesh.

Some public hospitals in Bangladesh had initiated telemedicine units as a part of their routine care system. However, telemental health services through Wellbeing Centers differ from general telemedicine in several ways. Telemental health often involves specialized platforms designed to provide psychological assessments, therapy, and psychiatric consultations. In contrast, telemedicine includes a broader range of remote clinical services, including primary care, specialist consultations, and follow-up visits. Telemental health is a specialized subset of telemedicine focusing on mental health. While both telemental health and telemedicine use videoconferencing, phone calls, and other digital communication tools, telemental health platforms are tailored to address the unique needs of mental health care, such as ensuring patient privacy and providing a comfortable environment for discussing sensitive issues. This specialization can lead to better patient engagement and satisfaction in mental health care compared to general telemedicine [47]. This type of service is expected to vary according to the differences in context and health systems. Our research focused on the implementation outcomes of telemental health care. This provides evidence to support the scale-up of telemental health care through Wellbeing Centers.

Adoption and Acceptability

A significant proportion of Bangladeshi mothers have common mental health issues during the antenatal and postnatal period [4,48]. Most mental health care facilities are clustered around urban areas, while rural women do not have access to mental health care in Bangladesh. Since maternal mental distress among these rural mothers may cause adverse maternal and child health outcomes, appropriate interventions can address maternal mental distress among the Bangladeshi maternal population. Evidence supports the effectiveness of digital psychological interventions,

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especially in low- and middle-income countries where mental disorders contribute significantly to the global burden of disease [49,50]. Globally, these services offer private, personalized support, connecting disparities in mental health care for those facing challenges accessing traditional services or face-to-face services [49]. Global evidence emphasizes the role of telemental health service as an equivalent and effective method, particularly in delivering mental health services to remote areas with limited resources. A significant number of users in our study provided strong evidence on the adoptability and acceptability of the telemental health services through Wellbeing Centers in Bangladesh. Services through Wellbeing Centers minimized travel, offering cost-effective and accessible psychological and psychiatric services.

Feasibility

The health care providers perceived that the telemental support through the Wellbeing Center is highly feasible. However, they also felt that the facilities lacked appropriately trained staff to maintain these centers. Banbury et al [51] stated that staff require comprehensive training to sustain and expand telehealth use in the facilities. These trainings should focus on knowledge, skills, and competencies in using telehealth as well as the broad factors of policies and understanding technologies to support the service providers [51]. Studies have discussed concerns around a lack of appropriate training to be able to conduct remote mental health care effectively and safely [52]. The government should ensure adequate training and supportive supervision for health providers (such as RMOs, physicians, gynecological consultants, and health workers) on mental health disorder assessments of pregnant and postpartum mothers, psychosocial services, as well as information and communication technology to maintain Wellbeing Center activities.

Accessibility

In the context of Bangladesh, mental health services face challenges due to limited resources and a shortage of professionals, relying heavily on the NIMH in Dhaka [53,54]. The new mental health policy of Bangladesh prioritizes community-based services, with nongovernment organizations contributing scalable models, including telemental health initiatives [55,56]. Access challenges still persist despite some voluntary counseling platforms, due to their lack of visibility [57,58]. These programs are not also integrated into the government system. Despite progress and current provisions for service delivery, issues like low help-seeking, inadequate service delivery, and persistent stigma emphasize the need for telemental health services on a larger scale [59]. Integrating telemental health services with these services is essential for improved mental health care [58]. Wellbeing Centers increased perceived accessibility among antepartum and postpartum women. Perceived accessibility was significantly higher among lower socioeconomic groups and lower educated groups. One of the reasons for this could be the free-of-cost facilities at public hospitals that are near their location.

Need

We looked into the need for well-being by looking at the depressive and anxiety symptoms prevalent among our targeted patients. Two-thirds of the women who sought services from the Wellbeing Center had moderate to severe indications of depression and anxiety. In addition, we observed a high level of anhedonia or lack of interest and tiredness among the women in the last 2 weeks. These highly prevalent symptoms indicated the need for Wellbeing Centers for the targeted mothers. El Sayed et al [60] reported that fatigue and anhedonia were prevalent and commonly reported in the post–COVID-19 period. A study by Costa et al [61] also reported that the prevalence of perinatal depression increased during the COVID-19 pandemic, which may be due to changes in the profile of specific depressive symptoms. Pearson et al [62] conducted a study where they reported that women experiencing anhedonic depressive symptoms during pregnancy had significantly larger systolic blood pressure responses toward infant distress than nondepressed pregnant women. Special attention should be given to anhedonia and fatigue-related symptoms of perinatal depression to ensure that they are adequately managed.

Among the other depressive symptoms, our finding that 3.8% (n=35) of patients experienced suicidal ideation is a significant concern, reinforcing the need for enhanced mental health interventions in Bangladesh. Scientific studies discussed the complexity of suicidal ideation, noting that it often goes unreported due to stigma and fear of judgment [63]. Suicidal ideation is influenced by a complex interplay of biological, psychological, and social factors. While some biomarkers have been identified to predict the risk of suicide, the underlying causes of suicide remain largely unclear. More research is needed to understand the root causes of suicidal ideation. Digital tools, such as mobile apps and telehealth services, can effectively monitor and reduce suicidal thoughts by providing real-time support [64]. Additionally, telehealth-supported decision-making has been found to significantly reduce suicidal ideation [65].

Our study also found that the level of worry and nervousness in the past 2 weeks was significantly higher among pregnant and postpartum women. More than half of the women experienced these symptoms of anxiety in the past 2 weeks almost every day. Tarafa et al [66] conducted a study in Ethiopia and assessed the factors associated with pregnancy-related anxiety among pregnant women attending ANC follow-up. Unwanted pregnancy, high perceived stress, young age, depression, low income, and poor social support were significantly associated with pregnancy-related anxiety. The overall prevalence of pregnancy-related anxiety in this study was slightly lower 32.7% [66]. It is worth noting that this study assessed only pregnancy-related anxiety while we included both pregnant and postpartum mothers. Appropriate intervention and focus are needed to address these worries and anxieties of pregnant women and postpartum mothers in Bangladesh through Wellbeing Center activities.

We report higher depression and anxiety and perceived accessibility among the women who took Wellbeing Center services at the district-level facilities compared to the subdistrict-level facilities. The reason can be regarded as an indirect effect of urbanization. A recent meta-analysis conducted by Cadman et al [67] assessed the influence of the urban environment in pregnancy and postpartum depression. Exposure

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to air pollution and road traffic congestion may increase maternal depression. The urban family structure, with a lack of family support, may also induce higher levels of depressive and anxiety symptoms in Bangladesh. A study conducted on adolescents researched screen-related sedentary behavior, finding that the use of social media caused 2 times higher depression among urban adolescents [68]. A large proportion of our users of Wellbeing Centers were adolescents. Therefore, urgent initiatives should be taken to control the spread of depression and anxiety among the urban population, especially for mothers. In summary, at the district-level facilities, the need for mental health services was higher among the antepartum and postpartum women, which necessitated a strengthened focus on providing equitable services through the Wellbeing Centers in Bangladesh.

Usefulness

While we found the Wellbeing Centers to be feasible and acceptable, our study also indicated small improvements during the follow-up counseling sessions for the targeted patients. A review by Hilty et al [34] reported that telemental health is effective for diagnosis and assessment across many populations, including adults, children, older people, and people of different ethnicities, and for disorders in home and facility settings. This review urged that more research should be conducted on service models, specific disorders, issues regarding culture and language, and cost. Ensuring follow-up visits after the first counseling session is important for the sustained impact of telemental health services. However, we have not observed many women taking follow-up services in our Wellbeing Centers. Special initiatives such as follow-up phone calls or reminders should be ensured to increase follow-up sessions when needed and recommended.

Experience, Perception, and Expectation

Our research explored the experiences and perceptions regarding the Wellbeing Center activities, which revealed several strengths of and barriers to using these services. The users acknowledged the positive attitude and patience of the counselors during the service sessions. In Bangladesh, in-person psychiatric services are expensive and may not be affordable for underprivileged women. The Wellbeing Center services were completely free of cost, which attracted the targeted patients. Furthermore, these Wellbeing Centers ensured the privacy and confidentiality of the patients while providing psychological or psychiatric support. Many women were comfortable while expressing their problems and mental health issues, as they were reassured by this confidentiality. Finally, the women praised the naming of the service, which also addressed the stigma around mental health. The women also mentioned that existing stigmas and taboos on seeking mental health services prevented them from seeking care. However, almost all users of the Wellbeing Centers agreed that these services were acceptable to them. Further research is necessary to understand the actual state of stigma in the community regarding mental health care seeking.

Our quantitative data suggested that more women during pregnancy used Wellbeing Center services compared to postpartum women. Our qualitative finding echoed this finding as women reported postpartum illnesses were a barrier for them to seeking mental health care. Finally, few women mentioned that the long waiting time repelled them to receive services from the Wellbeing Centers. With the high demand and popularity, the system experienced a high patient load and struggled to satisfy all patients with timely services.

Comparison With Prior Studies

Recent studies on telemental health interventions have shown promising results, particularly in the context of the COVID-19 pandemic, which accelerated the adoption of remote mental health care. Research indicates that telemental health, including videoconferencing and phone-based therapy, is generally as effective as in-person care for a variety of mental health conditions [47]. Our research found similar results in terms of feasibility, utility, and effectiveness. A recent systematic review on implementation strategies for telemental health published in 2023 by Appleton et al [52] highlighted that telemental health can improve access to care, especially for individuals in remote or resource-limited areas. Our study echoed them in terms of the role of telemental health support in increasing the accessibility of mental health care in Bangladesh. While most studies on telemental health mentioned positive outcomes, one of the meta-analyses on mobile phone–based telemental health interventions by Goldberg et al [69] suggested that the effectiveness of these interventions can vary based on the specific mental health condition and the technology used. Our study could not compare the efficacy of the Wellbeing Centers compared to other phone-based or community-based methods. We recommend further research and trials to understand the actual benefits of using Wellbeing Centers compared to other types of services.

Strengths

Our study has several strengths, based on which we have identified the major findings discussed earlier. This study was conducted in 6 facilities, which provided us a reasonably large sample of pregnant and postpartum women attending antenatal and postpartum care. It involved a rigorous analysis using WHO-guided implementation variable, which ensured standardization with other global implementation research on telemental health services. Our intervention was provided through the government system; therefore, these findings will be valuable for the GoB for scaling up the intervention to a higher number of facilities. This paper focused on the pregnant and postpartum women. However, the services are also provided to general patients. Therefore, findings might provide additional evidence while assessing the implementation outcomes for general patients.

Limitations

We also acknowledge some limitations of our study. First, this study was conceptualized based on the WHO framework and implementation outcome variables. The WHO's implementation outcome variables may have limited the opportunities of capturing other potential outcome variables that may be important for assessing implementation aspects of the Wellbeing Centers. Second, we acknowledge the fact that we did not randomly select our demonstration sites for Wellbeing Centers. Therefore, the result may not be generalizable to the whole

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country. In Bangladesh, there are regional variations that have an impact on access to health care as well as service quality. Our selected sites reasonably capture the variations of the service provision and quality. Third, we also acknowledge that we have selected the DHs based on their functionality. The inclusion of low-performing districts could make our results more generalizable. However, this was not possible because of implementation cost challenges. Fourth, in this analysis, we could not assess the rate of adoption of the Wellbeing Center services, as we could not capture the true denominator of how many women needed mental health support among those seeking ANC or PNC from the facilities. Finally, this analysis only assessed symptoms of depression and anxiety as mental health issue. Other disorders could also have been included to strengthen this study.

Conclusions

This implementation research study demonstrated the feasibility, acceptability, and usefulness of introducing the telemental health service Wellbeing Centers for antepartum and postpartum women at Bangladeshi facilities. We are confident in our conclusions, as we saw the services increased the perceived accessibility of mental health services with minimal influence from other factors. Appropriate staff training is required to maintain these centers. We recommend that psychologists and psychiatrists have patience and a positive attitude while maintaining the privacy of patients during the scale-up of the model. We also recommend future studies on cost-effectiveness and postimplementation follow-up to evaluate the sustainability, effectiveness, and impact over a longer time period. The experiences and learnings from this implementation research can support generating evidence-based decisions related to the introduction and scaling-up of the Wellbeing Centers in Bangladesh and other low- and middle-income countries.

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Authors' Contributions

ATH developed the manuscript as the first author with support from AER. AER and MSS guided ATH in designing the study and developing the manuscript as joint senior authors. SEA and MRA reviewed the results and guided the team in interpreting the results. MHR, RMM, and EA contributed to data management and statistical analyses. MAH conducted the qualitative interviews, and TA, NGU, and PC supported in qualitative data management. SMHI supervised the implementation and field activities. HUA, MKM, JMJ, FS, SAS, FA, and MJB provided guidance in validating the psychological and psychiatric information of the study. MAK and SMMR provided support in developing the intervention strategy. SA, SJ, and AA reviewed the first draft of the paper. All authors contributed to the interpretation of the results and read and approved the final version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Quantitative data collection tools to assess depression, anxiety, adoption, accessibility, acceptability, and usefulness for antenatal and postnatal women.
[DOCX File , 38 KB - pediatrics_v8i1e65912_app1.docx]

Multimedia Appendix 2
Data collection tool for feasibility assessment among the health facility managers.
[DOCX File , 24 KB - pediatrics_v8i1e65912_app2.docx]

Multimedia Appendix 3
Interview guideline for in-depth interviews with antenatal and postnatal women to explore their experiences, perceptions, and expectations regarding the telemental health counseling.
[DOCX File , 21 KB - pediatrics_v8i1e65912_app3.docx]

Multimedia Appendix 4
Interview guideline for key informant interviews with the counselors and health care providers to explore their experiences, perceptions, and expectations regarding the telemental health counseling.
[DOCX File , 22 KB - pediatrics_v8i1e65912_app4.docx]

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Multimedia Appendix 5
Flowchart of the selected antepartum and postpartum women.
[DOCX File , 50 KB - pediatrics_v8i1e65912_app5.docx]

Multimedia Appendix 6
Proportion of users who received follow-up counseling.
[DOCX File , 56 KB - pediatrics_v8i1e65912_app6.docx]

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Abbreviations

ANC: antenatal care
aOR: adjusted odds ratio
DH: district hospital
GAD-7: Generalized Anxiety Disorder
GoB: government of Bangladesh
icddr,b: International Centre for Diarrhoeal Disease Research, Bangladesh
IDI: in-depth interview
KII: key informant interview
NCDC: Non-Communicable Disease Control
NIMH: National Institute of Mental Health
PHQ-9: Patient Health Questionnaire-9
PNC: postnatal care
RMO: resident medical officer
UHC: upazila health complex
WHO: World Health Organization

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Pediatric Hearts and Minds: Reimagining Health Education Through Play and Narrative

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KEYWORDS

congenital heart disease; children health literacy; health education; health education interventions; patient-centered care; design; pediatric; PRISMA

As a student advocate actively involved in heart health promotion among youth, I was interested in the study entitled "Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review" [1]. The authors identified a gap in age-appropriate educational tools for younger children in the interventions, highlighting the importance of using playful, developmentally tailored strategies to engage them in learning about their cardiac condition.

This insight dovetails precisely with the broader realm of pediatric health literacy, wherein the convergence of cognitive development and medical comprehension calls to attention unique barriers. Children with congenital heart disease (CHD) face difficulties in understanding abstract medical concepts and their condition [2]. Considering this, narrative medicine holds great potential in increasing the relatability, digestibility, and applicability of knowledge by reframing biomedical concepts into metaphorical storytelling. Thus, children with CHD may be able to internalize their medical journey in ways that align with their developmental stage and personal experiences, gaining a sense of agency and coherence.

Similarly, the role of ludic and entertaining pedagogical tools emerges as a pivotal mediator of developmental trajectories across cognitive, social, and emotional domains. Health care providers, especially pediatricians and family physicians, must actively ensure that play is healthy and safe [3]. Whether it be a story-driven game or a cardiac-themed toy, interactive tools may significantly advance educational interventions through tangible learning modalities that convert abstract principles into concrete experiences. As such, the cardiac health journey becomes one of engagement, where the child becomes a conscious, active participant in their medical education rather than a mere recipient of information.

The teddy bear hospital concept in particular exemplifies this symbiotic relationship between play and education, demonstrating efficacy in reducing children's health care–related anxiety, improving their health care knowledge, and enhancing their well-being through playful role-playing in a health care setting [4]. By softening the edges of medical procedures, this model dismantles the intimidating walls of the clinical environment, transforming it into a less foreign and more approachable space for younger children who are not as impacted by traditional educational interventions.

Yet another crucial dimension of children's play surfaces through physical activity. Children with CHD and their parents recognize the importance of physical activity, but uncertainty in their health environment contributes to inactivity despite minimal professional restrictions [5]. An area ripe for intervention, physical activity guidelines could incorporate real-time feedback mechanisms that build confidence and ensure safety to promote physical exercise as an act of healing and empowerment, rather than a source of anxiety.

In tailoring educational messaging by age, we can raise the effectiveness of CHD interventions, recognizing and respecting that children are not simply "mini teenagers" and much less "mini adults." Such an approach must, therefore, incorporate elements of embodied cognition, experiential learning, and psychological support to create a comprehensive educational framework that addresses the specific cognitive and emotional needs of children with CHD. Only in this way can we create immersive and engaging learning environments that make complex cardiac concepts accessible to the young minds often underrepresented while fostering psychological resilience and physical confidence.

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Authors' Contributions

AY wrote, edited, revised, and reviewed this manuscript.

Conflicts of Interest

None declared.

Editorial Notice

The corresponding author of “Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review” declined to respond to this letter.

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Abbreviations

CHD: congenital heart disease

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A Holistic Digital Health Framework to Support Health Prevention Strategies in the First 1000 Days

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Abstract

The first 1000 days of a child's life, spanning from the time of conception until 2 years of age, are a key period of laying down the foundations of optimum health, growth, and development across the lifespan. Although the role of health prevention programs targeting families and children in the first 1000 days of life is well recognized, investments in this key period are scarce, and the provision of adequate health care services is insufficient. The aim of this viewpoint is to provide a holistic digital health framework cocreated with policy makers, health care professionals, and families to support more effective efforts and health care programs dedicated to the first 1000 days of life as the first line of prevention. The framework provides recommendations for leveraging on behavioral intervention technology and digital therapeutics solutions augmented by artificial intelligence to support the effective deployment of health prevention programs to families. The framework also encourages the adoption of a citizen science approach to co-design and evolve the digital health interventions with all relevant stakeholders in a real-world research perspective.

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KEYWORDS

digital health; digital therapeutics; behavioral intervention technology; prevention; citizen science; first 1000 days

Introduction

The first 1000 days is a continuum that begins with pregnancy and ends at the child's second birthday. It is a unique period laying down the foundations of optimum health, growth, and development across the lifespan [1], but it can also represent a period of potential vulnerability where the way mothers and children are cared for has a profound influence on a child's ability to grow, learn, and thrive [2]. Although the role of the first 1000 days of life is well recognized [2,3], investments in this key period are scarce, and the provision of adequate health care services and interventions is insufficient [1].

In this viewpoint, we address current challenges and opportunities in the development of effective health care interventions for the first 1000 days, by leveraging on a holistic digital health (DH) framework that can help to optimize efforts in the cocreation of these interventions with the support of policy makers, health care professionals, and families. The framework leverages on state-of-the-art approaches and opportunities in the design of behavioral intervention technology (BIT) and artificial intelligence (AI)–augmented digital therapeutics (DTx) for prevention and care, such as the Integrate, Design, Assess, and Share (IDEAS) framework [4] and the DTx Real-World Evidence (RWE) framework [5]. It complements these approaches by stressing the importance of facing the design and validation challenges within a longitudinal perspective based on citizen science and real-world evidence, to cocreate and evolve the DH interventions in a more pragmatic and sustainable way.

Health Prevention Strategies and Challenges in the First 1000 Days

The first 1000 days are characterized by 3 main periods of intervention, preconception, pregnancy, and infancy, which are key for ensuring children's healthy growth [1,3]. Health prevention programs and strategies during the preconception period address biomedical, behavioral, and social risks factors that may affect a pregnant woman's health, by providing nutritional and physiological support; identification and prevention of risks, such as toxic exposures [6,7]; and support in the adoption of changes in lifestyle [3]. Health prevention programs and strategies should also be maintained in the interconception period, going from childbirth until the birth of a subsequent child [8]. During pregnancy, the main areas of prevention typically regard nutrition, stress, and exposure to environmental contaminants [3,9]. The Italian Ministry of Health identifies 11 thematic areas that focus on prevention in the first 1000 days, including nutrition, lifestyle, parental literacy and skills, and mental health [10].

In different countries, public health care programs and interventions have been developed to support families in the

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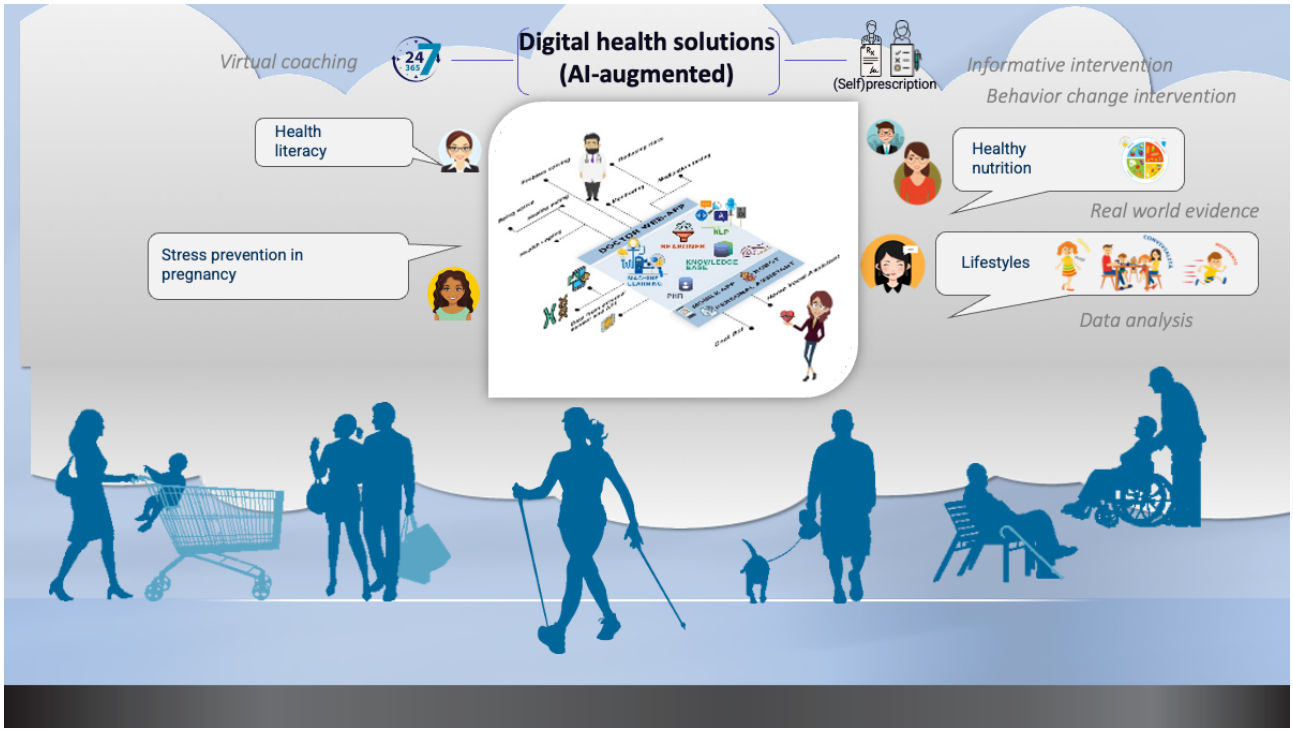
first 2 years after birth [11-14], promoting health literacy and behavioral change of parents in key areas such as nutrition, lifestyles, and mental health. Notwithstanding the large amount of data and guidelines supporting the importance of establishing efficient health care services in the first 1000 days, these health prevention strategies have not been efficiently converted into comprehensive and integrated programs enabling adequate support to parents and infants during this period [1,15,16].

In this viewpoint, we advocate that this gap is also due to a lack of deployment of DH solutions that support evidence-based educational and behavioral interventions for families and are designed for being acceptable, inclusive, engaging, equitable, scalable, and sustainable over the lifespan. Recent reviews of health professional-delivered interventions during the first 1000 days have shown that so far, most interventions were delivered in individual or group face-to-face sessions and that optimal intervention, in terms of timing, content, dose, mode of delivery, theory, and active ingredient, have yet to be established [15].

In our vision, DH technologies can play a key role in supporting the deployment of health prevention strategies and programs in the first 1000 days (as the first line of prevention) as well as over the individuals' lifespan. The kind of automation, engagement, and decisions supported by DH empowered by AI are commonly reviewed by domain experts before they can be implemented in a treatment plan, a process called augmented intelligence or intelligence amplification [17], wherein AI technology informs and augments, rather than replaces, health care professionals' experience and cognition [18].

As depicted in Figure 1, prevention programs addressing key areas of intervention, such as nutrition, lifestyle, mental health and well-being, health literacy, and education, may be more effectively translated into behavioral intervention solutions. These interventions should be informed by evidence-based theoretical approaches and a diversity of potential technologies to ensure a scalable, sustainable, accessible, and cost-effective delivery of prevention strategies. To address the challenges of effectively designing such solutions we call for a holistic DH framework helping to combine behavioral, technical, and methodological components in the intervention design process to ensure a translation of health strategies into better prevention and health outcomes for the target populations.

Figure 1. Digital health solutions delivering prevention programs in the first 1000 days and over the lifespan. AI: artificial intelligence.



A Holistic DH Framework for Cocreation With Stakeholders

Opportunities and Challenges of DH Deployment

Recent advances in the development of DH solutions provide unprecedented opportunities for deploying health prevention strategies and programs with the support of BITs or DTx. BITs typically include sensor-trackers (eg, heart rate and step count), AI-augmented chatbots (automated conversational agents), and momentary ecological assessments (which can repeatedly assess individual's behaviors and experience them in real time) [19-21].

DTx are defined as tools to deliver evidence-based health interventions (using, for example, cognitive behavioral theory as an active ingredient for treatment) through different types of potential technological solutions as excipients (eg, mobile health apps, web apps, chatbots, or virtual reality [VR] environments) [22-24].

Both BITs and DTx are DH solutions that can improve health outcomes, reduce burdens on health care professionals, and increase access to and usability of interventions [25,26]. Common goals of DH include improving lifestyle, by facilitating behavior change in diet, physical activity, or sleep, or improving mental health, such as care for depression, anxiety, or symptoms

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of stress. DH solutions are often complex interventions [27], as they can include multiple components, such as goal-setting or problem-solving elements and AI algorithms that adapt provision of support to each person's changing needs. The goal of including these components in DH solutions is that they can simultaneously provide safe, effective, accessible, sustainable, scalable, and equitable support for individual and population health [28]. However, accomplishing an effective integration of these components in DH solutions is very difficult, and recent efforts have been made to provide guidance in the design, development, and assessment of these solutions by leveraging on the evidence offered by real-world data produced over usage of these digital tools, to better understand the trajectories of intervention outcomes over time [5].

The Framework Development

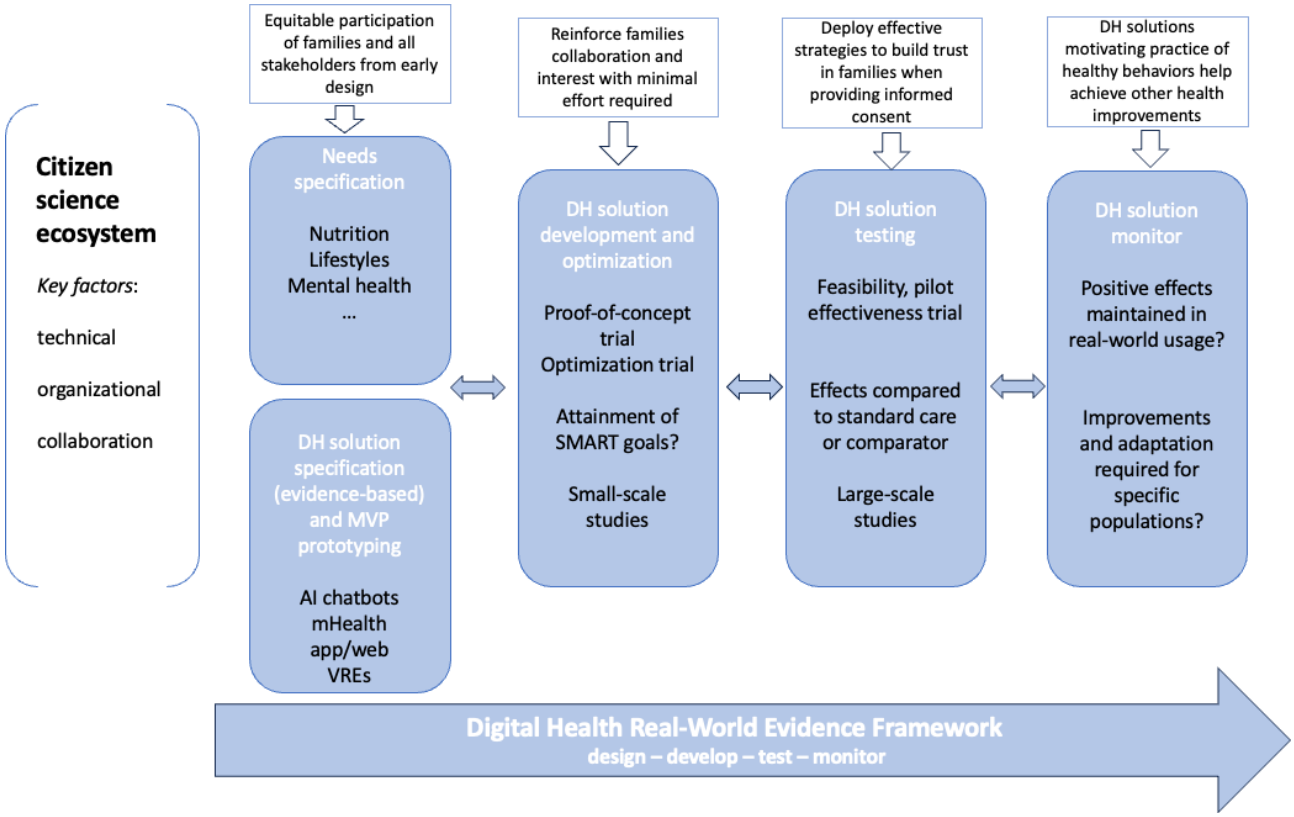
The holistic DH framework (Figure 2) is aimed at supporting the future deployment of DH solutions for prevention in the first 1000 days.

The authors of this paper first conducted a review of state-of-the-art frameworks relevant to inform the design and validation of these solutions. The review identified strengths and limitations of 4 main frameworks commonly deployed in the design of digital interventions: (1) the IDEAS framework, aimed at supporting the development of digital interventions for health behavior change and based on the IDEAS phases [4]; (2) the ORBIT (Obesity-Related Behavioral Intervention Trials) model [29], aimed at guiding the design of evidence-based behavioral treatments to prevent and treat chronic diseases, based on the 4 phases of design, preliminary testing, efficacy, and effectiveness research; (3) the MOST (Multiphase Optimization Strategy) model [30,31], aimed at optimizing the development of behavioral, biobehavioral, and biomedical interventions; and (4) the DTx RWE framework [5], inspired by ORBIT and based on the 4 phases model of development (design, develop, test, and monitor). The review also included the citizen science approach [32] as a relevant method informing the cocreation of DH solutions with the participation of all stakeholders. Citizen science has been defined as the general public engagement in scientific research activities, when citizens actively contribute to science either with their intellectual effort or surrounding knowledge or their tools and resources [33].

The holistic DH framework was then developed in a 2-way process. First, 1 author (SG) selected the combination of components from the DTx RWE framework and citizen science approach most relevant to provide a comprehensive overview of the research steps to be taken to design and deploy digital interventions for health prevention programs. In a second step, a draft version of the framework was discussed at length in a meeting among the 3 authors (SG, OMI, and SF) and revised based on the feedback provided.

We present the key components of the holistic framework in a case study providing guidance and recommendations for ensuring a more effective deployment of health prevention programs in the first 1000 days by, at the same time, leveraging on the potential of DH solutions.

Figure 2. Holistic DH framework to cocreate with stakeholders. AI: artificial intelligence; DH: digital health; mHealth: mobile health; MVP: minimum viable product; SMART: Specific, Measurable, Actionable, Realistic, Timely; VRE: virtual reality environment.



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Application of the Holistic DH Framework

To illustrate the potential of the holistic DH framework in guiding the cocreation of effective prevention programs in the first 1000 days, we present examples of ongoing activities started by our research team in tackling the issues of digitizing prevention programs currently available to citizens in the Trentino region (Italy) for the pregnancy and infancy periods (birth path), working together with health professionals (gynecologists, obstetricians, and pediatricians) at the local health care system, with policy makers at the local Department of Health and Innovation, and with the target user populations (families). The main intervention areas addressed so far regard providing parental literacy to women and families during the first 1000 days (Figure 3), and providing pregnant women with healthy nutrition and psychoeducational DH programs for stress prevention from the 4th month of gestation [34-37]. The overall goal of introducing digital tools to support current prevention programs was to facilitate the adoption of a holistic strategy to target barriers in the delivery of these programs, such as reaching women living in rural areas having difficulties in accessing health care services or belonging to vulnerable populations, but also to improve ongoing prevention programs' development by incorporating holism, precision prevention, timeliness, and cost-effectiveness [19,38].

The design phase for these DH solutions started from a series of participatory sessions with all stakeholder groups (health professionals, policy makers, and families) to achieve an in-depth knowledge of the prevention needs in the target areas and to specify the requirements and prototyping of the DH tools by providing equitable consideration of the different stakeholders' perspectives, as well as building empathy and acknowledgment of any power differential [32].

From a technological point of view, it was decided to realize a secure and privacy-preserving DH platform providing virtual coaching functionalities by means of AI-augmented digital assistants available on mobile app (or coaching avatars in VR) each specialized for delivering DH intervention in a target prevention area.

Chatbot technology, using AI-augmented tools including machine learning and natural language processing, has been introduced into the health sector to address current health care challenges, such as shortage of health care providers and lack of health care access, showing several positive effects in supporting tailored intervention, which is better able to address users' needs over a digital treatment [39].

At the current stage of DH solutions development, a chatbot-based mobile app supporting women and families during the first 1000 days, named TreC-Mamma (Digital Health Research and Digital Health Innovation Lab, Fondazione Bruno Kessler), has already been released, and it is in use by more than 1000 users in the region. The aim of the TreC-Mamma solution is to provide an initial platform for collecting real-world evidence on the impact of DH solutions deployment during the first 1000 days, thus informing the development and refinement of more advanced AI-augmented digital assistants for the different intervention areas, by relying on a larger involvement and participation of families in the cocreation process. Parallel research activities are ongoing for assessing the developed proof-of-concept DH solution minimum viable products (MVPs) targeting healthy lifestyles and stress prevention during pregnancy. Specifically, virtual coaching on healthy nutrition and physical activity is provided to pregnant women by using microlearning and motivational modules validated by domain experts. For stress prevention, a chatbot-based solution deploying a digitally adapted version of the Self-Help+ protocol developed by WHO (World Health Organization) [40] has been implemented and preliminarily validated with mental health experts.

Small-scale studies are currently running to assess the MVPs' usability, acceptance, scalability, etc for further refinement and optimization based on the attainment of benchmark criteria such as the SMART (Specific, Measurable, Actionable, Realistic, Timely) goals [41]. These studies, typically involving small samples of pregnant women and their families, are also contributing to reinforce their collaboration and interest in the research project goals in the long-term, aiming to minimize the effort requested from citizens if they participate in the cocreation process.

Once the development and optimization phase of the digital assistants is completed, these DH solutions will be integrated into the TreC-Mamma platform and will be available for use by families to undergo more large-scale testing in the form of feasibility pilot trials or effectiveness trials. The ultimate goal of this testing phase is to compare the effects of the DH interventions with standard of care in the local health care system, with other relevant comparators, or by means of randomized controlled trials. In preparation of this testing phase, we are already devising an effective strategy to build trust in the project aim and solutions among families that are using the TreC-Mamma platform, facilitating the collection of their informed consent through the platform (asking them to sign a so-called "agreement with the citizen"), and clearly explaining the type of data and intended use of their data for a dynamic improvement of the platform in a citizen science perspective.

In a more long-term view, the TreC-Mamma platform will allow us to monitor the effects of our released DH interventions to assess whether their positive effects are maintained over real-world usage. In this monitoring phase, additional requirements and needs may arise from families and other stakeholders, leading to improvements and further adaptations of our solutions to fulfill evolving needs to address new areas of prevention or specific needs of target populations. As a positive side effect of deploying our DH solutions for motivating families to practice healthy behaviors in the first 1000 days, we foresee the potential achievement of health improvements in other prevention areas (eg, chronic disease prevention, such as gestational diabetes, type II diabetes, and depression) contributing to the realization of more comprehensive prevention goals and strategies.

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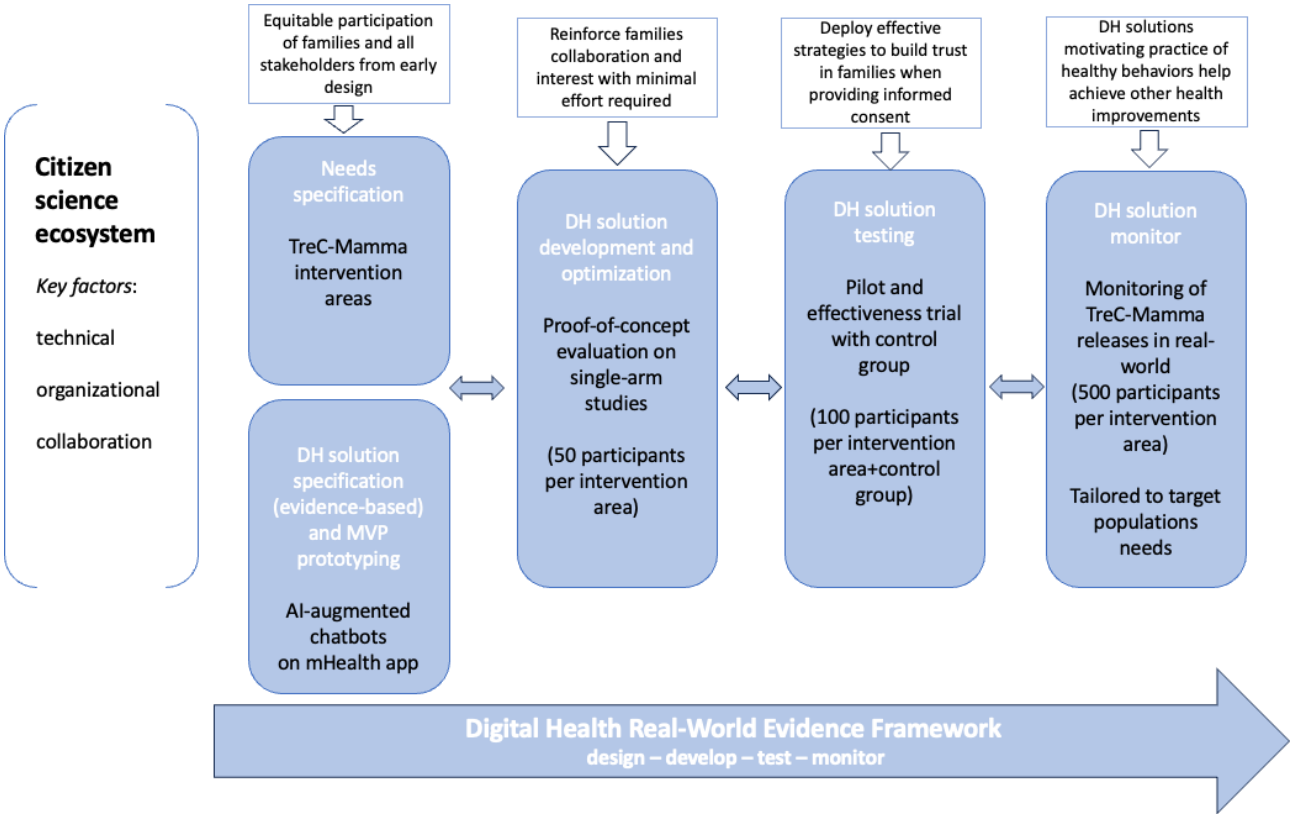
Figure 3. Holistic DH framework applied to *first 1000 days* interventions. AI: artificial intelligence; DH: digital health; mHealth: mobile health; MVP: minimum viable product



Conclusions and Future Work

The holistic framework presented aims to provide guidance in the design and deployment of DH solutions supporting prevention strategies in the first 1000 days. It can be used to realize DH interventions in a more effective and participatory approach, leveraging on the contribution of the different stakeholders. It can help researchers in addressing the complex goal of realizing AI-augmented DH solutions by optimizing the resources available in the design process. This can be achieved by deploying a sociotechnical platform able to facilitate the engagement of citizens in the different stages of the intervention validation, as well as the effective use of real-world data for supporting the evolution and adaptation of the intervention to the target user populations.

Among the strengths of the framework presented is that it sheds light on unprecedented opportunities for deploying DH technologies in the attempt to realize more scalable, sustainable, and cost-effective solutions for prevention. It is also based on a concrete example of ongoing applied research for prevention in the first 1000 days that is supporting the feasibility of the approach proposed. We also believe that the framework illustrated can be of help in designing DH solutions for different application fields targeting health prevention and care with other target populations. By combining real-world evidence with citizen science research, it can help to overcome some limitations of previous DH frameworks like IDEAS by, for example, better supporting multidisciplinary teams' work beyond the initial intervention design and refinement, providing evidence for the adoption of the most effective behavioral strategies as derived from large-scale deployment of the digital solutions, and showcasing the sustainability of the digital solutions deployment, which may facilitate their more structural adoption and support by policy makers and users in the target communities.

However, there are also some limitations involved in the framework adoption and in its generalization to different contexts. Most of the real-world experience reported in the case study presented regards DH solutions design and development, while key outcomes derived from the test and monitor phases are still lacking. Therefore, more validation data on the framework application in real-world settings are needed, and this objective will be part of our future work. In addition, the AI-augmented features recommended to tailor the coaching of the digital assistants to the user needs require considerable design and development efforts, which may consume more tangible and intangible resources [42]. Key ethical considerations should also be considered when applying AI algorithms and techniques in DH solutions development, including bias minimization, transparency, and users' privacy and safety protection [43,44].

Notwithstanding these limitations, we think that grounding DH design efforts in a real-world evidence practice informed by a citizen science approach may contribute to establishing more productive dialogues among the stakeholders involved, as well as to facilitating faster innovation outcomes in the implementation of prevention programs.

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Acknowledgments

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Disclaimer

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
BIT: behavioral intervention technology
DH: digital health
DTx: digital therapeutics
IDEAS: Integrate, Design, Assess, and Share
MOST: Multiphase Optimization Strategy
MVP: minimum viable product
ORBIT: Obesity-Related Behavioral Intervention Trials
RWE: Real-World Evidence
SMART: Specific, Measurable, Actionable, Realistic, Timely
VR: virtual reality
WHO: World Health Organization

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Integrating Infant Safe Sleep and Breastfeeding Education Into an App in a Novel Approach to Reaching High-Risk Populations: Prospective Observational Study

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Abstract

Background: Sudden unexpected infant death (SUID) is a leading cause of death for US infants, and nonrecommended sleep practices are reported in most of these deaths. SUID rates have not declined over the past 20 years despite significant educational efforts. Integration of prenatal safe sleep and breastfeeding education into a pregnancy app may be one approach to engaging pregnant individuals in education about infant care practices prior to childbirth.

Objective: This study aims to assess whether pregnant individuals would engage with prenatal safe sleep and breastfeeding education provided within a pre-existing pregnancy app. Secondary objectives were to compare engagement among those at high and low risk of losing an infant to SUID and to assess the importance of end user push notifications for engagement.

Methods: This prospective observational study was conducted from September 23, 2019 to March, 22 2022; push notifications were removed on October 26, 2021. TodaysBaby (University of Virginia, Boston University, and Washington University), a mobile health program in which safe sleep and breastfeeding video education was originally provided via texts, was embedded into the MyHealthyPregnancy app (Naima Health LLC). Pregnant mothers who received prenatal care within the University of Pittsburgh Medical Center hospital system were randomized to receive either safe sleep or breastfeeding education beginning at the start of the third trimester of pregnancy and ending 6 weeks post partum. Pregnant persons were designated as high risk if they lived in the 5% of zip codes in Allegheny County, Pennsylvania with the highest rates of SUID in the county. The primary outcome was engagement, defined as watching at least 1 video either in response to a push notification or directly from the app's learning center.

Results: A total of 7572 pregnant persons were enrolled in the TodaysBaby Program—3308 with push notifications and 4264 without. The TodaysBaby engagement rate was 18.8% with push notifications and 3.0% without. Engagement was highest in the initial weeks after enrollment, with a steady decline through pregnancy and very little postpartum engagement. There was no difference in engagement between pregnant persons who were low and high risk. The most viewed videos were ones addressing the use of pacifiers, concerns about infant choking, and the response of the body to the start of breastfeeding.

Conclusions: Integrating safe sleep and breastfeeding education within a pregnancy app may allow for rapid dissemination of infant care information to pregnant individuals. Birthing parents at high risk of losing an infant to SUID—a leading cause of infant death after 1 month of age—appear to engage with the app at the same rates as birth parents who are at low risk. Our data demonstrate that push notifications increase engagement, overall and for those in high-risk zip codes where the SUID education is likely to have the most impact.

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KEYWORDS

SIDS; infant death; sleep; sudden infant death; US; United States; infant; infancy; baby; prenatal; safe sleep; breastfeeding; infant care; pregnancy; app; randomized controlled study; TodaysBaby; mobile health; mHealth; smartphone

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Introduction

Sudden unexpected infant death (SUID) is a leading cause of death among US infants, with nonrecommended sleep practices reported in most of these deaths [1]. After a major decrease in the SUID rate immediately after the American Academy of Pediatrics released its 1992 recommendation that infants be placed on their backs to sleep, the rate has plateaued despite extensive educational efforts [2,3]. There continue to be racial and socioeconomic disparities in SUID, with rates higher among Black infants and infants who live in poverty [4-6]. The disparity can be marked, for instance, in Allegheny County, Pennsylvania in 2017 - 2022; 35% of all SUID occurred in 5.6% (7/124) of zip codes (Berger R, MPH, MD, unpublished data, personal communication, May 2024).

Parental education in the newborn nursery has been an important approach to reducing the risk of SUID [7-9]. Information about modifiable risk factors for SUID, including prone or side sleep position, not breastfeeding, sharing a sleep surface, use of soft bedding, and exposure to nicotine/smoking, alcohol, drugs, and illicit substances, when routinely incorporated into newborn education, can change parental practice [4,10]. In one 4-armed randomized controlled trial of hospital quality improvement (QI) and mobile health (mHealth) in 16 US hospitals, new parents were enrolled in an mHealth program (TodaysBaby; University of Virginia, Boston University, and Washington University). The videos in TodaysBaby were designed with parental input from mothers of young infants (our target population); mothers were involved design of the videos and provided suggestions before and during video production and provided feedback after video production [9]. Participants in the randomized controlled trial were randomized to receive emails or texts with links to short (<2 min) videos about either breastfeeding or safe sleep for 60 days. The videos were aimed at changing attitudes and dispelling misconceptions about safe sleep and breastfeeding. In this study, parents who received only safe sleep messaging were 10 percentage points more likely to use safe sleep practices than parents who received no safe sleep messaging. Additionally, racial and ethnic differences in reported safe sleep practices were eliminated in those who received safe sleep messaging. To our knowledge, this is the only randomized controlled trial evaluating video education as an approach to improving safe sleep practices.

The MyHealthyPregnancy (MHP; Naima Health LLC) app is a commercially available evidence-based patient-facing smartphone app and provider-facing portal developed to monitor and model individual risk during pregnancy and provide easy, actionable feedback to patients. The app also offers connection to relevant resources both within and outside the health care system and notifies the individual's care team if a critical risk (eg, preterm labor and suicidal ideation) is reported through the app. The primary goal of the app is to reduce unwanted outcomes both during pregnancy and in the early period after delivery through more timely risk detection and intervention [11-14]. End users were involved in the design, development, and deployment of the technology and the design approach was grounded in person-centered frameworks to advance reproductive health equity [11,15].

The primary objectives of this study were to assess whether the TodaysBaby educational program could be integrated into the MHP app, whether users of the app would engage with the TodaysBaby content, and whether there were differences in knowledge and attitudes related to safe sleep among pregnant persons who were assigned to the safe sleep versus breastfeeding education. A secondary objective was to assess whether parents of infants at the highest risk of SUID—as defined by zip code—were similar in their rates of engagement, knowledge, and attitude compared with those living in low-risk zip codes. TodaysBaby was the first infant-specific education to be integrated into the MHP app, which is otherwise entirely focused on pregnant persons' health and pregnancy.

Methods

Overview

Providers at prenatal clinics in the University of Pittsburgh Medical Center (UPMC) health system could prescribe the MHP app (iOS version 1.4.7, Android version 1.8) to pregnant patients at their first prenatal appointment as part of a prenatal care QI initiative sponsored by UPMC and at no cost to the patient. The internal protocol for prescribing MHP was to send a text-based invitation with a unique web link to the patient's phone, which allowed app users to download the app from the Android or Apple app store. App users electronically consented to share identifiable data with their health care provider and anonymized aggregate data for research. An additional specific consent was provided for enrolling in TodaysBaby. Participants did not receive financial compensation for app use or TodaysBaby participation. At the time of consent, patients were randomly assigned to the safe sleep or breastfeeding group in a 2:1 ratio. High-risk patients—defined by zip code as described below—were enrolled in a 3:1 ratio to the safe sleep group.

All participants were recruited during pregnancy at prenatal clinics. While we recognize that pregnant individuals and parents may be of any gender and that transgender men and gender-nonbinary people may also give birth, we did not collect additional information about biological sex or gender identity from participants. We refer to participants as pregnant persons throughout the manuscript.

MHP users completed an initial onboarding process in which they completed questions about demographics, medical history, and baseline risk factors. Throughout the course of their pregnancy, app users were offered the opportunity to answer questions about their experiences and symptoms through app-embedded screeners, questionnaires, and open-ended text entries. Starting at 32 weeks of pregnancy (based on the due date entered by the user), participants started receiving texts with links to videos ("push notifications" or "pushes") at predefined intervals. The decision to start TodaysBaby at 32 weeks was a change from the original TodaysBaby study, in which the education started at the birth of the infant [9]. We chose not to start earlier than 32 weeks to minimize the likelihood of pregnancy loss among study participants.

There were 21 pushes with 18 videos for each group (safe sleep and breastfeeding): 14 pushes in the prenatal period and 7 in

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the postnatal period. A total of 12 short quizzes about intentions related to sleep and breastfeeding were pushed at similar intervals. All videos were also available to all users in both groups at any time in the app's learning center (LC), which was a section of the app providing educational articles and video links on a variety of pregnancy-related topics.

The video topics for both the safe sleep and breastfeeding groups are summarized in Textbox 1.

Textbox 1. Video topics for the safe sleep and breastfeeding groups.

Safe sleep

- Importance of sleep position
- Choking and sleep position
- Importance of sleep space
- Bed-sharing
- Handling advice from others
- Mattress safety
- Soft bedding
- Feeding baby in bed
- Pacifiers
- Dangers of smoking
- Infant sleep patterns

Breastfeeding

- Importance of breastfeeding
- How to start breastfeeding
- How often to breastfeed
- Hunger cues
- What to do if baby is always hungry
- Benefits of breast milk
- How long it takes for milk to come in
- Latching on
- Avoiding breast discomfort/pain
- Dealing with fussy baby
- Getting support from others
- Economics of breastfeeding
- Breastfeeding when returning to work

On October 26, 2021, the push notifications and videos were removed; the videos remained in the LC for pregnant persons who downloaded the MHP app.

Ethical Considerations

The project was approved by the UPMC QI Committee (reference number 1613). App users consented the publication of anonymized aggregate data during app onboarding. An additional consent was provided during app onboarding to a subset of MHP users to opt in to participation in the TodaysBaby program.

Statistical Analysis

The number of videos watched via push notification or from the LC was aggregated. Data from the push notifications indicated that some videos were possibly clicked, so the aggregation was done once for definitely clicked videos and separately to include both and possibly clicked videos. Partial viewings of a video were counted as a viewing of that video. Engagement was defined as watching at least 1 video either in the LC or in response to a push notification. A binary indicator of high- versus low-risk zip codes was created.

Descriptive statistics such as frequency and percentages were used to examine demographic factors for the entire sample as well as the high- and low-risk groups. Individual chi-square tests were used to examine 2 × 2 combinations by group (safe sleep vs breastfeeding), engagement, high-risk zip codes, and frequency of video viewership. A standard of 5% probability of type 1 error was used.

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Results

Overview

Between September 23, 2019, and October 26, 2021, 43% (3635/8453) of pregnant persons who were prescribed the MHP app enrolled. Of these, 91% (n=3308) consented to receive TodaysBaby content—2407 in the sleep group and 901 in the breastfeeding group. There were no demographic differences between those who did or did not enroll in the MHP app [13]. The demographics of participants who enrolled in TodaysBaby are summarized in Table 1.

Table . Demographics of MyHealthyPregnancy app users who consented to TodaysBaby.

		Overall users (n=3308)	Pregnant person living in a higher SUID[a] rate area in Allegheny County (n=297)	Pregnant person living in a lower SUID rate area in Allegheny County (n=1562)
Maternal age (years), mean (SD)		29.8 (5.4)	30.3 (5.8)	30.7 (5.1)
Income (US $), n (%)				
	Under 10,000	282 (8.9)	43 (15.4)	105 (7.0)
	10,000-14,999	147 (4.6)	18 (6.4)	56 (3.7)
	15,000-19,999	107 (3.4)	11 (3.9)	39 (13.3)
	20,000-24,999	137 (4.3)	18 (6.4)	48 (3.2)
	25,000-34,999	233 (7.3)	21 (7.5)	86 (5.7)
	35,000-49,999	274 (8.6)	21 (7.5)	103 (6.9)
	50,000-69,999	351 (11.0)	28 (9.4)	140 (9.3)
	70,000-100,000	640 (20.1)	43 (15.4)	306 (20.4)
	>100,000	1011 (31.8)	77 (27.5)	618 (41.2)
Parity–Nulliparous, n (%)		1793 (54)	166 (56)	885 (57)
Maternal education, n (%)				
	Bachelor degree or higher	1881 (57)	158 (53)	1043 (67)
	Associate degree	356 (11)	29 (10)	137 (9)
	Grade school, some high school, high school, or GED[b]	1025 (31)	101 (34)	362 (23)
	Missing	46 (1)	9 (3)	20 (1)
Smoked tobacco, n (%)		219 (6.6)	20 (6.7)	70 (4.5)
Vaped, n (%)		64 (1.9)	3 (1.0)	24 (1.5)
Used marijuana, n (%)		104 (3)	18 (6.1)	39 (2.5)
Maternal race, n (%)				
	White	2608 (79)	164 (55)	1147 (73)
	Black	351 (11)	91 (31)	210 (13)
	East or South Asian	149 (5)	12 (4)	103 (7)
	Other	176 (5)	25 (8)	90 (6)
	No response	24 (0)	5 (2)	12 (1)

[a]SUID: sudden unexpected infant death.

[b]GED: General Educational Development.

Engagement

Video Watching in Response to a Push Notification

Overall, 11% (368/3308) of all participants clicked on at least one of the push notifications they received. Of those who clicked, 53% (194/368) clicked only 1, 26% (94/368) clicked on 2 unique notifications, and the remaining 21% (80/368) clicked on 3 or more unique push notifications (maximum 20 push notifications). An additional 36 participants clicked on at least 1 push notification but because they closed the app immediately after clicking on the notification, it is not possible to be sure whether they read the information provided. If the possible clicks are included, then 12.2% (404/3308) of all participants clicked on a push notification. By comparison, 9.0% (300/3308) of users clicked on at least 1 monthly mental health

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push notification which was part of the MHP app but not part of TodaysBaby.

Video Watching From the LC

Overall, 10.4% (347/3308) watched at least 1 video directly from the LC and not in response to a push notification; 6.2% (206/3308) watched at least 1 breastfeeding video from the LC, and 7.4% (345/3308) watched at least 1 safe sleep video from the LC.

Overall Engagement Rate

Overall engagement, defined as watching at least 1 video either in response to a push notification or from the LC, was 18.8% (623/3308).

Video Watching

The frequency with which videos were watched ranged from 1% (35/3308) ("why you should not smoke around your baby") to 4.7% (154/3308) ("a reminder about pacifiers"). Over 9% (300/3308) watched at least 1 of 3 pacifier-related videos. Over 98% (613/623) of the watched videos were watched only once (Table 2).

Table . Frequency with which the 10 most popular safe sleep and breastfeeding videos were watched.

Video name	Number of views
A reminder about pacifiers	154
Should I give my baby a pacifier?	106
Will my baby choke on the stomach?	105
Will my body know what to do when I start breastfeeding?	98
Why sleep position matters	97
How often should I feed my baby?	90
What is the safest mattress?	89
How do I know when my baby is hungry	86
What about bedding and bumpers?	84
What makes a baby a good sleeper	70

Timing of Video Watching

Timing of video watching during pregnancy could only be assessed for app users for whom the TodaysBaby integration took place during their first pregnancy with the app. The "weeks gestation" field was not consistently accurate for users who had used the app with previous pregnancies because some had not logged the date when the first pregnancy ended.

Of the 3308, 43% (n=1431) users were using the app for the first time. The mean time during gestation, when videos were watched, ranged from 19 weeks of gestation ("How long should I breastfeed?" and "More about pacifiers") to 32 - 33 weeks ("What can I do when my baby is fussy" and "Breastfeeding can save you time and money"). Many of these videos were watched through the LC before the TodaysBaby curriculum was available (at 32 wk of gestation) on the MHP app.

Engagement Rate After Removal of Push Notifications

From October 27, 2021 to March 22, 2022, after the push notifications were stopped, of the 4264 participants who downloaded the MHP app, 3.0% (n=127) watched any TodaysBaby videos. Overall, 2.0% (n=85) watched at least 1 breastfeeding video, and 2.0% (n=85) watched at least 1 safe sleep video. The use of the LC was also significantly lower among pregnant persons who did not receive pushes versus those who did (127/4264, 3% vs 347/3308, 10.4%; $P<.001$).

Engagement of Participants in High-Risk Zip Codes in Allegheny County

Of the 3308 users, 58% (n=1859) were from Allegheny County; of these, 16% (297/1859) lived in a high-risk zip code and 84% (1562/1859) lived in a low-risk zip code. Demographic characteristics of the TodaysBaby participants from high-risk and low-risk zip codes are found in Textbox 1.

Among those with high-risk zip codes, 219 were randomized to safe sleep and 78 to the breastfeeding group. Overall engagement in this group was 21.5% (62/297), 10.8% (32/297) clicked on at least 1 TodaysBaby push notification, and 12.5% (37/297) watched at least 1 video from the LC. View rates of safe sleep and breastfeeding videos were similar for both high-risk and low-risk groups.

There was no difference in the engagement of users from high-risk and low-risk zip codes, with the push notifications (32/297, 10.8% vs 185/1562, 11.8%; $P=.60$) or the LC videos (182/1562, 11.6% vs 37/297, 12.5%; $P=.70$).

Quizzes

Overall, 12.0% (409/3308) of all users took at least 1 of the 12 quizzes. Of those who took at least 1 quiz, 54% (222/409) took only a single quiz. Except for quizzes 1 and 6, the completion rate was very low (Table 3). Quizzes 1 and 6 coincided with the user getting a push notification on the same day related to a change in the stage of fetal development. The push notification on the day of quiz 1 (32 weeks gestation) was "Pregnancy is full of many joys and challenges! Reflect on yours now with

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your mental health check-in" and the one on the day of quiz 6 (35 weeks gestation) was "Welcome to week 35! Time to put that hospital bag next to your door! Visit MHP for a list of recommended items to pack." There was no difference in response rate between the safe sleep and breastfeeding groups or between high- and low-risk users.

Table . Number of responses to each of the 12 quizzes.

Quiz number	Number of responses
1	279
2	32
3	32
4	44
5	48
6	211
7	62
8	34
9	32
10	25
11	1
12	2

The responses to questions in quizzes 1 and 6 demonstrate that app users plan to breastfeed (83.2%), plan for their baby to sleep in a safe location (97.9%), and plan for their baby to sleep on his or her back (94.6%) (Table 4). There was no difference in the quiz responses between groups (safe sleep versus breastfeeding or high versus low risk).

Table . Responses to quizzes 1 and 6.

Quiz number and quiz question	Response
Q[a]1Ques[b]1: When I first bring my baby home, I plan to breastfeed	83.2% agree or strongly agree
Q1Ques2: When I first bring my baby home, I plan to have him/her sleep in an adult bed	2.1% agree or strongly agree
Q1Ques3: When I first bring my baby home, I plan to place him/her on the side to sleep	5.7% agree or strongly agree
Q1Ques4: When I first bring my baby home, I plan to place him/her on the stomach to sleep	3.9% agree or strongly agree
Q1Ques5: When I first bring my baby home, I plan to place him/her on the back to sleep	94.6% agree or strongly agree
Q1Ques6: When I first bring my baby home, I plan to give him/her a pacifier	34% agree or strongly agree
Q6Ques1: I will be taking a medication or substance that may make me sleep more deeply	10.9% yes or unsure
Q6Ques2: I am currently on prescribed opioids/pain medication/methadone or Subutex/suboxone	1.9% yes
Q6Ques3: I currently use tobacco products	7.6% yes

[a]Q: quiz.

[b]Ques: question.

Discussion

Principal Findings

This is the first study, to our knowledge, to evaluate the use of a mobile app as a means of delivering safe sleep education to pregnant persons with the goal of addressing the risk of SUID. While mHealth tools have been used to explicitly encourage breastfeeding and other care behaviors, the use of an mHealth tool to address safe sleep is novel [16,17]. Over the past 20 years, the way in which young adults receive information has shifted. Smartphone ownership is ubiquitous among reproductive-aged individuals in the United States, with similar distribution by race and ethnicity [18]. A vast majority of smartphone owners use their phones to access health

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information, with pregnancy being one of the most popular health app domains [19-21].

In addition to their popularity as an information source, there are several clear advantages to the dissemination of information through a mobile app. An app allows for the dissemination of information much more broadly and quickly than face-to-face education or information via educational pamphlets. It also provides the opportunity for users to obtain the information at a time and place which is convenient for them and it allows for the education to be provided as many times as desired and for it to be provided in the same way each time. Receiving inconsistent information even within a single setting such as a primary care physician's office or newborn nursery can contribute to misinformation.

Timing of education is also critical. While previous safe sleep and breastfeeding education programs have focused on parents after childbirth, parents make many decisions about sleep and feeding practices during pregnancy. In a study by our group, we found that pregnant mothers often purchased cribs and made decisions about sleep practices in their third trimester (Berger R, MPH, MD, unpublished data, 2021). Much of the safe sleep and breastfeeding education in the health care system takes place in a physician's office or newborn nursery after birth, which may not coincide with when parents or other caretakers want or need to hear this information. For this reason, we included TodaysBaby within the MHP app starting at 32 weeks, which was a change from the original TodaysBaby study, in which the education started at the birth of the infant [9]. Our data demonstrated that many of the videos in the LC center were watched before any of the app users began receiving the TodaysBaby curriculum. The LC provides the opportunity for pregnant persons to find the information they are most eager and willing to learn and may be most amenable to incorporating new information. As a result of this finding, integration of the TodaysBaby curriculum earlier in the pregnancy is a possible future change.

One of the challenges of safe sleep education provided in a physician's office or birthing hospital is that there is a set curriculum; it would be very difficult to tailor education to each parent. In a recent study by our group, parents described interactions with their pediatricians related to safe sleep. Most parents reported that their pediatricians asked if they were practicing safe sleep and if they responded they were, there was no further conversation (Sahud H, unpublished data, personal communication, 2024). Here, an additional advantage of app-based content delivery is that the education can be tailored. Our study showed distinct differences in popularity (as determined by number of views) depending on the topic of the videos. This suggests that parents know the specific topics they are interested in or need additional information about (eg, pacifier use) and may not want to spend time learning about other (potentially already-familiar) infant-related topics even though each of the videos was <2 minutes in length.

This study also allowed us to see the natural engagement rate with the TodaysBaby content when deployed outside the context of a controlled study environment in a nonincentivized manner. Our approach allowed for dissemination to a large number of users which would not be possible with an in-person dissemination strategy. Since the field of digital health does not yet have a consensus definition of how to measure and report engagement [22], and very few published studies share engagement rates for specific embedded features and content within a larger intervention (eg, embedding TodaysBaby within the MHP app), it is difficult to interpret our engagement rate of 18.8%. Two studies evaluating specific intervention-embedded content in nonincentivized tool use demonstrated much lower engagement rates (eg, <1% of users completed all modules in 1 mHealth tool; approximately 3.5% completed a single assessment in another) than ours [23,24]. There may be an opportunity to increase engagement by focusing on high-interest video topics and beginning the TodaysBaby curriculum earlier in pregnancy when the overall engagement with the app is higher. Although fewer than half of the videos were watched in response to pushes, when the pushes were removed, the overall engagement dropped from 18% to 3%. Moreover, engagement with quizzes was highest when those quizzes coincided with push notifications containing fetal development information. This suggests that push notifications are critically important to engagement, and push notifications with time-sensitive or high-interest content may be leveraged to engage individuals with aspects of the tool that they would otherwise not seek out. The similar engagement rates between users living in communities with high and low rates of SUID are consistent with other data from the MHP app which has demonstrated that pregnant persons at the highest risk for pregnancy-related complications had similar or higher levels of engagement (Naima Health, unpublished data). This finding has important implications for SUID prevention and potentially for the identification of populations most likely to benefit from access to the MHP app. It is also encouraging that the engagement with videos about maternal health within the MHP app was watched as frequently as videos within the TodaysBaby curriculum since it suggests that mothers are equally willing to watch videos about their baby's health and their own health.

Limitations

There are limitations to this study. Those individuals who downloaded the app may not be representative of the larger pregnant population. For example, these individuals may be more comfortable with seeking out information through technology and may not reflect the population in greatest need of the TodaysBaby information. Because of the low response rate for the quizzes, it was not possible to assess whether engagement with the app correlated with changes in safe sleep or breastfeeding intentions. All participants were English-speaking; there is current work on an app that will be in both Spanish and English (Krishnamurti T, unpublished data, personal communication, June 2024).

Conclusions

Our data demonstrate that it is possible to embed safe sleep and breastfeeding education into an app designed to improve outcomes during pregnancy; that the engagement level is encouraging, especially when compared with other published studies of intervention-embedded education within a health-related app; and that this engagement was equally as

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high among pregnant persons at the highest risk of an SUID. Using an app to disseminate information allows for widespread and rapid dissemination and provides users with the opportunity to choose which education they are interested in and when they are interested in receiving it. Simply having access to this education—as was available in the app LC—is not sufficient for engagement, and push notifications are critical for engagement. Future research should focus on assessing whether engagement with the app and TodaysBaby curriculum correlates with changes in safe sleep practices.

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Conflicts of Interest

Naima Health LLC provided the data for this study. The authors did not receive any financial or material compensation for conducting this study. TK is a cofounder and equity holder of Naima Health LLC, but did not receive compensation for conducting this study or disseminating the MyHealthyPregnancy app.

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Abbreviations

LC: learning center
mHealth: mobile health
MHP: MyHealthyPregnancy
QI: quality improvement
SUID: sudden unexpected infant death
UPMC: University of Pittsburgh Medical Center

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Original Paper

Efficacy, Feasibility, and Acceptability of an Emotional Competence Tele-Intervention for Mandarin-Speaking Children Aged 5 to 7 Years With Developmental Language Disorder: Pilot Study With an Interrupted Time-Series Design

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Abstract

Background: Children with developmental language disorder (DLD) often experience language difficulties that hinder their ability to acquire emotional competence. Poor emotional competence is associated with emotional and behavioral problems in young children.

Objective: This research involved two studies focusing on (1) the emotional competence of Mandarin-speaking children aged 5 to 7 years with DLD and (2) the efficacy, feasibility, and acceptability of a tele-intervention designed to enhance their emotional competence in Taiwan.

Methods: Five children with DLD from study 1 declined to participate in study 2, the emotional competence tele-intervention, and were excluded from the analysis. We compared the emotional competence of 20 Mandarin-speaking children with DLD to that of 24 children with typical language development (TLD). The children with DLD were, on average, aged 5.79 (SD 0.47) years, whereas the children with TLD were, on average, aged 5.93 (SD 0.31) years. We assessed the children's emotional competence, nonverbal ability, verbal comprehension, vocabulary acquisition, and expressive language skills. In study 2, all children with DLD included in study 1 engaged in an emotional competence tele-intervention. An interrupted time-series design was used to examine their emotional competence. In total, 20 children with DLD provided data on emotional competence evaluated using the Emotional Lexicon Test. These data were individually collected at 3 time points after study 1 (time 1). These phases included baseline (time 1 to time 2), during the tele-intervention (time 2 to time 3), and follow-up (time 3 to time 4), spanning approximately 18 to 20 weeks from time 1 to time 4. Recruitment, retention, and attendance rates were calculated to evaluate the intervention's feasibility, and participant mood was evaluated after each session to calculate the intervention's acceptability.

Results: No significant changes in the children's ability to understand basic or complex emotional terms were observed during the baseline period. However, changes were observed during the tele-intervention period, and these changes remained throughout the follow-up period. With a recruitment rate of 80% (20/25), all participants completed 4 intervention sessions, with retention and attendance rates exceeding 95% (19/20). A total of 90% (18/20) of the participants deemed each session to be acceptable.

Conclusions: Mandarin-speaking children aged 5 to 7 years with DLD exhibited lower emotional competence compared with their counterparts with TLD. Tele-interventions are effective in enhancing the emotional competence of children with DLD, demonstrating feasibility and acceptability for these children and their parents in Taiwan.

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KEYWORDS

language disorder; pediatrics; evidence-based intervention; telemedicine; tele-practice; visual support; mobile phone

Introduction

Background

According to the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (*DSM-5*) [1], language disorder (ie, developmental language disorder [DLD]) is a communication disorder that broadly refers to childhood language difficulties and is not associated with any known biomedical condition [2,3]. These language difficulties can hinder children's acquisition of emotional competence, including their understanding of the nature and causes of emotions, their own feelings, their physiological reactions to these feelings, and their cognition surrounding an emotion or emotive event [4-7]. Language is strongly associated with emotional competence, as evidenced in our use of prosody to interpret emotional cues, recognize emotions, and understand what others may feel in various situations [8]. When children experience communication difficulties, their opportunities for social learning diminish, making conversations harder to process, misunderstandings more likely, and participation in discussions or play activities more challenging, which can, in turn, hinder their emotional competence [9]. Language also provides access to mental terms such as *think* and *happy*, which help children mentalize and help them identify, understand, express, and regulate their emotions [10]. These capabilities facilitate social interactions and indirectly aid in understanding the mental states of others [11]. Therefore, children with language acquisition difficulties tend to struggle with using these mental terms to learn the emotional or cognitive aspects of theory of mind. Notably, verbal interactions with caregivers play a key role in the development of emotion regulation skills, primarily because discussing emotions helps children connect their emotions to events and learn how to manage these emotions [12]. As children with DLD grow, they struggle to develop the capacity to internally regulate their emotions, with language playing a crucial role in self-reflection, response inhibition, and guiding behavior [13]. Furthermore, in young children with typical language development (TLD), poor emotional competence has been shown to be associated with emotional and behavioral problems [14].

Previous research examining the emotional competence of children with DLD and children with TLD has rarely focused on children who speak Mandarin as their native language [4,11,15]. If studies indicate that the emotional competence of Mandarin-speaking children with DLD lags behind that of their peers with TLD, as is the case for non–Mandarin-speaking children with DLD, this finding will support the presence of cross-linguistic and cross-cultural consistency in the emotional challenges faced by children with DLD. In children with developmental delays, speech and language delays are the most common disabilities [16]. DLD is a highly prevalent neurodevelopmental disability in Mandarin-speaking children [17,18], highlighting the importance of focusing on the emotional competence of this population. Therefore, further research is needed to evaluate the emotional competence of Mandarin-speaking children with DLD and determine whether early intervention is necessary.

Tele-interventions constitute a promising tool that offers a timely, accessible, and cost-effective solution for overcoming barriers to medical service delivery, such as transportation issues, shortage of skilled therapists, and insufficient facilities in rural areas [19]. This approach is particularly significant given that the special needs of children with DLD living in rural areas are often less adequately addressed than those of children living in urban areas [20]. Adopting tele-practice for early interventions holds great potential to address these disparities and support the development of emotional competence in children with DLD in underserved rural areas [19]. In Taiwan, the procedures, advantages, and challenges associated with implementing such interventions remain unclear. Therefore, in this study, we examined the efficacy, feasibility, and acceptability of emotional competence tele-interventions designed for Mandarin-speaking children with DLD in Taiwan.

Multiple studies have indicated that social stories are an effective means to help children acquire emotional knowledge [21-23]. Social stories have been widely used in clinical practice for children with autism spectrum disorder (ASD) [24]; however, the application of these stories for children with DLD remain understudied. To the best of our knowledge, few studies have focused on children with pragmatic language impairments [25], language impairments [26], and pragmatic disorders with behavioral difficulties [24]. Among the key factors that contribute to the efficacy of a social story is the display of the protagonist's emotional state and social interactions [27], along with labeling affective, physical, and perceptual changes with words describing the protagonist's mental state. These labels help children understand that different experiences can fulfill the same function as long as these experiences are perceived as having the same meaning [28]. The use of visual aids such as pictures or videos can enhance the emotional representation of potential causes, subjective feelings, physiological responses, and cognition during social interactions [29]. Thought bubbles can also be used to clarify the protagonist's emotional state and thoughts within the social context [30,31]. Hence, emotional competence interventions conducted using social stories through remote interfaces, also referred to as social story tele-interventions (SSTIs), are expected to enhance the emotional competence of children with DLD.

Objectives

Preschool and early elementary school are critical periods in the development of a child's emotional competence; the child learns about self-regulation, and their level of emotional competence determines the severity and likelihood of behavioral problems [32,33]. In this research, we examined children in kindergarten and early elementary school. A total of 2 studies were conducted to explore 3 research questions. In study 1, our goal was to determine whether Mandarin-speaking children with DLD in Taiwan differ from those with TLD in emotional competence. We compared Mandarin-speaking children with

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DLD to those with TLD in terms of the size and depth of their understanding of emotional terms at the ages of 5 to 7 years. We hypothesized that Mandarin-speaking children aged 5 to 7 years with DLD would exhibit lower performance in the size and depth of their understanding of emotional terms compared with their counterparts with TLD even with family language characteristics such as maternal educational level accounted for. In study 2, we used an interrupted time-series design to explore two questions: (1) Do SSTIs enhance the understanding of emotional language by Mandarin-speaking children aged 5 to 7 years with DLD relative to their baseline performance (ie, before the intervention)? (2) Are SSTIs a feasible and acceptable intervention for these children in Taiwan? We hypothesized that SSTIs would enhance the emotional competence of Mandarin-speaking children aged 5 to 7 years with DLD and that this tele-intervention would be both feasible and acceptable for them and their parents in Taiwan.

Study 1

Methods

This case-control study was conducted to compare the emotional competence of children with DLD to that of children with TLD.

Participants

A total of 99 children aged 5 to 7 years were recruited from parenting websites and local pediatric clinics in northern and central Taiwan. Figure 1 shows the process of recruitment in study 1. Children with DLD meeting the following matching criteria were included in the study: being within 3 months of the specified age range, having Mandarin Chinese as their native language, and being of the same sex as their matched counterparts. If >1 participant with TLD met these criteria and could be matched with a participant with DLD, they were all included in the analysis. A total of 48 participants with TLD who did not meet the aforementioned criteria and who completed only the in-person evaluation at the preintervention 1 time point (time 1) were excluded from the final analysis. In addition, 2 participants with only a history of late talking who also completed only the in-person evaluation at the preintervention 1 time point (time 1) were excluded from the final analysis. A total of 5 parents refused to participate in the subsequent tele-intervention program. Therefore, of a total of 25 parents of children with DLD, only 20 (80%) participated. Furthermore, ultimately, 44 children were included in the final analysis in study 1: 20 (45%) in the DLD group (mean age 5.79, SD 0.47 years) and 24 (55%) in the TLD group (mean age 5.93, SD 0.31 years).

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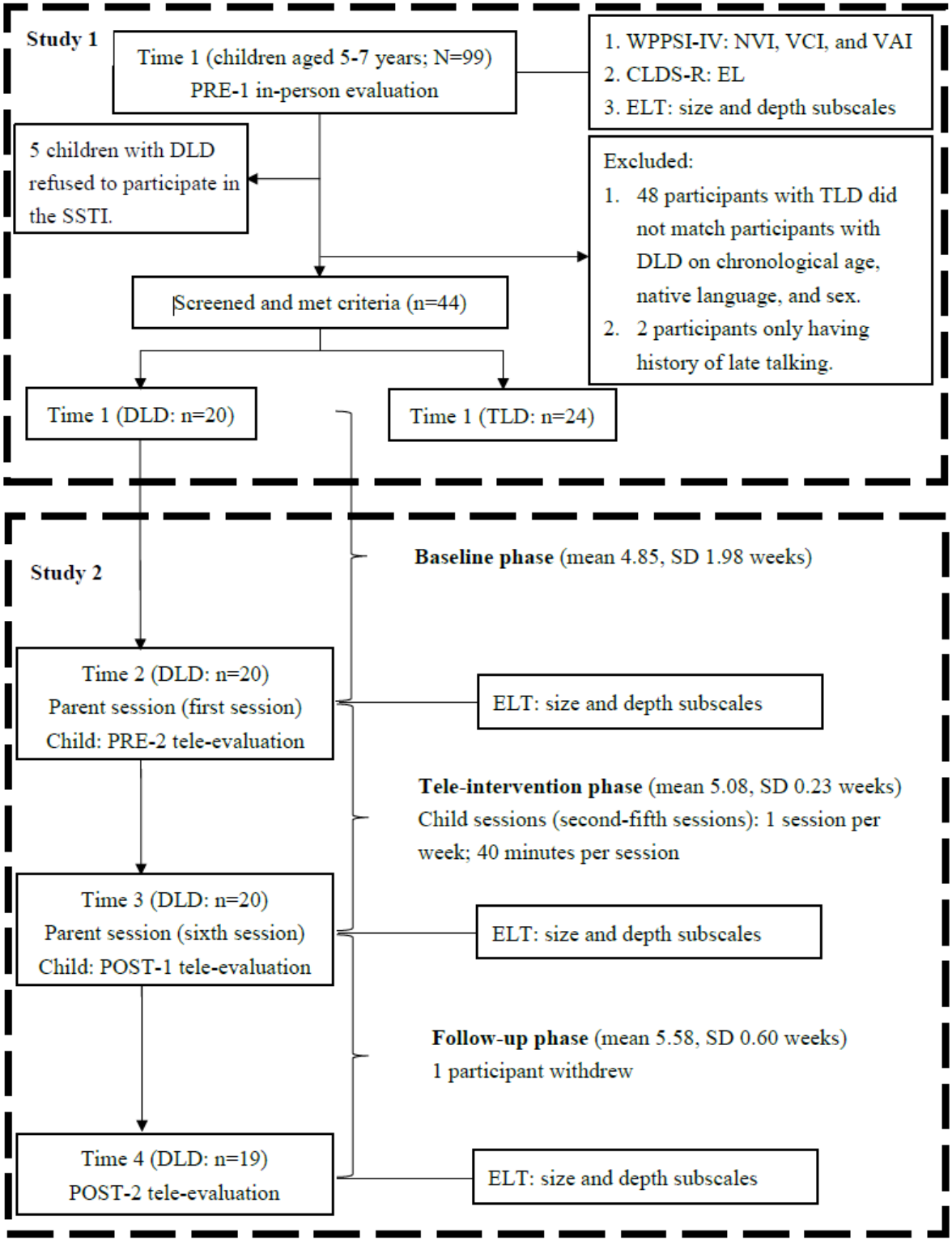
Figure 1. Flowchart of study 1 and study 2. CLDS-R: Child Language Disorder Scale–Revised; DLD: developmental language disorder; EL: expressive language; ELT: Emotional Lexicon Test; NVI: Nonverbal Index; POST-1: postintervention time point 1; POST-2: postintervention time point 2; PRE-1: preintervention time point 1; PRE-2: preintervention time point 2; SSTI: social story tele-intervention; TLD: typical language development; VAI: Vocabulary Acquisition Index; VCI: Verbal Comprehension Index; WPPSI-IV: Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition.



All participants with DLD had received a diagnosis based on the *DSM-5* criteria at the Early Developmental Evaluation Center, the official institution designated by the Ministry of Health and Welfare of Taiwan for identifying and evaluating children with developmental disorders before the age of 7 years. In Taiwan, the gold standard for diagnosing DLD requires confirmation through a converging evidence approach [34], which includes the assessment of delays in receptive and expressive language by board-certified speech and language pathologists using parental reports, standardized tests, and clinical observations. Clinical psychologists are required to confirm the absence of cognitive delays, and child psychiatrists and pediatric neurologists are required to determine whether any observed language delays are due to other

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neurodevelopmental (eg, ASD) or neurological (eg, epilepsy) disorders. Establishing a DLD diagnosis through a converging evidence approach in clinical assessments and decision-making scenarios by medical professionals should be considered the gold standard. Participants with TLD had no known developmental or cognitive impairments.

Measurement

Family Characteristics

Data on family characteristics, including paternal and maternal mean age, paternal educational level and marital status, monthly family income, and number of siblings of the child participant, were collected from parent reports.

Child Characteristics

Data on child characteristics, including age, sex, developmental risk factors, and medical diagnoses, were also collected from parent reports. To confirm that the children met the inclusion criteria, their parents provided an early intervention assessment report issued by the Ministry of Health and Welfare. Among the developmental risk factors considered in this study were biological factors (eg, premature birth, low birth weight, genetic disorders, perinatal complications, and neurological conditions) and medical factors (eg, chronic diseases, infectious diseases, and hearing or vision impairments).

Evaluation of Nonverbal Ability

Nonverbal ability was measured using the Mandarin Chinese version of the Nonverbal Index (NVI) of the Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition [35]. The NVI has an internal consistency reliability of 0.94 to 0.96 across various age groups and a test-retest reliability of 0.85 [35].

Evaluation of Language Abilities

A total of 3 dimensions of language abilities were evaluated: verbal comprehension, vocabulary acquisition, and linguistic expressivity. Verbal comprehension and vocabulary acquisition were evaluated using the Mandarin Chinese versions of the Verbal Comprehension Index (VCI) and Vocabulary Acquisition Index (VAI), respectively, of the Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition [35]. The VCI and VAI have internal consistency reliability levels of 0.92 to 0.94 and 0.84 to 0.92, respectively, and both have a test-retest reliability of 0.86 [35]. Expressive language ability was evaluated using the Mandarin Chinese version of the Child Language Disorder Scale–Revised (CLDS-R) [36]. This subscale evaluates expressive language skills across multiple domains. These domains include (1) the ability to retrieve vocabulary or construct short phrases or sentences in response to questions that evaluate knowledge (eg, functions, general information, and analogies) acquired in the classroom and from one's lived environment; (2) phonological working memory, measured through sentence repetition tasks in which children verbally recall sentences of increasing length and grammatical complexity; and (3) narrative skills, evaluated through spontaneous image description and story retelling tasks with or without the aid of sequenced images. The internal consistency reliability of each CLDS-R subscale across different age groups ranges from 0.80 to 0.96, with a test-retest reliability ranging from 0.92 to 0.98 [36].

Evaluation of Emotional Competence

Emotional competence was evaluated using 2 subscales from the Emotional Lexicon Test (ELT) [37]: a depth subscale and a size subscale. Illustrations were drawn without displaying the facial expression of the protagonist to avoid influencing the children's responses. The depth subscale was used to evaluate the depth of understanding of basic emotional terms (BETs) and complex emotional terms (CETs). After the examiner read a story, they asked each child to label the emotional state of the protagonist and state the reasons underlying their responses (ie, explain the reasons underlying the protagonist's feelings in this context). This subscale evaluates the ability of children to retrieve emotional terms through a recall mechanism. Responses are rated depending on their quality on a scale with end points from 0 to 2, reflecting the varying degrees of children's understanding of emotional terms. In terms of interrater reliability, this subscale was evaluated by 2 raters, who reported a 95% agreement. Discrepancies in scores were discussed by the 2 raters to reach a consensus. The size subscale was used to evaluate the size of BETs and CETs. After the examiner read a story, they asked each child to determine which of 2 emotional state terms (eg, joyful vs fearful, scared vs ashamed, and delighted vs sad) better described the protagonist's emotional state. This subscale evaluates the ability of children to recognize emotional terms through a recognition mechanism. Each correct recognition response is assigned a score of 1 point, indicating the size of the child's emotional lexicon. These 2 subscales have been adopted in other emotional lexicon tests [38]. Each subscale consists of 14 cards with short illustrated stories, of which 6 feature basic emotions (joy, sadness, happiness, anger, fear, and disgust) and 8 feature complex emotions (shame, contempt, guilt, hate, envy, jealousy, pride, and loneliness). Hence, the scores on the depth subscale range from 0 to 28 points, and the scores on the size subscale range from 0 to 14 points. Each item in the ELT includes images to convey the story content, which in turn reduces the semantic comprehension load of the participating child. In this study, before the formal items were used, 2 questions and 1 example item were presented to determine whether the children could match the images with the oral content, indicating their understanding of the story. ELT has an adequate to high internal consistency (0.70-0.71) for CETs [39]. Its criterion-related validity scores with the Metacognitive Vocabulary Test and Peabody Picture Vocabulary Test–Revised are 0.80 and 0.74, respectively [40]. In addition, both hard- and soft-copy versions of the ELT were used. The hard-copy version was used for in-person evaluations, whereas the soft-copy version was used for tele-evaluations.

Procedure

After the children arrived at the laboratory with their parents, all parents were informed of the research procedures. All children successfully completed the 2 questions and 1 example item before the administration of the ELT proper, indicating their understanding of the story. All tests were conducted by licensed clinical psychologists and graduate students trained in child psychological assessment.

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Ethical Considerations

The study design was approved by the institutional review board of Chung Shan Medical University Hospital in Taiwan (CS2-19046). During the in-person evaluation phase at the preintervention 1 time point (time 1), the researchers outlined the following: (1) study purpose, (2) data handling procedures, (3) privacy measures, and (4) participant rights, including the voluntary nature of participation and withdrawal options. All parents understood and provided their informed consent. This study was conducted in accordance with relevant guidelines and regulations for human participants. Privacy measures included secure data storage with access restricted to research team members only.

Data Analysis

Separate analyses of covariance (ANCOVAs) were conducted to determine the differences in the NVI, VCI, VAI, and linguistic expressivity scores between the 2 groups, with family characteristics used as a covariate. Chi-square and Fisher exact tests were used to compare group proportions with qualitative data for family characteristics (ie, parental educational level and marital status, monthly family income, and whether the child participant had siblings) and child characteristics (ie, sex and presence of developmental risk factors). In addition, a 3-way mixed-model multivariate ANCOVA was conducted, with group (TLD vs DLD) used as the between-group independent variable and emotion (basic vs complex) and understanding (size vs depth) used as the within-group independent variables, with maternal educational level used as a covariate. In case a statistically significant 3-way interaction was observed among group, emotion, and understanding, the simple main effects between TLD and DLD were examined. Effect sizes from ANCOVAs were calculated using the partial η_p^2, which could be directly translated into a percentage of explained variance. Using the basic framework by Cohen [41], we interpreted these effect sizes as small (η_p^2=0.01), moderate (η_p^2=0.06), or large (η_p^2=0.15). We also conducted a post hoc power analysis for ANCOVAs using G*Power (version 3.1.5) for a sample size of 44 participants, with α=.05 [42]. Post hoc power values of >0.8, between 0.6 and 0.8, and <0.6 were considered high, moderate, and low, respectively. All statistical analyses were conducted using SPSS Statistics (version 25.0; IBM Corp).

Results

Participant Characteristics

Table 1 presents the characteristics of the children and their parents in the TLD and DLD groups. Compared with the TLD group, the DLD group had a lower maternal educational level (N=44, χ^2_1=5.4, P=.04). Previous studies have found that mothers' educational level is related to children's social, emotional, and academic development [43]. Therefore, we controlled for this variable when conducting the ANCOVAs. However, no differences were observed between the 2 groups (P>.05) in terms of child characteristics (ie, mean age, sex, and risk factors) and family characteristics (ie, paternal and maternal mean age, paternal educational level and marital status, monthly family income, and whether the child participant had siblings).

Table 2 presents the NVI, VCI, VAI, and oral expression scores of the TLD and DLD groups during the evaluation at the preintervention 1 time point. No significant difference was observed in the NVI between the 2 groups (P>.05), as indicated by the ANCOVA results. However, compared with the TLD group, the DLD group exhibited significantly lower levels of verbal comprehension, vocabulary acquisition, and linguistic expressivity ($F_{1,\ 41}$=17.20, 11.89, and 10.91, respectively; P<.001, P=.001, and P=.002, respectively; η_p^2=0.30, 0.23, and 0.21, respectively; power=0.99, 0.94, and 0.92, respectively).

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Table 1. Characteristics of the children and their parents.a

Variable	TLD[b] (n=24)	DLD[c] (n=20)	*P* value
Child's age (y), mean (SD)	5.93 (0.31)	5.79 (0.47)	.26
Father's age (y), mean (SD)	40.58 (4.72)	42.05 (5.16)	.34
Mother's age (y), mean (SD)	37.54 (3.75)	39.65 (4.20)	.09
Child characteristics, n (%)			
Sex			.76
Male	17 (71)	15 (75)	
Female	7 (29)	5 (25)	
Developmental risk factors			.15
Yes	13 (54)	15 (75)	
No	11 (46)	5 (25)	
Family characteristics, n (%)			
Father's educational level			>.99
Below university level	3 (12)	3 (15)	
At or above university level	21 (88)	17 (85)	
Mother's educational level			.04
Below university level	1 (4)	6 (30)	
At or above university level	23 (96)	14 (70)	
Parents married and living together			>.99
Yes	22 (92)	17 (85)	
No	2 (8)	3 (15)	
Monthly family income			.14
<NT $[d] 59,999 (US $1821.35)	10 (42)	13 (65)	
≥NT $ 60,000 (US $1821.38)	14 (58)	7 (35)	
Child participants having siblings			.50
Yes	8 (33)	4 (20)	
No	16 (67)	16 (80)	

[a]All *P* values were obtained from ANOVAs or chi-square or Fisher exact tests.

[b]TLD: typical language development.

[c]DLD: developmental language disorder.

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Table 2. Nonverbal and language abilities of the participants[a].

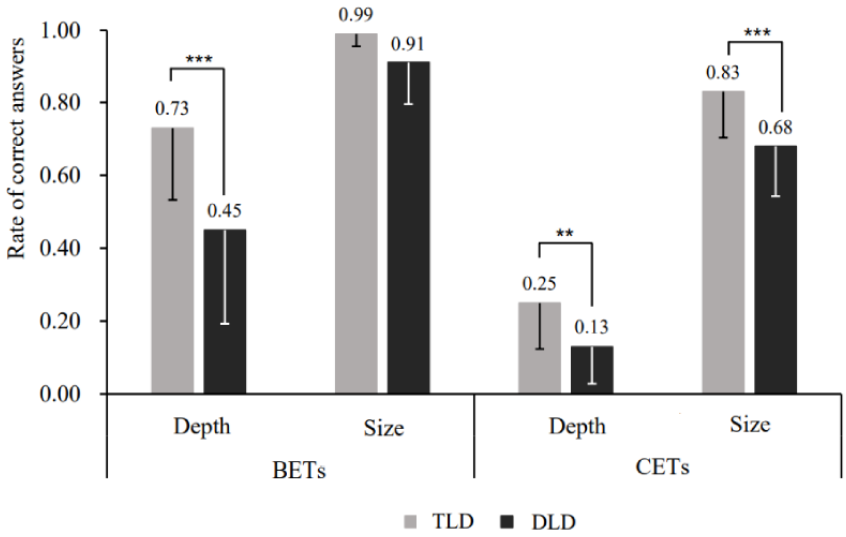
Variable	TLD[b] (n=24), mean (SD)	DLD[c] (n=20), mean (SD)	*P* value
NVI[d] (CS[e])	103.71 (9.14)	98.15 (14.79)	.23
VCI[f] (CS)	112.83 (12.67)	93.65 (15.52)	<.001
VAI[g] (CS)	111.63 (11.21)	96.55 (13.92)	.001
EL[h] (*z* score)[i]	−0.08 (0.90)	−0.97 (0.61)	.002

[a]All *P* values were obtained from analyses of covariance.
[b]TLD: typical language development.
[c]DLD: developmental language disorder.
[d]NVI: Nonverbal Index.
[e]CS: composite score of the Wechsler Preschool and Primary Scale of Intelligence, Fourth Edition, Chinese version.
[f]VCI: Verbal Comprehension Index.
[g]VAI: Vocabulary Acquisition Index.
[h]EL: expressive language.
[i]*z* score of the Child Language Disorder Scale–Revised, Chinese version.

Emotional Competence Among Children With TLD and DLD

Figure 2 illustrates the size and depth of understanding of BETs and CETs for the TLD and DLD groups during the evaluation at the preintervention 1 time point. It also shows the main effects of emotion (Wilks $\lambda_{1, 41}$=34.17; *P*<.001; η_p^2=0.45; power=0.99) and understanding (Wilks $\lambda_{1, 41}$=72.97; *P*<.001; η_p^2=0.64; power=0.99). A post hoc analysis revealed that BETs outperformed CETs (*P*<.001), with the number of recognized emotional terms being greater than that of recalled emotional terms (*P*<.001). A statistically significant 3-way interaction was observed among group, emotion, and understanding (Wilks $\lambda_{1, 41}$=12.39; *P*=.001; η_p^2=0.23; power=0.66). Simple-simple main effect analysis revealed that the DLD group scored lower than the TLD group in terms of the depth of understanding of BETs and the size and depth of understanding of CETs ($F_{1, 164}$=37.20, 11.48, and 6.54, respectively; *P*<.001, *P*<.001, and *P*=.01, respectively; η_p^2=0.18, 0.07, and 0.04, respectively; power=0.86, 0.43, and 0.26, respectively).

Figure 2. Mean rate of correct answers for basic emotional terms (BETs) and complex emotional terms (CETs) for the typical language development (TLD) and developmental language disorder (DLD) groups during the evaluation at preintervention time point 1 (time 1). The vertical lines represent error bars with 1 SD. The asterisks indicate the significant simple main effects of group, revealing a higher mean rate of correct answers for the TLD group than for the DLD group. ***P*<.01; ****P*<.001.



Discussion

Principal Findings

Few studies have compared the emotional competence of Mandarin-speaking children with DLD to that of children with TLD. In this study, we controlled for child and family characteristics in our research design and statistical analysis while comparing children with DLD and TLD. This approach increased the validity of our findings, indicating a lag between children with DLD and those with TLD in terms of emotional competence. It also enhanced the validity of study 2, which

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examined the improvement observed in emotional competence among children with DLD after undergoing a tele-intervention.

The size of understanding of BETs among children aged 5 to 7 years with DLD was similar to that among their counterparts with TLD, indicating that children with DLD can understand basic emotional states in typical social scenarios. However, the depth of understanding of BETs among children aged 5 to 7 years with DLD was considerably lower than that among their counterparts with TLD, indicating that the ability of children with DLD to express their emotions through BETs may be limited. In addition, children with DLD were slower in understanding CETs compared with children with TLD in kindergarten and early elementary school years, indicating the delayed development and mastery of such concepts. Overall, our findings are consistent with those of previous studies [5-7,14,44] indicating that Mandarin-speaking children with DLD also exhibit impaired emotional competence. These findings suggest that the lag observed in emotional competence in children with DLD is a universal characteristic across countries and ethnic groups [45]. These findings underscore the importance of early interventions in improving their conceptual knowledge of emotional states.

In this study, children with DLD exhibited language functioning within the low but normal range, although their scores were lower than those of their peers with TLD. The study explored whether these children experienced delays in their lexical, grammatical, or articulatory development. In study 1, all children had been diagnosed with DLD in accordance with *DSM-5* criteria at the Early Developmental Evaluation Center, an institution designated by the Ministry of Health and Welfare of Taiwan to evaluate developmental disorders in children aged <7 years. Diagnosing DLD through clinical assessments with a converging evidence approach for clinical decision-making is regarded as the gold standard in Taiwan. In this approach, no single method serves as the deciding factor in making diagnostic decisions regarding the receptive and expressive language skills of individuals with DLD. Converging evidence refers to the concept that multiple pieces of assessment data must align and point in the same direction to support a diagnostic decision [34]. In specific test areas, the cutoff score may vary to maximize sensitivity and specificity in identifying those who are at a high risk of developmental problems. Nevertheless, no consensus has been reached regarding the cutoff values for the VCI, the VAI, and the CLDS-R expressive language subscale required for determining whether a child has DLD. In this study, the VCI, the VAI, and the CLDS-R expressive language subscale were used only to evaluate the language capabilities of children with DLD and compare them to those of children with TLD. Our goal was to determine whether the language capabilities of children with DLD lagged behind those of children with TLD, unlike nonverbal capabilities, for which no differences were observed between the 2 groups. Notably, we did not use the VCI, the VAI, or the CLDS-R expressive language subscale for diagnostic purposes in this study.

According to Bishop [46], DLD involves heterogeneous language features. In this study, we examined only the verbal comprehension, vocabulary acquisition, and expressive language capabilities of children with DLD and did not evaluate their speech perception, phonological awareness, or understanding and use of grammar. Therefore, we could not confirm whether children with DLD lag in these language dimensions. In addition, no consensus has yet been reached regarding the definition of DLD in terms of whether receptive or expressive language should be scored at a threshold of <1 or 1.5 SDs in standardized language tests [47]. Of a total of 20 children with DLD, 6 (30%) had received physical therapy, 19 (95%) had received occupational therapy, 18 (90%) had received speech therapy, and 6 (30%) had received psychological therapy, indicating that these children continually underwent systematic and structured interventions implemented by medical professionals to optimize their development during sensitive periods [48-50]. Therefore, although DLD can be qualitatively defined in accordance with the *DSM-5* [1] in medical and research contexts, no consensus has yet been established regarding its quantitative definition, including which tests to conduct and which cutoff criteria to apply. Furthermore, each quantitative definition may have unique implications for specific contexts in different countries or cultures, presumably reflecting the use of different measurement tools and cultural perspectives on children's development and delays [51]. Bishop [46] emphasized the importance of establishing a consensus regarding the quantitative definition of DLD to facilitate cross-linguistic and cross-cultural comparisons of the characteristics, developmental changes, and emotional competence of children with DLD over time.

Conclusions

In this study, low power values were observed for the simple-simple main effects of the size and depth of understanding of CETs. According to Ryou et al [52], a lower power value indicates a higher risk of a type II error, also referred to as a false negative, in which a statistical test does not call for the rejection of the null hypothesis when the alternative hypothesis is true. However, our group comparisons for the size and depth of understanding of CETs were significant, with moderate effect sizes. These comparisons mitigated the risk of type II errors in comparison to scenarios in which group differences were not significant. Therefore, increasing the sample size in future studies may aid in achieving more robust results.

Study 2

Methods

In this study, we used a prospective 1-group interrupted time-series research design situated within the context of a response-to-intervention instructional framework [53]. This study comprised a baseline phase, a tele-intervention phase, and a follow-up phase.

Participants

The same 20 children with DLD who participated in study 1 were included in study 2.

SSTI Characteristics

Intervention Sessions

This 6-week emotional competence tele-intervention comprised 2 sessions for parents (first and sixth sessions) and 4 sessions

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for children (second to fifth sessions). In the first parent session, the mechanism of SSTIs designed for children to acquire emotional competence skills was introduced, whereas in the last parent session, the SSTIs and children's emotional competence skills acquired during the sessions and on a daily basis were reviewed. No home practice was offered after the 2 parent sessions, and no children were involved in these sessions. Each child's session included the presence of their parents and comprised the following elements: (1) a parent-child interactive game, that is, the finger trap game; (2) a 4-panel physical story comic; (3) a social story video (Multimedia Appendix 1) played for the participating child 3 times; and (4) a talk practice (retelling, prompting, self-narration, and imitation).

In the finger trap game, each parent places their palm facing down, and each child places their index finger underneath their parent's palm. Once a specific word (eg, *three*) is presented in a series of words (eg, *three*, *four*, *six*, *two*, *three*...), the parent attempts to rapidly close their open palm to catch the child's finger. Two 4-panel physical story comics are presented. The first comic, used in the first and second child sessions, depicts a balloon being blown away by the wind, floating up into a tree, getting caught on a branch, and popping. The second comic, used in the third and fourth child sessions, depicts a clear, sunny day that later turns cloudy and then rains heavily.

The themes and language content of these intervention sessions corresponded to the titles of 4 researcher-edited social story videos, namely, "Great with others," "Play game," "Grab a toy," and "Give a gift." In these social story videos, external causes lead the protagonist to have an emotional experience. The social stories developed in this study included 4 types of mental state terms: cognitive state terms such as *know*; desire state terms such as *want*; perceptual state terms such as *feel*; and basic emotional state terms such as *happy*, *sad*, *angry*, and *fear* [54]. Table 3 presents the mental state terms and their frequencies in each social story. Thought bubbles are used to display the beliefs, desires, intentions, knowledge, and moods of the story's protagonist as they arise from the interpretation of environmental cues (Multimedia Appendix 1). As shown in Multimedia Appendix 1, panel 2 displays the mental state for desire, panels 4 and 5 display the mental state for belief, panel 7 displays the mental state for intention, and panels 3 and 6 display the mental states for moods associated with desire and belief.

Table 3. Mental state terms and frequency, words, and length in each social story.

Social story	Mental state terms (frequency)	Words, N[a]	Length (seconds)
Great with others	• Know (n=6) • Want (n=6) • Feel (n=6) • Happy (n=6) • Sad (n=6)	115	95
Play game	• Know (n=6) • Want (n=6) • Feel (n=6) • Happy (n=6) • Angry (n=6)	118	104
Grab a toy	• Know (n=6) • Want (n=6) • Feel (n=6) • Happy (n=6) • Fear (n=6)	112	93
Give a gift	• Know (n=3) • Want (n=3) • Feel (n=3) • Happy (n=3) • Sad (n=3) • Angry (n=3) • Fear (n=3)	101	91

[a]Chinese character count.

The following instructions were given to the children for the talking practice. For retelling, the instruction was as follows: "Tell me about the story you just heard." For prompting, the instruction was as follows: "I have a few questions to ask you about this story." For self-narration, the instruction was as follows: "After listening to this story, it's your turn to share a story about how you grabbed a toy with someone." For imitation, the instruction was as follows: "Tell me the story one more time—I'll say a sentence, and then you repeat it."

Each session lasted approximately 40 minutes. A total of 4 sessions were delivered over 4 weeks, with 1 session per week. The quantitative and qualitative aspects of this intervention program are consistent with those outlined by Frizelle et al [55], who emphasized that, in an intervention program, the concept of efficiency is central to "dosage," which includes both quantitative (number of sessions, frequency, and duration) and qualitative (form) constructs.

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Tele-Intervention Information and Communications Technology

The technical setup used by the 3 interventionists in their workrooms included a laptop equipped with Google Meet, a broadband internet connection, a web camera, a flexible lighting device to achieve optimal lighting, and a backdrop of an image showing the name of the interventionist to ensure optimal visibility during the tele-intervention sessions. The technical setup used by the participants included their own personal desktop computer or laptop (9/20, 45%), tablet (3/20, 15%), or smartphone (8/20, 40%), all equipped with Google Meet; an internet connection; and a web camera. All parents reported having internet access at their homes (fixed line or 4G or 5G cellular internet). They also reported a sound level of 55 to 65 dB, measured using a sound meter app. Throughout the tele-intervention sessions, the participants were asked to keep the video call in full-screen mode. All interventionists used the screen-sharing tool to present visual stimuli for the social story video and prompt pictures during the talk practice stage.

Measurement

Assessment of Emotional Competence

In this study, the ELT was used to evaluate the emotional competence of children with DLD. The study 1 section provides more details regarding this test.

Assessment of the Feasibility and Acceptability of SSTIs

Feasibility was evaluated based on recruitment, retention, and attendance rates to each session, and acceptability was evaluated based on the outcomes of each session. The participants were asked to either select 1 of 4 affect categories (happiness, anger, fear, and sadness) or remain neutral. Reports of happiness and neutrality were considered acceptable.

Procedure

As shown in Figure 1, the DLD group completed the in-person evaluation at the preintervention 1 time point (time 1). After 5 to 6 weeks, the SSTIs were administered. The parents attended the first parent session, and the ELT was administered during the tele-evaluation at the preintervention 2 time point (time 2). After 1 week, the DLD group received the SSTIs, which lasted 4 weeks (second to fifth session). In the sixth session, the parents were evaluated, and the DLD group was administered the ELT again during the tele-evaluation at the postintervention 1 time point (time 3). Finally, 5 to 6 weeks after time 3, the DLD group was administered the ELT once again during the tele-evaluation at the postintervention 2 time point (time 4). Only 1 participant withdrew from the study during the tele-evaluation at the postintervention 2 time point. The mean number of weeks between time 1 and time 2 and between time 3 and time 4 was similar (P>.05). Figure 1 shows the participant recruitment process. The period from time 1 to time 4 spanned approximately 18 to 20 weeks for each participant with DLD.

Ethical Considerations

This study was conducted in accordance with relevant guidelines and regulations for human participants. Privacy measures included secure data storage with access restricted to research team members only. The study design was approved by the institutional review board of Chung Shan Medical University Hospital in Taiwan (CS2-19046).

Data Analysis

When the data suggest a nonlinear relationship, piecewise linear growth models can be used to divide growth trajectories into >2 linear components, such as in interrupted time-series data [56,57]. In this study, we used a piecewise linear growth model with 3 slopes for each outcome: slope 1 to evaluate changes from the preintervention 1 to preintervention 2 time points (baseline), slope 2 to evaluate changes from the preintervention 2 to postintervention 1 time points (tele-intervention), and slope 3 to evaluate changes from the postintervention 1 to postintervention 2 time points (follow-up). We also hypothesized that the tele-interventions would have an effect. Generally, the absence of an intervention effect for baseline and follow-up indicates that emotional competence did not increase during the baseline phase and did not decrease during the follow-up phase. The HLM software (version 7.03; Scientific Software International) [58] was used to fit the piecewise linear growth model. All other analyses were conducted using SPSS Statistics (version 25.0). Estimates of intraclass correlation coefficients (ICCs) are often used to analyze the power of piecewise linear growth models [59]. These coefficients measure the similarity between data points within the same cluster and those in different clusters. They typically range from 0 (no similarity between clusters) to 1 (complete similarity between clusters). ICCs of >0.20 indicate that the model can detect actual differences in growth rates across different time segments [60]. Sufficient power is essential for study accuracy, making piecewise linear growth models suitable for analysis. Effect sizes are typically calculated for each period using the Cohen d for repeated measures [61]. Values of 0.2, 0.5, and 0.8 indicate small, moderate, and large effects, respectively [62]. The Cohen d was calculated using G*Power (version 3.1.5) [63].

Results

Changes in Emotional Competence Among Participants With DLD

In this study, the ICCs for BET size, BET depth, CET size, and CET depth were <0.001, 0.34, 0.30, and 0.46, respectively. The ICCs for BET depth, CET size, and CET depth were >0.20, indicating that the piecewise linear growth model was suitable for analysis. Figure 3 shows the mean change trajectories for the size and depth of BETs and CETs. Table 4 presents the results of multilevel piecewise growth models for estimating mean changes in 4 emotion outcomes in the tele-intervention during the baseline (preintervention 1 to preintervention 2 time points), tele-intervention (preintervention 2 to postintervention 1 time points), and follow-up (postintervention 1 to postintervention 2 time points) phases. Regarding BET size, no statistically significant change was observed during the baseline, tele-intervention, or follow-up phase (P>.05). Regarding BET depth, the rate of correct answers significantly increased during the tele-intervention phase (P<.001), but no significant change was observed during the baseline or follow-up stage (P>.05). Regarding CET size, no statistically significant change was observed during any phase (P>.05). Regarding CET depth, the rate of correct answers significantly increased during the

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tele-intervention phase (*P*<.001), but no significant change was observed during the baseline or follow-up phase (*P*>.05).

Figure 3. Mean change trajectories for the size and depth of basic emotional terms (BETs) and complex emotional terms (CETs) during the baseline, tele-intervention, and follow-up phases. D-BET: BET depth; D-CET: CET depth; POST-1: postintervention time point 1; POST-2: postintervention time point 2; PRE-1: preintervention time point 1; PRE-2: preintervention time point 2; S-BET: BET size; S-CET: CET size.

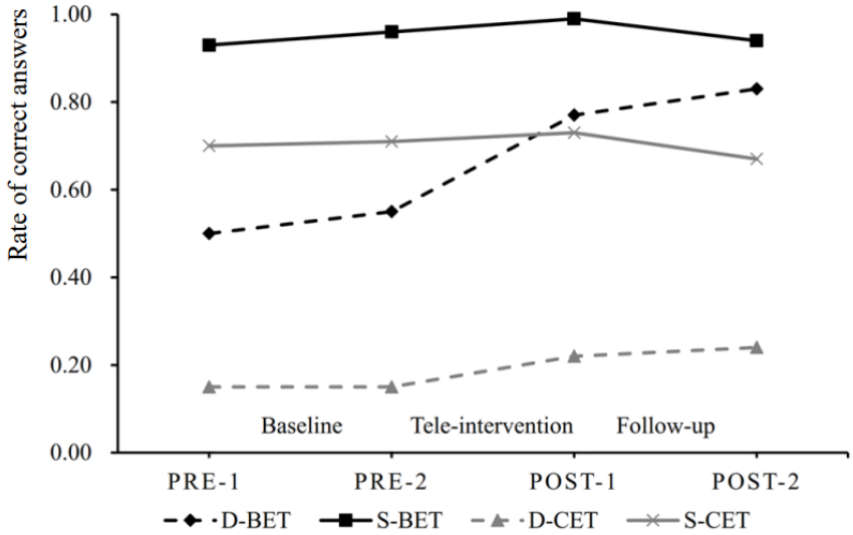

Table 4. Baseline, tele-intervention, and follow-up changes in multilevel piecewise models for emotional terms.

Variable	Size of BET[a], B (95% CI)[b]	Depth of BET, B (95% CI)[c]	Size of CET[d], B (95% CI)[e]	Depth of CET, B (95% CI)[f]
Fixed effect				
Intercept	0.93[g] (0.89 to 0.98)	0.50[g] (0.40 to 0.61)	0.69[g] (0.63 to 0.76)	0.15[g] (0.10 to 0.19)
Baseline	0.03 (–0.04 to 0.09)	0.05 (–0.03 to 0.13)	0.01 (–0.05 to 0.07)	0.00 (–0.05 to 0.05)
Tele-intervention	0.03 (–0.01 to 0.08)	0.21[g] (0.11 to 0.32)	0.03 (–0.05 to 0.10)	0.07[g] (0.04 to 0.10)
Follow-up	−0.02 (–0.04 to 0.00)	0.05 (–0.05 to 0.14)	0.001 (–0.09 to 0.09)	0.01 (–0.04 to 0.06)

[a]BET: basic emotional term.

[b]Random effect—intercept (U_0): χ^2_{19}=15.4; *P*>.50.

[c]Random effect—intercept (U_0): χ^2_{19}=116.3; *P*<.001.

[d]CET: complex emotional term.

[e]Random effect—intercept (U_0): χ^2_{19}=54.2; *P*<.001.

[f]Random effect—intercept (U_0): χ^2_{19}=98.6; *P*<.001.

[g]*P*<.001.

Table 5 presents the means and SDs of various emotional term measures at 4 measurement time points. The effect sizes for changes during the baseline period (from the preintervention 1 to preintervention 2 time points) were small (Cohen *d*=0.00-0.26), indicating that the depth and size of BETs and CETs slightly changed during this period. During the tele-intervention period (from the preintervention 2 to postintervention 1 time points), large effect sizes (Cohen *d*=0.88-0.94) were observed for the changes in depth of BETs and CETs, whereas small effect sizes (Cohen *d*=0.12-0.27) were observed for the changes in size of BETs and CETs. During the follow-up period (from the postintervention 1 to postintervention 2 time points), small effect sizes (Cohen *d*=0.01-0.39) were observed for the changes in depth and size of BETs and CETs.

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Table 5. Means, SDs, and effect sizes for emotional term measures.

	Rate of correct answers (PRE-1[a]), mean (SD)	Rate of correct answers (PRE-2[b]), mean (SD)	Rate of correct answers (POST-1[c]), mean (SD)	Rate of correct answers (POST-2[d]), mean (SD)	Effect size, Cohen *d*		
					Baseline	Tele-intervention	Follow-up
D-BET[e]	0.50 (0.25)	0.55 (0.30)	0.77 (0.19)	0.81 (0.21)	0.26	0.88	0.18
S-BET[f]	0.93 (0.10)	0.96 (0.09)	0.99 (0.04)	0.97 (0.06)	0.19	0.27	0.39
D-CET[g]	0.15 (0.10)	0.15 (0.11)	0.22 (0.13)	0.22 (0.13)	0.00	0.94	0.03
S-CET[h]	0.69 (0.15)	0.71 (0.10)	0.73 (0.20)	0.73 (0.10)	0.14	0.12	0.01

[a]PRE-1: preintervention 1 time point.
[b]PRE-2: preintervention 2 time point.
[c]POST-1: postintervention 1 time point.
[d]POST-2: postintervention 2 time point.
[e]D-BET: depth of basic emotional term.
[f]S-BET: size of basic emotional term.
[g]D-CET: depth of complex emotional term.
[h]S-CET: size of complex emotional term.

Feasibility and Acceptability of SSTIs

Of the 25 parents of participants with DLD, 5 (20%) did not take part in this study. Therefore, the recruitment rate for the program was 80% (20/25). At the preintervention 2, postintervention 1, and postintervention 2 time points, the retention rates were 100% (20/20), 100% (20/20), and 95% (19/20), respectively. During the 4 sessions, the attendance rates were 100% (20/20), 100% (20/20), 95% (19/20), and 100% (20/20). All participants (20/20, 100%) completed the 4 tele-intervention sessions, with only 5% of missing data at the postintervention 2 time point.

During the 4 sessions, the percentages of participants who reported being happy were 90% (18/20), 79% (15/19), 85% (17/20), and 90% (18/20), and the percentages of participants who reported being neutral were 10% (2/20), 11% (2/19), 15% (3/20), and 5% (1/20). Overall, the acceptability rates were 100% (20/20), 89% (17/19), 100% (20/20), and 95% (19/20) during the 4 sessions.

Discussion

Principal Findings

Tele-interventions are not a novel concept in medicine. However, to the best of our knowledge, this is the first study to integrate a social story intervention with a remote format to improve the emotional competence of children with DLD. In this study, a 3-stage process was used to observe changes in emotional terms among children with DLD. We discovered that changes in emotional competence occurred only during the tele-intervention phase, with no changes observed during the baseline phase before the intervention. These effects remained during the follow-up period after the intervention. Overall, this research design enhanced the validity of the results.

Our results indicated that SSTIs helped children with DLD deepen their understanding of BETs. In these SSTIs, 4 BETs were repeatedly used in various social contexts to reflect different individuals' mental states. This approach enabled the participants to understand that a single emotion word may be applicable to a range of scenarios (ie, unspecific use). The earlier these terms are integrated into the active vocabulary of children, the more their use aligns with that of adults. These findings are consistent with those of Grosse et al [64] indicating that children who learn words about emotions through cross-context scenarios can understand and use such vocabulary as adults. In this study, thought bubbles were used to enhance the children's understanding of representational mental states associated with emotional terms.

Although our intervention was not designed to introduce new CETs, we hypothesized that children with DLD would not seek to increase the size of their CETs and would rather seek to improve their understanding of the CETs that they had already learned. Overall, our findings indicate that SSTIs, which are based on a thorough understanding of BETs, can help children with DLD gain a deeper understanding of the CETs that they have already learned. Further systematic studies of domain-specific vocabulary are required to determine the effectiveness of SSTIs, including the size of emotion vocabulary and the depth of understanding.

Although social stories are often applicable to patients with ASD, similar to the application of such stories to children with ASD, the social stories designed in this study included visualizations of the story context, which can influence social storytelling by reducing extraneous cognitive demands [65]. When social stories are used as an intervention for children with DLD, adjustments may be required depending on the children's language levels. In this study, we used the thought bubbles corresponding to mental state words, which can also be used to clarify the protagonist's emotional state and mental thoughts within a social context. In other words, by making hidden thoughts and feelings explicit, children with DLD can gain a deeper understanding of their own and others' emotions and acquire the emotional language necessary to reflect upon and

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discuss these emotions [66]. Given that children with DLD represent a highly heterogeneous group, when social story interventions are implemented for these children, their language levels must be considered. In other words, the vocabulary, syntactic structures, and story elements included must be carefully planned to ensure that they are within the instructional level and not the frustration level [67]. These strategies have the potential to enhance the expressive language output of children for discussing emotional topics, processing targeted emotional components, and engaging in tele-interventions.

Among the indicators of feasibility for evaluating a pilot program are recruitment, retention, fidelity, acceptability, adherence, and engagement [68,69]. In this study, we evaluated the indicators of recruitment (proportion of parents who were willing to participate), retention (proportion of parents who did not withdraw), and attendance (proportion of parents who attended all 4 sessions). Retention rates are often used as evidence of feasibility in early intervention studies [70,71], particularly for pilot programs [69]. A high retention rate indicates that the program has promise for further development. Future research is required to evaluate the indicators of fidelity, adherence, and engagement to strengthen feasibility assessments.

According to Gartlehner et al [72], clinicians and policy makers tend to differentiate between efficacy and effectiveness. These 2 constructs exist on a continuum where efficacy and efficiency are about whether an intervention functions well under ideal and real-world conditions, respectively. This study was conducted under ideal conditions, supervised by a clinical researcher with expertise in children with DLD. The sample size was small, and the participants were carefully selected—only children with a confirmed diagnosis of DLD were included. The outcomes focused on specific aspects of emotional competence, such as the acquisition of emotional terms, rather than on broader health measures. A short-term intervention was implemented to provide initial evidence of efficacy, with strict protocols for both care providers and families. Future studies should explore the effectiveness of this program for Mandarin-speaking children with DLD, but first, it is necessary to establish the importance of continually evaluating its intermediate- and long-term efficacy. Chorpita et al [73] have argued that, even if >10 successful replications support a particular treatment, this information would not be sufficient to determine whether this treatment is more suitable for a particular child than a treatment supported by only 2 instances of replication assuming the absence of predictors of differences in outcomes. This assumption underscores the importance of conducting effectiveness studies to determine whether intervention programs can be widely implemented in clinical settings. Therefore, future studies should examine our program's real-world effects in hospital settings, including its acceptability, feasibility, and cost versus benefit. They should also explore broader mental health outcomes, such as increased self-regulation or decreased behavioral problems, of tele-interventions designed for Mandarin-speaking children with DLD.

Some parents raised concerns regarding their children facing difficulties focusing on their lessons and interacting with their instructors on-screen. Generally, in-person interventions involve physical contact and social interactions, such as high fives, contingency, eye contact, and joint attention, which can help children focus. In contrast, web-based interactions involve only visual support and behavioral management strategies to keep children engaged [74-76]. Despite these limitations, we discovered that the parents and children who participated in the intervention had high attendance rates and reported positive emotions after the intervention, indicating the feasibility and acceptability of SSTIs among them.

In the past few years, many hospitals were closed to the public because of the COVID-19 pandemic, thus preventing the implementation of in-person interventions. Early interventions for children with developmental delays were also suspended. These measures resulted in an increase in tele-evaluations and tele-interventions in medical scenarios. Although specialized hospitals are currently available for children, tele-practice interventions are particularly valuable for families living in rural areas, who tend to face challenges such as time constraints and lack of transportation. In these areas, enhancing the adoption of tele-practice requires software and hardware support because of these areas' limited internet access and lack of hardware [77]. Currently, Taiwan is striving to expand its 5G infrastructure (through platforms such as OpenGov Asia, the Ministry of Digital Affairs, and ComSoc Technology), particularly in remote areas such as Penghu, to improve digital accessibility and support tele-practice. Enhancing the degree of acceptance among health care professionals and parents is essential for promoting child language development and raising awareness of the benefits of tele-practice [78,79]. Finally, tele-interventions can also be used as a hybrid model in conjunction with in-person services to enhance learning experiences and make efficient use of resources.

This study has some limitations. First, emotional competence was exclusively measured by determining the number of emotional terms that children with DLD were aware of and examining the depth of their understanding of these terms. These measures did not reflect whether the children's emotional regulation strategies or behavioral problems improved as a result of our intervention. Therefore, further studies are required to explore these aspects of emotional competence. Second, the period during which we evaluated the effects of the intervention was short. Therefore, further long-term follow-up studies are required to determine the long-term and cumulative effects of our tele-intervention. Third, although the Italian version of the ELT has demonstrated strong psychometric characteristics [40] and assesses both basic and complex emotional competence in children, the Chinese version of this test lacks support from psychometric data. As in previous studies [38], we evaluated children's understanding of emotion-related words by making them listen to stories and choose the correct terms to determine the quantity of emotion words. We subsequently asked them to explain their choices to gauge their depth of understanding. This approach, which relies on a single test, limits the concept of emotional competence in children. Therefore, future studies should involve various additional measures such as the Emotional Competencies Scale for Young Children [80] or collect data through parent questionnaires or transcript analyses

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to determine whether children use emotion words in different contexts [81,82].

Conclusions

Mandarin-speaking children aged 5 to 7 years with DLD exhibit lower emotional competence than those with TLD even after adjusting for child and family language characteristics. Although DLD can be qualitatively defined in accordance with the *DSM-5* [1] in medical and research contexts, no consensus has yet been established regarding its quantitative definition, including which tests to conduct and which cutoff criteria to apply. Therefore, further research is required to establish a quantitative definition for children with DLD across languages and cultures and enable comparisons of emotional competence in children with DLD from different linguistic and cultural backgrounds. In addition, emotional competence tele-interventions effectively improve the emotional competence of children with DLD. They are also feasible and acceptable for both children and their parents. These findings indicate that tele-interventions can be a viable option for individuals who lack access to in-person services due to hospital shutdowns or barriers related to transportation, location, or time. Visual materials such as images and videos of children's interactions, implicit thoughts, and emotions should be used to understand and discuss emotional situations, with a preference toward realistic content. In addition, the language used in SSTIs should match the language capabilities of children. Although the results of our tele-intervention approach are satisfactory, future studies should explore its effectiveness in hospital settings to determine its real-world impact and examine broader mental health outcomes of tele-interventions for children with DLD. Further research is also required to address unresolved concerns regarding assessment, diagnosis, telephone consultation, internet support systems, and inconsistent intervention outcomes. Addressing these concerns can facilitate the expansion of tele-interventions to enhance other competencies in children with DLD and include a broader population with different medical conditions. Overall, this emotional competence tele-intervention, which can be used on pediatric populations, should be conducted as a participatory process involving children and their parents, with technology used to increase the convenience of the intervention, provided that efficacy is achieved. The findings show that using remote technology in home-based tele-interventions is effective, feasible, and well accepted. These interventions improve emotional skills in children with DLD and help support their parents.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Example of a social story video.
[PNG File , 348 KB - pediatrics_v8i1e60333_app1.png]

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Abbreviations

ANCOVA: analysis of covariance
ASD: autism spectrum disorder
BET: basic emotional term
CET: complex emotional term
CLDS-R: Child Language Disorder Scale–Revised
DLD: developmental language disorder
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
ELT: Emotional Lexicon Test
ICC: intraclass correlation coefficient
NVI: Nonverbal Index
SSTI: social story tele-intervention
TLD: typical language development
VAI: Vocabulary Acquisition Index
VCI: Verbal Comprehension Index

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Body Fat and Obesity Rates, Cardiovascular Fitness, and the Feasibility of a Low-Intensity Non–Weight-Centric Educational Intervention Among Late Adolescents: Quasi-Experimental Study

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Abstract

Background: Obesity rates among Saudi adolescents are increasing, with regional variations highlighting the need for tailored interventions. School-based health programs in Saudi Arabia are limited and often emphasize weight and body size, potentially exacerbating body image dissatisfaction. There is limited knowledge on the feasibility of non–weight-centric educational programs in Saudi Arabia and their effects on health behaviors and body image.

Objectives: This study aimed to (1) assess the prevalence of obesity using BMI-for-age *z* score (BAZ) and fat percentage among Saudi adolescents; (2) evaluate key health behaviors, cardiovascular fitness, and health literacy; and (3) assess the feasibility and impact of a low-intensity, non–weight-centric educational intervention designed to improve knowledge of macronutrients and metabolic diseases, while examining its safety on body image discrepancies.

Methods: A quasi-experimental, pre-post trial with a parallel, nonequivalent control group design was conducted among 95 adolescents (58 boys and 37 girls; mean age 16.18, SD 0.53 years) from 2 public high schools in Medina City, Saudi Arabia. Participants were randomly assigned to either the weight-neutral Macronutrient + Non-Communicable Diseases Health Education group or the weight-neutral Macronutrient Health Education group. Anthropometry (BAZ and fat percentage), cardiovascular fitness, physical activity, and eating behaviors were measured at baseline. Independent *t* tests and χ^2 tests were conducted to compare group differences, and a 2-way mixed ANOVA was used to evaluate the effect of the intervention on macronutrient knowledge and body image discrepancies. A total of 69 participants completed the postintervention assessments.

Results: The prevalence of overweight and obesity based on BAZ was 37.9% (36/95), while 50.5% (48/95) of participants were classified as overfat or obese based on fat percentage. Students with normal weight status were significantly more likely to have had prior exposure to health education related to metabolic diseases than students with higher weight status (P=.02). The intervention significantly improved macronutrient-metabolic knowledge ($F_{1,64}$=23.452; P<.001), with a large effect size (partial η^2=0.268). There was no significant change in students' body image from pre- to postintervention (P=.70), supporting the safety of these weight-neutral programs. The intervention demonstrated strong feasibility, with a recruitment rate of 82.6% and a retention rate of 72.6%.

Conclusions: This study reveals a high prevalence of obesity among Saudi adolescents, particularly when measured using fat percentage. The significant improvement in knowledge and the nonimpact on body image suggest that a non–weight-centric intervention can foster better health outcomes without exacerbating body image dissatisfaction. Region-specific strategies that prioritize metabolic health and macronutrient education over weight-centric messaging should be considered to address both obesity and body image concerns in adolescents.

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KEYWORDS

adolescent obesity; macronutrient education; cardiovascular fitness; body composition; health literacy; body image; macronutrient; educational; obesity; weight; overweight; fitness; nutrition; diet; patient education; student; school; youth; adolescent; teenager; metabolic; eating; physical activity; exercise

Introduction

Childhood obesity has become a significant public health concern globally, with projections indicating a continued upward trend in the coming decades. Obesity is expected to rise dramatically among children aged 5‑19 years, from an estimated 158 million in 2020 to 254 million by 2030 [1], representing a 60% increase over just a decade. Global estimates suggest that the overall prevalence of childhood overweight and obesity could reach 30% by 2030, with boys (34.2%) surpassing girls (27.4%) [2]. This trend is particularly alarming in middle- and high-income countries, where childhood overweight and obesity rates are projected to reach 58.3% by 2030 [2].

In Saudi Arabia, the obesity epidemic has mirrored global trends, with a marked increase in prevalence among both adults and adolescents. National estimates indicate that obesity prevalence among Saudi adolescents ranges from 22.3% to 23.5%, with some studies suggesting that nearly 35% of adolescents are overweight and 20% are obese [3-5]. Although BMI is a common tool for assessing obesity, it has limitations in distinguishing between fat and muscle mass. Notably, recent findings in Saudi Arabia highlight that BMI can underestimate obesity prevalence compared with body fat percentage [6]. For instance, while BMI data indicated an obesity prevalence of 29% (102/348) in men and 53% (314/593) in women, body fat percentage assessments revealed significantly higher rates of 83.9% (292/348) in men and 97.3% (557/593) in women [6]. This underscores the importance of using body fat percentage to provide a more accurate representation of obesity, particularly when evaluating related health risks.

Regional disparities in obesity prevalence further complicate the issue. Urbanized areas in Saudi Arabia report higher rates of obesity, influenced by factors such as physical inactivity, Westernized diets, and socioeconomic conditions [7]. Conversely, rural regions often exhibit lower obesity rates due to more traditional lifestyles that incorporate higher physical activity and different dietary patterns [7]. These regional differences emphasize the need to address physical activity behaviors and dietary habits in specific contexts. While all forms of physical activity are beneficial, current evidence indicates that vigorous-intensity exercise may be particularly effective in improving body composition, cardiorespiratory fitness, and cardiometabolic health markers in adolescents [8,9]. Despite this, there remains a gap in studies exploring the relationship between physical activity behaviors and cardiovascular fitness among adolescents in Saudi Arabia.

Adding to the complexity, decreased health literacy and higher-income levels have been linked to increased obesity rates in Saudi Arabia. This contrasts with trends observed in the United States, where lower-income levels are more commonly associated with higher obesity rates [10,11]. This highlights the crucial role of health literacy as a determinant of obesity prevalence and the importance of tailored educational interventions.

Despite the alarming trends, evidence-based interventions targeting adolescents in Saudi Arabia, particularly late adolescents in school settings, remain limited [12,13]. Schools provide an ideal environment for implementing cost-effective and sustainable obesity interventions, especially when these programs are theory-driven and tailored to meet the specific needs of the target population [14]. A review of the literature shows that only 7 school-based obesity intervention studies have targeted adolescents in Saudi Arabia, with an average age range of 12‑14 years, and none focusing on high school students [12,13,15]. Furthermore, only 3 of these studies used theory-based approaches [12], and all used weight-centric messaging.

Since 2020, more than 100 organizations worldwide, including scientific societies and academic institutions, have endorsed joint international statements to eliminate weight stigma [16]. Non–weight-centric approaches, which emphasize overall health and well-being rather than solely focusing on weight loss, have gained traction in school-based obesity interventions [17]. These programs encourage healthy behaviors and promote a positive body image without stigmatizing students, addressing the negative outcomes associated with weight stigma such as anxiety, disordered eating, and even weight gain [18,19]. However, designing obesity prevention programs that avoid weight-based stigma remains challenging, prompting calls for expanded research in non-Western cultural settings [16,20].

No study in Saudi Arabia has yet documented the development or efficacy of non–weight-centric interventions. This study focused on Medina City to examine the impact of healthy lifestyle factors on obesity rates among late adolescents and to assess the effectiveness and safety of a low-intensity, non–weight-centric, noncommunicable diseases (NCDs) educational intervention. This regional focus aims to provide insights that can inform targeted, culturally sensitive obesity prevention strategies.

In summary, this study sought to (1) identify the prevalence of obesity using both BMI-for-age *z* score (BAZ) and body fat percentage among Saudi late adolescents in Medina City; (2) characterize health-related behaviors, cardiovascular fitness, handgrip strength, and health literacy levels; and (3) evaluate the feasibility and safety of a low-intensity health educational intervention aimed at empowering adolescents with improved NCD knowledge while monitoring its effects on body image discrepancy. This research aims to contribute to the development of effective, culturally appropriate interventions that promote adolescent health without reinforcing weight stigma.

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Methods

Design

This study used a quasi-experimental, pre-post trial with a parallel, nonequivalent control group design to assess baseline anthropometry, health-related cardiovascular fitness components, handgrip strength, physical activity, and eating behaviors, as well as the feasibility of a low-intensity, school-based educational intervention aimed at improving critical thinking about the relationship between macronutrients and NCDs among high school students, while tracking safety measures such as body image discrepancy.

Participants

A total of 115 high school students from 2 public schools (1 for males and 1 for females) in Medina City, Saudi Arabia, were invited to participate. These schools were selected by the ministry of education's school health department. Of the invited students, 95 (58 males and 37 females) completed anthropometry and body composition measurements. Baseline surveys were completed by 85 students (53 males and 32 females). Four classes (2 females and 2 males) were randomly assigned to 1 of 2 intervention groups: the Macronutrient+ NCDs Health Education group (n=31) or the Macronutrient Health Education group (n=38).

Intervention: Green Apple

Overview

The LEAF program, an 8-session structured intervention, was developed to enhance critical thinking regarding macronutrients and their relationship to body energy and the prevention of cardiometabolic diseases. For this study, a pilot version, titled Green Apple, was conducted over two 45-minute sessions for female students and one 60-minute session for male students due to scheduling constraints. The intervention was based on best practices derived from evidence-based research into health literacy and behavior change [21]. The program was grounded in the Health Belief Model [22] and Social Cognitive Theory [23], incorporating the Transtheoretical Model for behavior change [24].

These theories provided the framework for understanding how adolescents perceive their risk of NCDs (eg, diabetes, hyperlipidemia, liver disease, stroke, and hypertension) and motivated them to adopt healthier behaviors through education, muscle building, and dietary modifications. The Green Apple program aimed to reduce chronic metabolic NCD risk by promoting visceral fat reduction and muscle building without focusing on weight loss or obesity. Participants were encouraged to follow the MyPlate dietary guidelines [25], emphasizing fiber and whole food consumption and engaging in muscle-building exercises. The program avoided topics related to obesity and sedentary behavior, instead focusing on metabolic health improvements.

Intervention Groups

The Macronutrient+ NCDs Health Education group included 3 educational topics covering nutrition and metabolic diseases (eg, diabetes and cardiovascular disease), highlighting the impact of macronutrition on metabolic health.

The Macronutrient Health Education group included 2 educational topics focused solely on healthy nutrition principles, dietary guidelines, food groups, and balanced eating.

Both groups received identical macronutrient content.

Measurements

Demographics

Baseline demographic data included age, self-reported weight and height, parental education levels, and monthly family income. Parental education was categorized as high (college degree or above) or low (high school degree or below).

Anthropometry

Body weight and height was measured using a portable digital scale (Omron BF511) to the nearest 100 g and a stadiometer to the nearest 0.1 cm. BMI was calculated as weight (kg) divided by height squared (m^2), and BAZs were classified using the World Health Organization 2007 Growth Reference for children and adolescents aged 5 - 19 years [26]. The BAZ categories were thinness ($-3 \leq$ BAZ < -2), normal weight ($-2 \leq$ BAZ $\leq +1$), overweight ($+1 <$ BAZ $\leq +2$), and obesity (BAZ $> +2$).

Fat percentage was assessed using a bioimpedance analyzer (Omron BF511). Classification was based on McCarthy's age- and sex-specific fat percentile references, with the 2nd, 85th, and 95th percentiles defining underfat, overfat, and obese, respectively [27].

Cardiovascular Fitness

The Queen's College Step Test, a submaximal exercise test, was used to estimate the maximal oxygen consumption (VO_2max). Participants stepped on a 30.5- cm box at a set rate for 3 minutes [28]. The 30.5-cm step height was chosen for its suitability for adolescents [28]. VO_2max estimation: The pulse rate was measured postexercise using a pulse oximeter, following McArdle's protocol [29]. The equations for estimating VO_2max were as follows: girls: 65.81 − (0.1847 × pulse rate) and boys: 111.33 − (0.42× pulse rate) [28].

Handgrip Strength

Handgrip strength was measured using a Takei Kiki Kogyo dynamometer, and the highest value from 2 trials for the dominant hand was recorded. Classifications followed age- and gender-specific percentiles [30].

Physical Activity

Physical activity was assessed using the Arab Teen Lifestyle Study physical activity questionnaire subscale [31], calculating total weekly energy expenditure in metabolic equivalent tasks (METs), with vigorous activities (6 METs) and moderate activities (4 METs) expressed in minutes per week.

Eating Habits

Eating habits were evaluated using the Arab Teen Lifestyle Study eating habits subscale, which measured positive eating habits (eg, fruit or vegetable intake) and negative eating habits

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(eg, sugary drinks or fast food) based on weekly frequency [31], with a total scores ranging from 0 to 28 for positive habits and 0 to 35 for negative habits.

Sedentary Behavior

Sedentary behavior was measured using the Arabic Sedentary Behavior Questionnaire (SBQ) for weekdays [32]. The questionnaire included 9 items, and a total sitting time was averaged over 5 weekdays. Sitting ≥7 hours per day was considered highly sedentary [33].

Exposure to NCDs Health Education

Exposure to health education on NCDs was assessed using 4 yes or no questions regarding prior education on chronic diseases. A total score (0 - 4) was calculated.

Macronutrient-NCDs Knowledge

Macronutrient and NCDs knowledge was measured using an 18-item true-or-false quiz developed based on the Green Apple content. A total score (0 - 18) was analyzed, with an urgent need for intervention indicated if 70% or fewer answered correctly, a considered need at 71% - 89%, and no need at 90% or more [34].

Body Image Discrepancy

Body image discrepancy was assessed using 4 body size silhouettes [35]. Participants selected their ideal and perceived current body images, with discrepancies indicating body image concerns. A negative score represented a drive for thinness, while a positive score reflected a drive for increased body weight [36].

Ethical Considerations

The study protocol was approved by the Shaqra University ethics committee (ERC_SU_20230005). Written informed consent was obtained from parents, and student participation was voluntary. To ensure privacy and confidentiality, participant data were anonymized using unique identifiers, and data access was limited to authorized personnel. Baseline assessments were conducted prior to the intervention. The intervention was delivered on different days for males and females due to scheduling constraints. Postintervention assessments for macronutrient-NCDs knowledge and body image discrepancy were conducted, and participants received a key chain medley as a token of appreciation for their involvement.

Statistical Analysis

Overview

Descriptive statistics (means, SDs, and frequencies) were calculated for all variables. Independent *t* tests were conducted to compare males and females and students with and with no overweight or obesity on continuous variables, while χ^2 tests were used for categorical variables. A 2-way mixed ANOVA design was used, with 1 between-subjects factor (intervention type: macronutrient-NCDs vs macronutrient) and 2 within-subjects factors (time: pre-test and post-test) for 2 dependent variables: macronutrient-NCDs knowledge and body image discrepancy. Gender was included as an additional between-subjects variable to assess potential interactions with time and intervention type.

Statistical significance was set at $P<.05$. Sample size calculations using G*Power 3.1 indicated a required sample size of 34 participants to detect medium effects ($f=0.25$) with 80% power. Although an initial plan accounted for a 30% attrition rate, the final sample size exceeded the minimum requirement for detecting a medium effect size with 80% power, ensuring sufficient study power.

A 2-way mixed ANOVA was conducted to evaluate the effect of the Green Apple intervention on students' macronutrient-NCDs knowledge scores before and after the intervention and to determine potential gender interaction effects, given the significant difference in mean scores between males and females at preassessment.

Two borderline outliers with studentized residuals of −3.02 and −3.03 were identified but retained in the analysis. The data were normally distributed, as assessed by the Shapiro–Wilk test ($P>.05$). Homogeneity of variances ($P>.05$) and covariances ($P>.001$) were confirmed by Levene test and Box M test, respectively, except for postintervention body image discrepancy, which required Welch ANOVA.

Missing Data

A missing data analysis was conducted, revealing that 4% of data were missing across all items, with a maximum of 7% missing for certain variables (eg, "minutes' walk per day," "number of stairs per day," and "SBQ-listening to music, using computer, crafting"). Little MCAR test was applied to assess the randomness of the missing data, yielding a nonsignificant result ($P>.05$), indicating that the data were missing completely at random [37]. Expectation-Maximization was used to impute missing data for variables with 5% - 7% missing values. For variables with <5% missing data, series mean and series median imputation methods were used.

Two items from the physical activity scale ("regular dancing" and "house cleaning") were excluded due to cultural factors that led to inconsistent responses between male and female participants. This decision was informed by a review of similar studies conducted in the region [38,39]. Furthermore, family income was excluded from analysis because female students were often unaware of this information, which is considered sensitive, and younger students may not accurately understand their family's financial status [40]. The high absenteeism rate among female students during the intervention (approximately 28%) also contributed to some missing data, consistent with previously reported absenteeism rates in Saudi schools [41].

Results

Baseline Characteristics and Prevalence of Overweight and Obesity

Table 1 shows the baseline characteristics of the 95 participants (37 girls and 58 boys). The mean age of the total sample was 16.18 (SD 0.53) years, with girls having a significantly higher mean age than boys ($P<.001$). The mean BAZ score for the total sample was 0.44 (SD 1.42), with a significant sex difference

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(*P*=.03). Furthermore, girls had a higher mean fat percentage than boys (28.58% vs 22.65%), but this difference was not statistically significant (*P*=.37). The combined prevalence of overweight and obesity based on the BAZ classification was 37.9% (36/95), with 16.8% (16/95) of participants classified as overweight and 21.1% (20/95) of participants classified as obese. When considering fat percentage, the combined prevalence of overfat and obesity was 50.5% (48/95), with 11.6% (11/95) of participants classified as overfat and 38.9% (37/95) of participants classified as obese. For the BAZ and fat percentage percentile categories, no significant sex differences were observed. Table 2 shows descriptive statistics for the distribution of the participants' weight status (normal BAZ and high BAZ) across different levels. These results suggest that there was no statistically significant relationship between parental education level (both mother and father) and the participants' weight category.

Table . Descriptive statistics based on sex (mean [SD] or fat percentage).

Variables	All (N=95)	Girls (n=37)	Boys (n=58)	Sex (significance) difference[a]
Age (years), mean (SD)	16.18 (0.53)	16.38 (0.64)	16.05 (0.39)	<.001
BMI (kg/m^2), mean (SD)	23.46 (6.07)	23.25 (5.24)	23.59 (6.59)	.05
BAZ[b], mean (SD)	0.44 (1.68)	0.44 (1.42)	0.44 (1.84)	.03
Fat percentage, mean (SD)	24.96 (9.54)	28.58 (8.62)	22.65±9.44	.37
BAZ percentile, n (%)				.39
Underweight	7 (7.4)	2 (5.4)	5 (8.6)	
Normal weight	52 (54.7)	22 (59.5)	30 (51.7)	
Overweight	16 (16.8)	8 (21.6)	8 (13.8)	
Obese	20 (21.1)	5 (13.5)	15 (25.9)	
Fat percentage percentile, n (%)				.44
Underfat	5 (5.3)	3 (8.1)	2 (3.4)	
Normal	42 (44.2)	16 (43.2)	26 (44.8)	
Overfat	11 (11.6)	6 (16.2)	5 (8.6)	
Obese	37 (38.9)	12 (32.4)	25 (43.1)	
Exposure to metabolic NCDs[c] education, mean (SD)[d]	3.19 (1.006)	3.72 (0.523)	2.87 (1.093)	<.001
Macronutrient-metabolic NCDs knowledge, mean (SD)[d]	10.64 (3.638)	12.13 (2.472)	9.74 (3.943)	.50
Body image discrepancy, mean (SD)[e]	−0.36 (0.94)	−0.69 (0.74)	−0.13 (1.00)	.005

[a]Independent *t* tests were conducted to compare differences between the 2 groups. Two-sided *P* values are reported when no significant difference was found between the groups. One-sided *P* values are reported when the 1-directional hypothesis was supported.

[b]BAZ: BMI-for-age *z* score.

[c]NCD: noncommunicable disease.

[d]The n values for these data are as follows: All (n=85); Girls (n=32); Boys (n=53).

[e]The n values for these data are as follows: All (n=78); Girls (n=32); Boys (n=46).

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Table . Weight category descriptive statistics (mean [SD] or fat percentage).

	All	Normal BAZ[a]	High BAZ	Significance[b]
Mother's education, n (%)				.99
Low education level	28 (34.6)	18 (34.6)	10 (34.5)	
High education level	53 (65.4)	34 (65.5)	19 (65.5)	
Father's education, n (%)				.07
Low education level	18 (21.7)	8 (15.4)	10 (32.3)	
High education level	65 (78.3)	44 (84.6)	21 (67.7)	
Fat percentage, mean (SD)	24.96 (9.54)	19.53 (6.10)	33.85 (7.16)	<.001
VO_2max (mL/kg/min), mean (SD)	53.33 (14.63)	53.68 (14.72)	52.77 (14.67)	.86
VO_2max boys (mL/kg/min), mean (SD)	62.65 (10.29)	63.43 (10.69)	61.46 (9.77)	.81
VO_2max girls (mL/kg/min), mean (SD)	37.90 (2.87)	38.84 (1.83)	36.10 (3.65)	.014
Handgrip strength max score (kg), mean (SD)	24.49 (7.85)	24.81 (8.81)	23.96 (6.04)	.15
Handgrip strength percentile, n (%)				.67
Low: ≤20	52 (54.7)	34 (57.6)	18 (50)	
Normal: 21 - 80	35 (36.8)	21 (35.6)	14 (38.9)	
High: >80	8 (8.4)	4 (6.8)	3 (11.1)	
Health-related behaviors based on weight status, mean (SD)				
Vigorous-intensity physical activity (METs[c] min/wk)	2038.91 (2560.25)	2360.92 (2914.76)	1505.56 (1743.45)	.047
Moderate-intensity physical activity (METs min/wk)	1038.90 (1219.13)	1009.073 (1174.13)	1088.286 (1307.99)	.39
Sedentary behavior per day during the week (h/d)	7.28 (3.93)	7.741 (3.11)	7.5064 (3.98)	.34
Positive eating behavior	16.43 (6.30)	16.838 (5.98)	15.7188 (6.84)	.22
Negative eating behavior	15.11 (6.62)	15.160 (6.22)	15.022 (7.34)	.46
Exposure to metabolic NCDs[d] health education topics	3.19 (1.01)	3.36 (0.76)	2.91 (1.28)	.02
Macronutrient-metabolic NCDs knowledge	10.64 (3.64)	10.90 (3.10)	10.13 (4.39)	.16
Need for educational intervention assessment, n (%)				.92
Urgent need	59 (69.4)	37 (69.8)	22 (68.8)	
Considered need	26 (30.6)	16 (30.2)	10 (31.3)	
No need	0 (0)	0 (0)	0 (0)	

[a]BAZ: BMI-for-age *z* score.

[b]Independent *t* tests were conducted to compare differences between the 2 groups. Two-sided *P* values are reported when no significant difference was found between the groups. One-sided *P* values are reported when the 1-directional hypothesis was supported.

[c]MET: metabolic equivalent task.

[d]NCD: noncommunicable disease.

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Cardiovascular Fitness and Handgrip Strength

Overall cardiovascular fitness levels, as measured using VO_2max, did not significantly differ between individuals in the normal and high body weight categories. The boys in the normal BAZ group had a slightly higher VO_2max (63.43 mL/kg/min, SD 10.69) than the boys in the high BAZ group (61.46 mL/kg/min, SD 9.77). However, this difference was not statistically significant (*P*=.81). There was a notable and statistically significant difference between the girls in the normal BAZ group (38.84 mL/kg/min, SD 1.83) and those in the high BAZ group (36.10 mL/kg/min, SD 3.65), with a *P* value of .014. This indicates that girls with overweight or obesity had significantly lower cardiovascular fitness levels than their peers in the normal group, suggesting a potential negative impact of higher body weight on cardiovascular fitness among girls. However, the distribution of handgrip strength categories did not show a statistically significant association with the BAZ classification (*P*=.67) (Table 2).

Health-Related Behaviors Based on Weight Status

Activity Behavior

Participants with a high BAZ had lower levels of METs minutes per week from vigorous-intensity activity (1505.56, SD 1743.45) than those with a normal BAZ (2360.92, SD 2914.76), with a significant difference (*P*=.047). No significant differences were observed in METs from moderate-intensity activity (*P*=.39).

Sedentary Behavior

The difference in sedentary behavior between the 2 groups was not statistically significant (*P*=.68), indicating similar levels of sedentary time regardless of weight status.

Eating Behavior

Positive eating behaviors were marginally lower in the high BAZ group (15.72, SD 6.84) than in the normal BAZ group (16.84, SD 5.98), but the difference was not statistically significant (*P*=.23). Furthermore, negative eating behaviors showed no significant differences between the groups (*P*=.93).

Macronutrient-Metabolic NCDs Knowledge and Need for Intervention

The participants with a normal BAZ reported higher exposure to metabolic NCDs education (3.36, SD 0.76) than those with a high BAZ (2.91, SD 1.28), with a significant difference (*P*=.02). However, no significant differences were observed in the macronutrient-metabolic NCDs knowledge scores between the 2 groups (*P*=.16). The majority of the participants were classified as having an urgent need for an educational intervention (59/85, 69.4%), and 30.3% (26/85) were classified as having a need for an intervention, with no statistically significant distribution between the 2 groups (*P*=.92).

The Green Apple Intervention Effectiveness

The final sample consisted of 69 participants, with 23 females (intervention=13, control=10) and 46 males (intervention=18, control=28).

Effect on Macronutrient-Metabolic NCDs Knowledge

There was a significant main effect of time on students' macronutrient-metabolic NCDs knowledge ($F_{1,58}$=23.263; *P*<.001), with a large effect size (partial η^2=0.286). This indicates that knowledge significantly improved from pre- to postintervention, and the magnitude of the change was substantial. Also, a significant main effect was found for intervention type ($F_{1,58}$=19.756; *P*<.001), with a large effect size (partial η^2=0.254). The Macronutrient + NCDs intervention had a greater effect on improving knowledge (Table 3). The interaction between gender and intervention type was nonsignificant ($F_{1,58}$=0.002; *P*=.99), with a very small effect size (partial η^2=0.00), indicating that the effect of the interventions on knowledge was consistent across genders.

Table . Changes in macronutrient-noncommunicable disease (NCD) knowledge and body image discrepancy across intervention periods.

	Baseline, mean (SE)	95% CI	Follow-up, mean (SE)	95% CI
Effect on macronutrient-metabolic NCDs knowledge				
Nutrition+ NCD	11.16 (0.56)	10.03 to 12.29	13.39 (0.42)	12.55 to 14.24
Nutrition	11.53 (0.55)	10.45 to 12.63	13.04 (0.41)	12.22 to 13.86
Effect on body image discrepancy				
Nutrition + NCD	−0.38 (0.17)	−0.72 to −0.03	−0.53 (0.19)	−0.90 to −0.16
Nutrition	−0.50 (0.167)	−0.84 to −0.17	−0.41 (0.18)	−0.77 to −0.05

Body Image Discrepancy

The effect of time on body image was nonsignificant ($F_{1,58}$=0.150; *P*=.70), with a small effect size (partial η^2=0.003), suggesting no significant change in students' body image from pre- to postintervention. Similarly, the interaction between gender and intervention type was nonsignificant for body image ($F_{1,58}$=0.182; *P*=.73), with a very small effect size (partial η^2=0.002), meaning that the interventions had similar effects on body image for both males and females. The effect of gender on body image was marginally significant ($F_{1,58}$=6.157; *P*=.052), with a medium effect size (partial η^2=0.064), suggesting a slight difference in body image perception between males and females. However, Welch ANOVA was used due to unequal variances between males and females on postintervention body image discrepancy, and the findings suggest that gender does play a

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role in postintervention body image, with a statistically significant difference detected between males and females (Welch $F_{1,66.977}$=5.385; P=.02). This suggests that after accounting for unequal variances (based on Levene test), gender does have a significant effect on postintervention body image.

The Green Apple Intervention Feasibility

The high recruitment rate indicates strong initial interest and willingness to participate in the intervention, with 82.6% (95/115) of invited students enrolling in the study. Nearly 90% (85/95) of the recruited participants were engaged enough to provide comprehensive baseline data. The overall retention rate, based on completion of the pre- and postintervention questionnaires, was 72.6% (69/95). This indicates that a significant majority of the participants remained engaged with the study through to its conclusion, although there was a drop-off of 27.4% (26/95) from baseline to the postintervention phase. This dropout rate highlights some challenges in maintaining participant engagement over the study period. The retention rate was notably higher among male participants (46/58, 79.3%) than among female participants (23/37, 62.2%). This disparity was related to high absenteeism in the female school. Furthermore, one of the key challenges encountered was scheduling conflicts, particularly in the male school. These constraints impacted the intervention delivery, reducing the planned 2 sessions over 2 weeks to a single session on 1 day.

Discussion

Principal Findings

This study aimed to assess the prevalence of obesity among late adolescents in Medina City, Saudi Arabia, using both BAZ and fat percentage, and to evaluate the feasibility and effectiveness of a low-intensity, non–weight-centric educational intervention focused on macronutrient-metabolic disease knowledge. The findings indicate a high prevalence of obesity in this population, surpassing national averages. The Green Apple intervention effectively improved students' macronutrient knowledge without negatively affecting body image discrepancy, demonstrating its potential as a health education tool.

The prevalence of overweight and obesity based on the BAZ classification was 37.9% (36/95), with 21.1% (20/95) classified as obese. When using fat percentage, the prevalence was even higher at 50.5% (48/95), highlighting that BMI alone may underestimate obesity rates. This aligns with regional data, indicating that adolescent obesity trends in Medina reflect broader patterns observed in the western region of Saudi Arabia [7]. The effectiveness of the Green Apple intervention in significantly improving macronutrient-metabolic NCDs knowledge without impacting body image discrepancy underscores the potential for brief educational programs to enhance adolescents' understanding of nutrition and health.

Our study's obesity prevalence rates are consistent with findings from prior research in the western region of Saudi Arabia. For instance, a 2019 study reported a 35.3% (121/342) obesity prevalence among university students in Medina [42], indicating a persistent trend across educational levels. A 2021 study also found a similar overweight and obesity prevalence of 38.5% (44,826/116,656) among participants aged 17 - 25 years across different Saudi regions [43]. The higher prevalence of obesity in males (15/58, 25.9%) than in females (5/37, 13.5%) aligns with national data showing higher obesity rates in male adolescents [10].

The use of fat percentage as an additional measure provided a more nuanced understanding, revealing an obesity rate nearly double that of the BAZ classification. This supports prior research suggesting that fat percentage often results in a higher reported prevalence of obesity compared with BMI, sometimes by 1.5-3 times [44-46]. BMI fails to distinguish between muscle and fat mass, making fat percentage a more accurate indicator of obesity [45,46].

The study also identified a significant difference in VO_2max scores between the normal and high BAZ groups among females, with the normal group demonstrating better cardiovascular fitness. This finding suggests an inverse relationship between BAZ and cardiovascular health, emphasizing the importance of maintaining a normal BAZ for better fitness. Similar studies have shown a negative relationship between BMI and cardiorespiratory fitness in Saudi youth aged 8 - 15 years [47]. Furthermore, while the normal BAZ group had higher handgrip strength, there was no significant difference in percentiles between groups, indicating that low muscle strength is common among adolescents regardless of BMI. Previous studies have also reported low muscle strength among Saudi male adolescents aged 17 years [48] and no significant association between BMI and strength in college-aged females [49]. This study is the first to report age- and sex-specific handgrip strength percentiles for this population, an essential aspect for future research [30].

Also, the lack of significant differences in dietary behaviors between weight groups suggests that suboptimal eating habits are widespread. Both groups showed low fruit and vegetable intake and high consumption of sugary drinks, aligning with global patterns [50]. Sedentary behavior was similar between groups, reinforcing the need for targeted physical activity interventions. Our finding that vigorous physical activity correlates with lower obesity rates aligns with the Green Apple program's emphasis on high-intensity activity for metabolic health [51]. Current evidence suggests that vigorous intensity exercise may be particularly effective for improving body composition and health outcomes in adolescents [8,9]. These modalities also show promise for improving adherence. However, proper supervision and safety considerations are important, especially for higher-intensity activities and more research is needed to determine optimal exercise prescriptions and implementation strategies for this age group [8,9].

Our findings further revealed significantly lower exposure to NCD education among students with overweight or obese status compared with those with normal weight, and male students reported lower exposure than females. This could be linked to lower NCD knowledge among male teachers, as suggested by a recent study in Saudi Arabia [52]. The lower awareness about NCDs among young adults highlights the need for targeted interventions to increase education and awareness [53,54]. Early

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education can lead to better outcomes by promoting preventive measures [54,55].

The efficacy of low-intensity, non–weight-centric educational interventions in improving knowledge is crucial for preventing metabolic NCDs. By focusing on macronutrient education without emphasizing weight loss, the Green Apple program demonstrates a promising approach to improving metabolic health in adolescents without affecting body image. Research on educational interventions in Saudi Arabia and Gulf Cooperation Councilcountries is limited, with existing studies primarily focusing on obesity awareness and metabolic NCDs such as diabetes [12,56]. Our study contributes to this field by showing that even low-intensity interventions targeting macronutrient and NCD knowledge can enhance health literacy. Importantly, this study targeted late adolescents, addressing a significant gap as previous research has mainly focused on younger adolescents (aged 12 - 14 years) [12,56]. The Green Apple program, as a pilot derived from the larger LEAF program, suggests a scalable model that integrates educational and behavioral strategies to promote sustainable health improvements by focusing on visceral fat reduction and muscle mass development.

The significant improvement in students' knowledge aligns with recent literature highlighting the importance of early NCD education [57,58]. The observed large effect size (partial η^2=0.286) further supports the intervention's effectiveness. Contextualizing nutritional information to metabolic health may enhance learning by linking knowledge to practical outcomes. Also, the nonsignificant interaction between gender and intervention type indicates that the content was equally effective for both male and female students, which is significant in a cultural context where gender-specific education is common [59]. This suggests that balanced content can be effective across genders. Finally, the nonsignificant effect on body image supports literature advocating for weight-neutral interventions to avoid adverse body image outcomes [60]. However, the significant postintervention body image difference between genders highlights the need for considering gender-specific perceptions in future program designs [61].

Limitations and Recommendations

Despite the positive outcomes, challenges such as scheduling and gender-specific retention highlight the need for flexible strategies. Limitations include the relatively small, single-region sample size, which may limit generalizability, and the short intervention period, which may not capture long-term effects. Self-reported data could introduce bias. Future research should involve larger, more diverse samples and longer interventions and consider digital family-based education methods, such as webinars and web-based workshops, to enhance parental involvement [62-64]. Engaging parents in school health education could yield better adolescent health outcomes [63,64].

Conclusions

This study underscores the high prevalence of obesity among Saudi adolescents and highlights the potential of low-intensity educational interventions to improve macronutrient knowledge. By emphasizing metabolic health and muscle building, the Green Apple program offers a promising non–weight-centric strategy for preventing chronic metabolic diseases. Future programs should focus on high-intensity physical activity and neutral weight messaging to address obesity and mental health comprehensively.

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Data Availability

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

Conflicts of Interest

None declared.

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Abbreviations

BAZ: BMI-for-age *z* score
MET: metabolic equivalent task
NCD: noncommunicable disease
SBQ: Sedentary Behavior Questionnaire
VO_2max: maximal oxygen consumption

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A Primary Care Group Resilience Intervention Promotes Child and Caregiver Behavioral Health

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Abstract

This pilot study of the redesigned Resilience Clinic, a group-based psychoeducational intervention designed to promote relational health and child and family resilience provides preliminary evidence that participation in this intervention is associated with decreased caregiver stress, anxiety, and child behavioral concerns.

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KEYWORDS

parenting education; parent-child relationship; adverse childhood experiences; child behavior; children; caregiver; caretaker; parenting; family; stress; anxiety; behavior; relational health; psychoeducation; psychological education; resilience intervention; group-based; pilot study

Introduction

Since adverse childhood experiences (ACEs) including child maltreatment, family violence, parental substance abuse, and parental mental illness may increase health and behavioral risks [1,2], further research into preventive early childhood interventions, before the onset of ACE-associated sequelae is required [3]. The Resilience Clinic (RC) [4] is a primary care-based group psychoeducational intervention promoting resilience among children exposed to significant adversity. Initially serving children of all ages, this program was redesigned based on significant parent feedback to focus on early childhood (ages 0 - 5); the curriculum incorporates Circle of Security-Parenting (building secure attachment) [5] and Dovetail Learning (mindful stress management) [6] in 6 weekly, hour-long group sessions. This study explored whether participation in RC decreased measures of (1) caregiver stress, anxiety, and depression, and (2) child behavioral challenges.

Methods

This pilot study analyzed pre-post differences in caregiver-reported measures of behavioral health after RC participation. Eligibility criteria included children aged 0 - 5, referred by primary care providers following positive ACE screening; siblings were excluded. Eligible participants were allowed to join the intervention without joining the study.

Study measures included the Child Behavior Checklist (CBCL) for ages 1.5 to 5 years [7] to assess child behavioral challenges, Generalized Anxiety Disorder (GAD-7) [8] for caregiver anxiety, Patient Health Questionnaire (PHQ-8) [9] for caregiver depression, and Perceived Stress Scale (PSS-4) [10] for caregiver stress. Caregivers completed measurements at baseline and 3 months after intervention completion.

To estimate intervention effect sizes, we used Cohen *d* or (standardized mean difference), for paired samples. Cohen *d* value cutoffs of 0.2, 0.5, and 0.8 are considered as small, medium, and large effect sizes, respectively. *P* values were constructed from the Wilcoxon signed-rank test since the variables were not normally distributed, with significance set at $P<.05$.

This study was approved by the host institution's Institutional Review Board (22 - 37781) as minimal risk research. Signed informed consent was obtained from all participating caregivers. Data was stored on secure institutional servers and deidentified prior to analysis. Participants could receive up to $190 for completing all study activities.

Results

A total of 28 caregiver/child dyads were recruited; of these, 79% (n=22) preferred Spanish and 14% (n=4) preferred English. Median child age was 4.5 years (IQR 1.66) and 50% (n=14)

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were male. Participants who completed both pre and post data collection were included in this analysis.

Three months post-intervention, caregivers reported large reductions in anxiety and perceived stress compared to baseline (Table 1).

Table . Pre-post changes in caregiver behavioral health measures.

Construct	Measures	Participants, n[a] (N=28)	Baseline scores median, (IQR)	Post intervention scores, median (IQR)	Cohen *d* (SMD)[b]	*P* value
Caregiver anxiety	GAD-7[c]	16	5.5 (1.75-9.25)	1.0 (0-4.25)	0.86	.01
Caregiver depression	PHQ-8[d]	4	8.0 (6.5-9.25)	5.5 (3.75-7.25)	0.63	.42
Caregiver-perceived stress	PSS)- 4[e]	18	7.0 (6-8)	4.0 (3-6)	0.92	.02

[a]Number of participants who completed both pre and postdata collection for that measure.

[b]SMD: Standardized mean difference.

[c]GAD-7: Generalized Anxiety Disorder-7-item.

[d]PHQ-8: Patient Health Questionnaire-8-item.

[e]PSS-4: Perceived Stress Scale-4-item.

Notably, the decrease in caregiver anxiety (GAD-7: d=0.86, P=.01) and caregiver-perceived stress (PSS-4: d=0.92, P=.02) suggested large and statistically significant intervention effect sizes for parental anxiety and perceived stress among RC participants. The PHQ-8 responses were limited as the full instrument was administered only if the PHQ-2 score exceeded 4, making it difficult to draw conclusions.

Similarly, moderate reductions were seen in postintervention measures of multiple child behavior challenges, including attention problems, aggression, externalizing problems, stress, and overall problems. The decrease in attention problems (d=0.72, P=.05) approached significance. Selected child behavior domains showing moderate postintervention score reduction are listed in Table 2.

All other CBCL domains showed small effect sizes (d<0.5), including emotionally reactive (0.27), anxious depressed (0.12), somatic complaints (0.46), withdrawn (0.36), sleep problems (0.16), internalizing problems (0.32), anxiety problems (0.02), autism spectrum problems (0.48), and oppositional defiant problems (0.40).

Table . Pre-post changes in the Child Behavior Checklist (CBCL).

Child behavior domain	Number of participants, n[a] (N=28)	Baseline scores, median (IQR)	Post-intervention scores, median (IQR)	Cohen *d* (SMD)[b]	*P* value
Attention problems	11	62 (57.5-67)	53 (51.5-62)	0.72	.05
Aggressive behaviors	11	64 (51.5-70)	56 (51-61)	0.53	.20
Externalizing problems	11	64 (53-70)	56 (48.5-60)	0.70	.11
Overall problems	11	68 (53.5-72)	58 (49.5-66.5)	0.50	.07
Stress	11	70 (53-72)	53 (52-62.5)	0.74	.09
Depression	11	63 (53-69.5)	56 (50-61.5)	0.52	.09
ADHD[c]	11	64 (59-71)	57 (52-65.5)	0.72	.08

[a]Number of participants who completed both pre and postdata collection for that measure.

[b]SMD: Standardized mean difference.

[c]ADHD: Attention deficit hyperactivity disorder

Discussion

Three months post-intervention, caregivers reported significant reductions in anxiety and perceived stress and moderate reductions in their children's attention problems, aggressive behaviors, externalizing problems, total problems, and stress and depressive problems. The decrease in caregivers' anxiety and perceived stress was significant (P<.05), and the reduction in child attention problems approached significance (P=.05). These findings suggest that participation in this group resilience intervention may help improve caregiver stress and anxiety and child behavior.

Study limitations include the small sample size and lack of a control group, which make the findings preliminary. Given these promising results, a randomized controlled trial is needed to confirm these intervention effects.

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Given the age of these children, when mental health diagnoses are rare, most children would not otherwise be receiving mental health services. This pilot study indicates that similar primary care-based, preventative group interventions may offer meaningful improvements in caregiver and child behavioral health in the context of childhood adversity.

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Conflicts of Interest

None declared.

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Abbreviations

ACE: adverse childhood experiences
CBCL : Child Behavior Checklist
GAD-7: Generalized Anxiety Disorder -7 item (screening tool for anxiety)
PHQ-8: Patient Health Questionnaire (PHQ)-8 item (screening tool for depression)
PSS: Perceived Stress Scale
RC: Resilience Clinic

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The Effect of COVID-19 on Health Care Utilization Among Children with Medical Complexity: Retrospective Chart Review Study

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Abstract

This study examines the trends, patterns, and potential health disparities in health care utilization among children with medical complexity, before and during COVID pandemic through a retrospective chart review. Our findings show significant differences in the average number of visits per patient over the years and support the adoption of telehealth consultations, while highlighting concerns about demographic disparities.

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KEYWORDS

children with medical complexity; pediatric; children; health care utilization; telemedicine; telehealth; virtual care; virtual health; COVID-19; SARS-COV-2; coronavirus; respiratory; infectious; pulmonary; pandemic; chart review; chart review study; retrospective chart review; retrospective chart review study

Introduction

Children with medical complexity are defined as children and youth with chronic and severe health conditions and substantial functional limitations that require specialized medical services, frequent hospitalizations, and coordinated care from various health care providers [1,2].

Telehealth was one of the efficient and creative solutions for care for children with medical complexity during the pandemic [3]. These children face numerous barriers to health care (eg, multiple visits per day, limited access and availability of clinicians, high cost of transportation, day-to-day life disruptions) [4]. Telehealth visits or remote virtual consultations offered numerous benefits at the onset of the COVID-19 pandemic, such as limited exposure, fewer transfers, and minimum travel for several types of patients and specialists, while also increasing the availability of consultations [5]. This alternative to in-person visits has proven to be effective in resource-limited countries with geographical barriers and has reduced the burden of negative consequences for chronically ill children [6]. After its rapid implementation during the pandemic, the attention has shifted towards equity and safety for children with medical complexity postpandemic, while focusing on clinical model refinement and addressing potential health disparities [7,8]. We explored health care utilization patterns among children with medical complexity over 3 years, before and after the pandemic.

Methods

Study Design and Participants

We performed a retrospective chart review study using data from a large health care setting on the East Coast between January 1, 2019, and December 31, 2021. Patients that were included in the study (N=435) were children with medical complexity (<22 years of age), diagnosed with ≥3 chronic conditions [9]. All patient mortality cases (n=5) during the selected period were excluded due to incomplete data for comparison.

Ethical Considerations

This study used deidentified chart data retrieved from electronic health records using *ICD-10* codes to identify the population. The data were fully anonymized before analysis, and no personal or identifiable information was accessed. The study was conducted in compliance with all relevant data protection regulations, including the HIPPA (Health Insurance Portability and Accountability Act). Institutional Review Board approval was obtained (IRB ID: Pro2023-0385) from Hackensack Meridian Health.

Data Processing and Analysis

A demographic summary and descriptive statistics were computed to analyze the distribution of demographic variables, years, and health care visit types, including counts, means, and standard deviations. To evaluate associations between these variables, the Pearson χ^2 tests of independence were conducted.

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For variables showing significant associations ($P<.05$), we reported the effect size using Cramer's V [5] to determine the strength of the relationship. Additionally, posthoc pairwise comparisons were performed using χ^2 tests with adjusted significance levels to identify specific category pairs contributing to the observed differences. All analyses were performed using Microsoft Excel and SPSS software (version 29; IBM Corp) to ensure accuracy and consistency.

Results

Demographic Summary

Table 1 presents the demographic summary of the patients included in the study.

Table . Demographic summary of patients.

Variables	Patients, n (%) (N=435)
Age	
Infants (1-2)	55 (12.6)
Children (3-11)	231 (53.1)
Adolescents (12-18)	104 (23.9)
Young Adults (18-21)	45 (10.3)
Race/ethnicity	
Asian	65 (14.9)
Black	65 (14.9)
Hispanic	82 (18.9)
NonHispanic White	85 (29.5)
Other	67 (15.4)
Unknown	71 (16.3)
Insurance method	
Managed Care	302 (69.4)
Private	99 (22.8)
Other	34 (7.8)

Statistical Analysis

Table 2 provides descriptive statistics for the entire dataset. The data reveal that the highest total average was 16.74 appointments per patient before the pandemic in 2019. In 2020, with the onset of COVID-19, telehealth became a viable means of communicating with patients, while other types of visits and inpatient admissions decreased, resulting in a total average of 10.34 appointments per patient. Although mean of all visit types, including inpatient admissions increased in 2021, they did not return to the 2019 levels, leading to an overall average of 13.22 appointments per patient.

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Table . Data description and findings. This table describes the mean and standard deviations of the number of visits for each visit type (telehealth, outpatient, emergency department) and admissions per patient.

Demographic variables	Visit types															
	Telehealth visits, mean (SD)				Outpatient visits, mean (SD)				Emergency department visits, mean (SD)				Inpatient admissions, mean (SD)			
	2019	2020	2021	*P* value	2019	2020	2021	*P* value	2019	2020	2021	*P* value	2019	2020	2021	*P* value
Overall[a]	0 (0)	2.84 (2.02)	2.01 (1.41)	<.001	6.01 (1.98)	3.50 (1.09)	5.33 (2.31)	<.001	7.31 (2.28)	2.44 (1.70)	3.40 (2.21)	<.001	3.42 (2.30)	1.56 (1.11)	2.48 (1.69)	<.001
Age[b]				.78				.15				.45				.86
Young adults	0 (0)	2.44 (2.23)	2.22 (1.41)		5.91 (1.78)	3.96 (1.02)	4.91 (2.33)		7.07 (2.32)	2.69 (1.49)	4.07 (2.04)		3.71 (2.14)	1.60 (1.16)	2.27 (1.47)	
Children	0 (0)	2.99 (1.94)	1.99 (1.39)		5.81 (2.06)	3.50 (1.08)	5.37 (2.27)		7.32 (2.32)	2.45 (1.72)	3.42 (2.19)		3.31 (2.35)	1.61 (1.09)	2.45 (1.73)	
Adolescents	0 (0)	3.09 (2.07)	1.99 (1.43)		6.17 (1.94)	3.46 (1.10)	5.35 (2.37)		7.24 (2.25)	2.49 (1.67)	3.21 (2.23)		3.61 (2.35)	1.51 (1.12)	2.52 (1.70)	
Infants	0 (0)	2.05 (1.87)	1.98 (1.46)		6.62 (1.79)	3.24 (1.09)	5.45 (2.36)		7.62 (2.16)	2.11 (1.80)	3.11 (2.33)		3.31 (2.13)	1.40 (1.13)	2.73 (1.72)	
Race/ethnicity[b]				.30				.04				.86				.85
Asian	0 (0)	2.80 (2.03)	2.26 (1.47)		5.49 (1.80)	3.35 (1.02)	5.51 (2.37)		7.35 (2.34)	2.46 (1.71)	3.52 (2.03)		3.51 (2.24)	1.71 (1.10)	2.71 (1.68)	
Black	0 (0)	2.91 (2.26)	2.09 (1.51)		6.46 (1.76)	3.51 (1.09)	5.22 (2.23)		7.22 (2.26)	2.51 (1.69)	3.86 (2.24)		3.37 (2.22)	1.54 (1.13)	2.31 (1.66)	
Hispanic	0 (0)	2.52 (1.95)	1.79 (1.39)		5.98 (1.81)	3.45 (1.11)	4.96 (2.19)		7.63 (2.27)	2.66 (1.76)	3.24 (2.30)		3.72 (2.22)	1.61 (1.04)	2.44 (1.74)	
Non-Hispanic White	0 (0)	2.65 (1.93)	2.02 (1.37)		6.49 (2.07)	3.71 (1.14)	5.38 (2.33)		7.31 (2.08)	2.13 (1.54)	3.40 (2.24)		3.41 (2.21)	1.59 (1.14)	2.35 (1.82)	
Other	0 (0)	3.30 (2.04)	1.87 (1.28)		5.60 (2.11)	3.66 (1.05)	5.30 (2.41)		7.10 (2.57)	2.57 (1.79)	3.36 (2.31)		3.06 (2.42)	1.57 (1.05)	2.66 (1.67)	
Unknown	0 (0)	2.97 (1.93)	2.08 (1.44)		5.93 (2.13)	3.31 (1.08)	5.65 (2.37)		7.18 (2.26)	2.35 (1.71)	3.08 (2.09)		3.39 (2.36)	1.32 (1.18)	2.46 (1.56)	
Insurance methods[b]				.86				.44				.43				.17
Managed Care	0 (0)	2.81 (2.02)	1.99 (1.42)		6.06 (1.98)	3.52 (1.07)	5.23 (2.34)		7.32 (2.27)	2.44 (1.66)	3.42 (2.19)		3.39 (2.30)	1.56 (1.11)	2.43 (1.68)	
Private	0 (0)	2.78 (1.99)	2.04 (1.39)		5.92 (1.98)	3.59 (1.11)	5.63 (2.34)		7.28 (2.36)	2.38 (1.77)	3.35 (2.20)		3.40 (2.36)	1.49 (1.12)	2.55 (1.74)	
Other	0 (0)	3.26 (2.09)	2.09 (1.38)		5.85 (2.06)	3.15 (1.16)	5.29 (1.93)		7.29 (2.21)	2.62 (1.86)	3.32 (2.50)		3.74 (2.09)	1.74 (1.08)	2.76 (1.69)	

[a]Overall averages for each year with a *P* value for difference between the years

[b]Averages per year for each demographic group with a *P* value for the difference between demographic categories.

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A χ^2 test of independence revealed significant differences between the years for telehealth visits (P<.001, Cramer's V=0.612), outpatient visits (P<.001, Cramer's V=0.396), emergency department visits (P<.001, Cramer's V=0.557), and inpatient admissions (P<.001, Cramer's V=0.405).

Among the demographic variables, a significant association was found between race or ethnicity and the number of outpatient visits for three years (P=.04, Cramer's V=0.008). Pairwise comparison for outpatient visits revealed three significant relationships between Asian (P=.02), Hispanic (P=.004), and other patients (P=.02) compared to nonHispanic White patients.

Discussion

Telehealth visits were introduced in 2020, and resulted in a notable decrease in other visit types and inpatient admissions, as reported in other studies [4]. Although 2021 saw an increase in these visit types compared to 2020, they did not return to prepandemic levels observed in 2019. This could be attributed to catch-up visits and admissions that were postponed due to safety reasons during the pandemic [10]. In addition, while many visits can be conducted via telehealth systems, some health care procedures require in-person visits; the safety of these in-person visits improved in 2021.

The reduction in in-person visits after introducing telehealth implementation aligns with another study showing lower hospitalization rates 3 months post discharge when telehealth was used for follow up [11]. Our study also found a reduction in emergency department visits after telehealth introduction, as shown in the literature [8]. Increasing the ease at which a family can access health care via telehealth can avoid some of the in-person struggles faced by families and improve satisfaction with health care interactions.

Our findings show that Asian, Hispanic, and other racial and ethnic groups, have significantly fewer outpatient visits, on average, than nonHispanic White patients. These findings partially align with recent research among Medicaid-insured children with medical complexity, which found that Black nonHispanic and Hispanic children had lower outpatient visit rates than nonHispanic White children [12]. Several reasons may contribute to lower out-patient visits among racial and ethnic minorities, including differential access to care [12], geographical dispersion, a reduced likelihood of receiving specialty referrals from primary care providers, and distrust in the health care system [13]. Significant differences in the number of visits could lead to health disparities, potentially disadvantaging minority groups, and should, therefore, be monitored and addressed.

The COVID-19 pandemic has shown the feasibility of telehealth visits. Although we found disparities based on race and ethnicity in outpatient visits, our findings support equity through telehealth visits for patients and reduced health care utilization. There was no increase in the need for inpatient services when using telehealth visits, which supports the idea that telehealth can be an effective solution for patients. Families can avoid transportation challenges and coordination issues when using telehealth visits.

Our study focuses on changes in health care utilization among children with medical complexity with 3 or more chronic conditions, providing valuable insights into trends within this population. However, we did not account for specific illnesses, clinical outcomes, or the quality of telehealth visits. Additionally, we did not consider environmental factors such as air pollution or pollen exposure, which could significantly influence utilization patterns among children with respiratory or allergic conditions [14]. To deepen our understanding, future research should include control groups or broader pediatric populations to contextualize these observed trends and address potential confounding factors. Additionally, qualitative analyses are needed to explore the reasons behind differences in utilization and disparities, offering a more comprehensive perspective on the challenges faced by this population.

In conclusion, our findings emphasize the need for continued adaptation and support for telehealth services among children, while monitoring demographic disparities in health care access. The introduction of telehealth at the onset of the pandemic coincided with significant decreases in in-person visits and inpatient admissions. Although health care utilization rebound in 2021, it remained below prepandemic levels, suggesting an ongoing adjustment in health care practices. Further, our findings indicate that racial and ethnic disparities persist in outpatient visit patterns. Continued support for telehealth implementation, coupled with targeted efforts to address disparities, are crucial for equitable health care access for all children with medical complexity.

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Authors' Contributions

Conceptualization: IS, KNC, OA, SP
Methodology: IS, KNC, OA, SP
Writing – original draft: IS, OA
Writing – review & editing: IS, KNC, OA, SP

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Conflicts of Interest

None declared.

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Abbreviations

HIPPA: Health Insurance Portability and Accountability Act

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Review

Assessing and Enhancing Nutrition and Physical Activity Environments in Early Childhood Education and Care Centers: Scoping Review of eHealth Tools

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Abstract

Background: Early childhood is a critical period for shaping lifelong health behaviors, making early childhood education and care (ECEC) environments ideal for implementing nutrition and physical activity interventions. eHealth tools are increasingly utilized in ECEC settings due to their accessibility, scalability, and cost-effectiveness, demonstrating promise in enhancing educators' practices. Despite the potential effectiveness of these eHealth approaches, a comprehensive collection of available evidence on eHealth tools designed to assess or support best practices for nutrition or physical activity in ECECs is currently lacking.

Objective: The primary objective of this scoping review is to map the range of available eHealth tools designed to assess or deliver interventions aimed at improving nutrition or physical activity in ECEC settings, while evaluating their components, theoretical foundations, and effectiveness.

Methods: This scoping review adhered to the Joanna Briggs Institute methodology, in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) checklist. The objectives, inclusion criteria, and methods for this review were predefined and specified. Eligibility criteria were (1) early childhood educators (population); (2) eHealth (digital) technologies, such as websites, smartphone apps, emails, and social media; and (3) tools designed to assess or deliver interventions aimed at improving best practices for nutrition, physical activity, or both within ECEC settings (context). A search was conducted across 5 electronic databases (PubMed, Scopus, CINAHL Plus, ERIC, and Embase) to identify white literature, and 3 electronic databases (ProQuest, Google Scholar, and targeted Google search), along with hand-searching of reference lists, were used to identify gray literature. All literature was reported in English or French, with the search extending until May 2024. Separate data charting tools were used for white and gray literature.

Results: The search strategy identified 3064 results for white literature, yielding 2653 unique citations after duplicates were removed. Full texts for 65 citations were retrieved and screened for inclusion, resulting in 30 studies eligible for data extraction and analysis. The most common study design was a randomized controlled trial, comprising 16 studies (53%). The largest proportion of studies were conducted in the United States (11 studies, 37%). In total, 19 eHealth tools were identified, targeting nutrition (8 tools, 42%), physical activity (5 tools, 26%), or both nutrition and physical activity (6 tools, 32%). All tools were web based (19 tools, 100%). The gray literature search yielded 1054 results, of which 17 were moved to full-text screening, and 7 met the eligibility criteria for data extraction and analysis. The tools identified in the gray literature originated in Canada (4 tools, 57%) and the United States (3 tools, 43%). The majority targeted nutrition (4 tools, 57%) and were primarily web based (6 tools, 86%), with 1 mobile app (1 tool, 14%).

Conclusions: This scoping review mapped the available eHealth tools designed to improve nutrition or physical activity environments in ECEC settings, highlighting the growing emphasis on web-based tools and the need for psychometric testing.

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Future research should systematically evaluate the effectiveness of these tools, particularly those addressing both nutrition and physical activity, to identify the key factors that contribute to long-term behavior change.

Trial Registration: Open Science Framework XTRNZ; https://osf.io/xtrnz

International Registered Report Identifier (IRRID): RR2-10.2196/52252

(JMIR Pediatr Parent 2025;8:e68372) doi:10.2196/68372

KEYWORDS

eHealth; early childhood educators; ECE; early childhood education and care; ECEC; knowledge synthesis; digital technology; health technology; digital public health; eating; diet

Introduction

Background

Unhealthy lifestyle factors, such as physical inactivity and unhealthy diets, are primary contributors to the rising incidence of chronic diseases [1-5]. These conditions are recognized as growing global public health problems, leading to significant treatment costs and imposing an economic burden on health systems, individuals, and society as a whole [6,7]. Health behaviors often originate in early childhood and can persist into young adulthood [8]. Research indicates that health behaviors, such as eating habits and physical activity levels, are modifiable risk factors for obesity and chronic diseases [9]. These behaviors often co-occur or cluster together [10,11]. An integrated approach to health promotion, addressing both dietary intake and physical activity simultaneously [10], is therefore essential during early childhood to improve population health across the lifespan.

The early years are a critical period for shaping health behaviors and outcomes [12], with early interventions regarded as an essential component of preventive health [13]. Early childhood education and care (ECEC) settings provide a unique opportunity to reach a large number of children during this pivotal developmental period, making them an ideal setting for behavioral interventions [12,14]. Moreover, early childhood educators, as part of the ECEC environment, are well-positioned to successfully implement nutrition and physical activity behavior interventions [15,16]. Evidence from prior research shows that professional training of early childhood educators in best practices for nutrition and physical activity is associated with improved dietary intake and increased physical activity levels in young children [17-20].

With the widespread use of the internet, online or eHealth interventions have experienced significant growth. eHealth refers to the use of digital technologies, such as the internet, digital gaming, virtual reality, and robotics, for promoting, preventing, treating, and maintaining health [21]. Examples of eHealth technologies include smartphone apps, websites, computer programs, SMS text messaging, and social media platforms [22]. Digital technologies offer several advantages, including lower costs, reduced participant burden, enhanced accessibility, and increased scalability, thereby extending the reach of behavioral interventions [23,24]. Prior research indicates that eHealth interventions within ECEC settings are highly acceptable and effective in improving early childhood educators' knowledge and practices related to nutrition and physical activity [25-27].

Behavior change theories can guide the selection of intrapersonal constructs to target in intervention development, as well as the choice of behavior change techniques to achieve desired behavioral outcomes [28]. Evidence suggests that behavior change interventions, whether internet-based or not, are more effective when guided by a theoretical framework [29]. A meta-analysis [29] found that interventions extensively informed by theory demonstrated larger effects compared with those lacking theoretical underpinnings. The use of theory not only enhances the efficacy of interventions but also facilitates their replication and future development [30]. Consequently, it is crucial to determine whether theory has been applied in the development of eHealth tools.

Recognizing the importance of early learning settings and educators in fostering healthy behavior development in children, researchers have developed, implemented, and evaluated health promotion interventions within childcare settings [31-33]. A preliminary search of PROSPERO, PubMed, the Cochrane Database of Systematic Reviews, and JBI Evidence Synthesis identified several relevant reviews. However, these reviews primarily focused on evaluating the effectiveness of in-person nutrition and physical activity interventions [34,35], interventions conducted in family-based centers [36,37], or those targeting older children and adolescents [33]. No current or in-progress systematic or scoping reviews address eHealth tools for promoting the best nutrition and physical activity practices in ECEC settings.

Objectives

To address this gap in the literature, we conducted a scoping review. This method is used to identify the types of available evidence in a field, explore key characteristics related to a concept, and analyze knowledge gaps [38]. This review aimed to achieve the following objectives: (1) identify existing eHealth tools used to assess or deliver interventions that improve nutrition or physical activity environments in ECEC centers; (2) describe the components of the eHealth tools, including technology type (eg, websites, smartphone apps, social media) and health purposes (eg, nutrition evaluation, physical activity promotion); (3) outline the psychometric properties of the eHealth tools, when applicable; (4) report the theoretical foundations used in developing the eHealth tools; and (5) identify any evidence gaps. The purpose of this study was to map the available evidence on eHealth tools currently used to

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assess and support best practices for nutrition or physical activity in ECEC centers.

Methods

Overview

This scoping review followed established methods for such studies [39] and adhered to the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) guidelines [40]. Methodological quality or risk of bias was not assessed, as the goal of this review was to provide a broad overview of existing evidence, regardless of methodological approach, to map the available evidence. This is consistent with guidance on scoping review methods [39]. Full details of the methods can be found in our published protocol [41]. The PRISMA-ScR checklist is included in Multimedia Appendix 1 [40].

Selection Criteria

Participants

This review considered studies involving early childhood educators within licensed ECEC programs, whether public or privately operated, providing full-day care for children aged 0-5 years. Studies focusing on educators in family-based settings, preschool programs where children attend for less than 4 hours per day, or before- and after-school care were excluded.

Concept

This review considered studies that explored eHealth tools designed to support nutrition or physical activity environments in the ECEC setting. eHealth tools were defined as digital technologies that (1) assessed or (2) delivered interventions to improve nutrition or physical activity environments and practices. eHealth tools that assessed the ECEC environment were included only if they provided feedback to the ECECs. Additionally, we included only studies where the eHealth tool was the primary component for assessment or intervention.

Context

This review focused on nutrition and physical activity environments in the ECEC setting, considering both the physical and social environments.

Types of Sources

For this scoping review, we considered all study designs, including quantitative, qualitative, mixed methods, protocols, experimental, quasi-experimental, and cross-sectional studies. Systematic reviews and meta-analyses were also included if relevant to the topic, with a primary focus on ECEC settings. Unpublished studies and gray literature were also considered as sources of information.

Search Strategy

Overview

The search strategy was developed in collaboration with 2 research librarians and aimed to capture both white and gray literature to encompass the full range of available eHealth tools.

White Literature

A preliminary limited search of PubMed and Scopus was conducted to identify articles on the topic. The text words in the title and abstract, along with the index terms used to describe the articles, were analyzed to develop a full search strategy for PubMed. This search strategy, incorporating all identified keywords and index terms, was then adapted for each included information source (see Multimedia Appendix 2). The databases searched included PubMed, Scopus, CINAHL Plus (EBSCOhost), ERIC (EBSCOhost), and Embase (OVID). The reference lists of all included sources of evidence were screened for additional white literature. The final search was conducted on October 4, 2023. For each database, a search alert was set up using its alert functions to track any new relevant publications for potential inclusion in the review. The final search alert was reviewed on May 5, 2024, and only 1 additional study was identified. All retrieved white literature was exported into Covidence software (Veritas Health Innovation) for screening and data extraction.

Gray Literature

Following the guidelines outlined by Godin et al [100], we conducted a thorough search of the gray literature to identify nonindexed sources such as dissertation abstracts, government documents, conference proceedings, educational materials, and reports. This was done through searches in (1) the ProQuest Database, (2) Google Scholar, (3) targeted web-based Google searches, and (4) hand searches of the reference lists of all included gray literature to identify additional relevant sources. The final gray literature search was conducted on April 30, 2024. All retrieved documents were exported into Microsoft Excel and assigned a unique identifier for screening and data extraction. Because of the potential volume of gray literature, we limited our review to the first 10 pages from Google Scholar and targeted web-based Google searches, based on title. Additionally, eHealth tools that required payment for access were excluded.

This review included studies and records published in English or French, with no date limitations.

Study Selection

Following the search, all identified records were uploaded into Covidence (for white literature) or Microsoft Excel (for gray literature). Title and abstract screening, full-text screening, and data extraction were performed by 2 independent reviewers (JH and LMZL) according to the inclusion criteria. Reasons for excluding full texts that did not meet the inclusion criteria were recorded and reported in the scoping review. Any disagreements between the 2 reviewers were resolved through discussion, and if consensus could not be reached, a third reviewer (KD) was consulted. The results of the search are reported and presented in a PRISMA-ScR flow diagram (Figure 1 in Results section).

Data Extraction

Separate data extraction charting tools for white and gray literature were developed by the reviewers (Multimedia Appendix 3), as outlined in our published protocol [41]. The extraction tools, used to capture relevant study and eHealth tool characteristics, were piloted before the review to ensure

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consistency in information collection. Any disagreements between reviewers were resolved through discussion.

Data Analysis and Presentation

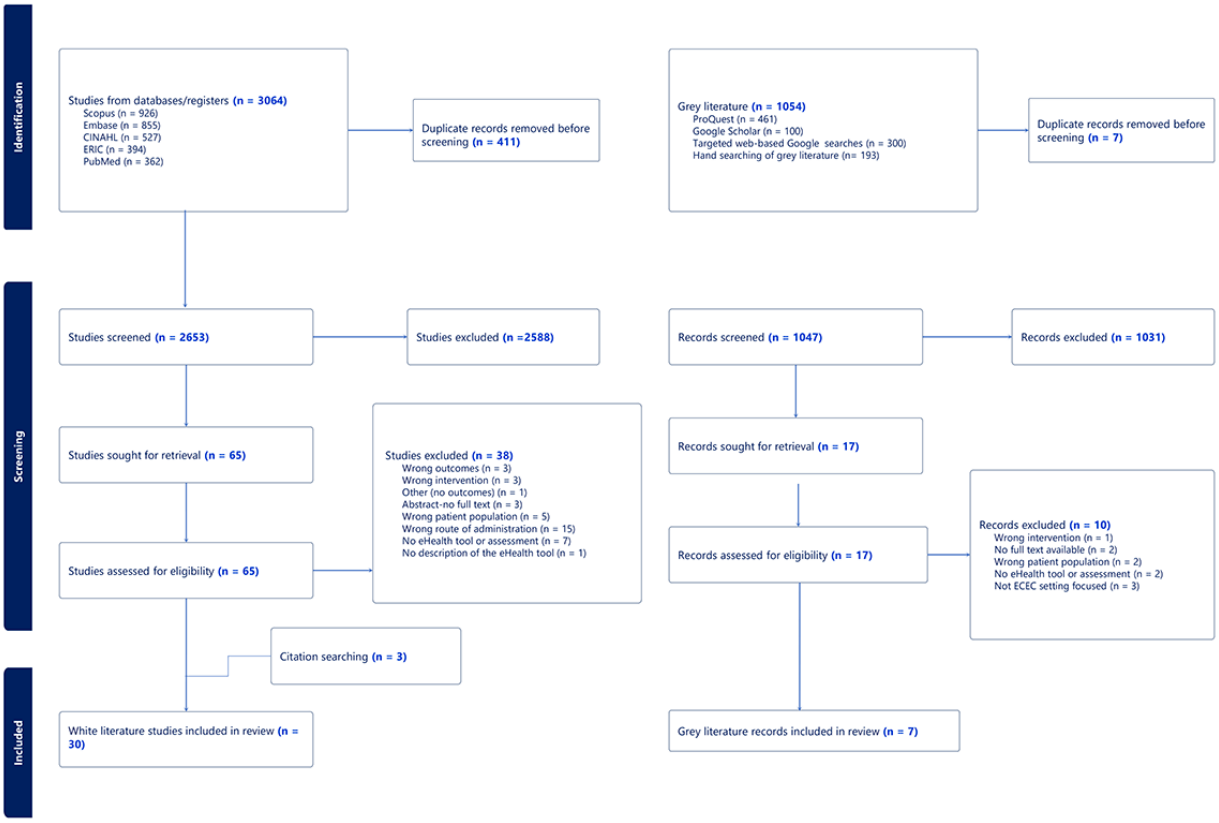
The extracted data were summarized using descriptive statistics (ie, frequency counts). The results were organized by each review question, highlighting study characteristics, eHealth tool characteristics, and the use of a theoretical framework. The findings are presented in a narrative summary, complemented by tables, charts, and illustrations.

Results

Literature Search and Selection Process

The white literature search yielded 3064 results, of which 411 were removed as duplicates. Titles and abstracts for 2653 records were screened for eligibility, and 2588 were excluded. Of the remaining records, 65 full-text articles were reviewed against the eligibility criteria. A total of 30 articles were included for data extraction (Figure 1). The gray literature search yielded 1054 results, of which 7 were removed as duplicates. Titles and abstracts of 1047 records were assessed against the eligibility criteria, and 17 were moved to full-text screening. Of these, 7 met the inclusion criteria and were included in the analysis. The PRISMA flowchart shows the selection process.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart.



Included Records

A total of 30 research studies identified in the white literature were included in this review (Figure 1). Of these, 16 were randomized controlled trials, 6 were protocol studies, 1 was a cross-sectional study, 1 was a nonrandomized experimental study, and 1 was a randomized crossover control trial (Figure 2). Specific characteristics of the included studies are presented in Table 1, which reflects the study design, setting, and outcome measures. The study aims along with additional study details are provided in Multimedia Appendix 4. The largest proportion of studies were conducted in the United States (n=11, 37%) and Australia (n=11, 37%), followed by Canada (n=6, 20%) and Norway (n=2, 7%; Figure 3). The studies were conducted between 2016 and 2022. The baseline sample size ranged from n=13 to 2932. Of the 10 studies reporting participant sex, females comprised the largest proportion of participants ranging from 85% to 100%, with an average of 96% (Table 1). The mean age of participants ranged from 37.1 to 49.6 years.

A total of 7 records were identified in the gray literature and included in this review (Figure 1). These records represented community-based eHealth outreach initiatives related to nutrition or physical activity support for the ECEC community. Four of these initiatives originated from Canada and 3 from the United States.

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Figure 2. Study designs of research articles identified in the white literature.

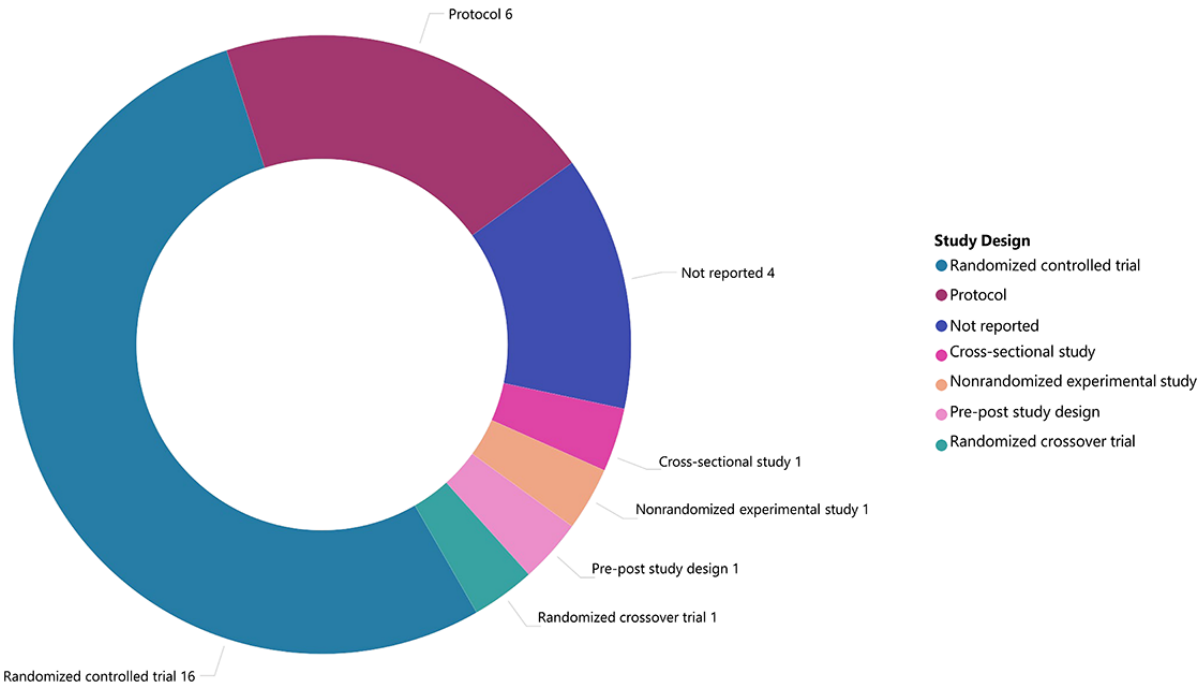

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Table 1. Characteristics of included studies from the white literature.

Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Barnes et al [42]: Australia	RCT[b]	Childcare centers	NR[c]	NR	NR	•Improving implementation of targeted healthy eating practices. •Child dietary intake of fruit and vegetable servings in care. •Child dietary intake of sodium, saturated fat, and added sugar in care. •Mean servings of fruits and vegetables packed within lunch boxes.
Barnes et al [27]: Australia	RCT	Childcare centers	Total: 22 (intervention: 11; control: 11)	NR	Intervention group: supervisors 37.68 (5.92) and center champions 44.17 (6.40); control group: supervisors: 43.91 (10.57)	• Implementation of targeted healthy eating practices. • Supporting families to provide healthier foods consistent with dietary guidelines. •Provision of intentional healthy eating learning experiences. •Using feeding practices that support children's healthy eating. •Staff participating in professional development targeting healthy eating. •Having a comprehensive written nutrition policy that outlines key healthy eating practices.
Blomkvist et al [43]: Norway	Protocol for RCT	Kindergarten	Total: 46 kindergartens (intervention: 31; control: 15)	NR	NR	• Primary outcomes: (1) child vegetable intake; (2) children's level of food neophobia; and (3) child dietary habits and food variety. • Secondary outcomes: (1) self-reported weight and height; (2) parental and kindergarten staff feeding practices.
Blomkvist et al [44]: Norway	RCT	Kindergarten	Total: 46 kindergartens (intervention: 31; control: 15)	NR	NR	•Child intake of intervention vegetables and all vegetables combined. •Level of child food neophobia.
Bruijns[d,e] et al [45]: Canada	Pre-post study design	Center-based childcare, kindergarten, and preschool	Total: 110 early childhood educators	99.2%	37.1 (9.5)	•Knowledge of PA, outdoor/risky play, and sedentary behavior concepts. •PA, outdoor/risky play, and sedentary behavior self-efficacy. •Behavioral intention and perceived behavioral control.

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Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Brussoni et al [46]: Canada	Protocol for RCT	ELCC[f]	Total: 324 ECEs[g] and ELCC administrators	NR	NR	•The primary outcome is increased tolerance of risk in children's play, as measured by the Teacher Tolerance of Risk in Play Scale. •The secondary outcome is self-reported attainment of a self-developed behavior change goal.
Brussoni et al [47]: Canada	RCT	ELCC	Total: 563 educators and administrators (intervention: 281; control: 282)	96.6%	NR	•Primary outcome: change in the total score on the T-TRiPS[h]. •Secondary outcome: participants' goal attainment at either follow-up time point (self-reported behavior change, measured by participants' self-reported progress in attaining the goal they set for themselves).
Chuang et al [48]: United States	RCT	ECE centers	Total: 111 ECE providers (intervention: 56; control: 55)	97.3%	43.55 (11.87)	• Psychosocial and behavioral measures: (1) nutrition knowledge, (2) mindful eating, (3) perceived barriers to eating fruits and vegetables, and (4) perceived barriers to promote healthy eating in classroom. • Environmental factors: (1) nutrition-related policy and practices at their ECE facilities and (2) number of healthy eating–related activities organized for the staff in the ECE center. • Individuals behavior: (1) dietary intake and (2) communication of nutrition information with ECE children and parents.
Clark et al [49]: United States	NR	Licensed childcare	Total: 38 childcare providers (intervention: 23; control: 15)	100%	NR	• Knowledge of and attitudes and behaviors toward feeding breast milk, formula, and solid food to the infants in their care.
Clarke et al [50]: United States	Protocol	ECE programs	Total: 2932 ECE providers	N/A[i]	N/A	• Uptake and perceived usefulness of on-demand online nutrition training.
Grady et al [51]: Australia	Nonrandomized experimental study	Long day care services	Total: 46 childcare services (intervention: 27; control: 19)	NR	Intervention group: 48.44 (10.36); control group: 43.74 (10.48)	• Uptake and use of the menu program: proportion of services adopting the program and proportion of services using the program as intended.

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Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Grady et al [52]: Australia	RCT	Long day care services	Total: 54 childcare services (intervention: 27; control: 27)	NR	Intervention group: 48.4 (10.4); control group 44.9 (10.5)	• Primary outcome: the mean number of food groups compliant with dietary guidelines •Secondary outcomes: (1) compliance with dietary guidelines for all food groups, (2) individual food group compliance with dietary guidelines, and (3) mean servings of individual food groups.
Green et al [53]: Australia	NR	Long day care, preschool, and occasional care	NR	NR	NR	• Nutrition practice achievements such as (1) lunch boxes monitored daily and (2) fruits and vegetables on menu. •PA practice achievements such as (1) tummy time for babies and (2) active playtime for at least 25% of opening hours.
Hazard et al [54][e]: United States	RCT	Licensed childcare centers	Total: 20 childcare providers	98%	NR	• Evaluation of accessibility, acceptability, and satisfaction of nutrition and online education courses.
Hoffman et al [55]: United States	RCT	Preschools	Total: 11 teachers and 2 site supervisors	NR	NR	• Implementation fidelity, acceptability, and feasibility of WE PLAY[j].
Hoffman et al [19]: United States	RCT	Preschools	Total: 25 teachers (intervention: 11; control: 14)	100%	Intervention group 40.7 (9.0); control group 45.9 (13.2)	• Children's MVPA[k] (MVPA accelerometer). •Teachers' changes in PA knowledge and attitudes toward PA promotion.
Kempler et al [56]: Australia	Cross-sectional study	Childcare services	Total: 64 participants	NR	NR	• Qualitative outcomes explored use and experience with the menu tool.
Kennedy et al [57]: United States	NR	Preschools	Total: 41 teachers	NR	NR	•The percentage of the 60-minute daily goal reached in each classroom. •The proportion of students actively participating in MVPA. •The percentage of time spent in MVPA. •Teachers' involvement with children during PA opportunities. •Child enjoyment (students having fun during the PA opportunities).
Lafave [58]: Canada	Randomized crossover trial design	ECEC[l] centers	Total: 72 educators	100%	NR	• Psychometric evaluation of nutrition and PA assessment—online inter- and intrarater reliability.

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Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Lafave et al [59]: Canada	Protocol for quasi-experimental study	ECEC centers	Total: 208 educators (intervention: 138; control: 50)	96.2%	40.05 (11.67)	•Food served in the center self-audit, eating environment/mealtime practices self-audit, nutrition education programming self-audit. •Mindful eating of educators. •Nutrition knowledge, attitude, and behaviors of educators. •Observation of nutrition environment in childcare. •Qualitative experiences of the nutrition environment. •PA environment self-audit. •Physical literacy knowledge, attitude, self-efficacy, and behaviors of educator and professional practices. •Objectively measured child PA levels. •Qualitative experiences of PA environment.
Lee et al [60][e]: United States	RCT	Licensed childcare centers	Total: 30 ECE or services (intervention: 19; control: 11)	NR	Intervention group 47.7 (10.8); control group 49.6 (12.	• Knowledge and awareness of and adherence to California's 2010 Healthy Beverages in Child Care Act.
Peden et al [61]: Australia	RCT	ECEC centers	Total: 104 educators	85%	NR	• Qualitative educator comments on the experience of the HOPPEL[m] program.
Peden et al [62]: Australia	RCT	ECEC centers	Total: 112 educators	85%	NR	•Changes in center-level healthy eating practices assessed using the EPAO[n] tool. •Changes in children's PA assessed using ActiGraph GT1M and GT3X + accelerometers.
Reilly et al [63]: Australia	RCT	ECEC services	Total: 1024 ECEC services (intervention: 684; control: 342)	NR	NR	•Intentions to adopt the guidelines. •Awareness and reach of the guidelines. •Knowledge of the guidelines. •Implementation of the guidelines. •Barriers to implementing the guidelines.
Saunders et al [64]: United States	NR	Preschools	Total: 818 teachers	NR	NR	• Classroom implementation completeness (ie, provision of 300 minutes of PA opportunities) and fidelity (ie, achieving PA fidelity and social environment fidelity).

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Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Ward et al [65]: United States	RCT	Full-time and part-time childcare center programs	Total: 33 ECE centers (intervention: 18; control: 15)	NR	NR	• Change in centers' nutrition environments: (1) foods provided, (2) beverages provided, (3) feeding environment, (4) feeding practices, (5) menus, (6) education and professional development, and (7) nutrition policy.
Ward et al [25][o]: Canada	RCT	Early childcare centers	Total: 191 (intervention: 102; control: 89)	NR	NR	•Healthy eating practices. •Perceived knowledge about fundamental movement skills. •PA practices.
Willis et al [66]: United States	Protocol for RCT	ECE centers	Total: 168 teachers	N/A	N/A	•Children's dietary intakes and Healthy Eating Index scores. •Teachers' dietary intakes and Healthy Eating Index scores. •Anthropometrics measurements (children and teachers). •ECE center nutrition environment. •PA (children and teachers using accelerometers). •ECE center PA environment.
Yoong et al [67]: Australia	Protocol for RCT	Childcare services	Total: 54 long-day-care services	N/A	N/A	•Mean number of food groups on childcare service menus that comply with dietary guidelines. •Proportion of services that comply with dietary guidelines for each of the 6 food groups. •Proportion of services that meet the recommended number of serves for all of the 6 Australian Guide to Healthy Eating food groups. •Child dietary intake. •Child BMI. •Child health-related quality of life.

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Reference: country	Study design	Study setting	Sample size (at baseline)	Sex of overall participants (% of females)	Participant age (years), mean (SD)	Nutrition or PA[a] outcome measures
Yoong et al [68]: Australia	RCT	Childcare centers	Total: 35 childcare centers	NR	NR	•Number of servings of the 5 core and discretionary food groups defined by the Australian Guide to Healthy Eating consumed in care. •Childcare educator–reported child diet quality. •Child BMI *z*-scores. •Child health-related quality of life. •Child diet outside of care.

[a]PA: physical activity.

[b]RCT: randomized control trial.

[c]NR: not reported.

[d]In Bruijns et al [45], participants included both preservice and in-service ECEs. Only data from in-service ECEs were reported, which aligns with our target population of educators in childcare centers.

[e]In Bruijns et al [45], Hazard et al [54], and Lee et al [60], participants included both center- and family-based childcare. For our purposes, we only included data from center-based childcare (eg, sample size). Gender and age are reported for all participants, as specific breakdowns were not provided.

[f]ELCC: early learning childcare center.

[g]ECE: early care and education.

[h]TRiPS: Teacher Tolerance of Risk in Play Scale.

[i]N/A: not applicable.

[j]WE PLAY: Wellness Enhancing Physical Activity for Young Children.

[k]MVPA: moderate-to-vigorous physical activity.

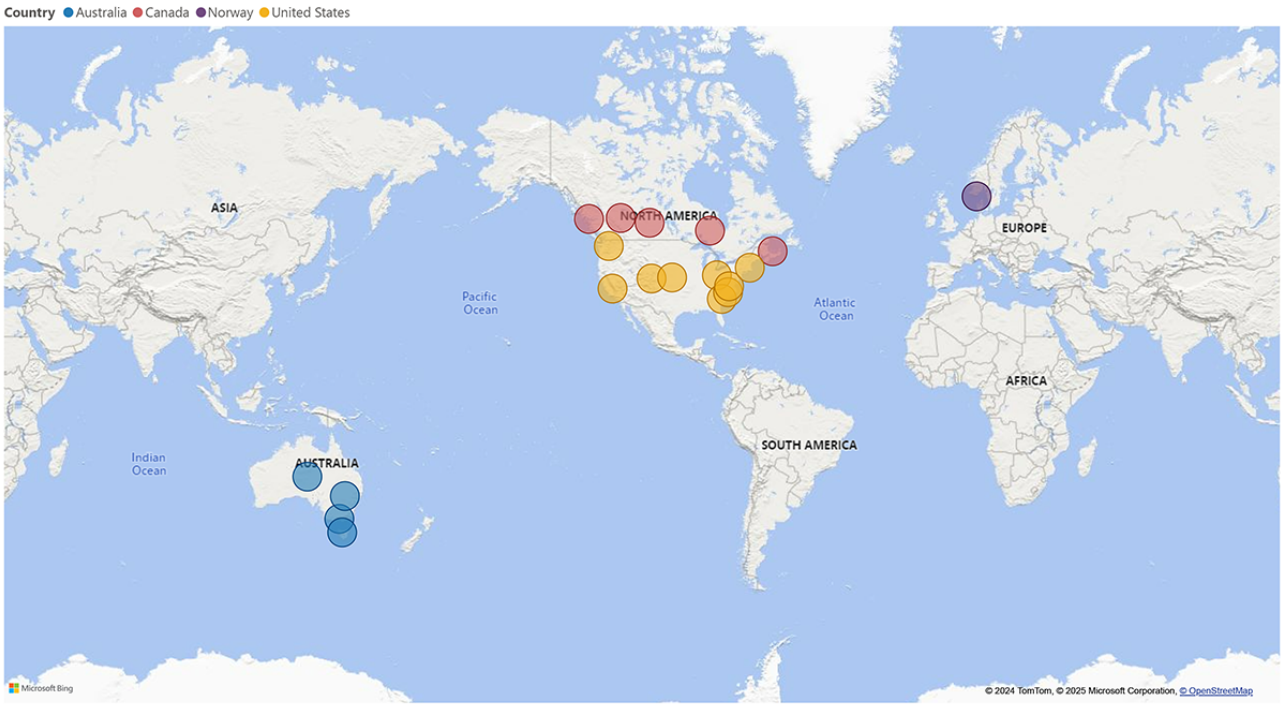
[l]ECEC: early childhood education and care.

[m]HOPPEL: Healthy Online Professional Program for Early Learners.

[n]EPAO: Environmental Policy Assessment and Observation.

[o]In Ward et al [25], the study included both in-person and online intervention groups. Our review focused only on extracting data from the online intervention group.

Figure 3. Country of study from eHealth research identified in the white literature and gray literature.



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eHealth Tool Characteristics

The 30 research articles included in the review identified 19 unique eHealth tools, with 12 categorized as intervention-based and 7 as both assessment and intervention tools. The characteristics of these eHealth tools identified in the white literature are summarized in Table 2, with additional details available in Multimedia Appendix 4. Among the 7 eHealth tools incorporating an assessment component, only 1 underwent evaluation of its psychometric properties. All eHealth tools were delivered via a web-based modality (7/7, 100%).

The characteristics of the eHealth tools identified in the gray literature are summarized in Table 3, with additional details provided in Multimedia Appendix 5. Of the 7 eHealth tools identified, all were intervention-only tools (7/7, 100%). Of these, 6 (86%) were delivered via a web-based modality, while 1 (14%) was delivered as a mobile phone app.

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Table 2. Characteristics of eHealth tools from included studies identified in the white literature.

eHealth tool	Country: References	Type of eHealth tool	eHealth modality[a]	Target of eHealth tool	eHealth tool component	eHealth tool description	Length of the intervention	Theoretical underpinning
Create Healthy Futures Program	United States: [48]	Intervention	Web based	Nutrition	Healthy eating practices	Self-paced web-based intervention on promoting healthy eating behaviors for ECE[b] providers	6 weeks	•Social Cognitive Theory •Social Ecological Model
CHEERS[c]	Canada: [58,59]	Assessment and intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices	Online educational modules and communities of practice to improve the nutrition and physical activity environment in ECECs[d]	10 months	•Social Cognitive Theory
EATS[e]	Australia: [27,42]	Assessment and intervention	Web based	Nutrition	Healthy eating practices	The web-based program supports center implementation of targeted healthy eating practices through self-assessment, feedback, and the development of an action plan	6 months	•Social Ecological Framework •Behavioral Change Wheel
FoodChecker	Australia: Kempler et al [56]	Assessment and intervention	Web based	Nutrition	Online menu planning	Web-based menu planning tool to support childcare services in planning healthy menus	NR[f]	NR
feedAustralia	Australia: [51,52,67,68]	Assessment and intervention	Web based	Nutrition	Online menu planning	Web-based menu planning program offering automated real-time assessment of childcare menu with feedback to support the planning of healthier menus	12 months	•Technology Acceptance Model •Theoretical Domains Framework
GO NAP-SACC[g]	United States: [50,65]	Assessment and intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices	Suite of online tools to guide ECE programs through a 5-step process to improve their nutrition and physical activity-related practices, including (1) self-assessment, (2) goal setting and action planning, (3) implementation, (4) education and training, and (5) reassessment	4 months	•Social Cognitive Theory •DESIGN[h] Procedure Framework •Theories of adult learning in public health practice •Behavior change techniques

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eHealth tool	Country: References	Type of eHealth tool	eHealth modality[a]	Target of eHealth tool	eHealth tool component	eHealth tool description	Length of the intervention	Theoretical underpinning
GO NAPSACC Cares	United States: [66]	Assessment and intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices (center level) + educator's personal diet and physical activity	The traditional GO NAPSACC program and embedded Staff Wellness website that focus on ECE personal healthy behavior change strategies including healthy eating, increased physical activity, and weight management	6 months	•Social Cognitive Theory •The Social Ecological Model
HOPPEL[i]	Australia: [61,62]	Intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices	Synchronous and asynchronous online professional development to promote physical activity and healthy eating	12 weeks	•Community of Practice •The Guskey model of teacher change
Healthy Start-Départ Santé	Canada: [25]	Intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices	Online modules to improve healthy eating and physical activity practices	4 hours	NR
InfaNET	United States: [49]	Intervention	Web based	Nutrition	Infant feeding practices	Bilingual (English and Spanish) website with childcare-specific infant feeding information	3 months	•Social Learning Theory
Munch & Move	Australia: [53]	Intervention	Web based	Nutrition and physical activity	Nutrition and physical activity practices	Professional development training for early childhood educators to support healthy eating and physical activity habits in young children	NR	•The Monitoring Framework
OutsidePlay-ECE risk-reframing intervention	Canada: [46,47]	Intervention	Web based	Physical activity	Outdoor/risky play	Fully automated web-based intervention to reframe ECEs' perception of the importance of outdoor play and its inherent risks and promote a change in their practice in supporting children's outdoor play in ELCC[j] settings	Up to 100 minutes	•Intervention mapping process •Social Cognitive Theory
Online training on healthy beverage best practices	United States: [54]	Intervention	Web based	Nutrition	Healthy beverage practices	Self-paced online modules (English and Spanish) on healthy beverage best practices for childcare providers	English (29-minutes); Spanish (37-minutes)	NR

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eHealth tool	Country: References	Type of eHealth tool	eHealth modality[a]	Target of eHealth tool	eHealth tool component	eHealth tool description	Length of the intervention	Theoretical underpinning
Online training on healthy beverage policy	United States: [60]	Intervention	Web based	Nutrition	Healthy beverage practices	Bilingual (English or Spanish) self-paced on-demand online training to increase knowledge and adherence of childcare providers to healthy beverage practices	30-minutes for the online training (+ with or without 6 months of online technical assistance)	•Implementation Science Framework •Humanistic Learning Theories
Online training to disseminate outdoor free-play information in relation to COVID-19 guidelines	Australia: [63]	Intervention	Web based	Physical activity	Outdoor/risky play	e-newsletter or animated video to increase ECEC service intentions to adopt an indoor-outdoor program for the full day and offer more time outdoors	e-newsletter (3 minutes); video (3.5 minutes)	•Model for Dissemination of Research •Interactive System Framework
SHAPES-D[k]	United States: [57,64]	Assessment and intervention	Web based	Physical activity	Physical activity practices	Self-assessment and online training modules to improve instructional physical activity practices and classroom social environment	12 weeks	NR
Tool to increase children's vegetable intake and reduce food neophobia	Norway: [43,44]	Intervention	Web based	Nutrition	Online menu planning and feeding practices	Access to online menu recipes to include vegetables each week, with or without pedagogical tools (sensory lessons, meal practice, and feeding practices recommendations)	3 months	NR
TEACH[l] e -learning course	Canada: [45]	Intervention	Web based	Physical activity	Physical activity and sedentary behavior	e-Learning course in physical activity and sedentary behavior comprising 4 modules	2 weeks	•Social Cognitive Theory •The Theory of Planned Behavior
WE PLAY[m]	United States: [19,55]	Intervention	Web based	Physical activity	Physical activity practices	Online asynchronous modules to promote physical activity	4 weeks	Social Cognitive Theory The Theory of Planned Behavior Quality Implementation Framework

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eHealth tool	Country: References	Type of eHealth tool	eHealth modality[a]	Target of eHealth tool	eHealth tool component	eHealth tool description	Length of the intervention	Theoretical underpinning
Online training on healthy beverage policy	United States: [60]	Intervention	Web based	Nutrition	Healthy beverage practices	Bilingual (English or Spanish) self-paced on-demand online training to increase knowledge and adherence of childcare providers to healthy beverage practices	30 minutes for the online training (+ with or without 6 months of online technical assistance)	Implementation Science Framework Humanistic Learning Theories

[a]eHealth modality (eg, web, app, or SMS text messages).

[b]ECE: Early Care and Education.

[c]CHEERS: Creating Healthy Eating and Active Environments Survey.

[d]ECEC: early childhood education and care.

[e]EATS: Child Care Electronic Assessment Tool and Support.

[f]NR: not reported.

[g]NAPSACC: Nutrition and Physical Activity Self-Assessment for Child Care.

[h]DESIGN: decide target behavior, explore determinants, select theory-based model, indicate objectives, generate education plans, and nail down the evaluation.

[i]HOPPEL: Healthy Online Professional Program for Early Learner.

[j]ELCC: early learning childcare center.

[k]SHAPES-Dissemination: Study of Health and Activity in Preschool Environments.

[l]TEACH: Training Pre - Service Early Childhood Educators in Physical Activity.

[m]WE PLAY: Wellness Enhancing Physical Activity in Young Children.

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Table 3. Characteristics of eHealth tools from included studies identified in the gray literature.

eHealth tool	Author/organization	Country: year	Participant information	Type of eHealth tool	eHealth modality[a]	Target of eHealth tool	eHealth tool description	Length of intervention
A Balanced Day: Tips and Guideline for Child Care Providers	Hastings Prince Edward Public Health	Canada: NR[b]	Childcare providers	Intervention	Web based	Physical activity	Online interactive modules (videos) on physical activity, sedentary behavior, sleep, and health messages for caregivers.	15 minutes
Boston Healthy Childcare Initiative	The Boston Public Health Commission	United States: NR	Early childhood educators	Intervention	Web based	Nutrition and physical Activity	Online training on evidence-based nutrition and physical activity best practices in early learning environments.	NR
Child Care Healthy Eating and Active Living Guidelines Training	Ottawa Public Health	Canada: 2015	Supervisors, childcare providers, and municipal cooks	Intervention	Web based	Nutrition and physical activity	Online training modules on healthy eating practices, environments, and physical literacy.	Part 1: Nutrition: 60 minutes; part 2: Active living: 30 minutes
Fostering Healthy Eating Habits	BC Provincial Health Services Authority—Interior Health	Canada: 2016	Childcare providers	Intervention	Web based	Nutrition	e-Learning course on healthy practices and environment.	1 hour
MyPlate on Alexa	United States Department of Agriculture	United States: 2020-2025	Everyone from parents and caregivers of babies starting at 4 months old through older adults (includes early learning professionals)	Intervention	App	Nutrition	An app that provides food and nutrition tips based on the Dietary Guidelines for Americans.	N/A[c]
Nourished and Active in Early Learning	University of Washington's Center for Public Health Nutrition and Washington State Department of Health	United States: NR	Early learning professionals	Intervention	Web based	Nutrition	Online course on healthy eating and beverages comprising 6 modules, strategies to support healthy eating, and common challenges.	NR
Nourishing Beginnings	Dairy Farmers of Canada	Canada: NR	ELCC[d] educators and directors as well as ELCC professors or program directors at colleges or universities.	Intervention	Web based	Nutrition	Online modules on healthy feeding practices	Module 1: 80 minutes; module 2: 70 minutes

[a]eHealth modality (eg, web, app, or SMS text messages).

[b]NR: not reported.

[c]N/A: not applicable.

[d]ELCC: early learning in childcare.

Practices Targeted

The majority of eHealth tools identified in the white literature (8/19, 42%) targeted nutrition practices, 6 of 19 (32%) targeted both nutrition and physical activity, and 5 of 19 (26%) exclusively addressed physical activity (Figure 4). The duration of intervention implementation ranged from 3 minutes to 12 months. The majority of eHealth tools identified in the gray

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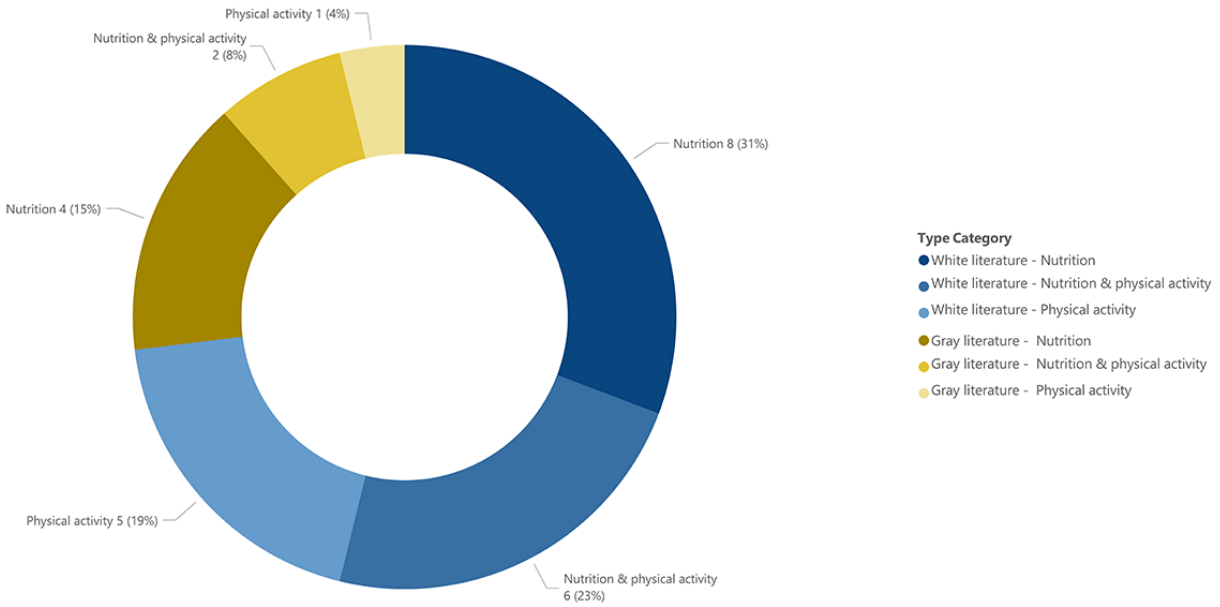
literature targeted nutrition (4/7, 57%), followed by tools targeting both nutrition and physical activity (2/7, 29%), and 1 focused solely on physical activity (Figure 4). For both the white (Table 2) and gray literature (Table 3), eHealth intervention tools targeting nutrition primarily addressed best nutrition and feeding practices, healthy eating or beverage practices, and menu planning. eHealth tools targeting physical activity mainly focused on best physical activity practices, outdoor play, and the reduction of sedentary behaviors.

Figure 4. Target of eHealth tool for white and grey literature.



Theoretical Framework of the eHealth Tools

Of the 30 research studies identified in the white literature, 21 reported the use of theoretical models (Multimedia Appendix 4). The most commonly cited theories include Social Cognitive Theory, Social Ecological Model, Theoretical Domain Framework, Theory of Planned Behavior, Behavior Change Wheel, and Quality Implementation Framework (Figure 5). None of the eHealth tools identified in the gray literature reported a theoretical underpinning (see Multimedia Appendix 5).

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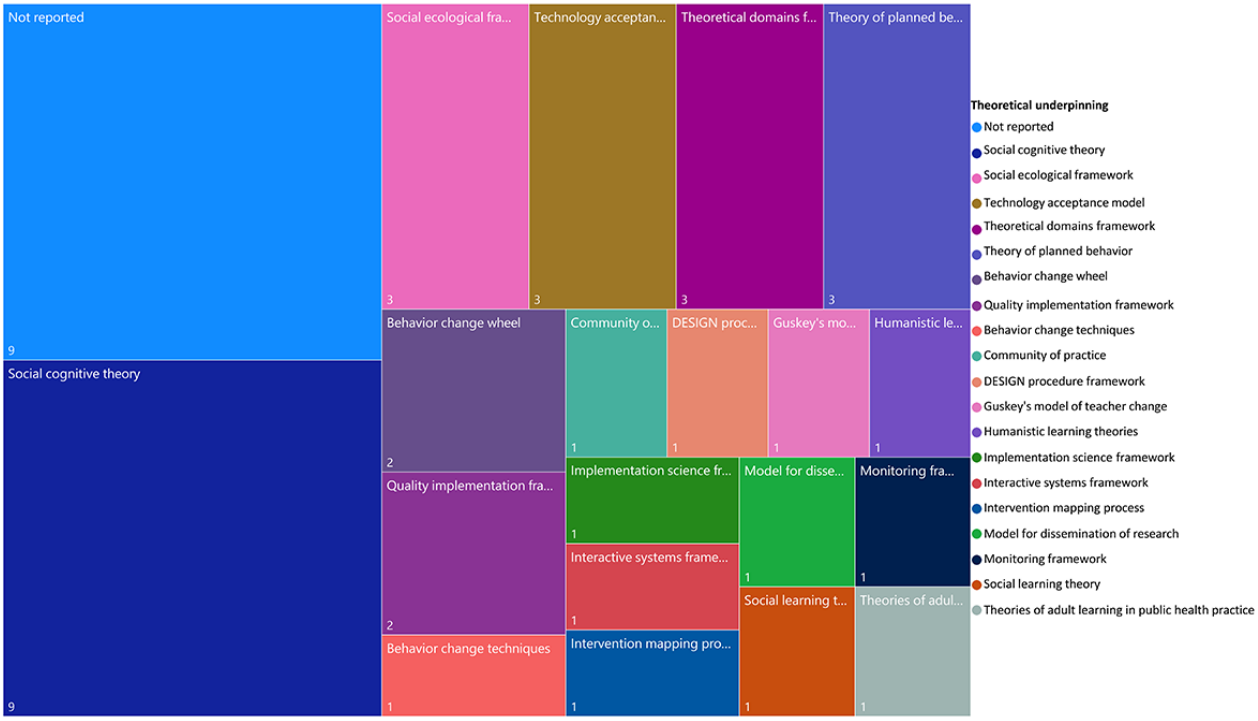
Figure 5. Theoretical underpinning from studies identified in the white literature search. DESIGN: decide target behavior, explore determinants, select theory-based model, indicate objectives, generate education plans, and nail down the evaluation.



Discussion

Principal Findings

The purpose of this scoping review was to explore the available eHealth tools developed to assess or deliver interventions aimed at improving the nutrition or physical activity environments in ECEC settings. The results of this review provide insights into the digital tools available, outlining their methodological approach and characteristics.

Mapping the included white and gray literature identified 26 eHealth tools, highlighting a growing interest in leveraging digital tools to enhance nutrition and physical environments in early learning settings. Notably, all tools were web based except for 1 delivered via a smart device application. This finding is striking, given the widespread adoption of mobile health apps in health promotion interventions [69,70]. A likely explanation is that the nature and timing of the intervention may influence the choice of eHealth modality. Mobile apps are typically utilized in interventions requiring rapidly changing data and real-time feedback, such as step tracking or patient self-care and symptom management [71,72]. By contrast, interventions targeting nutrition and physical activity practices in educational settings often focus on gradual changes implemented over extended periods. Additionally, mobile apps are generally more expensive to develop and maintain than web-based tools and require regular updates [73]. Furthermore, most educational settings rely on web-based systems and have access to computers and the internet, making web-based platforms a more convenient option for educators while facilitating the implementation of interventions. Lastly, mobile-based interventions are often more prevalent among youth populations (children and adolescents) due to their capacity to incorporate gamification—a popular and engaging approach for health promotion interventions within this demographic [74].

The identified eHealth tools employed diverse approaches and strategies to enhance nutrition and physical activity practices. Most tools focused on professional development, offering online modules and self-paced training with both synchronous and asynchronous components to improve educators' knowledge and behaviors related to best practices in nutrition and physical activity. Most of these tools (21/26, 81%) included educational videos to create engaging and interactive content, while just over half (15/26, 58%) incorporated quizzes or evaluation questions to reinforce learning and assess understanding. Additionally, a smaller proportion (10/26, 38%) provided technical support from experts or facilitators to offer guidance and enhance educator engagement. Research suggests that such human support can improve compliance and foster the adoption of new behaviors [75,76]. However, relying on human support may not be a sustainable approach due to the significant resources required and the challenges it poses for scalability [77]. A smaller proportion of tools (3/26, 12%) emphasized menu planning and provided tailored support to aid in the creation of healthier menus. Tools targeting physical activity primarily addressed best practices, highlighted the importance of outdoor and risky play, and aimed to reduce sedentary behaviors. Nutrition-focused tools concentrated on promoting best practices for nutrition and feeding while optimizing eating environments.

Less than one-third (8/26, 31%) of the identified eHealth tools addressed both nutrition and physical activity together. Evidence suggests that multibehavior interventions, which target multiple health behaviors simultaneously, are often more effective in driving meaningful change compared with interventions focused

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on a single behavior [78]. Given the interconnected nature of nutrition and physical activity, these behaviors play a crucial role in health and well-being [79,80] and are recognized as leading modifiable factors in the prevention of major chronic diseases [1,2]. Knowing that nutrition and physical activity tend to cluster together, addressing these behaviors collectively might enhance the effectiveness of interventions [11,81-84]. It has also been found that targeting both nutrition and physical activity behaviors can lead to synergistic effects on health outcomes [85-87]. Therefore, tools aimed at improving educators' nutrition and physical activity practices or the nutrition and physical activity environments in early learning centers should target determinants of both behaviors simultaneously.

Another key finding is that, among the 7 eHealth tools incorporating an assessment component, only 1 reported psychometric properties testing. Psychometric evaluations, such as reliability and validity testing, are crucial as they indicate the quality of the tools, ensure their effectiveness for the intended purpose, and support their reproducibility and replicability [88]. The lack of reported psychometric testing may be due to some tools originally being developed in a pen-and-paper format before being adapted to an online format. In the original articles describing the pen-and-paper versions, psychometric testing was reported [89]. However, it is important to recognize that tool validity and reliability are not static characteristics; rather, they are assessments of the tool's instrument scores within the context in which they have been evaluated [90]. It is therefore recommended to conduct and report updated psychometric testing when tools are adapted into digital formats to ensure that the validity and reliability of the results are maintained [91,92].

Among the 30 studies identified in the white literature, the majority (21/30, 70%) incorporated a theoretical framework in their design. The most frequently cited theory was the Social Cognitive Theory, which is commonly used in behavior change interventions, aligning with findings from other reviews [93-95]. A theoretical underpinning is a critical consideration when developing health promotion interventions. It serves as a blueprint for the study, structuring and guiding the intervention planning process, and also helps in understanding the factors that might influence behavior change and need to be targeted [96,97]. Previous reviews have indicated that health interventions grounded in theory are more effective [28] and are associated with positive significant outcomes, larger effect sizes [23,94,98], and the maintenance of behavior change [99]. Hence, future research designing eHealth tools should prioritize the use of theoretical underpinnings to increase effectiveness and ensure replicability. Regarding the gray literature findings, no reports on the theoretical underpinnings or reliability were identified for any of these tools. A possible reason for this could be that the gray literature often targets a general population audience, where the focus is on practical application, whereas in peer-reviewed literature, researchers look for evidence of theoretical grounding to evaluate and further refine or replicate these tools.

Implications/Recommendations

Future research involving the development and implementation of eHealth tools in ECEC settings should emphasize the integration of theoretical frameworks, consider comprehensive multibehavior intervention approaches, incorporate community perspectives in the development process, and prioritize long-term sustainability and scalability, with a focus on implementation and efficacy assessment. Theoretical frameworks provide essential guidance in identifying key determinants of behavior and mechanisms for promoting change. Incorporating theory can enhance the effectiveness of eHealth tools, ensure consistent implementation, and facilitate replicability across different contexts. Multipronged eHealth tools designed to target both nutrition and physical activity can lead to more beneficial outcomes, as these domains are interconnected. To enhance implementation and adoption, it is essential to involve a diverse range of stakeholders, such as educators, parents, and health professionals, in the development process. This ensures that the unique needs and cultural context of the targeted eHealth tool users are addressed. Additionally, researchers should prioritize long-term sustainability and scalability when designing these tools, ensuring that interventions can be maintained and expanded across various settings over time. Finally, the resulting eHealth tools should undergo rigorous testing, including pilot trials, to assess their usability, feasibility, and effectiveness in achieving the intended outcomes. This integrated approach provides a holistic strategy for fostering healthier environments in ECEC settings.

Strengths and Limitations

This review is the first to map and summarize the scope of available evidence on eHealth tools designed to assess or improve nutrition and physical activity environments in early learning settings. The findings from this review can guide future research on the use of eHealth technologies to promote healthy practices in childcare, ultimately contributing to improved children's health behaviors and outcomes. Two librarians with expertise in scoping and systematic reviews assisted in developing and refining the search strategy. The methodology employed facilitated a systematic search of both white and gray literature, ensuring a comprehensive review of available evidence. However, there are some limitations to this scoping review that should be considered. We only considered studies published in English or French, which may have led to the exclusion of relevant research in other languages. Additionally, this scoping review focused solely on full-time day care centers, excluding family-based day care and after-school programs. The primary reason for excluding family-based day cares was the lack of formalized data, and after-school programs were not included as they typically do not cater to children aged 0-5 years. Another limitation encountered during the search for gray literature was the presence of paywalls and restricted access to certain tools, which hindered our ability to fully explore available resources.

Conclusions

This scoping review explored the breadth of evidence on eHealth tools aimed at improving nutrition and physical activity environments in ECEC settings. Future research should conduct

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a systematic review to assess the effectiveness of these tools and identify the specific elements that contribute to a greater impact and sustained behavior change.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews checklist.
[PDF File (Adobe PDF File), 258 KB - pediatrics_v8i1e68372_app1.pdf]

Multimedia Appendix 2
Search strategy for the databases (PubMed, Scopus, CINHAL Plus [EBSCOhost], ERIC [EBSCOhost], Embase [OVID]).
[PDF File (Adobe PDF File), 94 KB - pediatrics_v8i1e68372_app2.pdf]

Multimedia Appendix 3
Data extraction forms for white and gray literature.
[PDF File (Adobe PDF File), 73 KB - pediatrics_v8i1e68372_app3.pdf]

Multimedia Appendix 4
Extraction sheet results for white literature.
[XLSX File (Microsoft Excel File), 66 KB - pediatrics_v8i1e68372_app4.xlsx]

Multimedia Appendix 5
Extraction sheet results for gray literature.
[XLSX File (Microsoft Excel File), 32 KB - pediatrics_v8i1e68372_app5.xlsx]

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Abbreviations

ECEC: early childhood education and care
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews

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Review

Exploring Health Educational Interventions for Children With Congenital Heart Disease: Scoping Review

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Abstract

Background: Congenital heart disease (CHD) is the most common birth defect, affecting 40,000 births annually in the United States. Despite advances in medical care, CHD is often a chronic condition requiring continuous management and education. Effective care management depends on children's understanding of their condition. This highlights the need for targeted health educational interventions to enhance health literacy among children with CHD.

Objective: This scoping review aims to map and explore existing health educational interventions for children with CHD. The review identifies the types of interventions, target populations, delivery methods, and assessed outcomes. The goal is to consolidate fragmented research, identify gaps, and establish future research agendas.

Methods: Comprehensive searches were conducted in February 2024 using the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) framework across multiple databases: APA PsycINFO, MedlinePlus via Ovid, Web of Science, ACM Digital Library, Scopus, and EBSCOhost (CINAHL Complete, CINAHL Ultimate, Health Source: Nursing/Academic Edition, and ERIC). The search covered health care, design, and human-computer interaction disciplines to capture the interdisciplinary nature of CHD health educational interventions. There was no predefined time limit due to the limited number of relevant studies. Eligible studies were in English, published in peer-reviewed journals, and focused on primary data about educational health interventions for children with CHD. We extracted and synthesized data using thematic analysis.

Results: The review identified 11 studies: 9 randomized controlled trials and 2 observational studies. These used 6 educational strategies: 3D patient-specific models (n=3), habit formation interventions (n=2), empowerment-based health education programs (n=2), rehabilitation interventions (n=2), web-based portals (n=1), and videotape presentations (n=1). Interventions ranged from brief outpatient sessions to 1.5-year programs, with follow-up from none to 24 months. Studies aimed to improve coping, self-management, and knowledge for children with CHD and their families. The most frequently used assessment method was the independent samples *t* test (n=4) for pre- and postassessments, and all 11 studies used questionnaires, 8 of which incorporated qualitative feedback. The target participants for these interventions were children aged 13 years and older (n=3), parents (n=2), and children of various ages and their parents (n=6). Outcomes included improved children's health literacy, reduced parental burden, and increased health care provider efficiency.

Conclusions: This review underscores the critical need for tailored educational interventions for children with CHD. Current research mainly focuses on adolescents and relies heavily on parental involvement, possibly overlooking the specific needs of younger children younger than 13 years of age. It is essential to develop engaging, age-appropriate interventions that actively involve children with CHD in their health care journey. Effective health educational interventions are crucial in empowering these young patients and improving their long-term health outcomes.

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KEYWORDS

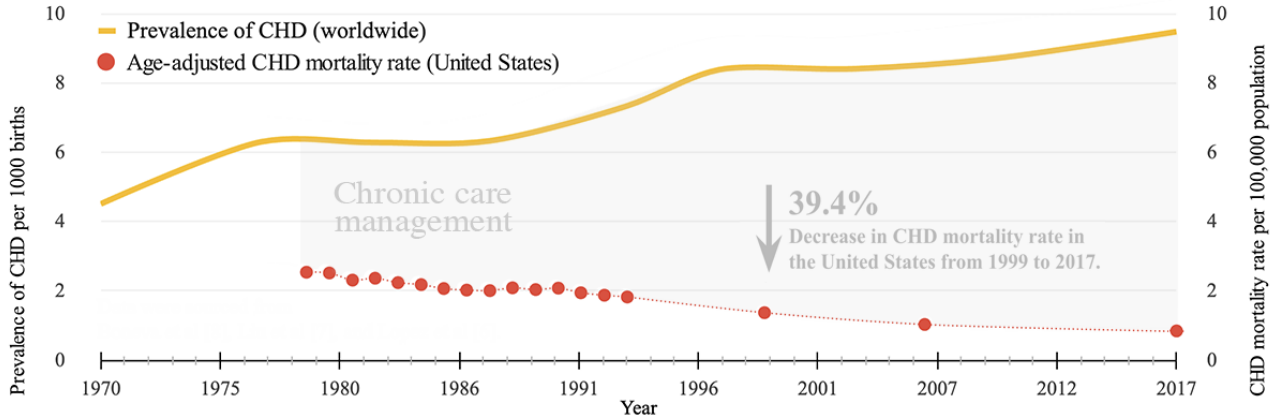
congenital heart disease; children health literacy; health education; health education interventions; patient-centered care; design; pediatric; PRISMA

Introduction

Background

Congenital heart disease (CHD) is a structural abnormality in the heart present at birth. It is the most common birth defect, affecting 1.35 million newborns worldwide and around 40,000 births annually in the United States. CHD often leads to other health complications and poses lifelong challenges to affected children, families, and health care systems [1-3]. Improved medical and surgical care have substantially increased survival rates, with up to 90% of children with CHD now surviving through to adulthood [4,5]. Despite improved medical care, CHD is more like a chronic condition that requires early diagnosis, timely treatment, and ongoing management. Figure 1 shows the worldwide prevalence of CHD from 1970 to 2017 and how survival rates in the United States since 1999 impact the need for continuing care [2,5-8]. Effective long-term care requires a comprehensive understanding of the condition by both pediatric patients and caregivers. Traditionally, health care providers have relied on parents to educate their children about their condition, assuming effective transmission of information. This approach often falls short, with parents struggling to comprehend and recall the information provided. Insufficient knowledge leads to extensive education during appointments, causing confusion and anxiety for children with CHD and their families [9-12]. Without proper education, the ability to proactively manage the condition diminishes, potentially leading to worse health outcomes, greater difficulty transitioning to adult care, and increased hospitalizations [4,13]. Accessible health information and organized educational support systems are crucial for improving health education, self-management skills, and health literacy (HL) among pediatric patients and caregivers [2,14].

Figure 1. Worldwide CHD prevalence and the effect of US survival rates on care management. Data were sourced from Boneva et al [8], Liu et al [7], Lopez et al [6]. CHD: congenital heart disease.



Prior Work

HL is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" [9]. However, there are uncertainties about the best educational and support approaches for improving HL in pediatric patients with CHD. Learning about this complex subject at a young age presents significant challenges. Limited learning opportunities hinder adequate information delivery and understanding [10]. Moreover, current educational materials (eg, pamphlets and postvisit summaries) are often inappropriate for young children and are primarily intended for their caregivers or parents [10,12]. To tackle these challenges, health educational interventions are designed to enhance individuals' knowledge, attitudes, skills, and behaviors to manage their condition [15]. These interventions are crucial for empowering children with CHD to understand their condition, adhere to treatment plans, and navigate the health care system effectively.

Recent focus has highlighted the importance of involving children with CHD and their caregivers in developing and executing their care plans through health educational interventions [10,12]. Despite this, the literature on educational interventions for children with CHD remains limited. To our knowledge, no systematic or scoping reviews have been conducted on this topic. Only a few scoping and systematic studies have attempted to understand the experiences of children with CHD, their families, and health care providers in managing CHD [2,16-18]. Furthermore, some studies focus on the coping mechanisms of parents and families of children with CHD rather than on the children themselves [19-21]. Therefore, a scoping review is necessary to consolidate fragmented research, identify existing gaps, and establish a future research agenda [22].

Purpose and Objectives

This scoping review systematically maps and explores existing educational interventions for children with CHD to identify intervention types, target populations, delivery methods, and assessed outcomes. Textbox 1 presents the PICOTS (population, intervention, comparator, outcome, timing, and setting) framework for educational interventions for children with CHD. PICOTS helps clarify and organize research questions. The key questions (KQs) addressed are:

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KQ1: What types of educational interventions are available for children with CHD?

KQ2: What are the study designs, target populations, and the roles of various stakeholders in these educational interventions?

KQ3: What outcomes are assessed, and what approaches are used for assessment?

KQ4: What gaps exist in the current literature regarding educational interventions for children with CHD, and what areas require further exploration?

Figure 2 presents the analytical framework for the scoping review. It outlines a structured approach to address KQs concerning CHD and educational interventions for pediatric patients. The review covers intermediate outcomes, including intervention details, study design, stakeholder involvement, and assessed outcomes. The primary outcomes are improved children's HL, reduced parental burden, and enhanced efficiency of health care providers. Suboutcomes related to children's HL enhancement include understanding CHD, self-management or habits, coping or quality of life, empowerment, health care use, and health outcomes. The review also focuses on providing educational, emotional, caregiving, and financial support to reduce parental burden. Additionally, it considers suboutcomes related to saving time or effort, treatment adherence, care coordination, shared decision-making, and patient or family satisfaction to enhance the efficiency of health care providers.

Textbox 1. PICOTS (population, intervention, comparator, outcome, timing, and setting) framework for key questions on health educational interventions for children with congenital heart disease (CHD).

Population

- Children diagnosed with CHD <18 years.

Intervention

- Educational interventions targeting health literacy improvement among children with CHD.

Comparators

- Any comparator (as this is a scoping review).

Outcomes

- Engagement (use and satisfaction).
- Improved health literacy in children with CHD (understanding of CHD, self-management or habits, coping or quality of life, empowerment, health care use, and health outcome).
- Reduced parental burden through effective educational support (educational support, emotional support, and financial support).
- Enhanced health care efficiency by minimizing education needs during medical appointments (saving time or effort, treatment adherence, care coordination, shared decision-making, and patient or family satisfaction).

Timing

- No restrictions.

Setting

- All types of studies (as this is a scoping review), including various health care (eg, hospitals and clinics), nonhealth care (eg, school and support community), and home settings.

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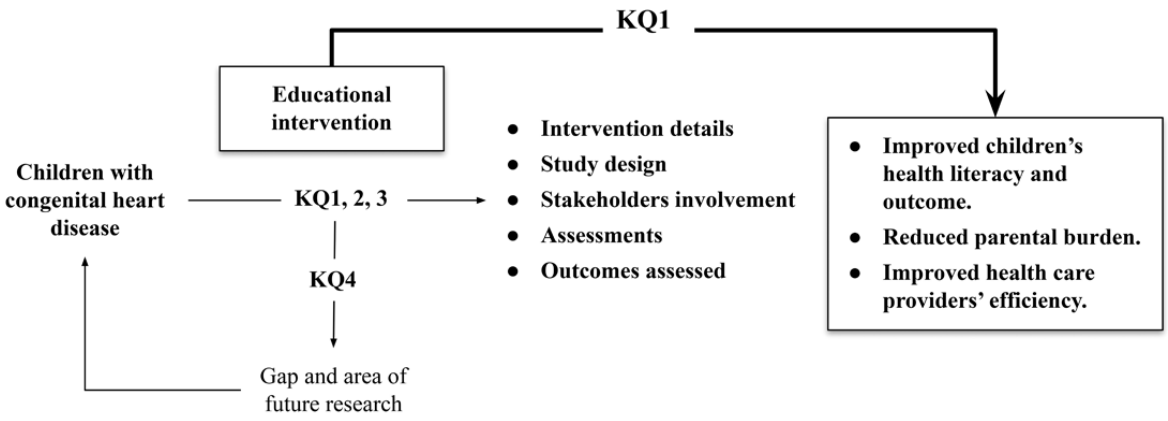
Figure 2. Logic model for the PICOTS (population, intervention, comparator, outcome, timing, and setting) framework and 4 key questions (KQs).



Methods

Literature Search Strategy

This study used a scoping approach guided by the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) framework [23]. Scoping reviews provide an overview of emerging evidence without aiming to appraise and synthesize results for a specific question. They are useful when it is still unclear what specific research questions a systematic review can address. Additionally, scoping reviews help inform and identify current research practices and methodologies in emerging research fields [22-25]. This research process was structured using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) framework, including four stages: (1) identification of relevant literature searches on various databases using specific keywords, (2) screening the title and abstract of the identified studies, (3) eligibility—full-text review of screened results to eliminate studies outside our intended scope, and (4) inclusion, helped extract relevant data that met the defined criteria [26]. The PRISMA-ScR checklist is available in Multimedia Appendix 1.

Eligibility Criteria

To be included in the review, studies must be written in English and published in a peer-reviewed journal to ensure accessibility and credibility. We only considered studies with a methods section, focusing on primary data and analyses rather than studies like systematic reviews. Our focus was on CHD in pediatric patients younger than 18 years of age, and the studies addressed educational interventions for this demographic, not just HL. We excluded studies that solely targeted parents or caregivers, focused only on health care providers, or related to transition care from pediatric to adult health care, as these areas fall outside our specific review scope. However, we included studies involving parents only when their participation aimed to improve the child's health outcomes, focusing on enhancing the children's educational experience rather than the parents. This selection process ensured that the included studies were directly relevant to pediatric CHD and educational health interventions.

Information Sources and Search

We conducted comprehensive searches across the following bibliographic databases during February 2024 to identify potentially relevant studies without a predefined time limit. Given the initial research indicating a scarcity of relevant studies, we maintained an open search time frame. We gathered relevant studies from APA PsycINFO and MedlinePlus via Ovid, Web of Science, ACM Digital Library, Scopus, and EBSCOhost, including CINAHL Complete, CINAHL Ultimate, Health Source: Nursing/Academic Edition, and ERIC. These databases cover health care, psychology, education, design, and human-computer interaction disciplines. They were selected to reflect the interdisciplinary nature of CHD health educational interventions.

Three main concepts were identified based on the research questions: HL, pediatric, and CHD. Synonyms and related concepts were incorporated to ensure a comprehensive search for related terminologies used in the literature. For example, synonyms of "pediatric" included "child," "children," "toddler," and "preschool," while related concepts like "boy" and "girl" were also included. Given the cross-disciplinary database search, listing each concept's relevant ideas and terms was important. MeSH terms and keywords were tailored to each database's specifications, as detailed in Multimedia Appendix 2. Boolean search strings were formulated using the OR operator for synonyms of the main concepts (ie, "children" OR "child" OR "pediatric") and the AND operator to combine the 3 main concepts (ie, "health literacy" AND "congenital heart disease" AND "pediatric"). The terms were refined through multiple iterations by adding new terms and synonyms or adjusting specificity to enhance the quality of results. For instance, recognizing that the term "health literacy" may be omitted in studies involving health education interventions, alternative terms such as "healthcare knowledge," "health awareness," and "health education" were included. Additionally, we intentionally avoided using "intervention" as a synonym for "health literacy" to ensure that studies focusing on clinical and surgical interventions in CHD were not included (Table 1).

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Table 1. Boolean search strings in categories.

Categories	AND or NOT	Boolean search string
Health literacy	AND	(“Health Literacy” OR “Healthcare Literacy” OR “Medical Literacy” OR “Health Understanding” OR “Health Education” OR “Healthcare Education” OR “Health Information Literacy” OR “Medical Comprehension” OR “Healthcare Knowledge” OR “Health Knowledge” OR “Health Proficiency” OR “Health Awareness” OR “Medical Awareness” OR “Health Competency” OR “Health Communication” OR “Information Literacy” OR “Patient Education” OR “Health Promotion” OR “Health Teaching”)
Pediatric	AND	(Children OR Child* OR Kid OR Kids OR Girl* OR Boy OR Boys* OR Toddler* OR Childhood OR Preschool* OR Pre-school* OR Kindergarten* OR School OR Minors OR Pediatric* OR Paediatric*)
Congenital heart disease	AND	(“Congenital Heart Defects” OR “Child Heart Disease” OR “Heart Defects” OR “Congenital Heart Disease” OR “Pediatric Cardiology” OR “Paediatric Cardiology” OR “Cardiac Defect*”)

The first author (NB) and a collaborator independently screened the titles and abstracts using the PICO Portal, reaching a consensus on selections for full-text screening and consulting the health librarian for final decisions in disagreements. Before and during the screening process, the first (NB), second (JYS), and last authors (CAL) held weekly meetings to clarify the selection of databases, concepts, and criteria as well as to draft an internal guideline. For example, following our discussions, we added the ACM Digital Library database to broaden our search to include technology-mediated solutions. These meetings continued during data charting and thematic analysis. We also sought guidance from a medical expert, a public health expert, and 2 librarians throughout the review. We used Zotero (Corporation for Digital Scholarship) for reference management and Google Sheets and Microsoft Excel for data abstraction. We established decision rules to guide the coding process and ensure consistency in cases requiring subjective interpretation.

The research team abstracted data on study characteristics: (1) study identification (ie, ID, author or year, country, title, study design, date of study, setting, and objective or purpose), (2) participant details (ie, target population, intervention tested on, sample size, demographic, inclusion or exclusion criteria, and CHD severity), (3) intervention specification (ie, intervention, format, description, comparison, stakeholders’ roles, duration, and follow-up), and (4) outcome specification (ie, outcome measures, results, and statistical analysis). Abstraction tables are shown in Tables S1-S5 in Multimedia Appendix 3 [27-37].

Data Synthesis

Due to the heterogeneous nature of the data, the research team used a qualitative approach using affinity diagramming and thematic analysis [38,39]. This approach enabled us to explore the data without predetermined frames and uncover emerging themes to answer our scoping review questions and objectives. We began by categorizing the studies based on the types of interventions they covered. We then performed open coding on all 11 papers to identify the specifications of educational interventions (ie, objectives, strategies, stakeholder involvement, and outcomes) for children with CHD. Through constant comparison and iterative coding, thematic categories emerged. Initially, open coding of studies yielded 43 discrete codes. Subsequently, these codes were iteratively aggregated based on commonalities, resulting in 15 representative codes. Next, affinity diagramming was used to cluster these 15 codes according to similarity, difference, and hierarchy relationships.

This process allowed us to establish high-level themes, refined through constant comparison and iterative coding. The key themes that emerged from the data include (1) types of educational interventions, (2) study design and stakeholder involvement, and (3) evaluation methods and outcome objectives. Each main theme was further divided into 2 subthemes (Textbox 2). This thematic synthesis provided a clear and structured understanding of the educational interventions for children with CHD, covering their implementation and evaluation.

Textbox 2. Identified themes and subthemes.

Types of educational interventions

- Educational strategies and objectives (eg, engaging sessions and disease education)
- Intervention duration (eg, duration and frequency of educational interventions)

Study design and stakeholder involvement

- Study design (eg, observational and randomized controlled trial)
- Target age groups and stakeholder involvement (eg, children and parents)

Evaluation methods and outcome objectives

- Assessed outcomes (eg, health literacy and health outcome)
- Data collection and analysis techniques (eg, questionnaires and interviews)

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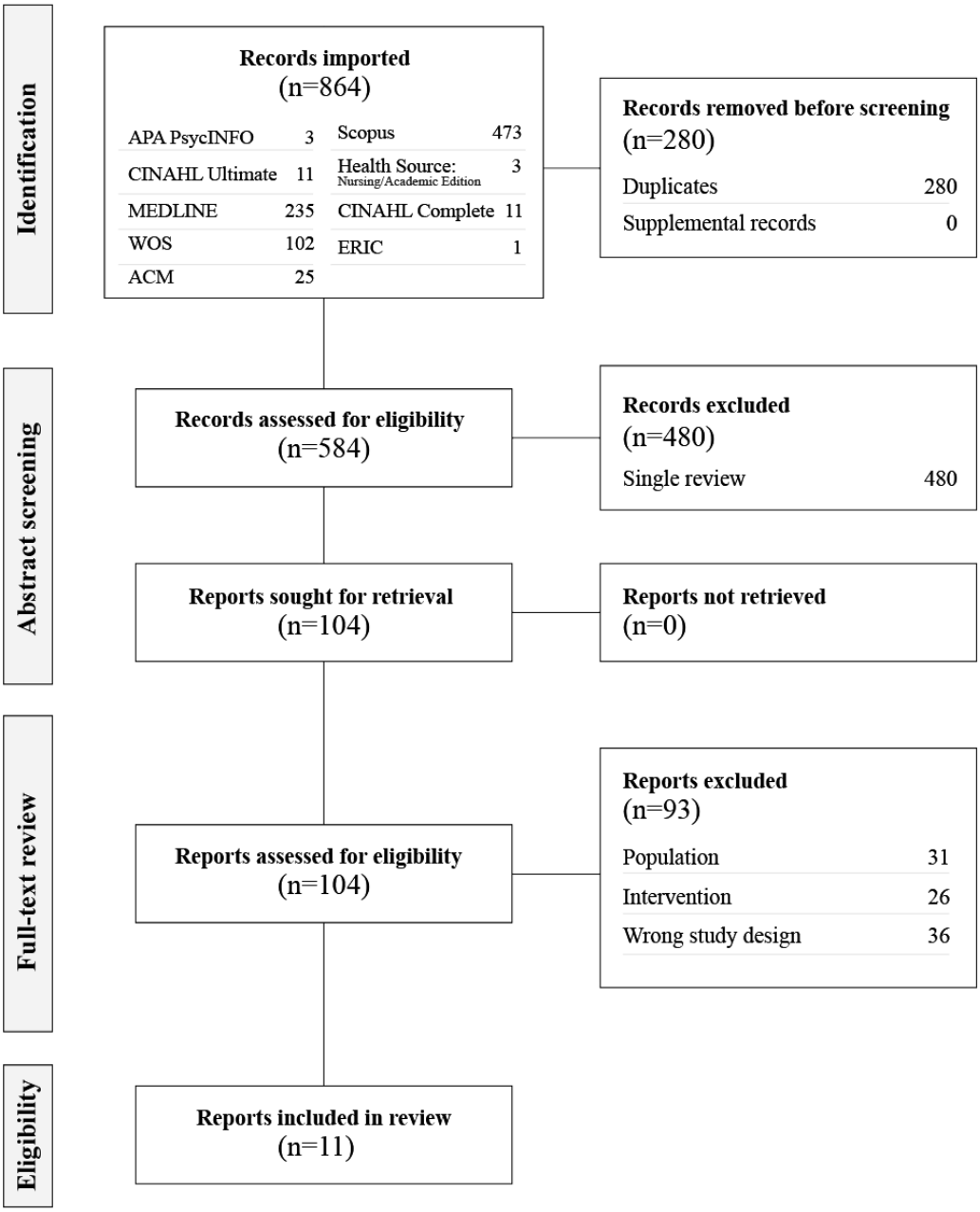
Results

Selection of Sources of Evidence

The literature search identified 864 records across 5 databases: APA PsycINFO (n=3), MEDLINE (n=235), Web of Science (n=102), ACM Digital Library (n=25), Scopus (n=473), CINAHL Complete (n=11), CINAHL Ultimate (n=11), Health Source: Nursing/Academic Edition (n=3), and ERIC (n=1). After removing 280 duplicates and supplemental materials, 584 records remained for abstract screening. Following abstract and title screening by the research team, 480 records were excluded for not meeting the review criteria. The full texts of the remaining 104 reports were assessed for eligibility. Of these, 93 reports were excluded for various reasons: 31 due to the population mismatch (ie, focusing on parents or caregivers or health care providers, participants aged >18 years, or studying general heart disease), 26 because the intervention was not relevant (ie, no interventions implemented, assessments used as interventions, or noneducational interventions), and 36 were excluded based on the wrong study design (ie, focusing on transitions to adulthood or objectives aimed at parents or health care providers). Finally, 11 reports met all the inclusion criteria and were selected for inclusion in the scoping review. Figure 3 illustrates the results of the literature search and screening. We used the PICO Portal review software to support the screening process. The reasons for exclusion at each stage were clearly documented, ensuring transparency and adherence to the PRISMA guidelines. References for papers excluded in the full-text review can be found in Multimedia Appendix 4.

Figure 3. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram of the literature review process.



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Characteristics of Sources Evidence

From 1982 to 2023, 11 studies were reviewed, focusing on educational interventions for pediatric patients with CHD [27-37] (Figure 4). There was a gap in the selected studies from 1982 to 2015. After that, 1 study was published every year until 2023, except for 2016, which had 2 studies [31,34]. Two studies were from the Netherlands in 2017 and 2018 [29,36], while 3 were from the United States in 1982, 2021, and 2022 [33,35,37]. Among these studies were 9 randomized controlled trials (RCTs) [27-32,34-36], with 1 covering both a pilot and RCT [29]. Additionally, 2 were observational studies [33,37]. Even though we searched design, human-computer interaction, and health databases, the studies were published in 9 medical and health-related journals. Two of the reviewed studies were published in the *International Journal of Cardiology* [27,31].

Figure 4. Characteristics of included studies [27-37]. RCT: randomized controlled trial.

Author (year)	Study design	Canada	China	Denmark	England	Finland	France	Netherlands	United States
Uzark et al (1982)	RCT								*Pediatric Cardiology*
Biglino et al (2015)	RCT				*BMJ Open*				
Ni et al (2016)	RCT		*Journal of Child Health Care*						
Klausen et al (2016)	RCT			*International Journal of Cardiology*					
Etnel et al (2017)	Pilot + RCT							*Frontiers in Cardiovascular Medicine*	
van der Mheen et al. (2018)	RCT							*BMC Pediatrics*	
Amedro et al (2019)	RCT						*International Journal of Cardiology*		
Lemire et al (2020)	RCT	*Contemporary Clinical Trials*							
Zablah et al (2021)	Observational								*Progress in Pediatric Cardiology*
Liddle et al (2022)	Observational								*Cardiology in the Young*
Karikoski et al (2023)	RCT					*Caries Research*			

Results of Individual Sources of Evidence

Overview

In exploring educational interventions for children with CHD, the first emergent theme is "types of educational interventions," with subthemes of "educational strategies and objectives" and "intervention duration." Educational strategies and objectives refer to the strategies used to support children with CHD and how these interventions address specific objectives, like disease education. Duration presents the timing and duration of these interventions, whether they are 1-time sessions, have follow-ups, or are repeated over time. This theme and its subthemes address KQ1: What types of educational interventions are available for children with CHD?

Educational Strategies and Objectives

Across the reviewed studies, 6 educational strategies were used to support children with CHD and their families (Figure 5). These strategies include the use of 3D patient-specific models, habit formation interventions, empowerment-based health education programs, rehabilitation interventions, a web-based portal, and videotape presentations.

3D patient-specific models are anatomical models created from medical imaging data like computed tomography or magnetic resonance imaging scans, providing a detailed representation of a child's heart. They help visualize and understand complex cardiac structures and treatment plans. Three studies used these models to educate about cardiac anatomy and treatment plans. These models were accompanied by engaging discussions and supplemented with diagrams or images, clarifying complex anatomical structures and treatment options. One of these studies specifically targeted adolescent patients, combining 3D models with tele-education. These interventions offered a visual understanding of the heart's structure and treatment procedures, including cardiac catheterization [28,33,37]. Habit formation interventions aim to instill healthy habits in children with CHD through structured programs. These interventions often involve multiple components, such as printed materials, toolkits, websites, and counseling sessions, to encourage and support the development of these beneficial habits. Two studies focused on these interventions. One aimed at promoting physical activity through a multifaceted intervention, including printed materials, a physical activity toolkit, and a website. The other focused on oral health promotion through counseling, distributing oral hygiene products, and providing written information [30,32].

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Figure 5. Educational strategies, objectives, and intervention durations [27-37]. CHD: congenital heart disease; NR: not reported.

Studies	Strategies	Objectives	Purpose	Duration	Follow-up
Biglino et al (2015) Zablah et al (2021) Liddle et al (2022)	3D patient-specific models	- Disease education	Provide a visual understanding of cardiac anatomy and treatment procedures, such as cardiac catheterization.	- Routine outpatient visits - Routine outpatient visits - 30-minute tele-education	- NR - NR - NR
Lemire et al (2020) Karikoski et al (2023)	Habit formation interventions	- Self-management skills	Promote physical activity and oral health—2 important habits—among children with CHD.	- 6 months (3-day workshop, conference call each month) - 1.5 years (sessions at 6, 12, 18 months)	- 6 months - 24 months
Ni et al (2016) van der Mheen et al (2018)	Empowerment-based health education programs	- Coping strategies - Disease education	Improve caregiving knowledge, caring behaviors, and self-efficacy of parents caring for children with CHD.	- 40 minutes + 3 monthly each 10 minutes - One-day workshop	- 1 month + 3 months after surgery - 6 months
Amedro et al (2019) Klausen et al (2016)	Rehabilitation interventions	- Self-management skills - Coping strategies	Enhance the quality of life, physical fitness, and health-related quality of life in adolescents and young adults with CHD.	- 12 weeks - 52 weeks	- 12 months - 12 months
Etnel et al (2017)	Web-based portal	- Disease education - Physician-patient communication	Improve patient knowledge and involvement and support physician-patient communication in the management of CHD.	- No limit	- 1 month
Uzark et al (1982)	Videotape presentation	- Coping strategies - Disease education	Enhance children's knowledge and coping during hospitalization for cardiac catheterization through visual education.	- 16 min	- 4 to 6 weeks after hospital discharge

Empowerment-based health education programs empower parents and family members by enhancing their knowledge, caregiving behaviors, and self-efficacy in managing a child's CHD. They typically include face-to-face education sessions, workshops, and follow-up support such as telephone calls, helping caregivers feel more confident and competent in their roles. Two studies implemented these programs to improve the caregiving knowledge, caring behaviors, and self-efficacy of parents or family members caring for children with CHD. One offered face-to-face education sessions and follow-up telephone calls, while the other conducted workshops [34,36]. Rehabilitation interventions aim to enhance the physical and psychological well-being of children and adolescents with CHD. These include structured cardiac rehabilitation programs (center or home-based) and eHealth interventions that use technology to improve physical fitness, activity levels, and overall health-related quality of life over an extended period. Two studies explored these interventions. One evaluated the impact of a combined center- and home-based cardiac rehabilitation program on the quality of life of adolescents and young adults with CHD. The other assessed the effects of a 52-week eHealth intervention on physical fitness and health-related quality of life in adolescents with CHD [27,31].

Web-based portals are digital platforms that enhance patient education, engagement, and communication. They provide accessible information about CHD, treatment options, and self-management strategies. These portals also facilitate communication between patients, families, and health care providers, ensuring continuous support and information exchange. Only 1 study assessed the effectiveness of these interventions in improving adolescent patient knowledge and involvement and supporting physicians in communicating with their patients [29]. Videotape presentations prepare children and their families for medical procedures and hospital stays. The videos use engaging, playful, and child-friendly formats, such as fictional or animated characters and stories, to simplify complex medical concepts and make them less intimidating. In 1982, a study evaluated the impact of a 16-minute videotape presentation on children's knowledge and coping skills during cardiac catheterization. The study featured a fictional lion who presented the videotape to guide hospitalized children through the events, sights, sounds, and sensations associated with the cardiac catheterization procedure [35].

Of the 11 studies reviewed, 7 offered disease education using the following methods: 3D patient-specific models, empowerment-based health education programs, web-based portals, and videotape presentations [28,29,33-37]. Four studies

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focused on improving self-management skills using 2 strategies: habit formation interventions and rehabilitation interventions [27,30-32]. Five studies aimed to teach coping strategies using 3 approaches: empowerment-based health education programs, rehabilitation interventions, and videotape presentations [27,31,34-36] (Figure 5). It is important to note that some studies addressed more than 1 aspect, which is why the numbers overlap across different categories.

Intervention Duration

The duration of educational interventions varied across the studies, as shown in Figure 5. Some interventions were brief sessions within routine visits, while others lasted up to 1.5 years. Follow-ups also differed. Some interventions had no follow-ups, while others included assessments at intervals of 1 month, 6 months, 1 year, or 2 years.

In total, 2 of 3 studies using 3D patient-specific models were integrated into routine outpatient visits without a specified duration. Another study used digital 3D heart models during a 30-minute tele-education session instead of in person. After the session, patients received a USB drive containing a video of their 3D heart and digital files for potential self-learning, with no follow-up mentioned [28,33,37]. In contrast, habit formation interventions, such as the oral health promotion intervention and a multifaceted physical activity intervention, spanned extended periods. Oral health promotion intervention lasted 1.5 years with sessions at baseline, 6, 12, and 18 months, followed by a 24-month follow-up. The multifaceted physical activity intervention spanned 6 months, including a 3-day workshop and monthly conference calls, with a follow-up period of 6 months [30,32].

As part of the empowerment-based health education program, 1 study included a 40-minute face-to-face education session with individualized instructions on the second day after surgery. There were also 2 monthly 10-minute telephone calls after the discharge to discuss the child's care and modify action plans. Subsequent assessments were conducted at 1 month and 3 months after surgery. Another study, the Congenital Heart Disease Intervention Program-Family intervention, involved a 1-day workshop and a 6-month follow-up session and assessment [34,36]. Using the rehabilitation interventions strategy, 1 study implemented the QUALI-REHAB cardiac rehabilitation program, consisting of a 12-week program with 5 days of hospitalization at the rehabilitation center and home-based training. Recall sessions were held every 3 weeks at the center, with a final evaluation at the end of week 12 and a 12-month follow-up period for outcome measurements. Another program, the Paediatric Rehabilitation for Vanguard in Lifeskills (PReVaiL), lasted 52 weeks, with a follow-up assessment conducted after 1 year. Patients received group-based health education sessions lasting 45 minutes and individual counseling sessions lasting 15 minutes [27,31].

Additionally, 1 study introduced a web-based portal during outpatient visits that could be used anytime, with follow-up assessments conducted 1 month after the visit [29]. Finally, 1 study conducted a 16-minute videotape presentation session 1 day before procedures, with a follow-up undertaken 4 to 6 weeks after discharge from the hospital [35]. In total, 3 studies had a 1-month follow-up timeline, while 2 had 6 months and 2 had 1 year.

Study Design and Stakeholder Involvement

Overview

The second emergent theme is "study design and stakeholder involvement," with subthemes of "study design" and "target age groups and stakeholder involvement." Study design focuses on the methodologies used in the studies and the size of participant samples. Target age groups and stakeholder involvement examines the target population's age range and impact on stakeholder roles. It analyzes whether parents, caregivers, or health care providers are involved in delivering or evaluating the intervention and identifies the target population. Together, these address KQ2: What are the study designs, target populations, and the roles of various stakeholders in these educational interventions?

Study Design

In total, 8 of the 11 studies used an RCT design, while 1 study included a pilot phase followed by an RCT [27-32,34-36]. The sample sizes in these RCTs ranged from 53 to 250, with a mean of 126.11 (SD 43.95). The intervention group size ranged from 31 to 125, with a mean of 63 (SD 25.20), and the control group size ranged from 22 to 125, with a mean of 62.78 (SD 24.60).

These RCTs varied in their approach, including prospective randomized clinical trials; questionnaire-based feasibility and acceptability studies; prospective clinical trials; single-center, single-blinded, randomized controlled trials; prospective, multicenter, randomized, controlled, parallel-arm studies; cluster randomized controlled trials; and multicenter stepped-wedge implementation trials. Additionally, 2 studies adopted observational study designs [33,37]. The observational studies explored a single-center cross-sectional study and a prospective pre-post study, with sample sizes of 46 and 22, respectively.

Reviewed studies used diverse settings for their interventions. Three studies implemented interventions across home settings, cardiac clinics, and digital or telehealth platforms [29,32,33]. Another 3 studies implemented interventions at home and children's hospitals [30,34,36]. One study used interventions in home settings, cardiac clinics, and rehabilitation centers [27]. Additionally, 1 study used home settings, rehabilitation centers, and digital or telehealth platforms [31]. In total, 2 studies were conducted at cardiac centers [28,37], while 1 was conducted exclusively at a hospital [35]. The study designs and settings are summarized in Figure 6.

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Figure 6. Study design and population characteristics [27-37]. N/A: not applicable; NR: not reported; RCT: randomized controlled trial.

	Authors and date	Biglino et al (2015)	Zablah et al (2021)	Liddle et al (2022)	Lemire et al (2020)	Karikoski et al (2023)	Ni et al (2016)	van der Mheen et al (2018)	Amedro et al (2019)	Klausen et al (2016)	Etnel et al (2017)	Uzark et al (1982)
	Strategy	3D patient-specific models			Habit formation		Empowerment health education		Rehabilitation		Web portal	Videotape
	Intervention tested on		Children	Children	Children	Children		Children	Children	Children	Children	Children
		Parent	Parent		Parent	Parent	Parent	Parent			Parent	Parent
Study design	**RCT studies**											
	Prospective randomized clinical trial											✔
	Questionnaire-based feasibility study	✔										
	Prospective clinical trial						✔					
	Randomized clinical trial									✔		
	Single-center, single-blinded, RCT							✔				
	Prospective, multicenter, RCT, parallel-arm study								✔			
	Cluster RCT				✔							
	RCT					✔						
	Pilot + RCT											
	Multicenter stepped-wedge implementation trial										✔	
	Observational studies											
	Single-center cross-sectional study		✔									
	Prospective pre-post study			✔								
Setting	Home			✔	✔	✔	✔	✔	✔	✔	✔	
	Children hospital					✔	✔	✔				✔
	Cardiac clinic or center	✔	✔	✔	✔				✔		✔	
	Rehabilitation centers								✔	✔		
	Digital or telehealth			✔	✔					✔	✔	
Population	**Stakeholders involvement**											
	Pediatric patients (children)		✔	✔	✔	✔		✔	✔	✔	✔	✔
	Parents or caregivers or family	✔	✔		✔	✔	✔	✔	✔	✔	✔	✔
	Health care providers	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
	Age range											
	Pediatric patients (children)	6-18 y	1 mo-21 y	13-18 y	5-17 y	0-24 mo	1 mo-5 y	4-7 y	13-25 y	13-16 y	Adolescent	3-12 y
	Parents or caregivers or family	35-51 y	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Sample size											
	Total	103	46	22	200	72	86	90	130	158	250	53
	Intervention group size	45	N/A	N/A	100	35	44	45	65	77	125	31
	Control group size	52	N/A	N/A	100	37	42	45	65	77	125	22

Target Age Groups and Stakeholder Involvement

In the reviewed studies focusing on educational interventions for children with CHD, stakeholder involvement varied depending on the participants' age range. This variation influenced the roles played by different stakeholders, such as parents or caregivers and health care providers, within these interventions.

The primary emphasis of this review was on educational interventions tailored for children with CHD, although not all studies exclusively targeted children as participants. Several studies also included parents of children with CHD within specific age groups to enhance the overall health outcomes for these children. Among the 11 studies examined, 2 exclusively focused on parents [28,34], while 6 involved both parents and children [29,30,32,35-37]. Additionally, 3 studies specifically targeted children aged 13 to 18, 13 to 25, and 13 to 16 years [27,31,33]. The youngest participants in the studies targeting just children with CHD were aged 13 years.

In a study conducted by Uzark et al [35], the researchers assessed the impact of a videotape presentation on the knowledge and coping of children with CHD aged 3 to 12 years during hospitalization for cardiac catheterization. The study also targeted the parents of these younger children to improve outcomes for both children and parents. Another study by Biglino et al [28] investigated the effectiveness of 3D patient-specific models of CHD as a communication tool during cardiology consultations for pediatric patients aged 6 to 18 years and their parents. The age range of parents included in this study was 35 to 51 years.

Lemire et al [32] studied children with CHD aged 5 to 17 years and their parents. The intervention aimed to assess whether providing resources and protocols would enable clinicians to counsel about physical activity during every pediatric cardiology appointment. In another study, Karikoski et al [30] targeted children with CHD up to 24 months old and their parents to investigate the effectiveness of repeated counseling provided by a dental hygienist in improving oral health behavior during the first 1000 days of life. They aimed to improve parental hygiene habits with the expectation that it would also enhance young children's hygiene habits.

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Ni et al [34] evaluated the effectiveness of an empowerment-based health education program for parents caring for children aged 1 month to 5 years who had undergone corrective surgery for CHD. Their goal was to improve the health outcomes for the children and not the parents. Van der Mheen et al [36] assessed the effects of a program on parental mental health and the psychosocial well-being of children with CHD aged 4 to 7 years. This program also involved siblings to help normalize the child's CHD position within their family dynamic.

In all 11 studies, key stakeholders—children, parents or caregivers, and health care providers—actively participated in the interventions. In total, 8 studies involved all these stakeholders [27,29-32,35-37], while 2 involved parents and health care providers [28,34], and 1 included children and health care providers [33]. The age ranges in these studies varied widely, from birth to 25 years. However, the age range for parents was not consistently provided across the studies. Only 1 study specified the age range for parents as 35 to 51 years, with children aged 6 to 18 years [28]. Figure 6 provides details of population specification, including stakeholder involvement, age ranges, and sample sizes across the reviewed studies.

Evaluation Methods and Outcome Objectives

Overview

Theme 3, "evaluation methods and outcome objectives," includes 2 subthemes: "assessed outcome" and "data collection and analysis techniques." Assessed outcomes discusses the specific objectives and goals the interventions aimed to achieve. Data collection and analysis techniques examines the methods and approaches used to gather and analyze data. Together, these subthemes address KQ3: What outcomes are assessed, and what approaches are used for assessment?

Assessed Outcomes

The outcomes assessed represent the specific objectives the reviewed studies measure to evaluate the effectiveness of their interventions. This scoping review categorized assessed outcomes into three main categories: (1) improved children's HL and outcome, (2) reduced parental burden, and (3) improved efficiency of health care providers. Figure 7 summarizes these categories, demonstrating the varied impacts of interventions on children with CHD, their parents or caregivers, and health care providers.

Improving children's HL involves various suboutcomes. These include understanding CHD, self-management and habits, coping and quality of life, empowerment, health care use, and health outcomes. Two studies evaluated the understanding of CHD, and both reported increased knowledge following the intervention [33,35]. Meanwhile, 3 other studies are still under investigation [29,32,36]. Three studies were conducted on self-management and habits. In total, 2 showed positive impacts [30,35], while 1 showed no change or impact [31]. Furthermore, 1 study found a relationship between the intervention and self-management and habits, indicating a need for further investigation in future studies [33]. Ongoing research is being conducted in 3 more studies under investigation [27,32,36].

Two other studies assessed coping and quality of life, one showing no change after intervention [31], and one showing improvement [35], while ongoing investigations continue in 4 studies [27,29,32,36]. Regarding empowerment, 2 studies showed improvement [33,35], with ongoing investigations in 2 more studies [29,36]. Health care use was evaluated once, with no observed difference [30]. Health outcomes were assessed in 2 studies, one indicating improvement [34] and the other showing no change [31]. Additionally, 2 studies without assessments reported a relationship between health outcomes and the intervention [30,35], while ongoing investigations are underway in 2 studies [27,36].

Reducing parental burden focused on various suboutcomes, including educational, emotional, caregiving, and financial support. In total, 4 studies assessed educational support, with 3 showing improvement [30,34,37] and 1 showing no change [28]. Two studies evaluated emotional support, both indicating improvement [34,35]. One study identified a relationship between intervention and emotional support without formal assessments [28], while 2 studies are under investigation [29,36]. Three studies assessed caregiver support, all of which showed improvement [30,34,37]. Similarly, 3 studies identified a relationship that needs further assessment [28,33,35], and 2 are still under investigation [29,36]. Financial support was not assessed in any of the reviewed studies.

Furthermore, regarding enhancing the efficiency of health care providers, one study assessed saving time and effort but found no significant time savings [28], while another study on this topic is still ongoing [32]. Treatment adherence was not directly assessed in any reviewed study, although 1 study noted a relationship without formal assessment [37]. Two studies evaluated care coordination, one indicating improvement [37] and another showing no change [30]. In total, 3 studies identified a relationship between the intervention and care coordination but did not conduct formal assessments [28,33,34], and 1 study is currently under investigation [32]. Shared decision-making and patient or family satisfaction were each assessed in 1 study, both showing improvement [33]. However, another study still investigates shared decision-making [29]. Additionally, 3 studies found a relationship between the intervention and shared decision-making [28,34,37], while 1 reported a relationship with patient or family satisfaction [28]. These findings suggest avenues for future research to assess these relationships more deeply.

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Figure 7. Evaluation methods and outcomes objectives [27-37]. ANCOVA: analysis of covariance; CHD: congenital heart disease.

⬆ denotes positive outcome, ⬇ denotes negative outcome, – denotes no change, o indicates a relationship is present but not assessed, **NR** indicates the statistic is under study and not reported yet, ✔ indicates the statistic was used in the study and the method.

	Authors and date	Biglino et al (2015)	Zablah et al (2021)	Liddle et al (2022)	Lemire et al (2020)	Karikoski et al (2023)	Ni et al (2016)	van der Mheen et al (2018)	Amedro et al (2019)	Klausen et al (2016)	Etnel et al (2017)	Uzark et al (1982)
	Strategy	3D patient-specific models			Habit formation		Empowerment health education		Rehabilitation		Web portal	Videotape
	Intervention tested on		Children	Children	Children	Children		Children	Children	Children	Children	Children
		Parent	Parent		Parent	Parent	Parent	Parent			Parent	Parent
Outcome	**Improved children's health literacy and outcome**											
	Understanding of CHD			⬆	NR			NR			NR	⬆
	Self-management or habits			o	NR	⬆		NR	NR	–		⬆
	Coping or quality of life				NR			NR	NR	–	NR	⬆
	Empowerment			⬆				NR			NR	⬆
	Health care use					–						
	Health outcome					o	⬆	NR	NR	–		o
	Reduced parental burden											
	Educational support	–	⬆	o		⬆	⬆	NR			NR	o
	Emotional support	o					⬆	NR			NR	⬆
	Caregiving support	o	⬆	o		⬆	⬆	NR			NR	o
	Improved health care providers' efficiency											
	Save time or effort	⬇			NR							
	Treatment adherence		o									
	Care coordination	o	⬆	o	NR	–	o					
	Shared decision-making	o	o	⬆			o				NR	
	Patient or family satisfaction	o		⬆								
Statistic	Repeated measures ANOVA				✔		✔	✔				
	ANCOVA analysis				✔					✔		✔
	Post hoc *t* test						✔					
	Independent samples t test	✔				✔	✔					✔
	Wilcoxon signed-rank test		✔	✔								
	Mann-Whitney *U* test		✔		✔	✔						
	Chi-square analysis (χ^2)	✔					✔					✔
	Fisher exact test					✔						
	Post hoc power analysis	✔										
	Cohen *d*							✔				
	Regression analysis							✔				
	Stepwise regression											✔
	Simple logistic regression					✔						
	Multiple logistic regression					✔						
	Logistic regression				✔					✔		
	Correlation analysis (*r*)											✔
	Cluster analysis											✔
	Weighted Cohen κ			✔								
Method	Software: STATA (ST), SPSS (SP)	(ST)	(SP)		(SP)	(SP)	(SP)			(ST, SP)		
	Quantitative questionnaire (ie, pre or post)	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔
	Medical record or device				✔		✔		✔			
	Qualitative feedback (ie, in-person digital interview, call, focus group)			✔		✔	✔	✔		✔	✔	

Data Collection and Analysis Techniques

Across the 11 reviewed studies, various assessment methods and statistical analyses were used to evaluate the effectiveness of interventions for children with CHD. These methods and analyses provided comprehensive insights into the outcomes measured and the statistical rigor applied.

As a statistical software, SPSS (IBM Corp) was predominantly used in 5 studies [30-32,34,37], reflecting its widespread utility for quantitative data analysis in health care research. Data collection methods varied, with all studies using questionnaires, often administered before and after the intervention. In total, 3 studies relied solely on questionnaires and quantitative methods [28,35,37], while 5 studies integrated questionnaire data with qualitative feedback from in-person or digital interviews, calls, or focus groups [29-31,33,36]. Two studies incorporated medical records or devices alongside questionnaires [27,32], and 1 used all 3 methods, including questionnaires, qualitative feedback, and medical records or devices [34].

Statistical analyses used in the reviewed studies to analyze the data included a wide range of methods. The most frequently used statistical analysis method was the independent samples *t* test, used in 4 studies primarily as pre- and postassessments [28,30,34,35]. Other common analyses included repeated measures ANOVA [32,34,36], analysis of covariance analysis [31,32,35], Mann-Whitney *U* test [30,32,37], and chi-square analysis [28,34,35], each used 3 times to assess various outcomes. Several studies have also applied regression analysis techniques such as stepwise regression [35], simple logistic regression [30], multiple logistic regression [30], and logistic regression [31,32].

Among the 11 studies, 2 statistical approaches were used in 3 studies [31,33,37]. Notably, 1 study in 1982 used 6 statistical

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techniques, including analysis of covariance analysis, independent samples *t* test, chi-square analysis, stepwise regression, correlation analysis (*r*), and cluster analysis [35]. Figure 7 provides an overview of the statistical approaches used across the studies, highlighting a range from 2 to 6 approaches per study.

The reviewed studies used various methods and statistical techniques, indicating no single approach to achieving their objectives. The frequent use of quantitative methods, primarily involving stakeholders other than children with CHD, suggests the need for tailored methods and techniques for this patient demographic.

Discussion

Principal Findings

Overview

This scoping review identified 11 studies conducted between 1982 and 2023, focusing on educational interventions for children with CHD. The studies included 9 RCTs and 2 observational studies. These studies used various intervention strategies, durations, study designs, and evaluation methods, offering a comprehensive overview of current research in this field. Six primary types of educational strategies were identified: 3D patient-specific models (n=3), habit formation interventions (n=2), empowerment-based health education programs (n=2), rehabilitation interventions (n=2), web-based portals (n=1), and videotape presentations (n=1). These interventions varied in duration, ranging from brief sessions during outpatient visits to programs lasting up to 1.5 years. Follow-up periods also varied, with 3 interventions having no follow-up, 2 having a 6-month follow-up period, 3 having follow-ups ranging from 4 to 6 weeks, and 1 study having a follow-up period of 24 months. The primary goals of these interventions were to improve the quality of life and coping strategies, self-management skills, and knowledge of children with CHD and their families. Among these studies, 3 interventions specifically targeted children above 13 years of age, 2 focused on parents, and 6 involved both children and parents. The primary statistical method used was the independent samples *t* test, used in 4 studies for pre- and postassessments. Outcome assessments focused on children's HL, reducing parental burden, and improving the efficiency of health care providers. These findings reveal the potential and the limitations of current health educational interventions, highlighting the need for more child-centric approaches to engage younger patients with CHD.

Limited Interventions for Children With CHD

This scoping review highlights the potential of educational interventions to significantly improve chronic care management for children with CHD and their families, aligning with previous findings [10-13,40-45]. Existing research indicates that well-informed pediatric patients can delay or prevent secondary illnesses, enhance their quality of life, and reduce health care costs [46-50]. However, many children with chronic conditions lack sufficient understanding of their illnesses, leading to confusion, anxiety, and other complications [51-54]. One contributing factor is the reliance on parents by health care providers to educate their children, assuming effective transmission of information [55,56]. Additionally, the development of interventions has mostly neglected children's perspectives, focusing primarily on feedback from health care providers and parents. Younger children face barriers to participation due to limited attention spans, difficulty understanding abstract concepts, and challenges in expressing their needs [57,58]. As a result, interventions typically depend on parental feedback as a proxy for testing and design insights [59].

The review also found that educational materials were predominantly designed for teenagers or parental caregivers, lacking age-appropriate and engaging solutions for children younger than 13 years of age. Among the 11 studies reviewed, only 3 [27,31,33] exclusively targeted children, focusing on those aged 13 years and older, likely due to usability challenges for younger children [58,60-62]. This is the case despite the review's specific focus on educational interventions for children with CHD. The concept that "children are not small adults" is widely acknowledged in pediatric care. It emphasizes that children represent a unique population with their own culture, norms, and complexities [63-65]. This understanding underscores the necessity for developing more inclusive and age-appropriate educational interventions for younger children with CHD.

Limited Engaging Strategies

Among the reviewed studies, 3D modeling emerged as a prominent strategy for educating pediatric patients and their families about CHD [28,33,37]. This approach offers engaging learning and improves communication between families and health care providers. However, despite its interactivity, 3D modeling and the other 5 strategies examined in this review lack engaging, playful interactions. Earlier educational tools, such as videotape presentations featuring friendly and playful characters like a fictional lion, effectively engaged young patients by making complex medical procedures more understandable and less intimidating through storytelling [35].

Playful strategies naturally engage children and facilitate learning through play. By communicating complex health information in an age-appropriate and engaging manner, they make a painful and tedious subject more approachable. In the 1920s, nurses Nightingale and Erikson first recognized the importance of systematizing play sessions to improve children's hospitalization experience and adherence to medical procedures [66-73]. Since then, strategies like pretend play [74,75] and serious games [76,77] have been used for chronic care management, educating children about their conditions, and helping them manage their fears. However, these strategies are rarely used for children with CHD. The evolution of educational interventions from videotape presentations in 1982 to patient-specific 3D printing indicates significant technological advancements. Integrating engaging and playful approaches into current interventions could substantially boost their effectiveness by involving children directly in their health care journey through their own language: play.

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Enhancing Methodological Approaches

The majority of the reviewed studies used RCTs [27-32,34-36], reflecting robust methodologies for evaluating educational interventions for children with CHD. However, except for 1 [33], many studies primarily assessed parental outcomes as proxies without adequately evaluating specific outcomes for pediatric patients themselves [28-30,32,34-37]. This highlights a gap in HL measures tailored for children with CHD. While parental involvement is essential, directly assessing children's HL, coping mechanisms, and overall well-being is equally vital.

One notable strength of these studies was the involvement of various stakeholders in intervention delivery, including pediatric patients, parents or caregivers, and health care providers. Eight studies involved all stakeholders, ensuring a comprehensive approach [27,29-32,35-37]. Nevertheless, there is a need for more extensive engagement, particularly with pediatric patients, throughout the intervention's ideation, design, and implementation phases. Early involvement of stakeholders, including children as design partners, enhances the integration of interventions into routine care, ensuring practicality, feasibility, and alignment with clinical needs [58,78-82].

While most studies used questionnaires supplemented by qualitative feedback, there is a major focus on quantitative approaches. Incorporating more qualitative studies in the initial stages could help identify challenges, barriers, and desires more effectively. Unlike quantitative methods, qualitative methods aim to explore, narrate, and explain phenomena, making sense of complex realities. Health interventions could develop as an outcome of qualitative research [83,84]. Statistical analyses were diverse, with the independent samples *t* test being the most commonly used method, typically involving defined objectives and pre- and postassessment measures. Despite the rigorous methodologies, there was a lack of long-term longitudinal studies to assess the sustained effectiveness of the interventions [85]. Most studies had follow-up periods ranging from 1 month to 1 year, with only 1 study extending to 24 months [30]. This highlights the need for future research to include extended follow-up periods to understand the long-term impact of educational interventions on children with CHD and their families.

By addressing these methodological gaps and expanding stakeholder engagement, particularly with pediatric patients, we can enhance the effectiveness of health educational interventions. Designers, health care providers, and policymakers should prioritize developing and implementing solutions with all stakeholders, not just for them. This collaborative approach can enhance care quality, coordination, and outcomes for children, families, and health care providers.

One effective strategy is to integrate engaging learning tools—both digital and physical—through play. For example, a playful, educational toy similar to Rufus the Bear with Diabetes (Empath Labs), used in diabetes education, can help children manage their health. A comparable toy featuring a simplified heart model allows children to explore their anatomy and medical routines through hands-on play, making complex concepts more accessible. Designed to meet developmental needs, these tools can reduce anxiety, foster independence, and help children manage fears through pretend play. By prioritizing children's needs rather than relying on parents to convey information, we ensure that health information remains relatable and engaging. Ultimately, these child-led strategies empower families to build the knowledge and resilience necessary for effectively managing CHD. Such efforts could improve health outcomes during the transition to adulthood, enhance autonomy in managing CHD, and streamline education and health care delivery.

Limitations

This scoping review has offered valuable insights but has limitations. First, the search was limited to English-language publications, which may have excluded relevant studies published in other languages. Second, despite efforts to conduct a comprehensive search, it is possible that some relevant studies were missed, thus introducing selection bias. Finally, the inclusion criteria were restricted to published peer-reviewed studies, which means that relevant gray literature and unpublished studies were excluded, introducing publication bias. It is essential to consider these limitations while interpreting the findings of this scoping review. Additionally, the limited number of studies meeting the inclusion criteria highlights the scarcity of research that focuses specifically on educational interventions for children with CHD. Moreover, the variability in study designs, intervention types, outcome measures, and follow-up periods across the included studies has limited the ability to conduct a meta-analysis and draw definitive conclusions about the effectiveness of educational interventions for children with CHD.

Research Directions

Educational interventions have shown promise in enhancing the quality of life, self-management skills, and knowledge of children with CHD and their families. However, there is a pressing need for further research to develop and evaluate HL-focused pediatric care interventions tailored specifically for patients with CHD younger than 13 years of age. Drawing from successful interventions in this review, such as the approach by Uzark et al [35] that engaged both pediatric patients and parents to enhance understanding and coping during hospitalization, offers a promising framework for younger children with CHD. This playful approach significantly improved HL, empowerment, and self-management skills. While this study focused exclusively on children with CHD and health educational interventions, future research could draw insights from playful interventions designed for other pediatric conditions like cystic fibrosis and diabetes. As part of our multiphase research project, this comparative approach will inform the iterative development of our health education intervention for younger children with CHD and their families.

Additionally, since no studies included in this review used qualitative approaches such as co-design, our research would prioritize integrating such methodologies to involve all stakeholders, including children, early on. This would enhance the relevance and effectiveness of the interventions. Acknowledging challenges and working with all stakeholders toward finding solutions is essential, as simply ignoring the problem will not lead to progress. Involving children as design

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partners, despite all the barriers, can ensure that the interventions are engaging, relevant, and effective in meeting the unique needs of children with CHD.

Conclusions

Educational interventions promise to enhance the quality of life, self-management skills, and knowledge of children with CHD and their families. However, insufficient evidence to support educational interventions for this pediatric population highlights a significant gap in the literature. While this scoping review aimed to identify these gaps, the scarcity of evidence highlights the need for further research. Advocating for such research is crucial to guide designers, health care providers, and policymakers in delivering effective interventions tailored to the specific needs of children with CHD. There is a clear need for more research explicitly addressing pediatric care interventions for children with CHD, focusing on developing age-appropriate, engaging, and engaging educational interventions. Improving HL in pediatric patients can reduce parental educational burden and increase health care provider efficiency by improving communication and patient empowerment.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews) checklist.
[DOCX File , 109 KB - pediatrics_v8i1e64814_app1.docx]

Multimedia Appendix 2
Search strategy.
[DOCX File , 23 KB - pediatrics_v8i1e64814_app2.docx]

Multimedia Appendix 3
Study characteristics.
[DOCX File , 354 KB - pediatrics_v8i1e64814_app3.docx]

Multimedia Appendix 4
Excluded full-text studies.
[DOCX File , 34 KB - pediatrics_v8i1e64814_app4.docx]

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Abbreviations

CHD: congenital heart disease
HL: health literacy
KQ: key question
PICOTS: population, intervention, comparator, outcome, timing, and setting
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews
RCT: randomized controlled trial

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